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Right or left endomyocardial biopsy? A systematic review with meta-analysis about complications and safety

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KEYWORDS:
endomyocardial biopsy;
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safety;
complications

BACKGROUND: Endomyocardial biopsy (EMB) is an invasive procedure used to diagnose myocarditis and investigate other nonischaemic cardiomyopathies. However, it is still contentious whether right ventricle endomyocardial biopsy (RV-EMB) is safer than left ventricle endomyocardial biopsy (LV-EMB). Therefore, we aimed to perform an updated meta-analysis comparing the outcomes of LV-EMB vs RV-EMB in patients submitted to this procedure.

METHODS: We searched PubMed, Embase, and Cochrane Central in January 2023 for studies comparing the outcomes of patients submitted to LV-EMB and/or RV-EMB. Outcomes were major and minor complications after the procedure: death, cardiac tamponade requiring pericardiocentesis, pericardial effusion without pericardiocentesis, stroke, transient ischemic attack, arrhythmias as permanent or transient atrioventricular block, atrial fibrillation, ventricular fibrillation, chest pain and local complications. Statistical analysis was performed using RevMan 5.1.7. Heterogeneity was assessed with I^2 statistics. The risk of bias of the studies has been evaluated with the ROBINS-I tool.

RESULTS: We included 6308 patients from 6 studies. The mean age was 49.8 years, with approximately 70% male patients. All studies were observational prospective or retrospective. Pericardial tamponade and/or pericardial effusion (odds ratio 0.54; 95% confidence interval 0.31-0.93; $p = 0.03$; $I^2 = 20\%$) after the procedure were significantly lower in patients submitted to LV-EMB compared with RV-EMB.

CONCLUSIONS: In conclusion, a minor rate of pericardial perforation was observed during LV-EMB compared to RV-EMB. It was also observed that LV-EMB provides a high diagnostic yield in diagnosing myocarditis and other cardiomyopathies.

LAY SUMMARY: Endomyocardial biopsy (EMB) is an invasive procedure used to diagnose cardiac diseases. Our aim is to study which side of the heart is safer for this procedure.

- Biopsy of left ventricle presented less perforation of the heart wall.
- Some studies suggest a better diagnostic performance of the left ventricle biopsy.

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Endomyocardial biopsy (EMB) is an invasive procedure employed in the evaluation of cardiac tissue. It was first introduced through vascular access in 1962 by Konno and Sakakibara to elucidate the pathogenesis of primary myocardial disease.[1] It provides valuable information about the composition and structure of the cardiac tissue from an extracted sample from the inner layers of the heart, enabling the analysis of inflammatory cells, viral presence, toxic injuries, and metabolic disorders and provides a useful tool for the in vivo histopathologic and molecular diagnosis of multiple cardiac disorders.[2] Advances in myocardial and viral molecular biology, as well as in image and electrophysiology guided biopsy, have contributed to the technique reaching prognostic and therapeutic value over the years in several conditions, such as chest pain, cardiomyopathies, myocarditis, arrhythmias, infiltrative and storage diseases, secondary involvement by systemic diseases, drug toxicity and cardiac tumors.[2,3] Nowadays, the main application of EMB is routine surveillance of heart rejection after transplantation,[4-6] while other clinical indications are individualized depending largely on the risk-benefit ratio of prognostic, diagnostic or therapeutic value, including assessment of high-risk major clinical syndromes, such as heart failure, complicated or not responding to standard optimized medical therapy in the short term.[2,4,6-8]

General terms, current practice and what is established

Biopsies can be extracted from the right ventricle (RV) and from the left ventricle (LV). RV EMB is often performed via the venous route, mostly through internal jugular, femoral, or brachial veins. The subclavian vein can also be an option.[4,7] The left ventricle may be biopsied through the femoral artery or radial artery. The transradial approach appears to be just as effective as the transfemoral artery access method when it comes to major complications and may even result in fewer incidents of bleeding at the access site when compared to the femoral approach.[4,9] To decrease sampling error, a successful procedure should provide at least 5 or more samples, ideally 3 to 4 mm^2 volume, usually pink in color and sinking in formalin.[3,10,11] All patients who undergo EMB are at risk of complications, whose rate is low but not negligible.[6,12] Complications likely vary with the experience of the operator, clinical status of the patient and repetition of biopsies, presence or absence of left bundle branch block, access site, and possibly bioptome.[6,7,10] Immediate risks include vasovagal syncope, puncture of central arteries, venous hematoma, arteriovenous fistula, ventricular perforation, pneumothorax, and transient arrhythmias; delayed risks include access site bleeding, tricuspid valve regurgitation, pericardial tamponade, deep venous thrombosis, pulmonary embolism and infection.[3,7,10] Life-threatening complications occur far less frequently.[12]

There are no clear recommendations for when to biopsy each side, but the procedural practicability, the clinical condition, and the risks of complications must be considered for the individual patient, in addition to each center's expertise.[6,13,14] Even though RV has historically been favored over LV, there is no evidence that the first is indeed safer than the latter and therefore should be preferred; it has even been demonstrated that diagnostic yield of EMB for multifocal involvement heart diseases may be optimized when samples from both ventricles are available.[14,15] Nevertheless, despite the increasing interest in the LV as a routine site of biopsy, it has yet to gain an official recommendation in guidelines due to concerns about bleeding and systemic embolization, as well as possible interference with the aortic valve or the mitral subvalvular apparatus.[14] For LV EMB to achieve wider use, it should prove equal or superior quality/reliability in diagnostic yield, while remaining safe and easily accessible. In the same manner, for RV EMB to be declared the gold standard approach, there should be evidence that RV EMB is safer than LV EMB.

Imaging to guide the biopsy and new technologies

Traditionally, the primary imaging methods used to guide endomyocardial biopsy have been X-ray fluoroscopy and echocardiography. Even though through fluoroscopy the bioptome is easily identified on monitor, there is limited to no visualization of heart anatomy and walls, which restricts safety and accuracy compared to other methods.[16,17] On the other hand, echocardiography allows for better identification of the myocardium, eliminates the need for X-ray exposure, and can also serve as a valuable prebiopsy parameter for evaluating heart function, as well as enabling the monitoring of cardiac complications during and after the procedure.[18-20] To our knowledge, there are no comparative clinical studies that could steer which imaging method would be most suitable for each cardiac chamber. X-ray fluoroscopy guidance, nonetheless, was the method of imaging employed on the procedures in the included studies.

In this context, endomyocardial biopsy has also been enhanced with the emergence of associated techniques that increase diagnostic accuracy and guide the procedure to reduce the risks of complications. One of these techniques is electroanatomical mapping (EAM) system. It is a novel technique that can increase EMB diagnostic yield and replace the fluoroscopy or the intracardiac echocardiography approach. EAM allows generating cardiac chamber 3D reconstruction and tagging of important anatomic landmarks.[21] Therefore, it can enhance the precision of sample collecting and avoid cardiac injury, which might cause cardiac tamponade. Moreover, with the EAM, it is possible to generate an electroanatomical voltage map (EVM) based on recorded intracardiac electrograms, that can be used to recognize areas from relatively normal tissue to areas with a complete absence of electrograms that suggest presence of scar.[21] This system is especially useful in conditions involving the myocardium in a small, segmental, or patchy distribution, which is related to a low sensitivity and high false-negative rate, such as myocarditis, arrhythmogenic right ventricular

cardiomyopathy, and sarcoidosis.[22,23] Regarding the EVM implementation, a cohort study also reported that it is safe and feasible, helping to improve the diagnostic yields of EMB.[24-26]

Objective of the study

Considering this unresolved issue, we performed an updated meta-analysis evaluating whether right ventricle endomyocardial biopsy (RV-EMB) is safer than left ventricle endomyocardial biopsy (LV-EMB) comparing major and minor outcomes of LV-EMB vs RV-EMB in patients submitted to this procedure.

Methods

Data sources and searches

A search of the PubMed, Embase, and Cochrane Central databases was performed using the terms "endomyocardial biopsy" AND ("LV-EMB" OR "LVEMB" OR "left ventricular endomyocardial biopsy") AND ("RV-EMB" OR "RVEMB" OR "right ventricular endomyocardial biopsy") in January 2023. No date limit was applied. We also used the PRISMA checklist when writing our report.[27]

Study selection

Two reviewers independently selected studies by screening of titles and abstracts for eligibility. After full-text articles assessment, more articles were excluded because they did not meet all the inclusion criteria. Reviewer 1 assessed risk of bias and collected the necessary data from each eligible study, while reviewer 2 checked reviewer 1's work. Reviewers used standardized forms and instructions for the selection of the studies including the eligibility criteria. Disagreement between the reviewers was resolved by discussion. We included prospective and retrospective studies about EMB on humans over 38 years reporting one or more of the following hard outcomes: death, cardiac tamponade requiring pericardiocentesis, pericardial effusion without pericardiocentesis, pulmonary embolization, stroke, transient ischemic attack, arrhythmias as permanent or transient atrioventricular block, nonsustained ventricular tachycardia, atrial fibrillation, ventricular fibrillation, chest pain and local complications. Studies must compare LV-EMB to RV-EMB. No randomized controlled trial was found.

Data extraction and quality assessment

We collected the following information from each study:

- General information regarding identification of the studies: study design, author name, year of publication, period of study, country of study, number of patients.
- Patient characteristics: sex, age, New York Heart Association (NYHA) Functional Classification/ dyspnea, reason for EMB.
- Interventions: right or left EMB, access vessel, number of samples, guiding sheath, or catheter used.
- Complications: death, cardiopulmonary resuscitation, cardiac tamponade, urgent cardiac surgery, pneumothorax, mitral injury, tricuspid injury, atrioventricular block, arrhythmias, cerebrovascular events, transient thoracic pain, transient hypotension, pulmonary embolism, intramyocardial hematoma, vasovagal reaction, femoral arteriovenous fistula, pseudoaneurysm.

We did not include abstracts from major studies that were later also published as articles. Instead, we prioritized the main articles to compare them with a more consistent number of participants and the outcomes that were available or reported in each study. We collected and calculated the odds ratio (OR) estimates with their 95% confidence interval (CI).

Seven potential risks of bias were evaluated with the ROBINS-I risk of bias table in order to determine the methodological quality of each study: bias due to confounding, bias in selection of participants into the study, bias in classification of interventions, bias due to deviations from intended interventions, bias due to missing data, bias in measurement of outcomes, bias in selection of the reported result[28] (Supplemental Table).

Data synthesis and statistical analysis

We performed a Mantel-Haenszel test with a fixed or random effects model, accordingly to heterogeneity, for the outcomes measured that were reported by more than 3 studies, with OR and 95% CI as a measure of effect size. We assessed for heterogeneity using Higgins and Thompsons' I^2 statistic. If $I^2 > 25\%$, heterogeneity was considered moderate to high and random effects model was used. We assessed the possibility of publication bias using funnel plot analysis. Statistical analysis was performed with Review Manager 5.4.1 (The Nordic Cochrane Centre, The Cochrane Collaboration, Denmark) (Supplemental Table).

Results

We identified 31 studies, 10 of which were selected for full-text article reading. The search strategy flowchart is summarized in Figure 1. Six studies met all inclusion criteria and were then selected.[13,15,29-32]

Quality assessment

All studies were retrospective or prospective studies, and overall had a serious risk of bias, as assessed by the ROBINS-I tool (Supplementary Table 1). Although there were different sizes of populations employed by the studies, the funnel plot did not show any significant heterogeneity (Supplementary Figure 1).

Studies and patients' characteristics

The period of assessment was from 1983 until 2021, ranging from 2 to 28 years, providing 6308 patients. The mean age was 49.8 years, with approximately 70% male patients. The characteristics of the studies and patients are shown in Table 1. In 1 study analyzed, biventricular EMB was performed in all patients whose conditions were possible[29]; in 3 studies, only selective RV and LV EMB were performed[30–32]; in 2 studies, selective RV, selective LV EMB, and BV EMB were performed; however, selective EMB

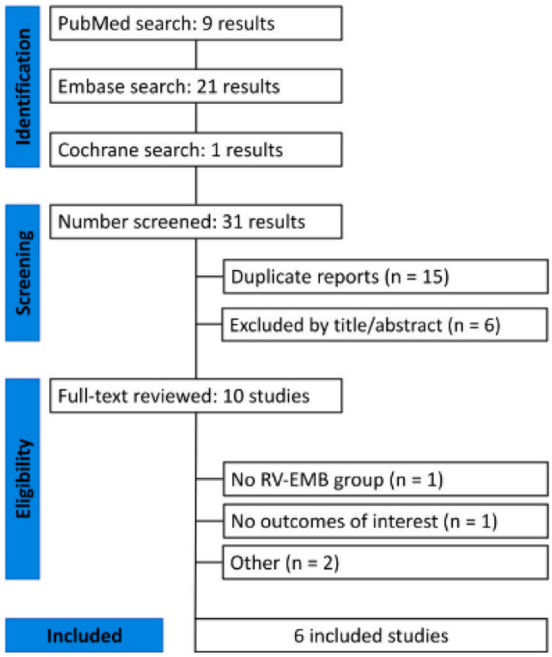

Figure 1 PRISMA flow diagram of study screening and selection. RV-EMB, right ventricle endomyocardial biopsy.

and BV EMB were merged in 1 group for analysis.[13,15] In the retrospective study of Bermpeis,[31] during assessment of postprocedure complications, the total number of EMBs included repeated EMB in the same patient; therefore, the total number of EMB is larger than the number of subjects.

Outcomes

In the overall population, there were 321 (3.21%) complications out of 10,000 procedures, of which 54 (16.8%) were major and 267 (83.2%) were minor. Cardiac tamponade and/or pericardial effusion were the most common complication observed (1%), followed by arrhythmias (0.3%) (Supplemental Figure 2).

Cardiac tamponade and/or pericardial effusion

Most of the analyzed studies[13,15,29,31] showed that cardiac tamponade with pericardiocentesis and pericardial effusion were less common in LV-EMB, and this meta-analysis confirmed that there were significatively less events reported in the LV-EMB group compared to the RV-EMB group (OR 0.54; 95% CI 0.31-0.93; $p = 0.03$; $I^2 = 20\%$; number needed to harm (NNH) = 703.9) (Figure 2).

Atrioventricular block

This outcome is composed of permanent and temporary atrioventricular (AV) block and was assessed in all studies.[13,15,29-32] The reduction of AV block compared to control group was significant in LV-EMB (OR 0.38; 95% CI 0.11-1.28; $p = 0.12$; $I^2 = 21\%$; NNH = 1231.61) (Figure 3).

Cerebrovascular events

This outcome includes stroke and transient ischemic attack and was present in all studies reviewed. Different from other complications, there was a significative reduction of events in RV-EMB compared to LV-EMB (OR 5.46; 95% CI 1.05-28.33; $p = 0.04$; $I^2 = 4\%$; NNH = 388) (Figure 4).

Other nonsignificative outcomes

All analyzed studies included some type of arrhythmias other than AV block, including nonsustained ventricular tachycardia and atrial fibrillation. There was no significative difference between control and intervention groups. Transient chest pain was assessed in 3 studies,[13,15,30] but no significant reduction of events in LV-EMB group was observed compared to RV-EMB group.

Discussion

We investigated the outcomes of left and right ventricular EMB reported in 6308 patients from 6 studies. We observed that RV-EMB was more associated with pericardial tamponade and/or pericardial effusion than LV-EMB. However, RV-EMB was favored in cerebrovascular events (i.e., stroke and transient ischemic attack). No literature reviews comparing the safety and complications of left and right ventricular EMB are available. We observed a higher rate of pericardial tamponade or effusion in RV-EMB, which might be explained by the right ventricle's thinner wall This characteristic could increase the risk of wall perforation by the bioptome during a free right ventricle wall biopsy performed by a nonexperienced interventionist.

Regarding cerebrovascular outcomes, slightly superior results were achieved with RV-EMB, and no article reported this outcome after RV-EMB. It is explained by the absence of a direct connection between the right ventricle and the cerebrovascular circulation. Consequently, an RV embolus would lead to pulmonary thromboembolism rather than a stroke/transient ischemic attack (TIA). Chimenti 2013, whose study contains the highest number of patients, demonstrated that 8 subjects out of 3549 had cerebrovascular outcomes after LV-EMB.[13] Considering the total number of patients from all 6 studies that reported cerebrovascular events after LV-EMB, only 0.22% had stroke or transient ischemic attack. In contrast, cardiac tamponade was reported in 0.95% of patients who underwent RV-EMB. There was no statically significant difference regarding major and minor outcomes.

When analyzing the NNH values, it is intriguing to observe that fewer individuals need to undergo LV-EMB to develop a Stroke/TIA outcome (NNH = 388) compared to the outcome of pericardial tamponade/effusion (NNH = 703.9). Forest plots reveal that pericardial tamponade/effusion is less frequent during LV-EMB, which appears to favor its utilization. However, in the case of LV

Table 1 Baseline Characteristics of Included Studies

Study	Design	Population	Location and period	Male % LV/ RV/BV	Age[a], y LV/RV/BV	Patients, *n* LV/RV/ BV (total)	Sample, *n* LV/RV	Access LV/RV	Guiding sheath or catheter LV/RV	NYHA LV/ RV	Dyspnea % LV/ RV/BV
Stiermaier 2017	PS	Clinically suspected myocarditis	Germany; 08/ 2012–05/ 2015	74.3[b]	42.8[b]	136[b]	NA	Femoral artery/ femoral vein	8 F JR4 guiding catheter/8 F Mullins sheath, pigtail	NA	37.7[b]
Arellano 2021[c]	RS	Heart transplantation	Spain; 01/ 2018- 03/2021	76/74	46.8 ± 14.5/ 53.0 ± 13.1	25/96 (121)	NA	Radial and femoral artery/ NA	NA	NA	NA
Yilmaz 2010	RS	Clinically suspected myocarditis and/ or CMP of nonischemic origin	Stuttgart/ Homburg, Germany; 2006-2008/ 1995-2008	65[b]	54 ± 17[b]	265/133/ 357 (755)	5.8 ± 1.5/ 5.6 ± 1.5	Femoral artery/ femoral vein	Guiding sheath 7 F, Cordis or guiding catheter 7 F, LA7-JR40/ AL10/JL40, Medtronic, Danvers[b]	III 277 (37%) IV 81 (11%)[b]	NA
Chimenti 2013	RS	Clinically suspected myocarditis or nonischemic CMP	Italy; 1983-2010	64.8/ 69.3/66.4	46.2 ± 14.4/53.4 ± 18.8/ 45.7 ± 15.4	1153/672/ 2396 (4221)	4.5 ± 1.2/ 4.2 ± 1.6	Femoral artery/ femoral vein	7 F (501-613A Cordis) long sheath[b]	NA	87.2/ 83.9/ 85
Bermpeis 2022	RS	Clinically suspected myocarditis, nonischemic CMP or for surveillance of allograft rejection	Belgium; 05/ 2011- 05/2021	72.3[b]	61[b]	(561)	3-6[b]	Right femoral artery/right femoral vein, right jugular	7 F 96 cm long sheath/7 F flexible bioptome using a 7 F 104 cm long sheath or an 8 F 11 cm long sheath	NA	NA
Göbel 2020	RS	Heart failure without evidence of significant coronary artery disease or valvular disease	Germany; 11/ 2013- 12/2018	70.5/70	55.1/53	461/53 (514)	5-7/3-7	Femoral or radial artery/ right femoral vein	7.5 F Eaucath system or 8 F MP GC system/ 9 F FastCath	I 104/12 II 96/19 III and IV 160/13	NA

CMP, cardiomyopathy; NA, not available; PS, prospective study; RS, retrospective study.
[a]Mean or median.
[b]No stratified information available.
[c]Conference abstracts.

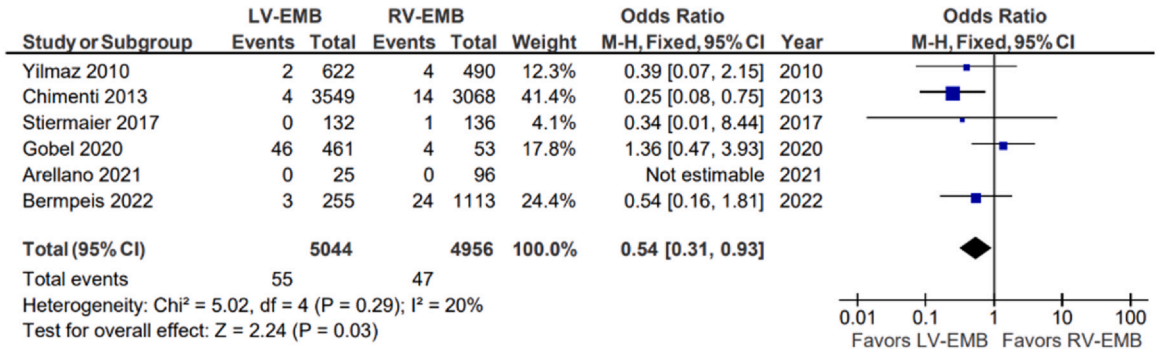

Figure 2 Forest plot of cardiac tamponade and/or pericardial effusion. CI, confidence interval; LV-EMB, left ventricle endomyocardial biopsy; RV-EMB, right ventricle endomyocardial biopsy.

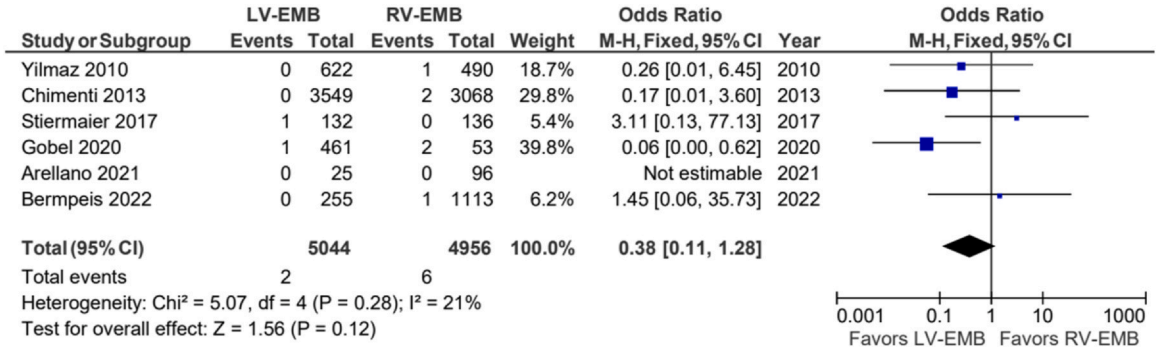

Figure 3 Forest plot of atrioventricular block. CI, confidence interval; LV-EMB, left ventricle endomyocardial biopsy; RV-EMB, right ventricle endomyocardial biopsy.

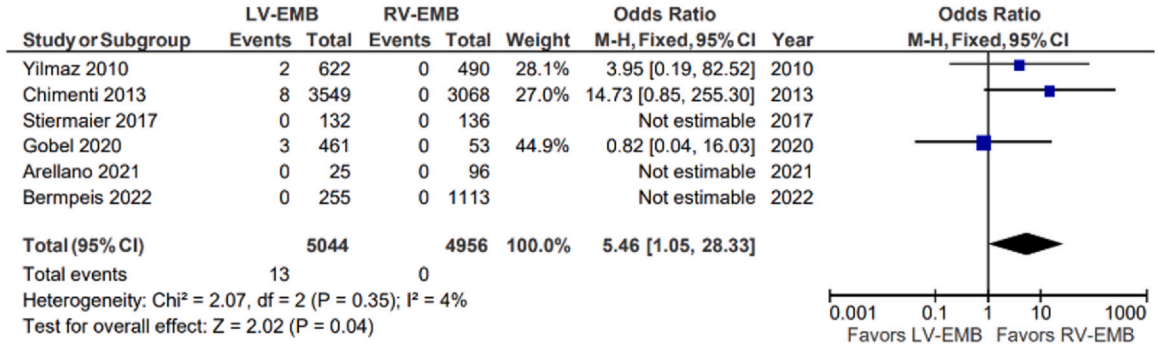

Figure 4 Forest plot of cerebrovascular events. CI, confidence interval; LV-EMB, left ventricle endomyocardial biopsy; RV-EMB, right ventricle endomyocardial biopsy.

biopsy, there is a higher likelihood of a cerebrovascular event occurring before perforation takes place.

The selected studies also indicate that LV biopsy provides greater diagnostic accuracy given that thicker ventricular wall allows for the collection of more samples, thereby enhancing the precision of histological analyses. Consequently, in comparison to the RV, isolated LV biopsy falls short on safety but gains in diagnostic yield. The adoption of new imaging technologies to guide the biopsy procedure could mitigate the risks associated with LV biopsy, such as using intracardiac echocardiography to identify thrombi during the procedure. Therefore, we emphasize the importance of more observational studies and the necessity for randomized controlled trials to evaluate these possibilities.

It is indeed true that our study presents limitations, since there are few studies in the literature comparing the outcomes of both procedures and those that do so are observational studies. It is worth noting that endomyocardial biopsy also may lack sufficient sensitivity considering the time, quality, and site of sampling, and a major weakness of the detection of histological findings, such as acute cellular

rejection, is the subjective component of interpretation of samples by cardio-pathologists.[33,34] In the CARGO II study, it was demonstrated that overall pairwise agreement of rejection grades between pathologists ranged from 65% to 77%, and the grading was more subjective when trying to detect significant acute cellular rejection.[33] Among the selected studies that compared EMB between the left and right ventricles, only 2 comprised cardiac allograft rejection surveillance.[31,32] This study aimed to evaluate the safety and viability of the EMB procedure, having therefore included not only studies of cardiac allograft rejection monitoring, but also of heart failure and myocarditis. Inclusion criteria were thus related to the outcomes of the EMB procedure rather than the methodology of histological analysis, which varied according to the subjacent cardiac pathology in each study. The included articles did not report details about the analysis conducted by pathologists on the collected samples, which is a minor limitation of the present study. Nevertheless, these articles did provide information about the specimen collection process. Overall, one common finding among these studies that may provide a resource in minimizing the variability was that the diagnostic value of the test was possibly increased in patients undergoing biventricular biopsy, precisely because the representative of specimens reduced sampling error.[13,15,29]

Also, EMB is the gold standard for diagnosis and surveillance of Heart Transplantation rejection status, but in recent years there has been a debate concerning the optimal timing and frequency of routine monitoring EMB.[4] It has been shown that clinically relevant cardiac rejection is uncommon in asymptomatic patients or in left ventricular systolic dysfunction[35] and increasing numbers of EMB have not been associated with improvement of overall survival of patients.[36] A revised schedule of less frequent routine-surveillance EMB, therefore, has been proposed.[37] However, for postcardiac transplantation patients with increase in LV mass, pericardial effusion, systolic/diastolic ventricular dysfunction, and stiffness, EMB provides essential information on myocardial histology. The International Society for Heart and Lung Transplantation provided a working formulation for the standardization of cardiac cellular rejection and biopsy grading system, as well as a summarization of consensus regarding its management.[38]

Conclusion

Even though there are no clear recommendations for when to biopsy the right or the left ventricle, RV has historically been favored over LV. This study, however, found that cardiac tamponade and/or pericardial effusion were the most common complications and significantly less frequent in LV-EMB. Therefore, we suggest that biventricular biopsy is significantly more advantageous in terms of diagnosis than selective biopsy of only one of the ventricles. Thus, implementing this approach in a center experienced in conducting the procedure is both feasible and potentially secure. In cases in which biventricular biopsy is not feasible, we recommend isolated LV biopsy, which offers greater diagnostic power than RV biopsy, albeit with a slightly lower safety profile, which could be mitigated using advanced imaging techniques (intracardiac echocardiography and EAM) during the procedure. It is worth noting that this information could potentially be corroborated by further studies in the field. Only in situations in which advanced imaging techniques are unavailable we suggest isolated RV biopsy, which has lower diagnostic power and a higher likelihood of pericardial tamponade/effusion but can be managed provided the center has well-defined protocols for handling these complications. For postcardiac transplantation patients who already undergo immunosuppression and are prone to complications related to significant morbidity and mortality, it is crucial to consider the procedural practicability, the center's expertise, the clinical condition, and the risk factors for the individual patient; for instance, if there is low risk of cerebrovascular events, LV-EMB should be a strong alternative.

CRediT authorship contribution statement

H.A.F.N. and G.Y.T. extracted and had full access to all the data in the study and take responsibility for the accuracy of the data analysis as well as its integrity. H.A.F.N., G.Y.T., and G.R.: analysis and interpretation of data. H.A.F.N., G.Y.T., B.S.Y., V.N.V.: drafting of the manuscript. H.A.F.N., G.Y.T., B.S.Y., V.N.V., G.R., and E.L.J.: critical revision of the manuscript.

Disclosure statement

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Appendix A. Supporting information

Supplementary data associated with this article can be found in the online version at doi:10.1016/j.jhlto.2023.100006.

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