

HEAL-IST Trial

New hybrid ablation technique for patients with inappropriate sinus tachycardia (IST)

- Inappropriate sinus tachycardia (IST) is a heart condition affecting otherwise healthy young people, causing an abnormally high heart rate.
- Medications like beta blockers and calcium channel blockers are usually first-line treatments but have not been proven effective.
- The HEAL-IST trial explores a new, less invasive technique called a hybrid sinus node-sparing ablation.
- Previous smaller studies which evaluated the hybrid sinus node-sparing ablation have demonstrated promising results to reduce heart rate and need for permanent pacemaker implantation.
- The HEAL-IST trial is evaluating the safety and effectiveness of a hybrid sinus node-sparing procedure, with hopes of providing a new treatment option for patients with IST.

Inappropriate sinus tachycardia (IST) is a complex heart condition affecting 1–1.2% of the general population, typically otherwise healthy young people. The condition is four times more common in women than in men, with the highest incidence occurring in women aged 20–40. It can significantly reduce their quality of life, bringing enormous suffering and morbidity to lives that are underlived from the overwhelming restrictions it imposes. IST is believed to be a nervous system disorder that impacts heart rate (HR); however, the exact cause of IST remains unknown.

Understanding IST

IST causes the heart's natural pacemaker, the sinus node (SN), to send electrical signals that elevate the resting heart rate to exceed 100 beats per minute (BPM). IST is distinct from postural orthostatic tachycardiac syndrome (POTS), where the average HR is less than 90 BPM.

IST is difficult to diagnose and often misdiagnosed as panic attacks or depression. Symptoms of IST include heart palpitations, chest discomfort, dizziness, fainting, lightheadedness, fatigue, and an exaggerated response to exercise and stress. Factors worsening IST include lifestyle choices (alcohol, caffeine, nicotine), certain drugs (cocaine, Adderall or Ritalin), viral infections (such as COVID-19), and previous heart procedures.

Unlike traditional catheter ablation, the hybrid sinus node sparing procedure is less invasive, allows better visualisation of the heart, and is intended to reduce the risk of damaging nearby tissues.

Current treatment landscape

Upon diagnosis, lifestyle modifications are essential, including avoiding stimulants like caffeine, alcohol, and nicotine to lower resting HR and blood pressure. At present, no therapies have been approved by the US Food and Drug Administration (FDA) or the European Medicines Agency (EMA). Medications such as beta-blockers or calcium channel blockers are first-line treatments; they aim to slow the heart rate by blocking the action of HR-increasing hormones but often prove ineffective with treating IST over the long term. Ivabradine, a newer drug, shows promise by selectively interfering with the heart's electrical signals to reduce HR.

If medication fails, patients may undergo radiofrequency catheter ablation, the conventional treatment option for patients with IST. This procedure involves inserting a thin, flexible tube (catheter) into a blood vessel to deliver radiofrequency energy to areas of the heart that cause abnormal rhythms, aiming to restore a normal heartbeat. However, it often only offers short-term relief with initial reductions in HR and frequently requires repeat ablations. If the SN is damaged during surgery, a permanent pacemaker – a small device placed under the skin near the heart – may be needed to regulate the heartbeat. A lot of patients are desperately looking for options that can change their life's trajectory.

What's new?

The HEAL-IST trial is currently underway to evaluate a new treatment called a 'hybrid SN-sparing ablation' in patients who no longer respond to current medications ('drug-refractory' IST). The hybrid SN-sparing ablation is designed to treat IST while protecting the SN, thus avoiding the need for a permanent pacemaker. This treatment uses specialised clamps and catheters to precisely target specific areas on the heart's outside surface, and sometimes inside the heart, to reduce the high HR responsible for IST. Unlike traditional catheter ablation, this procedure is less invasive, allows for better visualisation of the heart, and is intended to reduce the risk of damaging nearby tissues.

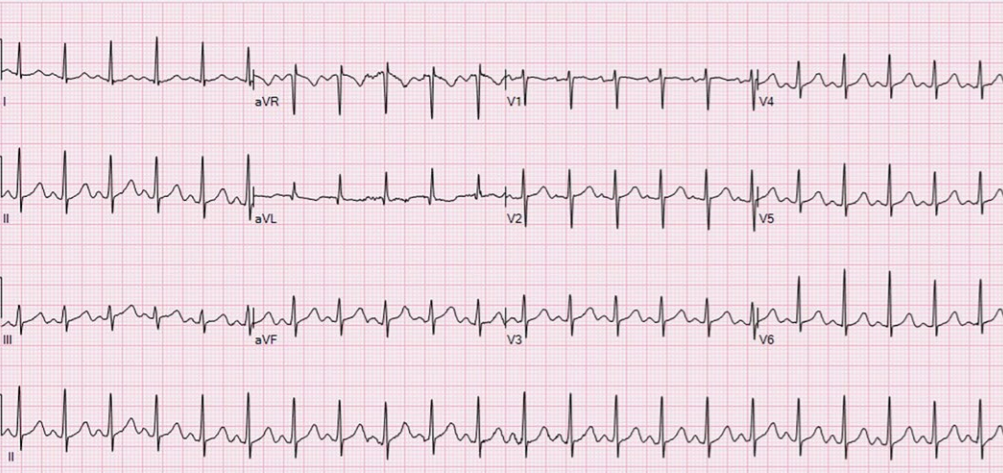
Professor Mark La Meir and Professor Carlo de Asmundis at the University Hospital in Brussels, Belgium and Dr DJ Lakkireddy at the Kansas City Heart Rhythm Institute, USA, along with other physicians at more than 25 research institutions in the US, UK and EU are recruiting patients in the HEAL-IST trial.

The sinus node-sparing approach

Preliminary studies led by Le Meir, de Asmundis and Lakkireddy have reported promising results. In one study, 255 patients (204 patients with symptomatic and drug-refractory IST and 51 with POTS) underwent the hybrid SN sparing procedure. Following the procedure, normal heart rhythm was restored in all patients, and after 6 months, 204 out of the 255 patients (80%) achieved a significant reduction in HR. In a similar but smaller study, the team demonstrated positive findings in 50 patients with symptomatic and drug-refractory IST or POTS. All patients experienced a significant reduction in HR and a normal response to exercise and stress, enabling them to discontinue their previous medications.

The researchers also evaluated the hybrid SN-sparing approach in the Sinus Node Sparing Hybrid Thoracoscopic Ablation Outcomes in Patients with Inappropriate Sinus Tachycardia (SUSRUTA-IST) Registry, which included 100 patients with IST. In this study, outcomes between the newer SN hybrid ablation and conventional radiofrequency catheter ablation techniques were compared, with 50 patients in each cohort. The results showed a significantly greater reduction in resting HR in the hybrid group compared to the conventional group (61 versus 82 BPM, respectively). The hybrid group also demonstrated greater improvements in a 6-minute walking test at 3-, 6- and 12-months follow-up, compared to the conventional group. However, the hybrid treatment group experienced longer intensive care unit stays than the conventional group.

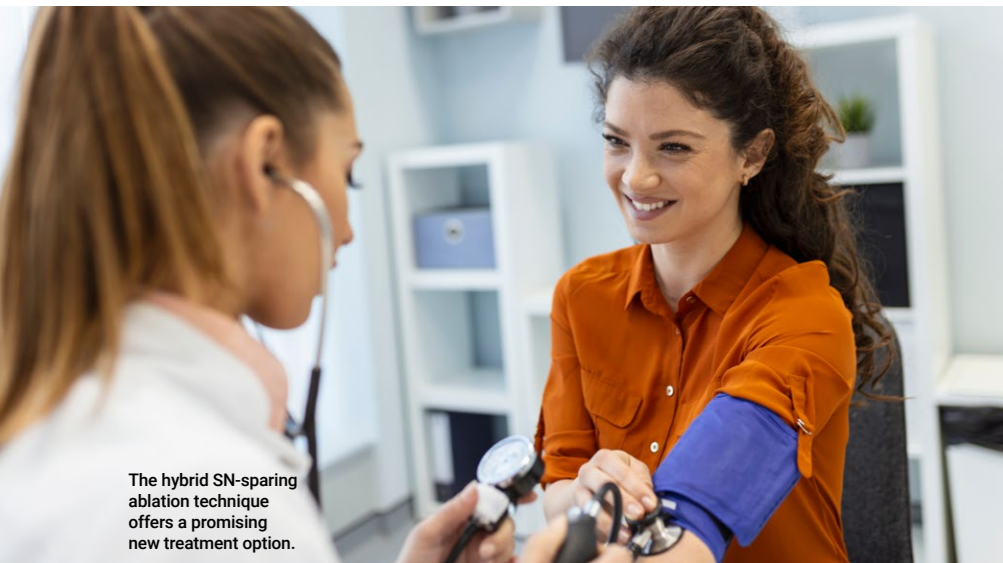




IST causes the sinus node to send electrical signals that elevate the resting heart rate to exceed 100 beats per minute.



First-line treatments for IST include beta-blockers or calcium channel blockers.



The hybrid SN-sparing ablation technique offers a promising new treatment option.



Lifestyle modifications may help lower resting heart rate and blood pressure.

Inappropriate sinus tachycardia affects the most productive and promising demographic of humanity. This condition brings enormous suffering and morbidity with lives that are underlived from the overwhelming restrictions it imposes. Often medications don't work. A lot of these unfortunate patients are desperately looking for options that can change their life's trajectory. I believe SN sparing surgery is a promising procedure that needs to be further explored. I strongly recommend patients with symptomatic, drug-refractory IST consider enrolling in HEAL-IST Trial." – Dr DJ Lakkireddy

Interestingly, significantly more patients in the conventional treatment group had complications and a higher prevalence of permanent pacemaker implantation compared to the hybrid treatment group. Notably, only 8% of the hybrid treatment group required repeat treatment compared to 100% in the conventional group. Quality of life and symptom improvements were also significantly better in the hybrid treatment group compared to the conventional treatment group.

The future of IST treatment

The hybrid SN-sparing ablation technique offers a promising new treatment option for patients with IST who haven't responded to other therapies. It offers a minimally invasive alternative to the traditional catheter ablation procedure, and research has demonstrated a reduced risk of requiring a permanent pacemaker and improved quality of life in patients with IST.

Lakkireddy strongly recommends patients with drug-refractory or drug-intolerant IST to consider enrolling in the HEAL-IST trial: 'I believe SN-sparing hybrid ablation surgery is a promising procedure that needs to be further explored.'

The HEAL-IST trial is evaluating the safety and effectiveness of the hybrid SN-sparing ablation procedure to provide further insights into the technique and new hope for those with symptomatic IST.

Personal response

What inspired you to conduct this research?

Patients affected by IST often have debilitating symptoms that bring enormous suffering with lives underlived. As of now, there are no approved therapies to treat symptomatic IST. Lifestyle modifications and medical treatment have limited effectiveness in reducing IST-related symptoms. Conventional ablation with sinus node modification has only demonstrated short-term success, but this treatment is fraught with procedural complications and a return of symptoms.

What do you anticipate the long-term outcomes might be for patients beyond the 12-month follow-up?

Preliminary studies suggest a hybrid sinus node sparing ablation

approach for IST may offer complete restoration of normal heart rhythm and reduced symptoms. These studies also demonstrate a low rate of pacemaker implantation and no major complications.

Do you see this technique replacing existing treatment options for patients with IST, or rather being a more effective treatment option compared to conventional ablation?

Compared to conventional ablation, early studies evaluating the hybrid sinus node sparing ablation show this approach to be more effective, safer and offer longer-term durability to reduce high heart rate recurrences in patients with symptomatic, drug-resistant IST. This treatment is an option for which lifestyle modifications and medications no longer provide relief for this debilitating condition.

Details



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Bio

Professor Mark La Meir is the head of the Department of Cardiac Surgery at the University Hospital in Brussels, Belgium. His research focuses on hybrid and concomitant treatment of heart rhythm disturbances and left atrial appendage management.

Professor Carlo de Asmundis is the Chair of the Heart Rhythm Management at the University Hospital in Brussels, Belgium. His research focuses on understanding the physiopathology of arrhythmias to develop effective treatments, advancing catheter ablation techniques, optimising use of implantable cardiac devices with novel engineering solutions, and refining pharmacological therapies. As a pioneer in personalised medicine for arrhythmia treatment, he ensures therapies are tailored to individual patient needs, ultimately improving outcomes for those with complex heart rhythm disorders.

Dr DJ Lakkireddy is the Medical Director at Kansas City Heart Rhythm Institute at HCA Midwest Health in Overland Park, KS. His research focuses on providing highly advanced treatment options to manage IST by performing a cutting-edge surgery called the sinus node-sparing hybrid ablation procedure. He also specialises in

electrophysiology and complex arrhythmia management.

References

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