"Laser-based therapy: is the right answer for pulmonary vein isolation?"

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## Abstract

Laser- based PVI has been around for many years and this modality of ablation is to provide a continuous circular overlapping lesions around the PVs' ostia. In order to ensure the continuity of the lesion, a camera is embedded in the system as to guide the placement of sequential applications with the target to make an adequate overlapping of two contiguous lesions as to reduce the likelihood of gaps. The first version of the system required the operator to manually rotate the catheter as to create a continuous arc of lesion around the PV's ostium. This approach is time-consuming, with a substantial overall time for each PV. The evolvement of the technique has been recently offered, with a novel semi-automated VGLA as to improve ablation efficiency by using a motorized system which moves the laser arc continuously in order to reduce the application time and, hopefully, minimize the creation of gaps.

"Laser-based therapy: is the right answer for pulmonary vein isolation?"

Short title: Laser therapy

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In this issue of the Journal Kuroki et al (1) explores the value of semi-automated (SA) visually-guided laser ablation (VGLA) for pulmonary vein isolation (PVI) in comparison with the more conventional manual

(MN) laser ablation. Laser- based PVI has been around for many years and the main aim of this modality of ablation is to provide a continuous circular overlapping lesions around the PVs' ostia. In order to ensure the continuity of the lesion, a camera is embedded in the system as to guide the placement of sequential applications with the target to make an adequate overlapping of two contiguous lesions as to reduce the likelihood of gaps. The first version of the system required the operator to manually rotate the catheter as to create a continuous arc of lesion around the PV's ostium.

The amount of energy delivered depends on the anatomic location, being higher in the anterior portion of the ostium and less in the posterior, so that the operator can properly titrate the application. This approach is still time-consuming, since each application takes 20" to be completed, thus a substantial overall time for each PV (2) The evolvement of the technique has been recently offered, with a novel semi-automated VGLA as to improve ablation efficiency by using a motorized system which moves the laser arc continuously in order to reduce the application time and, hopefully, minimize the creation of gaps.

## Is the energy source or the technique the "game changer"?

Point-by-point RF ablation has been the main ablation modality to achieve PVI and is still extensively applied in several EP laboratories. Needless to say that it relies on the operator's skill and can be time-consuming. The advent of balloon-based platform devices has been very welcomed, since the manipulation of the catheter is reduced, the learning curve for operators is pretty simple and fast and most importantly the clinical outcome is not significantly different from the conventional RF ablation (3). The use of balloon platforms has then gained popularity in the EP community, leading to a more extensive use in several EP Labs with an improved patient workflow. Keeping this in mind, VGLA belongs to this family of ablative approach. As compared to other balloon-based design catheters, VGLA offers the beauty to view the atrial tissue and, thus, theoretically to better and properly deploy the lesions.

One could raise the question whether is the energy source or the ability to a have a clear vision of the tissue the turning point for a more efficient ablation. In this regard, we diligently need to refer to the recent data collected in clinical studies comparing VGLA with point-by-point RF and cryoenergy ablation. A randomized clinical study comparing the laser balloon with RF in 353 paroxysmal AF patients showed longer procedure and fluoroscopic times  $(236\pm53 \text{ vs } 193\pm64 \text{ min}, P<0.0001, \text{ and } 36\pm18 \text{ vs } 30\pm21 \text{ min}, P=0.006)$  with 98% acute efficacy for PVI and an equal 12-months freedom of any atrial arrhythmias around 61% (3).

In more detail, laser ablation showed more diaphragmatic paralysis (6 vs 1) but fewer PV stenosis > 50% (0 vs 5). Furthermore, a recent European multicenter study (4) comparing the laser balloon with the cryoballoon showed that the procedure but not fluoroscopy time was significantly longer (96 $\pm$ 20 vs 51 $\pm$ 21 min, P<0.0001, and 8.4 $\pm$ 3.2 vs 7.4 $\pm$ 4.4 min, P=0.083), while efficacy close to 80% was the same for both procedures, and cryoballoon ablation was associated with a tendency of more transient phrenic nerve palsy (8 vs 2 cases). Based upon this clinical information, it appears that whatever energy source is chosen, the outcome is fairly comparable.

## Making the difference

Kuroki et al have elegantly investigated if an improved semi-automated VGLA system could ameliorate the efficiency of this technology compared to manual manipulation of the catheter. They have clearly demonstrated in experimental setting that the mean lesion counts were significantly reduced by using the SA as opposed to MN  $(5.3\pm5.9~{\rm vs}~33.7\pm10.0,~{\rm P=0.007})$ . This proves an improved efficiency of SA over the MN approach. Moreover, the lesion counts resulted favorable also in comparison with RF ablation  $(28.0\pm4.4,~{\rm P=0.019})$ . The catheter use time resulted shorter for SA as compared to MN in both acute and chronic study  $(28.0\pm12.1~{\rm to}~12.7\pm15.0~{\rm and}~28.8\pm3.8~{\rm to}~11.5\pm12.7~{\rm min})$ . Of course this represents an important advantage for the efficiency of the approach and it might constitute the basis for obtaining a similar outcome even in the clinical setting. What I would consider quite a fundamental result is that the SA mode is the homogenous circumferentiality of the lesion and the transmurality demonstrated both in acute and chronic studies. This suggests that the uninterrupted movement provided by the SA with continuous energy application could promote an improved transmurality over the MN and also with less propensity to create gaps.

The gross anatomy well shows the difference between the two modalities of laser ablation and support the value of the SA as the preferred mode of deploy laser energy.

The advantage of directly viewing the tissue is also revealed by the comparison between laser and RF application, being the level of RF application deeper in the vein. Therefore, one might conclude that SA laser modality of ablation ensures a higher level of proximal PV's ostium lesion continuity, transmurality and less gap formation. The dose of 13 and 15 W in the current clinically available SA VGLA (5) seems adequate to promote effective lesions even in humans (6-8). The improvement of the VGLA system portraying the novel SA modality can be rightly considered an effective, efficient approach for achieving a high rate of PVI. We all know there are several new technologies and tools reaching the EP field, each of them aiming at successful and durable PVI. We need to applaude Kuroki and co-workers, since their effort was to show the consistency and the value of VGLA energy applied through a novel SA technique.

Needless to remind us that other initiatives are taking place in the EP field, led by researchers and companies as to identify the most successful ablative approach for PVI. Laser therapy is an attractive technology belonging to the family of balloon-based platforms and plays a crucial role in achieving this goal. Reasonably, comparative studies will be required to establish the relative merit to each proposed ablative treatment strategy

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