Original Article

A quality improvement project decreases incidence of pulmonary embolism following arthroplasty

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ABSTRACT

Objective: To develop a quality improvement initiative to reduce the incidence of pulmonary embolism (PE) following elective lower extremity joint replacement surgery.

Methods: 866 Patients undergoing a total knee or total or partial hip replacement surgery at a from 2014 to 2016 were included in this prospective pre-post interventional study.

Results: There were 13 PE's before the intervention and 2 after the intervention. The incidence of PE was significantly higher prior to the intervention (2.8% vs. 0.7%; $p = 0.044$).

Conclusions: Our results suggest that our bundle of interventions was successfully implemented and helped to reduce the incidence of pulmonary embolism following surgery.

1. Introduction

Venous Thromboembolism (VTE), which includes Deep Vein Thrombosis (DVT) and pulmonary embolism (PE), is an extremely dangerous medical condition that results in high rates of morbidity and mortality.¹ Although not directly addressed in the 2015 Global Burden of Disease study, VTE associated with hospitalization was the leading cause of morbidity in low- and middle- income countries and the second leading cause in high-income countries.² General risk factors for VTE, highlighted by Virchow's triad, are stasis, vascular endothelial injury, and an inherited or acquired hypercoagulable state.³

Pulmonary embolism, the most lethal VTE variant, has a 30-day fatality rate of 4% and a 1-year fatality rate of 13%.⁴ Pulmonary embolism is especially common in hospitalized patients undergoing orthopedic surgery, with an incidence ranging between 0.3% and 2% in patients undergoing elective hip or knee replacement.⁵ While prophylactic anticoagulation has been responsible for decreasing the incidence of PE following joint replacement surgery, it does not completely eliminate the risk.⁶ Other interventions, such as early ambulation and mechanical intervention, also appear to be important in minimizing the risk.⁷

At our institution, we noted that there was a high rate of pulmonary embolism in patients undergoing elective joint replacement in 2014, despite patients receiving pharmacologic prophylaxis. The goal of the present study was to develop a quality improvement intervention designed to reduce the incidence of pulmonary embolism in patients undergoing elective hip and knee replacement.

2. Methods

This study was approved by the Institutional Review Board at Johns Hopkins Aramco Healthcare. Our prospective pre-post interventional study that we designed using six sigma methodology was conducted at Johns Hopkins Aramco Healthcare. This is a 350-bed private hospital that provides healthcare to Aramco employees and their families and is a Joint Venture between Saudi Aramco and Johns Hopkins Medicine.

2.1. Participants

866 Patients who underwent an elective total knee or total or partial hip replacement at our institution between January 1st, 2014 and March 31st, 2016 were eligible for inclusion in our study. Patients were

Abbreviations: PE, pulmonary embolism; VTE, venous thromboembolism; DVT, deep vein thrombosis; PACU, post-anesthesia care unit; SCD, sequential compression device; TED, thromboembolism deterrent

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Table 1
Interventions that were implemented to reduce the incidence of pulmonary embolism.

Topic	Intervention	Date implemented
VTE risk assessment	● Implemented a risk assessment tool to identify appropriate prophylaxis for each patient	July 2015
VTE prophylaxis protocol	● Implemented a new VTE prophylaxis protocol	June 2015
Physical therapy	● Physical therapy to see patients on post-op day zero. ● Group physical therapy sessions twice daily	May 2015
TED stockings	● Education sessions for nursing staff on importance of TED stockings ● Order more stockings so that all sizes are available	May 2015
SCDs	● Required SCDs to be worn pre-op and post-op day zero	May 2015

VTE – venous thromboembolism; TED – thromboembolic deterrent; SCD – sequential compression device.

excluded from the study if their joint replacement surgery was due to trauma or if the joint replacement surgery was a revision. There were 6 different orthopedic surgeons that performed these procedures. A total of 4 surgeons participated with the intervention, leaving 757 patients in the analysis.

2.2. Measures

Our primary outcome of interest was development of pulmonary embolism following surgery. Pulmonary embolism was suspected based upon clinical symptoms and the diagnosis was confirmed using CT pulmonary angiography. Notably, we did not conduct routine screening for deep-vein thrombosis (DVT) or PE per the American Academy of Orthopaedic Surgeons and American College of Chest Physician guidelines.⁸ ICD-9-CM codes 41511 (Iatrogenic pulmonary embolism and infarction) and 41519 (Pulmonary embolism and infarction, other) were used to document the development of a pulmonary embolism in a post-operative patient. These data were collected on an institutional level as part of a broader set of patient safety indicators and was obtained from patient discharge instructions. The incidence of PE was also monitored for patients after they had been discharged, as our hospital serves as the single provider for our patient population. Other patient level data including patient demographics, type of procedure, and duration of surgery were also recorded. A secondary outcome of interest was the length of stay in the hospital. Data was also collected on several process measures, including the use of an adapted order form and risk assessment form, after these new forms were introduced.

2.3. Process and barriers

In early 2015, an interdisciplinary quality improvement team consisting of a quality improvement specialist, the chief of orthopedic surgery, and a senior nurse was formed to develop an initiative to reduce the incidence of pulmonary embolism following elective joint replacement surgery. A process map was created to examine what steps are taken to ensure patients are adequately protected from developing a PE, and barriers at several steps in the process were identified. The issues that were encountered were further explored by constructing an Ishikawa fishbone diagram. A series of interventions were then decided based upon these findings.

2.4. Interventions

We implemented an evidence-based bundle of interventions in June 2015 to reduce the incidence of PE following elective hip and knee replacement surgery at our institution. Prior to the interventions, patients received chemical and mechanical thromboprophylaxis following surgery, but it was variably enforced and sometimes patients did not receive adequate prophylaxis when it was indicated. Further, placement of sequential compression devices was often delayed until after the patient left the post-anesthesia recovery unit. The interventions that were implemented were based upon the American Academy of Orthopaedic Surgeons clinical practice guidelines.^{8,9} First, we decided

that a risk assessment form would be required to be completed when a patient was scheduled for surgery (Fig. A1). This form was adapted from the Caprini risk assessment tool,¹⁰ the American College of Chest Physician guidelines,⁹ and the NSW adult thromboembolism risk assessment tool.¹¹ The risk assessment form was completed by the patient and the surgeon during the pre-operative clinic visit. All patients undergoing elective major lower extremity arthroplasty by default are considered higher risk, so the main utility of the form was to accurately identify if chemical or mechanical prophylaxis is contraindicated for a given patient. Second, we developed a new adapted order set specifically designed for post-op hip and knee replacement surgery patients that was required to be completed by the physician (Fig. A2). This was designed to ensure that patients would receive appropriate prevention to avoid developing a PE. Duration of pharmacological prophylaxis was chosen to be 14 days following knee replacement and 28 days following hip replacement. Multiple studies have shown no benefits of using anticoagulation beyond 10–14 days in total knee replacement patients. For total hip replacement, many studies and guidelines recommend at least 4 weeks of anticoagulation.¹² Per our protocol, if a patient had a relative or absolute contraindication to chemical prophylaxis, they would only receive mechanical prophylaxis. Third, we required that patients begin physical therapy twice daily on post-op day 1 and encouraged patients to begin ambulating on post-op day 0 if they could. Fourth, an effort was made to increase the wearing of TED (thromboembolism deterrent) stockings. We conducted an education session for nursing staff regarding this issue and all sizes of TED stockings were requested and made available for patients. Fifth, we required that SCDs be worn in the pre-op day surgery unit and the post-anesthesia care unit (PACU). A summary of the list of interventions that were performed can be found in Table 1.

Members of the quality improvement team were responsible for assuring compliance with the interventions. Compliance with the interventions was tracked over time and feedback was provided to the relevant parties monthly.

2.5. Analysis

Statistical analysis was performed using STATA 12 (StataCorp, College Station, Texas, USA). A p-value of ≤ 0.05 was considered statistically significant. The chi-square test and analysis of variance were used to compare the baseline characteristics for patients in three groups: patients before the intervention, patients after the intervention, and excluded patients. The chi-square test was used to compare the incidence of pulmonary embolism before and after the intervention and Fisher's exact test was used to compare the incidence of pulmonary embolism between patients after the intervention that received aspirin (and hence were excluded) compared to patients that received more aggressive anticoagulation (and hence were included). Multivariate logistic and linear regression were used to compare the incidence of pulmonary embolism and length of stay, respectively, to the predictor variables (baseline characteristics). All predictor variables were included in the multivariate analysis.

Table 2
Baseline data.

Characteristic	Pre-intervention (N = 467)	Post-intervention (N = 290)	Excluded (N = 109)	P-value
Age (years); mean (SD)	61.7 (10.7)	62.5 (9.2)	64.5 (10.4)	0.035
Male sex; N (%)	124 (26.6)	77 (26.6)	25 (22.9)	0.724
Knee surgery; N (%)	424 (91.0)	270 (93.1)	99 (91.3)	0.558
Surgery duration (mins); mean (SD)	142.2 (46.4)	144.5 (43.7)	139.1 (37.5)	0.537

Bold values signifies a statistically significant difference between the age of participants in the pre-intervention vs post-intervention period, with participants in the post-intervention period being slightly older.

3. Results

The baseline characteristics of patients included and excluded in the study are reported in Table 2. The mean age for patients included in the study was 62.0 years (SD = 10.1) and 201 of the patients were male (26.6%). There were 62 patients that had hip surgery (8.2%) and 694 patients that had knee surgery (91.8%). Mean time between entering and exiting the operating room was 2 h and 17 min (SD = 38 min) for knee surgeries and 3 h and 44 min for hip surgeries (SD = 55.3 min). None of the patients in the study had absolute or relative contraindications to chemical or mechanical prophylaxis.

During the study period, of the 757 lower extremity joint replacement surgeries, there were 15 PE's diagnosed (2.0%). All the PE's occurred during the patient's hospital stay. There were 13 PE's before the interventions were implemented and 2 PE's after the interventions were implemented. There was a statistically significant decrease in PE incidence following the intervention (2.8% vs. 0.7%; $p = 0.044$). Fig. 1 illustrates when the PE's happened over time and the number of surgeries that occurred in between cases that resulted in a PE. The number of surgeries between PE's increased following the intervention and there were no PE's after March 2016. After the intervention, in the patients that were excluded from the analysis because the surgeon continued to use aspirin, there were 4 (3.7%) PE's. There were significantly more PE's among surgeons that used aspirin compared to those who adhered to our protocol (3.7% vs. 0.7%; $p = 0.05$).

Table 3 reports the multivariate analysis results for the primary outcome variable (incidence of PE) and secondary outcome variable (length of stay). Older age was associated with a higher incidence of PE, whereas older age, longer surgery duration, and having knee surgery

Fig. 1. Control chart demonstrating the number of surgeries between operations that resulted in a pulmonary embolism before and after the bundle of interventions.

were all associated with longer length of stay in the hospital. All the PE's were in patients that had a knee surgery, all of them were detected before the patient left the hospital, and no patients died as a result. Patients that had a PE had a longer length of stay (14.4 vs. 5.3; $p = 0.00$). No major bleeding events were reported in our patient population.

Following the interventions, compliance with the new adapted order form and risk assessment form was 100% because otherwise the surgeon was not permitted to operate on the patient. Before the intervention, SCD use was variable, but after the intervention, all patients wore SCDs on post-op day 0 in the PACU, as stipulated by the adapted order form. Furthermore, before the intervention, some surgeons were using weaker blood thinners (e.g. aspirin), but after the intervention, this practice was no longer permitted. All patients participated in physical therapy sessions on post-op day 1 following the intervention.

4. Discussion

The issue of pulmonary embolism following joint replacement surgery is extremely important. Numerous guidelines exist that attempt to standardize venous thromboembolism prophylaxis following surgery,^{8,9,13} and each has their own advantages and disadvantages.¹⁴ However, substantial uncertainty still exists regarding the optimal prophylaxis regimen for a given patient. The results of our study suggest that our bundle of interventions was successful in reducing the incidence of pulmonary embolism in our patient cohort. The incidence of symptomatic PE in our patient cohort is similar to what has been reported in other studies after our intervention.^{5,6,15,16} We found that length of stay is significantly longer in patients that had a symptomatic PE, which is also consistent with prior literature.⁵

One of the challenges of implementing our intervention was that there was disagreement among the orthopedic surgeons in our hospital regarding the choice of pharmacological prophylaxis agent. There is a lack of consensus about whether aspirin is an appropriate agent to use for prophylaxis following arthroplasty. Some authors have argued that aspirin is a suitable pharmacological agent for the prevention of symptomatic PE in selected patients.¹⁷ However, in our study, the surgeons in our study that continued to use aspirin had a higher rate of pulmonary embolism, and eventually these surgeons switched to using a more aggressive regimen. We suggest this is due to the specific nature of our patient population, who tend to be more sedentary, more obese,^{18,19} and slower to access care than in other countries. While we agree that aspirin may be used for prophylaxis in certain patient populations, our study suggests that this is not the most suitable option in our patient population. Overall, while the guidelines are helpful, we think that it is important for individual hospitals to create and enforce their own prophylaxis protocol. Based on our experience through this quality improvement project, this has benefits for workflow and patient outcomes.

One aspect of our intervention that we consider was very successful is improving patient mobilization after surgery. Early mobilization is recommended following arthroplasty,⁸ but many of our patients were reluctant to ambulate after surgery due to a belief that they needed to rest in bed to recover. However, we were able to get all patients ambulating at least by post-operative day 1, and in many cases on post-op day 0 for patients that had surgery early in the day and who were recovering well. This was achieved through group physical therapy sessions starting on post-op day 1, which turned out to be a resource-effective and culturally-appropriate method for ambulating our post-arthroplasty patients. Another aspect that was successful was mandating that the risk assessment form and adapted order form be completed by the surgeon. This helped to improve workflow and prevent tasks from being forgotten.

Our study had some limitations. We implemented a bundle of interventions at the same time, so we cannot draw conclusions about the individual contributions of each of the interventions. Furthermore, we

Table 3
Multivariate analysis for incidence of pulmonary embolism and length of stay.

Characteristic	Incidence of PE			Length of stay		
	OR	95% CI	P-value	Coefficient	95% CI	P-value
Age	1.06	1.01–1.12	0.030	0.05	0.02–0.07	0.000
Male Sex	1.63	0.51–5.16	0.407	0.35	–0.16 to 0.85	0.183
Surgery duration	1.00	0.99–1.01	0.915	0.01	0.00–0.01	0.015
Knee surgery ^a	–	–	–	1.59	0.59–2.59	0.002

PE – Pulmonary embolism; OR – Odds ratio; CI – Confidence interval.

^a Omitted from incidence of pulmonary embolism analysis because all PE's were following knee surgery.

had a small sample of patients that developed pulmonary embolism, given that this is a rare event.

In summary, our quality improvement project was successful in reducing the incidence of PE following arthroplasty at our institution. Further research is required so that thromboprophylaxis can be further tailored to each patient post-arthroplasty. Due to the success of the risk assessment and adapted order forms that were used, these will be refined and implemented throughout the rest of our hospital.

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Conflict of interest

None.

Appendix A. Supplementary data

Supplementary data associated with this article can be found, in the online version, at <https://doi.org/10.1016/j.jor.2018.01.009>.

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