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Exploring the effects of His and left bundle branch pacing with stylet-driven lead on tricuspid regurgitation: A short-term follow-up study

Exploración de los efectos de la pulsación del Haz de His y la rama izquierda con un electrodo dirigido por estilete en la regurgitación tricuspídea: un estudio de seguimiento a corto plazo

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SUMMARY

The stylet-driven delivery system was replaced with a pre-shaped catheter delivery system for conduction system pacing several years ago, as it offered easier access to the pacing location. However, in several countries, including Indonesia, the availability of catheter systems remains limited. This study aimed to evaluate the occurrence and severity of tricuspid regurgitation when using the stylet-driven lead delivery system in patients undergoing His and Left Bundle Branch (LBB) pacing.

This retrospective cohort study involves forty-two patients who underwent His and LBB pacing using a stylet-driven delivery system (14 males and 28 females), all selected from the Makassar Permanent Pacemaker (PPM) Registry and meeting the inclusion criteria. Tricuspid regurgitation was assessed using echocardiography both before and six months after implantation. The lead position was evaluated using 3D echocardiography in patients without tricuspid regurgitation after implantation. Among all participants, 4 (9.5 %) showed improvements in tricuspid regurgitation. His bundle and LBB pacing using the stylet-driven lead delivery system exhibited no significant association with tricuspid regurgitation or improvements in tricuspid regurgitation grade after implantation. The stylet-driven system proves efficient and could be considered an acceptable option for His bundle and Left Bundle Branch pacing procedures.

Keywords: *Tricuspid regurgitation, his bundle pacing, left bundle branch pacing, echocardiography.*

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RESUMEN

Hace varios años el sistema de entrega impulsado por estilete fue reemplazado por un sistema de entrega de catéter preformado para la estimulación del sistema de conducción, ya que ofrecía un acceso más sencillo al lugar de estimulación. Sin embargo, en varios países, incluyendo Indonesia, la disponibilidad de sistemas de catéter sigue siendo limitada. Este estudio tuvo como objetivo evaluar la ocurrencia y los cambios en la gravedad de la regurgitación tricuspídea al utilizar el sistema de entrega de cable impulsado por estilete en pacientes sometidos a estimulación del Haz de His y la Rama Izquierda (LBB). El estudio se diseñó como un estudio de cohorte retrospectivo, que incluyó a cuarenta y dos pacientes que se sometieron a estimulación del Haz de His y LBB utilizando un sistema de entrega impulsado por estilete (14 hombres y 28 mujeres), todos seleccionados del Registro de Marcapasos Permanente de Makassar y que cumplían con los criterios de inclusión. Se evaluó la regurgitación tricuspídea mediante ecocardiografía tanto antes como seis meses después de la implantación. En los pacientes sin regurgitación tricuspídea después de la implantación, se evaluó la posición del cable mediante ecocardiografía 3D. De todos los participantes, 4 (9,5 %) mostraron mejoras en la regurgitación tricuspídea. La estimulación del Haz de His y LBB utilizando el sistema de entrega impulsado por estilete no presentó una asociación significativa con la regurgitación tricuspídea ni con mejoras en el grado de regurgitación tricuspídea después de la implantación. El sistema impulsado por estilete se demuestra eficiente y podría considerarse como una opción aceptable para procedimientos de estimulación del Haz de His y la Rama Izquierda.

Palabras clave: *Insuficiencia tricúspide, estimulación del haz de His, estimulación de la rama izquierda, ecocardiografía.*

INTRODUCTION

Tricuspid regurgitation (TR) is a problem that can develop after the implantation of a Cardiac Implant Electronic Device (CIED), including a pacemaker. Regurgitation occurs due to interference with the pacemaker lead passing through the tricuspid valve (TV) leaflet. Active right ventricular pacing (RVP) is associated with a significant increase in TR grade (1).

Instead of active right ventricular pacing (RVP), conduction system pacing offers alternatives such as His bundle pacing (HBP) and left bundle branch pacing (LBBP). This approach, which employs a specific pre-shaped catheter delivery system and lead (Medtronic's The Select Secure model 3830 with a fixed curve sheath, Medtronic C315 HIS), has shown reduced incidents of tricuspid regurgitation and notable enhancements in TR severity after implantation (2,3).

However, in Indonesia, the availability of selective leads and catheter delivery systems for HBP and LBBP is very limited. As an alternative, we utilized the style-driven lead delivery system. The stylet-driven delivery system has been in use for a long time, preceding the catheter delivery system (CDS) introduction in 2012 (4). The occurrence and changes in the severity of Tricuspid Regurgitation using the SDL delivery system in HBP and LBBP procedures remain unknown. This study aims to assess the short-term effects of HBP and LBBP using stylet-driven lead methods on the new occurrences or changes in the severity of tricuspid regurgitation.

METHODS

Data Collection

This retrospective cohort study involved the comparison of tricuspid regurgitation before and six months after HBP and LBBP implantation. The study was conducted at Makassar Cardiac Center, Dr. Wahidin Sudirohusodo Hospital, Indonesia. We enrolled consecutive patients who met the inclusion criteria between January and December 2022. Inclusion criteria encompassed patients with sinus node dysfunction (SND) and total atrioventricular block (TAVB) who had undergone HBP and LBBP implantation using a stylet-driven lead delivery system. Patients unwilling to participate in the research and those who passed away within six months of the procedure were excluded. Echocardiography data obtained before implantation was sourced from the Makassar Permanent Pacemaker (PPM) Registry and compared to data collected six months post-implantation. Echocardiography examinations were performed using the GE Vivid E95 Cardiac Ultrasound system and validated by a consultant cardiac echocardiographer at our center.

Statistical Analysis

The data are presented as n (%) for categorical variables and mean ± SD for continuous variables. The analytical approach involved both descriptive analysis and an examination of differences. Statistical tests included the Kolmogorov-Smirnov test to assess data normality and the Marginal homogeneity test to evaluate comparisons in new occurrences and severity changes in tricuspid regurgitation. Statistical test results were considered significant when the p-value < 0.05. Data analysis was conducted using SPSS version 25.

RESULTS

Characteristics of the study participants

In this study, 42 subjects were included, with the majority being 28 women (66.7 %) and 14 men (33.3 %). The average age was 65 ± 11.7 years. The most prevalent cardiovascular risk factor was hypertension, observed in 33 participants (78.6 %). The indication for pacemaker placement was a complete AV block in 25 participants (59.5 %) and sinus node dysfunction in 17 participants (40.5 %). His bundle pacing (HBP) procedures were performed on 21 (50 %) patients, with the remaining 21 patients (50 %) undergoing left bundle branch pacing (LBBP).

Tricuspid regurgitation was detected in 19 participants before implantation, with moderate regurgitation observed in 4 (9.5 %) patients and mild regurgitation in 15 (35.7 %) patients. The remaining 23 (54.8 %) participants displayed no tricuspid regurgitation. A summary of the participants' characteristics can be found in Table 1.

Table 1. Demographic and Clinical Characteristics of the Study Participants

Variables	Total (n= 42)
Baseline Characteristic	
Age (mean ± SD)	65 ± 11.37
Gender	
Male	14 (33.3 %)
Female	28 (66.7 %)
Cardiovascular Risk Factors	
Hypertension	33 (78.6%)
Diabetes Mellitus Type 2	3 (7.1 %)
Smoking	9 (21.4 %)
Dyslipidemia	7 (16.7 %)
History of Syncope	29 (69 %)
Have ≥ 2 CV risk factors	12 (28.6 %)
Indication for Pacemaker	
Sinus Node Dysfunction	17 (40.5 %)
Total Atrioventricular Block	25 (59.5 %)
Device of Pacemaker	
Biotronik	15 (35.7 %)
Medtronik	24 (57.1 %)
St. Jude	3 (7.1 %)
Echocardiography Characteristic	
Tricuspid Regurgitation	
None	23 (54.8)
Mild	15 (35.7)
Moderate	4 (9.5)
TAPSE (cm) mean ± SD	2.0 cm ± 0.26

*Data are presented in n (%) for categorical data and mean ± SD for numerical data

Tricuspid Regurgitation Occurrences and Severity Changes After Implantation

The baseline characteristics of this study revealed that 23 subjects had no tricuspid regurgitation before implantation. After six months of echocardiography evaluation, there were no new occurrences of tricuspid regurgitation in these 23 subjects (p= 0.04). Improvement in tricuspid regurgitation grade was observed in 4 patients. One patient with mild tricuspid regurgitation showed complete resolution (2.4 %, p= 0.04), and three patients with moderate tricuspid regurgitation improved to mild tricuspid regurgitation (2.4 %, p=0.04). The new occurrences and improvements in tricuspid regurgitation are detailed in Table 2. The proportions of tricuspid regurgitation severity before and after PPM implantation are illustrated in Figure 1.

DISCUSSION

In the present study, we observed no new occurrences of tricuspid regurgitation in 23 subjects (52.5 %) who had no prior TR. Grieco et al. investigated eighty-four patients, averaging 75.1 ± 7.9 years, and 64 % were male. Among these patients, forty-two (50 %) underwent

Table 2. Comparison of TR severity before and six months after PPM implantation

		After Implantation n (%)			P value
		None	Mild	Moderate	
Before Implantation n (%)	None (n=23)	23 (54.8)	0	0	
	Mild (n=15)	1 (2.4)	14 (33.3)	0	0.04*
	Moderate (n=4)	0	3 (7.1)	1 (2.4)	

Data is presented in n (%). Analysis using the Marginal Homogeneity Test, *p< 0.05

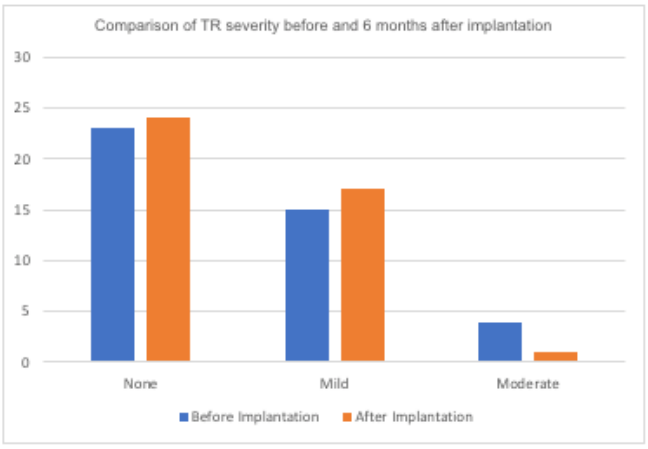

Figure 1. Proportion of TR severity before and six months after PPM implantation.

successful HBP, while the remaining 42 (50 %) underwent apical right ventricular pacing (RVP). In the 6-month follow-up, in contrast to RVP, HBP exhibited no new cases of tricuspid regurgitation and showed an improvement in the severity of tricuspid regurgitation (p=0.005), regardless of the lead position being above or below the tricuspid valve. After six months, there were no new occurrences of tricuspid regurgitation in 6 patients. It is important to note that the study of Grieco et al. utilized selective catheter delivery and the LLL 3830 lead (SelectSecure, Medtronic, Minneapolis, MN, USA) sheath instead of the stylet-driven lead delivery system (5). Studies have demonstrated a significant increase in tricuspid regurgitation grade with active right ventricular pacing (RVP), making it one of the complications associated with RV pacing. Vaturi et al. proposed that this effect of pacing is not primarily attributed to acute changes in the right ventricle area or interference of the electrode with valve closure movement. Instead, they suggest that alterations in contraction timing at this site, such as RV dyssynchrony, may impact the closure of tricuspid leaflets, ultimately leading to the development of tricuspid regurgitation or exacerbating existing regurgitation (1).

Current guidelines and pacemaker algorithms emphasize the importance of minimizing RVP whenever possible. As an alternative to RVP, researchers and electrophysiologists have explored and investigated other pacing sites, specifically the His bundle and Left bundle

branch, as alternatives to right ventricular pacing. Deshmukh et al. initially demonstrated His bundle pacing (HBP) in 2000, and it has since evolved into one of the most physiological forms of ventricular pacing (6). The advantages of HBP over RVP, such as improved QRS durations and ventricular activation patterns, are increasingly recognized. Developing new lumen-less leads and pre-shaped delivery catheters has significantly reduced the learning curve for operators performing HBP. Currently, HBP is the subject of clinical trials aimed at evaluating its potential clinical benefits compared to RVP or biventricular pacing (7,8).

Left bundle branch area pacing (LBBP) aims to provide physiological pacing by targeting the conduction system in the left bundle branch area. This technique is considered a novel pacing modality that focuses on capturing the left bundle branch area while avoiding the detrimental effects of right ventricular pacing. Several studies have employed lumen-less pacing leads (LLL), such as the Medtronic SelectSecure 3830, for this approach. In the earliest conduction system pacing studies, His bundle pacing (HBP) was performed using stylet-driven leads and custom curved stylets. However, implant success rates were low, and pacing thresholds remained frequently high and unstable. A new approach to HBP was introduced by Zanon et al. in 2006, utilizing long pre-shaped delivery sheaths to guide the pacing lead toward the His bundle area. These delivery sheaths led to a more stable lead position and improved contact with the His bundle area (6).

Zaidi et al. conducted a systematic review that focused on tricuspid regurgitation across ten studies involving 546 His bundle pacing (HBP) patients. Of these studies, only one reported a 5 % incidence of tricuspid regurgitation, while the other nine reported no new occurrences of tricuspid regurgitation following HBP (9). Tricuspid regurgitation after lead placement can arise from various mechanisms, including mechanical factors such as scarring on the lead or the presence of thrombi affecting valve closure. Valve leaflet perforation or tears are additional potential causes of tricuspid regurgitation. Another mechanism involves asynchrony, which may result from abnormal activation of the right ventricle due to pacemaker pacing (10). Hasumi et al. proposed that placing the His bundle pacing (HBP) lead in the commissural position is associated with less severe tricuspid regurgitation (TR). Their examination of the relationship between the HBP lead position and tricuspid valve (TV) function, using 3D echocardiography, revealed that positioning the tip of the HBP lead in the commissural position within the right ventricle does not impinge on leaflet mobility. These findings confirm that the HBP lead position does not affect TV function, even when the lead is implanted on the ventricular side of the His bundle. It is believed that HBP can be employed without negatively impacting the long-term prognosis compared to right ventricular apical or septal pacing (11). These findings align with our own study, where the lead position is in the commissural area of the anteroseptal tricuspid valve leaflet. This correlation has also been explained by Gelves et al. in their study, which demonstrated that a lead positioned in the anteroseptal commissure does not cause TR or impinge on the leaflet (12). The lead position in our study is visualized in Figure 2.

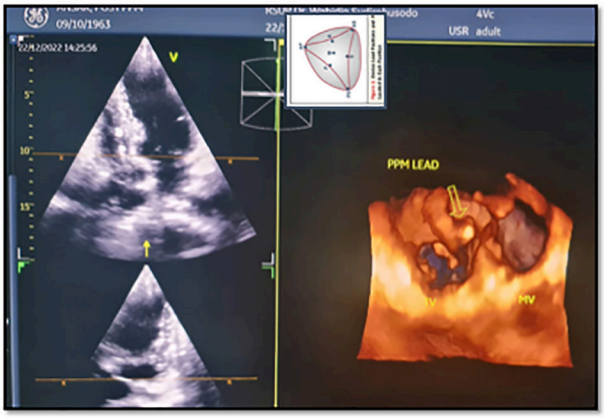

Figure 2. Pacemaker lead position on 3D echocardiography reveals that the lead is located at the anteroseptal commissure of the tricuspid valve.

Our study also revealed improvements in tricuspid regurgitation following a 6-month post-implantation period. Specifically, TR grade improved in 4 patients. These findings are consistent with those reported by Zaidi et

al., who observed a decrease in TR in HBP patients following implantation (9). Furthermore, studies by Wu et al. and Huang et al. indicated that TR improved from an average baseline up to 12 months of follow-up (13,14). In cases of atrioventricular (AV) block as the indication for pacemaker placement, Grieco et al. reported improvement from moderate to mild TR grade in 7 patients and a decrease in TR grade from severe to moderate in 2 patients (5). Similarly, Ma et al. reported reduced TR grade from baseline to 17 months of follow-up (15).

Hasumi et al. also reported statistical improvements in tricuspid regurgitation among patients with pacemakers in the His bundle. They observed that the pacemaker lead was positioned at the level of the tricuspid annulus commissure and assumed this was not the cause of regurgitation (11). An explanation for the improved TR severity after LBBP implantation has been proposed by Su et al. They suggest that LBBP results in left ventricular electrical resynchronization, leading to ventricular remodeling, improved left and right ventricular function, and restoring a normal atrioventricular conduction sequence in patients with AVB (2).

CONCLUSION

His bundle pacing (HBP) and Left bundle branch pacing (LBBP), using stylet-driven lead delivery, showed no new occurrences of tricuspid regurgitation and improved TR severity, offering promising alternatives for patients at risk of tricuspid regurgitation with potential implications for enhanced patient outcomes.

ABBREVIATIONS

AVB	Atrioventricular Block
CDS	Catheter Delivery System
CIED	Cardiac Implant Electronic Device
CSP	Conduction System Pacing
HBP	His Bundle Pacing
LBBP	Left Bundle Branch Pacing
LLL	Lumen-less Lead
LV	Left Ventricle
PPM	Permanent Pacemaker
RV	Right Ventricle
RVP	Right Ventricular Pacing
SDL	Stylet-driven Lead
SND	Sinus Node Dysfunction
TAVB	Total Atrioventricular Block
TR	Tricuspid regurgitation
TV	Tricuspid Valve

Ethics approval and consent to participate

This research received approval from the Biomedical Research Ethics Commission on Humans at the Faculty of Medicine, Hasanuddin University, Makassar, South Sulawesi, Indonesia, with the following reference: 263/UN4.6.4.5.31/PP36/2022 and protocol number: UH22050205.

Competing interest

The authors declared no competing interest.

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Authors' contribution

Conceptualization: MA, AFG, TA; Methodology: AAZ; formal analysis and investigation: TA; writing-original draft: TA; writing—review, editing, and provided final draft: AQ; supervision: MA, AFG, PK, AAZ; Validation: MA and AFG. The authors read and approved the final manuscript.

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Availability of data and materials

All data generated or analyzed during this study are included in this published article.

REFERENCES

1. Vaturi M, Kusniec J, Shapira Y, Nevzorov R, Yedidya I, Weisenberg D, et al. Right ventricular pacing increases tricuspid regurgitation grade regardless of the electrode's mechanical interference to the valve. Eur J Echocardiog. 2010;11(6):550-553.
2. Su L, Wang S, Wu S, Xu L, Huang Z, Chen X, et al. Long-Term Safety and Feasibility of Left Bundle Branch Pacing in a Large Single-Center Study. Circ Arrhythm Electrophysiol. 2021;14(2):e009261.
3. Hasumi E, Fujiu K, Kawata T, Komuro I. The influence of His bundle pacing on tricuspid valve functioning using three-dimensional echocardiography. HeartRhythm Case Rep. 2018;4(9):437-438.
4. Yamagata K, Ishibashi K, Nakajima K, Kataoka N, Kamakura T, Wada M, et al. Comparing the catheter delivery system and the stylet delivery system for ventricular lead placement in pacemaker implantation-The CATS delivery system randomized controlled trial. J Arrhythm. 2019;35(3):524-527.
5. Grieco D, Bressi E, Curila K, Padala SK, Sedlacek K, Kron J, et al. Impact of His bundle pacing on right ventricular performance in patients undergoing permanent pacemaker implantation. Pacing Clin Electrophysiol. 2021;44(6):986-994.
6. De Pooter J, Calle S, Timmermans F, Van Heuverswyn F. Left bundle branch area pacing using stylet-driven pacing leads with a new delivery sheath: A comparison with lumen-less leads. J Cardiovasc Electrophysiol. 2021;32(2):439-448.
7. Abdelrahman M, Subzposh FA, Beer D, Durr B, Naperkowski A, Sun H, et al. Clinical Outcomes of His Bundle Pacing Compared to Right Ventricular Pacing. J Am Coll Cardiol. 2018;71(20):2319-2330.
8. Lewis AJM, Foley P, Whinnett Z, Keene D, Chandrasekaran B. His Bundle Pacing: A New Strategy for Physiological Ventricular Activation. J Am Heart Assoc. 2019;8(6):e010972.
9. Zaidi SMJ, Sohail H, Satti DI, Sami A, Anwar M, Malik J, et al. Tricuspid regurgitation in His bundle pacing: A systematic review. Ann Noninvasive Electrocardiol. 2022;27(6):e12986.
10. Al-Bawardy R, Krishnaswamy A, Bhargava M, Dunn J, Wazni O, Murat Tuzcu E, et al. Tricuspid regurgitation in patients with pacemakers and implantable cardiac defibrillators: A comprehensive review. Clin Cardiol. 2013;36(5):249-254.
11. Hasumi E, Fujiu K, Kawata T, Komuro I. The influence of His bundle pacing on tricuspid valve functioning using three-dimensional echocardiography. HeartRhythm Case Rep. 2018;4(9):437-438.
12. Gelves-Meza J, Lang RM, Valderrama-Achury MD, Zamorano JL, Vargas-Acevedo C, Medina HM, et al. Tricuspid Regurgitation Related to Cardiac Implantable Electronic Devices: An Integrative Review. J Am Soc Echocardiogr. 2022;35(11):1107-1122.
13. Huang W, Su L, Wu S, Xu L, Xiao F, Zhou X, et al. Long-term outcomes of His bundle pacing in patients with heart failure with left bundle branch block. Heart. 2019;105(2):137-143.
14. Wu S, Su L, Vijayaraman P, Zheng R, Cai M, Xu L, et al. Left Bundle Branch Pacing for Cardiac Resynchronization Therapy: Nonrandomized On-Treatment Comparison with His Bundle Pacing and Biventricular Pacing. Canadian J Cardiol [Internet]. 2021;37(2):319–28.
15. Ma PP, Yang YH, Dai BL, Zhang RF, Wang N, Li DN, et al. Brady-arrhythmias in patients with atrial fibrillation and heart failure of reduced ejection fraction: is his-bundle pacing superior to biventricular pacing- Pacing Clin Electrophysiol. 2021;44(7):1193-1199.