

Effect of Teaching Booklet on Compliance to Oral Anticoagulant Drugs among Patients with Deep Venous Thrombosis

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Abstract

Background: Treatment for patients with deep venous thrombosis relies on persuading the patient to adhere entirely to the therapeutic plan. Patient education is an important aspect in increasing compliance. **Aim:** To evaluate the effect of teaching booklet on compliance to oral anticoagulant drugs among patients with deep venous thrombosis. **Research design:** Quasi-experimental research design. **Setting:** The study was conducted at vascular surgery department and trauma unit at Assiut University Hospital. **Sample:** A purposive sample of 60 male and female adult patients. This sample was divided into study and control group (30 patient for each) diagnosed with DVT, their age ranged from 18 to 65 years. **Tools:** Tool I: Patient assessment sheet, Tool II: Compliance of patients with medications by using Morisky Medication Adherence Scale. **Results:** There was a statistically significant difference between study and control group regarding compliance to oral anticoagulant drugs post application of teaching booklet. **Conclusion:** Teaching booklet was effective in improving patient's compliance to oral anticoagulant drugs, lower incidence of bleeding and recurrence of thrombus among patients with deep venous thrombosis. **Recommendations:** Teaching booklet for DVT patients to improve adherence to oral anticoagulant should be available in vascular surgery department.

Key Words: Compliance, Deep venous thrombosis, oral anticoagulant drugs.

Introduction:

Deep vein thrombosis (DVT), is the term that is used to define a blood clot that develops within a deep vein in the body, most usually in the large vein that run through the muscles of the calf and thigh. This can lead to pain and swelling in the leg (Mark, 2019). Risk factors for DVT include aging over 40, obesity, immobilization especially after long journeys, history of hypercoagulation, genetic factors contributing to thrombophilia, other blood disorders, cancer, heart failure, bone fractures, smoking and recent surgery (Piazza et al., 2018).

The most common side effects of anticoagulation drugs used for DVT are disease recurrence, post-thrombotic syndrome, and serious bleeding. In the first six months after the onset of the disease, a mortality rate of 6 per cent was recorded. Recent findings have shown a high prevalence of recurrent DVT (RDVT), with half the occurrence of DVT in the U.S. being the recurrence of the disease. Significant bleeding took place in 1.0 to 11 per cent of the patients treated with warfarin (Alton et al., 2015).

Patients undergoing major orthopedic surgery showed risk for postoperative deep vein thrombosis (DVT) ranging from 46% to 60%. Home rehabilitation is recommended to prevent this risk, including nursing and/or

physical therapy, careful monitoring of international standardized ratios (INRs), and compliance with anticoagulant drugs (Pinelliet et al., 2015).

Compliance is to the degree patients are obedient and follow the health practitioners' orders and medications. Compliance of patients with the medication regimen requires a major need as it has beneficial impact on the treatment of disease. In fact, drug therapy benefits can only be achieved if patients follow the recommended treatment regimens (Krot and Sousa, 2017).

Patient commitment to anticoagulation therapy is crucial to attain the therapy's benefits while preventing its negative effects. Compiled research data indicate enforcement concerns related to abnormal clinical INR ranges, improper administration of anticoagulation medication and insufficient dietary management. Patient teaching booklet should address taking the anticoagulants the same time each day, noting or logging INR blood levels and changing dosing information, and adhering to exacting dietary modifications (Schwartz & Smith., 2016).

Patient awareness is an integral aspect of improving compliance and can be seen as the basis for any patient-core intervention, encouraging patients to make choices about their care and promoting their willingness and desire to comply with medical treatment (Marcus, 2014). Nurse is the provider of direct care to patients, nurses are also responsible for educating patients about their medical problems and the future effects on their lives. Nurse will be able to advise patients to adhere to medication procedures effectively to improve health habits and facilitate recovery (Piazza et al., 2018).

Significance of the study:

From the researchers' experiences, it was noted that patients' knowledge about importance of compliance to oral anticoagulants drugs are inadequate and need for improvement. Therefore this study is considered the first one in this geographical location to help patients improving their compliance to oral anticoagulants drugs and reduce recurrence of thrombus. DVT is one of the most prevalent medical problems today, with an annual incidence of 80 cases per 100,000, each year in the United States (Paul et al., 2019). In 2019, 260 cases were reported and diagnosed as DVT according to records of the vascular surgery department at Assiut University Hospital.

Aim of the Study:

To evaluate the effect of teaching booklet on compliance to oral anticoagulant drugs among patients with deep venous thrombosis.

Research hypothesis:

- After applying teaching booklet, the study group will show more compliance to oral anticoagulant drugs than control group.
- After applying teaching booklet, the occurrence of bleeding and recurrent thrombus in study group will be lesser than those in control group.

Subjects and Method

Research design:

Quasi-experimental research design was utilized in this study.

Study variables:

The independent variable was the teaching booklet, while the dependent variable was the compliance to oral anticoagulant drugs.

Setting of the study:

The study was conducted at vascular surgery department, outpatient of vascular surgery and trauma units at Assiut University Hospital.

Sample:

Inclusion criteria: A purposive sample of 60 male and female adult patients diagnosed with DVT, their age ranged from 18 to 65 years, willing to participate in the study, and free from cognitive impairment or active psychiatric disorders. This sample was divided into two equal groups; study and control groups (30 patients each). The study group who received teaching strategies and control group received routine hospital care.

Sample size

The power analysis to estimate the sample size was performed based on the result of previous study. Assuming power of 0.80% and 0.05 (one sided equivalence test). A total sample size of 50 participants is required. The eligible patients were invited to participate after the assessment whether they meet all of the inclusion criteria $n = 60$.

Tools:

Tool I: Patient assessment sheet, it was developed by researchers to assess demographic data, medical data, laboratory investigations and four months incidence of bleeding and recurrent thrombus. It included four parts

Part one: Socio demographic data

It involved patient name, age, sex, marital status, educational level, and occupation.

Part two: Medical data: it included history taking (presence of cardiac disorder, nicotine use, hypertension, diabetes mellitus, and affected side).

Part three: Laboratory investigation (blood coagulation studies): it included prothrombin time (PT) and concentration (PC) and international normalized ratio (INR).

Part four: Incidence of bleeding and recurrent thrombus in four months**Tool II: Compliance of patients with medications by using Morisky Medication Adherence Scale (MMAS-8)**

It was developed by (Morisky et al., 2008). It is used for assessing patients' adherence level to oral anticoagulant drugs. Eight questions were used for evaluating the patients' forgetfulness, patients understanding of the need for continued medications and if the patient felt it was inconvenient adhering to daily treatment plan.

Scoring system:

A score of zero was given for a positive response while a score of one was given for a negative response for questions 1, 2, 3, 4, 6 and 7 (Yes= 0; No= 1). Contrariwise, for item 5, a score of zero was given for a negative response while a score of one was given for a positive response (Yes= 1; No= 0). For item 8, if a patient chooses response "0",

the score is “1” and if they choose response “4”, the score is “0”. Responses “1, 2, 3” are respectively rated as “0.25, 0.75, 0.75”. The total score was eight. Patients who had a score below 6 were considered having low adherence. Patients who had a score between 6 < 8 were considered having medium adherence. While patients who had a score equal 8 were considered having high adherence.

Content validity:

It was established by a panel of five experts (three experts from Medical Surgical Nursing staff and two Vascular Surgery staff) who reviewed the tool for clarity, relevance, comprehensiveness, understanding, and applicability. Minor modifications were required. Test reliability of the proposed tools was ascertained with Cronbach’s alpha =0.829. For Morisky medication adherence scale the total standardized Cronbach’s alpha as a measure of reliability was (0.80), which showed that the internal consistency of the tools was good.

Pilot study:

It was implemented on 10% of the sample (six patients), to find out the feasibility of the study, and identify any difficulties needed to be handled. No changes were done to the tools, so the sample of the pilot study was included in the actual study sample.

Ethical considerations:

Permission to carry out the study was obtained from the ethical committee of the Faculty of Nursing and from the hospital authorities of vascular surgery department and trauma department at Assiut University Hospital. Prior to the initial interview, the researchers

introduced themselves to patients. Oral agreement for voluntary participation was obtained. Anonymity and confidentiality were assured through coding of the data.

Procedure:

This study was carried out in three phases:

I: Preparatory phase:

A review of current and past, local and international related literature in the various aspects using books, articles, periodicals and magazines were done. The tools and educational booklet were developed and reviewed by experts.

II: Implementation phase:

- The researchers met the selected patients; each patient was fully informed with the purpose and nature of the study and the patients’ agreement was obtained. Base line data were established using **tool I (part 1,2,3)** also assess compliance to oral anticoagulant drugs using (**tool II**). For the control group they were given the routine hospital instructions.

- For the study group the researcher explained the teaching booklet. They were given teaching booklet in clear Arabic language; each patient was met for two sessions. Each session took about 30 min. The study was carried out in the morning shift.

- **First session:** the researcher started by introducing herself to the patients telling them aim of the meeting, orient patients regarding teaching booklet. Contents of this session include: definition of DVT, causes of DVT, treatment of DVT, complications of DVT. **Second session:** summary about what has been discussed in a previous session, objectives of the new session, and

contents of this session includes: oral anticoagulant drugs, action of warfarin, dose of warfarin, side effects of warfarin, contraindications, precautions during treatment with warfarin, drug- drug interactions, drug- food interactions, noncompliance outcomes and the session ended by a summary of its content.

- After each session there was 5-10 minutes for discussion and feedback. The researcher used pictures and diagram to help them retain the learned material.

- The researchers arranged with the patients the time and place for follow up which were after four months in the outpatient of vascular surgery at Assiut University Hospital.

III- Evaluation phase:

In this phase study and control group patients were evaluated after four months for their compliance with the oral anticoagulant medication using (**Tool II**) and evaluated for incidence of bleeding and occurrence of thrombus using (**Tool I**) part four.

Statistical analysis

The data were tested for normality using the Anderson-Darling test and for homogeneity variances prior to further statistical analysis. Categorical variables were described by number and percent (N, %), where continuous variables described by mean and standard deviation (Mean, SD). Chi-square test and fisher exact test used to compare between categorical variables where comparing between continuous variables was done by t-test and ANOVA, a two-tailed $p < 0.05$ was considered statistically significant. All analyses were performed with the IBM SPSS 20.0 software.

Results:

Table (1) shows that the highest percentage of study and control group their ages more than 40 years were (86.7%, 66.67%) respectively. The majority of studied patients were male (60%), married (93.3%, 86.7%). Regarding to occupation it was found that (33.3%) of study group were housewives and retired while (40%) of control group were housewives.

Table (2) illustrates that medical co-morbidities cardiac disorder, hypertension and diabetes mellitus were documented in (53.3%), (53.3%, 40%) for study group and (20%, 40%, 26.7%) for control group. As regard affected side the highest percentages in both groups suffered from left side DVT.

Table (3) shows that there was no significant difference between study and control group pre application of teaching booklet while there was significant difference between study and control group post application of teaching booklet regarding laboratory investigation level.

Table (4) illustrates that 20% of study group had recurrent thrombus while 53.3% of control group had recurrent thrombus after four months. As regard bleeding it was found that 6.7% of study group had bleeding while 20% of control group had bleeding.

Table (5) shows that the highest percentages of study group (80%) had high compliance with medication after teaching booklet while (46.7%) of control group had low compliance with medication. There was significant difference between study and control group according to compliance of medication post application of teaching booklet.

Figure (1) shows that there was highly significant difference between laboratory investigations level and compliance with medication.

Table (6) illustrates that there was highly significant difference (<0.001**)

Table (1):- The difference between study and control group as regarding socio-demographic characteristics (n=60).

between compliance with medication and recurrent thrombus after four months and there was no significant difference between compliance with medication and bleeding for studied groups after four months.

Socio-demographic	Study		Control		P. value
	N.	%	N.	%	
Age group					
Less than 30 years	0	0.0	2	6.67	0.128
from 31-40 years	4	13.3	8	26.67	
More than 40 years	26	86.7	20	66.67	
Sex					
Male	18	60.0	18	60.0	1.000
Female	12	40.0	12	40.0	
Marital Status					
Single	2	6.7	4	13.3	0.389
Married	28	93.3	26	86.7	
Education					
Read and write	16	53.3	9	30.00	0.194
Preparatory	8	26.7	11	36.67	
Secondary	0	0.0	2	6.67	
University	6	20.0	8	26.67	
Occupation					
Office work	4	13.3	4	13.3	0.240
Machinery work	0	0.0	4	13.3	
Farmer	4	13.3	4	13.3	
House wife	10	33.3	12	40.0	
Retired	10	33.3	4	13.3	
Not working	2	6.7	2	6.7	

Table (2):- The difference between study and control group as regarding medical data (n=60).

Medical data	Study		Control		P.value
	N.	%	N.	%	
Cardiac disorder					
Yes	16	53.3	6	20.0	0.007**
No	14	46.7	24	80.0	
Nicotine Use					
Yes	10	33.3	16	53.3	0.118
No	20	66.7	14	46.7	
Hypertension					
Yes	16	53.3	12	40.0	0.301
No	14	46.7	18	60.0	
Diabetes Mellitus					
Yes	12	40.0	8	26.7	0.273
No	18	60.0	22	73.3	
Affected side					
Right side	8	26.7	8	26.7	0.351
Left side	20	66.7	22	73.3	
Bilateral	2	6.7	0	0.0	

Table (3):- The differences between study and control group as regarding laboratory investigation Level pre and post application of teaching booklet

Laboratory investigation Level	Study		Pre Control		P. value	Study		Post Control		P. value
	N.	%	N.	%		N.	%	N.	%	
- Normal	18	60.0	14	46.7	0.143	20	66.7	10	33.3	0.031*
- Low	2	6.7	0	0.0		6	20.0	14	46.7	
- High	10	33.3	16	53.3		4	13.3	6	20.0	

Table (4):- The differences between study and control group as regarding incidence of hemorrhage and recurrent thrombus after four months.

Outcomes	Study		Control		P.value
	N.	%	N.	%	
Recurrent thrombus					
Yes	6	20.0	16	53.3	0.007**
No	24	80.0	14	46.7	
Bleeding					
Yes	2	6.7	6	20.0	0.129
No	28	93.3	24	80.0	

Table (5):- The difference between study and control group regarding compliance with medication.

Total compliance level	Study		Control		P. value
	N.	%	N.	%	
Low compliance	6	20.0	14	46.7	0.004**
Medium compliance	0	0.0	4	13.3	
High compliance	24	80.0	12	40.0	
Mean±SD	5.75±2.44		3.55±2.68		0.002**

Figure (1) Correlation between compliance with medication and laboratory investigation level for studied patients post teaching booklet.

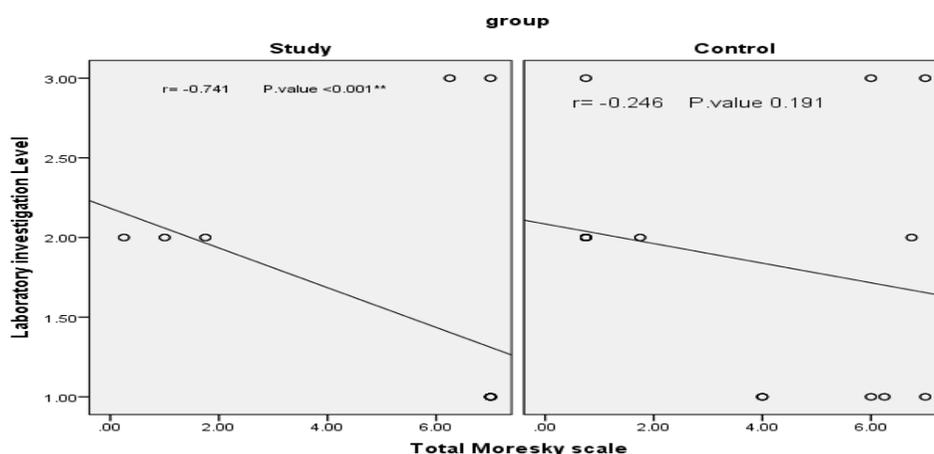


Table (6):- Relation between mean compliance with medication of the studied groups of patients and their outcomes after four months (n=60).

Outcomes	Study		Control	
	N	Mean±SD	N	Mean±SD
Recurrent thrombus				
Yes	6	1±0.67	16	1.63±2.03
No	24	6.94±0.21	14	5.75±1.22
P. value	<0.001**		<0.001**	
Bleeding				
Yes	2	6.25±0	6	4.58±3
No	28	5.71±2.52	24	3.29±2.6
P. value	0.770		0.299	

Discussion:

Medication non-adherence is an area of developing concern within healthcare. Patient compliance with anticoagulation therapy is vital to achieve the benefits of the therapy while avoiding its adverse effects. Compiled research data indicate compliance issues are related to irregular therapeutic INR ranges, improper anticoagulation medication administration, and improper dietary management (**John et al., 2016**).

Regarding Sociodemographic characteristics of patients, the present study showed that the highest percentages of both groups were their age more than forty years. This result represented that, the incidence of DVT increases with age. This finding was in line with a study conducted at the internal medicine of the University Hospital in Saarland by **Josef & Robert (2016)** revealed that elderly patients are at a high risk of DVT than younger patients. Also another study at American college of surgeons by **Baker et al., (2016)** reported that the incidence of DVT increases with age, and DVT is very rare in childhood.

Regarding sex the present study revealed that more than half of both groups were male respectively. This result in line with a study conducted at Jilin University, China by **Abdurrahman et al., (2018)** who showed that the incidence of both DVT and DVT recurrence is higher in men than women. Recurrent DVT was 1.8 times more common among men. This result disagreed with **Stone, (2017)** at Capella University who stated that, women are affected almost three times as often as men.

Regarding to occupation it was found that more than one third of study group were housewives and retired while

two fifth of control group were housewives. Study was done in Denmark by **Poul et al., (2012)** demonstrated that occupancy requiring longer and shorter sitting periods had a higher risk of venous thrombosis than community with more complex physical job requirements. From the researcher's opinion long period of sitting or standing increase risk for DVT.

Regarding medical co-morbidities; the results of the present study revealed that, the highest percentages in study and control groups had cardiac disorder, hypertension and diabetes mellitus. This result agrees with **Ljiljana et al., (2013)** who reported that cardiovascular disease had the highest incidence in population suffering from venous thrombosis. This finding emphasized the importance of careful preventive strategies in patients with cardiovascular disease. In clinical setting, higher levels of D dimer could implicate deep venous thrombosis. This result also supported by **Yunjian et al., (2016)** in China who reported that diabetes mellitus associated hyperglycemia increases the risk of recurrent thrombosis.

Regarding laboratory investigations the current study revealed that there was significant difference between study and control group post application of teaching booklet and there was highly significant difference between laboratory investigations level and compliance with medication in study group post teaching booklet. This result in the same line with study at Mansoura University, Egypt by **Mohamed et al., (2017)** who demonstrated that significantly better laboratory findings related to DVT risk among the patients in the study group. From the researcher's point of view compliance with medication improves coagulation factors and decrease recurrence of DVT.

The study results represented that, one fourth of study group had recurrent thrombus while more than half of control group had recurrent thrombus after four months. As regard bleeding it was found that one fourth of control group had bleeding after four months. These findings were supported by **Hamid et al., (2011)** who reported that patients who received a nurse-led education program on oral anticoagulant therapy had significantly lower incidence of hemorrhagic episodes at 3-month follow-up, compared with controls. From the researcher's point of view this may be due to, teaching on importance of compliance to medication decreased incidence of recurrent thrombus.

Study results represented that, the highest percentages of study group had high compliance while less than half of control group had low compliance. The study in India by **Nummy et al., (2018)** reported that after providing proper educational intervention there was improvement in adherence to more than half of study subjects was high adherence, one third of subjects was medium and less than one fourth of subjects was low adherence.

This highlights the fact that patient counseling can improve medication adherence. These finding was in line with a study at Sydney, Australia conducted by **Polis et al., (2016)** reported that the highest percentage of the patients reported a high adherence and the minority of them reported a low adherence. In Kenya **Waari et al., (2018)** they found that less than half of patients was fully adhering to the prescribed medications. Self-reported adherence to medication was high for less than half, medium for more than one fourth and low for less than one third of the study participants.

The present study illustrated that there was highly significant difference between compliance with medication and recurrent thrombus and there was no significant difference between compliance with medication and bleeding for studied groups. Study in Denmark by **Christensen et al., (2016)** reported that improving patient's knowledge as part of the complete treatment plan may reduce the chances of major bleeding incidents. From researcher's point of view, education and knowledge improvement for patients with DVT increase orientation for signs and symptoms of bleeding that decrease incidence.

My comment that strict commitment with teaching booklet increase compliance with medication and thus decreases recurrent thrombus and bleeding.

Conclusion:

Teaching booklet was effective in improving patient's compliance to oral anticoagulant drugs, lower incidence of bleeding and recurrence of thrombus among patients with deep venous thrombosis.

Recommendations:

Teaching booklet for DVT patients and their family members to improve adherence to oral anticoagulant should be available in vascular surgery department.

Conflict of interest

There were no conflicts of interest.

Funding

The author(s) received no financial support for the research, authorship, and/or publication of this article

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