ORIGINAL ARTICLE

Validation of a Smartphone Application for Assessment of Risk of Venous Thromboembolism in Obstetrics and Gynecology

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Submission: 12 Feb. 2017
Accepted: 7 Mar. 2017

Citation
Zaher GF, Adam SS. Validation of a smartphone application for assessment of risk of venous thromboembolism in obstetrics and gynecology. JKAU Med Sci 2017; 24 (2): 33-40.
DOI: 10.4197/Med. 24.2.5

Abstract

Venous thromboembolism is a serious but potentially preventable condition. However, morbidity and mortality occur due to lack of thrombo-prophylaxis. Obstetrics and gynecology patients are at risk for developing venous thromboembolism. To improve adherence to thromboprophylaxis in this patient population, we developed a smart phone clinical decision support system designed to assess risk score and recommend thromboprophylaxis. Clinical data were collected by review of electronic medical charts. The risk score and thromboprophylaxis recommendations were calculated for each patient by clinical decision support system and by an expert hematologist and results were compared for correlation. We hypothesize that the system is a valid tool for risk assessment in obstetrics and gynecology patients.

A total of 188 female patients admitted at King Abdulaziz University Hospital between December 2015 and March 2016 were included. One hundred and sixteen were gynecology, and 72 were obstetric patients with a mean age of 40.7 (± 12.8). The risk score obtained by the system showed a strong correlation with that of the expert hematologist's opinion (r = 83%). The clinical decision support system showed a good correlation for thromboprophylaxis decision as well. Accessibility and ease of use of clinical decision support system can improve the clinical outcome of hospitalized patients.

Keywords

Clinical decision support system; Smartphone application; Venous thromboembolism

Introduction

Venous thromboembolism (VTE) including deep vein thrombosis and pulmonary embolism is a preventable condition, yet considerable morbidity and mortality occur due to failure to provide prophylaxis to patients at risk[1].

Mortality related to VTE is more than combined deaths from breast cancer, motor vehicle collisions and

AIDS[2]. Available data show that hospital-acquired VTE can be prevented by early risk assessment and initiation of appropriate thromboprophylaxis[3-5]. However, patients are not always assessed for risk of VTE upon hospital admission, and thromboprophylaxis is vastly underutilized in the inpatient setting[6,7].

Many protocols were designed for obstetrics and gynecology patient to prevent VTE. However, evidence has demonstrated that passive promulgation of guidelines and education alone are unlikely to improve VTE prophylaxis[4]. Venous thromboembolism risk assessment tools in hospitalized patients may be a useful and practical way to provide physicians with an evidence-based medicine algorithm for thromboprophylaxis and ultimately improve inpatient outcome[8,9].

This pilot study is conducted to validate a smartphone application clinical decision support system (CDSS). We hypothesize that the VTE CDSS application is a valid tool for risk stratification and recommendation of VTE thromboprophylaxis among hospitalized obstetrics and gynecology patients.

Participants and Methods

Inclusion Criteria

All patients admitted to the obstetrics and gynecology ward at King Abdulaziz University Hospital (KAUH) between the period of December 2015 and March 2016, were included.

Exclusion Criteria

Patients with a diagnosis of acute DVT or PE were excluded from the study as well as patients with known thrombophilia.

Methodology

All patients admitted to obstetrics and gynecology ward at KAUH between December 2015 and March 2016, were included in the analysis.

Data were collected by review of patients' electronic medical records.

The following variables were extracted: age, admission diagnosis, acute infections, cardiac or respiratory diseases, active malignancy, recent surgery, previous VTE, and history of hormonal therapy. In obstetric patients, additional risk factors included preeclampsia, hyperemesis and mode of delivery whether vaginal delivery, planned caesarean section (CS), or emergency CS. Clinical contraindications for pharmacological thromboprophylaxis and thromboprophylaxis received during the same admission, were collected.

Clinical Decision Support System Tool Development

We developed a smart phone CDSS which include risk assessment tool, heparin exclusion centre, dose adjustment option in case of renal impairment and recommendation for thromboprophylaxis. The risk assessment is based on Caprini risk assessment model (RAM) for surgical patients, Padua score for medical patients and the Royal College of Obstetrics and Gynecology risk assessment model (RCOG) score for pregnant women[10-12].

A list of VTE risk factors were incorporated in the CDSS. A score of one was assigned for the following risk factors: Age > 35 years, body mass index (BMI) > 30, parity > 3, immobility for four days, varicose veins, systemic infections, pre-eclampsia, second or third trimester of pregnancy, hospital admission, multiple pregnancy, smoking and *in vitro* fertilization. Furthermore, a score of 1.5 was assigned for heart or lung disease, inflammatory diseases, nephrotic syndrome, surgery, oestrogen related VTE with negative family history or thrombophilia. Finally, a score of 3 was assigned for history of anti-phospholipid syndrome, unprovoked VTE, oestrogen related VTE with positive family history or positive thrombophilia screen or patients with history of recurrent VTE[12].

The CDSS also has a heparin exclusion centre which included the following criteria: active bleeding, hypersensitivity to heparins, heparin induced thrombocytopenia, recent intra ocular or intracranial surgery within the past three months, spinal tap within the past 24 hours, inherited or acquired coagulopathy, the use of oral anticoagulant, platelets less than 70 x 10^9/L, oesophageal varices, active peptic ulcers, and intracranial aneurysm or angioma [1].

Total score of equal to or more than four was identified as high-risk score and is an indication for thromboprophylaxis. Venous thromboembolism risk score assessment by an independent expert

hematologist was based on RCOG scoring system. The total risk score for VTE was calculated for each patient, both by using the smart phone CDSS and by an independent expert hematologist. Thromboprophylaxis decision generated by the smart phone CDSS was compared to that of the expert in terms of the indications for thromboprophylaxis whether thromboprophylaxis is indicated or not. Validity of the CDSS was tested by correlating the decision generated by CDSS to that of expert hematologist.

Statistical Methods

All the demographic data were entered into the predesigned proforma. Data was analysed using IBM SPSS Statistics for Windows, Version 20 (IBM Corp., Armonk, NY USA). Mean and standard deviation were calculated for quantitative variables like age and BMI. The correlation coefficient is a measure that determines the degree to which two variables' movements are associated. A positive corroboration, when r is greater than 0, signifies that both variables move in the same direction. The closer the value of r is to +1, the stronger the linear relationship. The Pearson's correlation coefficient analysis was done between the recommendation in each patient between CDSS and the expert. The percent correlation coefficient was used for validation.

Results

One hundred and eighty-eight patients were included in the study. Of these, 116 (61%) were gynecology patients, and 72 (39%) were obstetric. Age ranged between 17 and 81 (mean age 40.7 ± 12.8). Body mass index ranged from 16-54 (Mean = 28.4 ± 7.0). (Table 1). Sixty-seven percent of all patients were classified as high risk for developing VTE according to CDSS as shown in Figure 1.

Gynecology Patients

There were 116 (61%) patients with gynaecological diagnoses, with a mean age of 45.5 (± 13.5), and a mean BMI of 28.1 (± 6.8) (Table 1). Patients with a high score represented 54% (Fig. 1).

Figure 1. High-risk score among different patients group.

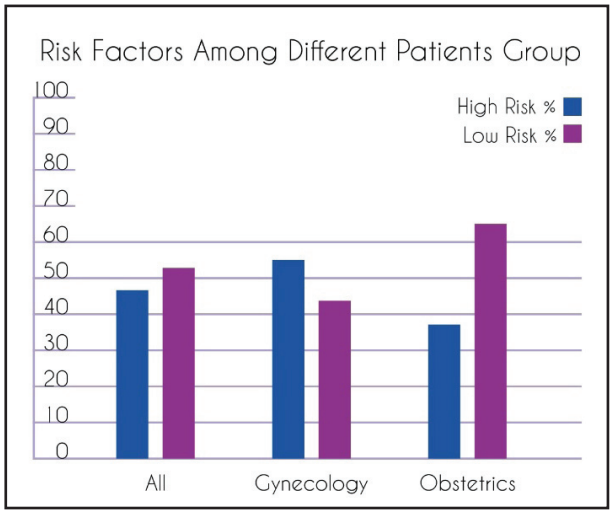

Table 1. Demographics of obstetrics and gynecology patients.

	ALL	Obstetrics	Gynecology
Number	188	72	116
Frequency		38.3%	61.7%
Age			
Minimum	17	21	17
Maximum	81	44	81
Mean	40.7	33.2	45.5
SD	12.8	6.2	13.5
BMI			
Minimum	16	18	16
Maximum	54	49	54
Mean	28.4	28.9	28.1
SD	7	7.2	6.8
Parity			
Minimum		0	0
Maximum		12	13
Mean		3.5	1.8
SD		3	2.7

BMI: Body mass index; SD: Standard deviation

Obstetric Population

Seventy-two patients (38.3%) were admitted during pregnancy. The mean age for obstetric patient was 33.2 (± 6.24). Of these 18% where primigravidae, 30.5% were admitted during the first trimester, 30.5% in the second trimester and 38.8% in the third trimester. The mean BMI was 28.9 (± 7.2). Patients with a high score represented 47% (Fig. 1). The prevalence of risk factors for VTE among obstetrics and gynecology patients are shown in Table 2.

Validation of Clinical Decision Support System

Correlation studies between expert opinion and CDSS regarding decision for thromboprophylaxis showed strong positive correlation in all patients; in gynecology and in obstetrics patients (r = 0.9, 0.94 and 0.81), respectively, using Pearson's correlation (Table 3).

Discussion

The risk of VTE among hospitalized patients can be markedly reduced with proper thromboprophylaxis[1]. However, there is poor adherence to thromboprophylaxis guidelines among hospitalized patients[13]. Furthermore, women are more likely than men not to receive thromboprophylaxis[14]. Risk factors for VTE include advanced age, obesity, smoking and the use of oral contraceptive pills[15-18]. Family history of VTE, inherited thrombophilia, recent surgery, and active malignancy are also major risk factors[19].

Table 2. Risk factors for venous thromboembolism in study population.

Risk Factors	All		Obstetrics		Gynecology	
	Frequency	%	Frequency	%	Frequency	%
Malignancy	24	12.8%	0	0%	24	20.7%
Heart	18	9.6%	2	2.8%	16	13.8%
Infection	6	3.2%	2	2.8%	4	3.4%
Preeclampsia	3	1.6%	3	4.2%	NA	NA
Hyperemesis	3	1.6%	2	2.8%	NA	NA
Lung	2	1.1%	2	2.8%	2	1.7%
OCCP	1	0.5%	0	0%	1	0.9%
History of VTE	2	2%	1	1.4%	1	0.9%

OCCP: Oral Contraceptive Pills; VTE: Venous thromboembolism; NA: Not Applicable

Table 3. Correlation coefficient between clinical decision support system and expert opinion in all patients and in obstetrics and gynecology patients.

	CDSS	Expert	Number
All			
CDSS			
Pearson's Correlation	1	.904	188
Sig. (2-tailed)		.000	
Expert			
Pearson's Correlation	.904	1	
Sig. (2-tailed)	.000		
Gynecology			
CDSS			
Pearson's Correlation	1	.949	116
Sig. (2-tailed)		.000	
Expert			
Pearson's Correlation	.949	1	
Sig. (2-tailed)	.000		
Obstetrics			
CDSS			
Pearson's Correlation	1	.818	72
Sig. (2-tailed)		.000	
Expert			
Pearson's Correlation	.818	1	
Sig. (2-tailed)	.000		

CDSS: Clinical decision support system

Venous thromboembolism prevalence, risk factors and risk assessment models vary between obstetrics and gynecology patients.

The hypercoagulable status of pregnancy is a physiological method of adaptation to reduce risk of haemorrhage during and after delivery. Pregnant women are at higher risk of VTE compared to non-pregnant women. Clinically significant VTE occurs in 1 of every 1000 pregnancy and 1 in 2000 deliveries and it is considered as one of the most common causes of maternal deaths[20]. The risk further increases to multiple folds in the third trimester and during hospitalization[21]. Treatment of VTE during pregnancy presents a significant challenge to healthcare providers[22]. Moreover, guidelines on the management of VTE, are developed based on data in the non-pregnant patient and extrapolated to obstetric patients[23]. On the other hand, risk factors for VTE among gynaecological patients include; high BMI, *diabetes mellitus*, longer hospital stay and longer operative time[24]. Following gynaecologic surgery, the incidence of VTE secondary to lack of thromboprophylaxis is between 17-40%[25]. The risk of VTE is particularly high following surgery for gynaecological malignancies and hysterectomy [26].

Despite the availability of RAM and guidelines for thromboprophylaxis, guidelines are generally underutilized[25]. Methods to improve adherence of thromboprophylaxis guidelines in the hospital include RAM tools whether as cards or in electronic form. Strategies for improvement of adherence to VTE prophylaxis such as laminated cards and educational training were not adequate to improve outcomes and reduce rates of VTE[4]. Risk stratification in the absence of a RAM tool can be challenging[27]. Clinical decision support system is an appropriate and easily accessible method for improving qualitative health care. Kucher *et al.*[29] showed that when computer-generated alerts highlight risk factors, improvement in adherence to VTE prophylaxis was noted. Physicians have started using computer-alert program resulting in reduced rates of VTE in hospitalized patients at risk[29]. Furthermore, a systematic review summarizing trials of CDSS implementation concluded that CDSSs are effective at improving health care process measures across diverse settings, but evidence for clinical, economic, workload, and efficiency outcomes remains sparse[30]. The review also concluded that CDSS systems with embedded algorithms have been used as an effective tool for prevention of VTE[30]. In addition, Haut *et al.*[31] showed that implementation of a CDSS significantly improved compliance with VTE prophylaxis guidelines in hospitalized adult trauma patients. This improved compliance was associated with a significant decrease in the rate of preventable VTE events. However, systematic testing of CDSS prior to release to general users is a critical aspect of high quality software design. Omission of this step may lead to potentially fatal condition of relying on a system with outputs of uncertain quality. Testing requires a great deal of effort and it requires attention to a large number of details.

In our study, we validated a locally developed smartphone CDSS for VTE risk stratification using the widely accepted RAM which generate a thromboprophylaxis decision among hospitalized obstetrics and gynecology patients. The routine use of this tool in a hospital setting could advance physician knowledge, enable physicians to intervene early, assist in choosing the most effective method of thromboprophylaxis and improve patient outcomes. Moreover, in remote areas and in facilities with limited resources or lack of specialists, CDSS could be a useful tool.

Limitations

The study limitations include small sample size. Furthermore, only one hospital was included in the study and the CDSS needs to be validated outside of experienced academic centres. In addition, for meaningful validation multiple expert hematologists should be included. Finally, the study did not address the clinical and economic outcomes.

Considerations for Further Research

Future research should be undertaken to establish validity using a larger, more diverse sample size. Furthermore, longitudinal follow-up of assessed patients for verification of our CDSS is required before it is introduced in routine clinical practice. In addition, post-implementation study should evaluate the effect of CDSS on physician compliance with evidence-based guidelines and on VTE outcomes in patient population.

Conclusion

Clinical decision support system has shown validity for risk stratification of hospitalized obstetrics and gynecology patients, when compared to an expert

opinion. Thus there is a role for CDSS as a RAM tool and for determination of thromboprophylaxis among hospitalized obstetrics and gynecology patients.

Conflict of Interest

The authors have no conflict of interest.

Disclosure

None of the authors received any type of commercial support either in forms of compensation or financial for this study. They have no financial interest in any of the products or devices, or drugs mentioned in this article.

Ethical Approval

Obtained.

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التحقق من صحة تطبيق الهاتف الذكي لتقييم خطر التعرض للجلطات الوريدية في مريضات قسم النساء والتوليد

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المستخلص. الجلطات الدموية الوريدية هي حالة خطيرة يمكن الوقاية منها. ومع ذلك، تحدث منها الوفيات بسبب عدم استخدام الطرق الوقائية. المرضى النساء خطر عرضة للجلطات الدموية الوريدية. لتحسين الالتزام بالوقاية في هؤلاءالمرضى، قمنا بإنشاء تطبيق على الهواتف الذكية نظام صمم لتقييم الخطر لحدوث الجلطات الدموية الوريدية والتوصية لاستخدام الطرق الوقائية. تم جمع البيانات السريرية عن طريق مراجعة الملفات الطبية الإلكترونية. تم حساب درجة الخطر و توصيات الوقائية لكل مريضة بواسطة أخصائي أمراض الدم و مقارنة النتائج بالتوصيات المستخلصة من تطبيق الهاتف الذكي. تم إدراج ١٨٨ مريضة تم ادخلهن لمستشفى جامعة الملك عبدالعزيز بين ديسمبر ٢٠١٥ ومارس ٢٠١٦. مائة وستة عشر من أمراض النساء، و ٧٢ من مرضى التوليد الذين يبلغ متوسط أعمارهم ٧,٤٠ (±٨,١٢). وأظهرت النتائج إن خطر الجلطات الدموية الوريدية المستخلصة من التطبيق على علاقة قوية مع خبير أمراض الدم (ص = ٨٣٪). كما أظهر التطبيق علاقة جيدة لقرار الوقائي مع رأي خبير أمراض الدم. و من ثم يعتبر تطبيق الهاتف الذكي أداة صالحة لتقييم الخطر لحدوث التجلطات الوريدية في مرضى النساء وأن سهولة الحصول وسهولة استخدام التطبيق يمكن أن يساهم في تحسن النتيجة السريرية للمرضى المنومين المستشفى.