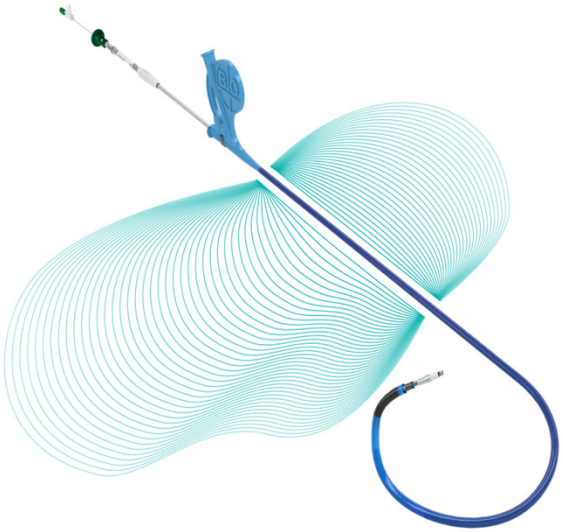

Physiologic Pacing Follow-up

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Disclaimer: Use of BIOTRONIK Products for LBBAP

- BIOTRONIK Selectra 3D and Solia pacing leads are FDA-approved for traditional lead delivery and placement, per the Indications for Use. Selectra 3D and Solia pacing leads are not specifically indicated for Conduction System Pacing, including His Bundle and Left Bundle Area Pacing.
- Commercial promotion of non-indicated use of BIOTRONIK devices, leads or delivery systems is strictly prohibited.
- Please note that there is a distinction between commercial promotion of a product by a medical device company and the use of a product by a physician in the practice of medicine; FDA does not regulate the practice of medicine.
- For any questions on this topic, please contact BIOTRONIK Regulatory Affairs.

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Current Indications For Use:

Solia Lead

The BIOTRONIK Solia S lead is a 5.6 French, transvenous, steroid-eluting (0.85 mg DXA), bipolar, IS-1 compatible, active fixation lead intended for permanent sensing and pacing in either the right atrium or right ventricle when used with a compatible pulse generator with IS-1 header. *(Note that IS-1 refers to the International Standard whereby leads and generators from different manufacturers are assured a basic fit [Reference ISO 5841-3:2000]).* The leads may be used with single or dual chamber pacing systems, dual chamber ICDs, CRT-P and CRT-D.

Selectra 3D Outer Guiding Catheter

In conjunction with the Selectra accessory kit, Selectra guiding catheters are used to facilitate lead implantation in the heart chambers or in the coronary veins via the coronary sinus.

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Objectives

Left Bundle Branch Area Pacing (LBBAP)

- Verbalize why a 12 lead ECG is necessary during follow-up of a Left bundle branch pacing (LBBAP) lead
- Identify the characteristics of a right bundle branch block on ECG
- Identify non-selective (ns-LBBAP) vs selective (s-LBBAP) capture during threshold testing for LBBAP lead
- Identify Anodal stimulation for a LBBAP lead
- Identify LV septal capture characteristics

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12 Lead ECG

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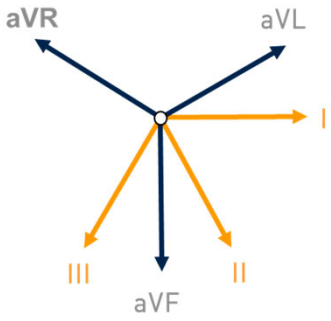
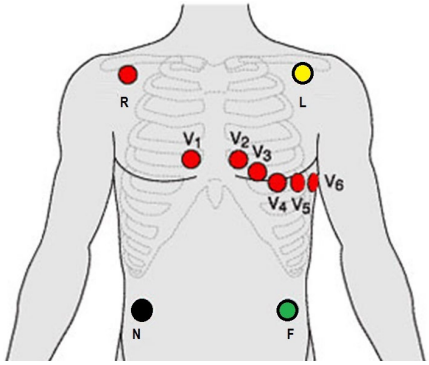
12 Lead ECG
Electrode Placement

- 12 lead electrocardiogram (ECG) is a representation of the heart's electrical activity recorded from electrodes placed on the body between 2 poles, a negative and positive pole
- 12 lead ECG is needed during follow-up for a LBBAP lead to visualize lead V1





6 | DECEMBER 28, 2023

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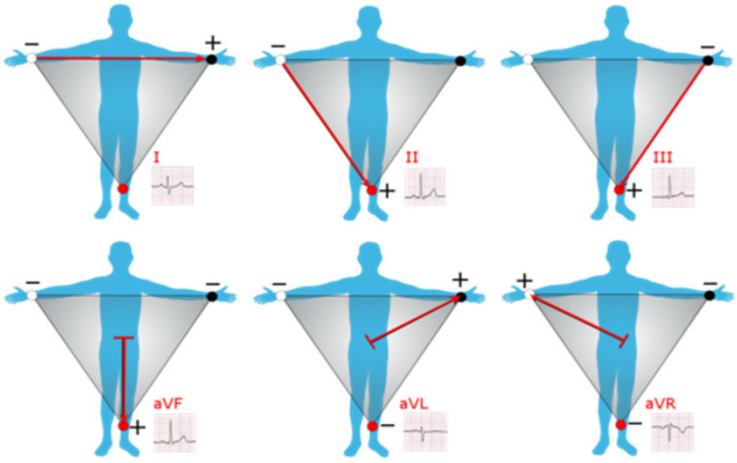
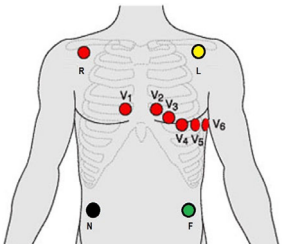
Basic 12 Lead ECG



12 Lead ECG consists of

- 3 bipolar limb leads: I, II, III
- 3 unipolar limb leads: aVR, aVL, aVF
- 6 unipolar chest leads V1-V6 (also known as the precordial leads)



Web: Student Physiology

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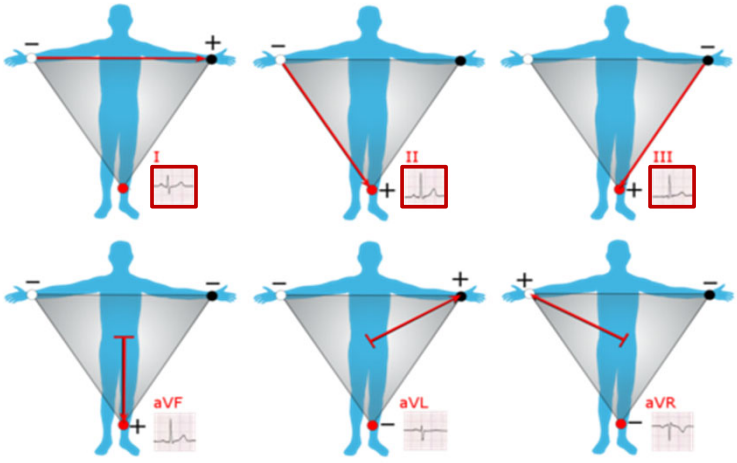
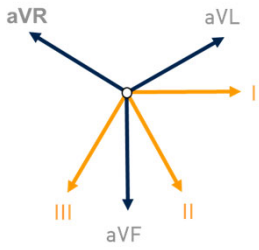
Basic 12 Lead ECG



- The wave of depolarization moving towards a positive electrode results in a positive deflection of the ECG
- The wave of depolarization moving towards a negative electrode results in a negative deflection of the ECG



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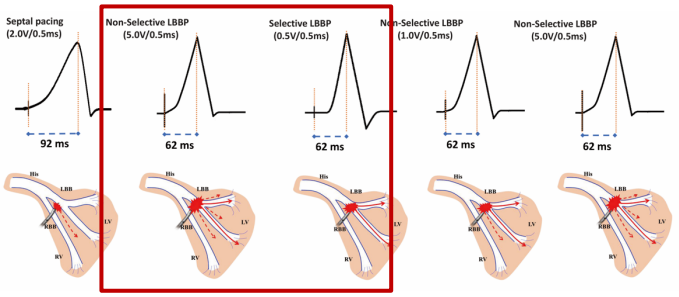
Why is a 12 Lead ECG necessary for LBBAP pacing lead?

- When performing threshold tests, a 12-lead ECG is important to recognize the various types of capture (selective versus non-selective conduction system capture, myocardial capture only or anodal capture)[1]
- Transition in QRS morphology is the gold standard to assess capture[2]
- Paced 12-lead ECGs are mandatory during in-person follow-up to assess LBBAP capture[2]



1. Bakelants E, Burri H. Troubleshooting Programming of Conduction System Pacing. Arrhythm Electrophysiol Rev. 2021 Jul;10(2):85-90. doi: 10.15420/aer.2021.16. PMID: 34401180; PMCID: PMC8335852.

2. Burri H, Jastrzebski M, Cano Ó, Čurila K, de Pooter J, Huang W, Israel C, Joza J, Romero J, Vernooy K, Vijayaraman P, Whinnett Z, Zanon F. EHRA clinical consensus statement on conduction system pacing implantation: endorsed by the Asia Pacific Heart Rhythm Society (APHRS), Canadian Heart Rhythm Society (CHRS), and Latin American Heart Rhythm Society (LAHRS). Europace. 2023 Apr 15;25(4):1208-1236. doi: 10.1093/europace/euad043. PMID: 37061848; PMCID: PMC10105878.

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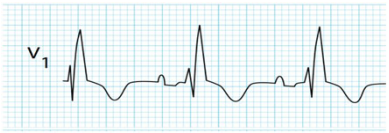
Why is a 12 Lead ECG necessary for LBBAP lead?

Why the need to visualize lead V1
- If capturing a portion of the left side conduction system, should be creating a right bundle branch block appearance on the ECG
- RSR prime in V1



With LBB pacing this is referred to as a terminal R wave
- The terminal R wave represents delayed activation of the right ventricle

Loss of a terminal R wave at follow-up
- If possible and available, compare current 12 lead ECG with post implant 12 lead ECG

Loss of terminal R-wave in V1 over follow-up was reported in 4% of patients in the MELOS registry. This highlights the importance of the 12-lead ECG at follow-up visits.[1]

1. Burri H, Jastrzebski M, Cano Ó, Čurila K, de Pooter J, Huang W, Israel C, Joza J, Romero J, Vernooy K, Vijayaraman P, Whinnett Z, Zanon F. EHRA clinical consensus statement on conduction system pacing implantation: endorsed by the Asia Pacific Heart Rhythm Society (APHRS), Canadian Heart Rhythm Society (CHRS), and Latin American Heart Rhythm Society (LAHRS). Europace. 2023 Apr 15;25(4):1208-1236. doi: 10.1093/europace/euad043. PMID: 37061848; PMCID: PMC10105878.

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Definitions

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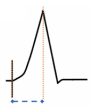
Conduction System Pacing

Definitions

LBBAP (S-LBBAP) and non-selective LBBAP (NS-LBBAP) are two subgroups of LBBAP

Non-selective LBBAP *No stim-QRS latency; no discrete local EGM separate from stimulus artifact*[1]	• LBB and adjacent myocardium are captured	
Selective LBBAP S-LBBAP: *Stim-QRS latency and discrete local EGM separate from stimulus artifact seen*[1]	• Only the LBB trunk or its proximal fascicles is captured • As pacing output is decreased, lose local myocardial capture	
LV Septal Pacing[1]	• Left ventricular septal myocardium only is captured	
Anodal Stimulation (Bipolar pacing configuration)[1]	• Stimulation of ring electrode captures right side of septum • Simultaneous LBB capture at Tip Electrode	

Reference: Zhu K, Chang D, Li Q. Which Is More Likely to Achieve Cardiac Synchronization: Left Bundle Branch Pacing or Left Ventricular Septal Pacing? Front Cardiovasc Med. 2022 Mar 28;9:845312.

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Non-Selective vs Selective vs LVS Pacing Criteria LBBAP

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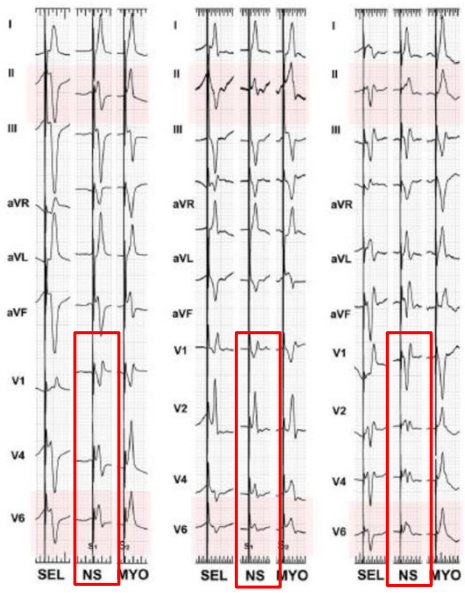
Selective vs Non-Selective LBBAP

Possible pacing responses with $LBBAP_1$

Differences best visualized in lead V1

NS-LBBAP:

- Fusion between S-LBBAP and LVSP
- Clear R' in V1, narrow QRS
- QRS waveform positive but less high in V4-V6



Documented with programmed ventricular extrastimuli pacing

1. Dr. Jan De Pooter, BIOTRONIK training, BIOTRONIK Training video 2022

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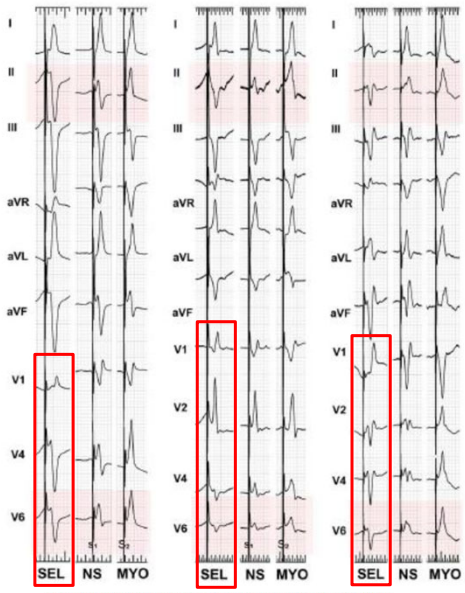
Selective vs Non-Selective LBBAP

Possible pacing responses with $LBBAP_1$

Differences best visualized in lead V1

S-LBBP:

- Large R' in V1
- Latency interval (separation) between pacing spike and QRS onset (not always clear)



Documented with programmed ventricular extrastimuli pacing

1. Dr. Jan De Pooter, BIOTRONIK training, BIOTRONIK Training video 2022

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Selective vs Non-Selective LBBAP

Possible pacing responses with $LBBAP_1$

Differences best visualized in lead V1

LVSP (myocardial capture):

- Broader and notched QRS morphology
- Most often R', but sometimes Loss of r' in V1

Documented with programmed ventricular extrastimuli pacing

1. Dr. Jan De Pooter, BIOTRONIK training, BIOTRONIK Training video 2022

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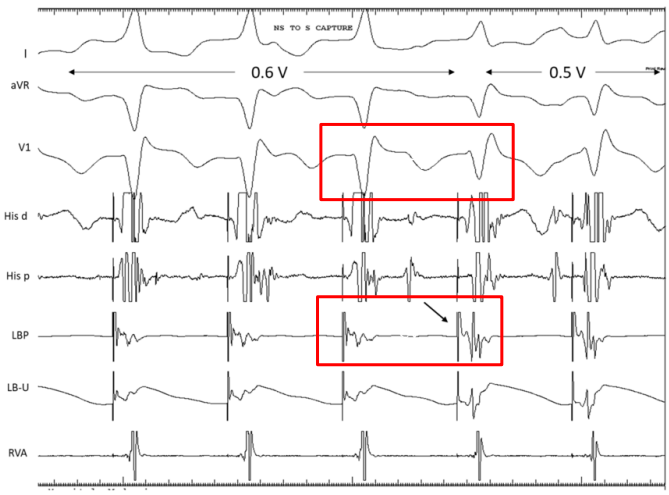
Left Bundle Branch Pacing

Non-selective-Selective LBBAP capture

Note the following changes during transition from ns-LBBAP to s-LBBAP

- Slight change in QRS morphology in V1
- Separation of pacing output from QRS with s-LBB capture



Reference: Ponnusamy, S.S., Muthu, G., Kumar, M. et al. Mid-term feasibility, safety and outcomes of left bundle branch pacing–single center experience. J Interv Card Electrophysiol 60, 337–346 (2021). https://doi.org/10.1007/s10840-020-00807-w

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Follow-up for a LBBAP lead

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Follow-Up Protocol

LBBAP follow-up may be less frequent as compared to His Bundle follow up and rely more on remote device management if capture thresholds are reliably measured by the device[1]

- Currently no defined criteria for frequency of follow-up for a LBBP lead
- Consider the following (clinician preference)
  - 1 week post operative
  - 3 and 6 months post operative
  - If lead remains stable at 6 months post op check, consider yearly check

1. Burri H, Jastrzebski M, Cano Ó, Čurila K, de Pooter J, Huang W, Israel C, Joza J, Romero J, Vernooy K, Vijayaraman P, Whinnett Z, Zanon F. EHRA clinical consensus statement on conduction system pacing implantation: endorsed by the Asia Pacific Heart Rhythm Society (APHRS), Canadian Heart Rhythm Society (CHRS), and Latin American Heart Rhythm Society (LAHRS). Europace. 2023 Apr 15;25(4):1208-1236. doi: 10.1093/europace/euad043. PMID: 37061848; PMCID: PMC10105878.

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Follow Up Testing on a Left Bundle Branch Pacing lead Best Practices

Perform a 12 lead ECG simultaneously with threshold test

- Why? need to visualize lead V1 to confirm LBBAP

Perform Sensing, Impedance, and Threshold testing on LBBAP lead

- Once threshold test is complete, go back and analyze the 12 lead ECG with each decrement
  - *Was there Anodal stim at high output?*
  - *Was there a transition from NS-LBB to S-LBB capture?*
  - *What was the threshold?*

Electrode and Lead placement; RN.com

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Left Bundle Branch Lead Testing

Steps when performing a threshold test

- Perform threshold test simultaneously with ECG
  - Set pulses to 3
- Continue to decrement output until LOC
- Review 12 lead ECG print out
  (decrement is every 3 pulses)
- Identify and document output at which transition(s) may occur
  - Transition from ns-LBB to s-LBB confirms LBB capture
- Identify and document output at which LOC occurs
  - Program output 2x safety margin

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Follow-up LBBAP Examples

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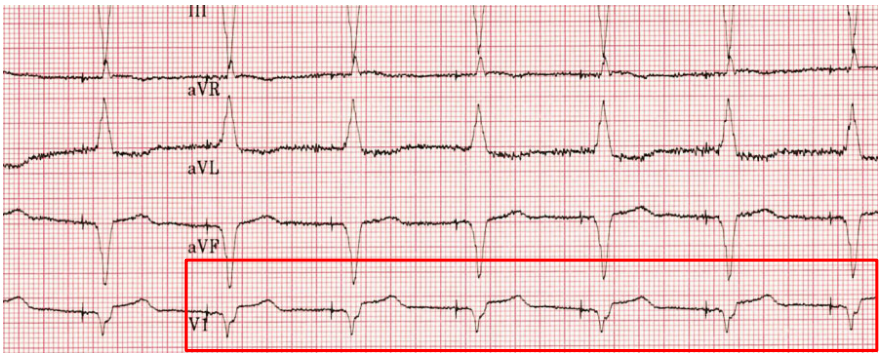
Left Septal Capture

Looking at a lead V1 in this example. What type of capture is occurring?

(Select the best answer)

- Non-Selective (ns) LBB capture
- Selective LBB capture
- Septal Capture
- None of the above



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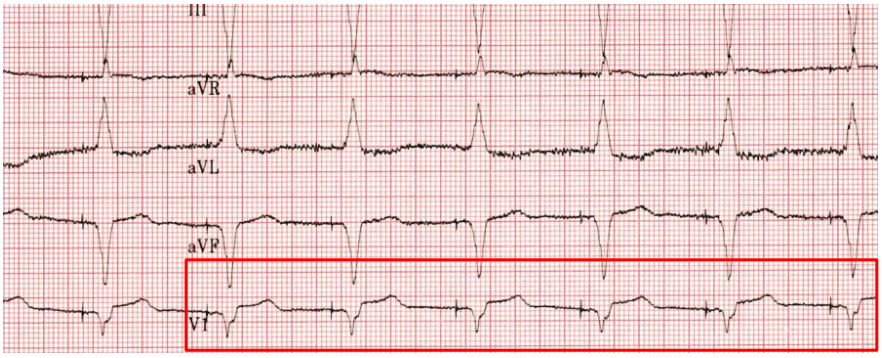
Left Septal Capture

Looking at a lead V1 in this example. What type of capture is occurring?

(Select the best answer)

- Non-Selective (ns) LBB capture
- Selective LBB capture
- **Septal Capture**
- None of the above



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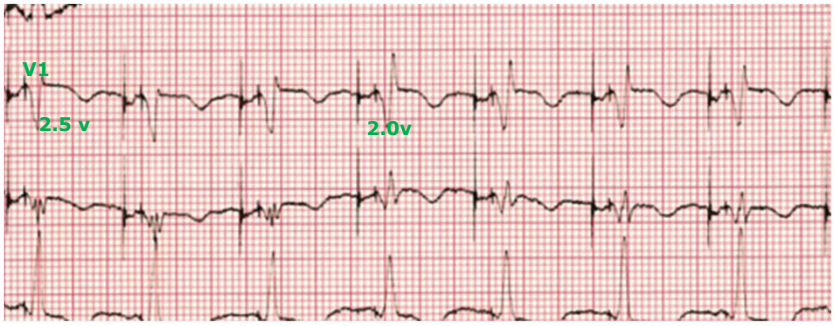
Anodal to ns-LBBAP

Looking at a lead V1 in this example. What type of capture is occurring?

(Select the best answer)

a. Non-Selective (ns) LBB capture
b. Selective LBB capture
c. Septal Capture
d. Anodal to ns-LBB capture



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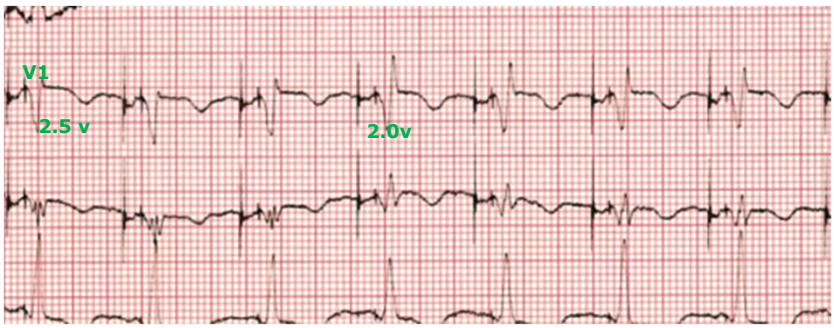
Anodal to ns-LBBAP

Looking at a lead V1 in this example. What type of capture is occurring?

(Select the best answer)

a. Non-Selective (ns) LBB capture
b. Selective LBB capture
c. Septal Capture
d. Anodal to ns-LBB capture



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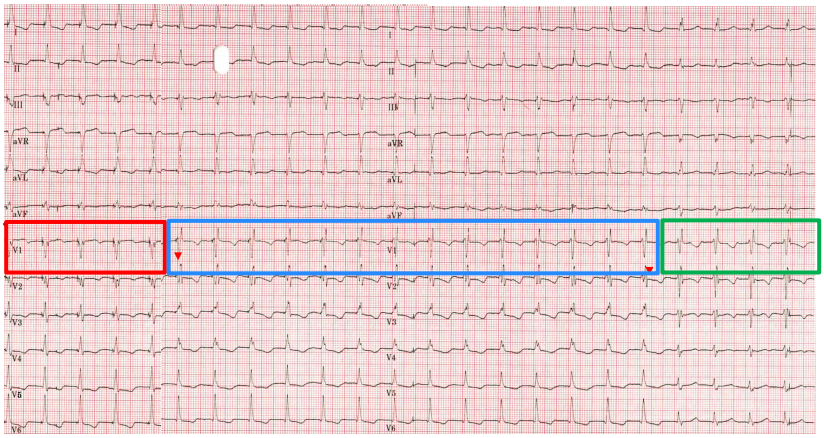
Case Study
Threshold Test

Looking at a lead V1 in this example. What type of capture is occurring?

(Select the best answer)

a. Non-Selective (ns) LBB capture
b. Selective LBB capture
c. Septal Capture
d. Anodal to ns-LBB capture to selective LBB capture



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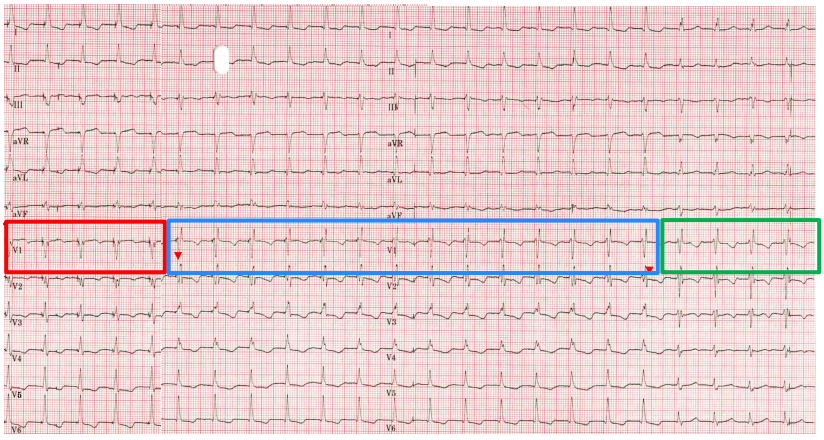
Case Study
Threshold Test

Looking at a lead V1 in this example. What type of capture is occurring?

(Select the best answer)

a. Non-Selective (ns) LBB capture
b. Selective LBB capture
c. Septal Capture
d. Anodal to ns-LBB capture to selective LBB capture

Identify the following
- Anodal stimulation
- NS-LBBAP
- S-LBBAP



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Programming Resource

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Programming LBBAP Per Physician Preference Not BIOTRONIK Specific

Table 1: Programming Recommendations for LBBAP

Parameter	Recommendation HBP	Recommendation LBBAP
Pacing mode	Single-chamber device: VVI Dual-chamber or CRT device: • HBP lead in a ventricular port: DDD(R), DDI or managed ventricular pacing mode • HBP lead in atrial port (chronic AF) with backup ventricular lead: DDD(R), DDI(R), or DVI(R) if available	Single-chamber device: VVI Dual-chamber or CRT device: • LBBAP lead in a ventricular port: DDD(R), DDI or managed ventricular pacing mode • LBBAP lead in atrial port (chronic AF) with backup ventricular or ICD lead: DDI(R), or DVI(R) if available
Pacing polarity	Unipolar (better visibility or the pacing spike to avoid confounding with intrinsic rhythm, lower capture thresholds) Bipolar (lower current drain due to higher impedance)	Bipolar (lower current drain due to higher impedance; anodal capture may narrow the QRS) Unipolar if anodal capture is not desirable
Sensing vector	Bipolar (unipolar can be tried if low sensing amplitude or P wave/HB potential oversensing)	Bipolar
Sensitivity	HBP lead connected to atrial channel: set to the maximum value (minimum sensitivity), as ventricular sensing is provided by the backup ventricular lead HBP lead connected to RV channel: adjust the level to ensure ventricular sensing, yet avoid oversensing of atrial or HB potentials.	Usually, not an issue as R waves are of high amplitude
Output voltage	2 x threshold voltage Fixed safety margin, e.g. 1V above the threshold, in non-dependent patients	2 x threshold voltage
Impulse duration	0.4 ms (1.0 ms if high capture threshold). 0.2-0.4 ms may be programmed according to chronaxle	0.4 ms (capture threshold is rarely an issue)
Automatic capture control algorithms	Deactivate, monitoring only (may be inaccurate or impossible to measure, especially if the HBP lead is connected to the atrial port), or activate only once the accuracy has been confirmed in the patient	Set to monitor or automatic once the accuracy has been confirmed in the patient
AV delay	HBP lead in ventricular port: Subtract HV interval (e.g. 40 ms) from desired AV interval	LBBAP lead in ventricular port: Subtract LBB-V interval (e.g. 20 ms) from desired AV interval

Troubleshooting Programming of Conduction System Pacing; Bakelants and Burri;2021, Arrhythmia and Electrophysiology Review, July 2021; 10(2) 85-90

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Programming LBBAP Per Physician Preference (continued) Not BIOTRONIK Specific

AV delay	HBP lead in ventricular port: Subtract HV interval (e.g. 40 ms) from desired AV interval HBP lead in atrial port with backup ventricular pacing: AV delay >His pace-RVSS interval (e.g. 150 ms) HBP lead in atrial port with HOT-CRT: optimize AV interval based on QRS narrowing, or program empirically to 60% of the His pace – RV sense interval (usually 40-60 ms)[8]	LBBAP lead in ventricular port: Subtract LBB-V interval (e.g. 20 ms) from desired AV interval LBBAP lead in atrial port with backup ventricular pacing: AV delay >LBBAP-RVS interval (e.g. 150 ms) LBBAP lead in atrial port with LOT-CRT: optimize AV interval based on QRS narrowing
VV delay (CSP lead connected to LV port)	With backup RV pacing: program maximum LV channel pre-excitation (e.g. 80 ms) In case fusion with RV pacing is desirable (e.g. in case of uncorrected RBBB): program LV channel pre-excitation 30-60 ms, optimized by surface ECG	With backup RV pacing (e.g. with ICD lead): program maximum LV channel pre-excitation (e.g. 80 ms)
Ventricular safety pacing	Deactivate if the HBP lead is connected to the atrial port with an RV back-up lead, after having verified absence of crosstalk	Deactivate if the LBBAP lead is connected to the atrial port with an RV back-up lead (e.g. with an ICD or in case of LOT-CRT), after having verified absence of crosstalk
Automatic sensing control algorithms	Deactivate (IP wave oversensing and HB sensing (may lead to asystole!)	Can be left on
Sensing if CSP lead connected to LV port	Deactivate (BIOTRONIK, Boston-Scientific)	Deactivate (BIOTRONIK, Boston-Scientific)
AV and VV optimization algorithms	Deactivate	Deactivate
Ventricular triggered pacing (ventricular sense response, etc.)	Deactivate	Deactivate

AV = atrioventricular; CSP = conduction system pacing; HB = His bundle pacing; HV = His-ventricle; HOT-CRT = His-optimized CRT; LBB = left bundle branch; LBBAP = left bundle branch area pacing; LOT-CRT = left bundle branch pacing optimized CRT; LV = left ventricular; RBBB = right bundle branch block; RV = right ventricular; VSP = ventricular safety pacing; VV = interventricular.

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BIOTRONIK Training and Education

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