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Evaluation of the role of post-operative Antibiotics Use after Lower Limbs Varicose Veins' Conventional Surgery as a Prophylactic Measure against Surgical Site Infection

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Background: Varicose veins (VV) surgery wounds are expected to be clean wounds that don't need a regimen of postoperative systemic antibiotics. Inspite of this, many surgeons in Egypt believe that they have to prescribe a short course of post-operative systemic antibiotics due to different cohort of patients we deal with, with different standards of life, hygiene & health awareness. **Aim:** To study the value of using oral systemic antibiotic regimen after conventional surgery for VV in prophylaxis against surgical site infections (SSIs). **Subjects and methods:** a randomized prospective study carried on sixty patients who were candidates for conventional VV surgery. Patients were randomized into two groups; first group (group A) received a preoperative single dose of antibiotic while the second group (group B) received pre and post-operative antibiotic regimen. All patients were subjected to full pre-operative examination and routine laboratory and radiological investigations. Patients with high risk factors for developing SSIs were excluded from the study to better evaluate the role of post-operative antibiotic regimen. Our primary endpoint was incidence rate of SSI in both groups while our secondary endpoints were developing hematoma or thrombophlebitis. **Results:** Patients were mostly females (68.3%) with no significant difference in the gender distribution among the two groups, mean age was 35; body mass index (BMI) mean was 23.8 with significant decrease in mean BMI in group B. SSIs occurred in 3 (5%) out of the 60 patients. Out of these three patients two (6.7%) were in group A and one (3.3%) was in group B (P value= 0.55). 17 patients (28.3%) had hematoma, out of those 10 were in group A, while 7 were in group B (P value= 0.39). 3 patients (5%) had thrombophlebitis all of them were in group B (P value=0.078). By using statistical analysis studies there was no significant correlation between using post-operative antibiotics and incidence of SSIs, hematoma and thrombophlebitis formation. **Conclusion:** using of post-operative oral antibiotic regimen after conventional VV surgery doesn't directly affect the incidence rate of surgical site infection (SSI) in SSI low risk patients.
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1. Introduction

According to American venous forum, an estimated 23% of United States adult population suffers from varicose veins and 5% of those suffer from skin changes and venous ulceration. ***(R. J. Winterborn and F. C. T. Smith, 2010).***

The occurrence of a surgical site infection (SSI) is one of the most common complications after surgery. SSI dissatisfies patients and providers; it also increases the cost of surgical care and increases morbidity. ***(C. W. Tran et al., 2015).***

SSI is recognized as a common surgical complication, occurring in about 2-5% of all surgical procedures. SSI represents the third most frequent nosocomial infection, accounting for 14-16% of all infections observed in hospitalized patients and up to 38% of those observed among surgical patients. ***(G. Sganga, 2014).***

In accordance with international data, the incidence of SSIs after vascular surgery in the groin are 3–44%, and deep groin infections with prosthetic material involvement are described in up to 6% of cases. The relationship between SSIs and morbidity correlates with extended hospital stay, severe limb ischemia, extremity loss, massive hemorrhage, systemic sepsis and septic embolization. ***(S. P. Pleger et al., 2018).***

Surgical site infection incidence rate after GSV ligation and stripping and phlebectomies is reported to be 8.2% with most cases of SSI being at the groin wound followed by calf and thigh wounds respectively. ***(R. Singh et al., 2012).***

Aim of the Study

This study aims to evaluate the role of using post-operative antibiotics after varicose veins conventional surgery as a prophylactic measure against SSI and to answer the question:

Do patients in Egypt need postoperative antibiotics following varicose veins surgery?

2. Patients and methods

The present work is a randomized prospective study.

Patients: The study was performed on 60patients who were candidates for VV conventional surgical treatment who received treatment in Ain Shams University and Maadi Military hospital vascular surgery departments in the period between September 2018 and July 2019. Patients of age group between 18 and 60 years with primary VV were included, while patients with recurrent VV, previous history of DVT, thrombophilia, concomitant arterial disease and those withrisk factors (e.g. Diabetes, BMI > 30, immunocompromised) for encountering SSIs were excluded. Patients receiving antibiotics for other cause were also excluded.

Method: All patients received conventional surgical treatment for VV in the form of Great Saphenous Vein (GSV) stripping and phlebectomies as required. Patients were allocated into two groups by simple randomization method which was using two groups of closed opaque envelopes corresponding to the two antibiotic regimens; each patient chose an envelope which was opened by the physician prior to patient preparation for surgery. Group A patients received single dose of antibiotic (Cefoperazone 1 gm) at induction of anesthesia, while group B patients received one dose of preoperative antibiotic and post-operative systemic oral antibiotic (amoxicillin 825 clavulinic acid 125) for one week post operatively.

All the patients were subjected to the following protocol preoperatively:

1. Thorough History taking including

- Age, sex & occupation.
- Presenting symptoms of CVD and VV (pain on prolonged standing, cosmetic disfigurement, edema, eczema, hemorrhage, ulceration and lipodermatosclerosis, superficial vein thrombosis.
- Past medical History DM, HTN, IHD, Liver cell failure and history of allergy. History of DVT, thrombophilia. For female patients the menstrual and obstetric histories were obtained.
- Past Surgical History including: any abdominal operation or incisions in the groin region and whether any previous surgery was complicated by SSI or hematoma.
- Family history of same condition of VV.
- Weight and height to calculate Body Mass Index (BMI).

2. Full physical examination

All patients were subjected to full examination of superficial venous system to identify:

- Location of all varicosities and their relation to great or small saphenous veins.
- The presence of incompetent perforators.
- Presence of venous ulcers.

CEAP classification was reported & Venous Clinical Severity Score were calculated for all patients.

3. Routine Pre-operative investigations including

- Complete blood picture.
- Coagulation profile (PTT, PT, INR).
- Other laboratory/ radiological investigations were ordered according to the preoperative anaesthetic assessment.

4. Radiological investigations

- Duplex scan of the affected lower limb to scan superficial and deep venous systems.

5. Consent

- Preoperative consents were obtained from all patients explaining to the patient what to expect from the surgery, recovery time after operation & complications that may occur intra and post-operatively (e.g. SSI, hematoma, thrombophlebitis, etc...) and all the patients included in the study accepted to be randomized to one of the two groups.

❖ **Intraoperative:**

- Each patient had received general or spinal regional anesthesia.
- Each patient had received Cefoperazone 1 gm at induction of anesthesia.
- Each patient had underwent the conventional GSV surgical stripping by a plastic stripper (Medistrip® disposable vein stripper, 100 cm length with 6/9/12/15 mm interchangeable heads) with the appropriate sized head.
- Stab phlebectomies were done afterwards if required according to each case.

❖ **Postoperative:**

All patients received NSAIDs for pain control (Paracetamol 500 mg 2 tablets when needed with a maximum dose of 8 tablets per day), and oral anti edematous Alphintern® (oral Chymotrypsin 300 E.A.U. (14 micro Katals). Trypsin 300 E.A.U. (5 micro Katals) tablets TID for 10 days).

Group B of patients received oral antibiotics post operatively in the form of co- amoxiclav Augmentin®tablets 1 gram (amoxicillin 825 mg/clavulinic acid 125 mg) twice daily for one week post operatively.

Patients were followed up one week then two weeks after operation. Full history taking & thorough

examination was done for all patients to identify symptoms and/ or signs of SSI in the wounds (1ry endpoint), thrombophlebitis or hematoma (2ry endpoints).

3. Results

The studied population included 60 patients candidate for surgical treatment of VV. Out of these 41 patients (68.3%) were females. The mean BMI of all patients was (23.8 ± 3.4) with the highest value of 29.8 and the lowest of 18.4. Only 5 patients had positive family history of CVD, out of the patients included 33 (55%) had VV of the left lower limb and 27 (45%) had their right lower limb affected. All sociodemographic data showed no significant difference between the two groups except for BMI which was significantly lower in group B (P= 0.013). Post-operatively three patients (5%) had surgical site infection, out of these three patients two (6.7%) were in group A and one (3.3%) was in group B (P value= 0.5), 17 patients (28.3%) had hematoma, 10 (33.3%) of them were in group A while 7 (23.3%) were in group B (P value= 0.39). Three patients had thrombophlebitis (5%) all were in group B (10%) (P value= 0.07). no significant statistical difference was noted between the two groups as regards endpoints of our study.

Table (1): post-operative end-points among 60 patients comparing the two groups:

Variable			A group (30)	B group (30)	Chi square test P value
1ry end-point	Surgical site infection	+ve	2 (6.7%)	1 (3.3%)	= 0.5569
2ry end-points	Hematoma	+ve	10 (33.3%)	7 (23.3%)	= 0.3941
	Thrombophlebitis	+ve	0 (0%)	3 (10%)	= 0.078

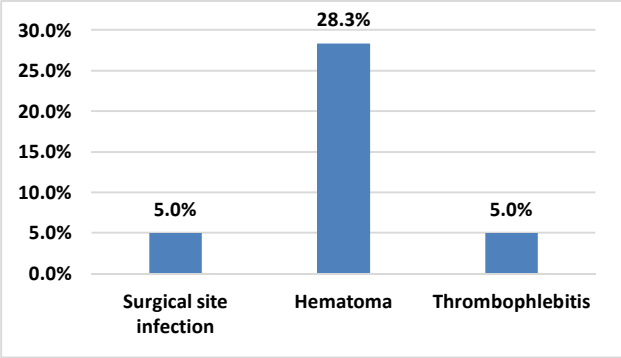

Fig (1): Post-operative end-points among 60 patients.

After using Roc-curve of antibiotic use to predict its relation to post-operative outcomes, no statistical significance was found between using post-operative antibiotics and the incidence rates of SSIs, hematoma or thrombophlebitis (P values were 0.55, 0.39 and 0.07 respectively).

Table 2: Roc-curve of antibiotic use to predict post-operative outcomes:

Variable		**AUC**	**SE**	**Sensitivity (%)**	**Specificity (%)**	**P value**
1ry end-point	**Surgical site infection**	0.517	0.0285	96.67	6.67	0.5592
2ry end-points	**Hematoma**	0.550	0.0588	76.67	33.33	0.3952
	Thrombophlebitis	0.550	0.0279	10	100	0.0726

ROC (Receiver operating characteristic), AUC= Area under curve, SE= Standard Error.

4. Discussion

SSIs are a devastating and common complication of surgery, occurring in 2% to 5% of patients undergoing surgery in the United States. ***(Popovic J, 2001)*** Approximately 160,000 to 300,000 SSIs occur each year. SSI is the most common type of health care–associated infection. ***(Lewis S. S. et al, 2013).***

SSIs rates in Africa/Middle East, Latin America, Asia, and China were found to be 10%, 7%, 4% and 4%, respectively in clean and clean-contaminated surgical wounds in these developing parts of the world. ***(D. Curcio et al, 2019)*** these results show that SSIs is not a problem to be ignored in these regions considering the burden on health care costs and increase in morbidity and mortality rates.

The search in the medical literature showed few studies discussing the same exact subject of this study. However In a large study conducted on 902

ambulatory surgery patients who underwent 953 consecutive RFAs of the GSV in combination with ligation and division of SFJ. A single dose of preoperative antibiotic was administered 1 hour before incision to some patients (n = 449 extremities), with all other patients receiving no antibiotic (n = 504). Primary outcome measure was SSI categorized based on type of therapy required (1: oral antibiotic, 2: hospitalization for intravenous antibiotic and/or wound debridement). SSI developed in78 patients (8.2%) with groin, thigh, and calf distributions of 47%, 8%, and 45%, respectively. All category 2 infections (n = 8, 10%) occurred in control subjects, and the majority were located in the groin. Body mass index significantly increased risk for both overall (odds ratio [OR]: 1.09, 95% confidence interval [CI]: 1.05-1.14, P < 0.0001) and groin (OR: 1.08, 95% CI: 1.02-1.14, P = 0.01) SSI. Diabetes was a significant risk for groin SSIs (OR: 5.13, 95% CI: 1.44-18.26, P = 0.01). Antibiotic was associated with a significantly reduced risk for both overall (OR: 0.54, 95% CI: 0.37-0.89, P=0.02) and groin (OR: 0.34, 95% CI: 0.16-0.73, P = 0.01) SSIs. Furthermore, prophylaxis eliminated category 2 infections (P = 0.008) ***(R. Singh et al, 2012)*** the mentioned study revealed the importance of preoperative antibiotic use in GSV stripping and didn't mention post operative antibiotic regimen as it is considered a outpatient clean operation with no significance of using antibiotics post-operatively, however it highlighted the importance of using preoperative antibiotic prophylaxis.

In a RCT study conducted comparing the outcome of using endovenous laser ablation, foam sclerotherapy, and conventional surgery for great saphenous varicose veins on 223 eligible patients, 240 legs were randomized for one of the treatments between January 2007 and December 2009. ***(Biemans A et al, 2013).*** Out of 68 patients who underwent conventional surgery, 3 encountered superficial wound infection requiring systemic antibiotics with a rate of 4.4% which is close to the rate of our study. The number of patients in this study with conventional surgery treatment is near the number of patients in our study (68 vs. 60). Gender ratio was also nearly the same with the majority of patients are females (67.6% in this study vs.68.3% in ours). The prophylactic antimicrobial regimen wasn't mentioned in this study unlike our study but we can conclude that no preoperative antibiotic was administered because all the cases were treated in an outpatient clinic setting and only the patients who developed wound infection received post-operative antibiotics.

In a non‐blinded randomized controlled trial conducted to compare endovenous laser ablation to conventional surgery on 280 patients, 137 patients received surgical intervention and out of them 8 (5.8%) patients had wound infection, 11 (8.3%) had hematoma and 6 (4.5%) had phlebitis. ***(Carradice et al. 2011)*** all patients in this study received preoperative single dose of antibiotics at induction of anaesthesia (antibiotic name wasn't mentioned) and no regimen of post-operative prophylactic antibiotic was mentioned. If we compared these results to results of group A patients in our study, where 2 (6.7%) patients developed infection, 10 (33.3%) had hematoma and none had phlebitis. The demographic data was close to our study where females formed the majority of patients (n=90, 65.7 %) BMI mean was 26 compared to 23.8 in our study. As with the previous studies no post-operative antibiotic regimen was mentioned and that highlights the fact that VV conventional surgical treatment is long considered to be a clean surgical operation and no need for post-operative antibiotic regimen is of proven value.

In a double blinded randomized controlled trial that was conducted to investigate the efficacy of single dose antibiotic prophylaxis in preventing wound related complications following varicose vein surgery at a single academic vascular surgical unit of a university hospital. A total number of 426 patients were randomized to two groups where 212 received preoperative co amoxiclav after induction of anaesthesia (treatment group) while 214 received no preoperative antibiotic prophylaxis (control group). Using ASEPSIS score, patients were instructed to fill a diary of wound condition status. Overall, significantly higher total ASEPSIS scores were recorded in the control group, with a median (interquartile range) score of 6 (0–15) *versus* 3 (0–9) in the treatment group (P = 0·013). Twenty‐one patients (9·9 per cent) in the treatment group and 39 (18·2 per cent) in the control group had total score of 21 or more, which, by ASEPSIS criteria, defines wound infection. ***(Mekako et al. 2009)***. In comparison to our study, gender ratio was predominantly female in both treatment and control group (67% and 59% respectively), median age was 46 and 49 and median BMI was 27 in both groups. The exclusion criteria differed for this study didn't include patients with high risk factors for developing SSI unlike our study. Their results showed five variables (receiving antibiotics, BMI, smoking, redo surgery and sex) to have direct effect on wound healing and incidence rate of SSI.

5. Conclusion

From the present study it was concluded that

- The incidence rate of SSIs in patients who didn't use post-operative antibiotics was 2 out of 30 patients (6.7%) and in those who used post-operative antibiotics it was 1 out of 30 (3.3%). Non-significant statistical difference was found between the two groups with lack of evidence in this study and other

reviewed studies that using post-operative antibiotics in clean operations decreases incidence rate of SSIs.

- Control of patient's known risk factors and proper preparation of the patient preoperatively is more important in reducing rates of SSIs in clean operations and in surgical practice in general.

Authors contribution:

Data collection (Mahmoud A Okaz), study design (Nader M Hamada, Mahmoud A Okaz), Statistics (Mahmoud A Okaz), Revision of the work (Nader M Hamada), Approval of the work (Khaled Z Mansour, Nasser S Hammad, Hany R Wakim).

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