

Incorporation of Evidence Based Guidelines on Bleeding Risk Assessment Prior to Surgery into Practice: Real Time Experience

Nada Al-Marhoobi¹, Manar Maktoom², Mohamed Elshinawy^{3,4}, Hanan Nazir^{3,4}, Khalid Al
hashmi⁵, Rashid Al-Abri⁶, Khalil Macki⁷, Abdulhakim Al-Rawas³, Fatma AlBulushi⁸,
Yasser Wali^{3,4*}, Doaa Khater^{3,4}

¹ENT Surgery, Oman Medical Specialty Board, Muscat, Oman

²Pediatrics, Oman Medical Specialty Board, Muscat, Oman

³Child Health, Sultan Qaboos University Hospital, Muscat, Oman,

⁴Pediatrics, Faculty of Medicine, Alexandria University, Alexandria, Egypt,

⁵Hematology, Armed Forces Hospital, Muscat, Oman

⁶ENT Surgery, Sultan Qaboos University Hospital, Muscat, Oman

⁷ENT Surgery, Armed Forces Hospital, Muscat, Oman

⁸Hematology, Sultan Qaboos University Hospital, Muscat, Oman

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**Corresponding author: yawali@squ.edu.om*

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Abstract

Background: Despite guidelines recommending no-need for coagulation testing prior to surgeries when challenging history of bleeding is negative, yet surgeons still overuse it in this part of the world. We aim to measure unbiased estimate of hemostatic outcomes in ENT surgeries and assess the surgeons' behavior of pre-operative coagulation testing.

Methods: All patients who underwent ENT surgeries during the period from July 2017 to January 2018 were enrolled. The primary outcome was post-operative bleeding. Surgeons were asked about their decision on history alone or doing coagulation testing and their reason.

Results: 730 patients were recruited; 372 were interviewed for a challenging bleeding history alone; group1 and 358 had pre-operative coagulation testing; group2. Coagulation testing was repeated twice or more in 55% of patients and more than half of them had coagulation factor and VWF assays. Most surgeons were doing the coagulation testing because of habitual practice.

Conclusion: Almost half of local surgeons consider coagulation testing as standard practice to evaluate bleeding risk prior to surgical procedures. This has resulted in unnecessary delays in surgeries, parents/patients anxiety and additional total cost. We recommend awareness campaigns for surgeons and involvement of surgical societies to adhere to guidelines of detailed hemostatic history.

Keywords: aPTT, Bleeding, Risk factor, Surgery

Introduction:

In spite of guidelines recommending the “no need for coagulation profile testing” prior to (Ear, Nose and Throat) ENT surgeries when proper bleeding history is taken (detailed history of previous surgery and trauma, a family history, and detail of anti-thrombotic medication) (1), yet local surgical practice did not change. High percentage of abnormal laboratory results that are not associated with significant bleeding disorders leads to over investigation and unnecessary concerns by surgeons (2). Cost and delaying surgeries are major issues faced when insignificant abnormalities are found in the coagulation profile results (3). In 2008, British Committee for Standards of Hematology has published guidelines on assessing the bleeding risk prior to surgeries or invasive procedures. It stated that the indication for sending a coagulation testing(Prothrombin time (PT), activated partial thromboplastin time (APTT), thrombin time (TT), fibrinogen level and platelet count) is based on the bleeding history of the patient. Bleeding history includes personal or

family history of bleeding following trauma or surgery and detailed of anti-thrombotic medication. It states clearly that patients with negative bleeding history do not require any coagulation testing (1). Also, according to Thomas Thiele et al the risk of post-operative bleeding depends on the extent of tissue perfusion, the condition of the wound and the type of the surgery itself (4). Moreover, low and moderate risk bleed surgeries do not need prior coagulation profile testing when the history of bleeding challenge is negative (4,5). Many surgeons in our region still send coagulation profile for every single patient undergoing ENT surgeries regardless of the risk of bleeds or a negative history of bleeding challenge. This study aimed to measure an objective estimate of hemostatic outcomes in ENT surgeries in relation to coagulation testing as a primary outcome. In Addition, we evaluate the reasons of ENT surgeons performing preoperative coagulation testing as a secondary objective.

Patients and Methods:
Settings and study design

This multi-center retrospective cohort study was conducted in 3 tertiary hospitals located at the capital of Oman including Sultan Qaboos University Hospital, Armed Force Hospital and Al-Nahdha Hospital. All patients who underwent ENT surgeries during a 6 months period from 1st July 2017 to 1st January 2018 were enrolled in the study. The study was approved by the Ethics Committee of the Sultan Qaboos University (SQU).

Patients

All pediatrics and adult patients who had ENT surgeries in the 3 main tertiary hospitals in Oman were included in the study. The retrieved data included gender, age, type of surgery, results of coagulation blood test (if done), other laboratory test results (complete blood count, biochemical profile, etc.), postoperative bleeds, how it was managed, need for blood transfusion and whether

the patient required another surgery to stop the bleeding or not. Patients with known bleeding history, previous coagulation derangement, on anti-coagulants, pregnant, acute renal failure, sepsis and known chronic medical conditions (Cancer, collagenic disorders, chronic liver disease, and chronic renal failure) were excluded from the study.

During a period of 6 months, 730 patient were included in the study. Ages ranged from 1 month to 85 years. Patients were divided into 2 groups according to whether coagulation profile testing was performed or not. Three hundred seventy patients were asked a detailed personal and family history which included bleeding history (due to trauma/surgery). On the other hand, 358 patients underwent the detailed history in addition to pre-operative coagulation testing which included prothrombin time (PT), activated partial thromboplastin time (APTT) and fibrinogen level. Patients were subcategorized according to the surgery they underwent into major or minor surgeries. Major surgeries included basal skull surgery, adenotonsilectomy, thyroidectomy, drainage of effusion in Otitis media, and peritonsillar abscess drainage. Whereas, minor surgeries included foreign body removal, functional endoscopic sinus surgery (FESS) and other endoscopies. We recorded Post-operative bleeds rates in patients where they were divided into primary (within 48 hours) and secondary bleeds (up to 10 days) along with how the bleeding was managed and if they required any blood products support.

At the same time, all ENT surgeons (57) from all the 3 tertiary hospitals were interviewed. They were asked about their decision on taking a preoperative history alone or doing a coagulation testing and their reason for ordering the coagulation profile. They were offered the choice to give more than one reason for sending pre-surgical coagulation testing).

Statistical Analysis:

Quantitative variables were expressed by mean (+/-SD). They were compared by chi-square test or ANOVA whenever appropriate. A p-value of ≤ 0.05 was considered significant. Statistical analyses were performed using Statistical Package for the Social Science (SPSS) software version-20 for Microsoft Windows and GraphPad Prism-5.0 (GraphPad Software).

Results:

The study included data from 730 patients who underwent ENT surgical procedures. They were 432 males and 298 females. Their mean age was 19.6 ± 16.92 year. Out the 730 patients, 372 patients were interviewed for a bleeding history alone (group 1) and 358 were interviewed plus a pre-operative coagulation profile check (Group 2); table 1. There was no statistically significant difference between the 2 groups regarding the gender distribution; chi-square value is 0.651 and P-value ≤ 0.419 . As regards the age distribution of the 2 groups, there was a highly significant difference as most of the older age group 40 and above had their coagulation testing done; chi-square value is 37.964 and P-value is ≤ 0.000 .

Table 1: Demographic and laboratory data of patients undergoing ENT Surgeries in both the studied groups

	Group 1 (Challenging history)	Group 2 (Coagulation testing)	Total	P value
Gender				
Male	226 (60.8 %)	206 (57.5 %)	432 (59.2%)	0.419

Female	146 (39.2 %)	152 (42.5 %)	298 (40.8 %)	
Age				0.000
<20	250 (67.2 %)	176 (49.2 %)	426 (58.4 %)	
20-40	101 (27.2 %)	116 (32.4 %)	217 (29.7 %)	
40-60	15 (4 %)	55 (15.4 %)	70 (9.6 %)	
>60	6 (1.6 %)	11 (3.1 %)	17 (2.3 %)	
Laboratory Testing:				
Repeat coagulation profile (twice or more)	-	197 (55%)		
Coagulation Factor Assay	-	106 (29.6%)		
Both VWF & Coag Factor Assay	-	77 (21.5%)		
Time wasted before surgery (months):				
Range:		6-14		
Median		9		

VWF = Von Willebrand Factor

A total of 14 patients (1.9 %) developed postoperative bleeding. Two patients had an intraoperative minor bleed that requires stitching (one in each group). Three patients in group 2 had post-operative secondary bleeding after 1 week that responded to local hemostatic measures. None of them was due to abnormal bleeding tendency and they did not require any hemostatic support. Six of them bled early (primary hemorrhage) while at the hospital due to surgical reasons (surgical site bleed that required suturing). Eight patients had delayed postoperative bleeds, after being discharged (due to eating hard food/Trauma). Only total of 4 patients had major bleeds, requiring surgical intervention; table 2. Coagulation profile testing was repeated in 55% of patients

who have been tested and more than half of them had coagulation and Von Willebrand Factor (VWF) assays. The time wasted for patients waiting to be cleared for surgery ranged between 6-14 months (Median 9 months).

Table 2: Surgical Procedures and post-operative bleeding events in both groups

	Group 1 (Challenging history)	Group 2 (Coagulation testing)	P-value (Fisher Exact Test)
Post-operative bleeding			
Primary	3 (0.8%)	3 (0.8%)	0.580
Secondary	6 (1.6%)	2 (0.5%)	
Control of bleeding			
Spontaneous/bedside	4 (1%)	2 (0.5%)	1
Operating theatre	5 (1.3%)	3 (0.8%)	
Surgical Procedure			
Major	370 (99.5 %)	354 (89.9%)	0.440
Minor	2 (0.5 %)	4 (1.1 %)	

The analysis of the surgeons' survey concluded that around half of surgeons 50.9 % do not do coagulation testing and depend solely on history of bleeding challenge . Twenty-eight surgeons

who preferred to do the coagulation profile for their patients answered the survey. Twenty two (78.5%) gave the reason of a habitual practice and overprotection, 2 were not confident with the current evidence, 2 had previous serious bleeding experiences with their patients, 1 was not confident with the history and 1 for fear of medico-legal issues; figure 1.

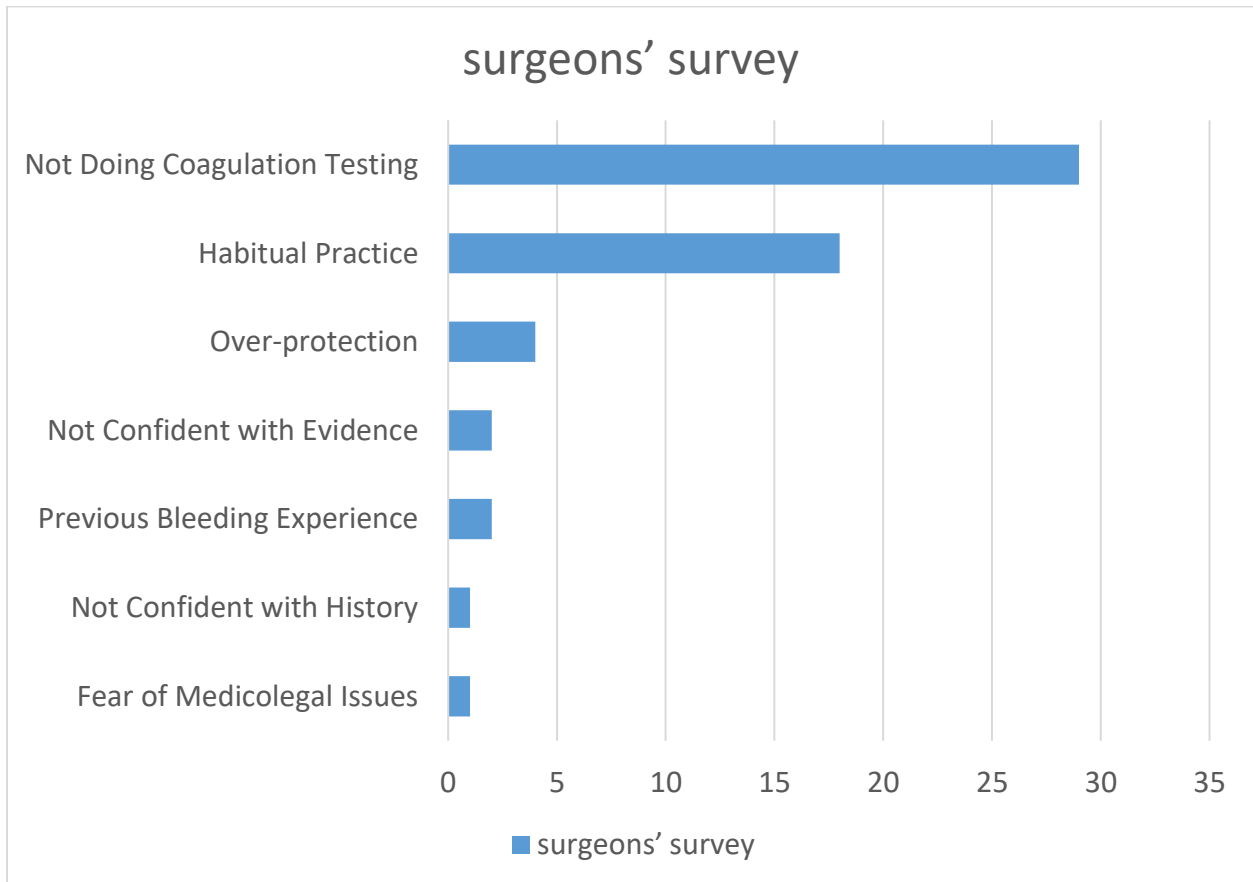


Figure 1: Number of ENT surgeons who were not doing the coagulation testing (29) and distribution of the reasons of ENT surgeons who were doing the coagulation testing (28).

Discussion:

In this study, we found that preoperative testing is overused and sending coagulation profile for patients prior to low or moderate bleeding risk ENT surgeries is still widely practiced by many. Almost 50% of patients had coagulation profile testing despite a negative history of

bleeding challenge. Moreover, in 55 % of them the test was repeated once or more, along with coagulation factor and VWD assays. We also found that neither coagulation testing nor abnormal results were associated with postoperative bleeding outcomes.

Normal coagulation profile results do not reliably exclude all bleeding disorders. Of note, platelet function disorders, factor XIII deficiency, VWD type 2N and vessel wall abnormalities are associated with perfectly normal coagulation screen results ^(6,7,8,9,10). On the other hand, abnormal coagulation profile doesn't necessarily indicate an underlying factor deficiency ^(11,12). Pre-analytical errors, prekallekrein deficiency, high-molecular-weight kininogen, lupus anticoagulant and other circulating inhibitors give rise to abnormal coagulation profile and they are not associated with any significantly increased bleeding risk ^(13,14,15,16). Moreover, factor XII deficiency is often encountered in this part of the world due to consanguineous marriages ⁽¹⁷⁾. Despite an alarmingly prolonged aPPT associated with the disorder, it is well known that it doesn't increase the risk of bleeding ⁽¹⁸⁾. The fact that 55% of the coagulation testing (aPTT) in our set-up was abnormal and repeated, highlights the major burden of re-testing and performing un-necessary coagulation and VWF assays which aggravates the patient and family anxiety and suffering, results in unnecessary delays cancellations, and rescheduling of surgeries.

A review on the guidelines for bleeding risk does not support coagulation testing prior to procedures for assessing bleeding risk and emphasized that abnormal coagulation results could not predict the increase risk of operative hemorrhage neither the risk of bleeding postoperatively ⁽¹⁹⁾.

Our data support that coagulation testing had no added value in predicting post-operative bleeding risk. Many surgeons send the pre-operative tests as a habit and not evidence based. Surgeons need to be educated more on the current evidence of the superiority of the history of bleeding

challenge over the routine coagulation tests. Pre-operative testing should be done only if history is suggestive of an underlying bleeding tendency.

Limitations of the study are being retrospective besides missing some initial and follow-up laboratory data..

Conclusion

In conclusion, despite the guidelines recommend no coagulation testing prior to surgeries, many local ENT surgeons still consider them as a standard practice to evaluate the patients bleeding risk prior to any surgical procedure. This practice resulted in unnecessary delay in surgeries (reaching more than a year in many patients) in addition to parents/patients anxiety and increased of total cost. We recommend adhering to guidelines of taking a detailed hemostatic history. We also recommend to use standardized questionnaires as for example, the MCM DM-1 VWD questionnaire.

Keywords: aPTT, Bleeding history, Risk factor, Surgery, Coagulation

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