RESEARCH ARTICLE

Short-term outcome of metabolic surgery versus intensive medical therapy among obese type 2 diabetics: a quasi-experimental study

Zahra Raza, Muhammad Burhan Ul Haq, Tashfeen Imtiaz, Muhammad Adnan Khokhar, Aatif Inam

Abstract

Objective: To compare the short-term outcomes of metabolic surgery and intensive medical therapy in the management of diabetes mellitus among obese persons with type 2 diabetes mellitus.

Methods: The quasi-experimental study was conducted at the Pakistan Institute of Medical Sciences, Islamabad, Pakistan, from March 2018 to February 2019, and comprised obese type 2 diabetes mellitus patients of either gender aged 20-65 years. Those undergoing metabolic and bariatric surgery were assigned group A, while those undergoing intensive medical therapy formed control group B. All patients were followed up for 6 months to monitor their metabolic profile, including body mass index, glycosylated haemoglobin and fasting plasma glucose. Data was analysed using SPSS 20.

Results: Of the 72 patients, 36(50%) were in group A; 23(63.9%) females and 13(36.1%) males with mean age 41.2 ± 10.2 years. The remaining 36(50%) patients were in group B; 22(61.1%) males and 14(38.9%) females with mean age 42.5 ± 10.6 years ($p>0.05$). At 6 months, mean body mass index, glycosylated haemoglobin and fasting plasma glucose values were significantly lower in group A compared to group B ($p<0.001$). There were 33(91.7%) patients in group A with remission of diabetes compared to 1(2.8%) patients in group B ($p<0.001$).

Conclusion: Bariatric surgery was found to produce a good early outcome in the management of diabetes in the obese population, leading to remission post-surgery.

Key Words: Bariatric surgery, Metabolic surgery, Obese T2DM, Diabetes remission, Diabetes.

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Introduction

Obesity has become a worldwide epidemic. In 2024, the Non-Communicable Diseases Risk Factor Collaboration (NCD RisC) published its findings, determining that more than a billion people in the world are living with obesity. These numbers have increased by more than three times between 1975 and 2022.[1] According to the National Health Statistics Report by the Centre for Disease Control and Prevention (CDC), the prevalence of obesity in the United States in the last two decades has seen a rise from 30.5% in 1999-2000 to 41.9% in 2017-20. During the same time, the prevalence of severe obesity increased from 4.7% to 9.2%.[2]

In Pakistan, there is limited data about the nationwide prevalence of obesity. According to the World Obesity Atlas, 2024, almost 50% of Pakistani population is either overweight or obese, placing Pakistan 10th among 188 countries. It is estimated that by 2030, 5.4 million children of school-going age will be suffering from obesity.[3] The Diabetes Prevalence Survey of Pakistan (DPS-PAK) in 2019 revealed that one in four Pakistanis was either prediabetic or fully diabetic.[4] The International Diabetes Federation Atlas in 2021 released data that was even more alarming, indicating a diabetes prevalence rate of 30.8% in Pakistan. Additionally, it is estimated that 26.9% of the cases remain undiagnosed, while around 10% have impaired glucose tolerance (IGT).[5] The burden of diabetes-related mortality among individuals aged <60 is estimated to be a staggering 17.5% in the country. Such a burden of disease has resulted in significant financial cost, with an estimated expenditure of US$2.63 billion in 2021 in Pakistan.[6]

An increase in body weight leads to the risk of developing IGT and type 2 diabetes mellitus (T2DM).[7] Obesity induces resistance to peripheral glucose uptake mediated by insulin. This might also lessen the beta cell sensitivity to glucose. In patients with established disease, reversing obesity enhances glycaemic control. The distribution of fat determines the risk of developing insulin resistance (IR) and T2DM. The incidence is highest in patients with central or abdominal obesity. Fat distribution patterns and the role of genetic and environmental factors in the development of T2DM are yet not fully known.[8]

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The management of obesity and its associated health issues poses a significant financial challenge.[9,10] In addition to the direct healthcare expenses, other costs include lost work productivity and lower household income. In 2010, worldwide expenditure on diabetes was conservatively calculated to amount to $376 billion, with forecasts indicating a rise to approximately $490 billion by 2030. Obesity cost the US about $1.4 trillion in 2017.[11] In the Swedish Obesity Study (SOS), obese individuals were three times more likely to receive a disability pension, took twice the sick days, and had greater annual drug expenses compared to individuals with normal weight.[12]

The standard medical approach for T2DM attains only partially sufficient glycaemic regulation and a decrease in cardiovascular risk. The management of T2DM is notably demanding in individuals with obesity. For two decades, bariatric surgery, following the 1991 National Health Institute criteria, sets the primary objective of the surgery as achieving weight-loss among individuals with body mass index (BMI) >40kg/m^2 or those with BMI >35kg/m^2 along with notable comorbidities. The 2013 guidelines from the American Heart Association (AHA), the American College of Cardiology (ACC) and The Obesity Society (TOS) have remained mostly unchanged.[13] They indicated a lack of adequate evidence to endorse bariatric or metabolic surgery as the primary approach for treating T2DM regardless of BMI criteria.[14,15] The guidelines published during the second Diabetes Surgery Summit Consensus Conference in 2015 received endorsement from over 50 diabetes and medical associations.[16] These recommendations endorse metabolic surgery and broaden its pertinence to address T2DM in individuals with BMI ranging from 30kg/m^2 to 34.9kg/m^2 (from 27.5kg/m^2 to 32.4kg/m^2 for Asians), provided oral or injectable medications inadequately manage hyperglycaemia. This was incorporated into recommendations of the 2018 Diabetes Standards of Care by the American Diabetes Association.[17]

The latest guidelines issued by the American Society for Metabolic & Bariatric Surgery (ASMBS) and the International Federation for the Surgery of Obesity and Metabolic Disorders (IFSO) in 2022 recommend metabolic and bariatric surgery for individuals with BMI of 35kg/m^2 or more "regardless of presence, absence, or severity of obesity-related conditions", and that it be considered for people with a BMI 30-34.9kg/m^2 and metabolic disease and in "appropriately selected children and adolescents". It was also recommended that the definition for obesity be tailored for the Asian population and surgery for obesity be considered in patients with BMI 27.5kg/m^2 or higher.[18]

Given the increasing prevalence of obesity and diabetes in Pakistan, the current study was planned to compare the short-term outcomes of metabolic surgery and intensive medical therapy in the management of diabetes mellitus among obese T2DM patients.

Patients and Methods

The quasi-experimental study was conducted at the Pakistan Institute of Medical Sciences (PIMS), Islamabad, Pakistan, from March 2018 to February 2019, after obtaining approval from the institutional ethics review committee. The sample was raised using non-probability convenience sampling technique from among patients attending the Obesity and Diabetic clinics run by the Department of General Surgery and the Department of General Medicine, respectively. Written informed consent was obtained from all the participants. Those included were T2DM patients of either gender aged 20-65 years having BMI 28kg/m^2 or higher. Patients of type 1 diabetes, those having had prior bariatric surgery, or cosmetic surgical procedures, such as abdominoplasty and liposuction, were excluded. Data was collected regarding age, gender, BMI, glycosylated haemoglobin (HbA1c), fasting plasma glucose (FPG), C-peptide levels, and pharmacological therapy for diabetes. The patients undergoing metabolic and bariatric surgery — either laparoscopic vertical sleeve gastrectomy (LVSG) or mini gastric bypass (MGB) — were assigned group A, while those undergoing intensive medical therapy formed control group B. The outcome was evaluated based on remission, defined as HbA1c <6% or FPG <126mg/dl that occurred spontaneously or after an intervention, and lasted a minimum of 3 months without the use of typical glucose-lowering medications. Regular follow-up was done for 6 months to keep track of the patients' metabolic profile, comprising BMI, HbA1C and FPG levels.

Data was analysed using SPSS 20. Quantitative variables were expressed as mean +/- standard deviation, while qualitative variables were expressed as frequencies and percentages. An independent sample t-test was used to compare intergroup HbA1C and FPG levels. $P<0.05$ was considered statistically significant.

Sample size was calculated using WHO sample size calculator[19] with the following parameters:

Level of significance- 5%

Power of Test-80%

Anticipated population proportion (rate of normal HbA1C of medical therapy group) =15.8

Anticipated population proportion (rate of normal HbA1C of surgical group) =36.2

Sample size=36 in each group

Total of 72 patients were included in this study.

Results

Of the 72 patients, 36(50%) were in group A; 23(63.9%) females and 13(36.1%) males with mean age 41.2 ± 10.5 years. The remaining 36(50%) patients were in group B; 22(61.1%) males and 14(38.9%) females with mean age 42.5 ± 10.6 years (p>0.05). In group A, 20(55.5%) patients underwent LVSG, while 16(44.4%) underwent MGB (Figure 1).

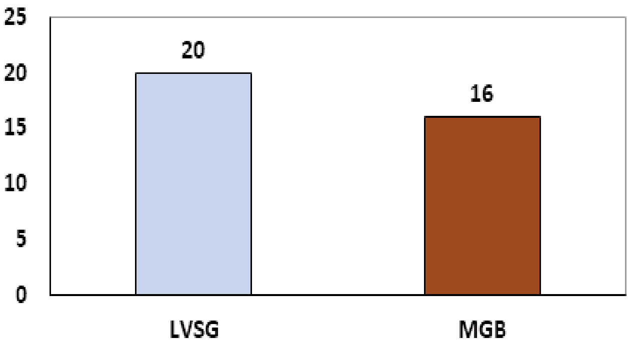

Figure-1: Procedures carried out in the surgical group.
LVSG; Laparoscopic vertical sleeve gastrectomy, MGB; Mini gastric bypass.

Table-1: Demographic characteristics.

Parameters	Metabolic Surgery Group	Intensive Medical Treatment Group	p Value
IMales	36.1% (n=13/36)	61.1% (n=22/36)	0.060
Females	63.9% (n=23/36)	38.9% (n=14/36)	
Mean Age ± SD	41.2 ±10.5 years	42.5 ±10.6 Years	0.616
20 to 40 Years	52.8% (n=19/36)	44.4% (n=16/36)	
41 to 61 Years	47.2% (n=17/36)	55.6% (n=20/36)	
Oral Hypoglycaemic Agents (OHAs)	63.9% (n=23/36)	77.8% (n=28/36)	0.220
Insulin	2.8% (n=1/36)	8.3% (n=3/36)	
OHA + Insulin	25.0% (n=9/36)	11.1% (n=4/36)	
No Medication	8.3% (n=3/36)	2.8% (n=1/36)	.

Table-2: Mean BMI, HBA1c and FPG values at baseline.

	GROUPS	N	Mean	Std. Dev	P-value t-test	SEM
BMI (Kg/m^2)	SURGICAL	36	37.7	±3.1	0.37	0.517
	MEDICAL	36	37.1	±3.3		0.55
HbA1c (%)	SURGICAL	36	8.3	±0.48	0.394	0.08
	MEDICAL	36	8.5	±0.51		0.085
FPG(mg/dL)	SURGICAL	36	139.9	±11.6	0.164	1..933
	MEDICAL	36	136.4	±9.4		1.567

BMI: Body mass index, HbA1c: Glycosylated haemoglobin, FPG: Fasting plasma glucose

Table-3: Mean BMI, HBA1c and FPG at 3 months

Variables	Surgical (n=36)	Medical (n=36)	*P-valuee* t-test
MEAN BMI (Kg/m^2)	27.8 ±10.2	36.7±6.3	<0.001
MEAN HBA1c (%)	5.9 ±0.88	7.5 ±0.63	<0.001
MEAN FPG (mg/dL)	118.8 ±3.4	131.8 ±5.3	<0.001

BMI: Body mass index, HbA1c: Glycosylated haemoglobin, FPG: Fasting plasma glucose.

Table-4: Mean BMI, HBA1c and FPG at 6 months

Variables	Surgical (n=36)	Medical (n=36)	*P-valuee* t-test
MEAN BMI (Kg/m^2)	27.1±6.8	35.9 ±6.2	<0.001
MEAN HbA1c (%)	5.6 ±0.9	7.1±0.65	<0.001
MEAN FPG (mg/dL)	110.5 ±4.5	128.2 ±6.4	<0.001

BMI: Body mass index, HbA1c: Glycosylated haemoglobin, FPG: Fasting plasma glucose

Table-5: Rate of remission at 3 months.

Remission (HbA1c ≤6% and FPG<126 mg/dL)	Groups Surgical	Medical	Total	P-Value Chi-Square
Achieved	33	0	33	<0.001
	91.7%	0%	45.8%	
Not Achieved	3	36	39	<0.001
	8.3%	100.0%	54.2%	
Total	36	36	72	
	100.0%	100.0%	100.0%	

Table-6: Rate of remission at 6 months.

Remission (HbA1c ≤6% and FPG<126 mg/dL)	Groups Surgical	Medical	Total	P-Value Chi-Square
Achieved	33	1	34	<0.001
	91.7%	2.8%	47.2%	
Not Achieved	3	35	39	<0.001
	8.3%	97.2%	52.8%	
Total	36	36	72	
	100.0%	100.0%	100.0%	

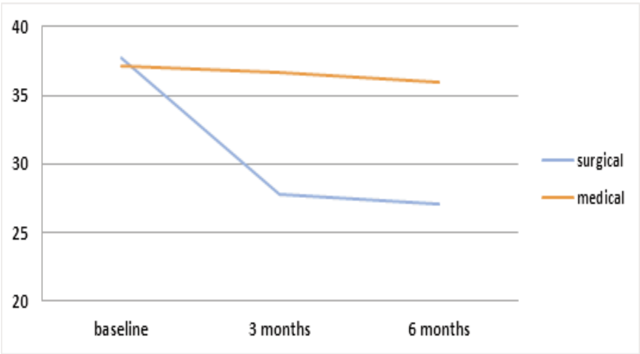

Figure-2: Declining trends of body mass index (BMI) in the study groups.

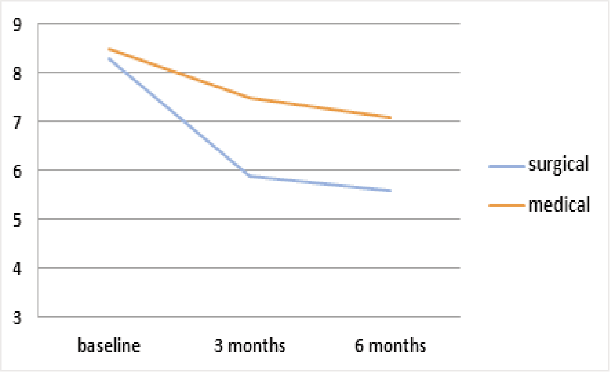

Figure-3: Declining trends of glycosylated haemoglobin (HBA1c) in the study groups

At baseline, mean BMI, HbA1c and FPG levels were not significantly different between the groups (Table 2). At 3 months, group A values were significantly lower compared to group B (Table 3). At 6 months, mean BMI, HbA1c and FPG values were significantly lower in group A compared to group B ($p<0.001$) (Table 4). At 3 months, 33(91.7%) group A patients demonstrated HBA1c <6% and FPG 126mg/dL without the help of antidiabetic medications (Table 5). At 6 months, there were 33(91.7%) patients in group A with remission of diabetes compared to 1(2.8%) patient in group B ($p<0.001$) (Table 6). Declining trend in BMI and HbA1c values at 3 and 6 months were noted (Figures 2-3).

Discussion

T2DM and obesity often coexist. Visceral obesity contributes significantly to the development of T2DM. Visceral fat releases inflammatory cytokines that contribute to insulin resistance. Around 85% of individuals diagnosed with T2DM meet the BMI criteria for either overweight or obesity.[20] For obese T2DM patients who do not respond to lifestyle changes and medical treatment, bariatric surgery can be a very effective solution. The extent of achieving sustained remission, varying between 23% and 60% of patients, depends upon the initial severity and duration of T2DM.[21]

Bariatric surgery improves all three aspects of metabolic syndrome: hyperglycaemia/ T2DM, hypertension and dyslipidaemia. The current study compared the early outcome of metabolic surgery with intensive medical therapy in the management of T2DM in obese population. The results showed that both treatment groups were similar in terms of mean BMI, HbA1c and FPG values at baseline, but at 3 and 6 months, the levels was were significantly lower in the surgical group compared to the medical group. Also, the surgical group experienced a higher remission rate compared to the medical group. It was likely because bariatric surgery exerts profound glucoregulatory effects potentially via neuroendocrine mechanisms.[21] Improvement in glycaemic control is reported within days to weeks of surgery, even before the patient has lost meaningful weight. This is due to an alteration in gastrointestinal physiology that is independent of weight loss.[22] A glucagon-like peptide-1 (GLP-1) mediated mechanism has also been implicated.[23,24] These metabolic effects were observed in the surgical arm of the current study where the majority of patients' plasma glucose levels returned to normal without the help of antidiabetic medications way before they lost their excess body weight.

A 2009 meta-analysis of 19 primarily observational studies found a 78% remission rate and an 87% improvement rate for T2DM after bariatric surgery within 1-3 years of follow-up.[25] In a trial from 2011, bariatric-specific data was gathered from over 100 institutions, involving more than 28,000 obese patients with T2DM. Within 12 months, 83% of those undergoing Roux-en-Y gastric bypass (RYGB), 55% undergoing Sleeve gastrectomy (SG), and 44% undergoing adjustable gastric banding (AGB) achieved remission or improvement in T2DM.[26] A study in Pakistan comparing outcomes of laparoscopic SG (LSG) and weight control programme among class 1 obese persons with T2DM concluded a significant reduction in HbA1c level in the surgery group.[27] This is in agreement with the current findings.

The sustainability of glycaemic control post-bariatric procedures has garnered substantial attention. Individuals having undergone RYGB were observed to have a higher likelihood of discontinuing antidiabetic medications compared to those who underwent SG or AGB.[28] More recently, MGB, also known as one-anastomosis gastric bypass (OAGB), is gaining popularity as a bariatric procedure due to its technical simplicity, lower complication rate, better, sustainable weight loss and metabolic effects. Preliminary findings suggest that OAGB shares a comparable capacity with RYGB to induce remission in individuals with T2DM.[29] One trial reported lower HbA1c (6.1% versus 7.1%) after OAGB than after LSG.[30] In 2018, a study described a significant decline in HbA1c at 3 and 6 months post-MGB. The resolution of T2DM was observed in almost 95% of patients, with significant reduction in BMI.[31] These results are comparable to the current results.

In the current study, 3 patients who failed to achieve remission after surgery were evaluated thoroughly. It was found that 1 patient who had preoperative HbA1c >10mg/dl failed to achieve remission within 6 months even though his HbA1c had reduced significantly. The other 2 patients with unfavourable outcomes had been non-compliant with diet and exercise due to pre-existing obesity-related osteoarthritis. Hence, the above-mentioned factors clearly played an important role in achieving remission after bariatric surgery.

To the best of our knowledge, the current study is the first done in Pakistan that compared medical and surgical management of T2DM with a stringent inclusion/exclusion criteria. However, the present study has several limitations. It employed convenience sampling technique and enrolled all consecutive patients due to time constraints. The sample size was relatively small even though it was enough to draw the relevant inferences. The study did not measure outcomes beyond 6 months, and did not take into account the effects of metabolic surgery on long-term complications associated with T2DM, such as microvascular changes like retinopathy, nephropathy and neuropathy. No mortality was recorded, and beyond that the study did not look further into the adverse effects, if any, among the subjects.

Studies with larger sample sizes are needed that may take into account other variables, like the sustainability of controlled glycaemic levels over longer durations and effects of metabolic surgery on long-term complications of T2DM.

Conclusion

Metabolic and bariatric surgery in obese patients with T2DM resulted in a better rate of remission after surgery compared to intensive medical treatment.

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Conflict of Interest: None.

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AUTHORS' CONTRIBUTIONS:

ZR: Data collection, statistical analysis, writing and responsible for integrity of research.
MBUH: Design, statistical analysis, writing, editing and drafting.
TI: Data collection and writing.
AK: Data collection, writing and editing.
AI: Design, reviewing and final approval.