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CLINICAL RESEARCH
Arrhythmias

Left bundle branch area pacing vs right ventricular pacing for atrioventricular block: the MELOS RELOADED study

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Abstract

Background and Aims Left bundle branch area pacing (LBBAP) promotes physiological synchronous activation of the left ventricle and may be particularly beneficial in patients with atrioventricular block (AVB), but its mortality benefit remains unclear. This study aims to compare long-term survival in AVB patients receiving either LBBAP or right ventricular pacing (RVP) and to analyse predictors of mortality during LBBAP.

Methods MELOS RELOADED, a multicentre European collaboration, was a registry-based study of pacemaker patients with AVB, left ventricular ejection fraction (LVEF) >40% and ventricular pacing >20%. The primary outcome was all-cause mortality based on national registries. A 1:1 propensity score matching was performed between the RVP and LBBAP groups. Kaplan–Meier curves and multivariable Cox proportional hazards models were used to estimate survival.

Results In total, 3382 patients receiving LBBAP or RVP were matched. At 4-year follow-up, the Kaplan–Meier curve showed an absolute difference in survival of 11.8% in favour of LBBAP ($P < .001$). LBBAP was a robust predictor of reduced mortality with a hazard ratio (HR) of 0.53 (95% confidence interval 0.42–0.65, $P < .001$). Within the LBBAP group, the following independent predictors of increased mortality were identified: lack of confirmed left bundle branch capture (HR 1.85, $P < .001$), lower percentage of ventricular pacing (HR 1.12), and age.

Conclusions This is the first large study demonstrating the long-term survival benefit of LBBAP. This strengthens the use of LBBAP in AVB patients with preserved/mildly reduced LVEF while awaiting the results of randomized trials. Confirmation of left bundle branch capture seems advisable to achieve optimal results with LBBAP.

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Structured Graphical Abstract

Key Question

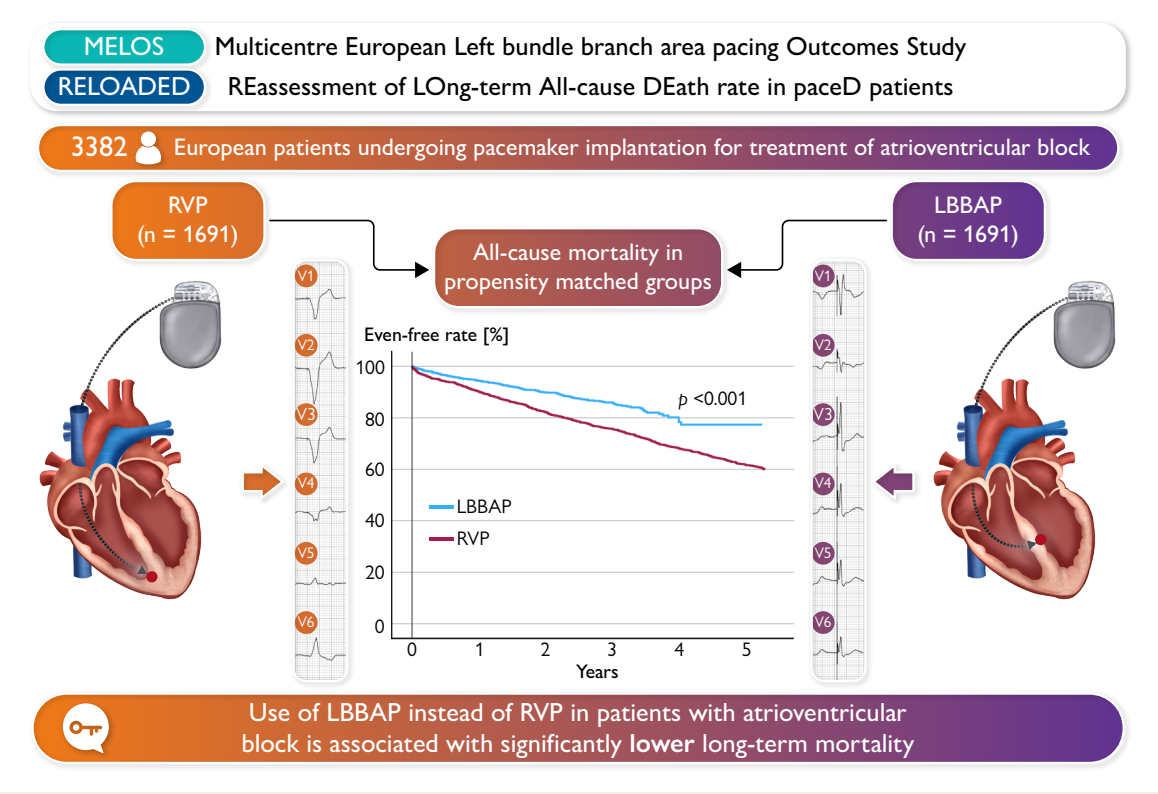
What is the optimal ventricular pacing modality in patients with atrioventricular block and a preserved or mildly reduced left ventricular ejection fraction (>40%) without indications for cardiac resynchronization therapy?

Key Finding

The main finding of this multicentre long-term comparison of left bundle branch area pacing (LBBAP) with right ventricular pacing was a reduction in mortality with LBBAP. In particular, this benefit was observed when conduction system capture was confirmed. Complications and pacing parameters were comparable.

Take Home Message

Thus, LBBAP might be preferred to conventional right ventricular pacing in patients with atrioventricular block and no indications for cardiac resynchronization therapy.



Findings from the MELOS RELOADED study: mortality in left bundle branch area pacing (LBBAP) vs right ventricular pacing (RVP) in patients with atrioventricular block.

Keywords Left bundle branch area pacing • Left bundle branch capture • Atrioventricular block • Mortality • Heart failure

Introduction

Mortality in patients with atrioventricular block (AVB) and right ventricular pacing (RVP) remains high.[1–3] Left bundle branch area pacing (LBBAP) is increasingly being used as a physiological alternative to RVP to treat patients with bradycardia.[4–6] LBBAP was shown to result in faster and more synchronous activation of the left ventricle in comparison to RVP.[7,8] However, the impact of LBBAP on long-term outcomes remains to be shown. The benefits of LBBAP are expected to be especially pronounced in patients requiring a high percentage of ventricular pacing and/or with underlying organic heart disease, both common features in AVB patients. To date, there is only one observational study of LBBAP vs RVP use in AVB patients. However, it was based on a small cohort ($n = 70$) and analysed echocardiographic endpoints rather than mortality.[9] Two other studies, albeit with a mixed population (sick sinus syndrome and AVB) and/or a mixed pacing strategy (His bundle pacing and LBBAP), indicated that LBBAP may be superior to RVP in AVB patients in terms of all-cause mortality.[10,11] There is still a lack of a large study analysing long-term mortality that would address the clinical need to determine the best pacing mode for patients with AVB who have preserved or mildly reduced left ventricular ejection fraction (LVEF).

The present investigation by the Multicentre European Left bundle branch area pacing Outcomes Study (MELOS[5]) group focused on the REassessment of LOng-term All-cause DEath rate in paceD patients (RELOADED). Specifically, we aimed to compare long-term survival

in patients with AVB without indication for cardiac resynchronization therapy (CRT),[12] who received either LBBAP or RVP. In addition, we sought to analyse predictors of adverse outcomes during LBBAP.

Methods

Study design, inclusion, and exclusion criteria

A total of 14 European centres (the MELOS group, listed in Supplementary data online, *Table S1*) were involved in the research project. This was a retrospective observational study based on pooled, mostly prospectively maintained, local LBBAP registries. Consecutive patients with AVB, preserved or mildly reduced LVEF (>40%), and ventricular pacing >20% (at last follow-up) who received a permanent LBBAP pacemaker were included. Patients receiving RVP pacemakers implanted in the same centres but shortly before the era of LBBAP (to minimize differences in treatment and clinical profile) served as the control group.

LBBAP pacemaker implantation technique closely adhered to the recommendations by the European Heart Rhythm Association (EHRA) consensus statement.[13] Minor modifications of the implantation technique were left at the discretion of the implanting physicians—all of whom were experienced implanters, mostly early adopters of the conduction system pacing technique. Both lumenless and stylet-driven LBBAP leads were allowed.

The study complies with the Declaration of Helsinki. Ethics committee approval was obtained at each centre; informed consent was obtained from the subjects.

Study definitions

The definitions of LBBAP capture types: left ventricular septal pacing (LVSP; left bundle branch capture criteria not met) and left bundle branch pacing (LBBP; confirmed capture of the left bundle branch) followed the recommendations of the EHRA consensus statement.[13] Left fascicular pacing (LFP) and proximal LBBP were categorized together as LBBP. Left bundle branch capture was diagnosed according to the generally accepted criteria [QRS transition during threshold test or programmed stimulation, short V6 R-wave peak time (RWPT), equal paced and native V6 RWPT, V6-V1 interval >44 ms],[14–16] V6-V1, endorsed by the EHRA,[13] but with some modifications according to the results of more recent studies.[17] Specifically, the optimal V6 RWPT cutoffs used to classify LBBP vs LVSP were 77.5 and 88.5 ms for narrow QRS or isolated right bundle branch block (RBBB) and the remaining wide QRS complex morphologies (including wide escape and paced rhythms), respectively.[17] The same capture criteria based on electrocardiogram measurements provided by the investigators were applied uniformly to all patients by a single core team.

Study endpoints and data sources

The primary endpoint was all-cause death after the index procedure.

The secondary outcomes were: (i) combined endpoint of heart failure hospitalization (HFH) and upgrade to CRT and (ii) pacing parameters and procedure-related complications.

Death status, censored on 31 December 2023 or 1950 days after the index procedure (whichever came first), was obtained directly from national registries. The observation time began on the day of device implantation. Patients' last follow-up dates were determined by the last time their device was checked during an outpatient visit. Time censoring in survival analyses was set by the time to a predefined event or last follow-up in the healthcare system, depending on the outcome. We obtained the date of HFH or CRT upgrade, demographic data, basic clinical characteristics, procedure-related parameters, and complications from local registries, hospital records, or direct patient contact.

Statistical methods

All data were presented as frequencies and percentages for categorical data and as the mean with standard deviation (SD) or the median with interquartile range (IQR) for continuous data. Descriptive statistics were reported for the full sample and stratified by LBBAP and RVP groups. The comparison between the groups was accomplished using the χ^2 or Fisher's exact test and the independent-sample Student's *t*-test or Mann–Whitney *U* test, as appropriate. Within-group comparisons were performed by means of a two-tailed paired Student's *t*-test.

To balance differences in characteristics between each pacing strategy, a propensity score matching approach was employed to match participants in the LBBAP and RVP groups at a ratio of 1:1. The matching using the nearest-neighbor method was performed on potential confounding factors, including age, sex, LVEF, indication for pacing, baseline QRS type, and comorbidities. The differences in baseline characteristics between the matched groups were presented as *P*-values and standardized mean differences (SMD), calculated using the methods of Cohen and Mahalanobis, respectively, for continuous and categorical variables.

The differences in mortality were assessed using the Kaplan–Meier curve, and the survival distribution between groups was compared using the log-rank test. Univariate and multivariable Cox proportional hazard models were used to estimate survival probability for the primary outcome and composite secondary outcome for the LBBAP and RVP groups, with adjustment for potential confounders, including adjustment for centre effect. Due to the unavoidable differences in follow-up time between the RVP and LBBAP groups, statistical analysis (log-rank test and multivariable Cox proportional hazard) was censored at 4 years. Initially, univariate analysis was carried out using variables previously determined to be clinically significant. The status of the covariates was determined during hospitalization, prior to device implantation. The percentage of ventricular pacing was obtained at the final follow-up.

Univariate predictors with $P < .10$ were entered into multivariate Cox proportional hazard models to determine significant independent predictors. Cox proportional hazards were formally evaluated using the Schoenfeld residuals test and the log-minus-log plot for each Cox regression model that was built. Competing risk analysis (cause-specific Cox regression) for HFH with mortality as a competing risk was performed to estimate the marginal probability of a certain event as a function of its cause-specific probability and overall survival probability. To mitigate the effects of immortal time bias and verify the consistency of the survival benefit of LBBAP over comparable timeframes, a landmark analysis was conducted after 2 years of follow-up.

Statistical analysis was performed with the use of SPSS software version 30 (IBM Corp, Armonk, NY, USA) and STATA 18 SE (StataCorp, College Station, TX, USA).

Results

Enrolment and baseline characteristics

A total of 3778 patients receiving a pacemaker from 14 centres across Europe were initially included. After the propensity score matching, a total of 3382 patients (1691 LBBAP and 1691 RVP) were studied. The range of enrolled patients per centre was 61–607, with the first LBBAP procedure in June 2018 and the last in November 2023. The RVP cases were implanted on average within the 25 months preceding the introduction of LBBAP in each centre (see Supplementary data online, *Table S1*). LBBAP was used as a routine implantation strategy in all consecutive AVB patients without any preselection; in most centres, this was based on the electrophysiology laboratory protocol, and in some centres, it was contingent on the policy of individual operators.

The baseline characteristics of the MELOS cohort, including comorbidities, baseline rhythm, LBBAP capture type, and QRS morphology types, are presented in *Table 1* for the matched LBBAP and RVP groups. The same data for all initially included patients are presented in Supplementary data online, *Table S2*. Data regarding electrophysiological characteristics of the LBBAP cohort are in Supplementary data online, *Table S3*. In brief, the included patients were predominantly elderly

Table 1 Basic characteristics of the matched patients ($n = 3382$)

	All, $n = 3382$	LBBAP, $n = 1691$	RVP, $n = 1691$	*P*	SMD
Age (years)	76.4 ± 12.3	76.4 ± 13.1	76.4 ± 11.3	.92	0.003
Male gender (*n*)	1654 (48.9%)	817 (48.3%)	837 (49.5%)	.51	0.019
Comorbidities (*n*)					
Diabetes mellitus	1033 (30.5%)	518 (30.6%)	515 (30.5%)	.94	0.004
CHD	887 (26.2%)	457 (27%)	430 (25.4%)	.31	0.036
Heart failure	703 (20.8%)	368 (21.8%)	335 (19.8%)	.16	0.047
Hypertension	2623 (77.6%)	1304 (77.1%)	1319 (78%)	.56	0.021
Valvular disease	887 (26.2%)	457 (27%)	430 (25.4%)	.31	0.036
Permanent AF	750 (22.2%)	376 (22.2%)	374 (22.1%)	.93	0.003
Pacing indication (*n*)				.93	0.005
AVB in sinus rhythm	2745 (81.2%)	1374 (81.3%)	1371 (81.1%)		
AF with AVB/brady	637 (18.8%)	317 (18.7%)	320 (18.9%)		
Baseline QRS type (*n*)				.15	0.05
Narrow/isolated RBBB	1825 (54%)	891 (52.7%)	934(55.2%)		
Other[a]	1557 (46%)	800 (47.3%)	757 (44.8%)		
Echocardiographic examination					
LVEF (%)	60 (55–60)	58 (53–60)	60 (55–61)	.2	0.11
LVEDD (mm)	48.2 ± 6.3	48.3 ± 6.3	48 ± 6.4	.23	0.043

CHD, coronary heart disease; AF, atrial fibrillation; LBBAP, left bundle branch area pacing; RVP, right ventricular pacing; LVEF, left ventricular ejection fraction; LVEDD, left ventricular end-diastolic diameter; AVB, atrioventricular block; LAFB, left anterior fascicular block; LPFB, left posterior fascicular block; RBBB, right bundle branch block; NIVCD, non-specific intraventricular conduction disturbance; LBBB, left bundle branch block; SMD, standardized mean differences.
[a]Left bundle branch block/non-specific intraventricular conduction delay/wide escape/asystole/right bundle branch block with fascicular block.

(76.4 ± 12.3 years), with nearly equal distribution of both sexes, with prevalent major comorbidities, mostly in sinus rhythm (81.2%), and with preserved LVEF (57 ± 6.5%). The initial RVP and LBBAP groups exhibited minimal differences prior to matching, with the LBBAP group having a higher prevalence of severe valvular disease (17.8% vs 13.6%), minimally lower LVEF (58% vs 60%), and a slightly lower proportion of patients with narrow QRS/RBBB (53.9% vs 57%). However, these differences were no longer significant after matching.

Primary endpoint

The median follow-up was 787 days (548–1046) for the LBBAP group and 1456 days (763–1950) for the RVP group. There were 200 (11.8%) deaths in the LBBAP group and 600 (35.9%) deaths in the RVP group. After 4 years of follow-up, the Kaplan–Meier curve (*Figure 1*) showed an absolute difference in survival of 11.8% ($P < .001$). In multivariable analysis, LBBAP was associated with improved survival (*Table 2*), being the strongest independent predictor after age with a hazard ratio (HR) of 0.53 [95% confidence interval (CI) 0.42–0.65; $P < .001$]. The hazard ratio for LBBAP became significant already after 157 days. Other independent predictors of increased mortality were lower LVEF and coronary heart disease (CHD).

The results of the analysis of mortality predictors within the LBBAP group alone are presented in *Table 3*. The strongest predictor of mortality was LVSP (i.e. the criteria for confirmation of LBB capture were not met) with an HR of 1.85. Other independent predictors of increased mortality were age and a low percentage of ventricular pacing. This result, indicating a clear difference in mortality between LVSP and LBBP, prompted a *post hoc* analysis of all three pacing capture types (RVP vs LVSP vs LBBP) in the whole cohort. Following a 4-year observation period, the Kaplan–Meier curve (*Figure 2*) demonstrated a significant absolute difference of 14.1% between RVP and LBBP, and a 6.1% difference between RVP and LVSP ($P < .001$).

The 2-year landmark analysis for all-cause mortality and secondary combined endpoint is shown in Supplementary data online, *Table S4*.

Secondary endpoints

There were 72 (4.3%) and 177 (10.5%) HFH in the LBBAP and RVP group, respectively. Upgrade to CRT was necessary in 5 (0.3%) and 13 (0.8%) patients in the LBBAP and RVP groups, respectively. Consequently, the combined secondary endpoint of HFH plus CRT upgrade was met by 77 (4.6%) in the LBBAP group and 190 (11.2%) in the RVP group. After 4 years of follow-up, the Kaplan–Meier curves for the combined secondary endpoint were separated by an absolute difference of 6.8% ($P < .001$) (*Figure 3*). In the multivariable analysis, independent predictors of HFH/CRT upgrade were LBBAP (HR 0.53; 95% CI 0.40–0.72), permanent atrial fibrillation (HR 1.52, 95% CI 1.13–2.05), severe valvular disease (HR 1.75, 95% CI 1.28–2.41), age (HR 1.56; 95% CI 1.33–1.83), and lower LVEF (HR 0.71, 95% CI 0.59–0.85) (*Tables 2* and *3*). A competing risk analysis for HFH and

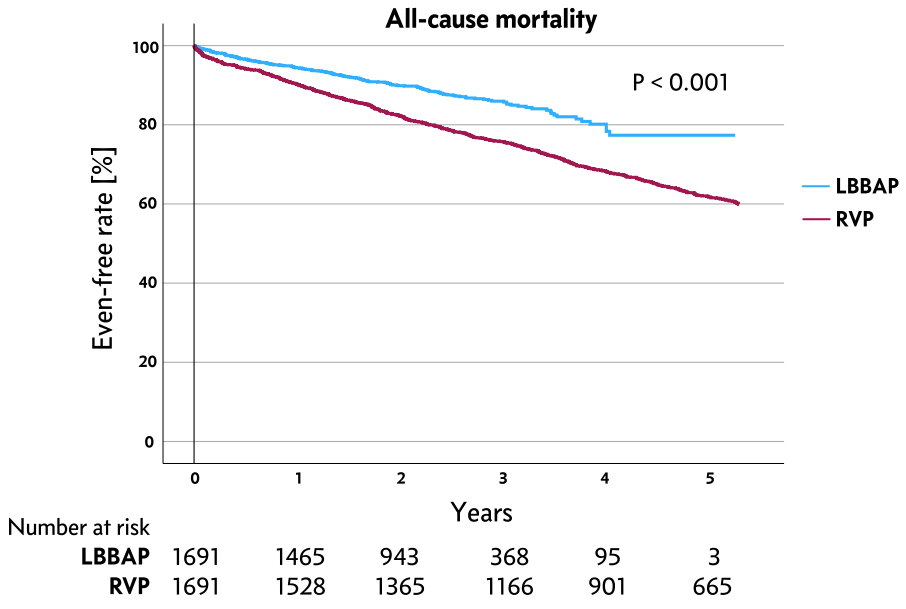


Figure 1 Kaplan–Meier survival estimates for all-cause mortality comparing right ventricular pacing (RVP) vs left bundle branch area pacing (LBBAP)

CRT upgrade (with mortality as competing risk) confirmed the significant reduction in HFH/CRT upgrade associated with LBBAP (HR 0.56, 95% CI 0.42–0.72, $P < .001$).

No difference was observed in capture threshold; however, ventricular sensing was higher in patients with LBBAP (*Table 4*). The overall incidence of acute and long-term complications (e.g. atrial lead dislodgement, ventricular lead dislodgement, haematoma requiring reintervention, pneumothorax and others) (*Table 5*) was similar in LBBAP and RVP (7.8% vs 6.4%).

Discussion

This European multicentre propensity-matched comparison of LBBAP vs RVP in patients with AV block, to our knowledge, is the only large and long-term mortality study in this field.

The main findings of MELOS RELOADED are as follows: (i) all-cause mortality was significantly lower with LBBAP while pacing parameters and complications were comparable (*Structured Graphical Abstract*); (ii) the absence of LBB capture confirmation during LBBAP was a robust predictor of increased mortality; and (iii) the HFH/CRT upgrade combined endpoint was significantly lower with LBBAP.

Mortality in paced AVB patients: LBBAP vs RVP

The mortality rate observed in patients with AVB and conventional RVP pacemakers remains high. A number of studies have reported 4-year all-cause mortality rates that are close to the mortality rate (38%) seen in the current cohort. The 4-year mortality rates in the studies by Brunner *et al.*, Simon *et al.*, Pyatt *et al.*, Shen *et al.*, and Toff *et al.* (UKPACE trial) were approximately 34%, 39%, 45%, 48%, and 61%, respectively.[1,2,3,18,19] Attempts to reduce mortality of AVB patients by more physiological activation of the ventricles using biventricular pacing-based CRT (BiV-CRT) have yielded negative/inconclusive results (BLOCK HF and BioPace trials).[20,21] The improvement in the primary composite endpoint in AVB patients with LVEF in the range of 36%–50% seen in BLOCK HF was driven by echocardiographic and clinical components rather than mortality, while BioPace failed to show any benefit of BiV-CRT. Moreover, a recent study revealed that the 4-year mortality rate in patients who have undergone BiV-CRT implantation using BLOCK HF criteria is notably high (38%)—the same as in our RVP cohort.[22] In contrast, LBBAP appears to significantly reduce mortality in AVB across the range of LVEF. This study is the first to provide supporting data based on long-term large cohort analysis. The use of LBBAP resulted in an 11.8% absolute reduction in mortality compared with RVP after 4 years of follow-up. LBBAP was identified as an independent predictor of better survival, with a hazard ratio of 0.53 for all-cause mortality. Despite the lack of analogous mortality studies of LBBAP in AVB patients that would allow a close comparison with our results, two observational studies of LBBAP vs RVP that analysed mortality and included a fair number of AVB patients are relevant.[10,11] In a comparative study of 321 LBBAP patients (including 213 AVB patients and 108 patients with other pacing indications) vs a similar RVP group, Sharma *et al.*[10] observed that the absolute mortality difference at 2.5 years was approximately 10%, a finding that closely aligns with the results of the MELOS RELOADED study. A recent study by Vijayaraman *et al.*[11], based on analysis of the Medicare database, compared 6197 patients (including 3162 AVB patients) with the RVP group. There was an absolute difference in mortality of about 2% at 6 months—also very similar to what we have seen at 6 months (2.3% reduction). The hazard ratio for all-cause mortality was also very similar (0.66 vs 0.53). This study differed from MELOS RELOADED not only by the very short follow-up, the parallel implantation of RVP and LBBAP in the same centres (unknown selection bias), and the lack of subcategorization of LBBAP capture type, but mainly by the inclusion of His bundle pacing (24% of patients) and non-AVB pacing indications (49% of patients). Interestingly, the very similar reduction in mortality in both studies suggests that this may be an effect characteristic of conduction system pacing in general, not just LBBAP.

Predictors of mortality during LBBAP

This is the first study to analyse predictors of mortality in patients with LBBAP. In addition to the usual, age and CHD (borderline, $P = .06$), two

Table 2 Predictors of all-cause mortality and secondary combined endpoint of heart failure hospitalization or CRT upgrade in multivariate Cox proportional hazards analysis (adjusted for centre effect) in the whole group of matched patients

	All-cause mortality		HFH + CRT upgrade	
	HR (95% CI)	P	HR (95% CI)	P
Left bundle branch area pacing	0.53 (0.42–0.65)	<.001	0.53 (0.4–0.72)	<.001
Age[a]	1.99 (1.77–2.26)	<.001	1.56 (1.33–1.83)	<.001
Male sex	0.9 (0.75–1.09)	.3	0.85 (0.64–1.12)	.25
Hypertension	0.87 (0.68–1.12)	.3	0.94 (0.65–1.35)	.74
Diabetes mellitus	1.19 (0.98–1.45)	.08	1.17 (0.92–1.64)	.17
Coronary heart disease	1.26 (1.02–1.55)	.03	1.28 (0.95–1.73)	.11
Permanent atrial fibrillation	1.11 (0.89–1.38)	.36	1.52 (1.13–2.05)	.006
Severe valvular disease	1.22 (0.96–1.55)	.1	1.75 (1.28–2.41)	<.001
Percentage of VP[b]	1 (0.99–1.01)	.41	1 (0.99–1.01)	.4
LVEF[b]	0.8 (0.7–0.92)	.001	0.71 (0.59–0.85)	<.001
Baseline QRS type[c]	1.1 (0.94–1.52)	.35	0.96 (0.72–1.27)	.76

HFH, heart failure hospitalization; CRT, cardiac resynchronization therapy; HR, hazard ratio; CI, confidence interval; VP, ventricular pacing; LVEF, left ventricular ejection fraction.
[a]Per 10-year increase.
[b]Per 10% increase.
[c]Left bundle branch block/non-specific intraventricular conduction delay/wide escape/asystole/right bundle branch block + fascicular block.

Table 3 Predictors of all-cause mortality and the secondary combined endpoint of heart failure hospitalization or CRT upgrade in multivariate Cox proportional hazards analysis (adjusted for centre effect) within the LBBAP group

	All-cause mortality		HFH + CRT upgrade	
	HR (95% CI)	P	HR (95% CI)	P
Age[a]	1.63 (1.33–2)	<.001	1.94 (1.46–2.58)	<.001
Male sex	1.04 (0.73–1.47)	.84	0.62 (0.38–0.99)	.047
Hypertension	0.83 (0.52–1.31)	.41	0.55 (0.32–0.95)	.03
Diabetes mellitus	1.04 (0.71–1.51)	.85	1.03 (0.62–1.71)	.92
Coronary artery disease	1.38 (0.89–1.91)	.08	1.3 (0.8–2.13)	.3
Permanent atrial fibrillation	1.3 (0.89–1.91)	.18	1.87 (1.15–3.06)	.01
Severe valvular disease	1.24 (0.81–1.9)	.32	1.36 (0.79–2.32)	.27
Percentage of VP[b]	1.12 (1.04–1.22)	.004	1.1 (0.99–1.23)	.08
LVEF[c]	1.01 (0.79–1.28)	.97	0.75 (0.54–1.02)	.06
Baseline QRS type[d]	1.22 (0.85–1.73)	.28	0.89 (0.55–1.04)	.64
LVSP	1.85 (1.32–2.63)	<.001	1.25 (0.75–2.09)	.39

HFH, heart failure hospitalization; CRT, cardiac resynchronization therapy; LBBAP, left bundle branch area pacing; HR, hazard ratio; CI, confidence interval; HFH, hospitalization failure hospitalization; VP, ventricular pacing; LVEF, left ventricular ejection fraction; LBBB, left bundle branch block; LAFB, left anterior fascicular block; LPFB, left posterior fascicular block; RBBB, right bundle branch block; LVSP, left ventricular septal pacing.
[a]Per 10-year increase.
[b]Per 10% decrease.
[c]Per 10% increase.
[d]LBBB, NIVCD, RBBB + LAFB/LPFB/NIVCD.

novel, specific for LBBAP and potentially modifiable independent predictors were identified: lack of LBB capture confirmation, i.e. LVSP (HR 1.85), and low percentage of ventricular pacing (HR 1.12).

Pacing the LBB area without direct capture of the conduction system, that is, LVSP only, clearly leads to less physiological activation of the left ventricle. LVSP results in a greater mass of septal and left

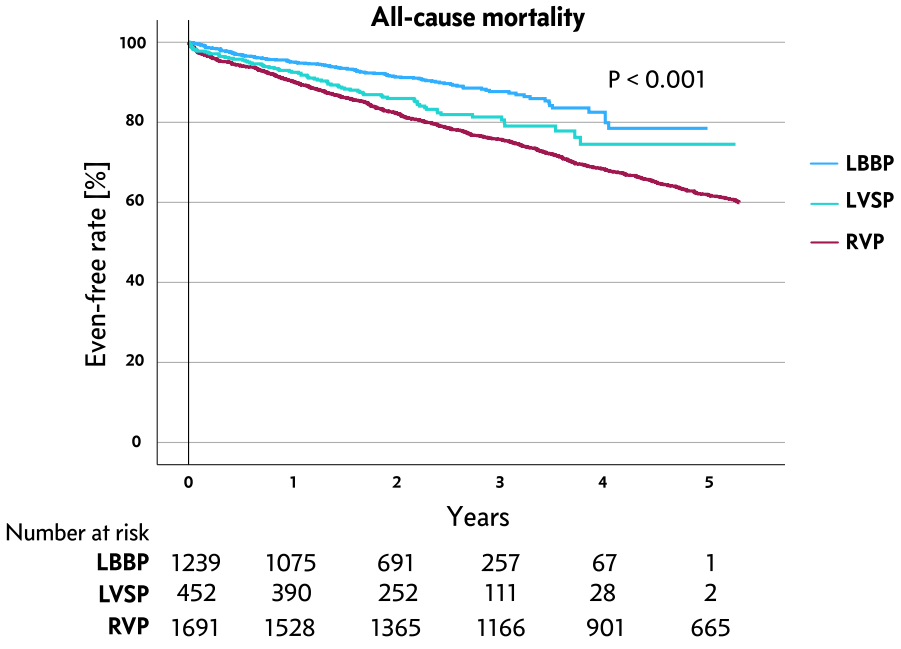


Figure 2 Kaplan–Meier survival estimates for all-cause mortality comparing right ventricular pacing (RVP) with left ventricular septal pacing (LVSP) and left bundle branch pacing (LBBP)

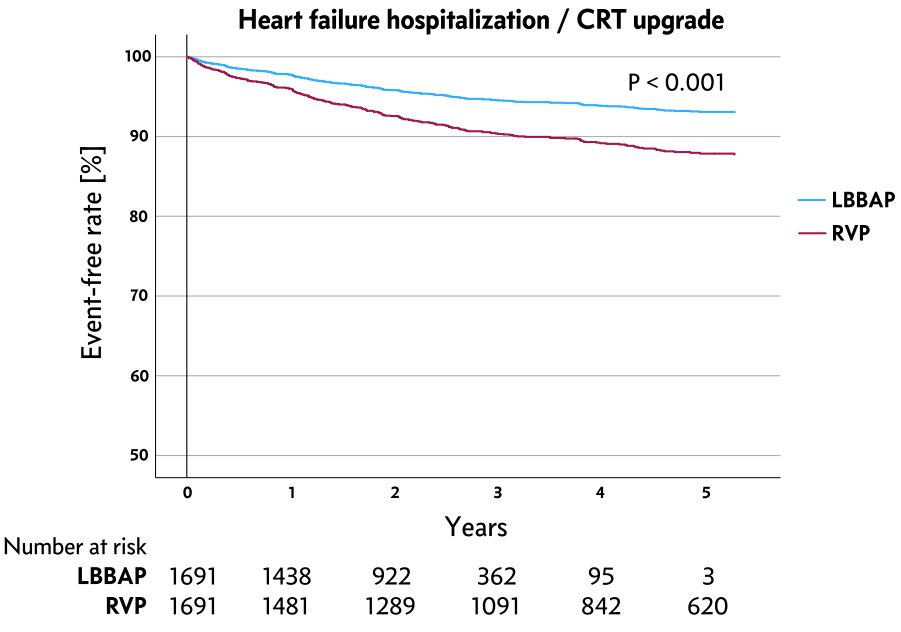


Figure 3 Survival curve estimates for the combined endpoint of heart failure hospitalizations and upgrade to cardiac resynchronization therapy (CRT) with mortality as a competing risk comparing right ventricular pacing (RVP) with left bundle branch area pacing (LBBAP)

ventricular myocardium depolarized directly, without the participation of the left conduction system, which is most likely only later secondarily engaged. This is reflected in the LVSP QRS with V6 RWPT, which is on average 17–20 ms longer than during LBBP (18.9 ms in the current study),[15,18] and in the commonly observed repolarization abnormalities in the lateral leads.[23] However, it was not known if this deviation from physiology translates into differences in clinical outcomes. The current study shows that lack of LBB capture was a robust independent predictor of mortality during LBBAP. It provides the first strong data that LBB capture should be the goal during an LBBAP procedure and that LVSP should not be accepted without serious attempts at LBB capture. This may be particularly relevant in patients with a high expected or desired percentage of ventricular pacing (see below). On the other hand, failure to achieve LBB capture should not be considered a failed LBBAP

Table 4 Procedure-related and follow-up characteristics of the propensity score-matched patients

	LBBAP ($n = 1691$)	RVP ($n = 1691$)	P
Fluoroscopy (min)	9 (6–13)	4 (3–8)	<.001
Paced QRS duration (ms)	138.1 ± 22.4	160.1 ± 17.5	<.001
Capture threshold at implant (V)	0.7 (0.5–1)	0.6 (0.5–0.8)	<.001
Sensing at implant (mV)	10 (7–15)	12 (9–15)	<.001
Lead impedance at implant (Ohm)	650 (520–830)	700 (600–850)	<.001
Capture threshold at FU (V)	1.0 (0.8–1.3)	1.0 (0.8–1.3)	.35
Sensing at FU (mV)	12 (9–20)	12 (10–15)	<.001
Ventricular pacing at FU (%)	99 (94–100)	98 (74–100)	<.001
LVEF at FU (%)	55.2 ± 9.2	52.8 ± 11.9	<.001

Numbers in parentheses represent the interquartile range.
LBBAP, left bundle branch area pacing; RVP, right ventricular pacing; FU, follow-up.

Table 5 Acute and late procedure-related complications among propensity score-matched patients

	LBBAP ($n = 1691$)	RVP ($n = 1691$)	P
Total (*n*)	141 (8.2%)	123 (7.3%)	.25
Coronary vessel fistula (*n*)	5 (0.3%)	0	
Acute coronary syndrome (*n*)[a]	3 (0.2%)	0	
Unscrewable LBBAP/RV lead (*n*)	1 (0.1%)	0	
LBBAP/RVP lead dislodgment/damage (*n*)	43 (2.5%)	37 (2.2%)	
Pocket haematoma (*n*)	9 (0.5%)	15 (0.9%)	
Pericardial effusion/pericarditis/tamponade (*n*)	9 (0.5%)	14 (0.8%)	
Atrial lead dislodgment/damage (*n*)	27 (1.6%)	29 (1.8%)	
Pneumothorax (*n*)	10 (0.6%)	7 (0.4%)	
Systemic/pocket infection (*n*)	7 (0.4%)	8 (0.5%)	
Exit block/threshold increase (*n*)[b]	0	5 (0.3%)	
Other	28 (1.6%)	8 (0.5%)	

LBBAP, left bundle branch area pacing; RVP, right ventricular pacing.
[a]Defined as chest pain with ST-segment elevation.
[b]RVP/LBBAP threshold increase necessitating reintervention.

procedure, as LVSP is still more physiological than conventional RVP. The MELOS study initially proposed this view,[5] and the MELOS RELOADED Kaplan–Meier survival curves now support it with the LVSP curve positioned between the LBBP and RVP curves. These data are consistent with a small number of studies comparing LBBP, LVSP, and RVP. These studies suggest that LVSP is less physiological and is associated with worse outcomes than confirmed LBBP. LVSP was found to result in longer V6 RWPT, non-physiological left ventricular activation sequence, higher electrical dyssynchrony on advanced electrical imaging, worse acute haemodynamic effect, and worse clinical and echocardiographic outcomes (in CRT-indicated patients) and was a predictor of LVEF decline (in patients with high ventricular pacing burden and no CRT indication).[15,24–29] In the study by Shroff *et al.*[30], clinical response to LBBAP was associated with the presence of LBB capture as evidenced by QRS transition, whereas QRS features typical of LVSP observed at follow-up were associated with non-response. However, when compared with RVP, the LVSP has a narrower QRS and much shorter V6 RWPT. It was shown that LVSP offers superior synchrony compared with RVP, and it may be comparable to BiV-CRT.[26,31]

The finding that the percentage of ventricular pacing during LBBAP should be maximized rather than minimized may appear counterintuitive in light of the prevailing concept that ventricular pacing is detrimental and that promoting native conduction is beneficial. However, data on the adverse effects of ventricular pacing and pacing minimization come from RVP studies, whereas studies of BiV-CRT have found that maximizing the percentage of ventricular pacing is beneficial.[32,33] This finding indicates that LBBAP in AVB patients may not only serve as a bradycardia therapy but also should be regarded as a form of CRT. Indeed, a

subanalysis of the current dataset shows that the percentage of ventricular pacing was an independent predictor of survival only in patients with a non-narrow QRS/non-RBBB QRS at baseline (the majority of the cohort studied)—Supplementary data online, *Table S5*.

Secondary outcomes

The incidence of HFH/CRT upgrade outcomes in the MELOS RELOADED study at 4 years was 6.6% and 13.4% in the LBBAP and RVP groups, respectively. In multivariable analysis, LBBAP was an independent predictor of reduced HFH/CRT upgrade with an HR of 0.53. This finding is consistent with the study by Sharma *et al.*[10], in which the incidence of HFH was 3.7% (12/332) and 10.5% (40/82) in the LBBAP and RVP groups, respectively. This resulted in a difference in HFH rates at 2.5 years, which was similar to that seen in MELOS RELOADED at the same time point, with similar separation of Kaplan–Meier curves for RVP and LBBAP. Numerous preceding studies have demonstrated that RVP is associated with exacerbation/development of heart failure and risk of pacing-induced cardiomyopathy.[32,34] Preserved or improved left ventricular synchrony with LBBAP, which is in contrast to the deterioration of synchrony during RVP, likely explains why HFH is significantly lower using this physiological pacing modality.[28]

LBBAP appears to be a safe procedure, with a complication rate in the present study and in other studies comparable to that seen with RVP.[35] As reported by Vijayaraman *et al.*[36], the LBBAP complication rate is lower than during BiV-CRT. However, the spectrum of complications is somewhat changed, with the most notable difference being the higher potential to damage coronary vessels, resulting in fistula formation, intraseptal haematoma, and/or acute coronary event (*Table 5*). These new complications occur in about 0.5% of LBBAP patients according to the current study and data from the literature.[35] In contrast to the MELOS study, in the MELOS RELOADED study, we did not include transient intraprocedural perforation of the interventricular septum by the pacing lead among the complications, as it is now considered a common, benign occurrence that is not known to have any negative sequelae.

The obtained electrical parameters in terms of capture threshold and sensitivity values were good and similar between the groups, both at implantation and at follow-up, and were comparable to those reported elsewhere for LBBAP and RVP.

Study limitations

The main limitation of the study is that it was non-randomized and partly retrospective, which could lead to selection bias, potential data gaps (HFHs), and undetected differences in characteristics that could affect the analysis of mortality. Moreover, censoring and differences in follow-up could introduce a bias. However, several measures were undertaken to address these limitations: (i) propensity score matching of the groups limited the differences in patient characteristics between the LBBAP and RVP cohorts; (ii) inclusion of only RVP patients implanted shortly before the introduction of LBBAP in the same centres to limit the selection bias and potential differences in treatment; furthermore, the very similar baseline characteristics of the two groups, even without matching, suggest the absence of significant selection bias; and (iii) majority of data came from our prospectively maintained LBBAP registries, and the death status was firmly determined via dedicated prospective national mortality registries.

The LBBAP capture classification was based on the results of manoeuvres and measurements performed locally by the implanting centres. This may have led to lower precision and some inconsistency in this categorization. However, the same criteria were applied uniformly to all patients by a single core team to minimize variability. The finding of increased mortality with LVSP vs LBBP and LVSP being an independent predictor of mortality does not prove a causal relationship between LVSP and increased mortality, as this is observational data. This finding may reflect an underrecognized selection bias; the inability to obtain LBB capture and increased mortality may have a common reason (e.g. septal fibrosis).

Finally, the substantial reduction in mortality with LBBAP should be interpreted with caution in view of the associative nature of the observed hazard ratio.

Conclusions

This is the first large study to provide data showing that routine use of LBBAP instead of RVP in patients with AVB without indications for CRT is associated with significantly lower long-term mortality. This strengthens the use of LBBAP in this population while awaiting the results of ongoing randomized trials. Confirmation of LBB capture and pacing percentage maximization seems advisable to achieve optimal results with LBBAP.

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Supplementary data

Supplementary data are available at *European Heart Journal* online.

Declarations

Disclosure of Interest

V.V., P.S., J.N-N, E.O., and D.G—nothing to declare. G.K., and P.M. report consultancy and/or speaker fees from Medtronic and Biotronik. W.H. reports consultancy and speaker fees from Medtronic and Abbott. M.J. declares consultancy, speaker fees, and/or advisory board honoraria from Medtronic, Biotronik, Abbott, and Boston Scientific. K.V. reports consultancy for Biosense Webster, Philips, Medtronic, and Abbott and reports speaker fees from Microport, and K.V.'s institution has received research and educational grants from Philips, Abbott, Medtronic, and Biosense Webster. J.L. reports a consultancy agreement with Medtronic and Abbott and a research grant from Medtronic; all payments made to the institution. O.C. reports consulting and speaker's fees from Abbott, Biotronik, Boston Scientific, Medtronic, and MicroPort. L.M.R. reports consultancy fees from Medtronic. F.Z. reports speaker fees (modest) from Abbott, Biotronik, Boston Scientific, Medtronic, and MicroPort. H.B. reports speaker and/or consultancy fees (minor) from Abbott, Biotronik, Boston Scientific, Medtronic, and MicroPort. Z.I.W. reports advisor, speaker fees, and research support from Medtronic and Boston Scientific and advisor and speaker fees from Biotronik and is an Abbott Advisory board member. J.D.P. reports speaker fees and honoraria from Medtronic, Boston Scientific, Abbott, and Biotronik. K.C. reports advisor and speaker fees from Medtronic and speaker fees from Biotronik. D.Ž. reports advisory board, consultant, and proctorship fees from Abbott, Biotronik, Boston Scientific, and Medtronic. P.K. reports speaker fees from BMS/Pfizer and Biosense Webster.

Data Availability

The data underlying this article will be shared on reasonable request to the corresponding author.

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Ethical Approval

The study complies with the Declaration of Helsinki. Ethical committee approval was obtained at each centre; informed consent was obtained from the subjects.

Pre-registered Clinical Trial Number

None supplied.

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