Specific aspects of bariatric surgery in French Polynesia

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Short-title: Bariatric surgery in Polynesia

Specific aspects of bariatric surgery in French Polynesia

Abstract

Introduction: There is a significant increase in obesity and diabetes mellitus prevalence in Polynesia. The objective of this study was to identify the effectiveness and safety of bariatric procedures in Polynesian population in the setting of a structured bariatric program led by a single bariatric surgeon.

Methods: This was a single-center study with a retrospective analysis of prospectively collected data. We retrospectively reviewed all patients supported in our institution for obesity surgery between May 2011 and June 2017. Sleeve gastrectomy (SG) and Roux-en-Y gastric bypass (RYGBP) were performed.

Results: 458 patients underwent bariatric surgery during the study period. Mean age was 39.5 ± 10 years, mean BMI was 46.8 ± 7.8. We did 185 RYGBP and 273 SG between 2011 and 2017. There was no statistically significant difference between RYGBP and SG for weight loss and comorbidities improvement or resolution. The risk of a postoperative biliary stones requiring cholecystectomy appeared to be greater after RYGBP than after SG although this difference did not reach statistical significance ($p = 0.08$).

Conclusion: In this isolated population, follow-up programs are difficult to implement. The SG is preferred in French Polynesia in front of its lower morbidity, the lesser seriousness of a non-vitamin supplementation and the reduction of the risks of biliary complications, with comparable results in terms of excess weight lost compared to the RYGBP.

Keywords: bariatric surgery, remote area, Polynesia, sleeve gastrectomy, safety

Highlights

In the manuscript intitled "***Specific aspects of bariatric surgery in French Polynesia***" we report the implementation of a bariatric program in remote area such as French Polynesia.

- This manuscript gives the opportunity to support a bariatric program in an area with low medical density.
- In this isolated population, follow-up programs are difficult to implement.
- The sleeve gastrectomy (SG) is preferred in French Polynesia because of its lower morbidity, the lesser seriousness of a non-vitamin supplementation and the reduction of the risks of biliary complications, with comparable results in terms of excess weight lost compared to the RYGBP. The paper provides evidence that the SG is a suitable procedure in this setting.

Introduction

High body-mass index (BMI) is an important risk factor for cardiovascular and kidney diseases, diabetes, some cancers, and musculoskeletal disorders [1]. Concerns about the health and economic burden of increasing BMI have led to obesity being included among the global non-communicable disease targets, with a target of halting, by 2025, the rise in the prevalence of obesity at its 2010 level [1,2]. Epidemiological studies have shown substantial risks in people with severe (≥35 kg/m^2) or morbid (≥40 kg/m^2) obesity [3].

Native Hawaiians and Polynesians living in economically disadvantaged communities suffer disproportionately from many health conditions, especially chronic diseases [4–6]. Regional mean BMI in 2014 was maximum in Polynesia and Micronesia: for men 29.2 kg/m^2 and 32.2 kg/m^2 for women [2]. During 1980-2009 there were significant increases in BMI and obesity in Polynesia [7]. Physical activity programs are built in urban areas of Polynesian islands to improve physical activity [8,9].

Age-standardized adult diabetes mellitus prevalence in 2014 was highest in Polynesia and Micronesia, at nearly 25% [10]. Native pacific islanders have higher rates of diabetes compared with other races/ethnicities [11]. Also in many remote pacific islands, health care is not provided [12]; the use of telemedicine in chronic disease management has potential to improve patient care in remote indigenous populations and may supplement patient-provider relationships [13].

In 2011 a comprehensive bariatric program was initiated in Polynesia by a single surgeon that had been previously specifically trained in a high-volume bariatric center in France.

The objective of this study was to identify the effectiveness and safety of bariatric procedures in Polynesian population in the setting of a structured bariatric program led by a single bariatric surgeon. In addition, we aimed to evaluate the impact of medical observance during post-operative follow-up.

Material and methods

This was a single-center study with a retrospective analysis of prospectively collected data. Patients were then selected preoperatively using the following criteria: 18 years old and less than 65years of age or good general condition, the existence of morbid obesity with BMI greater than 40 or 35 with presence of comorbidities related to obesity - radiologically proven osteoarthritis, hypertension, type 2 diabetes mellitus (T2D) or obstructive sleep apnea syndrome (OSAS). For each patient, the following data were collected prospectively: demographic data (age, gender), morphological and clinical data (weight, height, BMI) and past illness, details of surgery, postoperative complications, mortality, follow-up data (duration of follow-up, body weight, improvement and/or resolution of obesity-related comorbidities, compliance with vitamins and minerals supplementation).

We retrospectively reviewed all patients supported in our institution for obesity surgery between May 2011 and June 2017. Surgical technique: we performed sleeve gastrectomy (SG) and Roux-en-Y gastric bypass (RYGBP). Adjustable gastric binding (AGB) procedures were made in another institution.

Regarding the surgical technique, the RYGBP were privileged at the beginning of the experience of the center then the SG was quickly preferred to the RYGBP for its low morbidity and the simplicity of the post-operative follow-up. Currently the RYGBP is reserved for SG failure, patients with severe gastroesophageal reflux with erosive esophagitis, biopsy proven Barrett's esophagus. SG failure was defined as an overweight with postoperative one-year weight greater than the preoperative weight. Those patients have been excluded for GBP analysis. Considering the revisions from SG to GBP, analyses of the different outcomes (failure, vitamine intake etc...) were carried out with intention to treat. We did not include these SG failures in the GBP group in the study.

Definitions: we considered remission for diabetes, hypertension and obstructive sleep apnea syndrome, for patients with glycated hemoglobin (HbA1c) less than 7% without drug therapy, systolic blood pressure lower than 140 mmHg without medication and weaning from nocturnal non-invasive ventilation. Improvement was defined as the reduction in the use of medications for each condition. OSAS improvement was assessed by a pulmonologist using at least a 10% improvement in polysomnography or clinical symptomatology of OSAS. Adherence was defined as daily oral intake of vitamins supplementation. Random or incomplete supplementation was considered nil.

The type of the survey is the same for both procedures: medical consultation (every 3 months during the first year and then every 6 months) or a phone call if the patient was not able to come. The follow-up could be different depending of the location of patients. For those living close to Tahiti (the biggest island), it was a clinical follow-up; for inhabitants of remote islands, medical follow-up was generally a phone follow-up.

Cholecystectomy was performed after bariatric surgery in case of symptomatic gallbladder lithiasis.

Surgical complications were classified according to Clavien-Dindo [14]: stages 1 and 2 represent minor complications requiring the introduction of drug therapy without organ failure; stages 3 and 4 represent complications requiring interventional therapeutic under local anesthesia (stage 3a), under general anesthesia (3b) or the existence of organ failure (4a and 4b). Death is represented by stage 5. Only surgical complications ≥ 3 were reported.

Missing data management: during post-operative follow-up, for patients refusing to come for clinical exam or refusing to give their weight during phone call, we calculated their postoperative BMI from the last known weight or, if not applicable, the preoperative weight.

Statistical analysis was performed with free software ‘‘R’’ version 3.0.1 (R Development Core Team (2008), *R Software*. R Foundation for Statistical Computing, Vienna, Austria). Univariate analysis was performed by chi-square test and log-rank test. We considered as statistically significant if p-value<0.05. Multivariate analysis was performed for parameters whose univariate analysis was statistically significant.

Results

In total, 458 patients underwent bariatric surgery during the study period. Median age was 39.5 ± 10 years, mean BMI was 46.8 ± 7.8. We did 185 RYGBP and 273 SG. The demographic data are presented in Table 1. Forty-three patients were in failure of a previous procedure: 40 AGB and 3 SG. Five patients had a BMI less than 35 kg / m^2 but had a historical BMI greater than 35 with presence of comorbidities related to obesity.

The median follow-up of patients is 2.1 years [1.3 – 2.9]. Regarding the follow-up of the patients, 93 of them did not show up for their follow-up visit or did not wish to give their weight by phone.

There was no statistically significant difference between RYGBP and SG for weight loss and comorbidities improvement or resolution. Pre-operative and post-operative weight of both groups were different, with higher BMI for SG group. This is due to lower BMI included for bariatric surgery at the beginning of the center's experience. After a learning experience for non-surgical team, maximal BMI limit were increased.

The duration of follow-up was not the same between the two groups since the RYGBP were mostly proposed at the beginning of the center's experience (tables 2 and 3).

On the other hand, there was no statistically significant difference in vitamin supplementation ($p = 0.395$). Only 300 patients answered to the survey about their vitamin supplementation observance; in addition, the compliance rate was relatively low (52.2%).

The risk of a postoperative biliary stones requiring cholecystectomy appeared to be greater after RYGBP than after SG although this difference did not reach statistical significance ($p = 0.08$).

There were no deaths related to the surgery. The serious complications are presented in table 4: three leaks requiring surgical revision (1 for RYGBP and 2 for SG), 1 anastomotic stricture at the gastrojejunal anastomosis for RYGBP, two moderate strictures for SG treated by endoscopy. There was no statistically significant difference between the two surgical procedures with respect to the Clavien-Dindo ≥ 3 complication rate. We did not collect any data about reflux. In our experience we encountered a very low incidence of reflux. We did not need, in this population, to transform SG into RYGBP.

Discussion

The present study indicates that a bariatric program can be safely and effectively established in a remote area such as French Polynesia with a low medical density allowing results that are comparable to those obtained in metropolitan France. In our study, with a median 2.1 years follow-up, there was a 10.5 BMI loss and 29.3 kg weight loss for RYGB, and 10.3 BMI loss and 29.7 kg weight loss for SG. There was no statistically significant weight loss between SG and RYGBP (p-value = 0.855). However, the two groups were not strictly identical since the BMI baseline was higher in the SG group. In fact, at the beginning of the experience, RYGBP was the most frequently proposed procedure and the included BMIs were lower.

These results are comparable to those reported in the literature with BMI decrease of 13 to 14.2 and 31.5 to 36.8 kg weight loss for the RYGB at a mean 2.1 years [15] and BMI decrease of 13 at 2 years follow-up for the SG [16,17].

Patients who begin the process for bariatric surgery with the higher BMI will remain with a slightly higher BMI compared to those who went for surgery with a lower BMI. Likewise, those who achieved a lower BMI at the end of the first year following the surgery will have a greater chance of maintaining a lower BMI in the fifth post-operative year. It was observed

that patients with higher BMI and lower excess weight loss (EWL) with 1 year of surgery presented higher BMI at 5 years post-operatively [18]. A meta-analysis demonstrated that long-term EWL is independent of baseline BMI and age after RYGBP and SG. In addition, there was no significant association between EWL and length of follow-up after RYGBP and SG that confirmed sustainability of weight loss after these procedures [19]. Weight loss may be associated with geographic location and race; RYGBP is more effective than AGB for reducing weight in America (61.9 vs. 41.7%) and Asia (60.1 vs. 48.2%); however, in Europe the effectiveness of RYGBP is equal to AGB (56.3 vs. 55.9%). In contrast, the effect of SG on weight loss is the same in America, Asia, and Europe [19]. There is no study reporting the %EWL of RYGBP vs. SG in the Pacific area. In our study, the weight loss between SG and RYGBP is the same, while the baseline BMI is higher in the SG group. Even if the %EWL could be lower in the SG group vs. RYGBP, SG remains preferred for its lower morbidity and a lower rate of vitamin deficiencies and gallbladder stones related complications.

We also found a significant decrease for all obesity-related comorbidities and there was no statistically significant difference in the reduction of comorbidities by type of surgical procedure [20]. However, the comorbidities were not the same between the two preoperative groups: diabetes was more frequent in the RYGBP group ($p = 0.049$). In addition, the BMI was higher in the SG group, which was accompanied by a higher (not significant) incidence of OSAS compared to the RYGBP group. Post-operatively, OSAS and diabetes mellitus were more common in the SG group than in the RYGBP group, but this was not statistically significant. Thus, the RYGBP was more effective for the management of diabetes, in our study but significant differences in patients' characteristics at baseline in the two groups may account for this difference.

Although, some studies found a difference in the reduction of diabetes mellitus with a superiority of RYGBP over SG [21–23] a recent randomized trial, the SM-BOSS showed that the two procedures resulted in similar results in terms of weight loss and improvement in T2D at five years [24].

Adiposity has increased substantially more, in low and middle-income countries than in continental Europe and high-income Asia Pacific countries, especially in women [10].

Awareness, treatment, and control of hypertension remains also a challenge in middle- and low-income countries, such as Polynesian islands [7]. Easy access to medical care and aggressive use of pharmacotherapy are the key strategies which have proved to be successful in reducing the burden of hypertension on the population level [25].

SG has rapidly become the most performed bariatric procedure in France and in the world [26,27]. Indeed, SG carries several advantages over the more complex RYGB, including the easier surgical technique with no digestive anastomosis, the possibility to explore the whole digestive tract endoscopically after the procedure, and the avoidance of intestinal bypass and [28]. SG is also more easily accepted by patients that more easily understand the principles of the procedure and its related constraints that are lighter than those of a RYGB. Our results indicate that both the RYGB and the SG are suitable procedures to start a bariatric program in the setting of a remote area as the French Polynesia with excellent results in terms of safety, especially in case of surgeon already experienced. Interestingly, these procedures were also done in the case of AGB failure with no complication.

Bariatric surgery is cost-effective in comparison to non-surgical treatment in the reviewed published estimates of cost-effectiveness [20]. Although we were not able to do a medico-

economic analysis, as the improvement in obesity-related comorbidities and the rate of complications were comparable to those reported in the literature, it may be speculated that bariatric surgery in this new program may be considered as cost-effective.

The risk of nutritional deficiencies depends on the percentage of weight loss and the type of surgical procedure performed: RYGB has a malabsorptive component and carries an increased risk of deficiencies as compared to SG [29]. Routine nutritional screening, appropriate supplements and monitoring compliance are imperative, whatever the bariatric procedure [29].

In our experience, there was no statistically significant difference in vitamin supplementation: patients who had been operated by SG were more likely to continue vitamin supplementation ($p = 0.395$), in addition, the compliance rate was relatively low (52.2%).

Enteric hyperoxaluria is often present in patients after RYGB because of due to intestinal malabsorption [30]. This phenomenon contributes to the formation of oxal-calcium vesicular gallstones and increases the incidence of biliary complications in these patients. In our study, there is a trend in performing secondary cholecystectomy after bariatric surgery: 8.4% for SG vs. 14.1% for RYGBP ($p=0.079$).

Observations over the last few years in French Polynesia suggest that ongoing nutritional transition points toward an increase of chronic conditions. This phenomenon impacts young people more than older generations who still live according to traditional practices. Adolescent obesity prevention in French Polynesia is a public health imperative, but it is also important for the implementation of intervention programs to be inexpensive and easily reproducible [31]. Wide variations were observed in the prevalence and the management of hypertension between French overseas territories, and an especially challenging low control

of hypertension was found in French Polynesia. Obesity appears a key target to prevent hypertension, particularly in French Polynesia [32].

Limitations

Due to the large distances between the Pacific Islands and the low medical density, prevention and follow-up programs are difficult to implement in these populations. Two thirds of patients (300 out of 458) did answer by phone or physical examination concerning body weight, vitamins observance, comorbidities, etc. ; in many cases, it was difficult to obtain information on body weight, as they have no device or didn't want to clarify their answers on comorbidities. Others simply didn't want to answer. So, for inhabitants of remote islands, RYGBP remains a risky procedure due to the challenge in follow-up and patients' observance. The median surgical follow-up is 2.1 years for a study period of 6 years. This is due to a gradual start-up of the activity which took two years to reach full capacity. This short monitoring is also explained by the monitoring difficulties linked to the long distances between Polynesian islands and archipelagos. However, there are only 3 surgical centers throughout Polynesia and 7 general surgeons; therefore, complications are unlikely to have occurred without our knowledge. Complications occurred throughout the experience of the center, there was, for example, no major morbidity (Clavien-Dindo ≥ 3) the first year of the experience. This is due to the surgeon's surgical training which was carried out for 4 years in a high-volume university center.

Regarding the choice of the surgical procedure, we recommend in Polynesia, the SG for its low morbidity, the least need for vitamin supplementation, the lowest proportion of gallstone complications and an equivalent reduction in weight loss and BMI compared to RYGBP, the reduced risk of long-term surgical complications such as intestinal obstruction that may prove

life-threatening in such a setting.

Conclusion

The rapid increase in obesity is a major public health issue, particularly in poorer areas such as Pacific island populations. In this isolated population, follow-up programs are difficult to implement. Thus bariatric surgery reduces cardiovascular risks with a positive cost-effectiveness balance. The SG is preferred in French Polynesia in front of its lower morbidity, the lesser seriousness of a non-vitamin supplementation and the reduction of the risks of biliary complications, with comparable results in terms of excess weight lost compared to the RYGBP.

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Ethical consideration:

All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards. For this type of study formal consent is not required.

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	Total of patients (458)	SG (273)	RYGBP (185)	p-value
Mean age ± SD, y	40.9 ± 10	40.7 ± 10	41.1 ± 10	0.659
Sex ratio, M/F	101/357	68/205	33/152	0.094
Hypertension, %	24.9	26.4	22.7	0.435
OSAS, %	14.7	15.8	13	0.490
T2D, %	16.2	13.2	20.5	0.049
Osteoarthritis, %	11.4	11.4	11.4	1.000
Weight ± SD, kg	133.16 ± 26.9	141.9 ± 29.5	120.3 ± 15.2	< 0.001
Mean BMI ± SD, kg/m2	46.8 ± 7.8	49.3 ± 8.8	43 ± 3.7	< 0.001
BMI <40, %	15.9	13.2	19.5	
BMI 40-50, %	56.8	42.1	78.4	
BMI >50, %	27.3	44.7	2.1	

Table 1: pre-operative characteristics of patients treated by bariatric surgery

SG: sleeve gastrectomy ; RYGBP: Roux-en-Y gastric bypass ; SD: standard deviation ; M: male ; F: female ; OSAS: obstructive sleep apnea syndrome ; T2D: type 2 diabetes mellitus : BMI: body mass index

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	Total of patients (458)	SG (273)	RYGBP (185)	p-value
Hypertension, %	6.6	6.6	6.5	1.000
OSAS, %	3.3	4	2.2	0.404
T2D, %	2.2	2.6	1.6	0.725
Osteoarthritis, %	2.6	2.6	2.7	1.000
Mean BMI ± SD, kg/m2	36.4 ± 8.7	39 ± 8.7	32.5 ± 7.2	0.001
BMI <40, %	68.3	60.4	80	
BMI 40-50, %	24.5	27.5	20	
BMI >50, %	7.2	12.1	0	
Weight loss, kg	29.6	29.7	29.3	0.855
PO cholecystectomy, %	10.7	8.4	14.1	0.079
Vitamins observance, %	52.2	50.5	55.6	0.395
Follow-up, y	2.1	1.9	2.4	< 0.001

Table 2: post-operative characteristics of patients treated by bariatric surgery

SG: sleeve gastrectomy ; RYGBP: Roux-en-Y gastric bypass ; SD: standard deviation ; OSAS: obstructive sleep apnea syndrome ; T2D: type 2 diabetes mellitus : BMI: body mass index

	Pre-operative		Post-operative (all)			Post-operative (without lost of view)		
	Weight (kg)	BMI (kg/m2)	Weight (kg)	Weight loss (kg)	BMI (kg/m2)	Weight (kg)	Weight loss (kg)	BMI (kg/m2)
All procedures	133.2	46.8	103.6	29.6	36.4	96.7	37	34
RYGBP	120.3	43	90.9	29.3	32.5	83.1	37	29.8
Sleeve	141.9	49.3	122.2	29.7	39	102.7	32.1	35.87
Follow-up, y			2.1 [1.3 – 2.9]			2.3 [1.4 – 3.1]		

Table 3: follow-up of patients treated by bariatric surgery

SG: sleeve gastrectomy ; RYGBP: Roux-en-Y gastric bypass ; BMI: body mass index

Complications	Total of patients (458)	SG (273)	RYGBP (185)
Grade 3a	0		
Grade 3b	7		
leaks requiring surgical revision		2	1
moderate strictures treated by endoscopy		2	
stricture at the gastrojejunal anastomosis			2
Grade 4	0		
Grade 5	0		

Table 4: post-operative complications of patients treated by bariatric surgery (complication classified as Clavien-Dindo ≥ 3.