

# Incidence of Lower Limbs Deep Vein Thrombosis After Open and Laparoscopic Gastric Bypass: A Prospective Study

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## Abstract

**Background** Lower limbs deep vein thrombosis (DVT) and pulmonary embolism (PE) are major causes of morbidity and mortality and are even higher in bariatric patients. The longer operative time and higher immobility in these patients increase the DVT risk. Although deaths after

bariatric surgery have been reported, there is no consensus regarding the prophylaxis of DVT. This study's objective is to determine the incidence of lower limbs DVT in patients submitted to Roux-en-Y-gastric bypass (RYGBP) under prophylaxis by enoxaparin.

**Methods** Patients with body mass index (BMI) equal to or higher than 35 kg/m<sup>2</sup> who submitted to RYGBP by laparotomy or laparoscopy using 40 mg/day of enoxaparin for 15 days were recruited between October 2004 and August 2005. Individuals with previous DVT and heparin allergy were excluded. Patients were tested for DVT using color Doppler ultrasound performed before surgery and on the second and fifth weeks after surgery.

**Results** The study population included 136 patients, with 126 concluding the protocol. There were 79% (100/126) of female patients aged 19 to 65 years old, with mean of 40 years SD=10 and BMI between 35 and 61 kg/m<sup>2</sup>, mean of 43 kg/m<sup>2</sup> (SD=5). All patients who submitted to RYGBP were divided as 55% (69/126) by laparoscopy and 45% (57/126) by laparotomy. The incidence rate of lower limbs DVT was 0.79% (1/126).

**Conclusion** The low incidence rate of DVT found in our study suggests that obesity might not be a major risk factor for venous thromboembolism in patients submitted to RYGBP.

**Keywords** Venous thrombosis · Pulmonary embolism · Morbid obesity · Bariatric surgery · Color Doppler ultrasound · Power Doppler · Venous thromboembolism prevention

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## Introduction

Deep vein thrombosis (DVT) is a disease characterized by acute formation of thrombi in a vein in the deep venous system. DVT can occur in patients with various clinical and surgical conditions, as well as in individuals with normal clinical conditions. DVT is a major cause of morbidity and mortality in patients, especially those submitted to surgical treatment who could develop venous thrombosis and pulmonary embolism (PE) [1]. PE is a common disease with an average incidence of more than one case per 1,000 per year in the general population and almost 25% of the cases present as sudden death [2]. Patients admitted to surgical treatment are at higher risk of venous thromboembolism; the magnitude of excess risk depends on the type of surgery. Other factors that may have an influence are higher age and malignant diseases [3]. The global incidence of DVT evaluated by fibrinogen testing mark  $^{125}\text{I}$  in patients without prophylaxis in general surgery is 25% [4]. A retrospective study using 250 subjects to investigate the predisposing and precipitating factors of lower limbs DVT showed that 60% (132/218) of the patients had immobility as cause of DVT and 23.8% (52/218) had postoperative causes of DVT and these were the main risk factors for this disease [5]. Obesity has been identified as a risk factor for venous thromboembolism and BMI equal to or higher than  $25 \text{ kg/m}^2$  was associated with a higher risk of thromboembolism after hip arthroplasty [6]. Morbidly obese patients are at high risk of DVT complications in the postoperative period, especially if it is a long procedure, which can happen in bariatric surgery. Obesity is considered an important risk factor for DVT, likely caused by the difficult mobility of severe obese patients and also as a result of the decrease of fibrinolytic activity in these patients [7]. There is still no consensus regarding the ideal prophylaxis for venous thromboembolism in this group of patients, and the incidence of lower limbs venous thrombosis in morbidly obese patients submitted to surgical treatment is high in the medical literature [8]. The aim of this study is to assess the incidence of lower limbs DVT in patients submitted to gastric bypass using venous thromboembolism prophylaxis performing diagnosis using color Doppler ultrasound for a 30-day period postoperatively.

## Methods

A prospective study was performed in patients submitted to open and laparoscopic Roux-en-Y-gastric bypass (RYGBP) to estimate the incidence of DVT. The study population included 126 patients operated between October 2004 and August 2005 at São Rafael Hospital and Cidade Hospital,

Salvador, Bahia, Brazil from a total of 154 patients that fulfilled the criteria for bariatric surgery.

The patients included in the study were morbidly obese, with BMI equal to or higher than  $40 \text{ kg/m}^2$  and obese patients with  $35 \text{ kg/m}^2$  to  $39.9 \text{ kg/m}^2$  with associated comorbidities as diabetes, systemic arterial hypertension, and sleep apnea. Pharmacologic prophylaxis with subcutaneous enoxaparin 40 mg (Clexane<sup>®</sup>) was used right after the beginning of the operation and maintained for 15 days after surgery. Material resources such as elastic stockings and intermittent pneumatic compression were not used; however, physiotherapy and early ambulation was encouraged.

All patients were submitted to open and laparoscopic antecolic antegastric banded Roux-en-Y gastric bypass (ORYGBP) (LRYGBP) similar to the Fobi–Capella technique [9, 10]. The procedures were performed by the same team of three bariatric surgeons with the same standardization.

Patients with a previous history of DVT, mental illness, under 18 years old, a major amputation of lower limb (leg or thigh, unilateral or bilateral) were excluded from the study, as well as native Indians.

The primary endpoint studied was lower limbs DVT in patients submitted to gastric bypass during the first 30 postoperative days.

Colored Doppler ultrasound (CDU) of the lower limbs venous system was performed in each patient before surgery and on the second and fifth week after operation. The equipment used was the Siemens Sonoline G50 (Erlangen, Germany). A linear ultrasound probe with 7.5 MHz frequency and a convex probe with 3.5 MHz frequency were taken. The examination was performed with the patient in a supine position and horizontal dorsal decubitus for the study of the femoral vein segments and in a seated position for the study of the popliteal, tibial, fibular, and calf muscular vein segments. All venous segments of the lower limbs, from the groin to the ankle, with CDU and a compression maneuver were evaluated. Detection of venous flow was performed using spectral and colored Doppler. The CDU studied the following venous segments: femoral, ramified segment of the deep femoral, popliteal, posterior and anterior tibial, fibular, and calf muscular veins. The noncompressibility of the vessel, the presence of hypoecogenic image, the absence of spontaneous flow and fascic flow during breathing, and the non-increase of flow during the distal compression of the studied vessel were all interpreted as positive signs of lower limbs DVT. Secondary endpoints were: a) symptomatic PE, when PE was suspected exams such as lung scintigraphy (also known as ventilation perfusion scanning), thorax computed axial tomography (CAT) scan, and pulmonary angiography were performed to exclude or confirm it; and b) death.

## Ethics

This research was made under the ethical principles of the Declaration of Helsinki and Resolution 196/96 of the Brazilian National Council of Health and previously approved by the São Rafael Hospital Research Ethics Committee. The informed consent form was signed by every patient before entering the research.

## Statistical Analysis

Descriptive statistics were calculated including means, medians, and standard deviations for continuous variables, and absolute and relative frequencies for categorical variables. All statistical analyses were conducted using the statistical software package SPSS 9.0 [11].

## Results

From a total of 154 recruited patients, 136 patients were included in the study population; a total of 126 patients concluded the full evaluation. Six patients cancelled the surgery, two were excluded, one because of a previous heparin allergy and one because of a previous venous thrombosis, one patient was lost to follow-up and one patient died 7 days after surgery. The age ranged from 19 to 65 years, with a mean of 40 (SD=10) years. Seventy nine percent of the subjects were female (99/126) and 21% male (27/126). BMI ranged from 35 to 61 kg/m<sup>2</sup>, with a mean of

**Table 1** Characteristics of the study population (N=126)

Characteristics	Measurement
Age (years)	
Mean	40±10
Median	42
Variation	19–65
Gender	
Male	21% (27/126)
Female	79% (99/126)
Ethnicity	
White	67% (84/126)
Mixed race	14% (18/126)
African descent	19% (24/126)

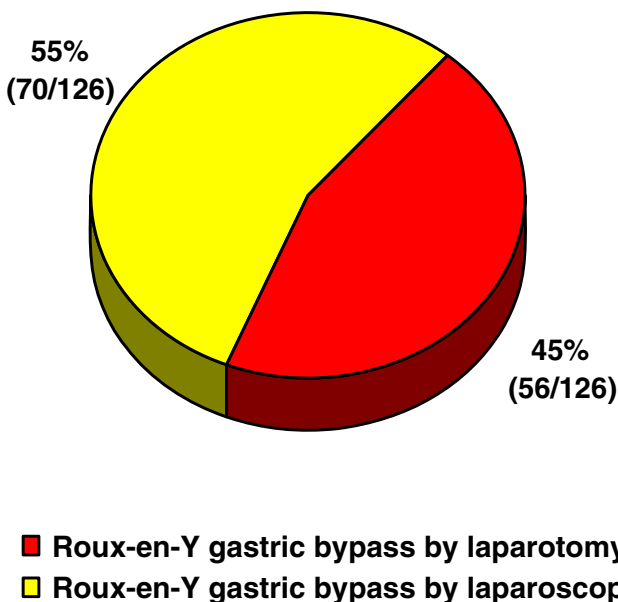
43±5 kg/m<sup>2</sup>. All patients were submitted to Roux-en-Y gastric bypass, 55% (70/126) by laparoscopy and 45% (56/127) by laparotomy (Fig. 1).

The surgery and anesthesia lasted between 165 to 505 minutes, a mean of 282±59 minutes. The patients evaluated were divided into 67% of white (85/126), 14% of mixed race (18/126), and 19% of African descent (24/126) (Table 1). The mean BMI was 43 kg/m<sup>2</sup>, with a total of 72% equal to or higher than 40 kg/m<sup>2</sup> (Table 2).

Forty six percent of patients had systemic arterial hypertension (58/127), 7% diabetes (9/127), and 20% were smokers (26/127). All patients used prophylaxis for DVT except for four patients: two did not take the medicine in the first 2 days because of spleen injury during surgery but resumed it on the third day after surgery and for 13 days thereafter. Two others did not make use of the prophylaxis scheme in the final 10 days after hospital discharge for personal reasons.

The distribution of blood type was: 29% (36/126) were A positive, 7% (9/126) A negative, 8% (10/126) B positive, 1% (1/126) B negative, 5% (6/126) AB positive, 1% (1/126) AB negative, 43% (54/126) O positive, and 7% (9/126) O negative.

The incidence of lower limb DVT was 0.79% (1/126), 95% confidence interval: [0.02–4.3%]. Only one patient presented symptoms or signs of lower limbs DVT in this series, and was diagnosed with calf vein thrombosis on the 10th day after surgery, which did not progress to the proximal veins. The patient who presented venous thrombosis followed the full prophylaxis pharmacology scheme through.



**Fig. 1** Surgical procedures type (n=126)

**Table 2** Body mass index and operative time (N=126)

	Mean/SD
BMI (kg/m <sup>2</sup> )	43±5
Operative time (min)	282±59

One patient was readmitted with respiratory distress on the 10th postoperative day. PE was not confirmed by lung scintigraphy or thorax CAT scan, but pulmonary edema caused by systemic hypertension was diagnosed; the patient had stopped taking the antihypertensive medication. There was no case of PE detected (0/126).

Mortality was low: 0.79% (1/127). One patient presented with bypassed stomach dilation 4 days after surgery because of bypassed stomach hemorrhage causing gastric rupture, which provoked sepsis and death. The patient was super-obese. There were four cases of postoperative hemorrhage, two of those caused by spleen injury and two others caused by staple line bleeding. One other patient was excluded from the study because of CDU detected signs of previous lower limb DVT during the selection process preoperatively.

## Discussion

The incidence of lower limbs DVT after gastric bypass was not well studied in medical literature. The clinical diagnosis of lower limbs DVT is not reliable because 50% of patients with the complaint do not present signs or symptoms [12], and the 50% who present clinical signs do not have a positive reading in imaging exams, which means no DVT [13].

We found a very low incidence of DVT in this work (0.79%), utilizing a relative low dosage of enoxaparin (40 mg), without elastic stockings and intermittent pneumatic compression.

This study used color Doppler ultrasound equipment for diagnostic investigation for its painless and noninvasive system, which is considered innocuous for human beings [14]. Although this method is operator dependent and is known for its reading limitations, using more sensitive color Doppler equipment and better training for operators has caused these problems to decrease even more. The most used complementary exam for DVT diagnosis is the CDU because of its accuracy, low-cost, availability, and tolerance by the patient [15].

The CDU is considered a safe exam on patients with symptomatic proximal DVT. It has a sensitivity of 97% (95% CI, 96–98%) and a specificity of 94% (95% CI, 90–98%) for diagnosis. Phlebography is considered the gold standard exam for DVT detection. The ultrasound on the calf veins had a sensitivity of 73% (95% CI, 54–93%) [16]. According to guidelines from the Brazilian Society of Angiology and Vascular Surgery, the ultrasound is considered the exam of choice for DVT diagnosis, and treatment should start shortly after it is diagnosed by this method, although phlebography is recommended in cases where it is doubtful [17]. This recommendation is maintained in the

latest version of the clinical regulation guidelines of this society [18]. Ultrasound with Doppler, commonly known as Duplex scan, is established as the method of choice for DVT diagnosis, replacing phlebography [19].

The risk of developing DVT after abdominal surgery is higher on the first and second postoperative weeks, but complications such as PE can develop later [3]. For precaution, a protocol of investigation was chosen to eliminate previous possible cases of venous thrombosis and respect the 30-day period after surgery, considered by many authors as the postoperative period of higher risk of vein thromboembolism in abdominal surgery [20], with one exam performed preoperatively and on the second and fifth weeks postoperatively.

The cases that presented postoperative bleeding could have been influenced by the use of enoxaparin or lack of appropriate hemostasis on the dissected area and there remained the doubt if the administration of 40 mg daily of enoxaparin would cause bleeding in obese patients. The two patients that presented postoperative bleeding had a BMI of 46.7 kg/m<sup>2</sup> (140 kg) and 50.1 kg/m<sup>2</sup> (166 kg).

The patients were operated on by laparotomy or laparoscopy almost in equal proportion, 45% and 55%, respectively. The laparoscopic procedure is regarded as a moderate risk for DVT, but CO<sub>2</sub> pneumoperitoneum and inverted Trendelenburg position are considered responsible for reducing lower limbs venous return inducing venous stasis and consequently a higher risk of venous thrombosis [21–23]. The latest consensus about venous thromboembolism prophylaxis agrees that the evidence in recommending that routine prophylaxis in patients submitted to laparoscopic procedures is inadequate. However, it is recommended only in patients under specific risk of venous thromboembolism [3].

It was not possible to compare the use of laparotomic and laparoscopic procedures because only one patient presented DVT and was submitted to ORYGBP (1/126).

It was questioned if the prophylaxis scheme would be efficient enough to reduce the incidence of DVT to close to zero, which would be in accord with a retrospective multicentered study where venous thromboembolism prevention was analyzed in 668 patients submitted to bariatric surgery. It suggests that extending the prophylaxis with enoxaparin after hospital discharge reduces the incidence of DVT [24].

This study could have limitations in diagnosing lower limbs DVT, once it analyzes obese patients under investigation of asymptomatic venous thrombosis. The accuracy of the CDU was questioned under those conditions by Kearon [16]; in a more recent study he suggests that DVT diagnosis in patients who were tested with noninvasive methods such as ultrasound for clinical or research purposes should have the diagnosis confirmed by phlebography [25].

Every resource was used when examining each patient, such as compression maneuver, colored and spectral Doppler, to improve as much as possible the accuracy of the exams, which were repeated when necessary.

Seventy five percent of lower limbs venous thrombosis start in the calf veins and around 25% of these thrombi progress to the proximal veins (popliteal and femoral), which make their diagnosis highly significant [26]. Using CDU equipment with Power Doppler that has good sensitivity, as the one used in this study for distal venous thrombosis diagnosis, reduces or suppresses any difficulties. When it was compared, a series of tests with Doppler Power and phlebography in 50 patients with suspected clinical DVT resulted in 100% sensitivity and 79% specificity [27].

Yet in this study, three exams in series were done during a 30-day period to improve this method's sensitivity as done by some authors. The incidence of venous thromboembolism was 1% (12/1703) after ultrasound exams were performed in a study with patients suspected of clinical venous thromboembolism in two consecutive weeks for 6 months, without anticoagulation. The study concluded that regular ultrasound exams performed in 2 consecutive weeks in patients suspected of clinical venous thromboembolism is a reliable diagnostic tool [28].

The results of this study can be compared to the ones encountered by Westling [29], where no cases of proximal venous thrombosis were found and only 2% (2/116) of fibular veins asymptomatic thrombosis and 1% (1/116) of PE were recorded, although no DVT was detected in this one patient after investigation with Doppler ultrasound equipment.

There is no consensus regarding DVT prevention in the morbidly obese patient, although there is a medical paper discouraging the administration of heparin in low dosages in preventive care for these patients [30]. It was taken into consideration that this study is 30 years old and used continuous wave Doppler ultrasound for venous thrombosis diagnosis.

When two different doses of enoxaparin were compared, 30 mg twice daily (60 mg/day) and 40 mg, also twice daily (80 mg/day) in 481 patients divided in two groups, 5.4% were diagnosed of thromboembolic events in group I (5/92), which was treated with 30 mg twice daily and 1% in group II treated with 40 mg twice daily (2/389). This study concluded that 80 mg of enoxaparin administered twice daily is better than 30 mg administered every 12 h for venous thromboembolism prevention in bariatric surgery, and there were no hemorrhage complications recorded [31]. These doses are high (60 and 80 mg) compared to 40 mg dose in general surgery prophylaxis as established in the Seventh Conference of the American College of Chest Physicians [3].

The incidence of PE in a study of 700 patients submitted to LRYGBP under venous thromboembolism prophylaxis regime, with nonfractionated heparin in adjusted doses controlled by activated anti-Xa factor at 0.11 to 0.25 UI/ml levels, was lower than 1% (3/700), and no cases of DVT brought to attention a specific protocol for thromboembolism prophylaxis for bariatric surgery [32].

## Conclusion

Our study found an incidence of lower limbs deep vein thrombosis in patients submitted to open and laparoscopic gastric bypass of 0.79% (1/126). The reasons for this lower rate compared to other studies might be the prophylaxis scheme used or the hypothesis, raised by some authors [29], that obesity might not be a major risk factor for venous thromboembolism. The findings of this study might suggest an outline for the ideal DVT prevention in these patients. In this study, enoxaparin (40 mg/day) was efficient and safe in preventing DVT.

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