

CLINICAL COMPENDIUM

The HeartLight® Endoscopic Ablation System
Putting a New Level of PVI Precision Close at Hand



CardioFocus.com

 HeartLight
Isolate with Laser Focus

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Published results summarized in this compendium may include references to both on-label and off-label usage of the HeartLight Endoscopic Ablation System.

INDICATION:

The HeartLight Endoscopic Ablation System is indicated for the treatment of drug refractory recurrent symptomatic paroxysmal atrial fibrillation.

CONTRAINDICATIONS:

The HeartLight System should not be used:

1. In patients who have had a ventriculotomy or atriotomy within the preceding four weeks as the recent surgery may increase the risk of perforation;
2. In patients with prosthetic valves as the catheter may damage the prosthesis;
3. In patients with an active systemic infection as this may increase the risk for cardiac infection;
4. In patients with unstable angina;
5. In patients with an interatrial baffle or patch because the opening could persist and produce an iatrogenic atrial shunt following transeptal puncture;
6. In the ventricle because of the danger of catheter entrapment in the chordae tendineae;
7. In patients with conditions where the manipulation of the catheter within the heart would be unsafe (for example, presence of intracardiac thrombus and myxoma);
8. In patients with one or more pulmonary vein stents

WARNINGS:

Only adequately trained personnel in a fully equipped electrophysiology laboratory should perform cardiac ablation procedures. This device should be used only by physicians fully trained in cardiac electrophysiology procedures. Prospective physician operators of the HeartLight Endoscopic Ablation System must complete specific training provided by CardioFocus prior to the first clinical procedure.

Operation Manual / Instructions for Use – Do not attempt to use the HeartLight System before reading and completely understanding the HeartLight Endoscopic Ablation System Operation and Maintenance Manual.

POTENTIAL COMPLICATIONS:

Adverse reaction to anesthesia, air embolism, anemia, anxiety, aspiration pneumonia, atrio-esophageal fistula, esophageal ulceration, esophageal tear, arteriovenous (AV) fistula, back pain, bleeding from puncture site, blood clot/thromboembolic event/deep vein thrombosis, blurred vision or vision changes, bradycardia, bronchitis, bruise, cardiac perforation/tamponade/tear, cardiopulmonary arrest, chest pain/ discomfort/pressure, complete heart block, coronary artery spasm, dissection thrombosis, cough, death, diarrhea, dizziness/vertigo, dysphagia, esophago-mediastinal fistula, fatigue, fever, headache, hematoma, hemothorax, hemorrhage, hemoptysis, hypertension/ hypotension, incision site pain/ tenderness, infection, major bleeding, myocardial infarction, nausea/vomiting, nerve injury, neurological deficits, pain or severe coughing during energy delivery, pericardial effusion, pericarditis, phrenic nerve damage leading to diaphragmatic paralysis, phrenic nerve palsy, pneumothorax, pleural effusion, pseudo-aneurysms, pulmonary edema, pulmonary vein stenosis/ occlusion, pyrogenic reaction, scarring, sepsis, shortness of breath, stroke / transient ischemic attack (TIA) / cerebrovascular accident, tachyarrhythmia, ulceration, urinary infection, wound healing difficulties, valvular damage, vascular complication requiring surgery, vascular damage / tear, vasovagal reactions

Refer to the device operating manual for detailed information regarding the procedure, indications, contraindications, warnings, precautions, and potential complications/adverse events and other important information. For further information, please call CardioFocus at 844-527-3723.

CAUTION:

Federal Law (USA) restricts this device to sale by or on the order of physician.

INTRODUCTION

The HeartLight System has been successfully used in more than 7,000 patients and featured in more than 125 peer-reviewed publications and abstracts. The clinical data demonstrates that:

- Efficacy of the HeartLight System compares well to other atrial fibrillation (AF) ablation modalities.
- The quality and durability of lesions produced by the HeartLight System are highly reproducible and well suited for establishing chronic pulmonary vein isolation (PVI).
- HeartLight allows for targeted and flexible energy titration strategies that accommodate significant variability in pulmonary vein (PV) tissue thickness.
- HeartLight is able to address wide-ranging PV variant anatomies, allowing for high rates of PV isolation without separate touch ups required.
- HeartLight represents a new paradigm in ablation of cardiac arrhythmias as it enables direct visualization and titratable laser energy on a universal, compliant balloon platform.

COMPARATIVE STUDIES

Efficacy of the HeartLight System compares well to other atrial fibrillation (AF) ablation modalities.

Pulmonary Vein Isolation Using the Visually Guided Laser Balloon: A Prospective, Multicenter and Randomized Comparison to Standard Radiofrequency Ablation

Dukkipati SR, et al. JACC. 2015.

- In this study, 353 patients with a history of paroxysmal AF (PAF) (178 HeartLight, 175 Irrigated Radiofrequency [RF]) were randomized across 19 highly experienced RF clinical sites.
- Efficacy was defined as freedom from: documented symptomatic AF, ablation-induced LA flutter or atrial tachycardia, failure to isolate all PVs, use of any anti-arrhythmic drug or additional intervention for AF was assessed through 12 months along with adverse events.
- Despite minimal prior experience, the efficacy and safety with HeartLight proved to be noninferior (similar) to RF. Efficacy rates were 61.1% for HeartLight and 61.7% for RF. Primary adverse event rate was 11.8% for HeartLight and 14.5% for RF.
- HeartLight demonstrated a statistically significant lower rate of reconnection in comparison to RF.
- When analyzing results of physicians who had performed a minimum of 15 procedures, HeartLight outcomes start to appear even more favorable.
- The results also compare well to the US Pivotal Trial with the CryoBalloon, which demonstrated 1-year efficacy of 49.7% in the STOP AF study.

Key Takeaway

In a randomized clinical trial, HeartLight demonstrated excellent efficacy and safety despite a significant difference in physician experience with the two modalities under evaluation.

Laser Balloon or Wide-Area Circumferential Irrigated Radiofrequency Ablation for Persistent Atrial Fibrillation*

Schmidt, B, et al. *Circ Arrhythm Electrophysiol.* 2017.

- This study compares the efficacy and safety of visually guided pulmonary vein isolation (PVI) using the laser balloon (LB) with the contemporary standard of wide-area circumferential PVI using irrigated radiofrequency (RF) ablation in patients with persistent atrial fibrillation (AF).
- 152 patients across 6 European centers were prospectively randomized in blocks in a 1:1 fashion. Of those patients, 134 completed the entire follow-up protocol consisting of a 72-hour Holter ECG at 3, 6, and 12 months.
- The primary efficacy endpoint was freedom from AF or any atrial tachyarrhythmia lasting >30 seconds between days 90 and 365 days after a single ablation procedure.
- Procedure times were similar in both groups, with an average of 135 minutes in the LB group and 128 minutes in the RF group.
- The percentage of PVs reconnected at the end of the 30-minute waiting period was 2.6% (7/272) for LB and 4.9% (13/264) for RF.
- The primary efficacy endpoint was met by 71.2% in the LB group versus 69.3% in the RF group, demonstrating similar outcomes.
- To assess how operator experience influenced procedural and clinical outcomes, data from 2 high-recruiting centers and 4 low-recruiting centers were compared. Procedural times were shorter for both LB and RF in high-recruiting centers. Success rates were similar for both groups in the high-recruiting arm while success rates were significantly better in the LB group for low-recruiting centers.

Key Takeaway

This is the first prospectively randomized trial assessing the performance of a balloon catheter system in comparison with wide-area circumferential PVI in patients with persistent AF. It showed that both ablation strategies had similar efficacy, with a 1-year AF-free success rate of about 70% following a single procedure. This suggests that patients with persistent AF may be ablated using a balloon catheter with PVI as an acceptable endpoint. A lower acute reconnection rate was also seen with LB than RF. The data from low-recruiting center suggests that new operators, or ones that have low volume, can achieve better clinical outcomes when using a balloon-based system for PVI versus RF.

Comparison of Balloon Catheter Ablation Technologies for Pulmonary Vein Isolation: The Laser Versus Cryo Study

Bordignon S, et al. *J Card EP.* 2013.

- In this study, 140 patients with a history of PAF were randomized to treatment with HeartLight (Gen 1) or CryoBalloon (Gen 1) in a 1:1 fashion and followed for 12 months in a single-center evaluation.
- Efficacy was defined as documented AF recurrence freedom from documented AF recurrence \geq 30 seconds between 90 and 365 days post procedure.
- At 12 months, 73% of the HeartLight group achieved the efficacy endpoint compared to 63% of the CryoBalloon group. The HeartLight group demonstrated a significantly lower fluoroscopy time (15 minutes) versus 21 minutes with the CryoBalloon. Procedural times were similar, 144 minutes with HeartLight compared to 136 minutes with the CryoBalloon.

Key Takeaway

In a randomized clinical trial as compared with the CryoBalloon, the HeartLight System demonstrated excellent safety and efficacy with lower fluoroscopy times.

*The HeartLight System is not indicated for use in the persistent AF population in the United States

META-ANALYSIS

Laser balloon ablation for AF: A systematic review and meta-analysis

Reynolds M., et al. *Journal of Cardiovascular Electrophysiology*. 2018.

- This study used previously published data from 17 studies which included 1188 patients from approximately 40 different centers in eight countries.
- Overall, 80% of the patients had paroxysmal AF (the other 20% persistent).
- 89.3% of pulmonary veins were isolated with first encirclement while 98.8% were successfully isolated by procedure end.
- 12-month success for patients with only paroxysmal AF was 74.3% while all AF types combined was 72.9%.
- The most common complication was phrenic nerve injury with an incidence rate of 2.6% (only 0.2% persisted through the end of study follow-up).
- The average procedure time was 183 minutes with centers observing a >60-minute decline from their earliest to their most recent groups of patients.

Key Takeaway

The laser balloon system is an effective option for achieving pulmonary vein isolation with a low rate of major adverse events and reported freedom from recurrent arrhythmia in the range of 70-75% at 12-months. On average, centers observed a greater than 60-minute decline in procedure time from their earliest to their most recent group of patients.

LONG-TERM RESULTS – SINGLE CENTER EVALUATIONS

Long-term results with the HeartLight System have shown consistently to be durable.

Visually guided laser ablation: a single-centre long-term experience

Sediva L, et al. *Europace*. 2014.

- In this study, 194 patients with a history of PAF or persistent AF (PsAF) were treated with HeartLight and followed for up to four (4) years to assess rates of freedom from AF.
- Recurrence of AF was defined as any documented AF episode of greater than 30 seconds.
- Follow-up demonstrated high and durable rates of AF freedom with 82% PAF patients free of AF at one year, 76% free at two years, 76% free at three years and 75% free at four years.
- Patients with PsAF demonstrated 75% freedom from AF at one year. Additional follow up on PsAF patients was not yet available as these patients were addressed much later in this clinical evaluation.
- Over the course of the site's experience, both procedure and fluoroscopy times improved substantially with mean procedure times of 150 minutes and mean fluoroscopy times of 13 minutes in its most recent cohort of patients.

Key Takeaway

In a large consecutive series of patients with long-term follow, HeartLight demonstrated impressive long-term results out to four years.

Electrical Isolation of Pulmonary Veins Using Laser Catheter in the Treatment of Paroxysmal and Persistent Atrial Fibrillation. One-year Results

Osca J et al. *Rev Esp Cardiol.* 2015.

- In this study, 71 patients with a history of PAF or PsAF were treated with HeartLight and followed for one year to assess rates of freedom from AF.
- Rates of AF freedom were 88% and 70% in the PAF and PsAF groups respectively with a mean follow up of 420 days.
- Isolation was possible in 275 of 278 pulmonary veins (99%).
- Procedure and fluoroscopy times improved through the course of the site's experience. Mean procedure time was 145 minutes and mean fluoroscopy time was 24 minutes in the final cohort of patients.
- Authors believe that positive results may be attributed to the routine use of higher energy in areas at higher risk of electrical reconnection, particularly at the ridge between the left atrial appendage and the left pulmonary vein.

Key Takeaway

In this single center initial series of patients with a mean follow up of 420 days, HeartLight demonstrated positive results with 88% of PAF patients remaining AF free.

LESION QUALITY

The quality and durability of lesions produced by the HeartLight System are highly reproducible and well suited for establishing chronic PVI.

A Randomized Trial to Compare the Acute Reconnection after Pulmonary Vein Isolation with Laser Balloon vs. Radiofrequency Ablation: RATISBONA TRIAL*

Ücer E, et al. *Journal of Cardiovascular Electrophysiology.* 2018.

- In this study, 50 paroxysmal atrial fibrillation (AF) patients were randomized 1:1 to pulmonary vein (PV) isolation (PVI) with either visually guided laser balloon (VGLB) or radiofrequency (RF) ablation.
- This is the first randomized study comparing the acute PV reconnection rate after PVI with VGLB versus RF ablation using an adenosine provocation test (APT).
- Each PV underwent an APT at least 20 minutes after isolation, looking at the acute PV reconnection rate between the two ablation methods.
- Significantly less PVs were reconnected during the APT in the VGLB group than in the RF group [10 PVs (10.8%) vs. 29 PVs (30.9%); $p = 0.001$].
- The rates of reconnection seen in both arms of this study, VGLB and RF, were consistent with previous studies.
- VGLB demonstrated a statistically significant higher rate of first pass isolation after the first encirclement in comparison to RF [78 PVs (80.4%) vs. 46 PVs (47.9%); $p < 0.001$].

Key Takeaway

Although tissue injury caused by laser energy and RF are both thermally mediated, there are differences. VGLB creates deep transmural ablation lesions, resulting in lower acute PV reconnection. The acute PV reconnection rate is significantly less with VGLB than with RF, suggesting ablation with VGLB is more durable in the acute phase than RF.

* According to the HeartLight Endoscopic Ablation System Instructions For Use (IFU), if the esophageal temperature exceeds 38.5°C, the operator should immediately stop energy delivery. Furthermore, when delivering energy into moving blood only use 5.5W for 30 seconds. Do not deliver energy into stagnant blood.

Unmasking the Dormant Pulmonary Vein Conduction with Adenosine Administration after Pulmonary Vein Isolation with Laser Energy

Ücer E, et al. *Europace*. 2015.

- This study assessed the quality of lesion creation with HeartLight through application of adenosine in 26 symptomatic paroxysmal AF patients.
- 97% of ablated PVs were acutely isolated followed by adenosine administration to assess reconnection induction. Only 6 PVs (6.7%) could be induced into reconnection by the adenosine administration.
- Studies of PV conduction recovery with adenosine provocation using conventional RF ablation catheters consistently report results of PV recovery that are approximately 4 times higher than HeartLight in this study.
- At 6 months, 81% of patients remained arrhythmia free.
- PVs that demonstrated reconnection during adenosine provocation had worse PV occlusion and a lower amount of energy delivered.

Key Takeaway

HeartLight results in very effective acute lesion formation that demonstrates durability even under adenosine provocation.

The Durability of Pulmonary Vein Isolation Using the Visually Guided Laser Balloon Catheter: Multicenter Results of Pulmonary Vein Remapping Studies

Dukkipati SR, et al. *Heart Rhythm Society*. 2012.

- This study consisted of a multicenter evaluation of HeartLight's PV isolation durability. 56 patients were evaluated with PVs acutely and chronically assessed.
- 98% (202 of 206) PVs were acutely isolated and 86% (162 of 189) PVs remained isolated during remapping at an average of 105 days in the 52 patients who underwent remapping. As part of the remapping procedure, un-isolated PVs could be re-isolated.
- Using powers higher than 5.5W / 30 seconds was associated with a lower reconnection rate during follow-up.
- For those operators who had performed at least 10 procedures, the rate of persistent PVs isolated at the time of remapping was 89.4%.
- The drug-free rate of freedom from AF or atrial tachycardia in the 52 patients that underwent remapping at an average of 12 months was 71.2%.

Key Takeaway

In this multicenter PV isolation remapping study, HeartLight demonstrated impressive lesion durability and AF freedom at one year.

Post-procedural LGE-CMR comparison of laser and radiofrequency ablation lesions after pulmonary vein isolation

Figueras I Ventura R., et al. Journal of Cardiovascular Electrophysiology. 2018.

- This study compares the anatomical characteristics of scar formation achieved by visually guided laser and radiofrequency (RF) in pulmonary vein isolation (PVI), using late-gadolinium-enhanced cardiac magnetic resonance imaging (LGE-CMR).
- 15 patients with paroxysmal or early persistent drug-resistant AF and no previous PVI procedures were treated with the HeartLight System and matched with a control group of 15 patients who underwent RF PVI.
- LGE-CMR was done prior to the procedure and 3 months post ablation. LGE-CMR evaluated percentage and location of gaps, scar area and width, and the extension of ablation scar inside the PV and into the LA body.
- The RF ablations were performed with contact force-sensing catheters.
- The patients were followed for 12 months with Holter monitoring and 12-lead ECG at 3, 6, and 12 months.
- Laser ablation resulted in significantly fewer gaps compared to RF. Complete anatomical PVI (circumferential scar around PV, without gaps) was achieved in 39% of veins with laser compared to 19.3% of veins in the RF group.
- The laser group showed a significant decrease in gaps at the superior and anterior left PV and posterior right PV antral regions, compared to the RF group.
- A recent study by Alarcon et al showed the importance of achieving durable anatomical PVI without gaps, correlating the length of gaps with the AF recurrence rate after ablation.
- Ablation scar had similar extension inside the PVs in both groups while the extension of scar on the atrial side was larger in the RF group.

Key Takeaways

Laser ablation provides a more complete anatomical PVI when compared with RF, especially in regions where the contact force achieved by the RF catheter is weaker (anterior aspect of left PVs and posterior aspect right PVs). Laser lesion sets are more defined, with less aggressive scarring into the left atrium.

MRI Evaluation of Radiofrequency, Cryothermal, and Laser Left Atrial Lesion Formation in Patients with Atrial Fibrillation

Khurram IM, et al. Pac and Clin Electro. 2015.

- This study consisted of an assessment of seventeen (17) AF patients who underwent PVI using Laser (n=5), RF (n=7), or Cryo (n=5) with a goal of comparing baseline to post-procedural change in left atrial (LA) scar burden.
- Assessments were made prior to, at 24 hours and at 3 months after PVI using Late gadolinium enhancement magnetic resonance imaging (LGE-MRI).
- While differences did not achieve statistical significance (low sample size), Laser demonstrated numerically a lower scar burden than RF and Cryo.
- Qualitatively, laser energy caused focused, discrete lesions compared to the diffuse lesion sets associated with RF and Cryo ablation as seen on three months images attained in the laser group.

Key Takeaway

Laser energy caused focused, discrete lesions at three months compared to the diffuse lesion sets associated with RF and Cryo ablation.

Visual Balloon-Guided Point-by-Point Ablation Reliable, Reproducible, and Persistent Pulmonary Vein Isolation

Dukkipati SR, et al. *Circ. Arrhythm Electrophysiol.* 2010.

- This study consisted two components: (1) an acute porcine assessment with 15 subjects and (2) a single-center clinical feasibility evaluation with 27 PAF patients.
- 97% (29 of 30) of PVs in animal subjects were found to be electrically isolated in acute and chronic phases. Histologically, lesions were shown to be circumferential in all cases (120 of 120 PV sections) and consistently transmural (116 of 120 sections).
- Mean atrial wall thickness was 3.0 mm \pm 1.0 in the acute porcine evaluation and 5.1 mm \pm 0.9 in the chronic evaluation.
- In the separate, second phase clinical evaluation, all PVs were able to be isolated with the HeartLight System and at 3 months 90% remained electrically isolated.

Key Takeaway

HeartLight produces lesion sets that are reproducibly contiguous, circumferential, transmural and durable, supported both by animal and human evaluation.

Pulmonary Vein Isolation Using a Compliant Endoscopic Laser Balloon Ablation System in a Swine Model

Gerstenfeld EP, et al. *J Interv Card Electrophysiol.* 2010.

- This study evaluated HeartLight PVI ablation in comparison to standard RF ablation in a swine model. Eight HeartLight subjects were treated and two RF subjects were treated.
- Evaluation of a lesion set was based upon a quantitative histopathologic assessment, incorporating a composite determination of circumferential and transmural lesion creation.
- Acute isolation was achieved in all subjects, although there was one audible steam pop in one of the RF subjects.
- Quantitative histopathologic assessment was completed approximately 30 days after initial treatment. Results showed that lesions with HeartLight were a composite of 99.9% circumferential and transmural in comparison to a composite score of 93.1% with RF.
- While the RF lesions were shown to be 100% circumferential, they were not transmural in all sections.

Key Takeaway

HeartLight produces lesion sets that are reproducibly circumferential and transmural with histologic confirmation.

DOSING / ENERGY TITRATION

HeartLight allows for targeted and flexible energy titration strategies that accommodate significant variability in pulmonary vein (PV) tissue thickness.

The influence of varying energy settings on efficacy and safety of endoscopic pulmonary vein isolation

Metzner A, et al. *Heart Rhythm* 2012.

- This study assessed the influence of varying energy settings on the outcomes of PVI with the HeartLight System.
- A total of 30 patients were included in the assessment (10 in each of three groups). Group A was treated with 5.5 W and 7.0 W, Group B with 7.0 W and 8.5 W and Group C with 8.5 W and 10.0 W along the posterior and anterior portion of each PV, respectively.
- The rate of PVI was significantly higher in group C than in group A ($p=.025$) and group B ($p=.045$). There was no difference in the detection of esophageal thermal lesions.
- Authors concluded that the use of higher energy settings increases the acute efficacy of HeartLight without compromising safety.

Key Takeaway

Study concluded that high dose laser ablation has superior outcomes.

Energy titration strategies with the endoscopic ablation system: lessons from the high-dose vs. low-dose laser ablation study

Bordignon S, et al. *Europace* 2012.

- This study assessed the effects of low-dose and high-dose ablation on acute and chronic success in patients with AF with the HeartLight System.
- Sixty (60) patients were divided into two groups (30 patients each). The low dose (LD) group was treated with 5.5 – 8.5 W and the high dose (HD) group was treated with more than 8.5 W.
- Acute and chronic efficacy was shown to be higher in the HD group.
- High dose laser balloon ablation allowed for an acute PVI rate of 89% and a chronic AF-free rate of 83% after a single procedure.

Key Takeaway

High dose laser ablation has superior outcomes compared with low dose laser ablation and can be enabled by suitable tissue contact.

LEARNING CURVE STUDIES

New HeartLight operators consistently demonstrate the ability to become highly proficient with the system through a short learning curve.

How to Learn Pulmonary Vein Isolation with a Novel Ablation Device: Learning Curve Effects Using the Endoscopic Ablation System

Perrotta L, et al. J Card EP. 2014.

- In this study, 150 patients with a history of PAF or PsAF were treated with HeartLight with their results analyzed in sequential tertiles of 50 patients in each cohort.
- Users were able to have positive outcomes from the beginning with the technology, demonstrating 96% of all PVs isolated acutely in the first tertile.
- Learning curve effects were also demonstrated with numeric improvements seen in procedure times, fluoroscopy times, adverse event rates and AF free rates at 12 months.
- In the third tertile, procedure times averaged 123 minutes, fluoroscopy times: 12 minutes, AF-free rate of 86% at 12 months and zero complications.

Key Takeaway

New operators can obtain very positive outcomes initially and experience improvements in procedural efficiency and outcomes as they gain more experience.

Visually Guided Sequential Pulmonary Vein Isolation: Insights into Techniques and Predictors of Acute Success

Schmidt B, et al. J Card EP. 2011.

- In this study, 35 patients with a history of PAF or persistent AF were treated with HeartLight and results analyzed to understand predictors of acute isolation.
- Results showed that both degree of PV occlusion (higher occlusion score correlated with higher likelihood of isolation) as well as the number of catheter repositionings (less repositioning correlated with higher likelihood of isolation) were predictors of acute isolation.
- Conduction gaps were detected at sites where there was suboptimal vessel occlusion as well as esophageal temperature elevations.
- Learning curve effects were also demonstrated with a statistically significant improvement in procedure time demonstrated between the first 12 cases (175 minutes) and the last 12 cases (138 minutes).

Key Takeaway

New operators can become facile with the HeartLight system quickly, reducing procedure times and potentially improving PV occlusion and catheter repositioning, which could be drivers of better outcomes.

ADDRESSING ANATOMIC VARIABILITY

HeartLight is able to address highly variable wide-ranging pulmonary vein (PV) variant anatomies, allowing for high rates of PV isolation without separate touch ups required.

Impact of pulmonary vein anatomy assessed by cardiac magnetic resonance imaging on endoscopic pulmonary vein isolation in consecutive patients

Metzner A, et al. *Europace*. 2011.

- In this study, the impact of variant PV anatomy on outcomes with the HeartLight System was evaluated in 51 patients with a history of paroxysmal AF.
- A total of 195 PVs were assessed by pre-interventional cardiac magnetic resonance imaging (CMRI).
- PV anatomy was found to be widely variable in terms of: number of PVs; separate vs common anatomy; PV diameter; round vs oval PV shape; level of first PV branching; and the level of insertion of the right inferior PV into the left atrium.
- PV isolation was achieved exclusively with the HeartLight System in 192 of 195 (98%) PVs. Isolation was achieved irrespective of variable PV anatomy.

Key Takeaway

Study validates the HeartLight system's universal balloon design, demonstrating that a single balloon can be used in highly variable PV anatomies, achieving a very high rate of isolation without the requirement of additional 'touch ups'.

Anatomical Predictors for Successful Pulmonary Vein Isolation using Balloon-Based Ablation Technologies

Tsyganov A, et al. *J Interv Card Electrophysiol*. 2015.

- Authors evaluated the correlation between pulmonary vein (PV) anatomy and acute and long-term success with HeartLight (Gen 1) and CryoBalloon (Gen 2).
- 100 consecutive patients with paroxysmal AF were analyzed in two equal groups (50 patients each) – and received either HeartLight or CryoBalloon ablation.
- Using multi-detector CT imaging, variant anatomy was discovered in 40% of the HeartLight group and 32% of the CryoBalloon ablation group.
- Peri-procedurally 194 of 206 PVs (94%) were successfully isolated with HeartLight alone and 193 of 199 PVs (97%) were successfully isolated with CryoBalloon alone.
- At 12 month follow-up, 84 percent of HeartLight patients remained AF free compared to 76% of CryoBalloon ablation patients.
- Of patients who presented with AF occurrence 38 percent treated with HeartLight were found to have PV conduction gaps and 52 percent treated with Cryoablation were found to have conduction gaps.

Key Takeaway

Study shows vast majority of PVs can be addressed with HeartLight balloon technology with positive long-term AF free results.

REVIEW ARTICLES

HeartLight represents a new paradigm in ablation of cardiac arrhythmias as it enables direct visualization and titratable laser energy on a universal, compliant balloon platform.

HeartLight: The Endoscopically Guided Laser Ablation System

Schmidt B. Asia Pacific Heart Rhythm Society. 2015.

- This review article gives an overview of the HeartLight technology and the clinical evaluations that have been undertaken to assess its clinical viability.
- The author provides a detailed description of how the technology functions and its system components.
- The review article also briefly touches on HeartLight's pre-clinical data and then provides a review of its clinical evaluations including data from its worldwide registry.
- The registry demonstrates an acute PV isolation rate of 98.1%, an average procedure time of 133 minutes and an average fluoroscopy time of 25 minutes.

Key Takeaway

HeartLight repeatedly demonstrates positive clinical outcomes based on a unique feature set with improvements seen over a short learning curve.

Endoscopic Ablation Systems

Bordignon S, et.al. Expert Rev. Med. Devices. 2013.

- This review article provides an in-depth description of the HeartLight technology, its components and how the system works functionally.
- The article further highlights procedural considerations, preclinical studies and initial clinical evaluations prior to randomized studies.
- The article also comments on ways in which the HeartLight System might undergo further development.

Key Takeaway

The HeartLight system offers unique, novel features, which resulted in positive outcomes during its initial clinical evaluation.



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