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ORIGINAL ARTICLE

Impact of vascular access site on procedural time of endomyocardial biopsy

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Abstract

Endomyocardial biopsy (EMB) is widely used for the diagnosis of unexplained ventricular dysfunction and for assessment of cardiac allograft rejection. But, the impact of vascular access site on procedural time of EMB is not well-known. From February 2014 to May 2016, consecutive patients requiring EMB were prospectively enrolled in this study. Vascular access, by either the jugular or femoral vein, was randomly assigned. EMB was randomly performed by 3 pre-identified physicians based on practical experience in EMB. Each case was required to obtain at least 3 samples. The primary endpoint was to compare the total time spent in acquiring EMB from the right ventricular septum between the jugular and femoral vein access groups. The secondary endpoints were evaluation of each set (1st to 3rd attempt) of EMB times and safety. In addition, factors affecting the EMB procedural times were evaluated. A total of 49 consecutive patients requiring EMB (3.9 attempts/patient) were enrolled (the jugular group: 23, the femoral group: 26), and 156 myocardial samples (3.2 samples/patient) were obtained. There were no significant differences in total biopsy procedural time between the 2 groups (16.3 ± 7.4 vs. 20.8 ± 9.9 min, $p = 0.075$). Independent predictors for longer procedural time of the 1st attempt included femoral access, non-expert operators, and larger right atrium according to multiple linear regression analysis. The complication rates were not significantly different between the 2 groups, except for catheter kinking as a technical factor. Total biopsy time was not significantly different between the jugular and femoral venous access groups. However, the 1st attempt EMB procedural time by non-expert operators was longer when using the femoral approach, especially in cases involving a larger right atrium diameter.

Keywords Endomyocardial biopsy · Access site · Time · Jugular · Femoral

Introduction

Endomyocardial biopsy (EMB) is widely used for the diagnosis of unexplained ventricular dysfunction and for assessment of cardiac allograft rejection [1]. The first transvenous EMB forcep was developed in Japan in 1962 [2]. Subsequent introduction of the flexible Stanford-Caves Shultz [3] and the King's bioptomes [4] further reduced the procedural risks of EMB, thereby increasing its value in cardiac care.

EMB was initially performed through the internal jugular vein and remains as the most common access site in the United States [3]. However, the advent of long, flexible bioptome devices enabled the performance of EMB via the femoral vein approach with a very low complication rate under fluoroscopic guidance [5, 6]. Currently, EMB from the right ventricle (RV) is usually performed through the jugular or femoral vein. However, each vascular access site has its advantages and disadvantages [5, 7].

There are significant time requirements involved in performing the procedures necessary in the diagnosis of unexplained ventricular dysfunction, including right heart catheterization, coronary angiography, left ventriculography and EMB. Therefore, reduction in examination time would benefit both patient and physician alike. Although data regarding efficacy and safety for access site of EMB are available, the impact of vascular access site on EMB procedural time is not well-known.

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Thus, the purpose of this study was to evaluate total procedural time in obtaining EMB specimens from the RV between jugular and femoral vein access groups, as well as factors affecting EMB procedural time.

Methods

Patient population

From February 2014 to May 2016, consecutive patients requiring EMB at Aichi Medical University Hospital (Nagakute, Japan) were prospectively enrolled in this study. Our hospital performs 30–40 EMB procedures per year and is categorized as a low to medium volume center concerning EMB. Biopsies were performed according to current guidelines as a tool for the diagnostic evaluation of suspected myocarditis, unclear heart failure, unexplained cardiomyopathy or assumed infiltrative and storage disease [8–10].

This study was conducted according to the Declaration of Helsinki. The study protocol was approved by the institutional review board, and informed consent was obtained from all individual participants included in the study.

EMB procedure

All patients underwent sequential vascular access puncture, Swan-Ganz catheter, coronary angiography (CAG) and EMB as their basic examination, and left ventriculography was performed in select cases as indicated.

Vascular access by either jugular or femoral vein was randomly assigned (the jugular group and femoral group), and all vein punctures were performed under the established echo-guided technique [11]. EMB was randomly performed by 3 pre-identified physicians defined as below:

Physician A: senior expert physician involved in > 75 EMB cases/previous 5 years.

Physician B: junior expert physicianinvolved in > 50 EMB cases/previous 3 years.

Physician C: non-expert physician involved in a few cases/year, and possibly needing assistance by an expert physician.

Via an 8-French sheath in the jugular or femoral vein, a 7.5-French guide catheter for EMB (Medikit catheter introducer™ CI60N80TPK: femoral or CI60P40TPK: jugular) was, respectively, advanced into the RV over a 5-French pigtail catheter for securing the ventricular position. As soon as the correct RV septum position of the guide catheter tip was verified by biplane projection, the pigtail catheter was removed, and biopsy forceps (Cook Flexible Biopsy Forceps™ FBF-5.2-120.) were inserted into the tip of guide catheter. After confirming the positioning of the guide catheter tip in a close position to the RV septum with contrast dye, the forceps were carefully advanced toward the septum and opened, and then advanced a little forward to get contact. As soon as the jaws were closed to obtain a sample, the forceps were then withdrawn outside immediately. Regarding the number of samples, modern pathology with newer technologies of immunochemistry, including DNA and RNA analysis, needs at least 5–6 specimens [12]. Since these newer modern pathological techniques are not always available in our low–medium volume center, each case was required to obtain at least 3 samples in this study. After the procedure, continuous electrocardiographic (ECG) monitored recordings were used to detect potentially developing pericardial tamponade. In addition, a 12-lead ECG and transthoracic echocardiography were performed to evaluate the incidence of arrhythmia, conduction abnormalities and pericardial effusion, both before and after the procedure.

Clinical outcome assessment

The primary endpoint was to compare total EMB time to obtain specimens from the RV septum between the jugular and femoral groups. The secondary endpoints were evaluation of each set (1st to 3rd attempt) of EMB times, complication rates of access site hematoma, neurological failure, arrhythmia, conduction abnormalities, possible perforation and defined perforation.

Procedural times were defined as follows:

- *Total EMB time* All procedure times for EMB, from 1st attempt to final attempt, to obtain 3 specimens including intervals for each EMBs.
- *First attempt EMB time* From insertion of the guide catheter for EMB into the 8-French sheath to forceps removal outside the body, regardless of obtaining specimen.
- *Second attempt EMB time and after* From insertion of forceps into the guide catheter for EMB to removal outside the body, regardless of obtaining specimen.

In addition, factors affecting the attempt EMB times were evaluated based on patient characteristics, including echocardiographic findings. Echocardiography was performed before EMB, and these findings were measured according to the guideline for the echocardiographic assessment of the American Society of Echocardiography.

Statistical analysis

Continuous variables are expressed as mean ± standard deviation, and comparisons between the jugular access group and the femoral access group were performed using unpaired Student's *t* test. Mann–Whitney *U* test was appropriately used when normality tests of these variables failed. Categorical variables are presented by patient number (%),

and were analyzed using Chi-squared test. Multiple linear regression analysis was performed to assess the factor prolonged EMB procedural time adjusted for all variables selected by stepwise analysis. One-way analysis of variance (ANOVA) was used to determine the mean variable differences of procedural times among all physician groups. If there were significant differences among the groups, Bonferroni correction was used as post hoc test. A p value < 0.05 was considered to indicate statistical significance. All statistical analyzes were performed with SPSS 22.0 statistical software (SPSS Inc., Chicago, IL, USA).

Results

Baseline patient characteristics

A total of 49 consecutive patients requiring EMB were enrolled (the jugular group: 23, the femoral group: 26) in this study. Baseline characteristics are summarized in Table 1. There were no significant differences in etiology, parameters of echocardiography and Swan-Ganz catheter data between the 2 groups, except for demographic parameters associated with patient height and weight.

Summary of procedure

Table 2 shows the procedural background. A total of 156 myocardial samples (3.2 samples/patient) were obtained. There were no significant differences between the 2 groups in total EMB times, which is the endpoint of the present study. However, regarding an average of 1st to 3rd attempt EMB time, procedural time in the femoral group was significantly longer compared with the jugular group. Specifically, only the 1st attempt EMB time was significantly longer in the femoral group compared with the jugular group. Difference in EMB time was reduced in the 2nd and 3rd attempts of EMB between the 2 groups (Fig. 1).

Technical factors and complications

Catheter kinking was frequently observed in the femoral group (Table 3), however, other unfavorable technical events did not differ between the 2 groups. With regard to complications, major complications such as tamponade were not observed in either group, but a few minor complications, such as vasovagal reflex and dysrhythmias, were observed only in the femoral group.

Table 1 Patient characteristics

	Jugular ($n = 23$)	Femoral ($n = 26$)	p value
Demographics			
Age, years	55.0 ± 13.4	60.1 ± 11.7	0.163
Male, *n* (%)	18 (78.3)	15 (57.7)	0.126
Height, cm	167.6 ± 10.4	160.2 ± 10.1	0.015
Weight, kg	70.0 ± 16.4	56.8 ± 16.1	0.007
Body Mass Index, kg/m^2	24.7 ± 4.4	21.9 ± 4.5	0.030
Body surface area, m^2	1.83 ± 0.25	1.62 ± 0.25	0.005
Cardiothoracic ratio, %	54.4 ± 4.6	55.2 ± 6.6	0.645
Sinus rhythm, *n* (%)	18 (78.3)	21 (80.8)	0.828
Etiology			
DCM, *n* (%)	7 (30.4)	10 (38.5)	
HCM, *n* (%)	7 (30.4)	4 (15.4)	0.450
Other, *n* (%)	9 (39.2)	12 (46.1)	
Echocardiographic data			
LVDd, mm	53.1 ± 11.0	53.4 ± 8.6	0.904
LAD, mm	40.3 ± 11.2	37.9 ± 8.7	0.390
RVDd, mm	33.0 ± 6.0	32.2 ± 6.3	0.623
RAD, mm	36.1 ± 8.1	35.3 ± 7.1	0.687
IVC, mm	14.6 ± 3.8	13.2 ± 4.0	0.215
Swan-Ganz catheter data			
PCWP, mmHg	14.8 ± 8.9	10.7 ± 6.2	0.066
Mean PAP, mmHg	22.7 ± 9.5	19.0 ± 7.6	0.133
RVP, mmHg	34.0 ± 10.2	31.1 ± 10.0	0.318
RAP, mmHg	8.9 ± 5.0	7.9 ± 3.2	0.428
CVP, mmHg	8.4 ± 4.9	7.8 ± 4.2	0.632

DCM dilated cardiomyopathy, *HCM* hypertrophic cardiomyopathy, *LVDd* left ventricular diastolic diameter, *RVDd* right ventricular diastolic diameter, *IVC* inferior vena cava, *PCWP* pulmonary capillary wedge pressure, *PAP* pulmonary artery pressure, *RVP* right ventricular pressure, *RAP* right atrial pressure, *CVP* central venous pressure

Factors affecting EMB procedural time

Since only the 1st attempt EMB time in the femoral group was significantly longer compared with the other attempt EMB times, we investigated predictors of 1st attempt EMB time using multivariate analysis (Table 4). Variables with $p < 0.1$ on simple linear regression analysis for predictors of 1st EMB procedural times were entered into the multivariate analysis model. The 3 parameters, right atrial diameter (RAD) assessed by echocardiogram based on linear dimensions, the minor axis of the RA measured in the apical four-chamber view [13], EMB procedure performed by Physician C, and femoral vein access, were independent predictors of longer procedural time of the 1st attempt biopsy by stepwise method as a multiple linear regression analysis model. The cutoff value of RAD to predict median

Table 2 Procedural characteristics

	Jugular ($n = 23$)	Femoral ($n = 26$)	p value
Operator			
Physician A	9 (39.1)	6 (23.1)	
Physician B	10 (43.5)	14 (53.8)	0.475
Physician C	4 (17.4)	6 (23.1)	
Endomyocardial biopsy			
Number of total samples	73	83	–
Average number of samples	3.2 ± 0.9	3.2 ± 1.2	0.953
Average number of attempts	4.1 ± 1.5	3.8 ± 1.5	0.523
Biopsy achievement rate, % (the rate of getting 3 samples or more)	19 (82.6)	20 (76.9)	0.622

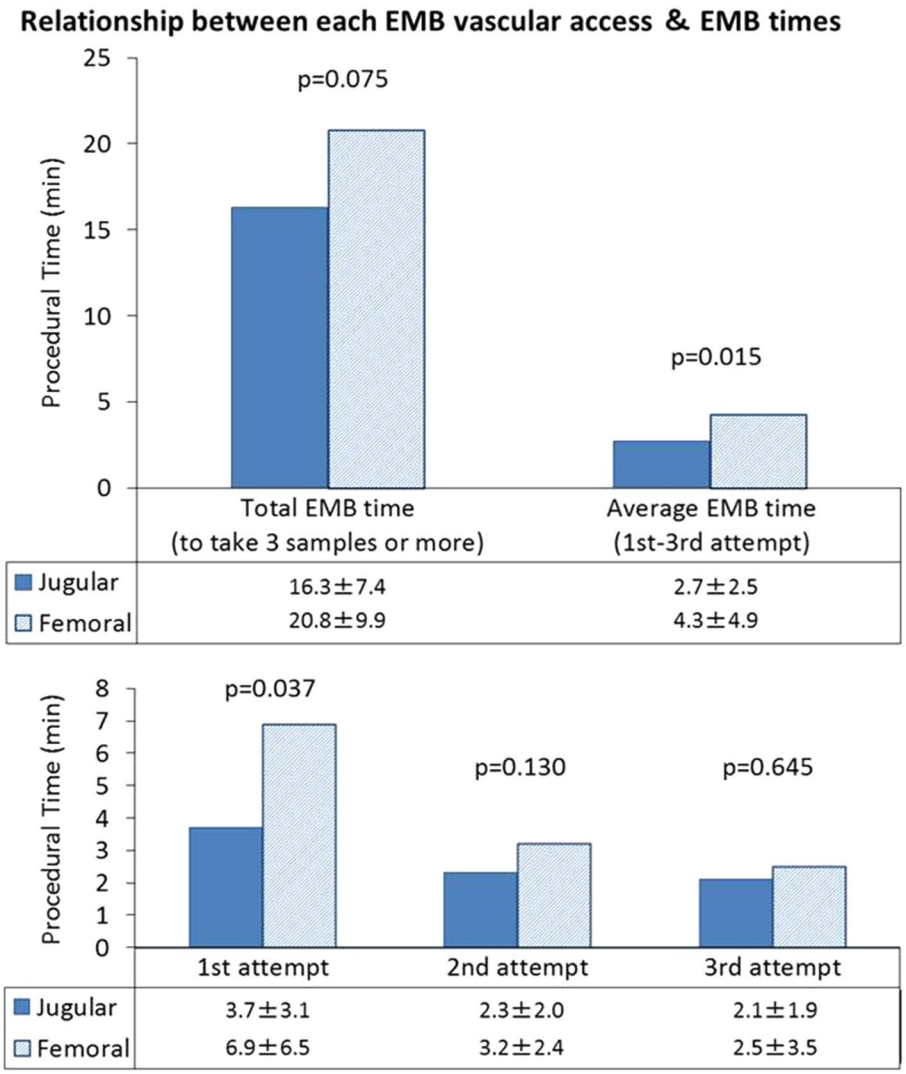

Fig. 1 Comparison of EMB times between jugular and femoral vein access. Total EMB times to take 3 samples or more did not significantly differ between the 2 groups. However, 1st to 3rd average attempt EMB time, especially 1st attempt EMB time, was significantly longer in the femoral group compared with the jugular group. Difference in EMB time between the 2 groups was reduced in the 2nd and 3rd attempts

Table 3 Technical factors and complications

	Jugular ($n = 23$)	Femoral ($n = 26$)	p value
Technical factors			
Contrast dose, ml	20.9 ± 6.0	19.2 ± 5.4	0.295
Complicated puncture, *n* (%)	2 (8.7)	2 (7.7)	0.898
Trouble with contrast injection, *n* (%)	1 (4.3)	0 (0)	0.283
Catheter kinking, *n* (%)	0 (0)	4 (15.4)	0.050
Complications			
Cardiac tamponade, *n* (%)	0 (0)	0 (0)	–
Pericardial effusion, *n* (%)	0 (0)	0 (0)	–
Ventricular arrhythmia, *n* (%)	1 (4.3)	0 (0)	0.283
Atrial arrhythmia, *n* (%)	1 (4.3)	0 (0)	0.283
AV block, *n* (%)	0 (0)	0 (0)	–
CRBBB, *n* (%)	0 (0)	1 (3.8)	0.342
Access site hematoma, *n* (%)	0 (0)	0 (0)	–
Vasovagal reflex, *n* (%)	1 (4.3)	0 (0)	0.283
All complications (per patients), *n* (%)	3 (13.0)	1 (3.8)	0.241

AV block atrioventricular block, *CRBBB* complete right bundle branch block

Table 4 Simple and multiple linear regression analysis for predicting 1st attempt EMB time

	Simple				Multiple			
	β	Standardized β	t	p value	β	Standardized β	t	p value
Male	2.703	0.240	1.692	0.097				
LAD, mm	0.157	0.292	2.091	0.042				
RAD, mm	0.267	0.375	2.775	0.008	0.276	0.388	3.326	0.002
RVDd, mm	0.340	0.388	2.887	0.006				
Physician C	5.322	0.405	3.040	0.004	4.993	0.380	3.254	0.002
Femoral access	3.173	0.299	2.151	0.037	3.133	0.296	2.524	0.015

Multiple analysis was evaluated with all variables showing $p < 0.1$ with simple linear regression analysis by stepwise regression analyses

1st attempt EMB time from femoral access of 4.5 min was 35.5 mm with receiver operating characteristic (ROC) analysis (AUC = 0.876, $p < 0.01$, Fig. 2).

Inter-observer variability

In all attempts of EMB using jugular access, there were no significant differences of procedural time among all physician groups. However, the non-expert physician C took significantly longer compared with the other expert physicians in the 1st attempt in the femoral access group (Fig. 3).

Discussion

The present study is a report prospectively examining the impact of vascular access site on procedural time of EMB. The main findings of this study are as follows: (1) There were no significant differences in total EMB time between the 2 venous access groups. (2) Regarding 1st to 3rd average attempt EMB time, especially the 1st attempt EMB time to obtain specimens, the femoral access group took longer than the jugular access group. (3) In cases with a larger RAD assessed by echocardiogram and being performed by a non-expert physician, the 1st attempt EMB time was longer, but became shorter after the 2nd attempt of EMB.

Right cardiac enlargement affecting EMB procedural time

In the present study, EMB procedural times were longer in the femoral group compared with the jugular group, only in the 1st attempt. In a retrospective analysis comparing jugular with femoral vein access on EMB procedural time, jugular vein access was associated with shorter operation time and radiation exposure times [14]. In jugular vein access, it is easier to insert biopsy forceps into the tip of the guide catheter because adequate backup force from the RA free wall could support the guide catheter tip to push against the RV septum [14]. In contrast, with the femoral vein

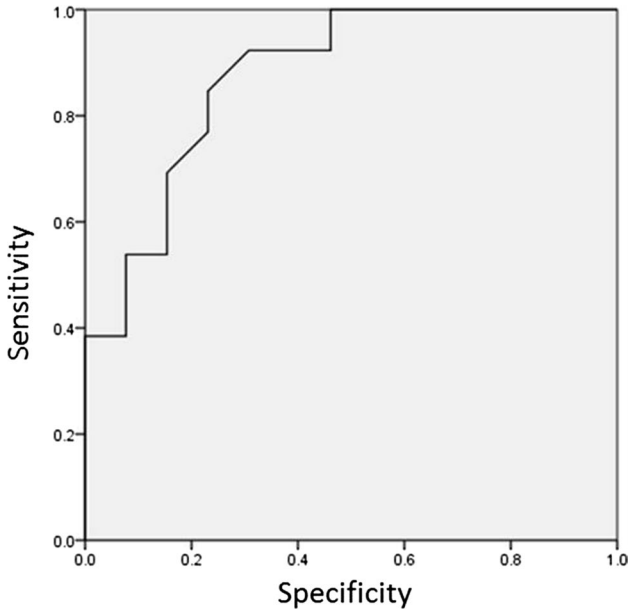

Fig. 2 ROC curve analysis. The cutoff value of RAD to predict median 1st attempt EMB time from femoral access of 4.5 min was 35.5 mm with ROC analysis (AUC=0.876, $p < 0.01$)

access, because there is no cardiac wall to secure backup force for the guide catheter pushing against the RV septum, and the rigid forceps shaft tends to cause the guide catheter to "jump" toward the pulmonary artery, it is necessary to provide clockwise torque to the guide catheter to fix into RV septum. According to our study, the main factors which prolonged the 1st attempt times were size of the right atrium and less experience with EMB techniques. In other words, it took additional time to perform EMB at the 1st attempt in cases with larger RAD by non-expert physicians. We believe that enlargement of the RA would reduce backup force for the guide catheter pushing against the RV septum, resulting in difficulty of appropriate positioning/direction of the guiding catheter via the femoral access, especially at 1st EMB procedure.

Technical experiment affecting EMB procedural time

As previously reported, the development of long, flexible bioptome devices permit the femoral vein approach of EMB with equal efficacy and safety compared to the jugular vein approach [5, 6, 15, 16]. However, those results were mainly obtained using experienced operators in high volume centers [17, 18]. Whether similar results can be replicated using

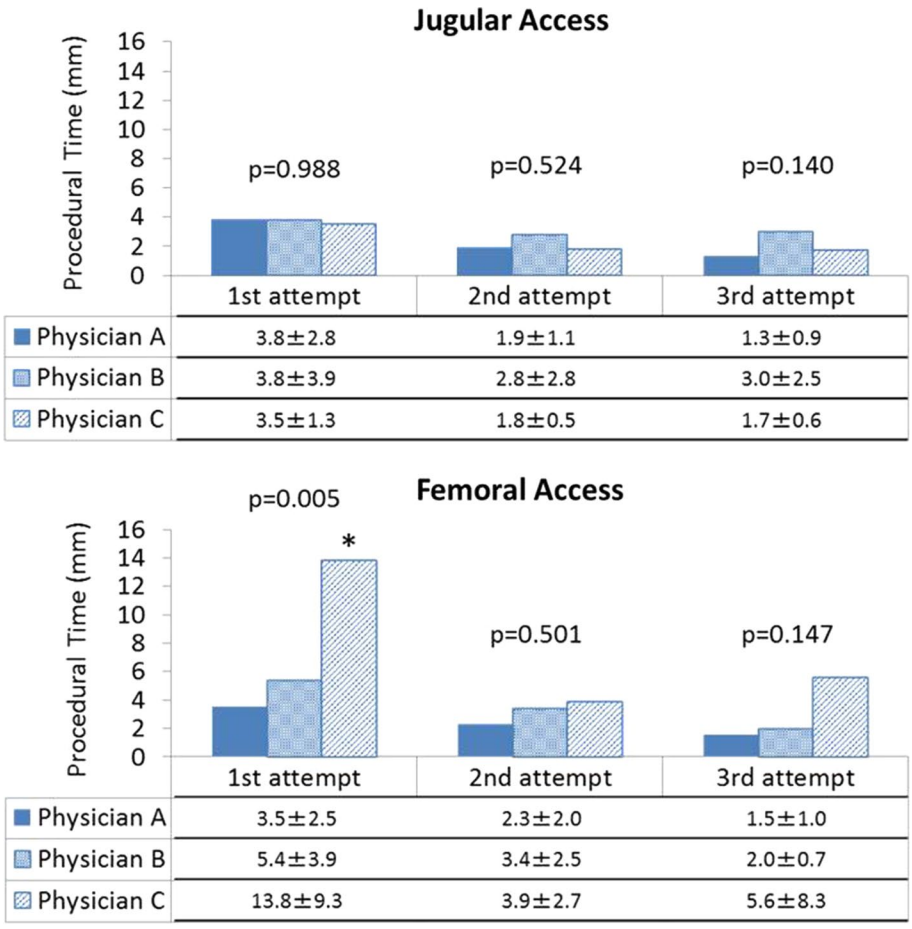

Fig. 3 Inter-observer variability. In all attempts of EMB via jugular access, there were no significant differences of procedural time among all physician groups. However, the non-expert physician C took significantly longer compared with the other expert physicians in the 1st attempt in the femoral access group (by one-way ANOVA). *$p < 0.010$ ($p < 0.017$ was significant difference after Bonferroni correction) vs. 1st attempt of physician A or B via femoral access

less experienced operators in low or medium volume centers remain unclear. In this regard, we investigated less experienced operators, who may have needed additional time to grasp the techniques of pushing the guide catheter against the RV septum suitably in their 1st attempt of EMB using femoral access. Overall, larger RA and less experienced operators contributed to prolonged time for the 1st EMB procedure.

Advantages and disadvantages of vascular access

Both vascular access sites have advantages and disadvantages. In terms of complications, there were no significant differences between the 2 groups except for catheter kinking as an unfavorable technical event in the present study. In general, in terms of advantages with femoral access, right-handed operators found it easy to perform the EMB procedure using their dominant hand. Further, femoral vein access avoids the risk of pneumothorax or hemothorax, unlike jugular vein access [14]. Disadvantages include potential risk of a deep vein thrombosis and pulmonary embolism due to the need for post-procedural immobilization [19]. The main advantage of jugular venous access is ease of the catheter being directed toward the RV septum. In terms of limitations, the operator must be positioned behind the X-ray tube, located at the head of the patient, with the monitor near the foot of the patient, which results in loss of monitor visibility as well as theoretically expected increased radiation exposure for the operator.

Clinical implications

EMB is required to diagnose unexplained ventricular dysfunction or assess cardiac allograft rejection. The frequency of the EMB procedure itself is not rare but is performed less often when compared to regular left heart catheterization, such as CAG, in daily clinical practice. Therefore, it takes longer to acquire procedural proficiency to ensure a safe procedure for select patients. Since our study showed that larger RA diameter, non-expert physicians, and femoral vein access were predictors for greater 1st EMB procedural time, less experienced physicians should begin their EMB training in patients with normal size RA and using the jugular vein access site. As such, appropriate selection of access site in consideration of RA size could lead to improved EMB procedural time for both the alike.

Limitations

There are several limitations in this study. First, this study was a single center study with a relatively small sample size. Second, although there were no significant differences between the experience of operators and case distribution, the operators were not randomized to cases commensurate with their experience.

Conclusions

Total EMB procedural time did not differ significantly between the jugular and femoral vein access sites. However, the 1st attempt procedural time of EMB by non-expert operators was longer in the femoral vein approach, especially when larger RA diameters were present in patients undergoing EMB procedure.

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Compliance with ethical standards

Conflict of interest The authors declare no conflict of interest.

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