









RESEARCH LETTER

Comparison of the Feasibility and Safety of a Deep Sedation Protocol for Pulmonary Vein Isolation With Pulsed Field Ablation, Cryoballoon Ablation, and Radiofrequency Ablation

Oskar Marian Galuszka, MD; Thomas Kueffer , MSc; Antonio Madaffari , MD; Nikola Kozuharov, MD; Gregor Thalmann , MD; Helge Servatius , MD; Andreas Haeblerlin , MD, PhD; Fabian Noti , MD; Hildegard Tanner, MD; Laurent Roten , MD; Tobias Reichlin , MD

Pulsed field ablation (PFA) is a novel, nonthermal ablation modality that is increasingly used for pulmonary vein isolation (PVI). Despite technical advancements, the procedure remains painful and uncomfortable, requiring adequate patient sedation. Previous studies demonstrated the safety of deep sedation protocols in patients undergoing PVI with cryoballoon (CBA) and radiofrequency ablation (RFA). However, data regarding the feasibility and safety of deep sedation protocols in PFA procedures are scarce^{1,2} and a comparison with CBA and RFA procedures is lacking.

Our aim was to compare the feasibility and safety of a deep sedation protocol in patients undergoing PVI using PFA (Farapulse, Boston Scientific), CBA (Arctic Front, Medtronic), or RFA (CARTO 3, Biosense Webster). The authors declare that all data used for the analyses included in this study are available within the article. Between January 2020 and April 2023, consecutive patients undergoing a first PVI with either of the 3 technologies were analyzed. All ablation procedures were performed using the same predefined

deep sedation protocol including midazolam, fentanyl, and propofol administered by a nurse under the supervision of the electrophysiologist.³ Procedural patient surveillance included continuous heart rate, peripheral capillary oxygen saturation, and transcutaneous carbon dioxide level monitoring and noninvasive blood pressure measurement at regular intervals, as clinically indicated. Exclusion criteria for the use of this protocol were a body mass index >35 kg/m², severe untreated sleep apnea syndrome, or any other indications requiring intubation and general anesthesia. The study was approved by the local ethics committee and all patients provided written informed consent.

A total of 1049 patients underwent a first PVI using the deep sedation protocol (median age, 67 years [interquartile range, 59–74], 29% female, 59% paroxysmal atrial fibrillation). The distribution among the 3 ablation modalities was PFA in 429 patients (41%), CBA in 412 (39%), and RFA in 208 (20%). Acute procedural success, defined as bidirectional block of all pulmonary veins, could be achieved in 99.7% of the patients (no differences between groups). Procedure duration

Key Words: atrial fibrillation ■ catheter ablation ■ deep sedation ■ pulsed field ablation

Correspondence to: Tobias Reichlin, MD, Department of Cardiology, Inselspital—University Hospital Bern, Freiburgstrasse 20, CH-3010 Bern, Switzerland. Email: tobias.reichlin@insel.ch

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was higher in the RFA group than in the CBA and PFA groups (RFA 161 ± 55 minutes; CBA 81 ± 29 minutes; PFA 93 ± 41 minutes; Figure [A]). As a consequence, mean total doses of propofol and fentanyl were higher in the RFA group (814 ± 351 mg and 185 ± 61 μ g) than in the CBA group (517 ± 213 mg and 139 ± 48 μ g) and PFA group (550 ± 204 mg and 157 ± 44 μ g; Figure [B] and [C]). After normalization for procedural time, mean doses of propofol and fentanyl per minute were higher in the PFA (6.4 mg and 2.0 μ g per minute) and CBA (6.6 mg and 1.8 μ g per minute) groups compared with the RFA group (5.2 mg and 1.2 μ g per minute; Figure [D] and [E]). Peri-procedural conversion to general anesthesia was necessary in 1/427 (0.23%), 2/410 (0.49%), and 0/208 (0%) patients in the PFA, CBA, and RFA groups, respectively (Fisher's exact test: PFA versus CBA $P=0.485$; PFA versus RFA $P=0.672$; CBA versus RFA $P=0.440$). The reasons for conversion were insufficient analgesedation resulting in pain and patient movement

in 2 cases and airflow obstruction in 1 patient with chronic obstructive pulmonary disease requiring intubation and mechanical ventilation.

Our data from 1049 patients indicate that a propofol-based deep sedation protocol is a safe and suitable sedation strategy for PVI using this particular pentaspline PFA system. After normalization for procedural time, the total doses of propofol and fentanyl required for the PFA procedures were comparable to CBA procedures and higher than in RFA procedures. We believe that this might be indicative of the fact that PFA and CBA are slightly more painful than RFA cases. Sedation complications were very low and comparable to PVI using CBA or RFA. Muscular fasciculations, which are not observed with either CBA or RFA, can occur with PFA and can result in significant patient movement. Although this is not an issue if PFA is used with fluoroscopy only, it will likely result in map shifts in some patients after full integration into 3-dimensional mapping systems. It will therefore have to be shown if

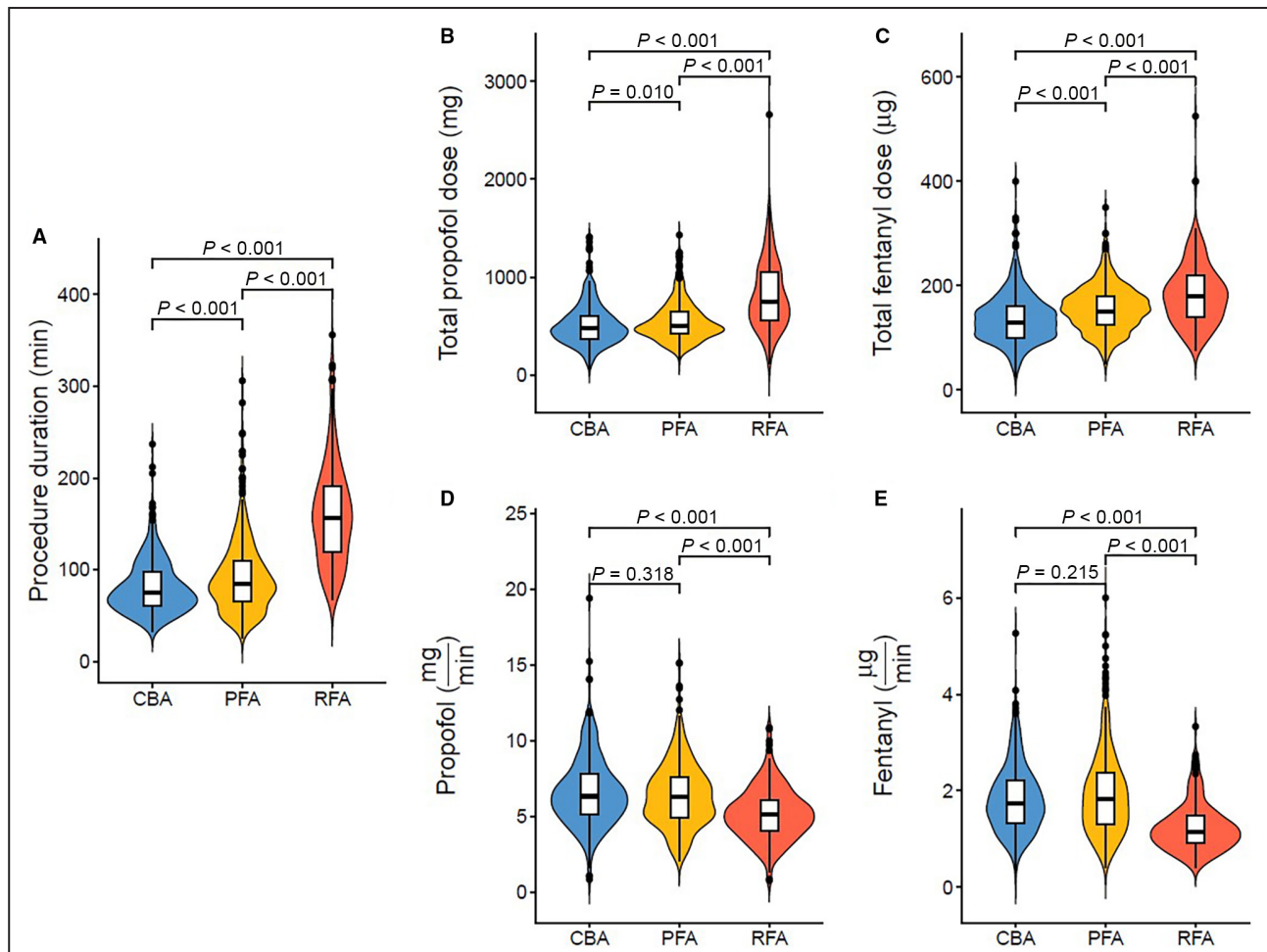


Figure. Deep sedation for different ablation modalities.

Procedure duration (A) and sedatives used (B through E) during deep sedation. The difference between cryoballoon ablation and pulsed-field ablation for total sedative dose (B and C) was not observed when correcting for procedure duration (D and E). Wilcoxon test was used for group comparisons. CBA indicates cryoballoon ablation; PFA, pulsed-field ablation; and RFA, radiofrequency ablation.

deep propofol sedation can provide sufficient stability for the routine use of 3-dimensional integrated PFA systems.

Limitations of our data include the following: first, patient satisfaction was not prospectively quantified in our study. However, we are not aware of any negative patient feedback in any of the 3 groups. Second, we performed PFA procedures using only 1 particular PFA device (Farapulse, Boston Scientific). Our findings therefore cannot be applied to other PFA devices. In particular, unipolar rather than bipolar PFA systems and also PFA systems with integrated 3-dimensional mapping might require different anesthesia protocols.

In conclusion, PVI procedures using this specific pentaspline PFA device can be safely performed using a propofol-based deep sedation protocol in selected patients under the supervision of the electrophysiologist, thus curtailing the need for general anesthesia for PVI procedures.

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Affiliations

Department of Cardiology, Inselspital, Bern University Hospital (O.M.G., T.K., A.M., N.K., G.T., H.S., A.H., F.N., H.T., L.R., T.R.); and ARTORG Center for Biomedical Engineering Research (T.K., A.H.), University of Bern, Bern, Switzerland.

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