Original Article

Use of dabigatran for treatment of left ventricular thrombus: A tertiary care center experience

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Abstract

Objectives: Direct oral anticoagulants (DOACs) are now replacing vitamin K oral anticoagulants (VKAs) owing to superior efficacy, rapid action, less bleeding, wider therapeutic range,and fewer food and drug interactions.Unfortunately, the available data on the use of DOACs, particularly dabigatran, for treatment of left ventricular thrombus (LVT) issparse.We have hereby presented the largest study on use of dabigatran in LVT. **Methods:** Retrospective data of patients having LVT as diagnosed by transthoracic echocardiography (TTE) was screened. Patients on dabigatran were included in the study and follow up data of 6 months was obtained through medical records. **Results:** Of the 15 patients included in the study, the most frequent etiology was ischemic heart disease (67%), including 7 patients of STEMI (47%), followed by non-ischemic cardiomyopathy in 5 patients (33%). Only one patient, with STEMI, developed mild gastrointestinal bleeding at 3 months. Complete clot resolution was seen in 2 patients (13%) at first week of follow up and total 5 patients (33%) at the end of second week. The rate of clot resolution at 1 month, 3 months, and 6 months were 80%, 93% and 100%, respectively. The median duration required for complete clot resolution was 30 days (IQR=14-30). **Conclusion:** Dabigatran appears to be safe, highly efficacious and results in rapid LV clot resolution. DOACs may be a suitable alternative to warfarin in treatment of LV thrombus. However, larger studies are required to validate this hypothesis.

Keywords: Direct oral anticoagulants, intracardiac thrombus, left ventricular clot, new oral anticoagulants, thrombus resolution

Introduction

Left ventricular thrombus (LVT) is usually seen in patients with significantly reduced left ventricular systolic function complicating both ischemic and nonischemic cardiomyopathies.[1,2] This is explained by presence of Virchow's triad in the ventricle – reduced wall motion, local myocardial injury, and hypercoagulability/stasis of blood flow.[3] A total of 80% of these cases are related to ischemia, most commonly ST-elevation myocardial infarction (STEMI), particularly anterior STEMI.[3] The life span of patients with ischemic heart disease is increasing due to consistent diagnostic and therapeutic advances.[3-7] With this the occurrence of post-myocardial infarction (MI) LV thrombus may have declined, but the prevalence of heart failure is increasing with improved survival.[2] The LVT is associated with increased morbidity, mortality, and high rates of thromboembolic complications such as stroke.[2] Anticoagulant therapy is, therefore, required to minimize the risk of systemic embolization.[8]

Currently, vitamin K oral anticoagulants (VKAs) are preferred for the treatment of LVT as recommended by guidelines.[9-11] Unfortunately, the data for VKAs are based on observational studies in the prethrombolytic and thrombolytic eras.[12,13] Non-VKA direct oral anticoagulants (DOACs) are currently replacing VKA in several clinical indications. DOACs are currently approved for venous thromboembolism (VTE), nonvalvular atrial fibrillation, and postoperative VTE prophylaxis.[14,15] The advantages of DOACs include superior effectiveness in

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preventing systemic embolism, rapid onset of action, lower incidence of major bleeding, wider therapeutic range not requiring monitoring and frequent dose adjustment, fewer food, and drug interactions and cost-effectiveness.[16]

DOACs are being increasingly used for the management of LVT. However, the available data on the use of DOACs are limited to individual case reports.[3,16-18] Dabigatran is a reversible direct thrombin inhibitor and is currently approved for the thromboprophylaxis in non-valvular atrial fibrillation and patients undergoing orthopedic surgery.[19] It is thought to have thrombolytic effect even on chronic clot by its potential to inhibit thrombin bound to fibrin and fibrin degradation products.[19,20] Moreover, it is comparatively less costly and is the only DOAC with an approved antidote (idarucizumab). However, data related to use of dabigatran in this context is very sparse as compared to other DOACs.[19,21-23] We have presented here the effect of dabigatran on LV clot resolution in both ischemic and nonischemic cardiomyopathies. To our knowledge, this is the largest study of dabigatran regarding its use in treatment of LV thrombus.

Materials and Methods

This was a single center, retrospective, observational study carried out over a period of 2 years from December 2016 to November 2018 at a tertiary care hospital. Consecutive patients with LVT of any origin not on any prior anticoagulation were screened and only patients where dabigatran was started were included in the study. LVT was assessed using transthoracic echocardiography, defined as an echo dense mass adjacent to the myocardium. The clot diameter was measured and area assessed by planimetry on 2-D echocardiography. Dabigatran was used in a dose of 220 mg/day along with antiplatelets and 300 mg/day without antiplatelets. In all cases, dabigatran was continued till 6 months even after clot resolution as recommended.[9-11] Data were obtained through medical records of each hospital visit and through phone if required. The first follow-ups were weekly till 2 weeks and thereafter all the patients were followed-up monthly. Follow-up data of at least 6 months were retrieved. All data were shown as means ± standard deviation for continuous variables and as numbers and percentages of patients for categorical variables.

Results

Baseline characteristics

The baseline patient characteristics are shown in Table 1. In this retrospective series, 60% patients (9/15) were males and the mean age was 41 years. All 15 patients had completed 6 months of follow-up. Ischemic etiology was seen in ten patients (67%), which included seven patients of STEMI. All these patients received dabigatran at a dose of 110 mg BD in addition to the required antiplatelet agents. Nonischemic cardiomyopathy was present in five patients (33%), with none having valvular heart disease. These patients were given dabigatran at a dose of 150 mg BD. Additionally atrial fibrillation was associated in three patients (20%). The mean baseline LVEF was 32%. The mean clot size was 157 ± 130 cm^2, with the largest clot being 25 mm in diameter. Interestingly, the patient with the largest clot had biventricular clot [Figure 1] (a case of dilated cardiomyopathy).

Table 1: Baseline patient characteristics (*n*=15)

Age (years), mean±SD	41±19
Male sex	9 (60)
LVEF, mean±SD	32±7
Etiology	
Ischemic cardiomyopathy	3 (20)
STEMI	7 (47)
Nonischemic cardiomyopathy	5 (33)
Valvular heart disease	0 (0)
Atrial fibrillation	3 (20)
Biventricular clot	1 (6.6)
LV thrombus size*, mean±SD	157±130 cm^2

Values shown represent numbers (percentages), except where otherwise noted. SD, standard deviation; CAD, coronary artery disease; LVEF, left ventricular ejection fraction; STEMI, ST-elevation myocardial infarction; LV, left ventricle. *Calculated by planimetry using transthoracic 2-D echocardiography

Table 2: Follow-up (*n*=15)

	2 weeks	1 month	3 months	6 months
Ejection fraction (%)	35±6	36±6	39±7	41±7
Stroke	0	0	0	0
Distal embolization	0	0	0	0
Any bleeding	0	0	1#	0
Complete clot resolution	5 (33)	12 (80)	14 (93)	15 (100)
50% clot resolution*	11 (73)	15 (100)	15 (100)	15 (100)
Clot recurrence	0	0	0	0
New clot	0	0	0	0

Values shown represent numbers (percentages), except where otherwise noted. *Calculated by planimetry using transthoracic 2-D echocardiography. #Gastrointestinal bleeding

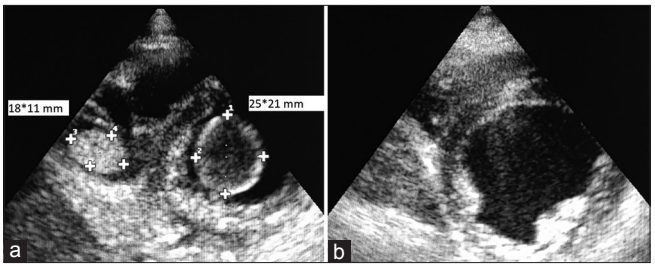

Figure 1: (a) Biventricular thrombus in a patient with dilated cardiomyopathy; (b) Complete thrombus resolution at 3 months with dabigatran 300 mg/day in bid dose

Follow-up

Follow up data is presented in Table 2. At 6 months of follow-up, there were no significant drug-related complications despite use of dabigatran along with antiplatelets in more than half of the patients (67%). Only one patient, with STEMI, developed mild gastrointestinal (GI) bleeding at 3 months. Dabigatran was stopped in this patient as the clot had already resolved and the bleeding improved without requiring any blood transfusion.

Complete clot resolution was seen in two patients (13%) at first week of follow-up and total five patients (33%) at the end of second week. By the completion of first month, clot was completely resolved in 12 patients (80%). At 3 months complete clot resolution was seen in 14 patients (93%). The single patient who still had clot at 3 months was a case of ischemic cardiomyopathy. In this patient, the dabigatran dose was increased from 220 mg/day to 300 mg/day and had a successful clot resolution at 6 months of follow-up. The median duration required for complete clot resolution was 30 days (Interquartile range (IQR) =14–30)). In all patients, at least 50% clot resolution (by area) was seen within 1 month.

Discussion

Warfarin (VKAs) remains the first choice of treatment for left ventricular thrombus. However, there use is based on observational studies done in past prior to availability of potent antiplatelet and antithrombotic agents.[12,13] Its use is declining in favor of DOACs for various indications owing to its narrow therapeutic index, the need for regular monitoring, dietary restrictions, and multiple drug interactions.[16] Studies have shown that anticoagulation with warfarin can resolve fresh ventricular thrombi, but not chronic thrombi after STEMI.[24] However, several case reports have recently shown that LV thrombi can be treated successfully with dabigatran.[19,21,23,25,26] In our study, there was complete resolution of LV clot both of acute and chronic etiology. This finding supports the thrombolytic action of dabigatran due to its specific binding to both free as well as clot-bound active thrombin molecules.[19,20]

The most common etiology of LVT in our study was prior STEMI (47%) and occurred predominantly in males (60%). Several meta-analysis and large studies of LVT have reported acute myocardial infarction as the most frequent cause and male preponderance of LV thrombus.[27-29] On the contrary, a recent large retrospective study reported heart failure (68.5%) to be the most common cause followed by acute MI (25.9%).[2] This probably may be due to rising prevalence of heart failure and improvement in management and system of care for STEMI. The incidence of LVT in patients with STEMI in the current era ranged from 4% to 15%.[30] The embolic complications were seen in 2–3% patients in thrombolytic era compared to 10–35% in the prethrombolytic era.[31] Transthoracic echocardiography (TTE) is the most commonly used modality to detect LVT. However, echocardiography, using delayed enhancement cardiovascular magnetic resonance imaging (CMR) as the reference, yielded a sensitivity of 33%, specificity of 91%.[32] Therefore, use of TTE may lead to considerable underdiagnosis and CMR may be preferred wherever feasible.

There is no consensus on dose of dabigatran for LVT because in the case studies the dose varied between 110 and 150 mg bid. We have used a dose of 220 mg/day in patients with ischemic heart disease taking antiplatelet agents and 300 mg/day in all other clinical conditions. This was based on European society of cardiology (ESC) guidelines recommending lower dose of DOACs (in the case of dabigatran 110 bid) along with antiplatelets to decrease hemorrhagic complications.[33] Dabigatran is associated with a lower risk of bleeding compared with VKAs, and may be preferred when given along with antiplatelet therapy in ischemic heart disease. The single patient in our study who did not respond to dabigatran at 220 mg/day till 3 months had complete clot resolution at end of 6 months after increasing the dose to 300 mg/day. This appears to be an attractive strategy of giving dabigatran trial of 220 mg/day for 3 months in ischemic heart disease and increasing the dose only if there is no clot resolution. This cautious approach may result in lower bleeding complications in this group of patients.

Complete clot resolution in our study was seen in two patients at 1 week (13%), five patients at 2 weeks (33%), 12 patients at end of first month (80%), 14 patients after 3 months (93%), and complete clot resolution was seen in all patients at completion of 6 months follow-up. In the previous cases, the resolution of the LV thrombi by dabigatran was confirmed after 3 weeks to 4 months.[34] In a recent report, clot resolution in a patient with anteroseptal MI was seen as early as 2 weeks.[23] Moreover, the median duration required for complete clot resolution was 30 days (IQR = 14–30) in our study. A recent meta-analysis of case reports regarding use of DOACs in 36 patients showed the median duration of treatment to clot resolution was 30 days (IQR = 22.5–47.0).[27] It is quite interesting that the rapidity of clot resolution by dabigatran is comparatively greater than the other DOACs. A meta-analysis including 41 patients reported the median time of LV clot resolution as 40 days, 36 days, and 24 days for rivaroxaban, apixaban, and dabigatran, respectively.[35] This is a clear advantage of DOACs over warfarin (VKAs) which has a slower action. Furthermore, this implies that the required duration of anticoagulation by dabigatran may be lesser than warfarin. The current guidelines recommend VKAs in patients with LVT for at least 3–6 months.[9-11] Though we continued treatment even after clot resolution till 6 months, but there is still controversy regarding stopping or continuing treatment after resolution of thrombus.[36]

Dabigatran in this study was highly efficacious resulting in LV clot resolution in all patients (100%). In a large retrospective study, including 128 patients with LVT, all patients who received DOACs experienced complete clot resolution.[2] Interestingly, although warfarin was still the most frequently used oral anticoagulant (87% vs 3.7% taking DOACs), clot resolution was seen in only 75% patients within one year.[2] A meta-summary of case reports showed LV thrombus resolution in 87.9% patients taking DOACs.[27] Additionally, a single center study including 35 patients reported clot resolution in 83% patients on follow-up by TTE.[28] Though this reflects that DOACs may be more efficacious than warfarin, but there is no study of direct comparison between the newer agents. Another recent meta-analysis of case reports showed thrombus resolution success rate of 81%, 100%, and 88.9% for rivaroxaban, apixaban, and dabigatran, respectively.[35] However, all these studies had

comparatively very few patients of dabigatran. Large randomized studies are definitely needed before drawing any conclusion.

It is noteworthy that the excellent results with dabigatran were achieved in this study without any significant complication. There were no episodes of stroke or peripheral embolism. Mild GI bleeding was seen in one patient (6.6%) taking antiplatelets which resolved after stopping dabigatran. In a large study of 52 patients, there was one transient ischemic attack and four bleeding events (7.7%) including three GI bleeds and one epistaxis requiring transfusion.[28] Similar to our study all these patients were on antiplatelet agents. In a metanalysis of 36 case reports, there was one nonfatal bleeding event (3%) and no thromboembolic event.[27] Another retrospective study of 98 patients showed no difference between warfarin and DOACs in terms of 1-year survival free of stroke or systemic embolism.[37] Additionally, over 6 months of follow-up we did not find any case of clot recurrence or new clot formation. In contrast, a prospective study of 35 patients with LVT after STEMI exclusively taking warfarin reported a recurrence rate of 18.5%.[38]

Implication for primary care/family physicians/ healthcare professionals

From this retrospective study and earlier case reports there is clear suggestion that dabigatran may be superior to VKAs by allowing rapid and complete clot resolution. Moreover, no thromboembolism occurred between treatment initiation and clot resolution. Additionally, treatment with DOACs may require shorter duration than with VKAs due to rapid clot resolution. Therefore, DOACs appear to be suitable treatment alternative for LVT and there is clear need for future research of larger and randomized nature. This view is further supported by the clear advantage of DOACs over VKAs in other clinical settings.

Study limitations

The major strengths of this study include the largest number of patients studied in context to dabigatran till date and relatively longer duration of follow-up. This series adds to the current evidence supporting use of DOACs in treatment of LVT. However, there are significant limitations too. First, this was a retrospective study from a single center. Second, sensitivity and specificity of echocardiography for the detection of LVT are limited compared to CMR. Third, the sample size of patients with LVT is small. Finally, the findings of this study are subject to confounding and bias that are inherent to the observational studies.

Conclusion

DOACs are rapidly gaining clinical acceptance in view of noninferior efficacy and limitations to using VKA including the need for regular monitoring and multiple dietary and drug interactions. This study demonstrates that dabigatran is highly efficacious and results in rapid LV clot resolution in varied clinical scenarios. Moreover, it can be safely used without increased risk of bleeding or systemic embolism. Although limited by retrospective nature and small sample, this study suggests that DOACs may be a suitable alternative to warfarin in treatment of LV thrombus. However, larger studies including randomized controlled trials are required to evaluate the safety and efficacy of DOACs compared to treatment with VKA.

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Conflicts of interest

There are no conflicts of interest.

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