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EVALUATION OF PREOPERATIVE THROMBOPROPHYLAXIS BY TWO DIFFERENT APPROACHES : RISK CLASSIFIED ANTICOAGULATION VS ROUTINE ANTICOAGULATION APPROACH IN TOTAL KNEE PATIENTS

Orthopedics

Atul Patil Assistant Professor, Dept. of Orthopedics, Government Medical College, Aurangabad, Maharashtra.

Dr. Ajay Gour Assistant Professor, Dept. of Orthopedics, Government Medical College, Aurangabad, Maharashtra.

ABSTRACT

Introduction: Currently followed preoperative thromboprphylaxis in TKR patients is routine anticoagulation for thromboprophylaxis in all patients undergoing lower limb arthroplasty irrespective of their DVT risk involved and thus subjecting everyone to undergo with it's own complications. There very few studies which compare results of randomly implementing routine and risk stratified thromboprophylaxis in patients undergoing total knee arthoplasty .

Methods: Study included 300 TKR surgeries which were divided in two equal groups i.e. Routine anticoagulation and Risk classified group. Irrespective of the DVT score patients allocated to routine anticoagulation received half prophylactic dose LMWH. Patients allocated to the risk stratification group received thromboprophylaxis as per their DVT score. Primary outcome was symptomatic DVT and wound complication.

Result: This randomized study showed that the symptomatic DVT rates after TKA were similar whether patients were routinely anticoagulated or selectively anticoagulated after risk screening. However there was A significantly higher incidence of wound complications after routine anticoagulation.

Conclusion: This study is to know and compare effectiveness of these two different approaches of preoperative thromboprophylaxis administration in TKR patients

KEYWORDS

TKR, DVT, Thromboprophylaxis, Wound complication.

INTRODUCTION :

The ultimate goal of any thrombo prophylactic regime in TKA is to prevent the formation of DVT and post phlebitic syndromes and the occurrence of PE, without affecting result of index surgery. Current prophylactic regimes include pharmacological methods such as aspirin, warfarin, and LMWH, and mechanical approaches such as intermittent pneumatic compression devices. [1,2,3]

The American College of Chest Physicians (ACCP) [4] has recommen ded routine anticoagulation for thromboprophylaxis in all patients undergoing lower limb arthroplasty irrespective of their DVT risk involved and thus subjecting everyone to undergo with its own complications e.g. increased bleeding, wound complications, drug reactions [5,6]. More ever there remains question regarding safety, efficacy, cost [7,8,9] of various chemical prophylaxis agent. There are very few studies which compare results of randomly implementing routine and risk stratified thromboprophylaxis in patient undergoing total knee arthoplasty . This study is to know and compare effectiveness of these two different approaches of preoperative thromboprophylaxis administration in total knee arthoplasty.

OBJECTIVE : This study is to know and compare effectiveness of two different approaches i.e. of randomly implementing routine and risk stratified thromboprophylaxis in patient undergoing total knee arthoplasty

STUDY DESIGN: Randomized control study carried out at tertiary care hospital after ethical committee approval

INCLUSION CRITERIA: All patient undergoing primary total knee replacement surgery or staged bilateral TKR surgery with minimal gap of 3 months and those who have consented for surgery

EXCLUSION CRITERIA :

1. Patient undergoing single stage bilateral total knee replacement
2. Those patients who are already on some kind of anticoagulation

METHODOLOGY :`This was a randomized control trial study. After explaining to patients regarding advantages and disadvantages of thromboprophylaxis strategies to patients, they were enrolled for study with valid consent. All patients were risk assessed for risk of VTE using a DVT risk-scoring chart (Fig. 1) based on AAOS guidelines. Following risk screening all patients were randomized as per computer generated block randomization. The thromboproph ylaxis therapy instituted to the patient was kept blinded by using sham anticoagulant injection in standard risk patients and placebo Aspirin tablets in high-risk patients. Using a unique therapy code in the hospital charts blinded the assessor. Thus equal number of subjects were divided in two groups randomly i..e.. Routine anticoagulation group and risk classified group. Total 300 patients were enrolled.

A. Routine anticoagulant group

Irrespective of the DVT score patients allocated to anticoagulation group received half of the recommended prophylactic dose of Low Molecular Weight Heparin (LMWH) starting 8 h after surgery and switched to full prophylactic dose on the first postoperative day which was continued for two weeks (Inj Enoxaparin 4 0 mg Subcutaneous), as in-patient.

B. Risk stratified group

All the patients allocated to the risk stratification group received chemical thromboprophylaxis as per their DVT score. Patients with a score of 2 or less were considered standard risk and were given Aspirin (325 mg) 12 hourly starting on the first postoperative day and continued for four weeks. All patients with a risk score of more than 2 were subjected to anticoagulation using thromboprophylactic dose of LMWH for two weeks, this was followed by 2 weeks of oral Aspirin(325 mg twice a day).

Risk classification

The Wells clinical prediction guide quantifies the pretest probability of deep venous thrombosis (DVT). The model enables us to reliably stratify patients into high or low-risk categories. The Wells clinical prediction guide incorporates risk factors, clinical signs, and the presence or absence of alternative diagnoses.

Table 1. Wells Clinical Score for Deep Venous Thrombosis

Clinical Parameter	Points
Active cancer (treatment ongoing, or within 6 months or palliative	+1
Paralysis or recent plaster immobilization of lower extremities	+1
Recently bedridden for more than 3 days or major surgery less than 4 weeks prior	+1
Localized tenderness along the distribution of the deep venous system	+1
Entire leg swelling	+1
Calf swelling more than 3 cm compared with asymptomatic leg	+1

Pitting edema (greater than asymptomatic leg)	+1
Previous DVT documented	+1
Collateral superficial veins (nonvaricose)	+1
Alternative diagnosis (as likely or greater than that of DVT)	-2

Pretest probability score calculated from the Wells DVT score can be stratified in either 2 risk group, patients are stratified as DVT unlikely (Wells score < 2) or DVT likely (Wells score =2).

Table 2. Wells Score Risk Stratification Grouped in 2 Risk Group Scoring System

Probability (2 Risk Group)	Total Score #	Probability of DVT %
Low risk (DVT unlikely)	<2%	6%
High risk (DVT likely)	=>2%	28%

Single Arthroplasty team led by senior arthroplasty surgeon performed all surgeries under Spinal anaesthesia. postoperatively limb was kept in elevated position for 48 h. All patients were made to perform regular ankle pumps as soon as the effect of regional anaesthesia wore off. Intermittent calf stimulator was used for mechanical prophylaxis starting immediately after surgery .Patient was ambulated same day evening. Depending on their recovery in five to seven days all patients were shifted to rehabilitation ward and discharged at 2 weeks after suture removal, if there were no wound complications. Subsequently they were followed up at six weeks, three months, six months and at one year. In case of any suspicion of DVT, they were advised to undergo Doppler scan.

All patients were assessed clinically for any symptoms of calf pain , chest pain, difficulty in breathing. Any signs of increased calf circumference, calf stretch pain (homan's sign), bleeding from operative wound, subcutaneous or intraarticular hematoma, signs of infection were noted. Patients with these signs and symptoms were evaluated with duplex ultrasound of symptomatic limb.

Statistical Analysis

A statistical analysis was performed with Stata Version 10. The distributions of patient demographics including Functional Co-morbidity Index (FCI) were compared between study groups to identify any differences that might confound outcome comparisons. The mean, standard deviation, and range were presented for continuous parameters. Two-sample independent t-test or the nonparametric Mann–Whitney–Wilcoxon test was used to compare continuous variables between the two groups according to the distribution of the variables. All the outcomes were discrete hence frequency and percentage were calculated. Differences in discrete outcomes between the two groups were assessed by chi-square test or Fisher's exact test where appropriate. Relative risk was calculated for complications. Given that this study had two unrelated outcome parameters, statistical significance was adjusted for multiple testing using the Bonferroni correction: a P value of less than 0.025 (i.e. 0.05/2) was considered significant.

SIGNIFICANCE OF STUDY:

If there is significant difference between clinical outcomes of these two different strategies of thromboprophylaxis administration then we will able to avoid suboptimal or undue thromboprophylaxis and their respective complications in current practice.

Table 3: Patients demographics .

Parameter	Routine anticoagulation group			Risk stratified group				'p' value
	N	Mean	SD	N	Mean	SD		
Age in years	150	65.8	8.0	150	63.5	8.0	1.000	
Gender	male	59			56			
	female	91			94			
Body Mass index	300	28.9	5.2	28.8	28	4.1	0.15	

Table 4: DVT Scores of patients

DVT Score		Routine anticoagulation group	Risk stratified group	'p' value
	Moderate /High risk (>2)	84	88	0.57
	Standard Risk(<=2)	66	62	

Table 5: Symptomatic DVT and Wound complications rates for routine anticoagualation and risk classified groups including Relative Risk and Significance.Table 5: Symptomatic DVT and Wound complications rates for routine anticoagualation and risk classified groups including Relative Risk and Significance.

	Group	Cohort	No.of cases	N	%	RR (95% Conf Limit	'p'value
Symptomatic DVT	Routine anticoagulation group		150	3	2	0.73	0.487
	Risk stratified group		150	4	2.6		
		LMWH	210	6	2.8	1.03	0.954
		Aspirin	90	2	2.2		
Wound complications	Routine anticoagulation group		150	12	8	1.9	0.014
	Risk stratified group		150	6	4		
		LMWH	210	17	8.09	7.69	0.0005
		Aspirin	90	1	1.1		

Demographics of patients

Total number of surgeries done were 300 in 270 number of patients. Second staged TKR was considered as new surgery and patients who underwent staged bilateral surgery were equally distributed among groups. Thus all subjects were divided and randomized in two groups i.e. Routine anticoagulation group and Risk classified group . Again risk classified group was further divided according to their individual DVT score i. e. standard risk group (<=2 DVT score) and high risk group (>2 DVT score). Standard risk group was given only oral aspirin therapy whereas high risk group received LMWH and Aspirin as thromboprophylaxis.

Mean age for routine anticoagulation group was 65.8 years and that for risk classified group was 63.5 years. Average BMI in routine anticoagulation group was 28.8 and that for risk classified group was 28. There were equal number of females in both groups . Average functional comorbidity index in routine anticoagulation group was 1.61 and in risk classified group was 1.46. As per DVT score approximately 60% patients were classified as high risk in both groups. As shown in the table there was no significant demographic differences in the two groups

Symptomatic DVT

Lower limb local ultrasound was the investigation used for identification of all symptomatic DVTs. Three patients (1.8%) in the routine anticoagulation group developed symptomatic DVT as compared to Four (2.4%) in the risk stratification group.

The relative risk of symptomatic DVT in the routine anticoagulation group was 0.73 (0.3–1.8) times that of the risk stratification group (Bonferroni-adjusted P = 0.487). Patients receiving LMWH or Aspirin as chemical thromboprophylaxis had almost similar incidence of symptomatic DVT .

Wound Complications

Routine anticoagulation group had 12 cases of wound

complication, as against six cases seen in the risk stratification group (P = 0.014). Patients in the routine anticoagulation group were almost twice as likely to have a wound complication as in the risk screening group. Patients who received LMWH were eight times more likely to

suffer from a wound complication as compared to those who received Aspirin (P = 0.0005).

Disscussion

Preoperative thromboprophylaxis in lower limb arthoplasty is a question of debate as there remains a lack of common agreement[8,9,10]. Recent clinical trials which recommend routine anticoagulation for all lower limb arthoplasty patients have come into questions as this approach unnecessarily puts all those patients at risk of various undesired effects of routine anticoagulants used for thromboprop hylaxis thus there is a question of safety and efficacy of various chemical thromoprophylactic agents. There is increased incidences of wound complications in those patients. Our study compares the effectiveness of two different approaches of pre operative throm boprophylaxis administration in patients undergoing total knee replacement surgery. There was a similar rate of symptomatic DVT in patients administered with routine anticoagulation thromboprop ylaxis and risk calssified selective chemical thromboprophylaxis. Our finding are similar to study published by V.Kulshrestha11 and et al. The overall symptomatic DVT is similar to many current studies [12 13]. There was increased twice relative risk of wound complication in routine anticoagualation group as compared to risk classified group. LMWH was associated with eight times higher risk of wound complication in terms of bleeding and persistant discharge thus increasing chances of superficial and deep infection post total knee replacement surgery . Our study did not have adequate power to look at the level of significance of this finding however anticoagulant thromboprophylaxis has shown a similar increase in the risk of infectious complications among patients undergoing TKA. [7,8]

This is study which compares two different approaches of pre operative thromboprophylaxis not various thromboprophylactic agents as most of other studies do. It help us to avoid suboptimal thromboprophylaxis in high risk group as well as undue thrombopro phylaxis in standard risk patients . In our study all patients and assessor were blinded to know which thromboprophylactic therapy being administered to patients thus reducing observer bias . Our study was not a funded trial and there was no conflict of interests.

Limitation of our study is that we used only LMWH as anticoagulant , hence our result only apply to this class of anticoagulant, which is commonly used in current arthroplasty practice. We used duplex Doppler scan as a confirmatory tool to establish DVT in symptomatic patients and did not perform the gold standard venography. [14 15] Literature supports use of Doppler study to be sufficient for diagnosis of DVT.

Conclusion:

Selective anticoagulation using a risk screening approach is a safer strategy to ensure adequate thromboprophylactic cover and minimize wound related complications.

References

1. Sugano N, Hidenobu M, et al. Clinical efficacy of mechanical thromboprophylaxis without anticoagulant drugs for elective hip surgery in an Asian population.J Arthroplasty 2009;24:1254.
2. Lachiewicz PF, Kelley SS. Two mechanical devices for prophylaxis of thromboembolism after total knee arthroplasty. A prospective randomized study. J Bone Joint Surg Br 2004;86:1137.
3. Chandrasekaran S, Ariaretnam SK, et al. Early mobilization after total knee replacement reduces the incidence of deep venous thrombosis. ANZ J Surg 2009; 79(7–8):526.
4. Geerts WH, Bergqvist D, t al. Prevention of venous thromboembolism: American College of Chest Physicians evidence based clinical practice guidelines (8th edition). Chest 2008;133(6 Suppl):381S.
5 30. Burnett RS, Clohisy JC, et al. Failure of the American College of Chest Physicians-1A protocol for Lovenox in clinical outcomes for thromboembolic prophylaxis. J Arthroplasty 2007;22:317.
6 Shaieb MD, Watson BN, Atkinson RE. Bleeding complications with enoxaparin for deep venous thrombosis prophylaxis. J Arthroplasty 1999;14:432.
7 Sachs RA, Smith JH, et al. Does anticoagulation do more harm than good? A comparison of patients treated without prophylaxis and patients treated with low-dose warfarin after total knee arthroplasty. J Arthroplasty 2003;18:389.
8. Patel VP, Walsh M, et al. Factors associated with prolonged wound drainage after primary total hip and knee arthroplasty. J Bone Joint Surg Am 2007;89:33.
9. NICE clinical guideline. Venous thromboembolism reducing the risk of venous thromboembolism (deep vein thrombosis and pulmonary embolism) in patients undergoing surgery. Available at http://www/guidance. nice.org.uk/CG46/ niceguidance/ pdf/English
10 Australia and New Zealand Working Party on the Management and Prevention of Venous Thromboembolism. Prevention of venous thromboembolism: best practice guidelines for Australia and New Zealand. 4th ed.. Sydney: Health Education and Management Innovations; 2007
11 Vikas Kulshrestha, Santhosh Kumar et al. DVT Prophylaxis After TKA: Routine Anticoagulation Vs Risk Screening Approach —A Randomized Study. The Journal Of Arthoplasty 2013;28:1868:1873.
12. Dorr LD, Gendelman V, et al. Multimodal thromboprophylaxis for total hip and knee arthroplasty based on risk assessment. J Bone Joint Surg Am 2007;89:2648.
13. Callaghan JJ, Warth LC, et al. Evaluation of deep venous thrombosis prophylaxis in low-risk patients undergoing total knee arthroplasty. J Arthroplasty 2008;23(6 Suppl 1): 20.
14. Ozbudak O, Eroğullari I, et al. Doppler ultrasonography versus venography in the detection of deep vein thrombosis in patients with pulmonary embolism. J Thromb Thrombolysis 2006;21(2):159.
15. Eikelboom JW, Karthikeyan G, et al. American Association of Orthopedic Surgeons and American College of Chest Physicians guidelines for venous thromboembolism prevention in hip and knee arthroplasty differ: what are the implications for clinicians and patients? Chest 2009;135:513.