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## **Original Research**

## Effects of bariatric surgery on Type-2 Diabetes Mellitus in a Caribbean setting

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## ABSTRACT

*Objectives:* To determine if there is a beneficial effect of bariatric surgery in the management of Diabetes Mellitus in obese patients in a Caribbean setting. *Methods:* A retrospective review of charts of all obese patients with Type-2 Diabetes Mellitus (DM) who had undergone Laparoscopic Roux en Y gastric bypass (LRYGBP) over a 4 year period was undertaken and clinical data recorded. A questionnaire was prospectively administered via telephone to determine the quality of life.

*Results*: Of 146 patients who underwent LRYGBP, 40 were found to have clinically significant DM. Patients of age < 50 years and females had a higher preponderance of DM. Patient body weight decreased significantly from a pre-operative131.2  $\pm$  21.6 [Mean  $\pm$  Standard Deviation (SD)] to 99.4  $\pm$  16.6 after surgery (p < 0.0001). There was also a significant reduction of BMI from 47.0  $\pm$  7.9 to 34.7  $\pm$  5.8 (p < 0.0001). There was complete resolution of clinically significant DM in 85% of patients, while in 15% there was a significant reduction in the dosage of anti-diabetic medications. Perioperative complications were minimal and there was no mortality. 96% of the patients reported a drastic improvement in their quality of life.

*Conclusions:* Bariatric surgery for obese diabetic patients resulted in complete resolution, improved diabetes control and overall improvement in the quality of life. Due to better outcomes, the surgery can safely be recommended in the Caribbean multiethnic setting where there is a high prevalence of obesity and Diabetes Mellitus.

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## 1. Introduction

Morbid obesity is a causative factor for many life-threatening co-morbidities including Type-2 Diabetes Mellitus (DM), cardiovascular disease and cancer.<sup>1</sup> Weight loss in these patients has led to improvements in management of co-morbidities and the inherent complications, resulting in reduced mortality.<sup>2</sup> Bariatric surgery in the obese population with impaired glucose tolerance (IGT) reduces the incidence of new onset diabetes by 58% and improves or resolves metabolic control of those with established Type-2 DM.<sup>3</sup> It has been shown that surgical treatment for morbid obesity has been more effective in achieving sustainable weight loss and resolving metabolic syndromes than non-surgical methods.<sup>4</sup> In addition, it is also noticed that euglycaemia and normal insulin levels can occur within days after surgery, long before there is sustainable weight loss raising

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questions as to the real mechanism of diabetic control after bariatric surgery.<sup>5</sup>

Since July 2003, laparoscopic roux-en-Y gastric bypass (LRYGBP) has been performed successfully in Trinidad. This study aims to highlight the experience with bariatric surgery in a Caribbean island (with 50% population belonging to Asian Indian descent) and to examine whether bariatric surgery had a beneficial effect on the management of Type-2 DM which is highly prevalent in this country. Additional objectives of the study include determining whether LRYGBP was able to achieve sustainable weight loss in obese patients and also to determine if there was an overall improvement in the quality of life in these patients after bariatric surgery.

## 2. Methods

After institutional approval, all patients with Type-2 Diabetes Mellitus who had undergone LRYGBP from July 2006 to August 2010 and had at least 3 months of follow-up were included in the study. Amongst the obese patients, only patients who met the criteria for bariatric surgery based on the proposal of the National Institutes of Health Consensus Conference Guidelines were selected for LRYGBP.

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These criteria include BMI > 35, other life-threatening co-morbidities such as DM, Hypertension, Obstructive Sleep Apnoea (OSA) etc.

The diagnosis and classification of Diabetes Mellitus was based on the guidelines established by the American Diabetic Association. The categories of fasting plasma glucose (FPG) include

- (1) FPG < 110 mg/dl (normal)
- (2) FPG > 110 mg/dl and  $<\!\!126$  mg/dl (impaired fasting glucose (IFG) or prediabetes)
- (3) FPG > 126 mg/dl (clinical diabetes).

In addition to 2 and 3 above, patients who were known to be Type-2 diabetics on medication (even with a normal FPG prior to surgery) were included in the study. The severity of diabetes mellitus was classified according to the treatment required to maintain euglycaemia. Severity classifications included patients with

- (1) Impaired fasting glucose
- (2) Diet controlled DM
- (3) Oral hypoglycaemic controlled DM
- (4) Insulin controlled DM
- (5) Combination of insulin and oral agents to control DM.

All patients underwent a rigorous pre-operative work-up which included a history and physical examination, nutritional and psychological evaluation and counselling, cardiology and endocrinology evaluation.

The bariatric surgical procedures were performed by the same surgeon (first author) using a standard six port technique. Under general anaesthesia, after pneumoperitoneum, the dissection started with identification of the angle of His. The gastric pouch was then created by transection of the stomach with linear staplers (Ethicon m) to create a pouch averaging 15–30 cc. The length of the Roux limb varied from 100 to 200 cm and the bilio pancreatic limb was 50 cm. The gastro-jejunal anastomosis was created with a linear stapler to a length of 10–15 mm and this anastomosis was routinely tested to ensure that it was both air and water tight. It was done in an antecolic and antegastric fashion.

Estimation of blood sugar was done every 6 h while in the hospital and patients were given insulin as needed. The patients were discharged on the second post-operative day once they tolerated oral feeds and were advised a 600 kcal liquid diet. On discharge, patients were advised to check the blood sugars at least twice daily and to restart medications only if the sugars were persistently above 150 mg/dl. The first three follow-ups following surgery were done at the surgical clinic and thereafter followed up at 2 weeks, then 6 weeks and then every 12 weeks in diabetic clinics. The dose of restarted medications, if any, was adjusted down to the least necessary for euglycaemia to prevent hypoglycaemia. HbA<sub>1</sub>C levels were done, if control was a problem. Physical exercise was started by two weeks.

Demographic and clinical data were recorded retrospectively from charts. Demographic data included age, gender, ethnicity of the patients and clinical data included diabetic status, co-morbidities, surgical procedure and duration, pre-operative and post-operative anthropometry including body weight(kg) and BMI (kg/m<sup>2</sup>).

A quality of life assessment was done via telephone using a self-designed questionnaire (Appendix). In this questionnaire, the questions pertaining to quality of life assessment alone were adapted from the well established SF-32 questionnaire. A five-point Likert scale ranging from 1 (poor) to 5 (excellent) was used to evaluate the quality of life and social and emotional status.

Data were entered into Statistical Package for Social Sciences (SPSS)—version 12 (Chicago, IL, USA) and analysed. Descriptive analyses of all data were done. For numerical data such as body weight and BMI, comparisons were made between preoperative and post-operative periods by 'Paired *t*-tests'. Categorical and ordinal data were compared by Chi-square analyses. Statistical significance was fixed at the level of p < 0.05.

#### 3. Results

One hundred and forty six patients had LRYGBP performed during the study period from July 2006 through August 2010. Of these, 40 (27.4%) patients were found to have clinically significant DM. 42.5% of the diabetic patients were above the age of 50 years and 57.5% were between ages 18–49 years. The gender distribution showed preponderance for females, accounting for 60% of the patients. The ethnic composition of the study group reflected the general population of the island with the majority being Indo-Trinidadians. Table 1 depicts the demographic variables. Fig. 1 shows the distribution of comorbid illnesses.

Patients belonged to all categories according to the severity of DM. Diabetes was present for less than 5 years in 26 (64%) of the

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Demographic	variables.

Age (y)		
Range		23-59
Mean (Standard	Deviation)	44 (10)
Gender	Male (%)	40
	Female (%)	60
Ethnicity	East Indian descent (%)	47.5
	African descent (%)	20
	Mixed (%)	20
	Other (%)	12.5

patients prior to surgery. Over 90% of these patients were compliant with their medications; however, diabetes control was only achieved in 58% of these patients as revealed by HbA<sub>1</sub>C measurements and daily glucometer readings.

Pre-operatively the body weight of the patients ranged from 90 to 177 kg with a mean of 131.2 kg (Standard Deviation (SD), 21.6). The BMI ranged from 34.9 to 64.8, with a mean of 47.0 (SD 7.9). 96% of these patients had BMI > 35. Post-operatively, the weight loss ranged from 21.3 to 72.7 kg with a mean of 37.3 (SD 10.5) kg. The comparisons between the pre-operative and post-operative parameters are shown in Table 2. The time period of patient follow-up ranged from 3 to 50 months with a mean of 15 months. The change in the BMI between pre-operative and post-operative periods in the different diabetic categories is shown in Fig. 2.

Post-operatively, there was a drastic change in blood glucose control. The changes were noted in the immediate post-operative period and progressively improved over time. Thirty of the 40 patients were never restarted on medications in the immediate post-operative period while 10 required some form of control (either insulin or metformin). Four of these patients resolved completely by 1 month and 6 remained on medications. Thus, there was complete resolution of clinically significant DM in 34 (85%) of these patients and a significant reduction in the number and dosage of medications to control DM in the remaining 6 (15%). In one of these latter patients, before undergoing surgery, the daily medications to control DM included 450 units insulin combined with 2 oral agents. Within one month after surgery, the other 5 patients were also controlled with metformin alone post-operatively. The comparison of interventions



Fig. 1. Distribution of comorbid illnesses. OSAS: Obstructive Sleep Apnoea Syndrome, CVI: Chronic Venous Insufficiency, COPD: Chronic Obstructive Pulmonary Disease, PCOS: Polycystic Ovarian Syndrome, RI: Renal Impairment, RA: Rheumatoid Arthritis.

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#### Table 2

Comparison of variables before and after surgery.

Variable	Before surgery	After surgery	Significance
Body weight (Mean $\pm$ SD)	$131.2\pm21.6$	99.4 ± 16.6	<i>p</i> < 0.0001*
$\frac{\text{BMI}}{(\text{Mean} \pm \text{SD})}$	$47.0\pm7.9$	$34.7\pm5.8$	<i>p</i> < 0.0001*
Number of patients on insulin (%)	27.5	2.5	<i>p</i> < 0.001§
Number of patients on metformin (%)	42.5	12.5	p < 0.001§
Quality of life score	3	5	p < 0.01§

\*Statistical significance by paired *t*-tests.

§Statistical significance by Chi-square tests.

during the pre-operative and post-operative periods in different diabetic categories is shown in Table 3.

There was no mortality in this study. Perioperative complications were limited to the occasional dumping syndrome and mild hair loss. There were no surgical complications such as leaks, infections or reoperation or other major morbidities such as DVT or pulmonary embolism in this cohort. One patient had mild chest pain which was thought to be coronary spasm syndrome and this settled uneventfully. Another patient was diagnosed to have aspiration pneumonitis, needed readmission but settled with conservative management.

The quality of life assessment showed that 60% of patients graded their quality of life in the pre-operative period as either 2 or 3; in the post-operative period all but one patient graded their quality of life as 5 (excellent) (p < 0.01 by Chi-square test) (Table 2), implying overall satisfaction with the surgery.

#### 4. Discussion

The major finding of the present study is the ability of bariatric surgery to adequately control Type-2 Diabetes Mellitus and to improve of the quality of life in obese patients in a Caribbean setting.

The global epidemic of Type-2 DM and obesity has afflicted the Caribbean region also.<sup>5–7</sup> Globally, approximately 150 million individuals are currently affected by Type-2 DM and it is estimated that by 2025, this may increase to 300 million.<sup>8,9</sup> Type-2 DM



**Fig. 2.** Change in BMI in the different diabetic groups I: Impaired glucose tolerance without overt DM, II: DM controlled by diet and exercise, III: DM controlled by oral hypoglycaemic agents, IV: DM controlled by insulin, V: DM controlled by insulin and oral hypoglycaemic agents.

### Table 3

Comparison of interventions for DM before and after surgery.

Severity of DM	Pre-operative n (%)	Post-operative n (%)
Impaired glucose tolerance without overt DM	9 (22.5)	0
DM controlled by diet and exercise	3 (7.5)	0
DM controlled by oral hypoglycaemic agents	17 (42.5)	5 (12.5)
DM controlled by insulin	6(15)	1 (2.5)
DM controlled by insulin and oral hypoglycaemic agents	5 (12.5)	0
Euglycaemia post-operatively not requiring any intervention	0	34 (85)

increases morbidity and mortality and is an economic burden on health budgets worldwide. Weight loss has been consistently associated with a better control of diabetes. The incidence of complications of Type-2 DM can be reduced with tight euglycaemic control using medical management, diet and exercise. However, compliance has been a major impediment to medical management, and seldom results in complete resolution.

The mounting evidence for surgery as a potential cure for Type-2 DM comes from observations of the resolution of Type-2 DM after bariatric surgery for morbid obesity, gastric surgery for gastric carcinoma, experimental evidence from rodents, human evidence and on-going trials on humans.<sup>10</sup> The present study supports the evidence for the resolution of Type-2 DM after bariatric surgery in the Caribbean.

Bariatric surgery has a profound and durable effect on the resolution of Type-2 DM. In a meta-analysis of 134 studies, Buch-wald et al reported varying percentages of Type-2 DM resolution following different types of bariatric surgery; 48% for laparoscopic adjustable gastric banding, 84% for gastric bypass and 98% for Bilio Pancreatic Diversion/Duodenal (BPD) Switch.<sup>11</sup>

Gastric bypass surgery decreases both the incidence and prevalence of Type-2 DM in patients. This resolution occurs within days after gastric bypass, before any significant weight loss and was sustained for a longer time period. Pories et al reported the long term results of 608 severely obese patients who underwent gastric bypass, with a 93% follow-up over 14 years.<sup>12</sup> Of the 146 patients with baseline DM, 83% continued to be normoglycaemic at 14 years. Glucose levels normalized within a few days after surgery, before significant weight loss occurred which was a finding in the present study also.

Bariatric surgery prevents the progression from impaired glucose tolerance to diabetes and hence reduces the incidence of Type-2 DM. Pories et al demonstrated resolution of glucose intolerance in 98.7% of patients undergoing gastric bypass.<sup>12</sup> In the Swedish Obesity Subjects trial, which compared the outcomes of surgical versus medical management of 4047 obese patients over a 10 year period, there was a reduction of 30 in the relative risk for developing Type-2 DM in the surgical arm.<sup>4</sup> In a Caribbean setting where there is high prevalence of Type-2 DM, this can actually change epidemiological characteristics.

Although weight loss was initially believed to be responsible for diabetic control following bariatric surgery, it was realized that gastric bypass resolved DM even before any significant weight loss occurred, which was a finding in the present study also. This has led to the postulation of the foregut and hindgut theories. Numerous other metabolites (including ghrelin) are also being investigated.<sup>13,14</sup>

The foregut theory suggests that the exclusion of a short segment of the proximal small intestine from ingested nutrients exerts a direct anti-diabetic effect. Rubino demonstrated that a duodeno-jejunal bypass in rats improved diabetic control.<sup>15</sup> These results have been reproduced in human studies of duodenal-jejunal

by pass showing improvement in glycaemic control in the obese and non-obese. ^{16}  $\,$ 

The hindgut theory suggests that after LRYGB, bilio pancreatic diversion (BPD) and ileal transposition, expedited delivery of ingested nutrients to the lower intestine increases the secretion of Glucagon like peptide (GLP-1). This is an incretin that lowers blood sugar. GLP-1 is increased after the above two procedures but not after gastric banding.<sup>17,18</sup>

In 2009, the American Diabetic Association (ADA) recommended that patients with a BMI > 35 and Type-2 DM should be considered for bariatric surgery due to growing evidence that various gastrointestinal (GI) operations were being used throughout the world to treat obese and non-obese diabetics with resounding results.<sup>19,20</sup> The consensus statement of the first Diabetes Surgery Summit, 2007 also suggested that GI surgery should be considered for the treatment of Type-2 DM in eligible surgical candidates with BMI < 35 who are inadequately controlled by lifestyle and medical therapy.<sup>21</sup> In our study, 96% of the patients had BMI above 35 and hence fit the above criteria. In fact, the effects of bariatric procedures on DM control and resolution are so profound that the field of 'metabolic surgery' is emerging exclusively to treat DM. In our study, 85% of our patients had complete resolution of their diabetes mellitus and the remaining 15% had a drastic improvement in their control.

It has been shown that the phenotypic makeup of the Asian population is different to that of their Caucasian counterparts and that the definition of obesity in this ethnic group should be different. Additionally, the Asian population is prone to high levels of metabolic risk factors at a relatively low BMI and this phenomenon may be attributable to the fact that Asians are more prone to central obesity. This trend includes Asian Indians, who form a major proportion of the Caribbean population.<sup>22,23</sup> Body fat of more than 25% in males and 35% in females is considered 'Excessive Body Fat'.<sup>24</sup> Studies suggest that the percentage of Excessive Body Fat was under-predicted by BMI in the Asian population.<sup>25</sup>

As a result of these differences, the first Asian Consensus Meeting on Metabolic Surgery, 2008 formulated guidelines for the use of surgery for Type-2 DM in the Asian population.<sup>26</sup> These guidelines have taken into consideration the unique differences with respect to BMI and central obesity prevalent in this ethnic

group. A high percentage of population in many Caribbean countries belong to the Asian Indian ethnicity which is especially true in Trinidad & Tobago and Guyana. This ethnic group in the Caribbean is unique in that they possess the 'Asian Indian' body habitus but consume mainly a 'Western' diet. This has resulted in a high prevalence of obese diabetics with early complications. This is also compounded by poor compliance with medical management and poor social service support, causing a strain on the health sector and a negative economic spin-off.<sup>27</sup> Type-2 DM and obesity are highly prevalent in the Caribbean society and their impact on increased mortality is well documented especially in those of the Asian Indian descent.<sup>28</sup> A vast majority of the patients in our study belonged to this ethnicity. The possibility of using bariatric surgery at a relatively lower BMI to treat and cure Type-2 DM may have a greater economic impact on the Caribbean society.

There were many limitations to the study; the major limitations being retrospective design, a relatively smaller sample size and inability to correlate severity of diabetes with variations in surgical procedure and overall outcomes. The questionnaire was a self-designed one, although the 'quality of life' part was adapted from an established validated questionnaire. The telephone interview is another limitation and there is a possibility that this would not have captured sufficient information similar to that of a face-to-face interview.

Nevertheless, in summary, the study was able to establish that bariatric surgery could be safely performed in the Caribbean environment and may result in an overall improvement in quality of life. The Asian ethnic group in the Western world is a special group and the indications for metabolic surgery may have to be tailored for this population.

Conflict of interest

None. Funding

None.

Ethical approval

Approval obtained from San Fernando General Hospital.

### Appendix

## Questionnaire

Name:						
Age: <18 18-29	30-39	40-49	50-59	>60		
Sex: male	female					
Ethnicity: Caucasian	h African	East In	dian	Chinese	Mixed	
Pre operative						
Weight(kg): BMI: <15 15-19. (kg/m2)	.9 20-24.9	25-29.9	30-34.9	35-39.9	>40	
Co-morbidities:						
N	Gallstones		OA/E	Back pain		PVD

HTN	Gallstones	OA/Back pain	PVD
DM	OSAS	Depression	Varicose veins
COPD/Asthma	Liver disease	MI	PCOS
RF	PUD/GERD	CVA	Other

Medications:

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Methods used to lose w	eight:						
Diet		Medi	cation			Herba	preparations
Exercise		Prave	r			Other	
Success: very poor	1	good		very goo	d		
1	2	3	4	5			
Level of Activity:	completely		normal	activities	/ al	bove nor	nal /
	1	2	3	anag	4	nginy act	uvç
	Ċ	~	5		•	5	
Quality of life: ver	ry poor		good		very good		
	1	2	3	4	5		
Operative							
Operative							
Date of surgery:							
Type of surgery:							
Type of surgery.							
Complications:							
Re-operation for leak				Hair	loss		
Obstruction				Dum	ping syndr	omes	
Gall-bladder disease				Othe	r		
Post-Operative							
Follow-up:							
(months)							
BMI: <15 15-19.	9 20-24	.9 25	5-29.9	30-34.9	35-39.9	>40	
(Kg/m2)							
Co-morbidities:							
HTN	Gallstor	es		OA/B	Back pain		PVD
DM	OSAS			Depre	ession		Varicose veins
COPD/Asthma	Liver di	sease		MI			PCOS
RF	PUD/GI	ERD		CVA			Other
Medications:							
Quality of life: very	y poor		good		very good		
	1	2	3	4	5		
Social & Emotional	functioni	ng					

Pre-opPost-opAbsence from work/daysUndertaking leisure activitiesCoping with daily activitiesHappiness with life

Where 0 indicates least desirable option and 5 indicates most desirable option

Insurance Company :

Physical strength Coping in social settings

Did Insurance Company Pay for Surgery: YES NO

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