SHOULDER

Incidence of deep vein thrombosis following shoulder replacement surgery: a prospective study

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Abstract

Background: The incidence of deep vein thrombosis (DVT) after shoulder replacement surgery is not well documented. Evidence that exists on thromboprophylaxis for upper limb surgery is based on level III and level IV studies. The hypothesis for the current study was that the incidence of DVT following shoulder replacement would be less than the published prevalence in hip and knee arthroplasties.

Methods: All participants who received shoulder arthroplasty surgery at the institution from 1 July 2013 to 30 June 2015 and who met the inclusion criteria were eligible for inclusion in the study. A duplex Doppler study was done on the affected limb of all participants on average ten days after the surgery. A study of all four limbs was done in selected participants.

Results: Fifty-seven participants (28 males and 29 females) with 30 reverse shoulder replacements, 22 hemiarthroplasties, and five resurfacing shoulder replacements were included. The incidence of DVT was 12.3% (7/57). Two axillary vein and three brachial vein DVTs account for the upper limb DVTs. Two DVTs were reported in the lower limb.

Conclusion: The study demonstrates that the incidence of DVT after shoulder replacement surgery was higher than anticipated and is similar to the DVT rates in lower limb arthroplasty.

Level of evidence: Level 4

Key words: shoulder replacement surgery, deep vein thrombosis, pulmonary embolism, thromboprophylaxis, venous thromboembolism

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Introduction

The incidence of deep vein thrombosis (DVT) after shoulder replacement surgery is not well documented. Although this is a rare entity, major thrombotic complications following upper extremity DVTs, including symptomatic and fatal pulmonary embolism, have been documented. 1-8

Shoulder replacement surgery requires the joint to be dislocated to allow for bone cuts, canal reaming, implant positioning and glenoid evaluation and/or preparation. The affected limb is often positioned in extreme external rotation for a prolonged period. Traction is applied to the flexed elbow.⁹ The hypothesis is that the traction and tortuous veins might be a precursor to the development of DVT. The axillary vein might also sustain intimal damage with the repeated internal and external rotation applied to the humerus during the procedure.¹⁰ The procedure is performed with the patient positioned seated in the so-called beach-chair position for the duration of the surgery.¹¹ This position causes the hips to be flexed, which can potentially increase the risk of iliac vein DVTs. It also causes pooling of the blood in the lower limbs in the absence of the calf pump mechanism.

Pharmaceutical prophylaxis for venous thromboembolism (VTE) is considered the standard of care for lower limb arthroplasty. Guidelines are mostly described in lower limb arthroplasty and trauma. 12 Although there is substantial proof describing optimal VTE prevention and treatment, a gap still exists in the optimal application.¹³ Evidence that exists on thromboprophylaxis for upper limb surgery is based on level III and level IV studies. 10 Therefore, the best practice for upper limb thromboprophylaxis in unclear. From an orthopaedic surgeon's perspective, it is a delicate balance between bleeding and clotting.¹⁴ Wound-related problems and subsequent periprosthetic infection with excessive thromboprophylaxis are worrisome.15 A recent epidemiologic study by Day et al.6 concluded that the bleeding risk combined with the fewer VTE events with existing lower rates of pharmaceutical thromboprophylaxis do not justify the routine use of anticoagulation therapy in shoulder replacement surgery.

The treating surgeon can either decide to prescribe thromboprophylaxis routinely, as is advocated for lower limb arthroplasties, or individualise treatment according to the patient's risk.

This prospective study was performed to evaluate the incidence of DVT following shoulder replacement surgery and to assess whether it is possible to predict who will need prophylaxis. Venous thrombosis of the upper extremity is defined as a thrombus in the subclavian, axillary or brachial vein.

The hypothesis for the study was that the incidence of DVT following shoulder replacement surgery would be less than the published prevalence in hip and knee arthroplasties and that the patients needing routine anticoagulation can be preselected and predicted. 16-17

A duplex Doppler study was done on all participants to evaluate the presence or absence of a DVT. The benign nature of the ultrasound and the relatively inexpensive cost in the clinical practice made this investigation the modality of choice. 18

Aims of the study

A cross-section analytic study was performed 1) to document the incidence of DVTs in the ipsilateral limb after 57 shoulder replacements at our centre performed by two surgeons, and 2) to document DVTs in general for the study population.

The study was approved by the ethics committee of the centre in which the surgeons work. Informed written consent was obtained from each participant before study enrolment. A unique identification number was assigned to each participant to maintain participant confidentiality.

Methodology

All participants who received shoulder arthroplasty surgery (resurfacing/hemi- or reverse shoulder replacement) at the institution from 1 July 2013 to 30 June 2015 and who were able to make use of their own transport to have the duplex Doppler done, were eligible for inclusion in the study. The institution treats a large patient population which includes a majority of orthopaedic-related tumours as well as implant-related sepsis. The surgery was performed by two surgeons (OK and TLB). Patients receiving routine pre-operative anticoagulation, such as heparin or warfarin; patients with active thromboembolic disease; and patients who declined to participate in the study were excluded. All patients who were eligible were enrolled.

The surgery was done in the beach-chair position with the arm draped free in all cases. A limb positioner was not used in any of the cases done. The participants had an interscalene block before being positioned. All were treated in an arm immobiliser for six weeks post-operatively. All participants were advised to do range of motion exercises of the elbow and wrist from day one. Pendulum exercises and passive assisted external rotation were advocated for the resurfacing and hemi shoulder replacement participants. A physiotherapist helped all participants with an aggressive ambulatory programme starting on the day of surgery.

None of the patients had a central venous catheter.

A Modified Caprini Risk Assessment form¹⁹ was completed on admission by OK for all patients who agreed to participate in the study. Clinical judgement was used in the decision on whether to prescribe thromboprophylaxis. Some participants in the study population mobilised to a wheelchair or were otherwise not mobilising adequately. In these cases, thromboprophylaxis was ordered. The decision was also based on the amount of drainage recorded in the Porto-Vac after 24 h. If excessive (>200 ml), no thromboprophylaxis was prescribed. Social habits like smoking were documented. The Body Mass Index (BMI) was calculated for every participant. Participants' age and site of the previous DVT, if applicable, were individually documented.

Factors affecting surgery-related variables (operative time; surgical approach) were recorded for every participant. Documented patient-related factors were the duration of hospital stay and time to independent mobilisation defined as being able to mobilise unassisted for a distance of 50 metres. The type of replacement was recorded as this influenced the duration of surgery as well as the surgical approach. Any second surgical procedure at the time of replacement was also documented, i.e. resection of a tumour together with the replacement.

The type of anticoagulation, as well as the dosage and duration of treatment, was also recorded. No routine anticoagulation medication was used in this series. Participants who used Ecotrin® 81 mg daily for cardiovascular or other reasons as part of their chronic medication continued with their routine medication before and after surgery. The low dose of Ecotrin® was retrospectively viewed as being an inadequate dosage. No mechanical prophylaxis was used.

Most of the participants were operated early on the list so that the physiotherapist could mobilise them actively on the same day. Their hydration status was also kept at optimum levels as far as possible via an intravenous line, and the patients were encouraged to drink adequate amounts of oral fluids. Participants also had to follow a bed programme prescribed by the physiotherapist.

A Doppler and colour flow venous duplex Doppler study was done on the affected limb of all participants within ten days of the surgery. The duplex Doppler was carried out in B-mode with compression. Compression ultrasound was performed by applying pressure to the overlying tissues to compress the visualised vein in the transverse plane. Non-compressibility of a venous segment and absence of flow defined the presence of a complete DVT.

Partial compressibility and partial flow represent the presence of a partial DVT. The absence of flow, particularly in a vein which cannot be compressed, also suggested a DVT.

The surgeons evaluated all participants on the day of the sonographic evaluation, and clinical suspicion of a lower limb DVT was documented for further investigation. A study of all four limbs was done in selected participants. All participants were followed up for a minimum period of six weeks following surgery and any DVT-related admissions or complications were recorded. All duplex Doppler studies were performed and interpreted by a single board-certified musculoskeletal sonologist specialising in ultrasonography. The presence, location, timing and severity of the DVT were documented.

The computer system at the institution was reviewed for any DVT-related admissions of all participants, should these participants have consulted at their respective units. There were no DVT-related admissions other than those mentioned in the results. Two of the participants passed away after completing their initial follow-up period, due to other medical reasons. One participant had to give up their medical aid due to personal reasons and was not re-evaluated after the initial six weeks.

The participants were responsible for their own transport arrangements as the sonar was done at another centre. At the institution, transport is arranged to and from the various units to the hospital, but no transportation was supplied by the institution to the centre for Duplex doppler evaluation.

Comprehensive follow-up of all participants was achieved thus minimising the possibility of missed outcomes.

Data analysis

The data was collected prospectively. The surgeon (OK) completed the Modified Caprini Risk Assessment form for every patient. This scoring system is widely tested, and the modified version was used for the 2012 American College of Chest Physicians (ACCP) Guidelines.²⁰

The data analysis was done in collaboration with the South African Medical Research Council. The outcome parameter of interest was the presence or absence of DVT. The descriptive statistics method was used to present summary statistics for the mean operative time, the average duration of stay in the hospital and mean time to independent mobilisation. The associated 95% confidence interval for the summary statistics was also presented. Also, the association between DVT and the demographic and lifestyle characteristics were evaluated using chi-square statistics. STATA 13 was the statistical package of choice.

Results

Fifty-seven participants (28 males and 29 females) with 30 reverse shoulder replacements, 22 hemiarthroplasties, and five resurfacing shoulder replacements were followed for six weeks (*Table I*).

The incidence of DVT was 12.3% (7/57) with a 95% confidence interval (CI) [5.1, 23.7]. No fatalities were reported.

Two axillary vein and three brachial vein DVTs accounted for the upper limb DVTs. Two DVTs were reported in the lower leg (four females, three males). All were reported as being of acute onset: two DVTs (one axillary vein; one peroneal vein DVT) were reported to cause partial obstruction of the vein. Incomplete DVTs count as DVTs as they have a similar effect as a complete obstruction on the clotting cascade.

The cardiology department handled the patients' management and dose adjustments for the treatment of a DVT. One patient with axillary vein and one with a brachial vein DVT were symptomatic. The mean age of the participants with a DVT was 63 years with a 95% CI [51.8, 74.2] (*Table II*).

Four participants with a DVT were on thromboprophylaxis at the time of diagnosis. Two of these were on Ecotrin® 81 mg daily for cardiovascular-related reasons. Two were on Clexane® 40 mg subcutaneously daily.

Eighteen participants received thromboprophylaxis due to their individual risk factors and not due to their Caprini scores. Of these, nine received adequate dosages of low-molecular-weight heparin (LMWH) at 0.5 mg/kg according to their body weight. There were no unusual wound complications or bleeding events recorded in the group that received thromboprophylaxis. None of the participants in the study population had a blood transfusion post-operatively.

Each participant reported on their social smoking habits. A total of ten participants smoked, and one of these had a DVT. There was no association demonstrated between smoking and an increased risk of a DVT in the study.

Females with reverse shoulder replacements had a longer post-operative stay (*Figure 1*).

The average Caprini score for the study population was 5.8 [2; 13]. For the participants with a positive duplex Doppler, the mean was 7.4 [4; 13]; the females with a DVT had an average score of 9.3 [7; 13], and the average score for the males was 5 [4; 6].

Four of the participants in the study had shoulder replacements due to trauma. They were all admitted via the emergency unit and surgery was scheduled for the next available elective list. Three participants received adequate thromboprophylaxis in the form of low-molecular-weight heparin 0.5 mg/kg daily (treatment was started on the day of admission). Of these four trauma participants, one had a DVT. The participant was on thromboprophylaxis since admission to the hospital and the DVT was symptomatic. The DVT was reported as an acute thrombus of the brachial vein diagnosed on day 3 post-operatively (four days after sustaining the fracture).

The average BMI of the study population was 32.1 [17.9; 51.6] with a mean age of 62.6 [35; 80] years. The participants mobilised independently to a distance of 50 m on average during the first day after the surgery. The mean operative time was 58.5 minutes [24; 135] for all types of replacements with an average length of hospital stay post-operatively of 3.9 days [1; 23].

There is no statistically significant difference between the duration of surgery between subjects with a DVT and those without.

One participant who had a DVT of the ipsilateral arm also had an unprovoked DVT of the iliac vein in 2003. This history was obtained at the time of the duplex Doppler studies as the participant forgot about the incident and never had any investigations done to rule out coagulation disorders at the time. This participant had an ipsilateral, symptomatic DVT in the axillary vein diagnosed on the ninth day post surgery. Adequate thromboprophylaxis, in the form of LMWH 0.5 mg/kg, was instituted 48 h after surgery. The start of the prophylaxis was delayed due to excessive drainage in the Porto-Vac in the first 48 h post-surgery. The current DVT was reported to be a complete, soft thrombus of 6.8 cm in length of the axillary vein. The DVT appeared soft and slightly dense; this is in keeping with the appearance of an acute DVT.

Discussion

Orthopaedic patients are at high risk for both bleeding and DVT and will remain a dilemma for treating surgeons and physicians.²¹ Even though understanding of DVT and PE remains incomplete, a survey of the members of the American Association of Hip and Knee Surgeons reported that 100% use some form of thomboprophylaxis.²² On the contrary, 58% of the members of the British Elbow and Shoulder Society do not use any routine thomboprophylaxis during shoulder surgery.¹⁰ However, the more these conditions are investigated, the more additional questions come to the fore.¹⁸

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Table II: Subjects with a DVT

Age	Sex	Location	Time to diagnosis	Complete/ partial	Prophylaxis
56	F	Axillary	9	Complete	LMWH 48 h postop
55	F	Brachial	9	Complete	None
43	М	Axillary	9	Partial	Ecotrin (chronic medication)
66	F	Brachial	3	Complete	LMWH preop
71	F	Brachial	9	Complete	None
74	М	Tibialis anterior	10	Complete	Ecotrin (chronic medication)
76	М	Peroneal	10	Partial	None

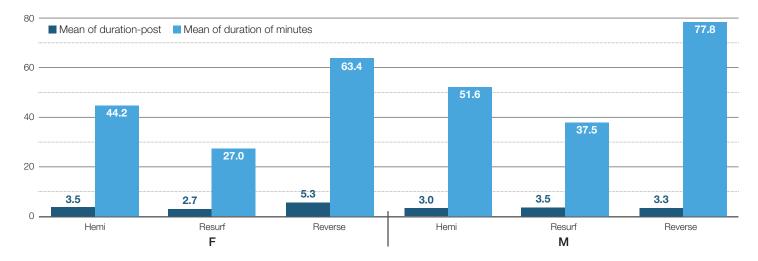


Figure 1. Graph of duration of procedure and stay post-operative by type of replacement and sex

Our data indicates a DVT rate of 12.3%. This value is similar to the 13% incidence of DVT in Willis and co-workers' series. The incidence of thromboembolic disease in Farng *et al.* 's⁵ study after shoulder arthroplasty was less than 0.6% in 15 288 shoulders. DVT of the lower extremity after shoulder arthroscopy has rarely been noted in the literature, with reported rates of symptomatic DVT and PE in 65 000 patients of less than 0.01%.²³

The remaining patient risk factors for sex, age, smoking, and duration of surgery were not statistically significant.

Ultrasound is the modality of choice when upper extremity DVT is suspected. 8,10,18,24 Upper extremity sonographic evaluation of the venous system is more challenging than that of the lower extremity. Attention to detail is critical in areas of duplicated veins to avoid overlooking a thrombus in one of the paired veins. Current literature shows the sensitivity of venous Doppler ultrasound for upper extremity DVT to range from 78% to 100% and its specificity ranges from 82% to 100%. 24-25

Ultrasound is a non-invasive investigation and does not result in radiation exposure. On B-mode imaging, acute thrombi may appear in areas of variable echogenicity within the vessel lumen. The present study made use of the so-called combined modality ultrasound (compression and Doppler ultrasound), as suggested in a recent evidence-based clinical practice guideline. Compression of a healthy vein completely closes the vessel lumen, whereas the presence of a DVT prevents coaptation of the vein walls. All of the DVTs reported were acute.

The mean length of surgery was 58.32 minutes for all types of replacements (*Figure 1*). A review article by Anakwe and co-workers used guidelines from the United Kingdom National Institute for Clinical Excellence (NICE) and interpreted major orthopaedic surgery as upper limb surgery lasting more than 90 minutes. ¹² The recommendation is that this should include the total anaesthetic

time. In the current study, the so-called skin-to-skin time was recorded. For shoulder surgery, the time positioned in the beach chair should be taken into account as the patient is supine for the rest of the procedures like the inter scalene block administration.

Multiple guidelines regarding appropriate thromboprophylaxis, in general, have been proposed. There is controversy within the orthopaedic community as to the adequate choice of prophylaxis.3 On the other hand, failure to prescribe thromboprophylaxis may be presented as a failure of care. 12 In-hospital mortality due to VTE is a common avoidable cause of death in trauma patients.29 Anticoagulation, on the other hand, is not a benign treatment option. It has significant bleeding complications without reducing clinically relevant symptomatic DVTs, PE and fatal PE rates.³⁰ In the current study four participants received some form of prophylaxis and still developed a DVT. Of these medications, most have drawbacks. LMWH and fondaparinux require nonoral administration. The newly introduced direct thrombin inhibitor is an oral agent that does not require monitoring; however, it causes elevation of transaminase levels and an increased rate of coronary events of unclear significance. Factor Xa inhibitor is also taken orally, but there are concerns regarding excessive wound complications.³¹ Vitamin K antagonists require close monitoring and have unpredictable pharmacokinetics.21

The ACCP provides evidence-based recommendations for VTE prevention in some clinical scenarios, but do not advise on prevention of upper extremity DVT. Recommendations broadly focus on the relative risk for thrombosis compared to bleeding. Furthermore, the assessment model provides a selection of mechanical and pharmacological prophylaxis.³²

The average BMI in our study was 32.1 which is similar to obesity rates in the United States. Adult obesity rates in the US have increased by 129% in the past decade, with more than 30% of the

adult population currently with a BMI of >30 kg/m². The very obese patients pose unique challenges during the procedure regarding optimum positioning in the beach chair, with pendulous bellies limiting the back upright positioning. It also affects the length of surgery. In the post-operative period, they lose an extremity to aid with mobilisation and often mobilise with difficulty. It is not surprising that the patients with a BMI of >50 kg/m² have a three times higher risk of VTE than the non-obese.³³

Virchow's triad of hypercoagulability, stasis and intimal damage is the historical foundation for the formation of a thrombus. These factors, in combination with elderly patients in a partially dehydrated state due to overnight starvation, make up the majority of participants in the study population. The physiologic stress response associated with major joint replacement surgery should not be underestimated. Several thrombogenic factors are released intra-operatively, and there is a significant pooling of blood in the lower extremities during the surgery.¹¹

The arm is routinely immobilised in a sling after shoulder replacement surgery, which causes stasis that contributes to the occurrence of thrombosis. There is a relatively lower gravitational stress in the upper extremity compared with lower extremity, and this might explain the lower incidence of DVTs. Prior history of DVT has been consistently demonstrated to be a predominant risk factor for post-operative DVT6 and is the only risk factor recognised in the 2010 guidelines of the American Academy of Orthopaedic Surgeons (AAOS). 15,22

Complications relating to VTE in shoulder arthroplasty are significantly increased in trauma shoulder replacements. The risk factors that have been associated with post-operative VTE are age, obesity, trauma, antithrombin III deficiency, protein S and C deficiency, malignancy, oral contraceptives or hormone replacement therapy, recent myocardial infarction, previous pulmonary embolism or DVT and prolonged immobilisation. The shoulder arthroplasty are significantly are significantly as a significant traumatical structure.

Malignancy is an important risk factor for thrombosis in the upper extremity. 36-37 Two participants in the current study had a shoulder replacement done for active metastatic cancer. Neither of them had a thromboembolic disease.

Anticoagulation with subcutaneous LMWH (enoxaparin) should be prescribed at a dosage of 0.5 mg/kg. This dose was not complied with, as the standard dosage was Enoxaparin 40 mg daily, even for those participants with a BMI of 50 and weight of 120 kg.

A total of ten participants smoked, of whom one had a DVT. Participants who smoke tend to mobilise sooner and mobilise further to smoking areas. The Caprini Score does not include smoking as a risk factor for a DVT.

Our study has limitations. The sample size is small. Four limb studies were done in 17.5% of the population. Asymptomatic DVTs of the lower limbs could have been missed. It should be highlighted that complete and comprehensive follow-up was achieved. However, a strength of the study is that all the surgery was performed by two surgeons and all duplex Doppler studies were conducted by the same sonologist. The participants furthermore represent a broad demographic population; this reflects on the scope of practice at the centre.

Conclusion

The current study demonstrates that the incidence of DVT after shoulder replacement surgery was higher than anticipated and is similar to the DVT rates in lower limb arthroplasty. We failed to predict correctly who would need routine anticoagulation. Even with prophylaxis, some participants developed a DVT. Therefore, we recommend that patients who receive reverse shoulder replacements, trauma replacements, females older than 70 years of age, patients who have tumour resection surgery and those with underlying active metastatic disease should receive routine and adequate thromboprophylaxis.

Due to the increase in BMI in the general population, surgeons should avoid excessive hip flexion when positioning patients in the beach-chair position. This is to prevent the pendulous abdomen from limiting further pelvic venous flow.

Surgeons should individualise those patients not in the above categories when deciding whether to give thromboprophylaxis. The Caprini score is useful and should form part of the consent process.

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Compliance with ethics guidelines

This study was approved by 1 Military Hospital Research Ethics Committee adhering to Good Clinical Practice/International Conference on Harmonisation and South African Clinical Trial Guidelines. Ethics approval number: IMH/302/6

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