Routine Anticoagulation for Venous Thromboembolism Prevention Following Laparoscopic Gastric Bypass

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ABSTRACT

Objective: To compare the rates of venous thromboembolism (VTE) by using routine postoperative enoxaparin versus early ambulation, SCDs, hydration, and selective prophylactic pharmacologic anticoagulation.

Methods: 1,692 patients undergoing laparoscopic gastric bypass from October 2001 to October 2008 were included and divided into 2 groups based on when they were operated upon. Group A (435 patients) received routine enoxaparin 12 hours after surgery. Group B (1,257 patients) received selective pharmacologic anticoagulation, in high-risk patients only.

Results: Mean operating time was 144±26 minutes (Group A) and 126±15 minutes (Group B). Mean length of stay was 2.3±1.5 days for Group A and 1.4±1.2 for Group B. Intraluminal bleeding occurred in 21 patients (4.8%) in Group A and 5 (0.9%) in Group B; none required intervention. Five pulmonary embolisms occurred in Group A (1.1%) and none in Group B. Seven patients in Group A (1.7%) and 6 (0.47%) in Group B had clinically evident DVT. Two non-VTE related deaths occurred in Group A.

Conclusions: Adequate VTE prophylaxis is achieved using SCDs, early ambulation, emphasis on hydration, and shorter operating times. Bariatric surgery can be safely performed without pharmacologic VTE prophylaxis in all but the high-risk population. Fewer bleeding complications occur without the use of anticoagulants.

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INTRODUCTION

Venous thromboembolism (VTE), the inclusive term for deep vein thrombosis (DVT) and pulmonary embolism (PE), is a major cause of morbidity and mortality in bariatric surgery patients. The reported incidence of DVT in the bariatric population ranges between 0.2% to 2.4% and the incidence of PE from 1% to 2%.[1–4] These events though rare can be devastating. The overall mortality rate following gastric bypass is reported to be between 0.5% and 1% with PE being the most common cause. The reported incidence of fatal PE ranges between 0.2% and 0.64%,[5,6] accounting for 30% to 50% of all deaths in bariatric surgery patients.[7,8]

Several risk factors exist that may increase the risk of DVT and PE, including advanced age, malignancy, prolonged operations, varicose veins, immobilization, estrogen medication, and obesity.[9–12] The pneumoperitoneum used for laparoscopic procedures has also been proposed as a potential risk factor for DVT secondary to decreased venous return to the heart and venous stasis.[13] Another risk factor in the bariatric surgery population is the acute angulation at the knee when the patient is placed in a modified lithotomy and steep reverse Trendelenberg position for the surgery.[14–18] This position predisposes the patient to venous pooling in the lower extremities, increasing the risk of DVT.

No uniform VTE prophylaxis regimen for bariatric surgery exists; however, most surgeons advocate the use of some form of prophylaxis mechanical, pharmaceutical, or both.[4,19–21] Because of the lack of uniform guidelines, we reviewed our experience since changing our postoperative protocol from routine chemoprophylaxis with enoxaparin to mechanical measures with SCDs, an emphasis on early ambulation, aggressive hydration, early discharge, and the selective use of anticoagulation and/or inferior vena cava filters. Incidence of DVT and PE, mortality, and postoperative intraluminal hemorrhage were evaluated.

METHODS

Between October 2001 and October 2008, 1,712 consecutive patients underwent laparoscopic RYGB by a single surgeon (CTF). Intraoperatively, all patients were distended to an intraabdominal pressure of 15mm Hg to 17mm Hg. A change in the postoperative care protocol occurred in January 2003; patients were divided into 2 groups based on whether their surgery was performed before or after this protocol change. Patients with a personal history of VTE were treated with inferior vena cava filters. In Group A, 3/438 (0.7%) patients were deemed to be high risk, received IVC filters, and were excluded from the study, leaving 435 patients. In Group B, 17/1274 (1.3%) were likewise excluded, leaving 1257 patients.

Patients in Group A were operated on between October 2001 and January 2003. All patients in this group were admitted to the ICU, received routine postoperative enoxaparin 40mg subcutaneously twice daily along with calf length sequential compression devices (SCDs).

Patients in Group B had SCDs placed, but did not receive routine anticoagulation. Patients with a personal or family history of a hypercoagulable state, or a family history of VTE did receive postoperative enoxaparin. All patients in Group B were admitted to a floor with telemetry monitoring, were aggressively hydrated, and required to ambulate within 2 hours of arrival to the floor. Nurses on the floor were educated and trained on the importance of SCD use and early ambulation. All patients were seen in follow-up at 1 week, 1 month, 3 months, 6 months, 1 year, and annually thereafter. A prospectively collected database was reviewed retrospectively to compare the incidence of VTE and bleeding complications between the 2 groups. Statistical analysis using the unpaired t test was used to compare continuous numerical data between the 2 patient groups. The level of significance was defined as $P < .05$.

RESULTS

The study population included 1692 patients. Group A had 435 patients with a mean BMI of 51.6 ± 4 (range, 39 to 91), while 1257 patients were in Group B with a mean BMI of 45.3 ± 3 (range, 35 to 67). Demographics were similar between the 2 groups. Mean age was 42.7 years (range, 14 to 72) and 84% were females. Operating times were 144 ± 26 minutes and 126 ± 15 minutes in Groups A and B, respectively.

In Group A, 7/435 (1.6%) patients developed a deep vein thrombosis, and 5/435 (1.1%) developed a pulmonary embolus; none were fatal. In Group B, however, only 6/1257 (0.47%) patients (0.47%) developed a DVT and no patients developed a PE. There were 2 non-VTE related mortalities, both in Group A **(Table 1)**.

Intraluminal bleeding, defined as melena and/or hematemesis occurred in 21/435 (4.8%) patients in Group A and 5/1257 (0.4%) in Group B. Patients required blood transfusions of 2.2 ± 1.1 units (range, 0 to 5) of PRBCs; however, no patients in either group required surgical or endoscopic intervention. Mean length of stay was 2.3 ± 1.5 days and 1.4 ± 1.2 days for Groups A and B, respectively. However, patients with intraluminal bleeding requiring transfusions had their hospital stay extended to 5.2 ± 2 days (range, 3 to 8).

Differences in the incidence of DVT and PE and intraluminal bleeding rate were all determined to be statistically significant.

DISCUSSION

Deep vein thrombosis and pulmonary embolism are major sources of morbidity and mortality in bariatric patients. Although some form of prophylaxis is generally accepted, current recommendations are not well defined, leaving surgeons to use their own clinical judgment as to the best regimen for their bariatric patients. A 2007 position statement by the American Society for Metabolic and Bariatric Surgery acknowledges the importance of early ambulation and sequential compression device use and recommends the use of chemoprophylaxis in all bariatric surgery patients unless contraindicated. It also recognizes that the choice of anticoagulant, dose, duration, and the role of inferior vena

Table 1.
Comparison of Patient Outcomes

	IVC filters	Number of nonexluded pts	Operating Time (min)	Length of stay (days)	DVT (%)	PE (%)	Intraluminal bleeding (%)	Mortality
Group A	3	435	144 ± 26	2.3 ± 1.5	1.6%	1.1%	4.8%	0.12%
Group B	17	1,257	126 ± 15	1.4 ± 1.2	0.48%	0%	0.4%	0%

cava filters are controversial and recommendations have not been established.[16] The Society of American Gastrointestinal and Endoscopic Surgeons guidelines recommend the routine use of sequential compression devices and either low-dose unfractionated heparin or low-molecular-weight heparin for laparoscopic gastric bypass patients.[17] In response to these 2 statements, routine anticoagulation is common practice among bariatric surgeons. According to a recent survey, 95% of bariatric surgeons use chemical prophylaxis to prevent venous thromboembolism.[22]

The use of anticoagulants does not come without a price, however. Several authors that routinely used pharmaceutical prophylaxis reported acceptable rates of VTE but often at an increased risk of intraluminal bleeding. Kothari and colleagues[23] compared 2 different anticoagulation regimens in 476 patients. They reported no DVTs and only one PE. But in the enoxaparin cohort, 5.9% of patients required postoperative transfusion, and 1.7% required reoperation for bleeding.

In another study, Miller and Rovito[24] evaluated the outcomes of 250 patients using their anticoagulation regimen. Their overall incidence of VTE was 1.2%, with a postoperative bleeding incidence of 2.4%.

The routine use of chemoprophylaxis is not universal, however. Clements et al[25] reported that the use of mechanical prophylaxis with SCDs, early ambulation, and short operative times were as effective as chemical prophylaxis in the prevention of VTE.

Likewise, our results demonstrate that the routine use of chemoprophylaxis for the prevention of VTE is unwarranted. A literature review of 5 recent studies[2,15,23,24,26] using pharmaceutical prophylaxis demonstrated acceptable rates of VTE events but with an incidence of major postoperative hemorrhage as high as 5.9%. This is in contrast to studies, including our own, utilizing mechanical prophylaxis, early ambulation and hydration where not only were postoperative bleeding rates significantly lower but in addition the incidence of DVT and PE was not only comparable but also often superior.[25]

Our regimen for the prevention of DVT and PE involves multiple factors, including placement of calf-length SCDs prior to induction of anesthesia and the use of a split leg table. This avoids placing the knee in acute angulation, preventing venous pooling in the lower extremities. In addition, short operating times are important in the prevention of VTE, because pneumoperitoneum and the reverse Trendelenberg position used in laparoscopic gastric bypass can increase the risk of VTE by lowering venous return to the heart.[14-18]

Avoidance of hemoconcentration with emphasis on hydration, both oral and intravenous, is also an important factor in prevention of VTE. Often bariatric patients present to the hospital dehydrated and hemoconcentrated secondary to undergoing a bowel prep the previous day increasing the risk of postoperative DVT and PE.[27,28]

The most important factor we believe, however, in the prevention of VTE is mandatory early ambulation.[25] In our opinion, the higher rates of deep vein thromboses and pulmonary embolisms despite chemoprophylaxis in our earlier experience were due to patient's immobility. At that time, patients were routinely admitted to the ICU where ambulation is somewhat prohibitory. In contrast, patients in Group B were invariably admitted to a telemetry floor, and were required to ambulate within 2 hours of arrival to the ward. In the authors' opinion, this factor more so than any other is the major cause of our more favorable recent results.

Our experience demonstrates that the routine use of pharmacologic prophylaxis for the prevention of VTE in the bariatric population is unwarranted. Diligent preoperative screening for patients at high risk for VTE is mandatory, and these patients should be identified and treated accordingly. The authors advocate the use of inferior vena cava filters in patients with a history of DVT or PE. In addition, patients with a personal or family history of a hypercoagulable state or a family history of VTE should be treated with chemoprophylaxis postoperatively.

When examining the results of this study, one may argue that the more favorable results in Group B may be due to the fact that patients in this group had a lower BMI. It is readily acknowledged that the 2 groups are somewhat different. While the authors acknowledge that the difference in BMI between the 2 cohorts is statistically significant, we would argue that the difference between a BMI of 51 versus 45 might not be clinically significant.

The argument for routine anticoagulation despite the increased risk of major postoperative hemorrhage has historically been viewed that surgeons can appropriately treat and control bleeding, but that is not the case with VTE. This belief, however, underestimates the consequences of postoperative bleeding in the bariatric patient. Bleeding at the gastrojejunostomy can at times stop spontaneously, and patients may be treated conservatively with only blood transfusions. If the bleeding continues, however, endoscopic management may be required, in-

creasing the risk of anastomotic perforation. Bleeding at the jejunojejunostomy is even more problematic, because if it does not stop spontaneously, reoperation and revision of the anastomosis is necessary. Furthermore, even if the bleeding does stop, the presence of a hematoma places the anastomosis at a high risk for disruption.

CONCLUSION

This study demonstrates that avoidance of acute angulation at the knee, expeditious operating times, routine use of sequential compression devices, emphasis on hydration, early ambulation, and early discharge obviates the need for VTE pharmacologic prophylaxis in all but high-risk bariatric patients.

Selective treatment of high-risk patients with an IVC filter or chemoprophylaxis as appropriate results in outcomes that are at least comparable if not superior to the routine administration of pharmacologic VTE prophylaxis in terms of the postoperative incidence of VTE and postoperative hemorrhage. The results of our study point to the need for multi-institutional, prospective, randomized studies to further investigate this issue.

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