



EDITORIAL COMMENT

The cusp-overlap technique for reducing pacemaker implantation after transcatheter aortic valve implantation: Game-changer or gimmick?



A técnica de sobreposição de cúspides para redução de implantação de pacemaker após TAVI: solução ou artifício?

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Transcatheter aortic valve implantation (TAVI) has probably been the most impactful technique in interventional cardiology in the past 10–15 years. The technique has proved to be safe and effective across multiple clinical trials and devices, moving from a niche approach for inoperable patients to the standard choice in many cases of everyday clinical practice, as recommended in current guidelines.¹

As the technique reaches maturity, addressing its lingering pitfalls becomes increasingly important. One of the most important of these is post-procedural permanent pacemaker (PPM) implantation, with rates of 19% in the Portuguese TAVI Registry,² sometimes even exceeding 20% in some series,³ with little improvement over the years. At first glance, this may not seem to be of particular concern, given that pacemaker implantation in elderly patients is commonplace. However, several reports have suggested that post-procedural PPM may be associated with increased risk of heart failure (possibly due to new-onset

left bundle branch block or pacemaker-induced ventricular dysfunction),⁴ costs and longer hospital stay.⁵ The impact on mortality is less clear, as some registries have found an association,⁴ while others have not.^{2,6} Additionally, it is also unclear how much of the prognostic impact is directly attributable to PPM implantation rather than simply reflecting an overall cohort of sicker patients. Notwithstanding, it is clear that efforts to reduce post-TAVI PPM implantations are important.

Several predictors of PPM implantation after TAVI have been identified. While some are intrinsic to the patient (such as right bundle branch block [RBBB]), it is well recognized that procedural factors such as implantation depth, post-procedure balloon dilation and prosthetic valve choice play a role, as self-expanding valves have been associated with increased post-procedural PPM implantation.^{7,8} Among these, the CoreValve family has received the most attention, given that it is one of the two device families that have been available for longest, while also being the subject of some of the largest datasets from both registries and clinical trials, in which significant rates of post-TAVI PPM implantation have consistently been found.

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In light of all of the above, the study by Moura et al. in this issue of the *Journal*⁹ is highly relevant, as it addresses one procedural technique aimed at the CoreValve prosthesis family that has been claimed to reduce the risk of PPM implantation after TAVI: the cusp-overlap projection (COP) approach. As the authors explain, instead of implanting the valve using the traditional coplanar technique, COP provides a better image display of the non-coronary cusp nadir, thereby enabling the valve to be positioned as high as safely possible. Because implantation depth has been associated with increased risk of post-procedural PPM implantation, the reduction enabled by the COP technique should theoretically reduce its incidence. While no randomized trials have confirmed this, available data suggest lower rates of PPM implantation, in some series as low as half of those with the conventional technique.¹⁰

It is therefore surprising that Moura et al.⁹ did not find similar results; there were no significant differences in the rate of PPM implantation between groups. To the authors' knowledge, as well as my own, no other studies have been published with non-positive findings concerning the impact of this technique on PPM implantation rates. What could be the explanation for these seemingly contradictory findings? Several non-mutually exclusive factors might have played a role.

First, and possibly most importantly, the authors reported that implantation depth did not differ significantly between the conventional and COP techniques. While there are several different methods for assessing the implantation depth, the recommended depth ranges from 3 to 5 mm.¹⁰ The implantation depth in this study, however, ranged from approximately 7 to 9 mm in the COP group, depending on measurement methodology. Given that the mechanism of the reduced PPM implantation rates is postulated to be largely related to this issue, this factor is very likely to have played a major role in the study's results.

Second, another explanation is that the COP technique does not in fact have a consistent effect, and the absence of published results in line with those of Moura et al.⁹ may in part be the effect of publication bias, whereby studies with neutral or negative findings are not submitted or accepted.

Third, the sample in this study is relatively small compared to others, which might have had an impact on its statistical power for assessing significant differences between groups. Two inconspicuous findings support this hypothesis. There was a small, albeit not statistically significant, trend for reduced implantation depth in the COP group, even though the overall depth was still lower than theoretically desired. Also, considering that fewer than 20 patients in each group received a pacemaker, minor non-significant differences in the baseline population may have affected outcomes. Indeed, a difference of three patients with first-degree atrioventricular (AV) block and/or RBBB in the COP group (as was the case), while not statistically significant, could have played a part – if 13 instead of 16 as opposed to 18 patients had received a pacemaker, this would translate to a ~22 versus a ~29% difference across groups (instead of ~27 versus ~29%). In fact, when analyzing the reasons for PPM implantation, severe conduction disturbances (complete or high-grade AV block) were less common in the COP group, although the difference was again not statistically significant. As mentioned, given the small sam-

ple size, whether such factors played a role cannot be truly ascertained.

Lastly, it is worth noting that the current study deals with a transitional phase. In daily practice, the valve position is also checked in the classical projection. This may induce operators to reposition it higher, all the more so during a period of transition, when physicians would have a greater tendency to fall back on an approach they already felt comfortable with. Given that this center has been implanting this valve type for a long time, an experience bias may have paradoxically been even more impactful than for operators and centers with less experience, who started using the COP technique shortly after their training or program began. Furthermore, despite the fact that first operator experience had no bearing on the results, as the authors tested, it is also common for younger operators to rely on the input of more seasoned colleagues who are available in the cath lab during the procedure, thereby mitigating differences across operators. It might be interesting to revisit the data in a few years' time, to see whether the findings concerning implantation depth and PPM implantation remain the same.

Despite its mostly neutral findings, Moura et al.'s study⁹ nonetheless provides important insights – the COP technique yielded similar results in terms of efficacy and safety as the conventional technique (in line with previous studies) with lower radiation dosage. As the technique is being embraced in more and more centers, these reassuring findings are very welcome. The authors should be congratulated for assessing their results, while having the insight and fortitude to submit a study with findings somewhat contrary to previously published data.

Conflicts of interest

The author has no conflicts of interest to declare.

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