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ORIGINAL ARTICLE

From diabetes remedy to diabetes remission; could single-anastomosis gastric bypass be a safe bridge to reach target in non-obese patients?☆,☆☆

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Summary *Background/Aims:* Type 2 diabetes mellitus (T2DM) is considered a chronic progressive incurable metabolic disease. Single-anastomosis gastric bypass (SAGB) has proved to be effective in obese patients, yet its impact on non-obese diabetics is not extensively studied.

The aim is to determine the anthropometric and glycemic outcomes of SAGB as a proposed line of treatment for T2DM patients with body mass index (BMI) 25–30 kg/m^2.

Methods: From November 2013 to March 2016, a prospective study has been conducted at Ain-Shams University Hospitals on 17 consecutive patients who have undergone SAGB. The demographic and anthropometric data, as well as the relevant laboratory results, were reported. Complete T2DM remission is considered if glycosylated hemoglobin (HbA1c) <6 % for at least 1 year without medication, whereas partial remission is considered if HbA1c<6.5%.

Results: The mean age was 42.6 ±13.8 years, mean BMI was 26.7 ± 2.3 kg/m^2 and mean duration of DM was 6.3 ± 2.7 years. The mean baseline values of HbA1c, FPG (fasting plasma glucose), and 2-hours postprandial glucose (2-H PPG) were 9.9%, 176.3 mg/dl, and 310.3 mg/dl respectively. These values significantly dropped at the 18th month to reach 5.8%, 93.4 mg/dl, and 156.2 mg/dl, with 13/17 patients became off-treatment (complete remission rate 76.4%).

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Conclusion: T2DM patients with BMI 25–30 kg/m^2 are considered the most controversial group. SAGB is an efficient metabolic procedure and could be integrated into the treatment algorithm of T2DM. Such line of treatment opens new horizons to change the concept of treatment from diabetes remedy to diabetes remission.

1. Introduction

Since the dawn of history, diabetes mellitus (DM) has been considered as a chronic progressive incurable metabolic disease.[1,2] The global prevalence reached 8.3%, a percentage that is increasing rapidly. The medical treatment achieves satisfactory glucose levels in less than 8% of the patients.[3]

Although the postoperative T2DM remission was observed four decades ago, the metabolic surgery has been restricted to those with a BMI ≥35 kg/m^2.[4] Based on numerous studies, the International Diabetes Federation (IDF) suggested that metabolic surgery could be beneficial also to patients with BMI 30–35 kg/m^2, who do not respond to medical treatment.[3,5] However, due to different pathophysiologic mechanisms, there was doubt regards the effectiveness of metabolic surgery in those with BMI< 30 kg/m^2.[6]

T2DM remission is a highly controversial issue; all experts[7–15] have agreed to define the remission as the ability to stop all diabetes-related medications for at least 1 year and maintain blood glucose levels and HbA1C within the normal range. However, this normal range is the main point of controversy. To address this dilemma, we summarize the different definitions of remission in Table 1.

Although metabolic procedures have been proved to treat T2DM, the physiology of remission is still vague.[1,16,17] SAGB was first carried out by Dr. Robert Rutledge in 1997.[18,19] It is referred to as mini-gastric bypass (MGB), one-anastomosis gastric bypass (OAGB), omega loop gastric bypass,[20] and BAGUA (Bypass Gástrico de Una Anastomosis) in the Spanish language.[21]

SAGB has been proved to be a safe effective procedure for obese patients; it offers durable T2DM remission in more than 75% of patients,[20,22–32] yet its effect on non-obese diabetics is not extensively studied.

2. Methods

2.1. Study design

Upon approval of the Institutional Review Board, a prospective study has been carried out from November 2013 to March 2016 on 17 consecutive T2DM patients with BMI (25–30) kg/m2 at Ain-Shams University hospitals, Cairo, Egypt. This study has been conducted in accordance with The Code of Ethics of the World Medical Association for experiments involving humans.

The aim of this study was to evaluate the short-term anthropometric and glycemic outcomes of SAGB as a proposed line of treatment for non-obese T2DM subjects. Type II diabetic patients aged 20–60 years of either gender irrespective of ethnicity were enrolled in this study, whereas those who have undergone previous bariatric surgery, controlled T2DM, duration of T2DM > 10 years, patients with endocrinal diseases, anemia, Bleeding disorders, Pregnancy, or those unfit for general anesthesia were excluded.

The preoperative demographic and anthropometric characteristics of the patients such as [age, gender, weight, height, BMI] were documented. The metabolic profile was assessed through a detailed history of T2DM status including but not limited to duration, and current antidiabetic treatment, hypertension, dyslipidemia, and the laboratory results [FPG, 2H-PPG, HbA1C and C-peptide] were evaluated. All patients submitted preoperative informed written

Table 1 Different definitions of T2DM remission.

Authors	Year	FPG	HbA1c	Others
Lee et al.[7]	2008	–	<7.0%	-Triglycerides <150 mg/dL.-LDL<100 mg/dl. –No treatment.
Buse et al.[8]	2009	<100.9 mg/dL.	<5.7%	–No treatment.
Breathauer et al.[9]	2012	<100 mg/dL.	<6%	–No treatment.
Milone et al.[10]	2013	<126 mg/dL.	–	–No treatment.
Aarts et al.[11]	2013	126.1 mg/dL.	<6.5%	–No treatment.
Yip et al.[12]	2013	–	<6.5%	–No treatment.
Arterburn et al.[13]	2013	<100 mg/dL.	<6%	–No treatment.
Guenzi et al.[14]	2015	–	<6%	–No treatment.
Purnell et al.[15]	2016	<126.1 mg/dL.	<6.5%	–No treatment.

consent and have been scheduled for laparoscopic SAGB. Prophylactic antibiotic, anticoagulation, and elastic stockings were routinely used.

2.2. Surgical technique

The surgical procedures were carried out by one of the authors under general anesthesia using the same technique. Through five ports, diagnostic laparoscopy of the whole abdomen was done, identification of the gastric incisura at the lesser curvature, then the creation of a window by the Ligasure® (Covidien, Autosuture, Mansfield, MA, USA). Gastric pouch was formed by applying the Endo GIA ® 60 mm articulating medium/thick reload with Tri-Staple technology (Covidien, Autosuture, Mansfield, MA, USA) horizontally, then vertically toward the angle of His under 36 French bougie guidance.

Dissection of the hiatus was done in 2 cases (associated hiatus hernia), with suturing of the crura only. An ante-colic isoperistaltic gastrojejunostomy is performed at about 120 cm distal to the ligament of Treitz. This modification of SAGB design with the tailoring of the bypass limb according to the BMI (exclude only 120 cm instead of the classic 200 cm length) allow balanced weight loss resulting in minimization of the risk of nutrient deficiencies. An anchoring suture was made to ensure foregut exclusion and minimize pancreaticoduodenal reflux. An intraoperative leak test was performed using methylene blue dye, after which drain was inserted.

Postoperatively, patients were put on a sliding scale, starting oral fluids in the 2nd day (after negative contrast study), then soft diet. Discharge usually happens on the 3rd day. The operative time and complication, postoperative length of stay, morbidity, as well as mortality, were documented.

The follow-up visits were scheduled for 1,3,6,12 and 18 months postoperatively. In each follow-up visit, we asked about the current medication and symptoms of hypoglycemic or hyperglycemic episodes to determine the precise status of T2DM. Also, we routinely measured arterial blood pressure (ABP) and weight routinely, besides BMI was calculated. We obtained FBG, 2H-PPG, HbA1C, and CBC for all patients. In addition, the 12-month and 18-month follow up visits, fasting C-peptide was requested. Data were collected and statistically verified checking for its significance.

Complete T2DM remission is considered if HbA1c is less than 6% for at least 1 year without medication, whereas partial remission is considered if HbA1c is less than 6.5% for at least 1 year without medication.

2.3. Statistical analyses

The standard descriptive statistics were used to analyze the demographic and clinical data. Continuous variables with a normal distribution were expressed as a range (minimum and maximum), mean ± standard deviation (SD), categorical variables were expressed as frequencies. The paired t-test was used to unveil the changes in results between the baseline and final results. Data were analyzed using Statistical Package for Social Science Version 22 software package for Windows (*SPSS, Inc., Chicago, Illinois, USA*). Statistical significance was considered if P-value < 0.05.

3. Results

This study was conducted on 17 patients including 5 males (29.41%) and 12 females (70.58%), their ages ranged from 21.1 to 58.6 years with a mean of 42.6 ± 13.8 years. Baseline anthropometric and metabolic patients' characteristics are shown in Table 2.

Preoperative anti-diabetic medications were shown in the Chart 1. In addition, 8 patients (47.05%) were on antihypertensive medications and 6 patients (35.29%) on hypolipidemic agents. All operations were completed laparoscopically without intraoperative complications. The mean operating time was 67.2 ± 21.7 min, the shortest time was 41.7 min, the mean hospital stay was 3.2 ± 1.1 days.

Early results at the 1st month were encouraging as regards the weight and glycemic parameters, the mean body weight decreased by 4.1 ± 1.9 kg in the 1st month (from 74.3 ± 7.5 kg to 70.2 ± 6.9 kg, P = 0.019). Also, the mean BMI decreased 1.2 ± 0.9 kg/m^2 in the 1st month (from 26.7 ± 2.3 kg/m^2 to 25.5 ± 1.9 kg/m^2, P = 0.019), weight loss continued till the 12th month.

The mean FPG decreased slightly from 176.3 ± 29.4 mg/dL to 170.6 ± 16.1 mg/dL (P = 0.535), while the 2H-PPG showed marked drop from 310.3 ± 29.8 mg/dL to 221.1 ± 18.3 mg/dL (P = 0.036). The HbA1C level started to decrease from 9.9 ± 1.8% to 8.1 ± 0.9% (P = 0.041) as illustrated in Chart 2.

Moreover, eight patients discontinued their antidiabetic treatment (with HbA1c< 6%), six patients received less dose of their treatment (either insulin or oral agent), and the last three patients were switched from insulin to oral treatment, the remission rate was 52.9%.

At the 6th month follow-up, both FPS and 2H-PPG decreased to reach 105.2 ± 18.3 mg/dL and 162.1 ± 17.6 mg/Dl respectively. Besides, eleven patients stopped the treatment with HbA1c < 6% (64.7%), which increased at 1-year to reach 76.4% with 13/17 became off-treatment.

At the 12th month follow-up, we found significant decrease in the FPG, 2H-PPG and HbA1C as illustrated in Table 3 and Chart 2. The final results at the 18th month showed significant improvement in both anthropometric and metabolic parameters (Table 4).

Table 2 Baseline anthropometric and metabolic parameters.

Baseline parameters	Range	Mean ± SD
Weight (kg).	(64.8–81.2)	74.8 ± 7.5
Height (cm).	(162.6–189.3)	171.7
BMI (kg/m^2).	(25.1–29.7)	26.7 ± 2.3
Duration of DM (year).	(3.8–8.9)	6.3 ± 2.7
FPG (mg/dL).	(144.3–181.8)	176.3 ± 29.4
2H-PPG (mg/dL).	(266.4–348.6)	310.3 ± 29.8
HbA1C (%).	(7.7–10.8)	9.9 ± 1.8
C-peptide (ng/ml)	(0–4.1)	2.38 ± 1.3

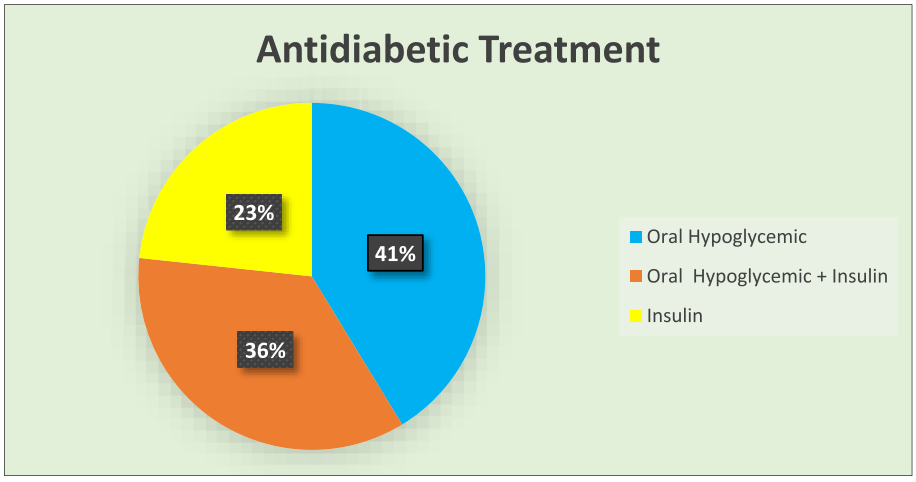

Chart 1 Preoperative antidiabetic treatment.

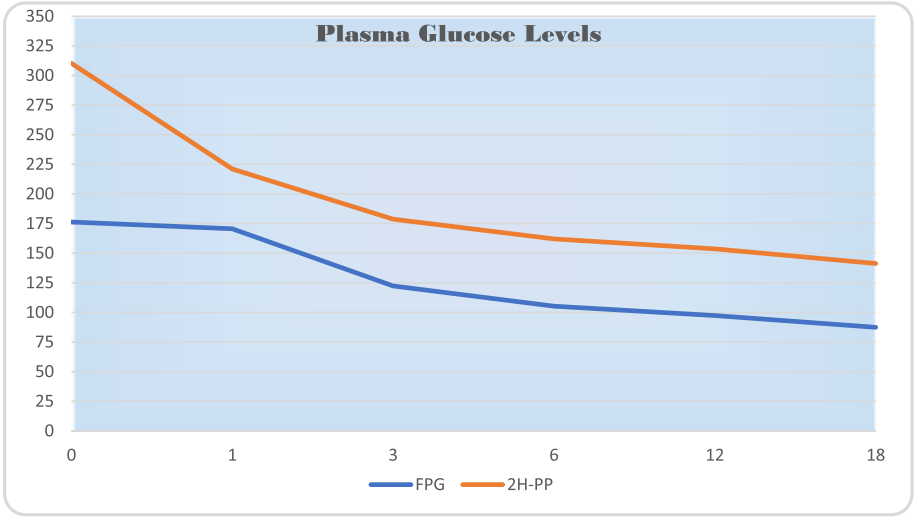

Chart 2 Postoperative glycemic state.

Table 3 Anthropometric and metabolic parameters change 12-months post-SAGB.

Data	Baseline	Postoperative (12th month)	P-Value
Weight (kg)	74.8 ± 7.5	66.7 ± 4.6	0.031
BMI (kg/m2)	26.7 ± 2.3	24.1 ± 1.3	0.041
FPG (mg/dL)	176.3 ± 29.4	97.3 ± 21.6	0.009
2H-PPG (mg/dL)	310.3 ± 29.8	153.6 ± 24.4	0.011
HbA1C (%)	9.9 ± 1.8	6.1 ± 1.1	0.029
C-peptide (ng/ml)	2.38 ± 1.3	2.45 ± 1.2 ng/ml	0.61

Table 4 Anthropometric and metabolic parameters change 18-months post-SAGB.

Data	Baseline	Postoperative (18th month)	P-Value
Weight (kg)	74.8 ± 7.5	63.2 ± 5.2	0.022
BMI (kg/m2)	26.7 ± 2.3	22.8 ± 2.5	0.038
FPG (mg/dL)	176.3 ± 29.4	93.4 ± 19.1	0.002
2H-PPG (mg/dL)	310.3 ± 29.8	156.2 ± 27.9	0.005
HbA1C (%)	9.9 ± 1.8	5.8 ± 1.3	0.024
C-peptide (ng/ml)	2.38 ± 1.3	(2.49 ± 1.1 ng/ml)	0.49

The complete remission has occurred in 13/17 patients (76.47%), and partial remission in 1/17 (5.88%) with HbA1C (6.3%). There is no improvement in two patients (11.76%) whereas the remaining one developed recurrence.

The differential analysis of the serum fasting C-peptide level showed slight non-significant increase from 2.38 ± 1.3 ng/ml preoperatively to 2.45 ± 1.2 ng/ml at the 12th month (P-value = 0.61) and continued to rise slightly to reach 2.49 ± 1.1 ng/ml at the end of the study (P-value 0.47).

The last step in data analysis was allocation of patients who had remission into Group A and those who did not have

a remission into Group B, then comparing their data by the 2-sample t-test. The statistical analyses were done for some preoperative data to detect its predictive value and for some postoperative value to record its differential pattern of change post-SAGB.

Reanalysis revealed a significant difference of all glycemic level parameters (FPG, 2H-PPG, HbA1C and C-peptide) between both groups as illustrated in Table 5.

Moreover, analysis of the preoperative C-peptide levels by the 2-sample t-test, revealed a significant difference between both groups (2.39 ± 1.1 Vs 0.11 ± 0.1) (P-value = 0.009).

This improvement in the glycemic state is associated with a similar improvement in the other comorbid metabolic diseases, we found that 7/8 (87.5%) hypertensive patients and 5/6 (83.33%) dyslipidemia patients discontinued their medications.

We experienced one minor complication in the form of mild wound infection that responds to antibiotic course and wound dressing, also three late complications were encountered, the first had mild bleeding (5.8%), mostly from the staple-line and was treated conservatively, while the second developed iron deficiency anemia (5.8%) at the 12th month, and treated successfully with iron therapy. No mortality cases were reported in this study.

4. Discussion

The growing pandemic of T2DM remains one of the most challenging contemporary issues. IDF estimated that there are 366 million people suffering from T2DM, more than 90% of them are obese.[3] The T2DM patients of BMI (25–30) kg/m^2, are considered the most controversial group from the pathophysiological point of view [28]; The beta cell deficit represents the most significant known pathophysiological factor, whereas the insulin resistance plays a less important role which is the reverse in the obese diabetic equivalents.[6]

A thorough analysis of the current knowledge gaps unveils a very important fact that albeit the presence of level 1A evidence regarding the impact of metabolic surgery on obese patients, there is a paucity of data about its efficacy in non-obese patients.

The 2nd Diabetes Surgery Summit (DSS-II) added the metabolic surgery as an additional therapeutic option for non-obese diabetic subjects.[33,34] Moreover, Cummings & Cohen in their meta-analysis provides another level 1A evidence that surgery is superior to medical treatment for T2DM remission irrespective of their BMI.[4]

Table 5 Differential postoperative data analyses between both groups.

Postoperative Variables (at 18 m)	Group A (Remission) (n = 14)	Group B (Non-remission) (n = 3)	P-value
FPG	106.3 ± 4.3	88.3 ± 6.1	0.024
2H-PPG	151.2 ± 10.8	169.7 ± 12.3	0.016
HbA1C	5.6 ± 0.6	8.9 ± 1.6	0.009
C-peptide	2.41 ± 1.2	0.13 ± 0.09	0.006

In this study, postoperative weight loss occurred early (which may be due to caloric restrictions), continued till the 12th month, and then plateaued without significant changes. The Chart 1 illustrates that the improvement of glycemic state started early in the 1st month and continued with a less degree from the 3rd to the 12th month, reaching a nadir thereafter till the end of the study thereafter.

All parameters of the glycemic state improved but not with the same pattern; The 2H-PPG showed earlier improvement in the first three postoperative months than the FPG with a sharper steep curve of descent. This dynamic pattern of improvement is also described by Kim et al[2] in their prospective study on 12 patients with BMI 23–30 kg/m^2, they were concerned mainly about the incretin effect (meal-related insulin secretion). They noticed no change in the FPG in the 1st month, in contrast to the mean 2H-PPG that showed a significant change.

This phenomenon of delayed improvement of the FPG could be attributed to three major causes: impaired insulin secretion increased glucagon release, and increased endogenous glucose production (due to increased gluconeogenesis, proteolysis, and/or lipolysis). All these metabolic alterations could counteract the glucoregulatory effect of the SAGB on the FPG.

In this series, one-month post-SAGB, the HbA1C levels significantly decreased from 9.9 ± 1.8% to 8.1 ± 0.9% (P = 0.041), continuing to improve till reached 5.8 ± 1.3% at the 18th month. This is similar to another series[32] in which the mean HbA1c descended from 9.7% to 6.7% at the 6th month (the follow up in their study is 6 months only).

In this study, the remission rate at 1 month was 52.9%. It increased to 64.7% at the 6th month, then continued to improve till reached 76.4% at the 12th month, a percentage that was maintained until the end of the study. García Caballero et al[6] reported a remission rate of 67% in their study which has been conducted on sixty patients, of whom thirty-five patients had BMI (30–34) Kg/m^2 and the rest had BMI (24–29) Kg/m^2, they did not find any significant difference in the remission rate between the two groups.

Kim and Hur[35] reported a remission rate of 53% that increased to 63% and 90% in the 1st, 2nd and 3rd year, respectively. They observed that the BMI curve reached a nadir at the 12th month, followed by weight regain in 34 patients after the 1st year, with T2DM recurrence observed in 31% which could be attributed to fundus preservation.

García Caballero et al. in another study[28] fashioned a bigger gastric pouch and excluding only 100 cm jejunum in thirteen patients, mean preoperative BMI = 27 kg/m^2, reported 77% remission (decreased to 65% remission at 2 years) with mean postoperative HbA1c 6.6% and mean FPG 100 mg/dL.

The final results had showed that complete remission has occurred in 13/17 patients (76.47%), and partial remission in 1/17 (5.88%) with HbA1C = 6.3%. There is no improvement in two patients (11.76%) whereas the remaining one developed recurrence of T2DM after initial improvement; this patient who developed recurrence was a male 57 years old, preoperatively he was on combined insulin and metformin, with 7.8 years' duration of DM and previous history of hospital admission for diabetic

ketoacidosis. The postoperative investigation showed initial partial improvement for 6 months that followed by gradual re-increase of the glucose level at the 12th month.

In addition, reanalysis of the final data by the 2-sample t-test revealed a significant difference between the two groups in the postoperative levels of all studied glycemic parameters (FPG, 2H-PPG, HbA1C and C-peptide) as illustrated in Table 5.

Moreover, analysis of the baseline fasting C-peptide levels of patients by the 2-sample t-test, revealed a significant difference between both groups (2.39 $\pm$ 1.1 Vs 0.11 $\pm$ 0.1) (P-value = 0.009). This further confirmed the predictive value of the C-peptide level in determining who will benefit from SAGB and go into remission.

The glycemic level parameters are comparable with the other studies. However, we should put in mind while comparing final remission rate in between different series that there are a lot of factors that could affect it such as age, BMI, C-peptide (fasting), Duration of DM, previous antidiabetic treatment especially insulin and incretins, type of procedure, the length of follow-up, and the definitions of remission applied by the authors.

All these variables were extensively investigated. Moreover, many researchers try to gather them in the form of scoring systems as ABCD Diabetes Surgery Score,[36] DiaRem score (for RYGB only)[37] and Diabetes Remission Score.[38] Yet, this issue is still controversial and is surrounded by many question marks leaving the answer about its exact efficacy to the future.

Other outcomes of interest were that resolution of hypertension and dyslipidemia in 87.5% and 83.33% of patients respectively. As regards the major complication, we had one case of mild bleeding, and another one of iron deficiency anemia (5.8%), both were treated conservatively with no need for re-exploration. These results are comparable with that published by the other authors (4.9%—7.6%).[20,22,26,31,39,40] Recurrence of T2DM documented in one patient, no mortality has been occurred in this study.

The limitations of this single-center study include the relatively small number of patients, and the short-term follow up. Further multi-center controlled studies with long-term follow-up are needed to unveil the durability of these changes.

5. Conclusion

Non-obese T2DM patients are considered the most controversial group of diabetic patients in terms of etiology, pathophysiology, and pharmacotherapy. SAGB had shown excellent results, it achieved 76% complete remission rate. Hence, it could be integrated into its treatment algorithm. The simplicity of SAGB design may be the secret of its success, it opened new horizons in the treatment of non-obese T2DM patients changing the old concept "Diabetes Remedy" into a new one "Diabetes Remission". Serum fasting C-peptide has a good predictive value for remission.

Author contributions

Authors make an equal contribution to this study from its conception, design, literature review, data acquisition, collection and analyses, and writing, editing and approving the final manuscript.

Conflict of interest statement

Dr. Tarek Abouzeid, Dr. Ahmed Adel and Dr. Karim Sabry have no conflicts of interest or financial ties to disclose.

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Appendix A. Supplementary data

Supplementary data related to this article can be found at https://doi.org/10.1016/j.asjsur.2018.04.002.

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