31st Annual International Conference of the IEEE EMBS
Minneapolis, Minnesota, USA, September 2-6, 2009

Exit vs. entrance block testing for cardiac lesion assessment

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Abstract—**Cardiac lesions are created to act as barriers which prohibit the transmission of cardiac myocyte contractile activity from one side of the lesion to the other. Testing for conduction block is the main way to acutely confirm the effectiveness of this therapy. There are two general methods used to test for conduction block. These methods are called: 1) "exit block testing" and 2) "entrance block testing." In this study, two different devices were used on n=5 swine to determine if the method of lesion assessment (exit vs. entrance block testing) affected the ability to correctly identify if acute conduction block was achieved. No significant difference was found between conclusions drawn from either method of lesion assessment. However, the most robust lesion assessment will occur when both methods are employed so that the physician has the most information available for analysis.**

I. Introduction

THE goal of surgical ablation is to make contiguous, transmural, linear lesions on the heart. It is of utmost importance to test the integrity of the lesions; a lesion that does not stop the transmission of contractile activity can be even more dangerous than no lesion at all, as incomplete lesions can facilitate the maintenance of further arrhythmias[1].

Lesion assessment in the form of conduction block testing is important not as proof of transmurality [2,3], per se, but as a quality control measure to ensure that the lesions created will acutely accomplish their purpose.

Conduction block testing is generally performed by assessing entrance or exit block (i.e. conduction entering or exiting the isolated area). Exit block testing involves attempting to pace the heart within the isolated area of interest and observing if pacing capture occurs beyond the isolation; whereas, entrance block testing consists of sensing electrogram (EGM) signals within the isolated area of interest to determine if signals are conducting through the isolating lesions. If pacing in the isolated area captures the heart or signals are sensed in the isolated region, one can conclude that the lesion is not complete and additional ablation is necessary to gain complete conduction block.

The aim of this study was to investigate (using two different devices to perform the measurements) if the method of lesion assessment (exit vs. entrance block testing) affected the ability to correctly conclude if a lesion blocked the conduction of cardiac contractile activity. Currently, *if* a surgeon performs conduction block testing to assess lesions, he or she generally uses one method of testing or the other, though some surgeons perform both. It is important to know if these methods produce results that lead to similar conclusions or if one method proves to be superior, so that surgeons can be informed as to which method can most reliably assess lesions.

II. Methods

A. Animal Preparation

Following a prescribed quarantine, n=5 swine were selected for this study. Animals were cared for according to the Medtronic Physiological Research Laboratories' Standard Operating Procedures and The Guide for Care and Use of Laboratory Animals. Following proper anesthetizing, the animal was prepped and clipped for a sternotomy.

B. Equipment

Two devices were used to assess both exit (pace) and entrance (sense) block in this study. Using two devices to assess the lesions allowed for insight as to the possibility of dependency of method on device-type.

One of the devices used was the Cardioblate® BP2 (Medtronic model #60831, Medtronic, Inc. Minneapolis, MN). This is a single-use, surgical radiofrequency (RF) ablation device which delivers energy via bipolar, malleable jaws. The BP2 has an irrigation system to deliver normal saline at the tissue/electrode interface to cool the tissue during the delivery of RF energy.

Fig. 1: The Cardioblate® BP2 clamp is a bipolar RF surgical ablation device.

The other device used to assess lesions in this study was the Cardioblate® MAPS (Medtronic model #49205, Medtronic, Inc. Minneapolis, MN). This is a single-use, surgical mapping

Manuscript received April 7, 2009. This work was supported by Medtronic, Inc.

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(sensing), ablation, pacing, and high-rate stimulation device. The MAPS device has a concentric bipolar electrode for pacing and sensing and a saline irrigation system that delivers fluid at the tissue/electrode interface to cool tissue during RF energy delivery.

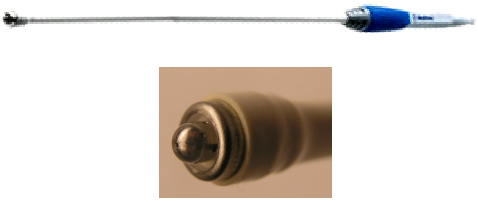

Fig. 2: The Cardioblate® MAPS pen (above) is a surgical mapping (sensing), ablation, pacing, and high rate stimulation device. The electrode is bipolar and concentric (below).

Both devices were plugged into the Medtronic Cardioblate® 68000 Generator (Medtronic, Inc. Minneapolis, MN) for the delivery of RF energy. The devices were plugged into the Medtronic Model 2090/2290 programmer/analyzer, (Medtronic, Inc. Minneapolis, MN) for sensing and pacing.

C. *Surgical Procedure*

The Prucka CardioLab® 8000 (software version 6.5)(GE Healthcare Technologies, Waukesha, WI) and Medtronic 2090/2290 Programmer/Analyzer were set-up for simultaneous bipolar EGM (electrogram) measurement. Channels on the Prucka were assigned to the BP2 and the MAPS for EGM sensing. On the Prucka, filters were set at 5Hz to 1000Hz (band pass) and the 60Hz notch filter (band stop) was disabled.

A median sternotomy was performed to access the heart. The pericardium was reflected and right atrial appendage (RAA) was exposed. Tissue ablation was performed using the Cardioblate® BP2 clamp until transmurality was indicated on the 68000 generator. Device and settings used were recorded.

D. *Baseline Measurements*

Pulmonary veins (PV) change in composition from cardiac muscle (proximal to the heart) to collagenous, non-conductive tissue (distal to the heart). The distance that the musculature travels along the length of the PV varies between subjects. Therefore, baseline measurements were important to collect for verification that data was collected from regions of the heart that had electrical continuity with the atrium, and not regions that were non-conductive to begin with.

Baseline measurements of EGM signals and pacing thresholds were recorded as reference measurements for entrance and exit block testing, respectively. These measurements were made at regions 1 (proximal to the future lesion) and 2 (distal to the future lesion) (see Figures 3 and 4) with both the BP2 and MAPS devices. The heart was paced by each device at both sites at a rate between 110 and 150 bpm. The pacing thresholds found with each device were recorded.

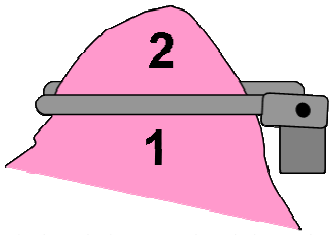

Fig. 3. Depiction of where lesion was placed (beneath clamp jaws) on the RAA, and definition of regions 1 (proximal to lesion) and 2 (distal to lesion).

E. *Lesion Creation and Assessment*

Using the BP2, the RAA was clamped at the predefined lesion site (see jaw placement in Fig. 3) and a lesion which spanned the complete width of the appendage was created with 2 applications of RF. Following the creation of the lesion, pacing and sensing from both the BP2 and MAPS devices were performed again, to assess exit and entrance block across the recently created lesion, using the same procedure as was used when collecting the baseline measurements.

Following the completion of this procedure on the RAA, it was repeated in exactly the same fashion on the LAA and on the caudal PV.

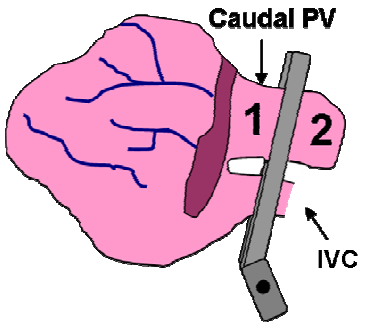

Fig. 4: Posterior view of heart. BP2 clamp placed for lesion creation on caudal pulmonary vein. Region 1is proximal to lesion, region 2 is distal to lesion.

F. *Data Analysis*

Electrophysiological (EP) and hemodynamic data were saved on the Prucka CardioLab® and the Medtronic 2090/2290 Programmer/Analyzer. Post-study analysis involved assessing the ability of the devices to "capture" the heart while pacing to assess exit block and comparing the local EGM signals from both devices on the "isolated" tissue and "non-isolated" tissue to assess entrance block.

G. *Expected v. Unexpected Results*

In order to best understand the findings of this study, it is important to know what an "expected" versus an "unexpected" result is. An "expected" result is one that confirms what is assumed based on the physical condition of the tissue of interest. For instance, on "isolated" tissue, one

would expect the heart to "not capture" when paced, and to show no local electrical activity while EGM sensing. An "unexpected" result occurs when the opposite is seen (i.e. on "isolated" tissue, the heart captures when paced and shows an active EGM when sensed). This implies that either the lesion is not complete/transmural or the assessment of the lesion was performed improperly.

H. Agreement v. Disagreement

Observing agreement in results between devices implies that the result is not device-dependent. Observing agreement in results between lesion assessment methods implies that both methods are assessing the lesion appropriately. This remains the case even when agreement is observed which yields an unexpected result. When disagreement between devices or methods occurs, one must assume that one of the devices and methods is giving the correct assessment and the other method or device is giving an incorrect assessment, for any number of reasons. In this study, if a discrepancy occurred, determination of which assessment was correct was made by the analysis of the tissue from the necropsy report.

I. Statistical Analysis

Minitab® 15.1.1.0 (Minitab, Inc., 2007©, USA), was used to evaluate agreement between lesion assessment methods using a 2-sample proportions test and a Fisher's exact test in where $p<0.05$ was considered statistically significant. Confidence intervals (CI) were determined as well.

III. RESULTS

A. Pathological Results

In post-operative analysis, all lesions were found to be transmural by staining with 2,3,5-Triphenyltetrazolium chloride (TTC) and pathological examination. Transmurality was confirmed by histological analysis in unclear instances[4].

B. MAPS v. BP2 Measurements

No statistically significant difference was found between the performance of the MAPS and the BP2 in terms of correctly assessing lesions for conduction block with either exit or entrance block testing.

C. Exit (pacing) and Entrance (sensing) Block Assessment

1) Exit Block Assessment

During exit block testing, baseline pacing was performed prior to the creation of the lesion, both proximal and distal to the lesion site, with both devices. Post-lesion, measurements were performed again at both sites with both devices. A total of n=120 sites were examined between both devices and across 5 animals.

Of the 120 measurements, only 3 resulted in unexpected results (2.5%, 0.5-7.1% with a 95% CI), and none of the 3 affected the proper assessment of the lesion (none of the unexpected results were found distal to the created lesion). The 1st unexpected result was found prior to lesion creation (baseline): the BP2 could not capture the heart distal to the future lesion site. The other two unexpected results found were post-lesion: neither the BP2 nor the MAPS device could capture the heart with pacing, proximal to the lesion. Therefore, the 2nd and 3rd unexpected results actually agree in their assessment.

An unexpected disagreement occurred in 1 instance out of 120 measurements (0.83%, 0.02-4.5% with a 95% CI).

2) Entrance Block Assessment

During entrance block testing, baseline EGM sensing was performed prior to the creation of the lesion, both proximal and distal to the lesion site, with both devices. Post-lesion, measurements were performed again at both sites with both devices. A total of n=120 sites were examined between both devices and across 5 animals.

Of the 120 measurements, 7 resulted in unexpected results (5.8%, 2.4-11.6% with a 95% CI), and all 7 instances affected the proper assessment of the lesion (distal to the created lesion). However, over half of these instances represented situations when both devices gave the same unexpected interpretation of the lesion. In other words, they had unexpected agreement in evaluating the lesion (assessed the tissue distal to the lesion of interest as "alive," although the necropsy report defined all lesions as transmural, meaning all tissues distal to lesions were expected to be found to be non-conductive).

An unexpected disagreement occurred in 3 instances out of 120 measurements (2.5%, 0.5-7.1% with a 95% CI).

3) Exit v. Entrance Block

When comparing the ability of exit vs. entrance block to appropriately assess lesion integrity, four different instances were examined: 1) the number of unexpected results throughout all measurement sites (n=120) between sensing and pacing including "agreements"; 2) the number of unexpected results throughout all measurement sites (n=120) between sensing and pacing, *not* including "agreements"; 3) the number of unexpected results for measurement sites only distal to the lesion (n=30) between sensing and pacing including "agreements"; 4) the number of unexpected results throughout for measurement sites only distal to the lesion (n=30) between sensing and pacing *not* including "agreements."

In none of the above stated instances was a statistically significant difference found between pacing and sensing for lesion assessment. However; in the 3rd instance, a p-value of 0.052 was determined, possibly implying a trend toward a

difference between pacing and sensing, with sensing showing 5 instances of unexpected results and pacing showing none.

IV. Discussion

In none of the analyses presented in this paper was a significant difference found between exit and entrance block testing for lesion assessment. This suggests that neither method is necessarily more or less qualified than the other to appropriately assess the integrity of a lesion. This does *not* mean, however, that the two techniques should be used interchangeably in a clinical scenario. It should also be noted that verification of *bidirectional* conduction block is the preferred method among many electrophysiologists and surgeons when evaluating cardiac lesions [5].

The main reason that these methods should not be used interchangeably in a clinical scenario is that the physiological condition of the patient could affect the ability of the method to appropriately identify lesion transmurality. For instance, if the patient has a supraventricular tachycardia (SVT), such as atrial fibrillation (AF) or flutter, the atrium may not be able to be captured by pacing. In the event of AV block or existing pacemaker, the ventricular response rate may not correlate with atrial capture. In these particular cases, entrance block testing should be used.

Additionally, the clinician performing the testing should be well-versed in the interpretation of EP signals. From time-to-time, when performing entrance block testing, far-field ventricular or atrial signals may be sensed in the absence of a local atrial response. If these signals are not identified as "far-field," a misinterpretation of conduction status could occur [6] (see far-field ventricular signals sensed in Fig. 5).

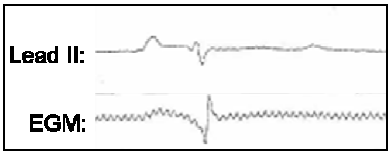

Fig. 5: Far-field ventricular signals sensed by the BP2 device while clamped on the left atrial appendage; note the absence of an atrial signal.

No statistically significant difference was found in the lesion assessment outcomes between devices, indicating that the method employed is not device-dependent.

The pathological results of this study reported that all lesions made were transmural, which led to the assumption that regions distal to the lesion would be non-conductive. In two cases, however, we observed that both the MAPS and BP2 devices indicated otherwise using entrance block testing, but not with exit block testing. The fact that entrance block testing indicated disagreement with the pathological results, whereas exit block testing agreed with the results led us to question either the true transmurality of the lesion or the dependability of the lesion assessment technique. This was a rare occurrence within the full context of the study, but the fact that when this *did* occur, it was with the same testing technique both times, raises questions as to whether entrance block testing could be too sensitive, possibly picking up far-field signals which could be misinterpreted.

Because there were no cases of agreement between methods (exit and entrance block) that yielded "unexpected results," we are led to believe that the method that produced results that agree with the pathological results is the most accurate.

V. Conclusion

Lesion assessment is of the utmost importance for verification of success of conduction block. Findings from this study indicate that both exit and entrance block testing are reliable methods for assessing conduction block and that the conclusions drawn from these testing methods are not significantly different from each other.

While both lesion assessments are reliable, they both have their shortcomings and strengths depending on the patient and clinician. Therefore, for patients who do not have SVTs, especially AF and flutter, or a pacemaker, either method can be used to assess conduction block. The most robust lesion assessment will occur when both methods are employed so that the physician has the most information available for analysis. For patients who do have SVTs or a pacemaker, entrance block testing should be employed with careful attention paid to interpretation of the local EGM signals.

Acknowledgment

Much gratitude is owed to the staff and personnel at Medtronic's Physiological Research Laboratories, specifically to study director: Erin Grassl, PhD.

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