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INDEX

Sr. No	Title	Author	Subject	Page. No.
1.	Statistical Optimization Of Ferulic Acid Esterase Production In Aspergillus Niger Isolate Using Response Surface Methodology	Balljinder Kaur , Neena Garg	Biotechnology	1-6
2.	Development Of Forest Area In Tropics: The Urgency Of People's Participation In The Indian Context	Dr. M. P. Naik	Commerce	7-8
3.	Opportunity For International Corporations At Bop Segments Of Emerging Markets (Focus : India)	Bhudhar Ranjan Chatterjee , Sukanya Chatterjee.	Commerce	9-11
4.	Retail Trade	Viram. J. Vala , Dr. (Prof.) Vijay Kumar Soni	Commerce	12-15
5.	Determinants Of Market Value Added Some Empirical Evidence From Indian Automobile Industry	Dr. A. Vijayakumar	Commerce	16-20
6.	The Welfare Facilities Available To The Workers In Paper Mills In Madurai	Dr. M. Sumathy , A. Vijayalekshmi	Commerce	21-24
7.	Green Marketing - New Hopes And Challenges	Dr. Prashant M. Joshi	Commerce	25-27
8.	A Study On Employee Welfare Measures In Maharashtra State Transport Corporation With Special Reference To Kolhapur District.	Dr. H. M. Thakar , Prof. Urmila Kisan Dubal	Commerce	28-30
9.	Business Environment In South Korea An International Perspective	Dr. M. Kamalun Nabi , Dr. M. Saeed	Commerce	31-35
10.	Market Timing - Implications Of Market Valuation On Share Issues By Indian Companies	L. Ganesamoorthy , Dr. H. Shankar	Commerce	36-38
11.	The Conceptual Framework Of Corporate Social Accounting	Rechanna , Dr. B. Mahadevappa	Commerce	39-50
12.	Labour Welfare Measures And The Extent Of Satisfaction Of Tirupur Garment Employees	Mr. S. Hariharan , Mr. N. Selvakumar, Dr .H. Balakrishnan	Commerce	51-53
13.	Mahila Savstha Aur Jacha-Bacha Ko Bachane Ko Chunoti	Dr. Anup Chaturvedi	Community Science	54-55
14.	Mapping Of Existing Waste Dumping Sites And Newly Proposed Waste Dumping Sites In And Around Chitradurga Taluk, Karnataka State, Using Remote Sensing And GIS Techniques.	Sunil Kumar R. K Chinnaiiah , Suresh Kumar B.V	Earth Science	56-58
15.	A Role Of Municipal Council And Corporation Of Financial Problems In Nanded District (Maharashtra)	Dr. A. S. Pawar	Economics	59
16.	Impact Of Institutional Credit On Weaker Section In Akola District	Dr. Devyanee K Nemade, Dr. Vanita K Khobarkar	Economics	60-62
17.	Right To Education In India	Dr. Pawar A. S.	Economics	63-65
18.	Gramin Ayam Adivasi Mahilo Ke Arthik Shakti : Sukhma Virti (Adipur Jila Ke Gramin Ayam Adivasi Mahilao Ka Ek Ayaktik Adhiyan Shobha Gupta	Shobha Gupta	Economics	66-67

19.	Knowledge On Food Security Education Among Higher Secondary Students	Dr. P. Paul Devanesan , Dr. A. Selvan	Education	68-69
20.	Family Environment As A Determinant of Academic Anxiety And Academic Achievement	Dr. RajKumari Kalra , Ms. Preeti Manani	Education	70-71
21.	Awareness On Man-Made Disaster In Environmental Education Among High School Students	Dr. A. Selvan , Dr. P. Paul Devanesan	Education	72-73
22.	Teaching Strategies For Simplifying Fractions In Mathematics	M. Kavitha , Dr. A R. Saravanakumar	Education	74-76
23.	Mahatma Gandhi National Rural Employment Guarantee Scheme (MGNREGA): A Boon to Tribal Women	Dr. Sherly Thomas	Education	77-78
24.	Sports as a Tool for Interest Oriented Learning	E. Baby Sumanna	Education	79-80
25.	Balanced Scorecard for Higher Education	Jyoti D Joshi	Education	81-83
26.	A Study Of The Interactive Influence Of CAI Package On Academic Achievement	Kunal D. Jadhav	Education	84-85
27.	Reduction Of Fault Current Using SFCL At The Suitable Location In The Smartgrid	Pudi Sekhar , K .Venkateswara Rao , M. Ebraheem , P. Nageswara Rao	Electronics	86-88
28.	HRD Climate in Private Manufacturing Sector: An Appraisal	Dr. Sukhwinder Singh Jolly	Engineering	89-90
29.	Wireless Speed Measurement And Control Of Universal Motor	G. Prasad , G. Ramya Swathi, Dr. P. V. N. Prasad , A. Muneiah	Engineering	91-94
30.	Design Of Decentralized Load-Frequency Controller For Deregulated Hydro-Thermal Power Systems With Non-Linearities	M. Vinothkumar , Dr. C. Kumar , Dr. S. Velusami	Engineering	95-99
31.	Optimization Of Process Parameters For Gas Tungsten Arc Welding Aluminum Alloy A6061 By Taguchi Method	P. Hema , K. Allama Prabhu , Prof. K. Ravindranath	Engineering	100-103
32.	Numerical Approach To Predict The Thermal Performance Of Parallel And Counter Flow Packed Bed Solar Air Heaters	Satyender Singha , Prashant Dhiman , Ritika Kondal	Engineering	104-108
33.	Institute For Entrepreneurship Development Amongst Farmers- Especially Small And Marginal Land Holders.	Sweta Sanjog Metha	Entrepreneurship Development	109-111
34.	Phytoplankton Diversity From Godavari River Water (Maharashtra)	Satish.S.Patil , Ishwar.B.Ghorade	Environmental Science	11-114
35.	Nutrient Adequacy Among Selected Tribal Adolescent Girls Of Kattunayakan Tribes In Tamil Nadu	Somishon Keishing , Saranya .R	Home Science	115-116
36.	Vaigyanic Sacharata Aur Arthik- Samajik Vikas	Dr. Sudobh Kumar	Humanities	117-118
37.	E-Pharmacy In India For Reducing Inter-State Accessibility Dispersion	Satinder Bhatia	Information Technology	119-121
38.	Impact Of Intermediaries' Service Delivery In Insurance Sector	Dr. P. Anbuoli , R. Meikanda Ganesh Kumar	Insurance Sector	122-124

39.	Fate And Human Endeavour In The Mahabharata	Dr Maneeta Kahlon	Literature	125-127
40.	Facets of Hunger in Bhabani Bhattacharya's So Many Hungers and Kamala Markandaya's Nectar in a Sieve	Dr. Paramleen Kaur Syali , Ruchee Aggarwal	Literature	128-129
41.	Business Financial Strategy In Small And Medium Scale Brick Industries In Kolar District, Karnataka State.	Muninarayanappa , Dr. S. Muralidhar	Management	130-132
42.	A Study On Brand Equity Analysis Foreign Global Brands Vs Domestic Popular Brands Of Adult Consumer's Perspective In Coimbatore City	A.Pughazhendi , S. Susendiran , R. Thirunavukkarasu	Management	133-135
43.	Comparative Analysis of Cellular Phone Usage Outline of Undergraduate Students.	Atul Patel	Management	136-138
44.	A Study On Management Practices Of Entrepreneurs In Informal Sector	Dr. P. Vikkraman , Mr. S. Baskaran	Management	139-142
45.	E-commerce: Emerging Channel for Marketing in India	Dr Mahalaxmi Krishnan	Management	143-144
46.	The Role Of Educational Institutions In Imparting Entrepreneurship Qualities Among Student Community	Dr. N. Ramanjaneyalu	Management	145-147
47.	Impulsive buying and In-store shopping environment	Dr. Surekha Rana , Jyoti Tirthani	Management	148-149
48.	A Study On Management Practices Of Entrepreneurs In Informal Sector	Dr. P. Vikkraman , S. Baskaran	Management	150-153
49.	Risk Management Processes And Techniques For Resolving Customer - Supplier Relationship Issues	Pramod Kumar , Prof (Dr.) S.L.Gupta	Management	154-160
50.	Risk Management Processes & Techniques For The Successful Delivery Of Web Based Software Projects	Pramod Kumar , Prof (Dr.) S. L. Gupta	Management	161-166
51.	Effect Of Brand Equity On Consumer Purchasing Behaviour On Car: Evidence From Car Owners In Madurai District	R. Suganya	Management	167-169
52.	Relationship Management Model For Global It Industry.	Rishi Mohan Bhatnagar , Prof (Dr.) S. L. Gupta	Management	170-173
53.	It's A Myth That Kirana Stores Will Be Wiped Out If FDI Is Allowed In Multi Brand Retail Sector In India	Shweta Patel , M R Brahmachari	Management	174-176
54.	Learning Organization	Sitheswaran K , Dr. K. Balanaga Gurunathan	Management	177-178
55.	Behavior Management: A Ready-made Soup For Indian Managers	Winnie Jasraj Joshi	Management	179-180
56.	Customer Relationship Management In Public Sector Banks	Dr. P. Anbuoli , T. R. Thiruvén Kat Raj	Marketing	181-182
57.	Nifedipine Compared With Isoxuprine In Treatment Of Preterm Labor	Dr. Santosh Khajotia	Medical Science	183-184

58.	Single Intraoperative Dose of Tranexamic Acid In Orthopedic Surgery (A Study of Bipolar Modular Prosthesis and Dynamic Hip Screw fixation)	Dr. B. L. Khajotia , Dr. S. K. Agarwal, Dr. Prasant Gadwal	Medical Science	185-187
59.	MVA - A Simple & Safe Surgical Procedure For First Trimester Abortion / Medical Termination Of Pregnancy (MTP)	Dr. Priyamvada Shah , Dr. Sameer Darawade	Medical Science	188-190
60.	Pneumococcal Septic Arthritis in an Infant A Case Report	Dr. Vrishali A Muley , Dr. Dnyaneshwari P Ghadage, . Dr. Arvind V Bhore	Medical Science	191-192
61.	A Clear CSF may not be a Normal CSF A Case Report	Dr. Dnyaneshwari P Ghadage , Dr. Vrishali A. Muley , Dr. Arvind V. Bhore	Medical Science	193-194
62.	Neurectomy For Tic How Much Reliable?	Dr. Monali H. Ghodke , Dr. Seemit V. Shah , Dr. Smita A. Kamtane	Medical Science	195-198
63.	To Assess Acceptability Of Female Condom As A Method Of Temporary Contraception Among Indian Women	Dr Priyanka Shekhawat , Dr. Col (Retd) Gulab Singh, Dr Vidula Kulkarni Joshi	Medical Science	199-200
64.	A Study To Evaluate The Efficacy Of Teaching Intervention On Reduction Of Pediatric Immunization Pain Among Nursing Students	Dr. Ramachandra , Dr. S. Valliammal, Mr. Raja Sudhakar	Nursing	201-202
65.	Screening Of Antenatal Patients For Thalassemia	Dr Mukta Rayate , Dr Durga Karne , Dr Shilpa Bhat, Dr Hemant Damle , Dr Sameer Darawade, Varsha Gogavale	Obstetrics & Gynaecology	203-204
66.	Reservoir Rock Quality of the Lakadong Member in the Eastern Part of Upper Assam Basin, India	Dr. Pradip Borgohain	Petroleum Geology	205-207
67.	Study Of Refractive Index And Excess Parameters For Different Liquid Mixtures At Different Temperatures	Sheeraz Akbar , Mahendra Kumar	Physics	208-210
68.	Refractometric And Excess Parameter Study For Liquid Mixtures Containing High Order Alkanes (C17) And 1-alkanols At Different Temperatures	Sheeraz Akbar , Mahendra Kumar	Physics	211-213
69.	Assessment Of Knowledge About Health Services Available At Subcentre Level Among Village Inhabitants	Balpreet Singh , Jayanti Dutta	Public Health	214-215
70.	Effect Of Yogic, Aerobic And Laughter Exercises On Body Composition (An experimental study)	Dr. Manjappa. P. , Dr. Shivarama Reddy. M	Sports	216-220
71.	Age At Menarche In Physically Active And Non Active Urban Girls Of Patiala District	Jyoti Sharma , Dr. Ajita	Sports Science	221-222
72.	Use Of Ranks For Analysis Of Groups Of Experiments	Dr. Vanita K Khobarkar , Dr. S. W. Jahagirdar, Dr. N. A. Chaube	Statistics	223-225



Single Intraoperative Dose of Tranexamic Acid In Orthopedic Surgery (A Study of Bipolar Modular Prosthesis and Dynamic Hip Screw fixation)

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ABSTRACT

Multiple studies suggest tranexamic acid reduces blood loss and blood transfusions in patients undergoing orthopedic surgeries (THR, TKA, BMP & DHS). However, many of the dosing schedules in these studies are not ideally suited for routine application.

Aim of study - We thought whether one 20 mg per kg intraoperative dose of tranexamic acid in patients under going for Bipolar Modular Prosthesis (BMP) and Dyanemic Hip Screw(DHS) fixation would (1) decrease perioperative blood loss and blood transfusion rates.

Patients and Methods We retrospectively reviewed the records of 323 patients operated on from January1,2008 to December 31,2009 (before our study protocol) and 368 Patients from January1,2010 to November 30,2011 with the single-dose protocol. We then compared change in hemoglobin transfusion rates, hemoglobin at discharge, hospital length of stay, and complications between the two groups. No other routine patients care practices were altered during this time.

Results : We found a reduction in the decrease in hemoglobin in two year (2008 & 2009) compared with two year(20010&2011) for Bipolar Modular Prosthesis (BMP) and Dyanemic Hip Screw(DHS) fixation (4.6 to 3.9 g/dL and 4.5 to 3.6 g/dL, respectively), which led to a reduction in transfusion rates (54% to 28.8% and 53.6% to 24%, respectively) and higher hemoglobin levels at discharge. There were no recorded major adverse events associated with the introduction of this protocol.

Conclusions : Single 20-mg per kg intra-operative dose of tranexamic acid reduced the peri-operative decrease in hemoglobin and blood transfusion rates in patients having Bipolar Modular Prosthesis (BMP) and Dynamic Hip Screw(DHS) fixation compared with those of a similar cohort of patients in whom the protocol was not used. This weight increment dosing facilitated pharmacy drug preparation, led to minimal dose variability and wastage, and resulted in a substantial estimated cost savings.

Keywords : Ttranexamic acid , Bipolar Modular Prosthesis, Dynamic Hip Screw

Introduction

Tranexamic acid (TEA), A synthetic analog of the amino acid lysine, acts by competitively blocking the lysine binding site of plasminogen, which leads to inhibition of fibrinolysis². As TEA enters the extra vascular space and accumulates in tissues for up to 17 hours, the basis for its mechanism of action is thought to be inhibition of tissue fibrinolysis and consequent stabilization of clots¹¹. Multiple studies show TEA can reduce blood loss and red blood cell transfusion in patients undergoing primary arthroplasty^{1, 3, 5, 7, 9, 10, 13, 14, 16}. However, the dosing schedules of either an initial bolus of TEA followed by a 6- to 12-hour infusion of multiple intravenous bolus doses are cumbersome and labor-intensive, making them difficult to introduce in a busy operating room schedule.

In a meta-analysis, Cid and Lozano⁴ reported the reduction in risk of receiving a blood transfusion was independent of the total dose of TEA given. In another review

of the use of antifibrinolytic therapy to reduce transfusion in patients undergoing orthopedic surgery, Dagoma et al⁹ considered 21 studies in which the dose of TEA ranged from 10- to 20-mg initial bolus followed either by an infusion of 1 to 10 mg per kg per hour for 4 to 30 hours or repeated doses of the initial dose of TEA every 3 hours for one to four doses. As the most commonly prescribed dose of TEA was a 10-mg per kg initial bolus dose followed by second similar dose at 3 hours, we decided to adopt one dose of 20 mg per kg to be given before the onset of fibrinolysis. We presumed a second dose would not be required owing to its prolonged extra vascular effectiveness.

Single-dosing schedule had been administered to all patients undergoing arthroplasty of one of the authors (JH) who had pervious experience with the use of TEA. Reduced transfusion rates between the patient of this surgeon and rest of the patients of the arthroplasty group with no apparent increase in postoperative thromboembolic events encouraged introduction of the routine use of TEA in our entire population of patients undergoing arthroplasty.¹

Therefore, we thought whether this dosing protocol could complement our Patients (1) by reducing perioperative blood loss and blood transfusion rates. 323 patients operated on from January1,2008 to December 31,2009 (before our study protocol) and 368 Patients from January1,2010 to November 30,2011 Bipolar Modular Prosthesis (BMP) and Dynamic Hip Screw(DHS) fixation

Material and Methods

A retrospective comparative study for two year period beginning from January1,2008 to December 31,2009. We prospectively studied all 368 Patients from January1,2010 to November 30,2011 (218 patients having Bipolar Modular Prosthesis (BMP) and 150 Dynamic Hip Screw(DHS) fixation) who had been administered TEA using our dosing protocol. Our protocol was to exclude patients with a documented history of a venous thromboembolic event being treated with lifelong anticoagulation, patients with a known congenital thrombophilia, or patients who had a venous thrombo-embolic event within the 12 months preceding surgery. As control group, we obtained data for 323 patients (178 who had BMP and 145 who had DHS) prospectively followed and who were operated on from January1,2008 to December 31,2009, when this protocol was not in place. No other routine patient care of surgical practices were altered during this time. For the study group (new protocol), all scheduled patients were seen preoperative before their surgery, At preoperative assessment visit, we ordered one intraoperative dose of 20 mg TEA per kg to be given immediately before the skin incision. We believed consistent specific timing of the administration of the TEA dose allowed for its maximum anti-fibrinolytic effect. In our institution, preoperative antibiotics are administered in the operating room by the anesthesiologists, so this was not a new situation for them.

All Data collected included preoperative and postoperative hemoglobin (mean reduction in hemoglobin), allogeneic blood transfusions, length of hospital stay, and complications. Pre-operative hemoglobin levels were drawn before surgery as part of our preadmission process..

Table 1. Tranexamic acid dose

Weight of Patient (kg)	43-47	48-52	53-57	58-62	63-67	68-72
Dose of Tranexamic acid (mg)	900	1000	1100	1200	1300	1400
Weight of Patient (kg)	73-77	78-82	83-87	88-92	93-97	98-102
Dose of Tranexamic acid (mg)	1500	1600	1700	1800	1900	2000

Postoperative hemoglobin levels were drawn routinely as part of complete blood cell count on Postoperative Days 1 and 3. The mean reduction in hemoglobin was calculated by subtracting the lowest mean postoperative hemoglobin level from the mean preoperative hemoglobin level. Complications, namely thromboembolic events, were identified for any adverse events and by manual chart review. We used an independent-samples test (normal distribution) to compare change in hemoglobin or transfusion rates, for Bipolar Modular Prosthesis (BMP) and Dynamic Hip Screw(DHS) fixation) separately between the two groups

Results

The decrease in hemoglobin was less in (2008 & 2009) than in (2010 & 2011) for patients who had Bipolar Modular Prosthesis (BMP) and Dynamic Hip Screw(DHS) fixation) (4.6 to 3.9 g/dL [p<0.001], respectively) Table 2). There was a reduction in transfusion rates in (2010 & 2011) compared with (2008 & 2009) for patients who had BMP s and DHS s (54% to 28.8% [p<0.001] and 53.6% to 24% [p<0.001], respectively. Greater hemoglobin levels at discharge were observed in patients in (2010 & 2011) than in (2008 & 2009), more so for patients who had DHSs (p<0.001) than for patients who had BMP (p= 0.143). The mean length of stay in hospital was shorter in (2010 & 2011) than in (2008 & 2009) for patients who had BMPs (7.8 days from 8.4 days) and DHSs (6.5 days from 7.8 days). Three of the 691 patients (.5%) had a deep

vein thrombosis (DVT) identified on clinical examination and confirmed with an ultrasound of affected extremity; two of these were patients who had DHS. One patient who had BMP,. These three patients were treated with therapeutic low molecular heparin without additional complications. All patients received the TEA as ordered. We identified approximate 26.2% (range, 54% -28.8%) and 29.6% (range,53.6% -24%) reductions in transfusion rates using TEA for patients having BMP s and DHS s, respectively.

Table 2. Blood Transfusion and laboratory data

Parameter	Bipolar 2008 & 2009	Bipolar 20010 & 2011	DHS 2008 & 2009	DHS 20010 & 2011
Number of patients	178	218	145	150.
Blood transfused	96(54%)	64. (28.8)*	76 (53.6%)	36(24%)*
Hb Pre-operative (g/dL)†	13.9 ± 1.2	13.9 ± 1.1	13.9 ± 1.1	13.9 ± 1.1
Hb discharge (g/dL)†	9.9 ± 1.4	10.2 ± 1.3	9.7 ± 1.0	10.4 ± 1.2*
Hb change (g/dL)†	4.6 ± 1.2	3.9 ± 1.2*	4.5 ± 1.2	3.6 ± 1.1*

* Significant difference from (2008 & 2009) (p< 0.05); †values are expressed as mean ± SD; Hb = hemoglobin.

Discussion

Despite aggressive attempts to reduce perioperative transfusion rates through our blood conservation program, we believed we had reached a plateau in our endeavors and looked for alternative strategies. We reviewed the literature regarding the use of antifibrinolytics, specifically TEA, and were impressed that multiple studies showed the ability of TEA to reduce blood cell transfusion in patients undergoing primary arthroplasties 1,3,4,7,8,9,10,13,14,16 (Table 3). We concluded the most commonly used protocol of TEA reported in the literature was that of two doses of 10 mg per kg given 3 hours apart.

We believed this would be a difficult protocol to institute as the second dose would be due at the time the patient was being discharged from the postoperative recovery room back to the floor and therefore either would be forgotten or delayed. We therefore asked whether one 20-mg per kg intraoperative dose of TEA in patients having Bipolar Modular Prosthesis (BMP) and Dynamic Hip Screw(DHS) fixation would (1) decrease perioperative blood loss and red cell transfusion rates .

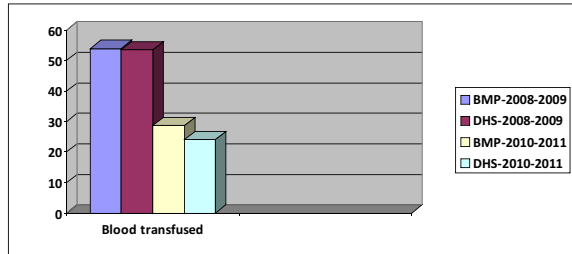
Limitations. of our study

First, we used a database for all information, and such databases have inherent limitation to the quality of data collected. . Our hospital contains documented hemoglobin levels and transfusion rates for all patients having arthroplasty. Second, we used the mean reduction in hemoglobin as a surrogate marker for blood loss other factors may have led to a reduction in the mean hemoglobin, such as hemodilution from perioperative fluid resuscitation and the type of anesthetic used. Third, neuraxial anesthesia has been associated with less perioperative blood loss in patients having BMP s and DHS, compared with general anesthesia¹¹. The majority of patients at our institution receive spinal anesthesia for arthroplasty. Moreover, Zufferey et al¹⁶ did not find the type of anesthesia modified the results in their meta-analysis on the use of TEA. Fourth, our study was restricted to quantifying blood loss through the mean reduction in hemoglobin and blood transfusion requirements. We considered other potential sources of blood loss, such as wound drainage and wound hematomas, as beyond the scope of this study. Additional studies are needed to better to address these issues. An analysis of major complications and there were no any infections or re-operations in the two groups.

One advantage of our study is that it compares a prospective cohort of patients operated on by the same surgeon group. In their meta-analysis of randomized controlled trials comparing the risk of receiving transfusion of allogeneic red blood cell units after BMP between patients who received TEA or not, Cid and Lozano⁴ showed the ability of TEA to reduce blood transfusions in this population was independent of dose. They reported similar reductions in transfusion rates whether a low-dose (15-35 mg /kg or a high-dose (135-150 mg/kg) protocol was used⁴. Other publications

Regarding the use of TEA in orthopedic surgery also have shown the ability of TEA to reduce blood loss and red blood cell transfusion in patients undergoing primary arthroplasties^{1,3,5,7,8,9,10,13,14,16}.

Bar Diag.-Percentage of Patient required blood transfusion in study group & controlled group



One of our major concerns with the initiation of this protocol was that the antifibrinolytic effect of this medication might

lead to an increase in venous thromboembolic events. However, two recent publications suggest TEA dose not result in an increase in thromboembolic events^{1,9}. Lozano et al¹⁰ also reported the use of TEA was not associated with an increase in thrombotic complications either clinically or as documented by Doppler study. In addition, because inflammation and coagulation are directly associated, any change in one may indirectly affect the other. Nilsson et al¹⁶. found allogeneic transfusion was independently associated with a 1.5-fold increase in the risk of development of thromboembolism postoperatively.

We found on 20-mg per kg intraoperative dose of TEA in our patients having primary, elective BMP s and DHS s reduced the perioperative decrease in hemoglobin compared with similar cohort of patients for whom the protocol was not used. More importantly, this protocol led to a reduction in blood transfusions, which can have associated severe immunomodulatory consequences¹⁵. We have found this protocol has well accepted by the nurses, anesthesiologists, and arthroplasty surgeons.

Table 3 : Studies using tranexamic acid

Study	Study design	Patients	TEA dose	Blood loss	Transfusion	Risk of VTE	Unique features of study
Johansson et al. [10] (2005)	Double-blind RCT	100 THA	15 mg/kg	Reduced blood loss	Reduced transfusion requirements	No VTE complications	Cost-effective: savings 47 euros per patients
Cid and Lozano [4] (2005)	Meta-analysis (9 RCTs through 2004)	9RCTs for TKA	Low dose (15-35 mg/ kg) High dose 135-150 mg/kg)	Reduced the number of patients requiring RBC	10X reduction in the risk of having transfusion if TEA administered	8 of 9 studies reported use of DVT prophylaxis; no analysis of DVT rates between groups	Only in TKA
Orpen et al. [18] (2006)	Double-blind RCT	29 TKA	15 mg/kg	Reduced blood loss in early postoperative period	Not powered to show difference in transfusion requirements	No evidence of DVT with duplex ultrasound	Use of set transfusion trigger of 9 g/dL
Claeys et al. [5] (2007)	Double-blind RCT	40 THA	15 mg/kg	Reduced total blood loss	Reduced RBC transfusion requirements	Higher DVT by ultrasound in TEA group	None
Alvarez et al. [1] (2008)	Double-blind RCT	95 TKA	10 mg/kg, then 1 mg/kg/hour infusion	25% reduction in total blood loss	Reduced RBC transfusion requirements	No VTE seen in either study group	Combined with an active perioperative blood conservation
Rajesparan et al. [19] (2009)	Retrospective study	73 THA	1 g IV at induction	Estimated total mean actual blood loss was less	Reduced RBC transfusion requirements	No increased incidence of DVT	Dose at discretion of surgeon
Kagoma et al. [12] (2009)	Meta-analysis (1966-2007)	29 RCTs for THA and TKA	10-15 mg/kg	Reduced blood loss	Reduced transfusion requirements	No difference in VTE rates between groups	Also compared EACA and aprotinin
Current study	Retrospective cohort	631 BMP and DHS	20 mg/kg	Reduced blood loss	Reduced RBC transfusion requirements	No difference in VTE rates between groups	acceptable regimen for BMP s and DHS

VTE= venous thromboembolic event; RTC= randomized control; RBC = red blood cell; TEA = tranexamic acid; DVT = deep vein thrombosis; EACA = epsilon-aminocaproic acid.

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