Multielectrode Pulmonary Vein Isolation Versus Single Tip Wide Area Catheter Ablation-Paroxysmal Atrial Fibrillation: Is There Any Mystery in Pulmonary Vein Isolation?

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In the past decade, catheter ablation of atrial fibrillation (AF) has evolved as one of the most frequently performed procedures in tertiary arrhythmia centers worldwide. With the observation of the actively firing trigger originating from within the pulmonary veins (PVs), ablation strategies have focused at least in paroxysmal AF patients on complete isolation of the PVs.1,2 Several different ablation devices (cryogenic energy, ultrasound, laser, etc) have been investigated to achieve more durable isolating lines around the PVs, with most of these novel ablation catheters allowing for a single-shot approach. Multielectrode-phased radiofrequency ablation probes (PVAC; Medtronic, Minneapolis, MN) have been proposed using the standard radiofrequency energy through smaller but multiple electrodes.3-5 The aim of all these ablation devices is not only to improve outcome but also to allow an easier ablation procedure eventually being performed by nonelectrophysiologists to be able to respond to the growing demand for AF ablation.

The results of the prospective, randomized Multielectrode Pulmonary Vein Isolation Versus Single Tip Wide Area Catheter Ablation (MYSTIC) trial are reported in this edition,5 which compared standard, irrigated tip radiofrequency ablation with multielectrode-phased radiofrequency ablation (PVAC). As per the reports from 4 experienced centers in the Netherlands and Belgium, rates of single-procedure acute success rates were identical and without any serious adverse events in the first 30 days. Only secondary study end points, such as procedure duration, fluoroscopy time, and radiofrequency delivery time, showed significant reductions, while the clinical outcome was the same (76.3% versus 81% at 12 months).

These results are much in line with previous comparative trials reporting on other single-shot devices. Dukkipati et al6 reported on the laser ablation balloon randomized trial (also a noninferiority trial design), which achieved identical primary outcomes (61.1% in the visually guided laser balloon group versus 61.7% in controls). More trials are underway to report on similar comparisons of cryo versus radiofrequency or even among single-shot devices.7-9 Most of these are designed to demonstrate noninferiority to the control group with regard to the most important end point of freedom from arrhythmia.

Although outcome is the obvious and most important outcome of any ablation procedure, additional parameters such as procedure duration and fluoroscopy exposure are important. The shorter the overall duration to deliver an effective ablation, the lower the exposure to periprocedural risk (eg, stroke). With shorter procedure duration, more patients could potentially be treated by the same team, which could lower the burden on the waiting time for paroxysmal AF ablation. And finally, even untrained nonelectrophysiologists could carry out single-shot ablation procedures.

Lesser Need for Training and Experience?
Interestingly, the investigators in MYSTIC required operators to have an experience of at least 50 cases with each ablation technique to allow them to perform study procedures. This is probably why the procedure times are shorter in comparison with previous trials using PVAC.7,10

In comparison, the control-irrigated radiofrequency group received more fluoroscopy exposure, which is somewhat surprising, given the fact that after the transseptal puncture an experienced operator essentially does not need to use fluoroscopy at all.11,12 This author’s own experience used to range around 15 minutes average fluoroscopy time (when still performing PV angiography) and is now <10 minutes total exposure since using 3-dimensional image integration in nearly all cases. A detailed analysis of the mapping time in the standard, irrigated tip radiofrequency ablation group versus the time to position the PVAC catheter and the need for fluoroscopy and angiography would allow a better understanding of when the need for fluoroscopy occurred. Also using double (standard, irrigated tip radiofrequency ablation) or single transseptal access (PVAC) could have made potentially a difference because the PVAC can be also used to assess completeness of the PV isolation. If the standard, irrigated tip radiofrequency ablation group also only had a single transseptal access, then the need to exchange the mapping catheter for a circular mapping catheter would have added to both procedure and fluoroscopy exposure.
the course of a trial may change recruitment numbers.\textsuperscript{13,14} By
now, both ablation tools used in the study seem outdated and one
wonders what a head-to-head comparison with the new
tools (contact force radiofrequency versus GOLD-PVAC)
would show in a similar study design?

The Most Important Question: Is PV
Isolation Really Enough in Paroxysmal AF?
Overall, the study outcome is somewhat sobering, although
the noninferiority end point of the trial was well demonstrat-
ed. What are the reasons for the success rates of $\approx 61\%$
in both groups? Is it that both PV isolation techniques have
about the same amount of PV reconnection rate? Or is the
end point of PV isolation not the only important end point?
Maybe non-PV targets such as autonomic innervation, rotors,
and non-PV triggers are more important for the mainte-
nance of sinus rhythm even in this most simple group of paroxys-
mal atrial fibrillation patients with normal atrial size? Unfor-
unately, we do not learn much about lesion completeness
in this trial. And even from the 2 patients requiring reablation
within the 3 months blanking period, we have no knowledge
of line completeness or in fact which randomization arm they
belonged to in the first place.

As long as we still do not achieve durable PV isolation,
we still cannot solve the question if this end point is in fact
enough. The recently published GAP-AF trial demonstrated
that the acute end point of complete PV isolation is definitely
better in predicting SR in follow-up; however, the amount of
reconnection assessed in a mandatory invasive reprocedure at
3 months was high.\textsuperscript{15} Again, one can only speculate how the
same trial would fair if more durable ablation lesions could
be achieved.

Recently, the importance of non-PV targets and the new
light shed on the innervation of the atria as modulators for
the maintenance and also for the initiation of AF by adjunct
ganglionated plexus ablation\textsuperscript{16,17} or renal denervation\textsuperscript{18}
leads to a new understanding of the underlying pathophysiology.
This leads to the concept that achieving PV isolation alone
will not solve the entire AF riddle. It is high time for improved
outcomes (procedure duration and fluoroscopy exposure),
timing defining the only discernible difference in secondary
outcomes (procedure duration and fluoroscopy exposure),
which demonstrates in return that this is not (yet) an ablation
for the general interventionalist. Finally, PV isolation alone,
irrespective of the tool that it was achieved with, might not
be the final solution, and alternative ablation strategies need
to be further investigated.

Conclusions
Single-shot devices for PV isolation in paroxysmal AF
patients have been tested in the past 10 years and are by
now routine ablation tools in many electrophysiology labo-
ratories in the world. With the growing experience of the
operators, outcomes and procedural complication rates have
reached equality to the standardradiofrequency ablation
techniques. Operator skills still are the most important fea-
ture defining the only discernible difference in secondary
outcomes (procedure duration and fluoroscopy exposure),
which demonstrates in return that this is not (yet) an ablation
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Disclosures
Dr Ernst is a consultant to Biosense Webster and Stereotaxis.

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