**Venous Thromboembolism prevention protocol: The Madre Teresa's Hospital experience in 2000 cases**

**Abstract:**

**Background:** Venous thromboembolism (VTE) is known as a possible complication after total knee arthroplasty. In an attempt to standardize prevention measures against this phenomenon was implemented in a tertiary institution prevention protocol in 2015. The objective of this study is evaluate the impact of this protocol for the prevention of venous thromboembolism in 2005 patients submitted to primary total knee arthroplasty.

**Material and Methods:** Data from medical records of patients submitted to total knee arthroplasty before (n=1115) and after (n=889) institutional protocol implantation, totaling 2005 patients, were retrospectively reported. Demographics, comorbidities, and outcomes were analyzed.

**Results:** There was no significant change in the cases of DVT (1.6% X 2.4% *p* = 0.211). There was an increase in cases of Pulmonary Embolism (PTE) (0.2% X 0.8% *p* = 0.049).

**Conclusion:** Despite the implementation of the prevention protocol, no reduction in studied events were observed. The small global incidence of it makes further studies with larger series necessary to confirm or rule out these findings.

**Study Design**

Level III - retrospective comparative study

**Keywords**

Thromboembolism; primary knee arthroplasty;complications; risk factors

**Introduction**

Total knee arthroplasty (TKA) is one of the most realized orthopedic procedures worldwide.1,2 More than 600.000 of these surgeries are annually realized in USA.1 Different complications were described and one of the most feared were venous thrombus embolism (VTE): Deep vein thrombosis (DVT) and pulmonary embolism (PE).2

Without prophylaxis DVT, symptomatic or not, could be detected in 41 to 84% of the image exams.3 PE is not that common with variations between 1,5 and 10% but with mortality rates between 0,1 and 1,7%.4 Many risk factors were described: age over 60 years, obesity, oral contraceptives, hormonal reposition therapy, bowel inflammatory disease, personal or familiar history of DVT or PE and long tourniquet time.5

Basically there is mechanical and pharmacological methods to prevent PE and DVT. Up to 2015, many of them were used for prevention after TKA in \*\*\* name removed to first assessment. After that was initiated an institutional prevention protocol to standardize its prevention. We hypothesize that after protocol implantation smaller numbers of DVT and PE may be found. The objective of this study is verify if this new standardize protocol interfered in VTE incidence after primary TKA.

**Material and Methods**

Data from primary TKA patients realized between January 2011 and December 2017 were retrospectively collected from \*\*\* name removed to first assessment database, totalizing 2005 patients. This study was approved by the ethical committee of the Institution. An informed assigned consent was obtained before the study. No financial incentive was offered to any participant. Every primary TKA patients were included. Exclusion criteria was another surgical procedure together with TKA and infectious disease associated.

Every patient was operated on by the same surgical team with pneumatic tourniquet through anterior approach and medial parapatelar arthrotomy. Every TKA was with posterior cruciate sacrifice and both components were cementite at the same time. Patellar component was not used. Up to December 2014 there was not a standard protocol regarding VET prophylaxis, pharmacological or mechanical, inside or outside the Institution. It was executed according each surgeon orientation to the patient. Starting in January, 2015 Madre Teresa Hospital standardized a clinical protocol to deal with VET prevention (Figure 1). In this protocol every patient received low molecular weight heparin (LMWH) subcutaneously 40 mg starting 6 hours after the end of the surgery and continuously every 24 hours up to the discharge to home. In this occasion was initiated oral anticoagulants (factor Xa inhibitors) up to 14 days in the post op. (PO). The same dose of LMWH was used every 12 hours if the patient had body mass index (BMI) over 30. Among mechanical measures, full weight bearing with a walker was initiated in the first day PO after peripheral nerve recovery or after intensive care unit release. The average length of stay in the hospital was 54 hours. Rehabilitation was prescribed to home for every patient and to ambulatory physiotherapy facilities as well.

Patient data analyzed were sex, age, weight, height, classification according American Anesthesiology Association (ASA), presence of diabetes, high blood pressure, smoking habits, time to the first walking, anticoagulant use after discharge, EP or DVT history and its occurrence up to 6 months PO. Only VE symptomatic cases were analyzed as well as those who needs any form of treatment. Asymptomatic cases were not studied.

*Statistical Analysis*

Data were analyzed using averages and standard deviation. Categorical data were compared using qui square and exact test of Fischer. To continuous variables was realized an evaluation regarding a normal distribution using Kolmogorov-Smirnov test. The difference between averages was calculated using parametric Student T test and for others, the non-parametric test of Mann-Whitney. Significance was accepted with value of 0,05. Statistical analysis was made using soft where SPSS, 20® (IBM Corp. 2011. IBM SPSS Statistics for Windows, version 20.0 Armonk, NY: BM Corp).

**Results**

2005 were analyzed. In the group operated before protocol implantation, 275 patients were male (24,7%) and 840 (75,3%) females. The average age was 72 years old. The average weight was 78,9 kilograms and average height was 1,63 meters, with 29,69 of average BMI. Were classified as ASA I 4,8% of patients, ASA II 91,4% and ASA III 3,8%. *Diabetes Mellitus* (DM) was present in 14,9% of the patients and 60,9% had high blood pressure (HBP). Smoking were 2,5% of the patients. Walking training starts in up to 24 hours after surgery in 85,8% of the patients. In this group 44,1% used anticoagulants up to 2 weeks in the PO. DVT or PE history were present in 3,8% of the cases. DVT was detected in 1,6% of the patients and PE in 0,2%.

In the group operated after protocol implantation, 233 were male (26,2%) and 657 females (73,8%). The average age was 72 years old. The average weight was 78,3 kilograms; the average height was 1,63 meters with 29,47 of average BMI. Were classified as ASA I 9,7% of patients, ASA II 83,6% and ASA III 6,7%. DM was present in 22,7% of the patients and 76,9% had HBP. Smoking were 5,2% of the patients. Walking training starts in up to 24 hours after surgery in 78% of the patients. In this group 98% used anticoagulants up to 2 weeks in the PO. DVT or PE history were present in 4,8% of the cases. DVT was detected in 2,4% of the patients and PE in 0,8%.

Comparing the results between two groups, statiscally difference were found between ASA classification (*p*<0,05). Critical cases (ASA III) were much more frequent after protocol implantation (*p*<0,05). Statiscally significant differences were found between patients with DM (*p*<0,05), HBP (*p*<0,05) and smoking (*p*<0,05). After protocol these characteristics were more frequent. After protocol time for walking training was significant late (*p*<0,05). Use of anticoagulants were higher as well (*p*<0,05). No difference was found in DVT numbers (*p*>0,05) and PE were considered statiscally significant (*p*=0,049). Results were summarized at Table 1.

**Discussion**

The main result of this study was despite the fact of this protocol implantation there was not a reduction in DVT cases with an increase in PE numbers. We should be aware of the increase in the comorbid numbers with a significant increase in intensive care utilization in the PO. The walking training delay could explain the increase in VTE numbers because patients are not able to walk during its time inside de intensive care. Walking is a proved way to reduce VTE. Chandrasekaran et al. described 0% incidence in a population which initiated walking training in the first 8 hours in the PO.4 Andersen et al. described 25% reduction in VTE when first walking was initiated in up to 24 hours PO.6

Several studies found the important relation between VTE and TKA. Khokhar et al. described 13% DVT and 3% PE.3, O Reilly et al., using only symptomatic cases found 0,6 to 5,7% VTE with 0,33 to 2,1% DVT and PE between 0 and 1%.7 Song et al. used bilateral phlebography in 109 patients and found symptomatic DVT in 4,6% of the patients and asymptomatic in 18,3%.8 Without prevention DVT could reach 60% in the first 90 days PO9, and fatal PE could be 1,5%.10 In this study the general incidence was 2,3% of VTE with 1,6% and 2,4% DVT and 0,2% and 0,8% PE pre and post protocol implantation respectively.

Several risk factors were related with VTE. Zhang et al. made a metanalysis and evaluated 1.150.000 patients after total knee and hip replacements. They found as a risk factors age over 70 years old, female sex, BMI over 30, black race, and ASA ≥3.11 Besides several studies showing prevention protocol decrease VTE incidence, we found an increase in VTE complications after TKA. An explanation would be the increase of patient’s complexity and comorbidities. In this study we found an increase in DM, HBP and smoking, although these are not related to the higher prevalence of VTE. The small numbers of patients with previous or familiar history of VTE could explain the lack of relation observed in cases with DVT and PE.

Azboy et al., in a retrospective study with 26.415 primary and revision TKA, recommended VTE prevention in the first 2 weeks PO as they found 81% of the documented or symptomatic cases of PE in the first 3 days after surgery, 89% in the first week and 94% in the first 2 weeks PO.12 We did not found prophylaxis protocol similar to that one used in this series. The association between LMWH and Xa inhibitors is not described. Every analyzed study used the same drug during the entire prophylaxis period.4,7,9,13 Different factor Xa inhibitors was not considered a confusion factor because despite different drugs used (Rivaroxaban, Apixaban and Dabigatran) all had the same site of function and were used in prophylactic doses, regarding manufactures recommendation.1

The fragility of this study relay on the fact that it was retrospective, based in Hospital database. The search strategy using procedure codes and careful reading of each record tried to minimize this facts. Because VTE is a low prevalence event more follow up time would be necessary to check the real number of this events.

**Conclusion**

Despite prevention protocol implantation was not observed reduction in the studied events. The small global incidence of it demands more studies with longer follow up to confirm or deny these findings.

**Disclosures**

None

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