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The utility of a CHA_2DS_2-VASc score in predicting the presence of significant stenosis and occlusion of veins with indwelling endocardial leads

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ABSTRACT

Background: Currently, there are no studies in which a CHA_2DS_2-VASc score has been used to predict the risk of venous stenosis and occlusion (VSO) in patients after the implantation of a cardiac implantable electronic device (CIED).

Methods: The material consists of the records of 223 consecutive patients qualified for transvenous lead extraction, generator change and system revisions or upgrades in whom we assessed the utility of a CHA_2DS_2-VASc score in the prediction of VSO. The CHA_2DS_2-VASc score was calculated retrospectively based on the clinical data. The whole study population was divided into two groups, based on the presence (group I) or absence (group II) of VSO. Using the receiver operating characteristic (ROC) curve, we identified the optimal cut-off point for the CHA_2DS_2-VASc score that allowed the prediction of the absence of VSO.

Results: The venography was performed in 223 consecutive patients aged on average 68.2years (25.7–95.3), 77 females (34.5%). The presence of VSO was detected in 79 (35.4%) patients aged 68.3 ± 14.1 years, 30 female (40%) patients—group I. The level of the cut-off point for the CHA_2DS_2-VASc score that allowed the prediction of the absence of VSO was 3.0.

Conclusion: In the whole population the incidence of VSO amounted to 35.4%. The result of the CHA_2DS_2-VASc score was a destimulant of VSO occurrence and was characterized by moderate sensitivity (73.4%) and specificity (42.4%) in predicting the absence of VSO. The most significant factor, which prevented VSO development was diabetes.

1. Background

A CHA_2DS_2-VASc score (congestive heart failure, hypertension, age ≥ 75 years, diabetes, prior stroke or TIA, vascular disease and female gender) is currently a simple, useful and validated clinical prediction rule for estimating the risk of ischemic stroke in patients with non-valvular atrial fibrillation [1]. The lack of an organized atrial contraction in patients with AF can result in blood stagnation, mainly in the left atrial appendage [2]. Increased propensity for thrombus formation can result in ischemic embolization, mostly of the central nervous system (CNS) and less frequently peripheral embolisms [2]. The risk of ischemic stroke to the CNS in patients with non-valvular AF is 5-fold higher than in patients with sinus rhythm [3] and AF-related stroke is one of the leading causes of mortality around the world [4].

Each of the factors listed in the score corresponds to a greater risk of stroke in patients with AF. Overall, the score could represent an independent marker of morbidity and poor prognosis due to cerebrovascular accidents (CVA), defined as stoke and arterial thromboembolic events [1]. Furthermore, it might be used to assess the overall morbidity of the population [5].

On the other hand, there are data available about the increased risk of CVA in patients with higher CHA_2DS_2-VASc scores without diagnosed AF [6–9].

Currently, there are no studies in which a CHA_2DS_2-VASc score has been used to predict the risk of venous stenosis and occlusion (VSO) in patients after the implantation of a cardiac implantable electronic device (CIED): pacemaker (PM), implantable cardioverter-defibrillator (ICD) or cardiac resynchronization therapy (CRT). Due to the frequently asymptomatic development of VSO, its incidence is difficult to determine [9]. According to current data, its incidence is estimated to range from 23 to 64% [10–16]. Given the high prevalence of VSO along with the increasing number of device implantations, venous complications are becoming a significant clinical problem [17]. The

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presence of VSO impedes the placement of an additional lead during device upgrade procedures [11] and has a significant impact on transvenous lead extraction procedures (TLE) [14]. Therefore, we designed a retrospective study to assess the utility of a CHA_2DS_2-VASc score in the prediction of VSO in patients with CIED referred for the following procedures: TLE, generator change and system revision or upgrade.

2. Methods

The material consists of the records of 223 consecutive patients qualified for TLE (156 pts), generator change (39 pts) and system revisions or upgrades (28 pts). The CHA_2DS_2-VASc score was calculated retrospectively based on the clinical data. In all patients, clinical examination of the ipsilateral venous confluence with indwelling endocardial leads was performed. Prior to the operation, a contrast medium was injected through the peripheral arm vein on the side, which was to be studied. The study was approved by the Ethics Committee at our institution. The study inclusion criteria involved the absence of contraindications to venography and written consent obtained from the patient.

2.1. Performance and assessment of venography

In the operating room, 10 to 20 ml of high-quality Iomeron 350 contrast medium (350 g iodine/ml) was injected through the peripheral arm vein on the side with indwelling endocardial leads. The venous contrast medium flow was filmed using fluoroscopy in frontal (PA) projection with a Siemens Arcadis C-arm X-ray system. In the event of the detection of lead presence on both sides of the chest, a bilateral venogram was performed.

A positive result from the venography, referred to as a significant abnormality in venous patency, was defined as a total venous occlusion or visible stenosis with collateral circulation on the venogram.

2.2. Assessment according to CHA2DS2-VASc score

The CHA_2DS_2-VASc score was calculated individually in each patient according to ESC guidelines [18]. The study population was divided into two groups based on the presence or absence of VSO: group I-patients with VSO; group II–patients without VSO.

Groups were compared in regard to the following parameters:

1. demographic baseline characteristics: female sex as one point on the CHA_2DS_2-VASc score, age ≥65 as one point on the CHA_2DS_2-VASc score, age ≥75 as two points on the CHA_2DS_2-VASc score,
2. comorbidities which are included in the CHA_2DS_2-VASc score: congestive heart failure or left ventricular diastolic dysfunction–defined as a state in which cardiac output is insufficient to meet the metabolic needs of the tissues or in which the cardiac output is maintained by elevated diastolic filling pressure,
3. additionally: hypertension, vascular disease (e.g. peripheral artery disease, myocardial infarction, aortic plaque), diabetes, prior stroke or transient ischemic attack or thromboembolism,
4. comorbidities which are not included in the CHA_2DS_2-VASc score: chronic kidney disease defined as a creatinine level above 2 mg/dl, neoplastic disease, a history of venous thrombosis,
5. paroxysmal or permanent supraventricular tachyarrhythmia: atrial flutter/fibrillation (AT/AF),
6. the result of calculation of the CHA_2DS_2-VASc score,
7. data concerning the implanted device: number, type and age of the leads,
8. selected risk factors for VSO: history of surgical procedures and injuries in the area of the neck and chest, and
9. use of antiplatelet/anticoagulant drugs and statins.

The analysis of the diagnostic ability of a CHA_2DS_2-VASc score in predicting venous occlusion/stenosis was performed. The threshold value of the result of the CHA_2DS_2-VASc score was specified in order to discriminate VSO.

We assessed whether the CHA_2DS_2-VASc score is a stimulant or destimulant of the occurrence of VSO.

2.3. Statistical analysis

StatSoft, Inc. (2014) STATISTICA (data analysis software system), version 12 was used to perform all the calculations. Quantitative variables are presented as a mean with standard deviations. Categorical variables are presented as an exact number and as a percentage of the whole analyzed group. Normality of continuous variables was evaluated using the Shapiro–Wilk test. Differences between the two groups were tested with the U Mann–Whitney test. The comparisons of categorical variables (frequency tables) were analyzed using the chi-square independence test. Two-way tables were assessed with the chi-square test, chi-square test with Yates correction or Fisher exact test. The predictive ability of continuous variables, along with the search for the optimal cut-off point was evaluated using ROC curves. Univariate and multivariate analyzes of factors affecting the CHA_2DS_2-VASc score were performed. Multivariate analysis using logistic regression was performed for those data, which in univariate analysis reached a P value < 0.2. Multivariate analysis was performed using the step backwards method. A P-value < 0.05 was considered significant.

3. Results

The venography was performed in 223 consecutive patients aged on average 68.2 years (25.7–95.3), 77 females (34.5%). None of the patients exhibited any adverse reaction to the contrast dye.

The presence of VSO was detected in 79 (35.4%) patients aged 68.3 ± 14.1 years, 30 female (40%) patients—group I. In group II (patients without VSO) there were 144 patients (64.6%) aged 68.1 ± 11.5 years, 47 females (32.6%)—Table 1.

Both analyzed groups were similar in terms of the mean number of implanted leads (1.78 ± 0.61 in group I vs 1.67 ± 0.70 in group II, P = 0.146). The leads had had a long dwell time in the cardiovascular system (CVS): 104.7 ± 75.1 months in the group with VSO and 106.0 ± 79.0 months in the group without VSO, P = 0.988.

The mean result of the CHA_2DS_2-VASc score calculated for the whole population was 3.0 ± 1.66. The mean result was significantly higher in group II (3.19 ± 1.7) compared with group I (2.63 ± 1.55; P = 0.017). There was a significant difference in the prevalence of comorbidities which are included in the CHA_2DS_2-VASc score: hypertension and diabetes were more frequent in group II. The remaining parameters included in the score did not differ significantly between both groups–Table 1.

The influence of the factors included in the CHA_2DS_2-VASc score on VSO assessed in univariate analysis is presented as a forest plot of the categorical variables–Fig. 1.

In multivariate analysis, the only statistically significant factor which prevented VSO in the group without VSO was diabetes–Table 2. The influence of the CHA_2DS_2-VASc score on the incidence of VSO assessed in multivariate analysis is presented as a forest plot–Fig. 2.

Using the receiver operating characteristic (ROC) curve, we identified the optimal cut-off point for the CHA_2DS_2-VASc score that allowed the prediction of the absence of VSO. The level of the cut-off point for the CHA_2DS_2-VASc score was 3.0–Fig. 3.

A higher CHA_2DS_2-VASc score result was present in the group without VSO, which means that the higher the result of the score the lower the likelihood of VSO and that the CHA_2DS_2-VASc score is a destimulant of the incidence of VSO in patients with endocardial leads.

The tested parameter was characterized by moderate sensitivity (73.4%) and specificity (42.4%) in predicting the absence of VSO.