High shock impedance during subcutaneous implantable defibrillator generator replacements

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studies and in 30% of patients in CABANA.[2] Patients in CAPA chose not to receive CA even after failing pharmacotherapy (i.e. reaching a primary and/or secondary endpoint). This is inconsistent with contemporary guideline recommendations and routine medical practice. To the best of our knowledge, this has not been observed in any previous RCT in this space, and it has implications for external validity.

- CAPA found substantial quality-of-life improvement across all sub-scales of the generic SF-36 instrument. Previous studies of pharmacotherapy and ablation have failed to observe such a consistent improvement and have also shown that the superiority of ablation over AAD for the improvement of quality of life is early but non-sustained.[3] How do the authors explain these differences?
- The Kaplan–Meier (K–M) curves in CAPA demonstrate a unique pattern of arrhythmia recurrence. Despite enrolling a population at high risk of recurrence, relatively low rate of AAD use in the control arm, and the use of longer-term rhythm monitoring, the arrhythmia-free survival in the two groups did not show any divergence in the 1st year. Previous trials of CA and pharmacotherapy have consistently shown that arrhythmia recurrence tends to be 'front-loaded', with the K–M curves separating very early on and then continuing to diverge more gradually over time[4,5] (*Figure 1*). Can the authors explain this discrepant finding CAPA?

There is now a debate amongst the cardiology community regarding the potential impact of AF CA on 'hard' endpoints. Publication of the large benefits seen in CAPA will likely influence this debate and perhaps practice and guidelines. Any light that the authors can help shed on our queries should help contextualize their study findings relative to previous trials.

Conflict of interest: none declared.

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Improvement in hard outcomes following catheter ablation for atrial fibrillation: the debate is far from over—Authors' reply

We read with interest the letter by Gupta *et al.*[1] We thank these authors for their interest in our study (CAPA study).[2] Gupta *et al.* were concerned about patients in CAPA crossed-over from antiarrhythmic drug (AAD) to catheter ablation (CA) treatment. The CAPA was designed in 2012. At that point in time, the cost of atrial fibrillation (AF) ablation was about $15 000 in China, which cannot be reimbursed by the medical insurance. Due to the high out-of-pocket medical expenses, almost all patients in CAPA chose not to receive CA even after failing pharmacotherapy. Furthermore, 11 patients in the pharmacotherapy group dropped out of our study. Several of them sought to receive CA in other electrophysiology centres due to the recurrence of AF.

Gupta *et al.* also mentioned that previous studies of pharmacotherapy and ablation have failed to observe a substantial improvement of quality-of-life (QoL) in AF patients. We respectfully disagree with the idea of Gupta *et al.* Ample evidence demonstrated that CA-based treatment could improve QoL in AF patients.[3] Additionally, previous studies have also shown that the superiority of CA over AAD for the QoL improvement during the long-term follow-up,[4] which is consistent with our study.

Finally, Gupta *et al.* pointed out that unlike previous trials,[5] the arrhythmias-free survival curves in CAPA showed an overlap of outcomes during the first year, followed by a marked departure afterwards. In CAPA, patients in the pharmacotherapy group received an aggressive rhythm-control strategy by treatment with AADs, electric cardioversion, or both. The CA and pharmacotherapy strategies displayed similar effects on sinus rhythm (SR) restoration during the first year. However, some patients in the pharmacotherapy group ultimately switched to a rate control strategy due to the side effects of AADs and/or AF recurrence, especially during the second year of follow-up. Therefore, a higher rate of SR maintenance was observed later in follow-up in the CA group, which resulted in arrhythmias-free survival curves began to separate at 12 months.

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High shock impedance during subcutaneous implantable defibrillator generator replacements

We would like to congratulate van der Stuijt *et al.*[1] with their efforts on systematic evaluation

of subcutaneous implantable cardioverter-defibrillator (S-ICD) replacements. In this single-centre study, they have performed 72 device replacements, a remarkably large population with this relatively new technique. Dutch centres have been instrumental in the development of S-ICD therapy[2] and 'early adopters' with a large population with relatively long follow-up.[3] The current study shows low complication rates of S-ICD device replacement but the actual strength of the manuscript is the systematic analysis of defibrillation testing. This was performed in 63 patients and the first shock efficiency was coined high with 91.4%. Shock impedance at first implant and during device replacement was available in 48 patients. It was higher during replacement (86 ± 26Ω vs. 77 ± 28Ω) with a very large variability. In some patients, shock impedance was almost doubled between the two tests. We wonder if impedance changes occurred in the five patients where the device pocket was modified due to high PRAETORIAN scores. Most likely, high impedance is due to excess fibrous tissue occurring around the parasternal shock coil.

The results from van der Stuijt *et al.* are somewhat better than in the smaller study from Rudic *et al.*[4] that reported 20% shock failure in 25 S-ICD replacement procedures. Both reports are leading to doubts about the long-term performance of S-ICDs. High shock impedance and failed first shock during induced ventricular fibrillation might be an indication of higher risk for shock failure during real-life ventricular arrhythmias. Ventricular fibrillation induced during defibrillation testing in a patient under general anaesthesia might be easier to terminate than more stable rhythms such as fast monomorphic ventricular tachycardia in awake haemodynamically compromised patients . High shock impedance patients might thus be at risk of inefficient shock therapy with a false sense of security of a second successful shock during defibrillation testing. What we need is a systematic registry of shock efficacy during long-term follow-up of patients with S-ICDs. To prevent underreporting of failed ICD shocks, we should take any effort to receive device read-outs of all ICD patients that died with an active device. A previous study by Tseng *et al.*[5] that prospectively collected data from autopsies in San Francisco county demonstrated unexpected failure of pacemaker or ICD devices in a large proportion of sudden cardiac death. They calculated that 6.4% of ICD deaths were related to device malfunction. With S-ICD being a relatively new technology, efforts should be undertaken to prevent ineffective shock therapy at long-term follow-up.

Conflict of interest: none declared.

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High shock impedance during subcutaneous implantable defibrillator generator replacements: Authors' reply

We thank Dr Maass *et al.*[1] for their interest in our study[2] and are pleased to provide a reply to their questions.

The authors express their concern about the long-term performance of the subcutaneous implantable cardioverter-defibrillator (S-ICD), considering the increase in shock impedance in the years after implantation. According to Ohm's law, a higher shock impedance results in a lower shock success rate. However, despite the significant increase in shock impedance in our analysis, we showed a first shock success during defibrillation testing (DFT) of 91.4% during the replacement procedure. This is similar to the DFT success rate in *de novo* S-ICD implants and in transvenous devices.[3,4] Four of the patients with a high PRAETORIAN score underwent a DFT after pocket revision during the replacement procedure. These patients were among those with the largest increase in shock impedance (103Ω ± 37Ω during implant vs. 145Ω ± 47Ω during replacement). DFT was successful after one 65 J shock in three of these patients (75%), whereas the fourth patient had a successful DFT at 80 J, similar to his implant procedure. These results suggest that impedance is not as predictive of defibrillation success as anticipated.

Shock impedance represents the resistance between the coil and the generator of the S-ICD and depends mostly on generator-lead distance and the body tissues between these electrodes. As Dr Maass *et al.* described, excess formation of fibrotic tissue around the lead or generator or weight gain can result in an increase in shock impedance. Shock impedances >100Ω are associated with a higher chance of DFT failure, but a positive predictive value of 23% indicates this variable is unsuited as a predictor for shock success.[5] Moreover, a low shock impedance does not necessarily correspond with a successful DFT. When the generator is too anteriorly positioned, the electrical current may shunt over the thoracic wall, resulting in a conversion failure with a low shock impedance. Alternatively, the non-invasive PRAETORIAN score evaluates the implant position of the S-ICD and takes generator-lead distance and adipose tissue into account. A retrospective validation of the PRAETORIAN score demonstrated that half of all patients with a high PRAETORIAN score failed their DFT.[5] In our study, we showed a high defibrillation success and a low overall PRAETORIAN score, despite increases in impedance. Moreover, a recent analysis of 566 patients showed that patients with a high PRAETORIAN score have a 19-fold higher risk on ineffective shocks during follow-up (hazard ratio = 19.03; confidence interval 4.75–76.20; $P = 0.003$).[6] This seems to confirm our suggestion that the PRAETORIAN score is a better predictor for shock success than impedance.

As mentioned by Dr Maass *et al.*, a successful shock on an induced arrhythmia during the implant or replacement procedure does not guarantee shock success during a spontaneous ventricular arrhythmia. The ongoing PRAETORIAN DFT trial, of which the results are expected in 2024, will prospectively validate the PRAETORIAN score and compare the predictive values of the PRAETORIAN Score and DFT for shock success in spontaneous arrhythmias.[7]

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