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¹Department of Clinical Pharmacy, Pharmacy Sciences, Al-Sadr Medical City, Al-Najaf Health Directorate, Al Najaf Al-Ashraf, Iraq

²Faculty of Pharmacy, University of Kufa, Iraq

3Department of Pharmacology and therapeutics, Faculty of Medicine, University of Kufa, Iraq

Corresponding author: Najah R. Hadi, Department of Pharmacology and therapeutics, Faculty of Medicine, University of Kufa, Iraq, E mail: drnajahhadi@yahoo.com, ORCID ID: https://orcid.org/0000-0001-9084-591X.

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Evaluating the Current Practice of Post Cesarean Thromboprophylaxis and Enhancing Guideline Adherence in Al-Najaf Hospitals

Safa Emad J. Suker¹, Ayad A Hussein AL-Ameen², Najah R. Hadi³

ABSTRACT

Background: Venous thromboembolism (VTE) is one of the most common cardiovascular disorders in the United States and is manifested as deep vein thrombosis (DVT) and pulmonary embolism (PE) which represented as the most important cause of death in pregnant women after cesarean section. Venous thromboembolism (VTE) is representing the second direct cause of death which is accounting for 13.8% of all mother's death in the world. The most common risk factor of venous thromboembolism (VTE) is cesarean section. Objective: The study aims to study the current practice of post-cesarean thromboprophylaxis in dosing calculation and duration of therapy. Methods: Between September 2020 and January 2021, an observational- interventional prospective pre and post-study, was conducted in all hospital of Najaf in the City center and the suburbs that contain gynecology and obstetric ward to assess the current practice of post-cesarean thromboprophylaxis and to evaluate the impact of pharmacist intervention program to improve guideline adherence then after intervention. Another 102 patients were enrolled to analyze the change thromboprophylaxis according to the guideline. Results: From patient data, the rate of adherence to guidelines raised significantly among the post-intervention patients' group by thromboprophylaxis dose according to body weight was increase significantly (p<0.001) from 56.9% in the observation phase to 83.3% after intervention and about the duration of thromboprophylaxis is significantly (p<0.001) from 18.6% in the observation phase to 52.0% after the intervention. Conclusion: This study showed that the clinical pharmacist's multifaceted intervention has resulted in encouraging guideline implementations as reflected by improving the proper use of thromboprophylaxis the duration anddosing calculations according to body weight.

Keywords: Venous thromboembolism, deep vein thrombosis, pulmonary embolism.

1. BACKGROUND

Venous thromboembolism (VTE) is one of the most common cardiovascular disorders in the United States. VTE is manifested as deep vein thrombosis (DVT) and pulmonary embolism (PE) resulting from thrombus formation in the venous circulation (1).

The true incidence of VTE in the general population is unknown because many patients, perhaps more than 50%, have no overt symptoms or go undiagnosed (2). The median absolute VTE risk during pregnancy is reported to be 5.7 per 10,000 deliveries, with the preponderance of studies showing an increased risk of VTE through each passing trimester of pregnancy, a peak one to three weeks postpartum and then a decline in risk equivalent to a non-pregnant state by 6 weeks postpartum (3).

The postpartum period is higher risk than the intrapartum period and women delivered by elective cesarean section have at least double the postpartum risk of VTE compared with vaginal birth (4). The risk of postpartum VTE after an emergency Cesarean section is twice that after an elective cesarean section and four times that after vaginal delivery (5).

2. OBJECTIVE

The study aims to study the current practice of post-cesarean thromboprophylaxis in dosing calculation and duration of therapy.

3. PATIENTS AND METHODS

Study Design and Setting for the Patient: between September 2020 and January 2021, an observational interventional prospective pre and post-study, was conducted in all hospital of Najaf in the city center and the suburbs that contain Gynecology and Obstetric ward at Najaf governorate, Iraq to the current practice of post-cesarean thromboprophylaxis and to evaluate the impact of pharmacist intervention to improve guideline adherence.

Study Population and Sample of the Participants Patient

Observation Phase (Pre-intervention)

For evaluation of the current practice, 102 patients' cases from Gynecology and obstetric wards were taken pre-intervention. Patients' medical records were excluded where data concerning unclear handwriting, and incomplete patient information. A purpose-designed data sheet was used to collect patients' details from the patient then compare them with a medical file. Regarding the main barriers and reasons behind the current prescribing of thromboprophylaxis, we designed a qualified questionnaire directed to main decision-makers in the hospital who are the obstetricians and collecting their opinion for the main reasons contributing to the current practice of post-cesarean thromboprophylaxis whether related to patients, health care system, as well as pharmacist, nurse and/or prescriber himself. 110 patients were reviewed for eligibility. Among them, 8 patients were excluded because of exclusion criteria, and 102 patients were enrolled and reviewed to evaluate the current practice of thromboprophylaxis of each patient.

Inclusion criteria

Women undergo Cesarean section.

Exclusion criteria

Contraindication of pharmacological thromboprophylaxis include one or more of the following: Evidence of active bleeding or high-risk bleeding or if the patient has a history of Heparin-Induced Thrombocytopenia (HIT) in which the platelet account less than 100000/ mm3.

Intervention phase

After the observation phase and because the obstetricians are the decision-maker and the leader of any team in the operation room, the study intervention was implemented in which the clinical pharmacist performed a lecture presentation activation the role of a clinical pharmacist to participate in the regulation dose and working as a team and to create awareness of the clinical pharmacist in the ward about VTE problem and the administration of dose according to body weight and the guideline recommendations according to the RCOG consensus guideline for VTE (6). The pharmacist multifaced intervention includes:

- A lecture presentation;
- Distribution of booklets to all clinical pharmacist, obstetricians, and all residents in Gynecology and Obstetric wards;
- Posters hanging in the gynecology and obstetric wards including the risk score to increase the

	Patients' Group					
Variable		Before inter- vention (N = 102)			After intervention (N=102)	
		No.	%	18 17.6 3 2.9 82 80.4 17 16.7 26 25.5	%	
Age	Age \leq 35	84	82.4	84	82.4	- 1.00
луе	Age > 35	18	17.6	18	17.6	1.00
\\/_:	< 50	3	2.9	3	2.9	0.861
Weight	50 - 90	79	77.5	82	80.4	
(kg)	91 - 130		16.7	-		
	Illiterate	21	20.6	26	25.5	0.539
	Read and Write	23	22.5	21	20.6	
Education	Primary	17	16.7	15	14.7	
	Secondary	24	23.5	25	24.5	
	College or higher	17	16.7	15	14.7	
Occupa-	Housewife	70	68.6	74	72.5	- 0.926
tion	Employed	32	31.4	28	27.5	

Table 1. Demographic characteristics of selected patients before and after intervention program

		Patients' Group					
Variable		Before inter- vention (N = 102)		After inter- vention (N=102)		P. value	
		No.	%	No.	%		
Crovid	1 - 2	47	46.1	44	43.1		
Gravid- ity	3- 4	22	21.6	27	26.5	0.715	
ity	> 4	4 33 32.4 31 ulliparous 23 22.5 25 - 2 34 33.3 32	30.4				
	Nulliparous	23	22.5	25	24.5	- - 0.953 -	
Darity	1 - 2	34	33.3	32	31.4		
Parity	3 - 4	30	29.4	28	27.5		
	> 4	15	14.7	17	16.7		
A I	None	69	67.6	66	64.7		
Abor-	1 - 2	29	28.4	34	33.3	0.568	
tion	3 or more	4	3.9	2	2.0	-	
History of Ce-	None	51	50.0	48	47.1		
	1 - 2	31	30.4	36	35.3	0.752	
sarean sections	3 or more	20	19.6	18	17.6	- 0.752	

Table 2. Obstetrical history of patients before and after intervention program

.knowledge of all health care provides include the nurse, pharmacist, obstetricians, and residents **Post-Intervention phase**

Out of 115 patients examined for eligibility, 13 patients did not meet the inclusion criteria or Patients' medical records were excluded where data concerning unclear handwriting, and incomplete patient information, and 102 patients were enrolled in this phase of the study. That was to check the improvement of thromboprophylaxis agent dose according to guideline recommendations.

Data collection from the patients

We examined the demographic variables of the patient about their age, weight, height to calculate the BMI which is an important risk factor for prophylaxis and the weight is important for the dose of the drug and ask

Patients' Group							
Туре	Before intervention (N = 102)		After intervention (N=102)		P. value		
	No.	%	No.	%			
Elective	79	77.5	75	73.5	0 515		
Emergency	23	22.5	27	26.5	- 0.515		
Total	102	100.0	102	100.0			

Table 3. Type of cesarean section labor of patients before and after intervention program

Preexisting Risk factor	Before interven- tion (N = 102)		After intervention (N=102)		P. value
	No.	%	No.	%	-
Age > 35	18	17.6	18	17.6	1.00
Parity \geq 3	42	41.2	45	44.1	0.661
Obesity	38	37.3	35	34.3	0.671
Smoking	11	10.8	8	7.8	0.47
Previous VTE	2	2.0	3	2.9	0.651
Previous VTE provoked by major surgery	3	2.9	2	2.0	0.561
Known high risk thrombo- philia	1	1.0	1	1.0	1.00
Comorbidities	11	10.8	14	13.7	0.522
Family history of VTE	2	2.0	1	1.0	0.561
Immobility/ dehydration	0	0.0	1	1.0	0.316
Gross Varicose Veins	17	16.7	13	12.7	0.429

Table 4. Distribution of Preexisting Risk factors of patients before and after intervention program

the patient about the residence, occupation, education, gestational age, obstetric history (gravidity, parity, and abortion or stillbirth deliver), medical history, surgical history, type of Cesarean section and then finally make an assessment about the risk factors and ask them for all risk factors and additional information about the pharmacological prophylaxis after Cesarean section either elective or emergency and the dose with the duration of LMWH after delivery depending on individual risks of the patient. Then includes the evaluation performed by the clinical pharmacist who could improve VTE prophylaxis through the assessment of reporting of risk factors, receiving thromboprophylaxis when patients had absolute indications, Initiation of thromboprophylaxis, Thromboprophylaxis dose according to body weight, and duration of thromboprophylaxis according to patient calculated risk score.

4. **RESULTS**

After review of patients' medical records by the researcher, before and after intervention program to assess Thromboprophylaxis administration and adherence to VTE prophylaxis guidelines, it had been found that before intervention, risk factors of VTE were optimally reported in 63.7% of patients and scored according to

Obstetrical Risk factor	Before inter- vention (N = 102)		After tion (N=10	interven-)2)	P. value
	No.	%	No.	%	
Preeclampsia	27	26.5	24	23.5	0.628
Assisted reproduc- tive therapy	20	19.6	15	14.7	0.353
Multiple pregnancy	4	3.9	5	4.9	0.733
Prolonged labor	6	5.9	4	3.9	0.654
Emergency Cesare- an section in labor	23	22.5	27	26.5	0.710
Post-Partum Hem- orrhage	3	2.9	5	4.9	0.517
Preterm birth < 37 weeks	23	22.5	17	16.7	0.471
Stillbirth in current pregnancy	5	4.9	3	2.9	0.290

Table 5. Distribution of obstetrical risk factors of patients before and after intervention program

	Patier	_			
Transient Risk factor*	ventio	Before inter- vention (N = 102)		After interven- tion (N=102)	
	No.	%	No.	%	
Any surgical procedure in pregnancy	2	2.0	0	0.0	0.477
Dehydration	14	13.7	16	15.7	0.693

Table 6. Distribution of Transient Risk factor of patients before and after intervention program *Other transient risk factors were not reported among the patients

the guideline. Vast majority of patients (98%) with absolute indication, received thromboprophylaxis, Proper initiation of thromboprophylaxis reported in 96.1%. Optimal thromboprophylaxis dose according to body weight was administered in 56.9%, and optimal duration of thromboprophylaxis reported in 18.6% of patients. After intervention the corresponding percentages of these evaluation items was optimized to a proportion of 80.4%, 100%, 97.1%, 83.3%, and 52%, respectively (Table 7).

Regarding the barriers of administration thromboprophylactic guidelines and adherence, high cost was the main cause of non-adherence with the guidelines which was reported by (86%), followed by concern about bleeding risks reported by 71.9%. Difficult or inconvenient to use guidelines in our patients, and patients complain and incompliance (52.6%). Other barriers are demonstrated in (Table 8).

5. DISCUSSION

During the observation phase, we found the obstetricians prescribe thromboprophylaxis and they initiated proper thromboprophylaxis. However, the risk factors are not well reported that means the obstetricians depend on their experience, knowledge, and practice to decide and calculate the risk factors, and decided

	Patients' Group					
Category	Before interven- tion		After intervention		P. value	
	No.	%	No.	%	_	
Optimal reporting of risk factors	65	63.7	82	80.4	0.008 sig	
Thromboprophylaxis prescribed to patients with absolute indica- tions	100	98.0	102	100.0	0.477 ns	
Proper initiation of thrombopro- phylaxis	98	96.1	99	97.1	1.00 ns	
Optimal Thromboprophylaxis dose according to body weight	58	56.9	85	83.3	< 0.001 sig	
Optimal Duration of thrombopro- phylaxis	19	18.6	53	52.0	< 0.001 sig	

Table 7. Results of Evaluation of practice and adherence to guidelines before and after intervention

Barrier	No.	%
1-High costs	49	86.0
2-Concern about bleeding risks	41	71.9
3-Difficult or inconvenient to use guidelines		
in our patients, and patients complain and	30	52.6
incompliance		
4-Lack of awareness of guidelines	28	49.1
5-Need for new resources or facilities that	27	47.4
are not available in our hospitals	21	47.4
6-Lack of familiarity with guidelines	19	33.3
7-Concern about infection resulting from	14	24.6
wound hematomas		21.0
8-Lack of self-efficacy of some physicians	14	24.6
(perceived inability to follow guidelines)		21.0
9-Disagreement between guidelines is	6	10.5
confusing	0	10.5
10-VTE not practiced as a problem in our	3	5.3
experience	5	5.5

Table 8. Barriers and causes of current practice versus guideline adherence reported by obstetricians

the treatment indicated or not based on their experience. However, one of the main finding that we found a significant gap in the dosing calculation according to bodyweight which is the main responsibilities of clinical pharmacist to optimize the patient therapy management and this can be done via joining obstetricians in the morning tour to ensure optimum dose calculations.

The use of thromboprophylaxis during the postpartum period and pregnancy is an important topic in the many literature and societies of obstetricians and gynecologist by using the correct thrombophylactic agent, timing, and dosing that interfere significantly with the outcome of the pregnancy and postoperatively in women undergoing Cesarean section (CS) (7, 9). The duration of the treatment is reported by the obstetricians according to the guideline but the true cause of nonadherence of the patient is the cost of the drugs and the patient can't buy the treatment from out pharmacy lead to nonadherence to thromboprophylaxis where the majority of obstetricians (86%) stated that they prescribed thromboprophylaxis but non-compliance of the patient to reject using the prophylactic agent due to high cost. In the previous multinational, longitudinal, observational study only 63.4% of patients are prescribed the same after hospital discharge.

The main reasons for the observed gap between real-life clinical practice low perception of the patient at hospital discharge and high cost of prophylaxis (10). During the last four years data available from the Ministry Of Health (M.O.H) showed that the incidence of VTE among patients undergo C.S is increasing for instance available data from the Department of Public Health in Najaf Health Directorate for this period revealed an increasing number of C.S which leads to

increase in the risk of VTE; However among the different causes of maternal mortalities VTE particularly PE was a major cause of maternal mortality which is ranked number one among these cases and contributed 24% of all maternal mortality causes. Therefore, we needed to minimize any barrier to behind the current gap in prescribing practice of thromboprophylaxis. Another barrier is about 47.4% is no resources or facilities that are available in our hospitals that increase the compliance of the patients such as availability of LMWH for outpatient is very important to improve the adherence to guideline the correct duration should be supported by giving the patient all treatment before discharge. The duration of thromboprophylaxis which related to the absence or not the availability of the product in the hospital and the cost of the drug is high and the patient culture. Thirty obstetricians (52.6%) said that difficult or inconvenient to use guidelines in our patients, patients complain or in compliance due to pain at the site of injection or poor knowledge about VTE complication and this similar to the previous study have reported that poor adherence of patients and poor knowledge about VTE complications in the long term lead to noncompliance to their medication (11).

The major barrier to their use or practice of thromboprophylaxis the obstetricians was about 71.9% of them concerning bleeding risk this finding similar to a multicenter study by involving healthcare providers including physicians, pharmacists, and research coordinators in 27 intensive care units in Canada, certain barriers to thromboprophylaxis practices were identified. These include, in order of decreasing frequency; cost of acquiring drugs, fear of patient bleeding, lack of resident information (12). Then in the intervention phase, we initiated multifaced intervention to support the already existing program about thromboprophylaxis use which was started by the gynecology and obstetrics branch of medicine collage of Kufa University in collaboration with the Al-Najaf Heath Directorate since years in addition to activation the role of a clinical pharmacist to participate in the regulation dose and there is improvement in the reporting of risk factors, thromboprophylaxis dosing according to body weight andduration of thromboprophylaxis according to score. This is similar to a previous study from the Kingdom of Saudi Arabia reported by Al-Tawfiq and Saadeh that the use of multiple interventions increased the VTE prophylaxis compliance rate (13). In another study in Italian, Teaching Hospital observed that the adoption of multiple interventions including presentation, pocket guidelines, implementation of the working group to identify barriers to change resulted in an increase as well as appropriate use of VTE prophylaxis among surgical patients from 64% to 97% (14).

6. CONCLUSION

This study showed the current practice of post-cesarean thromboprophylaxis need further optimization in dosing calculation and duration of therapy according to patient risk score and the clinical pharmacist's multifaceted intervention resulted in improving thromboprophylaxis prescribing pattern in accordance with guideline recommendations.

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REFERENCES

- Schiro TA, Sakowski J, Romanelli RJ, Jukes T, Newman J, Hudnut A, et al. Improving adherence to best-practice guidelines for venous thromboembolism risk assessment and prevention. Am J Health Syst Pharm. 2011 Nov 15; 68(22): 2184-2189. doi: 10.2146/ajhp110102. PMID: 22058105
- Heit JA. Epidemiology of venous thromboembolism. Nat Rev Cardiol. 2015 Aug; 12(8): 464-474. doi: 10.1038/nrcardio.2015.83.
- Carballes MG, Ríos-Vives MA, Fierro EC, Azogue XG, Herrero SG, Rodríguez AE, et al. A Pictorial Review of Postpartum Complications. Radiographics. Nov-Dec 2020; 40(7): 2117-2141. doi: 10.1148/rg.2020200031.
- Domingues RMSM, Dias MAB, Schilithz AOC, Leal MdC. Factors associated with maternal near miss in childbirth and the postpartum period: findings from the birth in Brazil National Survey, 2011-2012. Reprod Health. 2016 Oct 17; 13(Suppl 3): 115. doi: 10.1186/s12978-016-0232-y.
- 5. Jackson E, Curtis KM, Gaffield ME. Risk of venous thromboembolism during the postpartum period: a systematic re-

view. Obstet Gynecol. 2011; 117(3): 691-703. doi: 10.1097/ AOG.0b013e31820ce2db.

- 6. Royal college of obstetritian and gynicologist. Reducing the risk of venous thromboembolism during pregnancy and the puerperium. Green Top Guidel. 2015; (37a): 1-40.
- Bates SM, Middeldorp S, Rodger MR, James AH, Greer I. Guidance for the treatment and prevention of obstetric-associated venous thromboembolism. J Thromb Thrombolysis. 2016 Jan; 41(1): 92-128. doi: 10.1007/s11239-015-1309-0.
- Bates SM, Rajasekhar A, Middeldorp S, McLintock C, Rodger MA, James AH, et al. American Society of Hematology 2018 guidelines for management of venous thromboembolism: venous thromboembolism in the context of pregnancy. Blood Adv. 2018 Nov 27; 2(22): 3317-3359. doi: 10.1182/bloodadvances.2018024802.
- Goecke T, Voigt F, Rath W. Thromboprophylaxis following cesarean section-a nation-wide survey from Germany. J Matern Fetal Neonatal Med. 2020 Jul; 33(14): 2359-2365. doi: 10.1080/14767058.2018.1550064.
- Arcelus JI, Felicissimo P, DEIMOS Investigators. Venous thromboprophylaxis duration and adherence to international guidelines in patients undergoing major orthopedic surgery: results of the international, longitudinal, observational DEI-MOS registry. Thromb Res. 2013 Jun; 131(6): e240-6. doi: 10.1016/j.thromres.2013.03.014.
- Alzoubi KH, Khassawneh BY, Obeidat B, Asfoor SS. Awareness of patients who undergo cesarean section about venous thromboembolism prophylaxis. J Vasc Nurs. 2013; 31(1): 15-20. http://dx.doi.org/10.1016/j.jvn.2012.07.001
- Cook D, Duffett M, Lauzier F, Ye C, Dodek P, Paunovic B, et al. Barriers and facilitators of thromboprophylaxis for medical-surgical intensive care unit patients: a multicenter survey. J Crit Care. 2014; 29(3): 471-e1
- Al-Tawfiq JA, Saadeh BM. Improving adherence to venous thromoembolism prophylaxis using multiple interventions. Ann Thorac Med. 2011; 6(2): 82. doi: 10.4103/1817-1737.78425
- Scaglione L, Piobbici M, Pagano E, Ballini L, Tamponi G, Ciccone G. Implementing guidelines for venous thromboembolism prophylaxis in a large Italian teaching hospital: lights and shadows. Haematologica. 2005 May; 90(5): 678-684.