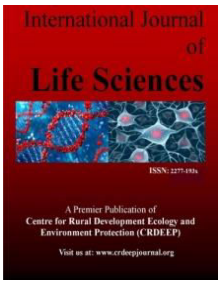
Vol. 9. No. 1. 2019.

Contents available at:
www.crdeepjournal.org

International Journal of Life Sciences (ISSN: 2277-193x) SJIF: 5.79



Full Length Research Paper

Efficacy of Prophylactic Measures in Prevention of Venous Thromboembolism in Bariatric Patients

Ahmed Mohamed Kamal Ahmed [1], Abdulrahman Mohamed Ahmed Salem [2] and Ahmed Samir Mohamed Gamal Eldin Othman [1]

[1] *General Surgery, Department, Faculty of Medicine, Ain Shams University, Egypt.*
[2] *Vascular Surgery Department, Faculty of Medicine, Ain Shams University, Egypt.*

ARTICLE INFORMATION

Corresponding Author:
Ahmed Mohamed Kamal Ahmed

Article history:
Received: 23-10-2019
Accepted: 27-10-2019
Revised: 02-09-2019
Published: 06-09-2019

Key words:
Prophylactic Measures, Venous Thromboembolism, Bariatric Patients

ABSTRACT

Background: Obesity is a medical condition in which abnormal or excessive fat has accumulated to the extent that it may have an adverse effect on health, leading to reduced life expectancy and/or increased health problems. Objectives: To compare between patients receiving anticoagulant prophylaxis only to patients receiving mechanical prophylaxis only. Patients and Methods: This prospective study includes 6o morbidly obese patients undergoing laparoscopic Sleeve Gastrectomy surgery in Ain Shams University Hospitals and Ahmed Maher Teaching Hospital over a 1-year period from May 2018 to June 2019. The age of the patients is > or = 19 years with a preoperative BMI>35kg/m2 with co-morbidities (Hypertension, Dyslipidemia, Type 2 DM, sleep apnea, etc...) or with a preoperative BMI > or = 40 with or without co-morbidities. Results: There is no difference among morbidly obese patients having bariatric surgery regarding incidence of DVT either in patients having chemoprophylaxis (LMWH) and those that did not have any chemoprophylaxis provided that they all had the same operative and postoperative sequel. Conclusion: We have noticed that all our morbid obese patients that had lap sleeve operations which were not at high risk for developing DVT, as demonstrated in inclusion and exclusion criteria, with average operation time and early ampulation as long as good hydration after surgery, there was no difference in DVT incidence between patients receiving chemoprophylaxis and those not receiving any chemoprophylaxis before and after Lap Bariatric Surgery.

Introduction

Obesity is a medical condition in which abnormal or excessive fat has accumulated to the extent that it may have an adverse effect on health, leading to reduced life expectancy and/or increased health problems (Sharma et al., 2017). Surgical approaches to weight loss, bariatric surgeries, are commonly performed procedures for morbidly obese individuals; the estimated number of bariatric procedures in the USA alone was close to 180,000 in 2013. Bariatric surgery is effective in achieving weight loss and improving obesity-related complications (Kang et al., 2017). As a result of new technologies with lower risks and better long-term results, bariatric and metabolic surgeries have grown in popularity in recent years. The number of operations performed is rapidly increasing. However, bariatric surgery is associated with numerous peri- and postoperative complications (Stroh et al., 2016).

Venous thromboembolism is the commonest postoperative complication. Obesity needs to be considered as one of the most serious factors predisposing patients to the development of thrombosis and pulmonary embolism (Stroh et al., 2016). Deep venous thrombosis may occur in up to 1.3% of patients after open or laparoscopic bariatric surgery.

Despite the early mobility after laparoscopic surgery, the incidence of DVT may not be reduced as much as expected because the benefit of early mobility may be offset by the tendency of pneumoperitoneum to promote DVT (Stroh et al., 2016). Despite universal agreement on the need for thromboprophylaxis, no clear consensus has been reached regarding the best regimen and treatment duration. Current modalities of thromboprophylaxis include subcutaneous injection of unfractionated or low molecular weight heparin, pneumatic compression devices, elastic stockings, and inferior vena cava filters (Vandiver et al., 2016). Most series evaluating prophylactic strategies for bariatric patients include some form of mechanical prophylaxis. Because of concerns of bleeding complications associated with chemoprophylaxis (2% incidence of bleeding complications in a recent systematic review when a standardized definition of hemorrhage was used), several studies have examined the use of mechanical compression only in bariatric surgery patients (Venclauskas et al., 2018).

Aim of the work

To compare between patients receiving anticoagulant prophylaxis only to patients receiving mechanical prophylaxis only.

Patients and methods

Study design

This prospective study includes 60 morbidly obese patients undergoing laparoscopic Sleeve Gastrectomy surgery in Ain Shams University Hospitals and Ahmed Maher Teaching Hospital over a 1-year period from May 2018 to June 2019. The age of the patients is > or = 19 years with a preoperative BMI>35kg/m^2 with co-morbidities (Hypertension, Dyslipidemia, Type 2 DM, sleep apnea, etc…) or with a preoperative BMI > or = 40 with or without co-morbidities.

Then the study population was divided into two groups:

- ***Group A:*** This group was subjected to mechanical thromboprophylaxis and early ambulation was encouraged.
- ***Group B:*** This group was subjected to only chemical thromboprophylaxis in the form of 12 hours preoperative clexane (40 IU /day) S.C and postoperative clexane (40 IU /day) for 1 week and early ambulation was encouraged.

Inclusion criteria:

1. All morbid obese patients undergoing Laparoscopic sleeve gastrectomy.
2. No history of recent or old thromboembolism.

Exclusion criteria:

1. Documented congenital / acquired coagulation disorders.
2. Concomitant anticoagulant for other risk factors.
3. Hypersensitivity to heparin and derivatives.
4. History of recent or old thromboembolism.
5. Patient not compliant to therapy.
6. Primary deep venous reflux.
7. Duplex proven deep venous abnormalities e.g. congenital stenosis.
8. Patients that didn't tolerate fluid intake early postoperative period.
9. Bed ridden patients or limitations of self dependant ambulation.

Patient evaluation

All included obese patients in this study were subjected to the following scheme in a predesigned sheet in order to clinically evaluate the patients and to detect different risk factors of every patient to develop DVT.

Clinical evaluation

A- History

I- Personal History:

- Name
- Age
- Sex
- Occupation
- Special habits of medical importance
- History of previous DVT

II- Present History:

- Stressing on the history of recent leg swelling and / or aching pain. The risk factors presented by medical history (e.g. age, obesity, and prolonged bed rest) were asked about and documented.

III- Past History:

- History suggestive of DVT.
- History suggestive of other diseases.
- History of coronary attacks
- History of cerebro-vascular accidents

IV- Family History:

- Especially of DVT and varicose veins.

B- Clinical examination

- Full clinical examination of the patients including assessment of general, abdominal and the lower limbs.

I) General examination:

- Vital signswere recorded in every patient:
  - Pulse
  - Temperature
  - Blood pressure
  - Respiratory rate
- Patients were also evaluated for signs of pulmonary embolism (chest pain, cyanosis, tachycardia, and tachypnia).
- Abdomino-pelvic examination.

II) Local examination of affected limbs:

- Oedema: the circumference of the limb is measured by tape. The healthy limb was considered normal (control) to compare it with the swollen limb.
- Color changes.
- Tenderness of the affected limb.
- Presence or absence of varicose veins.

C- Investigations

I- Routine investigations:

- CBC.
- Blood sugar: fasting and postprandial.
- Renal function tests.
- Liver function tests.
- Bleeding time, clotting time, PT, APPT, prothrombin time and INR.

II- Specific Investigations:

A) Duplex Scanning:

- All limbs were subjected to duplex scanningto study:
  - Deep venous system to evaluate patency of the vein, function of the valve and level of the thrombus. Also as a baseline study for further comparisons.
  - Superficial venous system.
  - Detection of incompetent perforators.

Pre-operatively:

1- Measurement of the weight, height and calculating body mass Index

2- All patients received information about surgical technique and risks of the operation.

3- Giving instructions to patients about the importance of early ampulation after surgery

Statistical analysis

Data were collected, revised, coded and entered to the Statistical Package for Social Science (SPSS) version 20 and the following were done: Qualitative data were presented as number and percentages while quantitative data were presented as mean, standard deviations and ranges. So, the p-value was considered ± significant as the following: P > 0.05: Non significant, P < 0.05: Significant, P < 0.01: Highly significant.

Results

Table (1): Demographic data.

		Group A	Group B	Test value	P-value	Sig.
		No. = 30	No. = 30			
Age	Mean±SD	37.27 ± 10.09	38.27 ± 11.97	-0.350•	0.728	NS
	Range	23 – 58	19 – 60			
Sex	Female	14 (46.7%)	19 (63.3%)	1.684*	0.194	NS
	Male	16 (53.3%)	11 (36.7%)			

*P-value > 0.05: Non significant; P-value < 0.05: Significant; P-value < 0.01: Highly significant *: Chi-square test; •: Independent t-test*

The mean age of the cohort was 37.77 ± 10.98 years (range 19 – 60). 33 out of 60 patients were females (55.0%) and 27 out of 60 patients were males (45.0%). In Group (A) Mean±SD age is 37.27 ± 10.09 years while in group (B) Mean±SD age is 38.27 ± 11.97 years with P-value 0.728.

Table (2): Comparison between two groups in weight, BMI and operative time.

		Group A	Group B	Test value•	P-value	Sig.
		No. = 30	No. = 30			
Weight	Mean±SD	132.93 ± 18.43	127.10 ± 17.17	1.268	0.210	NS
	Range	103 – 176	103 – 175			
BMI	Mean±SD	44.97 ± 8.33	42.90 ± 4.99	1.165	0.249	NS
	Range	36 – 65	37 – 55			
Operative time (min)	Mean±SD	53.33 ± 6.34	59.00 ± 8.14	-3.008	0.004	HS
	Range	45 – 65	45 – 75			

The Mean BMI for group (A) is 44.97 ± 8.33 with range (36-65) while that of group (B) is 42.90 ± 4.99 with range of (37-55) P-value 0.249.

Table (3): Previous medical history.

		Group A		Group B		Test value*	P-value	Sig.
		No.	%	No.	%			
Medical History	Negative	23	76.7%	18	60.0%	1.926	0.165	NS
	Positive	7	23.3%	12	40.0%			
Asthma	Negative	28	93.3%	30	100.0%	2.069	0.150	NS
	Positive	2	6.7%	0	0.0%			
HTN	Negative	26	86.7%	22	73.3%	1.667	0.197	NS
	Positive	4	13.3%	8	26.7%			
DM	Negative	26	86.7%	24	80.0%	0.480	0.488	NS
	Positive	4	13.3%	6	20.0%			
COPD	Negative	29	96.7%	30	100.0%	1.017	0.313	NS
	Positive	1	3.3%	0	0.0%			
IHD	Negative	30	100.0%	27	90.0%	3.158	0.076	NS
	Positive	0	0.0%	3	10.0%			
Hypothyroidism	Negative	30	100.0%	29	96.7%	1.017	0.313	NS
	Positive	0	0.0%	1	3.3%			

In Group A 4 patients out of 30 patients had hypertension, 4 patients had type 2 DM, 2 patients were asthmatic and one patient with COPD. In group B 8 patients had HTN, 6 patients had type 2 DM, one patient with hypothyroidism and 3 patients with IHD.

Table (4): Comparison of post operative LL pain or swelling and post operative dyspnea in both groups.

		Group A		Group B		Test value	P-value	Sig.
		No.	%	No.	%			
Post operative LL pain or swelling	Negative	25	83.3%	28	93.3%	1.456	0.228	NS
	Positive	5	16.7%	2	6.7%			
Post operative dyspnea	Negative	30	100.0%	30	100.0%	NA	NA	NA
	Positive	0	0.0%	0	0.0%			

There was no clinical evidence of Pulmonary embolism in our study.

Table (5): Comparison of incidence of DVT in both groups.

		Group A		Group B		Test value	P-value	Sig.
		No.	%	No.	%			
2 weeks post	Negative	30	100.0%	30	100.0%	NA	NA	NA
operative Duplex LL	Positive	0	0.0%	0	0.0%			
3 months post	Negative	30	100.0%	30	100.0%	NA	NA	NA
operative Duplex LL	Positive	0	0.0%	0	0.0%			
6 months post	Negative	30	100.0%	30	100.0%	NA	NA	NA
operative Duplex LL	Positive	0	0.0%	0	0.0%			

*P-value > 0.05: Non significant; P-value < 0.05: Significant; P-value < 0.01: Highly significant *: Chi-square test*

There was no sonographic evidence of thrombi in the femoral, or popliteal or infrapopliteal veins in any of the patients in this study in early and late post operative period (including group (A) and group (B) which were evidenced by Duplex venous scan.

Discussion

VTE continues to be an important source of postoperative morbidity and mortality among patients undergoing bariatric surgery, despite current VTE prevention methods. In the modern era of bariatric surgery with a majority of programs having VTE prophylaxis protocols in place, the incidence of symptomatic deep venous thrombosis (DVT) and pulmonary embolism (PE) ranges from 0%–5.4% and 0%–6.4%, respectively. A recent systematic review of 19 studies evaluating VTE after laparoscopic bariatric surgery reported an incidence of pulmonary embolism of 0.5%, and the Michigan Bariatric Surgery Collaborative published 2 large series from their quality collaborative registry that showed overall VTE rates less than 0.5% in average risk bariatric patients. Accurate evidence-based risk assessment tools for VTE in bariatric patients are not currently available, but the literature highlights several risk factors that must be taken into consideration when determining a prophylaxis strategy. These risk factors may include prior VTE, higher body mass index (BMI), age, gender, immobility, use of hormone therapy, obesity hypoventilation syndrome, pulmonary hypertension, venous stasis disease, operative time, and procedure type and approach.

Data published in 2009 from the multicenter prospective Longitudinal Assessment of Bariatric Surgery (LABS) study reported a 30-day incidence of VTE complications of 0.4% and the risk increased with increasing weight. More recently, LABS data were used to determine whether prophylactic anticoagulation added to compression devices prevents VTE. The overall 30-day VTE rate among 4416 patients was low (0.25% among patients receiving sequential compression alone [n = 396] and 0.47% when anticoagulation was added [n = 4020]). This study concluded that there was insufficient evidence to make a specific recommendation regarding VTE prophylaxis after bariatric surgery and that a sufficiently powered trial to answer this question is impractical

The ASMBS recommends prophylaxis with a combination of early ambulation and mechanical prophylaxis for all patients. They state that use of pharmacologic prophylaxis “should be considered based on clinical judgment and risk of bleeding”. The ASMBS expresses a preference for LMWH over UFH, although they stipulate that there is conflicting data regarding the type of pharmacologic prophylaxis to use.

The American College of Chest Physicians (ACCP) does not offer specific recommendations for bariatric surgery patients, but includes this group with patients having other abdominal, vascular, or plastic reconstructive surgery. The ACCP recommends using either a Rogers et al or Capriniscore to stratify patients as low, moderate, or high risk of VTE. Given usual body habitus and type of surgery, bariatric surgery patients typically will be considered moderate to high VTE risk, depending on comorbidities. The ACCP also recommends stratifying bleeding risk to determine a prophylaxis plan. For patients with a moderate VTE risk who are not considered to be at high bleeding risk, LMWH, UFH, or IPC may be used; for moderate VTE risk but high bleeding risk, IPC alone is recommended. For patients with a high VTE risk, a combination of mechanical (IPC or ES) and pharmacologic (either LMWH or UFH) measures are recommended, unless the bleeding risk is high (IPC alone is recommended).

The Interdisciplinary European Guidelines on Metabolic Surgery recommend VTE prevention for all bariatric patients through LMWH administration, use of LEC (both ES and SCD), and early postoperative ambulation. These guidelines do not address the questions of augmented LMWH dosing, post discharge anticoagulation, or VCF placement.

The American Association of Clinical Endocrinologists, the Obesity Society, and the American Society for Metabolic and bariatric Surgery (AACE/TOS/ASMBS) together have produced guidelines for bariatric surgery. Early ambulation and IPC as well as postoperative UFH or LMWH are recommended. Anticoagulant dosing is not specified, but post discharge pharmacologic prophylaxis is recommended for “high-risk” patients, such as those with history of DVT; no specific duration of therapy is suggested.

In our study we reveal that DVT and VTE are minimally affected by bariatric surgery regarding that the patient had no coagulation system affection and had appropriate surgery with optimum operation time, early postoperative ambulation and good perioperative hydration.

We can conclude that there is no difference among morbidly obese patients having bariatric surgery regarding incidence of DVT either in patients having chemoprophylaxis (LMWH) and those that did not have any chemoprophylaxis provided that they all had the same operative and postoperative sequel.

Conclusion

We have noticed that all our morbid obese patients that had lap sleeve operations which were not at high risk for developing DVT, as demonstrated in inclusion and exclusion criteria, with average operation time and early ampulation as long as good hydration after surgery, there was no difference in DVT incidence between patients receiving chemoprophylaxis and those not receiving any chemoprophylaxis before and after Lap Bariatric Surgery.

We need further investigations including coagulation profile and congenital anticoagulation abnormalities to give an

accurate idea about the influence of laparoscopic Bariatric Surgery on the incidence of thromboembolic events.

References

Kang, Jenny H., & Quang A. Le. (2017): Effectiveness of Bariatric Surgical Procedures: A Systematic Review and Network Meta-Analysis of Randomized Controlled Trials. Medicine, 96(46), e8632-e8632.

Sharma AM, & Campbell-Scherer DL (2017): Redefining Obesity: Beyond the Numbers. Obesity, 25(4), 660-661.

Stroh C, Michel N, Luderer D, et al. (2016): Risk of Thrombosis and Thromboembolic Prophylaxis in Obesity Surgery: Data Analysis from the German Bariatric Surgery Registry. Obesity surgery, 26(11), 2562-2571.

Vandiver, Jeremy W, Ritz, et al. (2016): Chemical Prophylaxis to Prevent Venous Thromboembolism in Morbid Obesity: Literature Review and Dosing Recommendations. Journal of thrombosis and thrombolysis, 41(3), 475-481.

Venclauskas, Linas, Maleckas, et al. (2018): European Guidelines on Perioperative Venous Thromboembolism Prophylaxis: Surgery in the Obese Patient. European Journal of Anaesthesiology (EJA), 35(2), 147-153.