



Full Length Article

Thromboprophylaxis after major orthopedic surgery: Improving compliance with clinical practice guidelines



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ABSTRACT

Introduction: Identifying risk factors and strategies for the prevention of deep venous thromboembolism in major orthopedic surgery has allowed the development of Clinical Practice Guidelines (CPGs). Currently, there is a gap between clinical practice and the implementation of the recommendations of CPGs. The purpose of this paper is to report the impact of the implementation of improvement strategies on adherence to venous thromboembolism (VTE) prophylaxis guidelines.

Materials and methods: We defined 3 quality indicators to assess the adequate use of thromboprophylaxis according to CPGs. We obtained a baseline measurement and identified several barriers for adherence. Six improvement strategies to promote adherence to CPGs were designed and applied. A systematic monitoring of these indicators was performed in real time and a description of the data was completed for patients undergoing primary joint replacement of the hip, knee and shoulder, during February 2012 and August 2014.

Results: Data from 773 patients were obtained. In the first trimester, the average of adherence was: 98.3% for medical order in the post-operative note, 60.3% for opportune administration and 67% for adherence to therapy at home. In the trimester, the rates of adherence were 100%, 95.7% and 100% respectively.

Conclusions: Combined strategies for improvement of adherence to VTE prophylaxis is associated with higher compliance with clinical practice guidelines.

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1. Introduction

Thromboembolic disease is one of the most frequent causes of morbidity and mortality after joint replacement surgery [1] and in order to prevent this outcome after primary hip, knee or shoulder arthroplasty a strict implementation of thromboprophylaxis regimens is required. When no prophylaxis is used, thromboembolic events may occur in more than 20% of the patients [2–4]. In contrast, the literature has demonstrated that with the use of effective thromboprophylaxis, the incidence of symptomatic thromboembolic disease can be significantly reduced to 2.8% for hip replacement and 2.1% for knee replacement [5].

Identification of risk factors and the preventable nature of this disease [6] has promoted the development of Clinical Practice Guidelines (CPG) for prevention of deep venous thrombosis and pulmonary embolism [4,7,8]. Nevertheless, several limitations for the implementation of these guidelines have been recognized. In two studies conducted in

hospitals in North America, the average compliance to CPG recommendations was less than 50%, increasing the probability of occurrence of adverse events [5,9]. Similarly, results from the ENDORSE study for Colombia showed that adherence to the ACCP guidelines was only about 60% [10].

We adopted the recommendations for prevention of thromboembolic disease in primary joint replacement patients (CG-92) from the National Institute for Health and Clinical Excellence (NICE) [7] and the Institutional Guidelines for the Management of Thromboprophylaxis in Orthopedics (Table 1) developed in our hospital. Although the prevalence of symptomatic thromboembolic disease after major orthopedic surgery in our center is less than 3% [11], to evaluate our rate of compliance to CPG recommendations is critical to improve patient outcomes.

The extent of compliance to CPG recommendations can be assessed by systematic measurement of performance indicators. From the information obtained with this process, different improvement strategies can be created, implemented and evaluated in real time [12–14]. Similarly, the implementation of these strategies represents an effective methodology for the prevention of venous thromboembolism and a decrease in the incidence of related adverse events [15,16].

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Table 1

Recommendations for thromboprophylaxis from the *Institutional Guidelines for the Management of Thromboprophylaxis in Orthopedics*.

Hip and knee arthroplasty
1. Thromboprophylaxis with both mechanical and pharmacological methods is indicated.
2. During the surgical procedure use anti-embolism stockings and intermittent pneumatic compression devices on the contralateral limb.
3. During hospitalization use:
a. Enoxaparin, dabigatran, rivaroxaban, apixaban or fondaparinux.
b. Anti-embolism stockings and intermittent pneumatic compression devices on both limbs, until the patient has restriction of movement.
4. Continue prophylaxis during 35 days after surgery.
Shoulder arthroplasty
1. Thromboprophylaxis with both mechanical and pharmacological methods is indicated.
2. During the surgical procedure use anti-embolism stockings and intermittent pneumatic compression devices on the legs.
3. During hospitalization use:
a. Enoxaparin or rivaroxaban.
b. Anti-embolism stockings and intermittent pneumatic compression devices on both limbs, until the patient has restriction of movement.
4. Continue prophylaxis during 13 days after surgery.

Our main objective is to describe the impact of a quality improvement program for the adherence to the CPG recommendations, through a systematic monitoring and measurement of performance indicators.

2. Materials and methods

We implemented a continuous quality improvement program to enhance the compliance to thromboprophylaxis guidelines. This program included: 1. Definition of performance indicators, 2. establishment of a baseline of the rate of compliance (February 2012), 3. implementation of improvement strategies [17–19], and 4. systematic monitoring of performance indicators (February 2012 to August 2014).

2.1. Definition of indicators

In order to assess the level of adherence to CPG recommendations for thromboprophylaxis, we selected, defined and validated the following performance indicators: 1. Correct order of thromboprophylaxis in the postoperative note, 2. timely administration of thromboprophylaxis according to CPG and 3. adherence to post-discharge thromboprophylaxis.

The definition of these indicators was carried out by a non-formal consensus product of weekly meetings of our working group in joint replacements. We also considered the library of quality indicators provided by JCI. The selection of a given indicator was based on the morbidity rates [5,11,20], structure and relevance of each indicator. Finally, they were externally validated according to the parameters from the *National Guideline Clearinghouse* and by an independent consulting firm [21]. All indicators belong to the “process” domain. The analysis of “outcome” indicators is beyond the scope of this study.

2.1.1. Medical order of thromboprophylaxis in the postoperative note

The indicator of medical order of thromboprophylaxis in the postoperative note represents the standardization of the use of antithrombotic prophylaxis and a safety barrier to ensure drug administration. Cases in which thromboprophylaxis was ordered and recorded in the postoperative note according to CPG recommendations, were considered as cases of completion. The numerator was defined as number of patients in whom the indicator was met, and the denominator as the total number of patients undergoing surgery. The goal of the indicator was set at 100%.

2.1.2. Timely administration of thromboprophylaxis according to CPG

The indicator for timely administration of thromboprophylaxis was defined according to what is recommended by the CPG regarding the start of each antithrombotic agent: rivaroxaban, enoxaparin and fondaparinux should be administered between 6 and 10 h after skin closure, and dabigatran between 1 and 4 h [7]. Timely administration contributes to the prevention of venous thromboembolism and the reduction of adverse events related to these drugs. Completion of the indicator was defined as the cases where the drug was administered within the time frame specified. The numerator was the number of patients in whom the indicator was met, and the denominator was the total number of patients undergoing surgery. The target of this indicator was also set at 100%.

2.1.3. Thromboprophylaxis continued at home

As the risk of developing thromboembolic events is maintained up to 90 days after surgery [22,23], an indicator of thromboprophylaxis continued at home was created. CPG recommend that thromboprophylaxis should be extended during 30 days after discharge, and for a period no longer than 35 days, for patients who underwent hip or knee replacements, and between 10 and 14 days for shoulder arthroplasty. Completion of the indicator was defined as: cases in which the patient had completed extended thromboprophylaxis according to CPG recommendations. This was assessed by a telephone follow up where the patient was asked for how many days he had taken the medication. The numerator was the number of patients in whom the indicator was met, and the denominator was the total number of patients undergoing surgery. The target was set at 100% as well.

2.2. Systematic monitoring of indicators

After obtaining approval from the Institutional Ethics Committee, we performed a descriptive analysis of the evolution of the percentage of completion of the performance indicators.

Monthly monitoring of all indicators was performed in real time by reviewing all medical records and by telephonic follow-up at 90 days after surgery. We included all patients undergoing primary joint replacement of the hip, knee or shoulder, for primary or secondary arthritis, or fracture, during February 2012 and August 2014. Patients undergoing joint replacement surgery for oncologic pathology and patients in whom the administration of antithrombotic prophylaxis differ due to a medical indication (e.g. hemodynamic instability), were excluded. Results are described as the percentage of completion of each indicator and its variation over time.

2.3. Implementation of improvement strategies

Different improvement strategies were developed and implemented. Due to idiosyncrasies of the indicators these strategies were

Table 2

Description of demographic characteristics of patients included in the analysis.

	Number of patients
Joint replacement	
Hip	425
Knee	331
Shoulder	17
Total	773
Gender	
Female	561
Male	212
	Mean
Age (years)	68.68
Surgeries per month	24.94

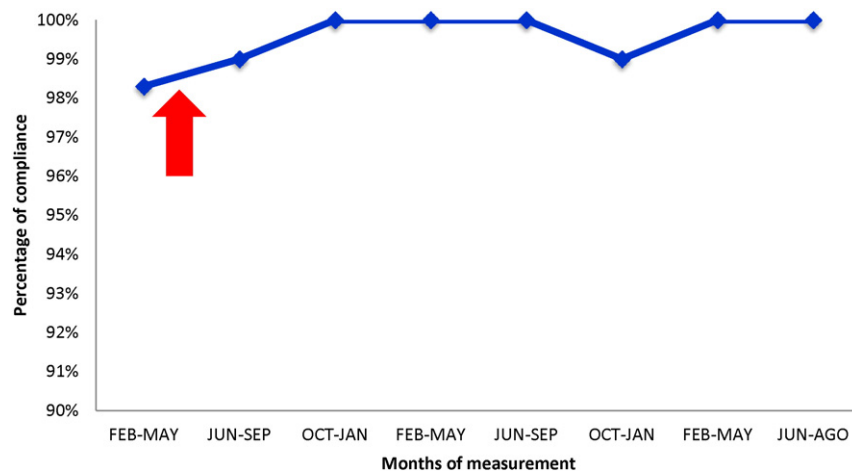


Fig. 1. Graph of the evolution of the performance indicator: *Medical order of thromboprophylaxis in the postoperative note*, during February 2012 and August 2014. Red arrow indicates the moment (March 2012) when improvement strategies were initially implemented.

designed considering the surgical/nursing teams involved in prescription and administration of thromboprophylaxis, the barriers for completion, the requirements for standardization of clinical processes and the identification of opportunities for improvement. We also considered the methods that were previously described in the literature to be effective increasing compliance to CPGs [24–27]. The most relevant strategies are the following:

1. *Communication of the relevance of each indicator and its supporting evidence:* during scheduled meetings with surgeons, anesthesiologists, residents and nurses, we presented the standardized clinical care protocol for joint replacement patients, the CPGs recommendations and all performance indicators, including their evidence-based rationale. We also presented the barriers for completion that we had identified and the mechanisms for standardization.
2. *Creation of a postoperative checklist:* standardization of postoperative orders was carried out through an informal consensus among the working group in joint replacements. This included the act of prescription of antithrombotic medications according to CPGs.
3. *Distribution of printed material with indications for adequate formulation of the postoperative checklist:* we designed an educational brochure containing a summary of the postoperative checklist. In this brochure, adequate formulation of thromboprophylaxis was described with examples that are easily remembered. Printed and electronic copies of the checklist were

distributed among surgeons and medical staff in training (orthopedic residents).

4. *Feedback on cases of non-compliance:* cases of non-compliance were reported and reviewed during scheduled meetings with the working group in joint replacements. In addition, individual feedback was given to the treating physician and its team. The barriers for compliance and the incorporation of new strategies to overcome these, were also discussed during these meetings.
5. *Education for the nursing team:* we developed a two-day conference aimed at all nurses in the hospital. Members of our working group gave talks about the following topics: conformation of a CCP in joint replacements, joint disease and joint replacement, prevention of perioperative complications, thromboprophylaxis according to CPG and the standardization of clinical processes and performance indicators.
6. *Patient and family education:* an educational brochure including all aspects of joint replacement surgery was designed and distributed among patients. The booklet included a section reminding the importance of timely administration of thromboprophylaxis and the extended therapy (10 or 30 days after discharge, depending on the procedure). In addition, during the week before surgery, patients were asked to attend a seminar, in which the content of the brochure was discussed and question from patients were answered.

3. Results

We obtained data from 773 patients during the 30-month study period: 425 were hip replacements, 331 were knees and 17 were shoulders, of which 561 were females and 212 were males. The mean age was 68.68 years. On average, 24.95 patients were operated each month (Table 2).

3.1. Medical order of thromboprophylaxis in the postoperative note

During the first quarter of monitoring (February to May 2012), the percentage of completion of this indicator was 98.3%. We identified 1 case of non-compliance. We implemented all improvement strategies described previously, but we focused on group and individual feedback about adequate formulation of thromboprophylaxis. We implemented these strategies on monthly basis. The behavior of the indicator over time is described in Fig. 1. The average percentage of completion of this indicator during the last trimester (June, July and August 2014) was 100%.

Table 3

Non-compliance cases and barriers for completion for the indicator: *Timely administration of thromboprophylaxis according to CPG*.

Number of non-compliance cases	Barriers for compliance	Improvement strategies
27	Unawareness of the defects within the process Unfamiliarity with the evidence that supports the process Inadequate administration thromboprophylaxis Inadequate registration of the administration of the drug	Group and individual feedback of cases of non-compliance Socialization of the purpose of the indicator and the supporting evidence to the surgical and nursing teams Distribution of electronic and printed material with indications for adequate formulation among surgeons and residents Education seminars for nurses

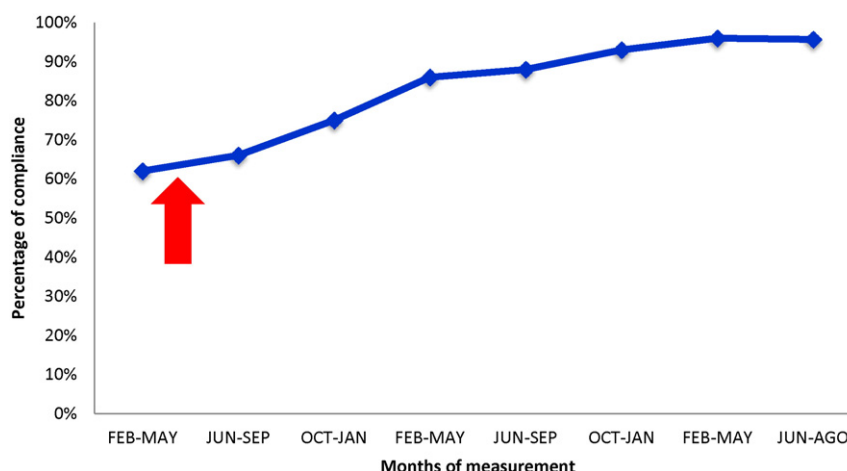


Fig. 2. Graph of the evolution of the performance indicator: *Timely administration of thromboprophylaxis according to CPG*, during February 2012 and August 2014. Red arrow indicates the moment (March 2012) when improvement strategies were initially implemented.

3.2. Timely administration of thromboprophylaxis according to CPG

During the first quarter, the percentage of completion of this indicator was 60.3%. Cases of non-compliance, barriers for completion that were identified and their respective improvement strategies are described in Table 3. During the following months, we could observe a trend towards improvement, but the rate of non-compliance, still varies widely with time (Fig. 2). The percentage of completion during the last three months of monitoring was 95.7%.

3.3. Thromboprophylaxis continued at home

The percentage of completion for this performance indicator was 67% during the first quarter. Similarly, barriers for completion were identified and improvement strategies applied also on a monthly basis (Table 4). The evolution of data obtained from the measurement of this indicator can be observed in Fig. 3. The percentage of compliance during the last trimester was 100%.

4. Discussion

Clinical Practice Guidelines summarize the most appropriate measures for prevention of venous thromboembolism and pulmonary embolism, after major orthopedic surgery. However, there are limitations in the incorporation of these recommendations to practice [5,9,15]. The applicability of quality management tools, such as the Deming Cycle (Plan–Do–Check–Act) and Six Sigma Methodology to patient care, allows the identification of defects in clinical processes and the implementation of improvement strategies to overcome those defects, as

they are detected in real time [12–14]. Executing a continuous quality improvement program can enhance the adherence to CPG recommendations, and becomes an essential part of an efficient and safe clinical care [13,18,25].

Rates of compliance to CPGs recommendations are typically described between 40 and 54% [5,16,18]. However, in a study carried out by Merli et al., adherence to CPG was reported to be around 12% [19]. Compliance to CPGs. Our results differ from what has been reported in the literature, as most of the adherence is reported to be above 60%.

Although the outcomes found with this systematic monitoring were favorable, after implementation of the different improvement strategies, we achieved the goal of 100% of compliance [28]. As previously described, these strategies were developed, tailored and implemented as the results were obtained. Accordingly, we observed that during last trimester of monitoring, the percentage of compliance was 100% for *Medical order of thromboprophylaxis in the postoperative note* and 100% for *Thromboprophylaxis continued at home*. For the indicator of *Timely administration of thromboprophylaxis according to CPG*, the average completion during the last trimester was 95.7%. This performance indicator is not within the target that was set and still has a large variation that has been difficult to control. However, we can observe a trend towards improvement, when the average of the last three months is compared to the initial measurement (Fig. 3). We acknowledge that we must continue to apply and reinforce our improvement strategies in order to reach and maintain a level of 100% adherence to this indicator.

Our results suggest that, a systematic monitoring of performance indicators and a continuous implementation of quality improvement strategies, have a positive impact on reaching complete adherence to CPG recommendations, as the main strategy for prevention of venous thromboembolism [5,29,30]. This is consistent to what was reported by Bateman et al. [31] and Hsieh et al. [17]. They describe an improvement in the rates of adherence after the implementation of different improvement strategies. However, these studies were developed in acute hospitalized and non-surgical patients (including cerebrovascular events), making it difficult to compare their results with ours. Meanwhile, multi-center studies like ENDORSE [32] and DEIMOS [33] only describe the rate of adherence and the reasons for non-adherence, without implementing strategies to improve their findings.

Actions carried out to adjust defects found within clinical processes, or to generate a cultural change that impacts the adequate prescription of thromboprophylaxis, produced a significant improvement in the percentages of completion of performance indicators. Thus, adherence to CPGs recommendations for prevention of thromboembolic disease after joint replacement surgery was enhanced. However, due to the

Table 4
Non-compliance cases and barriers for completion for the indicator: *Thromboprophylaxis continued at home*.

Number of non-compliance cases	Barriers for compliance	Improvement strategies
22	Inadequate formulation of thromboprophylaxis	Distribution of electronic and printed material with indications for adequate formulation among surgeons and residents
	Recall bias by the patient	Patient and family education
	Unawareness of the importance of extended prophylaxis	Education seminars for nurses

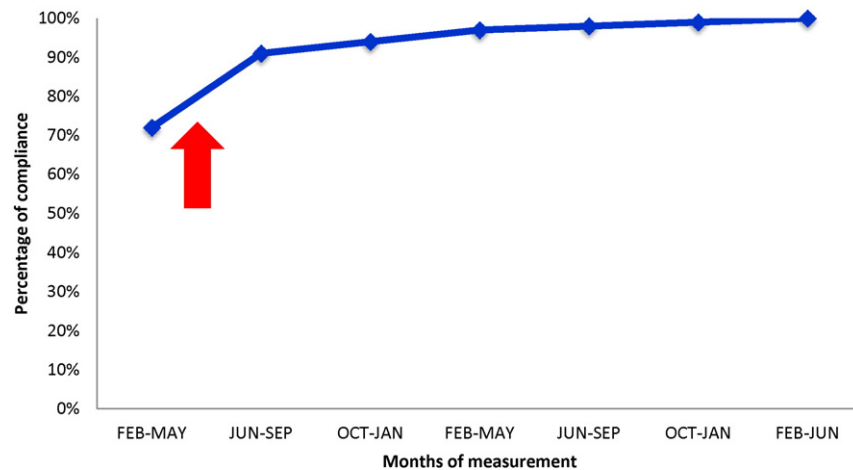


Fig. 3. Graph of the evolution of the performance indicator: *Thromboprophylaxis continued at home*, during February 2012 and June 2014. Red arrow indicates the moment (March 2012) when improvement strategies were initially implemented.

multifactorial nature of the improvement strategies that were presented in this paper, there are limitations to identify the isolated effect of each strategy that was implemented.

The fact that this is a single-center study questions whether these strategies could be implemented in other settings. Therefore, the external validity of this study depends on the ability of each hospital to implement this program. However, to our best understanding, there are no evident reasons that could limit its replication in centers qualified to perform joint replacement surgery.

The cost of implementation of this protocol may be another relevant issue. Although it could be time consuming, in our case resources were common to multiple quality improvement programs previously established, therefore limiting our ability to calculate individual costs. Furthermore, large variations in operative costs between centers, arises the need of an individual calculation of costs of application of these strategies. Finally, cost-effectiveness remains to be determined for centers that are interested in this topic.

We recommend that hospitals willing to implement quality improvement programs, in addition to the strategies highlighted in this paper, consider the use of digital tools as online courses, smartphone apps, or electronic record alerts, since they have demonstrated to be effective in both increase in adherence rates and decrease rates of VTE [34].

Based on the findings of this study, we can conclude that the implementation of a quality improvement program to achieve a 100% adherence to CPGs recommendations is a cyclic process based in the systematic monitoring of performance indicators, the continuous identification of improvement opportunities and the standardization of clinical care. This allows to provide high quality health care and reduction of the prevalence of adverse events related to major orthopedic surgery.

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