Venous thromboembolism after total knee replacement or total hip replacement: what can be learnt from root-cause analysis?

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ABSTRACT

INTRODUCTION Because of the high risk of venous thromboembolism (VTE) in total hip replacement (THR) and total knee replacement (TKR), guidelines are used widely to enhance effective (yet safe) prophylaxis. If patients develop VTEs despite use of such guidelines, then the reasons are that the guidelines were: (i) followed but the VTE occurred anyway; (ii) not implemented appropriately. All VTEs are assessed routinely by root-cause analysis (RCA).

METHODS The records and subsequent RCA reports for each patient who experienced clinically significant VTE after THR or TKR were reviewed. We established adherence to the guidelines (deemed to be ‘unavoidable’ with scope to improve the guidelines) and non-adherence (deemed to be ‘avoidable’ with scope to improve implementation).

RESULTS Of 2,214 patients undergoing THR ($n=1,330$) or TKR ($n=884$), 25 (1.13%) experienced VTE. Four THR patients experienced VTE (2 of which were avoidable) and 21 TKR patients experienced VTE (5 of which were avoidable). There were significantly more VTEs in TKR patients than THR patients ($p<0.0001$).

CONCLUSIONS A proportion of patients will experience VTE even if guidelines are followed (a baseline effect). Administration of chemical prophylaxis earlier might reduce this baseline effect further. This approach should be taken cautiously with due respect for the alternative risk of bleeding. Improvement in hospital routine may reduce the risk of VTE yet further.

KEYWORDS

Venous thromboembolism – Hip – Replacement – Knee – Root-cause analysis

Accepted 12 June 2016

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Thromboprophylaxis can reduce the prevalence of venous thromboembolism (VTE) significantly. Administration of chemical prophylaxis can increase the risk of bleeding.¹ Hence, guidelines vary with regard to the timing and content of chemical prophylaxis.^{1–5} Guidelines from the UK National Institute of Health and Clinical Excellence (NICE) recommend a combination of mechanical methods and chemical agents after surgery.¹

The protocol at University Hospital Southampton (UHS; Southampton, UK) (Fig 1) allows (providing there are no contraindications) patients to be given mechanical pumps in the operating theatre. These pumps are continued until the patient is mobile, with chemical prophylaxis (we use the anti-Xa agent rivaroxaban^{1,6}) on the morning of the first postoperative day (POD1), and continued for 14 days (total knee replacement (TKR)) or 28 days (total hip replacement (THR)). The rationale is to provide a chemical agent sufficiently early to elicit a thromboprophylactic effect but sufficiently delayed to avoid bleeding. Patients usually have regional anaesthesia; early mobilisation (as soon as practicable) is encouraged.

Since 2010, it has been mandatory in our institution to carry out root-cause analysis (RCA) of VTEs occurring <90

days of THR or TKR.⁷ RCA data have been collected at UHS since 2010. The RCA Report states whether the VTE was deemed ‘avoidable’ (the protocol was not followed correctly) or ‘unavoidable’ (the protocol was followed correctly but the patient experienced VTE anyway).

The aim of the present study was to evaluate RCA data for all symptomatic VTEs after THR and TKR between January 2010 and June 2013 to ascertain if the current protocol can be implemented more accurately, or amended to reduce the number of avoidable VTEs.

Methods

Subjects

Since 2010, all cases of symptomatic VTE within 3 months of admission for THR or TKR at UHS have been referred by the Governance Department to the senior Author to examine the clinical circumstances of the VTE. Each case is reviewed and discussed by the RCA panel (clinicians, pharmacists, governance staff) who ascertain if the event was ‘avoidable’ or ‘unavoidable’. The patients identified by this process who experienced a VTE after THR or TKR between 1 April 2010 and 31 March 2013 are the subjects of this study.

Data collection

We reviewed patient files, imaging reports, minutes of RCA meetings and RCA reports. Information relevant to the study was extracted (Table 1). To ascertain if the VTE was avoidable or unavoidable, the criteria shown in Table 2 were used.

Data analyses

Chi Squared was employed to examine the difference between the proportions of patients experiencing VTE in THR and TKR. Confidence intervals for proportions were calculated using Vasserstats.net.

Results

Of 2,214 patients who underwent THR (1,330 patients) and TKR (884 patients), 25 (1.13%, 95% CI 0.70 to 1.77%)

Table 1	Headings under which data were extracted
Surgeon name	
Patient number	
Date of surgery	
Age of patient at surgery	
Type of procedure – THR or TKR and whether it was primary or revision	
Date of event (days postoperatively)	
Date of symptom onset	
Date of test	
Test used – ultrasound, computed tomography angiography or VQ scan	
Pulmonary embolism, deep-vein thrombosis, both or fatal pulmonary embolism	
Bleeding complications – haematoma, unusual oozing or bleeding elsewhere	
Which drug was given	
How many hours after surgery the drug was given	
How long the drug was continued for	
Type of mechanical prophylaxis given	
Duration of mechanical prophylaxis	
When mechanical prophylaxis was started – in the operating theatre, in recovery, or on the hospital ward	
Appropriate and full completion of risk assessment	
RCA: determine if the VTE was avoidable or not	
Risk factors – as outlined by University Hospital Southampton (previous VTE, family history of VTE, morbid obesity (body mass index >30 kg/m ²), active malignant disease, significant comorbidities)	
VTE = venous thromboembolism	

experienced VTE (Table 3). Of these, 4 were THR patients (0.30%, 95% CI 0.12 to 0.77% of all THR procedures) and 21 were TKR patients (2.38%, 95% CI 1.56 to 3.61% of all TKR procedures). Two THR cases and 16 TKR cases were deemed ‘potentially unavoidable’. There were significantly more VTEs in TKR patients than THR patients (p<0.0001).

Avoidable VTE after THR

Two patients experienced potentially avoidable VTE after THR (0.15% of THR patients). One patient started rivaroxaban 1 day too late (on POD2) despite having a documented extra risk factor for VTE. This patient and the other patient were deemed to have avoidable VTE due to inadequate documentation of intermittent pneumatic compression (IPC) use.

Unavoidable VTE after THR

Two patients experienced unavoidable VTE (0.15% of all THR patients). One patient had an additional risk factor for

Table 2	Assessment criteria for categorising avoidable and unavoidable events
Avoidable	
• Wrong or no drug given	
• Drug started late	
• Drug given for incorrect duration	
• Mechanical prophylaxis not given	
• Incorrect mechanical prophylaxis	
• Mechanical prophylaxis given late	
• Incomplete/inaccurate risk assessment	
Unavoidable	
• Correct drug given	
• Drug given correctly for recommended duration	
• Mechanical prophylaxis given correctly	

VTE (thrombophilia) and the other had full and appropriate implementation of UHS guidelines.

Avoidable VTE after TKR

Five patients (0.57% of all TKR patients) experienced potentially avoidable VTE. One patient commenced rivaroxaban 1 day too late (on POD2) due to an issue with electronic prescribing as well as having no documentation of use of anti-embolism stockings or IPC in theatre. Two patients had no documentation of ICP use in the operating theatre. One patient had no record of the time that the drug was given. One patient took rivaroxaban for only 1 week postoperatively and then stopped on the advice of his general practitioner even though the prescription upon hospital discharge was for 14 days of rivaroxaban.

Unavoidable VTE after TKR

Sixteen patients (1.81% of all TKR patients) experienced unavoidable VTEs. Five had additional risk factors according to the risk assessment *proforma*.

Discussion

The Guideline Development Group that constructed the NICE guidelines¹ could not establish the UK incidence of pulmonary embolism and deep-vein thrombosis (DVT) after THR or TKR. They highlighted this knowledge gap as an area for future research.

Table 4 compares the prevalence of VTE in our study with the Global Orthopaedic Registry.⁸ The prevalence obtained in the present study compares well with that of the Global Orthopaedic Registry, probably because of a well-structured and monitored system of risk assessment and prophylaxis. Nevertheless, we consider there to be scope for improvement (particularly for TKR).

Risk assessment

Risk assessment is a mandatory task and non-adherence is captured by RCA. The RCA panel deems an event to be avoidable if the risk assessment is incomplete. However, we considered the event to be avoidable only if the prophylaxis protocol was different from that which would have been administered had the risk assessment been carried out. Three cases of VTE in our series (12%) had an incomplete risk assessment. It is unlikely that factors identified in the risk assessment would have altered prophylaxis because even if risk factors are identified, our protocol remains the same (chemical prophylaxis is administered at the same time postoperatively).

THR

Avoidable VTE in THR patients: One patient in this category had a history of DVT and yet the drug was given late (POD2) in relation to normal guidelines (POD1). This is an issue relating to the system, which must be addressed to prevent further avoidable VTEs. The other patient was not documented to have had IPC in the operating theatre. This may have been an unavoidable VTE because IPC may have been applied, but not documented. Emphasis should be placed on full and accurate documentation of prophylaxis to enable optimal effective use of RCA.

Unavoidable VTE in THR patients: One patient in this category did not have additional risk factors and this represents an inevitable VTE. The other patient had thrombophilia, a

Table 3	Distribution of venous thromboembolism with 95% confidence intervals (lower percentile to higher percentile)	
	THR	TKR
Total venous thromboembolism	0.3% (0.12 to 0.8)	2.38% (1.5 to 3.6)
Deep-vein thrombosis	0.3% (0.01 to 0.58)	1.7% (1.0 to 2.8)
Pulmonary embolism	0.15% (0.01 to 0.58)	0.9% (0.4 to 1.8)
Fatal pulmonary embolism	0.08% (–0.07 to 0.23)	0.1% (–0.11 to –0.31)
Two THR patients and 8 TKR patients had both non-fatal PE and DVT (1 fatal in each group). THR = total hip replacement, TKR = total knee replacement		

Table 4 Performance in the present study compared with the Global Orthopaedic Registry⁸ data for prevalence of deep-vein thrombosis and pulmonary embolism after total hip replacement or total knee replacement.

Patient group	Global Orthopaedic Registry	Present study
Patients experiencing DVT after THR	1.14%	0.30%
Patients experiencing PE after THR	0.17%	0.15%
Patients experiencing DVT after TKR	1.63%	1.70%
Patients experiencing PE after TKR	0.22%	0.90%
DVT = deep-vein thrombosis, THR = total hip replacement, PE = pulmonary embolism, TKR = total knee replacement		

risk factor for VTE development. UHS guidelines recommend rivaroxaban at 9am on POD1. This guideline varies slightly with NICE guidelines, which recommend offering rivaroxaban 6–10 hours after surgery.¹ If UHS guidelines were changed so that identification of risk factors allowed surgeons to move the timing of the drug closer to surgery, (trading bleeding risk for thrombosis risk) then VTEs deemed unavoidable currently might be avoided. Clinical judgement would be essential because ascribing a relative value to bleeding and thrombosis is controversial.⁹

Assuming that the systems-based errors underpinning avoidable VTEs (omission of prophylaxis or omission of recording) can be eradicated by addressing peri-operative routines, a very small proportion of patients (0.08–0.15%) experiencing VTE after THR would result. This strategy suggests that, as long as UHS guidelines are adhered to (and systems-based issues are eliminated), symptomatic VTE after THR will be almost always prevented and the current protocol should continue. A pragmatic *caveat* would be to allow the surgeon to administer the drug closer to the time of surgery if there are additional risk factors for VTE (as long as the increased risk of bleeding is understood).

TKR

Avoidable VTE in TKR patients: The issues accounting for these 5 avoidable events are late administration of the drug, lack of documentation with regard to IPC or rivaroxaban, and early cessation of rivaroxaban by the GP.

One patient in this category was given the drug at the wrong time despite clear instruction from the surgeon in the operating notes. The new electronic-prescribing system was felt to have contributed to this mistake. The RCA panel established that this was a systems-based issue and made recommendations regarding the ward routine, as well as improved training in the electronic-prescribing system. Prevalence of avoidable VTE after TKR might have been as low as 2/884 (0.23%) if all those with poor documentation

had in fact been given mechanical compression or drug in time. As a result of identification of this shortcoming, RCA suggests that two factors must be addressed: (i) each patient should receive IPC in the operating theatre which should be continued until the patient is fully mobile (unless contraindicated); (ii) this regimen must be recorded.

Unavoidable VTE in TKR patients: Additional risk factors were seen in 5 of the 16 (31%) patients in this category. Hence, 11 of 884 TKR patients (1.3%) of patients experienced VTE even though the protocol was followed correctly and they had no identified predisposition to VTE. This figure may have been even higher (1.7%) if the 4 cases for which mechanical prophylaxis or drugs were not documented actually had in fact them. This relatively high prevalence (compared with 0.08–0.15% in THR) identifies a clear area for reconsidering current guidelines.

The fragile soft-tissue envelope of the knee joint is more susceptible to anti-coagulation than the hip joint because haemarthrosis has greater consequences in TKR. This vulnerability is a challenge because the risk of bleeding must be minimised to avoid TKR revision.¹⁰ Of all 21 TKR patients who experienced VTE (avoidable and unavoidable), only 2 patients had bleeding complications (1 knee haematoma and 1 with oozing that continued for 2 days postoperatively). Whilst bleeding may be considered a threat to the joint, nevertheless all patients had VTE, which may be considered potentially threatening to the limb (post-phlebotic syndrome)¹¹ or even life (pulmonary embolism). It might seem intuitive, therefore, to adjust the protocol to incur a slightly greater risk of bleeding by prescribing the anticoagulant closer to the time of surgery, in accordance with NICE guidance. However, consideration should be given to whether the number of patients who would benefit is sufficiently high to merit the increased risk of bleeding from administering chemicals closer to the time of surgery. The relative gain may be small because some patients may have been particularly thrombogenic and would have developed VTE in any event. A sophisticated risk assessment by testing for blood disorders which predispose to VTE is not cost-effective,^{3,4} and may still fail to detect rare or unknown thrombophilic factors.

Guidelines should be responsive to changing data and opinions.¹¹ Indeed, the American Association of Orthopedic Surgeons and American College of Chest Physicians^{2,3} now give greater weight to the risk of bleeding than thrombosis. They advise that if patients carry a low risk of thrombosis, beyond the joint replacement itself, mechanical methods and aspirin alone may suffice. The use of multi-modal techniques, with a combination of regional anaesthesia, earlier mechanical methods and later chemical methods, is likely to develop further as new guidelines are implemented.

The individual patient should have a thorough risk assessment in which the relative risk of thrombosis and bleeding is balanced. If the relative value of bleeding and thrombosis is assessed, involving due discussion with the patient, unacceptable bleeding will be minimised but there will always be a small risk of 'breakthrough' VTE.

Conclusions

This study demonstrated a high level of success in THR patients, whereas TKR patients experienced considerably more VTEs. RCA showed that administration and documentation of prophylaxis should be improved. TKR guidelines could be adapted but the balance between bleeding and thrombosis must be addressed carefully.

Acknowledgments

The authors acknowledge the help of Tracy Mahon and Kerry Oakley of the UHS Governance team for their help in data collection.

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