

Efficacy of Intra-gastric Balloon Placement in Changing Metabolic Dysfunction Associated Fatty Liver Disease

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Abstract:

Background: Metabolic associated fatty liver disease (MAFLD) affects about a quarter of the global adult population, often progressing to non-alcoholic steatohepatitis (NASH) and cirrhosis. Effective management remains challenging, necessitating alternative treatments such as intra-gastric balloon (IGB) therapy. This study aims to evaluate the impact of IGB placement on metabolic parameters and liver health in patients diagnosed with (MAFLD). **Methods:** This prospective cohort study included one hundred patients undergoing IGB placement at Benha Teaching Hospital from November 2023 to September 2024. Patients were assessed for metabolic markers and liver health through laboratory tests and imaging pre- and post-IGB placement. **Results:** Post-IGB placement, significant improvements were observed: waist circumference decreased to 107.5 ± 5.3 cm ($p < 0.001$); Body mass index (BMI) reduced to 31.8 ± 2.6 kg/m² ($p < 0.001$); Systolic blood pressure (SBP) dropped to 118.4 ± 10.2 mmHg ($p < 0.001$); total cholesterol decreased to 180.2 ± 30.5 mg/dL ($p < 0.001$); fasting blood glucose fell to 98.2 ± 15.8 mg/dL ($p < 0.001$); Alanine aminotransferase (ALT) reduced to 26.2 ± 9.1 U/L ($p < 0.001$); Aspartate aminotransferase (AST) decreased to 22.3 ± 8.2 U/L ($p < 0.001$); and Fibrosis 4 index for liver fibrosis (FIB-4) score improved to 1.5 ± 0.3 ($p < 0.001$). **Conclusion:** IGB therapy is an effective and safe treatment for MAFLD, resulting in improved metabolic and liver health parameters, indicating its potential to reverse disease progression. Further studies are warranted to explore its long-term effects across diverse populations.

Keywords: Metabolic associated fatty liver disease; Metabolic Dysfunction; Intra-gastric Balloon; Liver Enzymes; Fibrosis.

Introduction

Non-alcoholic fatty liver disease (NAFLD), a term that describes a clinical condition where fat accumulates in the liver without alcohol involvement, potentially leading to non-alcoholic steatohepatitis (NASH) and cirrhosis ⁽¹⁾. Affecting approximately 25% of the global adult population ⁽²⁾, NAFLD is expected to become the leading reason for liver transplants by 2030 ⁽³⁾. NAFLD encompasses a spectrum that includes simple steatosis (NAFL) and steatohepatitis (NASH), progressing through stages from fat buildup and inflammation to fibrosis and cirrhosis ⁽⁴⁾.

In NASH, hepatic steatosis occurs alongside distinct histological features, including hepatocyte ballooning and hepatic inflammation, which are not seen in simple NAFLD ⁽⁵⁾. NAFLD patients may show mild to moderate increases in AST and ALT levels, though normal levels do not exclude the disease, nor do elevated levels indicate the severity of inflammation or fibrosis ⁽⁶⁾. Reflecting the disease's metabolic basis, experts proposed the term metabolic dysfunction-associated fatty liver disease (MAFLD), encompassing obesity, type 2 diabetes, and other metabolic disorders, and suggested diagnostic criteria to improve patient stratification and management, while fostering new avenues for research and treatment ⁽²⁾.

Treating patients with MAFLD remains challenging, with lifestyle modifications and metabolic disorder control as key strategies. While pharmacological treatments show promise, they have yet to demonstrate effectiveness in reversing inflammation and liver fibrosis associated with disease progression ⁽⁷⁾. Sustained weight loss of 7–10% of body weight is recommended to reduce steatosis, inflammation, and fibrosis, though only 10–20% of patients achieve this target ⁽⁸⁾. Bariatric surgery has shown success in resolving steatosis and fibrosis in 66% and 40% of patients, respectively, though it

can also lead to new or worsening NAFLD features in about 12% of cases ⁽⁹⁾. It is more effective than medical or lifestyle interventions for sustained weight loss and diabetes remission, though not cost-saving, as its health benefits outweigh associated costs in obese patients ⁽¹⁰⁾. Research into alternative treatments for MAFLD has highlighted endoscopic bariatric and metabolic therapies, particularly the intragastric balloon (IGB), as a safe, minimally invasive option. IGB aids short-term obesity control by delaying gastric emptying, increasing satiety, and reducing caloric intake, with various models available to suit different clinical needs ^(11, 12).

This study aims to evaluate the impact of IGB placement on MAFLD through the assessment of liver enzymes (ALT, AST) and various certain metabolic markers (lipid profile, fasting blood glucose, glycosylated haemoglobin, fasting insulin levels, homeostatic model assessment for insulin resistance, imaging as abdominal CT to measure liver volume and fibrosis 4 index for liver fibrosis).

Patients and methods

Design and population

This cohort prospective study included 100 patients who attend for placement of IGB at Gastroenterology and Infectious Diseases Department Benha Teaching Hospital, during the period from 1st November 2023 to the 30th of September 2024.

The study was done after being approved by the Research Ethics Committee, Faculty of Medicine, Benha University. An informed consent was obtained from the patients.

Inclusion criteria were patients of both genders who are older than 18 years with BMI > 25 kg/m² and confirmed or previously diagnosed MAFLD show ultrasonography-confirmed hepatic steatosis plus at least one metabolic condition, such as diabetes, obesity, or metabolic dysfunction. Metabolic

dysfunction requires at least two criteria, including increased waist circumference, pre-diabetes, elevated blood pressure, low HDL cholesterol, high triglycerides, a HOMA-IR score ≥ 2.5 , or CRP > 2 mg/L ⁽²⁾. **Exclusion criteria** were patients with a history of steatotic drug use (e.g., corticosteroids, contraceptives), alcohol consumption, viral hepatitis, autoimmune hepatitis, other chronic liver diseases, gastric surgery, respiratory, heart failure, or renal diseases. Pregnancy and a history of H. pylori infection are also exclusion factors.

Operational design

All studied cases were subjected to detailed history taking, full clinical examination with stress on [Blood pressure measurements, BMI and Waist circumference], laboratory investigations and radiological investigations.

Eligible patients for IGB placement first underwent diagnostic endoscopy to rule out contraindications. Under deep sedation and monitored by an anesthesiologist, a nonadjustable IGB (MediStars) was inserted below the gastroesophageal junction and filled with 500 ml of saline and 20 ml of methylene blue to signal balloon rupture. **Figure 1.** Patients were monitored post-procedure, beginning a fluid diet on day two, progressing to solids by week two, with a low-calorie diet (900–1200 kcal/day). A proton pump inhibitor, antiemetics, and anti-gas medication were prescribed. The balloon was removed after six months, and changes in MAFLD were assessed by comparing baseline and six-month laboratory and radiological data **Figure 2.**

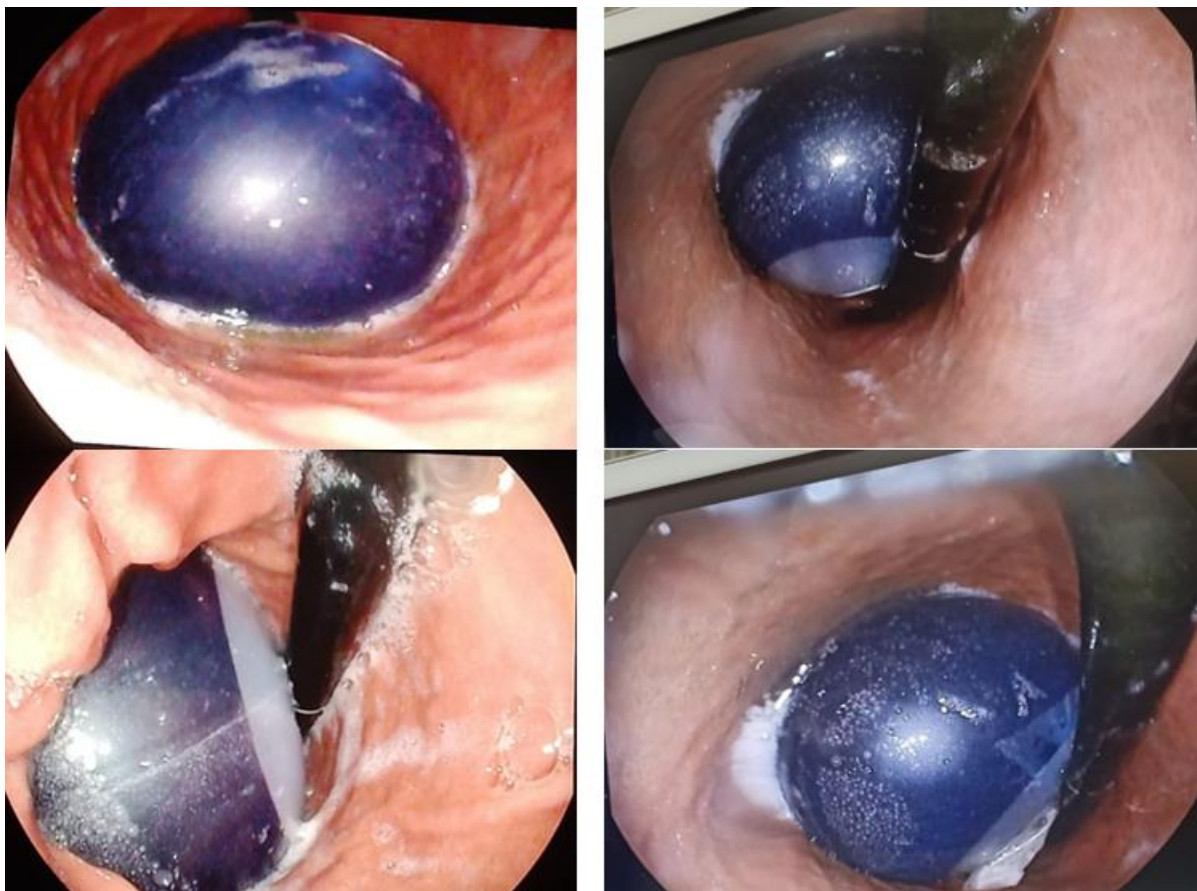


Figure 1: Endoscopic picture showing intragastric balloon placement (MediStars IntraGastric Balloon).

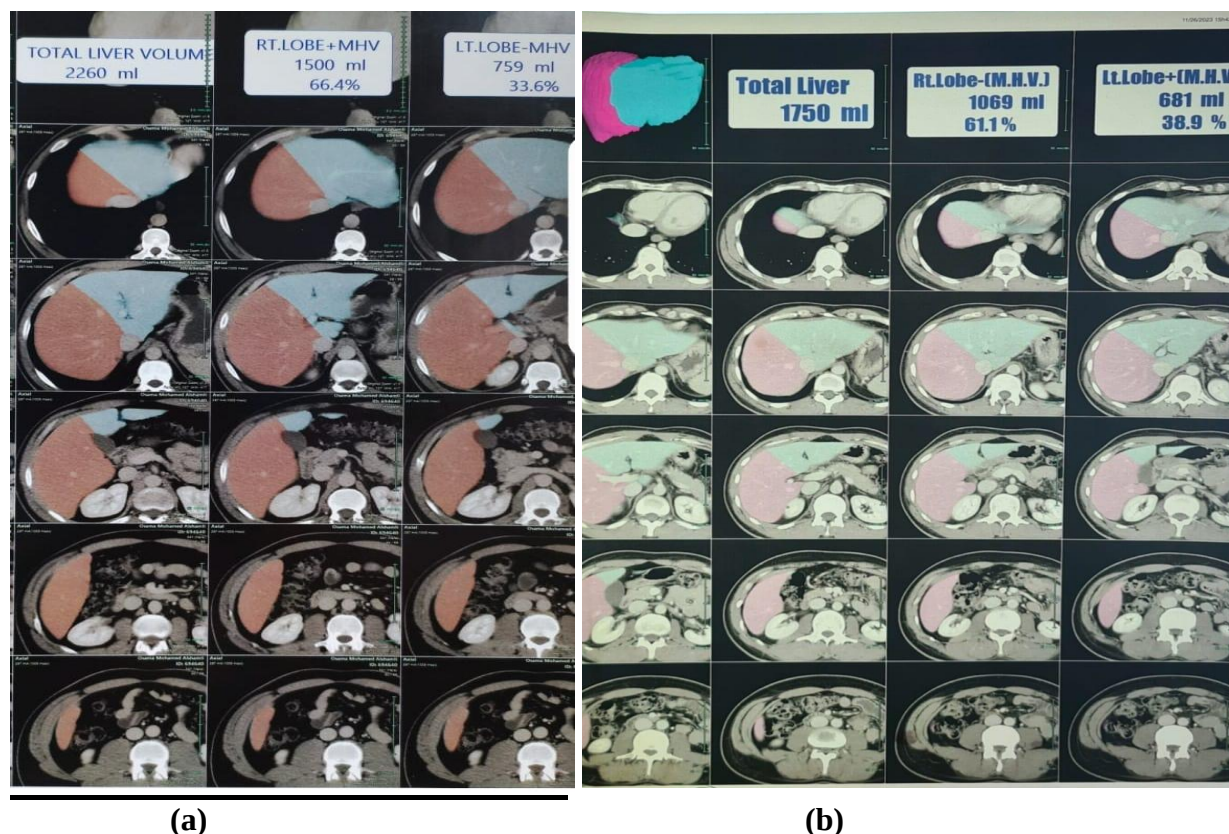


Figure 2: liver volume by CT volumetry; picture (a): showing liver volume before IGB placement measuring 2260cm³, picture (b): showing liver volume of the same patient measuring 1750cm³ after IGB placement .

Statistical analysis

The collected data was revised, coded, and tabulated using the Statistical Package for Social Science (IBM Corp. Released 2017. IBM SPSS Statistics for Windows, Version 25.0. Armonk, NY: IBM Corp.). Data was presented, and suitable analysis was conducted according to the type of data obtained for each parameter. Quantitative variables were expressed as mean $\pm$ SD and range, while qualitative variables were presented as frequency and percentage. The level of significance was set at $P > 0.05$. The following tests were used: paired samples t-test (Pt); sometimes called the dependent samples t-test, which is used to determine whether the change in means between two paired observations is statistically significant.

Results

Most studied patients are females (60%), the mean age of studied patients was

35.1 $\pm$ 7.8 years, most cases (69%) were from urban areas, 3% of cases were smokers 5% were DM and 3% had HTN. The mean waist circumference in the studied group was 119.8 $\pm$ 6.1 cm, the mean BMI was 36.6 $\pm$ 2.9, the mean systolic blood pressure (SBP) was 127.2 $\pm$ 12.6 mmHg, and the mean diastolic blood pressure (DBP) was 80.2 $\pm$ 8.1 mmHg. The patients exhibited normal mean values for CBC parameters, but had elevated lipid profile tests, increased fasting blood sugar (FBS), elevated HbA1c, higher homeostasis model assessment-insulin resistance (HOMA-IR) scores, elevated liver enzymes, and high Fibrosis-4 (FIB-4) scores. Imaging results revealed hepatomegaly, increased liver echogenicity on ultrasound, and an increase in liver volume as assessed by CT volumetry. **Table 1**

Table 1: Clinical data and descriptive analysis of laboratory tests and imaging of the studied group.

Variables	Mean±SD	Minimum	Maximum
Waist circumference (cm)	119.8±6.1	101.8	128.0
BMI (kg/m²)	36.6±2.9	31.10	40.90
SBP (mmHg)	127.2±12.6	110	160
DBP (mmHg)	80.2±8.1	70	100
Complete blood count			
PLT (x10 ³ /L) [N: 150-450]	290±77	151	449
HGB (mg/dl) [N: F: 12-16] [M: 14-18]	12.2±1.9	8.5	16.1
TLC (x10 ³ /L) [N: 4-11]	6.6±2.5	3.0	11.0
Lipid profile			
Total cholesterol (mg/dl) [N: <20]	186.7±36.1	126.0	288.0
HDL-C (mg/dl) [N: >50]	47.8±9.3	30.0	66.0
LDL-C (mg/dl) [N: <100]	117.2±48.5	35.0	163.0
TG (mg/dl) [N: <150]	148±32	110	175.0
Blood sugar & insuline resistance			
FBS (mg/dl) [N: 70-100]	123±44	78	198
HbA1c (%) [N: <5.7]	6.8±1.7	4.5	10.3
Fasting insulin (mIU/L) [N: 30-42]	12.2±6.5	2.9	36.7
HOMA-IR [N: 0.5-1.4]	3.8±3.3	0.6	12.8
Kidney functions			
Creatinine (mg/dl) [N: 0.6-1.1]	0.85±0.24	0.30	1.60
Blood urea (mg/dl) [N: 5-20]	23.1±9.6	6	42
Liver functions			
ALT (IU) [N: 4-36]	102.7±36.6	21.0	178.0
AST (IU) [N: 4-36]	79.8±35.1	18.0	169.0
FIB4 score			
FIB4 score	1.29±1.09	0.28	5.550
[N: <1.30 low risk for advanced fibrosis]			
Liver imaging			
Liver span by US (cm) [N: 13-15]	18.2±1.1	16	20.2
Grade of echogenicity by US [N: 0]	2.2±0.7	1	3
Liver volume by CT [N: 1533 ± 375]	2129±171	1866	2430

SBP: systolic blood pressure, DBP: diastolic blood pressure, BMI: body mass index, PLT: platelets, HGB: hemoglobin, TLC: total leucocyte count, HDL: High density lipoprotein, LDL: low density lipoprotein, TG: triglyceride, FBS: fasting blood sugar, HbA1c: glycated haemoglobin, HOMA-IR: Homeostasis Model Assessment of Insulin resistant, ALT: Alanine transaminase, AST: aspartate aminotransferase, FIB4: Fibrosis-4.

After IGB placement, there was a highly statistically significant decrease in waist circumference, BMI, SBP, and DBP ($p < 0.001$). However, no significant differences were found in Hb level, platelet (PLT), or total leukocyte counts (TLC) before and after placement. Additionally, total cholesterol, LDL

cholesterol (LDL-C), and triglycerides (TG) significantly decreased ($p < 0.001$), while HDL cholesterol (HDL-C) levels showed no significant change ($p = 0.354$). There were also significant reductions in fasting blood sugar (FBS), HbA1c, fasting insulin, and HOMA-IR levels post-IGB placement ($p < 0.001$). **Table 2**

Table 2: Comparison of presenting clinical data, complete blood, lipid profile and insulin resistance before and after IGB placement.

Variables		Study group		Mean $\pm$ SD	Test	P value
		Before	After			
Waist circum. (cm)	Mean $\pm$ SD	119.8 $\pm$ 6.1	106.3 $\pm$ 5.3	13.4 $\pm$ 3.1	Pt=44.4	<0.001*
	Range	101.8-128	90.5-112.2			
BMI (kg/m ²)	Mean $\pm$ SD	36.6 $\pm$ 2.9	30.9 $\pm$ 2.9	5.6 $\pm$ 0.6	Pt=98.2	<0.001*
	Range	31.1-40.9	25.1-35			
SBP (mmHg)	Mean $\pm$ SD	127.2 $\pm$ 12.6	115 $\pm$ 5.2	11.6 $\pm$ 5.6	Pt=9.9	<0.001*
	Range	110-160	105-130			
DBP (mmHg)	Mean $\pm$ SD	80.2 $\pm$ 8.1	70.3 $\pm$ 3.4	10.1 $\pm$ 5.3	Pt=13.6	<0.001*
	Range	70-100	63.7-77.7			
HGB (g/dl)	Mean $\pm$ SD	12.2 $\pm$ 1.9	11.9 $\pm$ 2.1	0.3 $\pm$ 0.1	Pt=1.2	0.238
	Range	10.5-16.1	10.3-14.8			
PLT (x10 ³ /L)	Mean $\pm$ SD	290 $\pm$ 77	294 $\pm$ 87	4.5 $\pm$ 2.8	Pt=0.6	0.582
	Range	151-449	151-449			
TLC (x10 ³ /L)	Mean $\pm$ SD	6.6 $\pm$ 2.5	7.1 $\pm$ 4.2	2.7 $\pm$ 1.3	Pt=1.7	0.092
	Range	3-11	3.2-12.7			
Total cholesterol (mg/dl)	Mean $\pm$ SD	186.7 $\pm$ 36.1	151.3 $\pm$ 18.8	35.4 $\pm$ 7.3	Pt=9.2	<0.001*
	Range	126-288	115.2-179.7			
HDL-C (mg/dl)	Mean $\pm$ SD	47.8 $\pm$ 9.3	48.6 $\pm$ 7.3	0.8 $\pm$ 0.5	Pt=0.93	0.354
	Range	30-66	37-60.4			
LDL-C (mg/dl)	Mean $\pm$ SD	117.2 $\pm$ 48.5	85.7 $\pm$ 26.3	31.5 $\pm$ 11.9	Pt=6.06	<0.001*
	Range	35-163	42-136.1			
TG (mg/dl)	Mean $\pm$ SD	148 $\pm$ 32	114.7 $\pm$ 11.4	53.6 $\pm$ 15.6	Pt=15.1	<0.001*
	Range	110-175	93.4-139.5			
FBS (mg/dl) N(70-100)	Mean $\pm$ SD	123 $\pm$ 44	103.9 $\pm$ 17.1	19.4 $\pm$ 9.4	Pt=4.9	<0.001*
	Range	78-198	81-150			
HbA1c (%) N(<5.7)	Mean $\pm$ SD	6.8 $\pm$ 1.7	6.1 $\pm$ 0.8	0.7 $\pm$ 0.5	Pt=4.3	<0.001*
	Range	4.5-10.3	4.4-7.7			
Fasting insulin mIU/L N(30-42)	Mean $\pm$ SD	12.2 $\pm$ 6.5	8.5 $\pm$ 3.8	3.7 $\pm$ 1.9	Pt=6.2	<0.001*
	Range	2.9-36.7	3.8-16.8			
HOMA-IR N(0.5-1.4)	Mean $\pm$ SD	3.8 $\pm$ 3.3	2.5 $\pm$ 0.9	1.2 $\pm$ 0.9	Pt=4.1	<0.001*
	Range	0.6-12.8	0.8-6.1			

Pt: Paired student t-test, *: significant, SBP: systolic blood pressure, DBP: diastolic blood pressure, PLT: platelets, HGB: hemoglobin, TLC: total leucocyte count, HDL: High density lipoprotein, LDL: low density lipoprotein, TG: triglyceride, FBS: fasting blood sugar, HbA1c: glycated hemoglobin, HOMA-IR: Homeostasis Model Assessment of Insulin resistant.

There was no statistically significant difference in creatinine levels ($p = 0.236$) and blood urea levels ($p = 0.192$) between results before and after intragastric balloon (IGB) placement. However, there was a highly statistically significant decrease in ALT and AST levels following IGB placement ($p < 0.001$). Additionally, the FIB4 score significantly decreased after

IGB placement ($p < 0.001$). There were also highly significant reductions in the grade of echogenicity on ultrasound and liver volume measured by CT ($p < 0.001$) after IGB placement, although no significant difference was observed in liver span by ultrasound between the two time points. **Table 3**

Table 3: Comparison of Liver Imaging, FIB4 Score, and Kidney and Liver Function Tests Before and After IGB Placement.

Variables		Study group		Mean ±SD	Test	P value
		Pre	Post			
Creatinine (mg/dl) N (0.6-1.1)	Mean±SD	0.85±0.24	0.82±0.12	0.3±0.2	Pt=1.2	0.236
	Range	0.3-1.6	0.67-1.09			
Blood urea (mg/dl) N (5-20)	Mean±SD	23.1±9.6	24.2±8	0.9±0.6	Pt=1.9	0.192
	Range	6-42	17-42			
ALT (IU) N (4-36)	Mean±SD	102.7±36.6	57.3±23.6	62.3±20.6	Pt=6.9	<0.001*
	Range	21-178	19.7-119			
AST (IU) N (4-36)	Mean±SD	79.8±35.1	40.6±22.6	49.1±20.3	Pt=8.1	<0.001*
	Range	18-169	15-100			
FIB4 <1.30 low risk of advanced fibrosis	Mean±SD	1.29±1.09	0.8±0.4	0.52±0.11	Pt=4.8	<0.001*
	Range	0.28-5.6	0.2-1.8			
Liver span by US N (13-15)	Mean±SD	18.2±1.1	17.9±1.2	0.3±0.1	Pt=0.6	0.63
	Range	16-20.2	15-20			
Grade of echogenicity by US N (0)	Mean±SD	2.2±0.7	1.1±0.6	1.1±0.3	Pt=13.2	<0.001*
	Range	1-3	0-2			
Liver volume by CT N (1533±375)	Mean±SD	2129±171	1761±144	368.7±141	Pt=26.1	<0.001*
	Range	1866-2430	1610-2080			

N: normal range, Pt: Paired student t-test, X2: Chi-square test, *: significant, FIB4: Fibrosis-4, ALT: Alanine transaminase, AST: aspartate aminotransferase

Discussion

In the current study, there was a highly statistically significant decrease in waist circumference, BMI, SBP, and DBP in patients after IGB placement compared to before the procedure. These findings align with those of some authors who reported a significant reduction in BMI at the time of balloon removal ⁽¹³⁾, as well as other authors noted substantial body weight loss and waist circumference reduction in patients at a six-month follow-up after IGB placement ⁽¹⁴⁾.

In the present study, there was no statistically significant difference in Hb levels, PLT, or TLC before and after IGB placement. However, a highly statistically significant decrease in total cholesterol, LDL-C, and TG was observed post-IGB placement. No significant difference in HDL-C was found between the pre- and post-IGB measurements. These results align with the findings of some authors who noted significant improvements in lipid profiles, including total cholesterol and triglycerides ⁽¹³⁾.

In contrast, our results differ from the results of a published study which reported no significant differences in pre- and post-intervention lipid levels ⁽¹⁵⁾, and from other study which found no changes in total cholesterol or LDL post-intervention. These discrepancies between results may be explained by different basic criteria and comorbidities in patients from different studies, also may be related to type of IGB used ⁽¹⁶⁾.

In the present study, a highly statistically significant decrease in FBS, HbA1c, fasting insulin, and HOMA-IR levels was observed in patients after IGB placement compared to their pre-IGB levels. These findings are consistent with some authors who noted significant improvements in FBG and postprandial blood glucose (PPBG) at the time of balloon removal ⁽¹³⁾. Additionally, it was reported that significant decreases in HbA1c, fasting glucose, and aspartate aminotransferase at the time of balloon removal ⁽¹⁶⁾.

In the current study, there was no statistically significant difference in creatinine and blood urea levels before and after IGB placement, while a highly statistically significant decrease in ALT and AST levels was observed post-IGB placement. These findings align with those of some authors who reported significant improvements in HOMA-IR scores, serum ALT, and GGT levels after six months of IGB therapy in patients with elevated HOMA-IR at baseline ⁽¹⁷⁾.

In the present study, a highly statistically significant decrease in the FIB4 score was observed in patients after IGB placement compared to before the procedure. This finding is supported a published study which reported a significant reduction in FIB-4 scores and liver stiffness measurements following similar interventions, further indicating the efficacy of IGB placement in improving liver health indicators ⁽¹⁴⁾.

In the current study, a highly statistically significant decrease was observed in the grade of liver echogenicity by ultrasound and liver volume by CT following IGB placement. However, no statistically significant difference was found in liver span by ultrasound after IGB placement. These findings align with a published journal article which reported a significant reduction in liver steatosis through serial abdominal ultrasonography in patients who achieved substantial weight loss after IGB treatment, which correlated with a notable decrease in HOMA-IR scores ⁽¹⁸⁾.

Conversely, the results contrast with those of some authors who found a mean reduction in liver volume after six months of IGB use, but this change lacked statistical significance. These discrepancies between results may be explained by different number and ethnicity of studied groups, basic criteria and comorbidities in patients from different studies, also may be related to type of IGB used ⁽¹⁹⁾.

Our results indicate that IGB therapy is a safe and effective treatment for MAFLD,

potentially reversing its natural history, including NASH, despite the intervention's short duration. The logistics of IGB placement facilitate accurate risk stratification for patients, reducing the need for further investigations and clarifying the actual risks associated with MAFLD. Supporting this, a meta-analysis by some authors reported improvements in steatosis, NAS score, and HOMA-IR, with most patients also showing reduced liver volume via CT ⁽²⁰⁾. Similarly meta-analysis highlighted enhancements in liver enzymes and metabolic markers related to the progression of MAFLD, further affirming the benefits of IGB therapy ⁽²¹⁾.

Yet our study has some limitations as the study population is neither ethnically diverse nor representative of all obesity classes. This lack of diversity limits the generalizability of results, given that MAFLD behavior may differ according to the ethnicity and may very well have a different response in greater or lesser BMI.

Conclusion

The IGB showed significant efficacy in reducing liver enzymes in patients with MAFLD as well as improving metabolic parameters related to disease progression such as systolic blood pressure, triglycerides, HOMA-IR, waist circumference and glycated hemoglobin.

Author contribution

The authors contributed equally to the study.

Conflicts of interest

No conflicts of interest

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