

Systematic Education about Anticoagulant Drugs: For Better Patient Compliance and to Extenuate Complications in Postcardiovascular Surgery Patients

Arun Kumar Haridas, Bharathi Shridhar Bhat

Department of CTVS, Dhiraj Hospital, Vadodara, Gujarat, India

Abstract

Background: Patients' knowledge about the necessity of taking anticoagulant medication to look upon their condition is a component that determines the long-term outcome of cardiovascular surgery. **Materials and Methods:** This is a prospective randomized controlled trial comprised a group of patients who received detailed education about oral anticoagulants (OACs) and a control group who received standard management without education. This study tested the impact of regular patient education on drug compliance. Four hundred and twenty-five patients were analyzed. The patients included were on oral anticoagulation for vascular procedures, cardiac valve replacements, and coronary artery bypass surgery with endarterectomy. **Results:** The patients who attended the awareness class had better drug compliance at 1 month and 6 months. A higher postclass score was associated with better and longer drug compliance. Although higher education translated into better test scores, it was revealed that regular classes allowed all patients to score higher, regardless of their academic literacy. **Conclusion:** This study establishes that an educational intervention improves adherence to anticoagulant therapy. It has diminished the incidence of complications in experimental group in contrast to the control group.

Keywords: Anticoagulation, coronary artery disease, education, valve, vascular disease

INTRODUCTION

A successful cardiovascular surgery and best long-term outcome is found if patients adhere to the medicines prescribed. It is an essential determinant of treatment benefit.^[1] Nondrug compliance contributes to the deterioration of disease, failure of surgical intervention, graft occlusion, and valve malfunctions. The complications are serious. The majority of complications culminate in increased morbidity and mortality. The clinical challenge after surgical intervention in patients on anticoagulants is to encourage maintaining prothrombin time (PT) and international normalized ratio (INR) in the therapeutic spectrum, by adherence to the medication. Adherence to drug compliance is a complex clinical behavior.^[2] Some aspects that influence drug compliance are linked with the patient, patient-physician relationship, education about disease, and the treatment.^[3] Poor adherence to anticoagulants has been singled out as a critical factor in therapeutic failure and the risk of adverse complications of medicines.^[4,5]

Patient education about their disease and the medication used associated with enhanced drug compliance and reduction in complication eventually benefits survivability.^[6] The value of patient's education has been extensively reviewed in Western countries. Few reviews are available about patient knowledge and forms of education on oral anticoagulants (OACs) and its impact on surgical results in Indian patients. The significance of education about OAC is ignored in spite of low drug compliance and high drug and device related complications.^[7] In our prospective randomized clinical study, the impact of educational intervention on drug compliance to anticoagulants and PT(INR) maintenance in therapeutic range was analyzed.

Address for correspondence: Dr. Arun Kumar Haridas,
Dhiraj Hospital, B K Shah Medical College, Vadodara - 391 760,
Gujarat, India.
E-mail: arunkumarharidas@gmail.com

This is an open access journal, and articles are distributed under the terms of the Creative Commons Attribution-NonCommercial-ShareAlike 4.0 License, which allows others to remix, tweak, and build upon the work non-commercially, as long as appropriate credit is given and the new creations are licensed under the identical terms.

For reprints contact: reprints@medknow.com

How to cite this article: Haridas AK, Bhat BS. Systematic education about anticoagulant drugs: For better patient compliance and to extenuate complications in postcardiovascular surgery patients. *J Pract Cardiovasc Sci* 2018;4:96-101.

Access this article online

Quick Response Code:



Website:
www.j-pcs.org

DOI:
10.4103/jpcs.jpcs_26_18

MATERIALS AND METHODS

Study design

Our study is a prospective, single-center, randomized clinical study that took place in Dhiraj General Hospital, from August 2014 to August 2017. The Ethics Committee approved the study. All patients gave us their informed written consent. The study compared the two groups comprising experimental group and control group of patients receiving OACs with and without detailed education about OACs, respectively. Patients included those who had undergone vascular surgery, cardiac valvular replacement, and coronary endarterectomy during coronary artery bypass grafting (CABG). Experimental group took part in preclass testing, class, and postclass testing. Control group took part only in preclass testing but were not in the explicit class about OACs. It excluded patients younger than 15 years and older than 75 years from the study. Out of the 425 patients included in the study, ten patients were lost to follow-up over a period due to mortality. All patients completed a preclass test questionnaire. We maintained patients' confidentiality.

Educational class

Classes used a PowerPoint presentation in patients' own language, teaching the relevance of anticoagulation and the precaution to be taken while on the regimen. Objectives were to enhance the patients' awareness about the disease, the value of drug compliances, and the complications of not having OACs. Patients in the control group were given standard medical care. Senior residents in the department instructed the classes. Classes were taken for all patients in the experimental group before surgery and every month during their regular monthly follow-up, for a period of 6 months.

Test for the assessment of efficacy of the educational class

Efficiency of the classes was determined by applying the score of questionnaire which comprised of ten questions about the disease, action of OACs, and the complications of drug noncompliance. Score ranged from 0 (all answers incorrect) to 10 (all answers correct). The test was given to all patients in the study group before the first class and surgery. Preclass score was taken as baseline knowledge. It was repeated in the experimental group after the class and then every month, during the follow-up for 6 months. The drug adherence was determined by PT-INR of the patient tested once in a month, from the 1st to 6th month.

Statistical analysis

The evaluation was conducted using IBM corp. (2011). IBM SPSS Statistics. V 20, Armonk, Newyork. The analyzed population comprised of all randomized patients who had completed the preclass questionnaire and the experimental group who completed the class and postclass questionnaire and came for follow-up till 6 months. We have used independent Student's *t*-test to find significant mean difference between the two different groups, while paired *t*-test had been used to find significant mean difference between pre- and post-test

scores for experimental group. ANOVA test has been used to find significant mean difference in test score between different educational groups. Repeated measures ANOVA has been used to find significant mean pre- and post-test scores and Bonferroni *post hoc* analysis was also used.

RESULTS

A total of 425 patients (controls [$n = 210$] and experimental [$n = 215$] patients) were randomized. A total of 213 experimental patients completed the pre class test, class and post class test. They thereafter attended regular monthly follow-ups for 6 months. Two patients in the experimental group died during the follow-up period. Out of the 210 patients of control group, seven patients died during the follow-up period.

A total of 252 patients had undergone various vascular procedures as follows: 107 aorto bifemoral bypass (25%), 49 femoropopliteal bypass (11.52%), and 96 femoral artery embolectomy (22.5%). One hundred and fifty-seven patients had undergone cardiac valve replacement with mechanical prosthetic valve, 48 mitral valve replacement (11.29%), 52 aortic valve replacement (12.23%), and 57 mitral and aortic valve replacement (13.41%). Twenty-five patients underwent coronary artery endarterectomy (5.88%) during CABG surgery.

There was no significant difference in the baseline score between male and female patients ($P = 0.253$). Postclass, both male and female patients showed improvement in knowledge and had similar drug compliance ($P = 0.450$) [Figure 1, Tables 1-3].

At preclass test, the patients with no formal education performed poorly compared to patients with higher formal education in both groups ($P = 0.0001$) [Figure 2, Tables 4 and 5].

There was a significant improvement in test scores after class in all the four educational groups ($P = 0.0001$) [Figure 3, Table 6].

Table 1: Baseline pre class test (experimental group)

Sex	<i>n</i>	Mean	SD	<i>P</i>
Male	116	2.93	1.50	0.253
Female	97	2.68	1.66	

SD: Standard deviation

Table 2: Baseline pre class test (control group)

Sex	<i>n</i>	Mean	SD	<i>P</i>
Male	110	2.53	1.617	0.502
Female	100	2.68	1.604	

SD: Standard deviation

Table 3: Baseline post class test (experimental group)

Sex	<i>n</i>	Mean	SD	<i>P</i>
Male	116	6.57	1.82	0.450
Female	97	6.38	1.78	

SD: Standard deviation

The knowledge score at the 1st month follow-up showed a dip. The knowledge score increased with repeated classes [Table 7].

After 6 months of education, there was difference in the knowledge level based on formal education ($P = 0.0001$) [Figure 4 and Table 8].

It was found that drug compliance and optimization (PT/INR) was superior in experimental group compared to controls [Figures 5-7].

There was a significant difference in complications between control and experimental groups ($P = 0.001$) [Tables 9 and 10].

DISCUSSION

There is an increasing trend in the number of patients who are receiving the anticoagulants for various cardiovascular diseases worldwide.^[8]

Post cardiovascular surgery, most of them are recommended to be on oral anticoagulation (OAC) drug after the surgery for life to avert complications induced by mechanical malfunction of prosthetic valves, vascular graft occlusion, abnormal rhythm, impaired myocardial function, deep vein thrombosis, and pulmonary embolism. OACs are dangerous if not optimized. If OACs are not taken, it contributes to device malfunction, graft blockage, and stroke. Excessive OAC dosage can cause massive bleed in brain or other organs of the body leading to serious disability and sometimes death. Hence, patient

education about oral anticoagulation is imperative to preserve the life and avoid complications.^[9]

The published articles related to patient education pertaining to anticoagulation are varied. Prioritizing patient education,

Table 4: Baseline pre class test score (experimental group)

Education	n	Mean	SD	P
Illiterate	105	1.50	0.75	0.0001
Primary	51	3.55	0.81	
Secondary	42	4.40	0.83	
Graduation	15	5.13	0.83	
Total	213	2.82	1.57	

SD: Standard deviation

Table 5: Baseline pre class test score (control group)

Education	n	Mean	SD	P
Illiterate	113	1.40	0.801	0.0001
Primary	45	3.26	0.567	
Secondary	30	4.30	0.883	
Graduation	22	5.00	0.970	
Total	210	2.60	1.609	

SD: Standard deviation

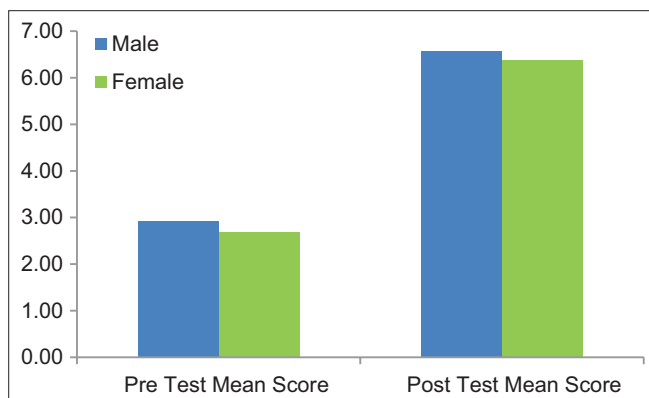


Figure 1: Gender-based pre- and post-class test scores.

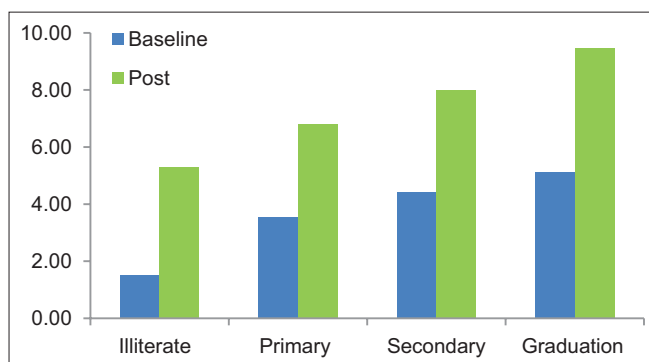


Figure 3: Correlation of pre- and post-test scores and literacy.

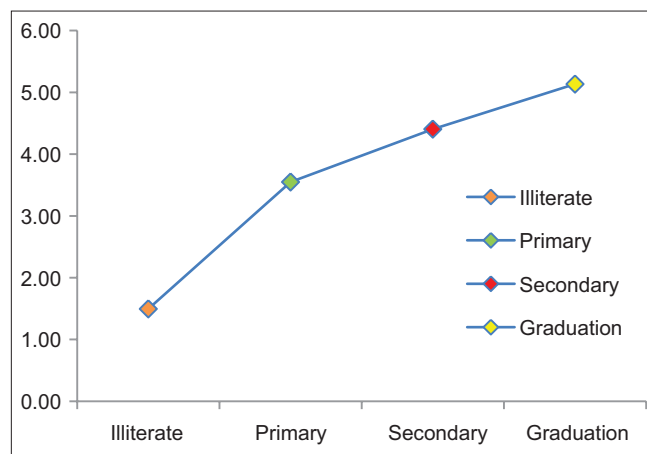


Figure 2: Preclass test score and literacy.

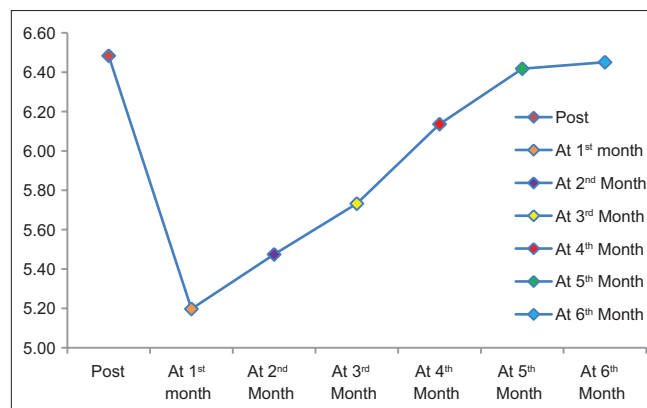


Figure 4: Knowledge score rate for 6 months.

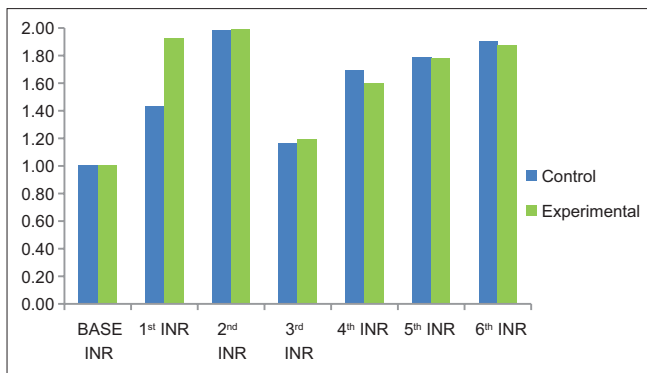


Figure 5: Vascular surgery and prothrombin time/international normalized ratio.

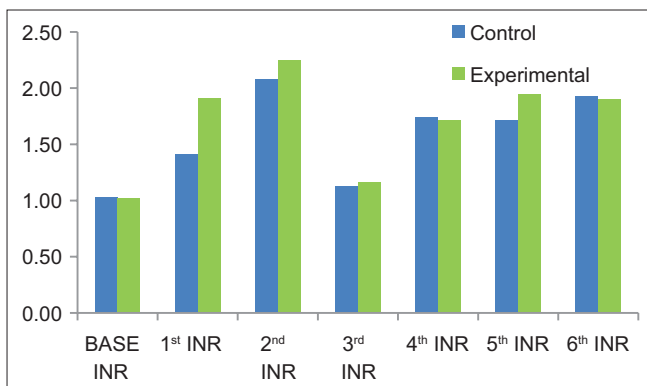


Figure 6: Mechanical prosthetic valve and prothrombin time/international normalized ratio.

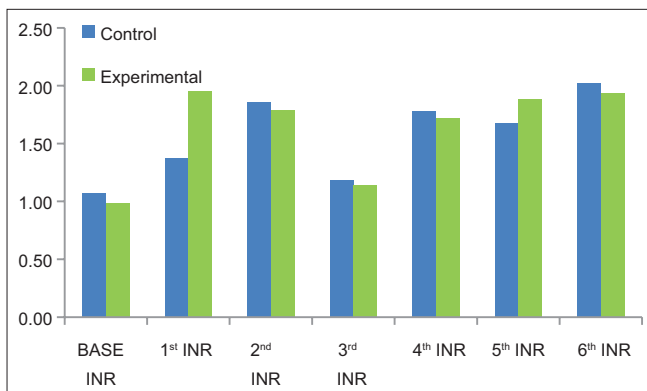


Figure 7: Coronary endarterectomy and prothrombin time/international normalized ratio.

institutionalizing the educational composition, and delivering the content are paramount. Oral anticoagulation is the second-most frequent cause of adverse drug events presented in emergency department all over the world. Risk of the major bleed is 8% per year.^[10]

To avoid the aforementioned complications, educating patients should be the primary objective in all who are undergoing cardiovascular surgery. Written and oral information about oral anticoagulation enhances compliance to maintain adequate PT/INR.^[11,12] It is proven beyond ambiguity that patient

Table 6: Post class test score (experimental group)

Education	n	Mean	SD	P
Illiterate	105	5.30	1.12	0.0001
Primary	51	6.78	1.12	
Secondary	42	8.00	1.62	
Graduation	15	9.47	0.64	
Total	213	6.48	1.80	

SD: Standard deviation

Table 7: Monthly average post class test score

Test score	Mean	SD	P
Post	6.48	1.80	0.0001
At 1 st month	5.20	2.24	
At 2 nd month	5.47	1.86	
At 3 rd month	5.73	1.57	
At 4 th month	6.14	1.42	
At 5 th month	6.42	1.19	
At 6 th month	6.45	1.14	

SD: Standard deviation

education is associated with better long-term outcome, but controversy remains alive about education design. It is the reason behind deficient standard protocols.^[13,14]

Medical education has to be given by the personnel those who are associated with caring for the patient taking oral anticoagulation. The studies have been done about outcome of medical education given by physicians, pharmacists and nurses. It is proved that the treating physician would be the better person to educate the patients.

Patients should be educated in detail about the nature of drugs, drug benefits, dosage, complications, diet, relevance of Vitamin K, and the test required to optimize the dosage. Studies have confirmed that repeated education enhances the knowledge of the patient to deal with anticoagulation therapy.^[15] Education has been found to reduce complication rates and promotes the quality of life. Precise repeated education is useful in controlling target PT/INR values and reducing the adverse events.^[16] Education about OACs has associated with immense satisfaction of treatment received with the lowered incidence of complications among patients.^[17]

Education can be in the form of physical, one-to-one education, telephonic education, and videotape education. Studies have revealed that these forms of education have made no distinction among the patients' knowledge and outcome. In our study, one-to-one session of personal class suits the most, but it is cumbersome and time-consuming.^[18]

The higher the patient's literacy, the better is the awareness about OAC and conformity with prescriptions. Our studies found similar findings, but a repeated class enhances the knowledge even in poorly educated patients.^[19] Illiteracy and poverty are the major obstacles for elaborate education and are the reason for the high rate of complications.^[20,21] Educating patients in their own language is found to be more

Table 8: Post hoc analysis (Bonferroni)

(I) Factor 1	Mean difference	P	95% CI for difference	
			Lower bound	Upper bound
Post				
At 1 st month	1.29	0.00	0.81	1.76
At 2 nd month	1.01	0.00	0.53	1.49
At 3 rd month	0.75	0.00	0.31	1.20
At 4 th month	0.35	0.56	-0.13	0.83
At 5 th month	0.07	1.00	-0.39	0.52
At 6 th month	0.03	1.00	-0.39	0.46
1st month				
Postclass	-1.29	0.00	-1.76	-0.81
2 nd month	-0.28	1.00	-0.81	0.25
3 rd month	-0.54	0.01	-1.01	-0.06
4 th month	-0.94	0.00	-1.47	-0.41
5 th month	-1.22	0.00	-1.76	-0.68
6 th month	-1.25	0.00	-1.76	-0.74
2nd month				
Postclass	-1.01	0.00	-1.49	-0.53
1 st month	0.28	1.00	-0.25	0.81
3 rd month	-0.26	1.00	-0.76	0.24
4 th month	-0.66	0.00	-1.14	-0.18
5 th month	-0.94	0.00	-1.43	-0.46
6 th month	-0.98	0.00	-1.42	-0.53
3rd month				
Postclass	-0.75	0.00	-1.20	-0.31
1 st month	0.54	0.01	0.06	1.01
2 nd month	0.26	1.00	-0.24	0.76
4 th month	-0.40	0.02	-0.78	-0.03
5 th month	-0.69	0.00	-1.07	-0.30
6 th month	-0.72	0.00	-1.11	-0.32
4th month				
Postclass	-0.35	0.56	-0.83	0.13
1 st month	0.94	0.00	0.41	1.47
2 nd month	0.66	0.00	0.18	1.14
3 rd month	0.40	0.02	0.03	0.78
4 th month	-0.28	0.45	-0.66	0.09
6 th month	-0.31	0.25	-0.70	0.07
5th month				
Postclass	-0.07	1.00	-0.52	0.39
1 st month	1.22	0.00	0.68	1.76
2 nd month	0.94	0.00	0.46	1.43
3 rd month	0.69	0.00	0.30	1.07
4 th month	0.28	0.45	-0.09	0.66
6 th month	-0.03	1.00	-0.39	0.32
6th month				
Postclass	-0.03	1.00	-0.46	0.39
1 st month	1.25	0.00	0.74	1.76
2 nd month	0.98	0.00	0.53	1.42
3 rd month	0.72	0.00	0.32	1.11
4 th month	0.31	0.25	-0.07	0.70

CI: Confidence interval

beneficial, so language of the patient should be the form of education regardless of the method of education. It has a prodigious impact and is found to enhance the compliance to treatment.^[22] Good communication between doctor and patient,

Table 9: Incidence of complications

Group	Complication (%)	P
Experimental	9 (4.19)	0.001
Control	28 (13.33)	

communication in patient language, study design made as per patient literacy, and repeated communication establish a significant rate of benefits.^[22-25]

In our study, the benefits of an educational class for the patient's drug compliance to OACs was proved in the experimental group, in immediate postclass test score, at the 1st month and 6th month. Measurement of drug compliance is difficult, in a randomized study directed at improving drug compliance to OACs. Regular monitoring of PT/INR and education itself may increase drug compliance. Most of our patients demonstrated good drug compliance in the experimental group.

There was consistent improvement in patient drug compliance over the 6-month follow-up, as showed by enhanced knowledge score and maintenance of PT-INR in therapeutic range. The patient group in our study was of varied diagnosis and found significant improvement in drug compliance across all groups. poor compliance of OAC led to major complications such as graft occlusion, mechanical valve malfunction, myocardial infarction, and stroke.^[26,27]

In our study, men and women showed uniform benefits with OAC education. There was a difference in knowledge score according to the level of formal education. Illiterate patients had the lowest scores than the graduates, but the improvement in drug adherence was significant across patients of all educational groups, proving the efficacy of teaching the patients about OACs. In our study, it has been evidently proven that compliance to OACs can be improved with repeated education of patients.

CONCLUSION

Worldwide, the usage of oral anticoagulation (OACs) has been increased among cardiovascular disease and postcardiovascular surgery patients. Oral anticoagulation is associated with complications such as device malfunction, graft occlusion, and hemorrhage. Adverse effects of OAC lead to permanent disability and sometimes death.

It is obligatory to educate the patients who are on oral anticoagulation. Patients must be educated upon knowledge about disease, drug, PT/INR monitoring test, adverse reaction of drugs, the pattern of diet, and complications. Education should be in patient's language, graded as per the level of literacy. Repeated, face-to-face discussion is desirable which benefits the most.

Patient education increases drug compliance and reduces complication rates. Usage of social media application might enhance the results of educating patients on OACs.

Table 10: Spectrum of complications

Category	Complication	Control	Experimental	Total
CABG	MI	3	1	4
Valve replacement	Struck valve	2	0	7
	Cerebral bleed and hemiplegia	2	0	
	Hematoma	1	0	
Vascular Bypass surgery	Epistaxis	1	1	
	Graft thrombosis	10	5	15
	Requiring embolectomy			
	Graft occlusion	9	2	11
	Requiring redo bypass			
Total		28	9	37

CABG: Coronary artery bypass grafting, MI: Myocardial infarction

Financial support and sponsorship

Nil.

Conflicts of interest

There are no conflicts of interest.

REFERENCES

- Jimmy B, Jose J. Patient medication adherence: Measures in daily practice. *Oman Med J* 2011;26:155-9.
- Goujard C, Bernard N, Sohier N, Peyramond D, Lançon F, Chwalow J, *et al*. Impact of a patient education program on adherence to HIV medication: A randomized clinical trial. *J Acquir Immune Defic Syndr* 2003;34:191-4.
- Stone VE, Hogan JW, Schuman P, Rompalo AM, Howard AA, Korkontzelou C, *et al*. Antiretroviral regimen complexity, self-reported adherence, and HIV patients' understanding of their regimens: Survey of women in the her study. *J Acquir Immune Defic Syndr* 2001;28:124-31.
- Carter SA, McDevitt E, Gatje BW, Wright IS. Analysis of factors affecting the recurrence of thromboembolism off and on anticoagulant therapy. *Am J Med* 1958;25:43-51.
- Sise HS, Moschos CB, Gauthier J, Becker R. The risk of interrupting long-term anticoagulant treatment. A rebound hypercoagulable state following hemorrhage. *Circulation* 1961;24:1137-42.
- Parietti JJ, Verdon R, Bazin C, Bouvet E, Massari V, Larouzé B, *et al*. The pills identification test: A tool to assess adherence to antiretroviral therapy. *JAMA* 2001;285:412.
- Obamiro KO, Chalmers L, Bereznicki LR. Development and validation of an oral anticoagulation knowledge tool (AKT). *PLoS One* 2016;11:e0158071.
- Blann AD, Landray MJ, Lip GY. ABC of antithrombotic therapy: An overview of antithrombotic therapy. *BMJ* 2002;325:762-5.
- Wofford JL, Wells MD, Singh S. Best strategies for patient education about anticoagulation with warfarin: A systematic review. *BMC Health Serv Res* 2008;8:40.
- Wysowski DK, Nourjah P, Swartz L. Bleeding complications with warfarin use: A prevalent adverse effect resulting in regulatory action. *Arch Intern Med* 2007;167:1414-9.
- Kagansky N, Knobler H, Rimon E, Ozer Z, Levy S. Safety of anticoagulation therapy in well-informed older patients. *Arch Intern Med* 2004;164:2044-50.
- Tang EO, Lai CS, Lee KK, Wong RS, Cheng G, Chan TY, *et al*. Relationship between patients' warfarin knowledge and anticoagulation control. *Ann Pharmacother* 2003;37:34-9.
- Newall F, Monagle P, Johnston L. Patient understanding of warfarin therapy: A review of education strategies. *Hematology* 2005;10:437-42.
- Davis NJ, Billett HH, Cohen HW, Arnsten JH. Impact of adherence, knowledge, and quality of life on anticoagulation control. *Ann Pharmacother* 2005;39:632-6.
- Khan TI, Kamali F, Kesteven P, Avery P, Wynne H. The value of education and self-monitoring in the management of warfarin therapy in older patients with unstable control of anticoagulation. *Br J Haematol* 2004;126:557-64.
- Gadisseur AP, Breukink-Engbers WG, van der Meer FJ, van den Besselaar AM, Sturk A, Rosendaal FR, *et al*. Comparison of the quality of oral anticoagulant therapy through patient self-management and management by specialized anticoagulation clinics in the Netherlands: A randomized clinical trial. *Arch Intern Med* 2003;163:2639-46.
- Sawicki PT. A structured teaching and self-management program for patients receiving oral anticoagulation: A randomized controlled trial. Working Group for the Study of Patient Self-Management of Oral Anticoagulation. *JAMA* 1999;281:145-50.
- Stone S, Holden A, Knapic N, Ansell J. Comparison between videotape and personalized patient education for anticoagulant therapy. *J Fam Pract* 1989;29:55-7.
- Hu A, Chow CM, Dao D, Errett L, Keith M. Factors influencing patient knowledge of warfarin therapy after mechanical heart valve replacement. *J Cardiovasc Nurs* 2006;21:169-75.
- Brigden ML, Kay C, Le A, Graydon C, McLeod B. Audit of the frequency and clinical response to excessive oral anticoagulation in an out-patient population. *Am J Hematol* 1998;59:22-7.
- Arnsten JH, Gelfand JM, Singer DE. Determinants of compliance with anticoagulation: A case-control study. *Am J Med* 1997;103:11-7.
- Nadar S, Begum N, Kaur B, Sandhu S, Lip GY. Patients' understanding of anticoagulant therapy in a multiethnic population. *J R Soc Med* 2003;96:175-9.
- Kravitz RL, Hays RD, Sherbourne CD, DiMatteo MR, Rogers WH, Ordway L, *et al*. Recall of recommendations and adherence to advice among patients with chronic medical conditions. *Arch Intern Med* 1993;153:1869-78.
- Estrada CA, Hryniewicz MM, Higgs VB, Collins C, Byrd JC. Anticoagulant patient information material is written at high readability levels. *Stroke* 2000;31:2966-70.
- Yu SM, Huang ZJ, Schwalberg RH, Overpeck MD, Kogan MD. Association of language spoken at home with health and school issues among Asian American adolescents. *J Sch Health* 2002;72:192-8.
- Hart RG, Boop BS, Anderson DC. Oral anticoagulants and intracranial hemorrhage. Facts and hypotheses. *Stroke* 1995;26:1471-7.
- Riaz H, Alansari SA, Khan MS, Riaz T, Raza S, Luni FK, *et al*. Safety and use of anticoagulation after aortic valve replacement with bioprostheses: A meta-analysis. *Circ Cardiovasc Qual Outcomes* 2016;9:294-302.