

BACKGROUND

Dual intra-gastric balloon therapy (DIGB) is a non-surgical, restrictive method of weight loss.

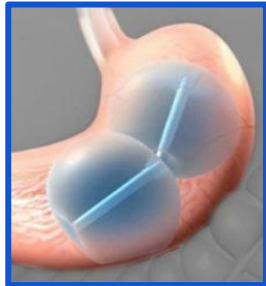
The primary objective of this study is to evaluate the efficacy of DIGB therapy on weight loss at time of balloon removal and whether this weight loss is sustained over time. The secondary objectives include measurement of patient satisfaction with DIGB therapy and identifying any adverse events associated with DIGB.

METHODS

A retrospective evaluation of 35 patients who had DIGB therapy from 2016 to 2019 was conducted. Weights at baseline, balloon removal, and follow-up were identified, as well as adverse events. Patients were asked to complete a satisfaction survey.

Technique:

- The DIGB is placed with endoscopic guidance while under sedation.
- The balloons are each filled with 350 to 450 ml of saline mixed with methylene blue depending on the patient's height. Methylene blue serves as an indicator in case of balloon deflation where the urine color becomes green due to its absorption.
- Balloons were removed after a six month period



RESULTS

Of the 35 patients, 29 (83%) were females, and 6 (17%) were males. The mean age of patients was 45.2±13.5 years.

Balloon Therapy Period

Mean DIGB therapy period was a duration of 8.7±5.1 months.

The mean weight loss was 6.9±7.4 kg.

Weight and BMI were decreased significantly at removal compared to baseline (Table 1).

Mean %TBWL at the end of the balloon therapy period was 7.1±7.4%.

Mean %EWL was 31.6±36.6%.

Fifteen patients (43%) had >25% EWL.

Six patients (17%) had increased weight at the end of the balloon therapy period.

Table 1

Balloon therapy period (n=35)

| | Baseline mean | Removal mean | p value (paired t-test) |
|------------------------|---------------|--------------|-------------------------|
| BMI, kg/m ² | 35.0±4.6 | 32.4±4.9 | <.001 |
| Weight, kg | 98.1±17.8 | 91.2±18.7 | <.001 |

Table 2

Follow-up period (n=31)

| | At removal, mean | At follow-up, mean | p value (paired t-test) |
|-------------|------------------|--------------------|-------------------------|
| Weight loss | 6.7±7.7 | 0.9±8.6 | <.001 |
| %TBWL | 7.0±7.82 | 0.9±9.4 | <.001 |
| %EWL | 32.4±38.8 | 4.7±42.7 | .001 |

Table 3

Follow-up weight comparison (t-test)

| | Gained weight up to or above baseline, mean (n=17) | Maintained weight loss below baseline, mean (n=14) | p value |
|----------------------------------|--|--|---------|
| Age, years | 49.2±13.9 | 39.8±13.1 | .063 |
| Baseline BMI, kg/m ² | 35.3±4.2 | 33.9±4.3 | .361 |
| Weight loss at removal, kg | 4.4±5.2 | 9.3±9.5 | .077 |
| %TBWL at removal | 4.5±5.5 | 10±9.3 | .048 |
| %EWL at removal | 17.9±25.9 | 49.9±45.1 | .02 |
| Balloon therapy duration, months | 8.7±6.3 | 8.9±3.6 | .916 |
| Length of follow-up, months | 21±10.4 | 24±10.9 | .434 |

Adverse Events

Adverse events seen in 51% of the patient's medical records, including:

- nausea (11)
- abdominal pain (5)
- reflux (3)
- gastric ulcers (2)
- pancreatitis (1)
- gastric outlet obstruction (1)

Balloon rupture was seen in two patients.

Hospitalization or emergency department visit was required in 26% (9/35).

Early balloon removal before six months occurred in 14% (5/35) due to pancreatitis, gastric ulcer, balloon rupture, nausea, and abdominal pain.

Follow-up Period

Follow-up weight was identified on 31 out of 35 patients (89%).

Mean length of follow-up 22.4±10.6 months.

There was no significant correlation between follow-up time and the amount of weight lost or regained (r=-.19, p=.31).

The mean %TBWL and mean %EWL were both significantly decreased compared to %TBWL and %EWL at time of removal (Table 2).

71% of patients (22/31) gained weight after balloon removal.

55% (17/31) had regained weight up to or above their pre-balloon baseline.

The group that maintained weight loss below baseline at follow-up had greater initial %TBWL and %EWL at balloon removal compared to the group that regained weight (Table 3).

Two patients went on to have a second balloon placed. Seven patients subsequently underwent laparoscopic sleeve gastrectomy.

Satisfaction

Twenty-five out of 35 patients provided satisfaction survey responses. Three (12%) patients were satisfied with DIGB therapy. Twenty-two (88%) patients were not satisfied.

23 (92%) patients were not satisfied with the cost effectiveness.

Twenty-three (92%) patients, in retrospect, would not choose the DIGB for weight loss therapy.

CONCLUSION

Dual intra-gastric balloon therapy was associated with weight loss in the majority of patients, however, on average this weight loss was not sustained over time after the DIGB was removed. The majority of patients were not satisfied with the DIGB as a method of weight loss.