Have lasers finally found their niche in interventional cardiology?

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Catheter ablation has become an accepted treatment strategy for patients with paroxysmal atrial fibrillation (AF). A multicentre prospective randomised trial showed a dramatic and significant improvement in freedom from AF after catheter ablation compared with anti-arrhythmic drug therapy.¹ The Heart Rhythm Society/European Heart Rhythm Association/European Cardiac Arrhythmia Society guidelines² currently list catheter ablation as an accepted treatment modality for paroxysmal AF after a patient has broken through a single anti-arrhythmic drug. The foundation of the current ablation strategy is electrical isolation of the pulmonary veins. Currently, catheters originally designed for ablating focal tachycardias and single accessory pathways are being used to deliver multiple radiofrequency lesions in a connect the dots pattern around the pulmonary veins. The procedure typically uses an electroanatomical mapping system, intracardiac echocardiography, an irrigated radiofrequency ablation catheter and requires considerable operator expertise. In addition, the Achilles’ heel of the procedure is the problem of pulmonary vein reconnection after ablation, which accounts for the majority of AF recurrences.³

Newer technologies are evolving that are designed specifically for pulmonary vein isolation. However, despite the inherent attraction of balloon-based ablation strategies, early technologies struggled to achieve safety and efficacy endpoints. The first ultrasound balloon ablation technology never made it to market.⁴ A later ‘focused’ ultrasound balloon entered clinical trials but was abandoned because of the higher than expected complication of left atrial—oesophageal fistula.⁵ The cryoballoon catheter became the first balloon catheter to undergo a prospective randomised study. Cryoballoon ablation demonstrated superiority to anti-arrhythmic drugs, although several complications were noted including phrenic nerve palsy and pulmonary vein stenosis.⁶

The next balloon technology on the horizon is the endoscopic laser balloon ablation system. This technology uses a 980 nm diode laser to perform ablation through a compliant balloon. The balloon is filled with deuterium oxide (D₂O or ‘heavy water’) that allows transmission of the laser energy to the pulmonary veins. The other novel attribute of this technology is that the catheter contains an endoscope that allows direct visualisation of the pulmonary veins during ablation. As the balloon is compliant, the diameter can be varied from 25 to 32 mm by varying the inflation pressure, and a single balloon can be used for multiple pulmonary vein shapes and sizes. The lesion generator emits a 30° spot ‘arc’ of laser energy that is applied in 20–30 s applications and is gradually rotated around the pulmonary vein circumference. Special software is used to track the lesions and avoid leaving gaps.⁷

The data behind the laser balloon is scant but accumulating. Reddy and colleagues⁸ examined the utility of an earlier version of the balloon that used a 90° laser arc in 30 patients. Acute isolation was achieved in 105/116 (91%) of pulmonary veins and 12-month AF freedom was 67%. Complications included one stroke, one transient phrenic nerve palsy, one cardiac tamponade and no pulmonary vein stenosis. Dukkipati et al.⁹ from the same group performed a short-term 27 patient study using the newer compliant balloon with 30° laser arc; when feasible all patients were restudied at 3 months to see if the pulmonary veins remained isolated. Using the new compliant balloon 100% of pulmonary veins were acutely isolated and 90% remained isolated at 3 months. Metzner and colleagues⁵ studied 40 patients with paroxysmal atrial fibrillation ablated using the laser balloon. They were able to isolate 99% of the targeted pulmonary veins acutely, and after a mean of 402 days 24/40 patients (60%) remained free of AF without antiarrhythmic drugs. No pulmonary vein stenoses were identified.

In a preliminary study by Schmidt et al.,¹⁰ 50 patients undergoing laser balloon ablation all underwent endoscopy immediately following ablation; oesophageal ulcerations were found in four of 27 (15%) patients, although all healed without any sequelae.

The recently published NICE guideline for laser pulmonary vein isolation¹¹ (see box 1) emphasises that data supporting the laser balloon technique are limited and that the technique should be used only with special arrangements for clinical research. Procedures should be performed by experienced cardiac electrophysiologists and patients should be enrolled in an outcome registry. Further research should define appropriate patient selection, complications and long-term outcome.

All these comments are certainly reasonable. As discussed above, promising aspects of the laser balloon include performing ablation under direct visualisation of the pulmonary vein, the ability to achieve isolation of nearly all pulmonary veins without the need for using additional catheters, a low complication rate with no reported pulmonary vein stenosis, and a high rate of persistent pulmonary vein isolation. However, it should certainly be noted that initial single-centre reports using a new technology are often optimistic and are performed in motivated centres with extremely experienced operators. Despite this, at least one report demonstrated a clinical efficacy (60%) similar to standard catheter ablation, and complications including cardiac tamponade, phrenic nerve palsy and oesophageal ulcerations have been reported. Therefore, it seems prudent that caution should be exercised...
and patients should be fully informed of the risks and benefits and followed closely in a registry. Standard precautions should be used during laser AF ablation, including using lower power on the posterior wall, oesophageal temperature monitoring, and pacing of the phrenic during ablation of the right pulmonary veins. All the initial laser ablation studies have also been performed in patients with paroxysmal AF, defined as AF that lasts for fewer than 7 days and terminates spontaneously. Whether this technology will be used in more persistent forms of AF is unknown.

A 100 patient feasibility study using the laser balloon system was recently completed in the USA, and a 1-year follow-up will be completed in early 2012. A multicentre randomized study between open irrigated radiofrequency and laser ablation is planned and should start enrolling its first patients in the USA in late 2011. The laser balloon technology appears promising, however, until data from the planned multicentre clinical trial become available, informing patients of the early phase of the technology and proceeding with caution is advisable.

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**Box 1 Summary of NICE Guidelines for Laser Pulmonary Vein Isolation**

1. Current evidence on the safety and efficacy of percutaneous endoscopic catheter laser balloon pulmonary vein isolation for AF is inadequate because of the limited number of patients reported. Therefore this procedure should only be used with special arrangements for clinical governance, consent and research.

2. Clinicians wishing to undertake percutaneous endoscopic catheter laser balloon pulmonary vein isolation for AF should inform the clinical governance leads about the procedure’s safety and efficacy, and provide them with clear written information.

3. Patient selection and treatment should be carried out only by interventional cardiologists with expertise in electrophysiology and with experience in performing complex ablation procedures.

4. This procedure should be carried out only in units with arrangements for emergency cardiac surgical support in case of complications.

5. Clinicians should enter details about all patients undergoing percutaneous endoscopic catheter laser balloon pulmonary vein isolation for AF onto the UK central cardiac audit database.

6. Further research should define patient selection criteria and should clearly describe adverse events and the long-term control of AF.