Hemolysis Profile of a Novel Balloon-Filled Basket Pulsed Field Ablation Catheter

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Background

Pulsed field ablation (PFA) can cause hemolysis depending on the field delivered into the bloodstream. While any PFA system can theoretically cause hemolysis, the degree to which this happens is system dependent.

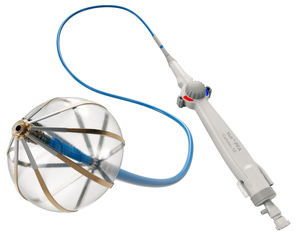


Figure 1. VOLT™ PFA Catheter, Sensor Enabled™

Objective

To assess the degree of hemolysis caused by a balloon-filled basket PFA catheter in an in vivo pre-clinical model.

Methods

Six canines were treated with a novel 12.5F, deflectable, variable diameter, balloon-filled, 8-spline-electrode basket PFA catheter (VOLT™ PFA Catheter, Sensor Enabled™, Abbott) (see Figure 1). Canines were survived for either 5-7 (N=3) or 30-32 days (N=3). All four pulmonary veins (PV) were treated in each animal with PFA dosing at twice the recommended upper limit (with respect to the number of applications) to create a challenge condition for hemolysis. For 20/24 PVs, this meant 16 applications per vein at 1800V. Six applications per vein of 1400V were delivered to the remaining 4 PVs (all RSPVs) due to proximity to the phrenic nerve. Samples were collected for plasma free hemoglobin (FH), hemoglobin (HGB) and serum creatinine (CR) at baseline (T0), after all PFA treatments in the left atrium (T1), and at termination at either 5-7 days or 30-32 days (TERM). Statistical analysis was completed using SigmaPlot 15.

Results

No acute complications were observed during PFA application, and all six canines survived until termination. T1 mean plasma FH concentration was statistically less than the clinical threshold of 50 mg/dL defining major hemolysis (one sample t-test, $p<0.001$, with upper end of 95% confidence interval = 23.4 mg/dL)[1,2]. Plasma FH increased from a baseline (T0) mean of 6.6 ± 5.8 mg/dL to 16.4 ± 5.6 mg/dL immediately after all PFA applications in the left atrium (T1). This returned to 12.1 ± 6.5 mg/dL at TERM. For HGB, values were 13.0 ± 1.7 g/dL at T0, 11.5 ± 0.5 g/dL at T1, and 13.4 ± 1.6 g/dL at TERM. For CR, values were 0.9 ± 0.1 mg/dL, 0.8 ± 0.1 mg/dL, and 0.9 ± 0.1 mg/dL at T0, T1, and TERM respectively. The above results along with additional serum values are depicted in Table 1.

Table 1.

	T0	T1	TERM	p-value[3]
Plasma FH (mg/dL)[1,2]	6.6±5.8	16.4±5.6	12.1±6.5	0.128
HGB (g/dL)[1]	13.0±1.7	11.5±0.5	13.4±1.6 §	0.014
Creatinine (mg/dL)[1]	0.9±0.1	0.8±0.1	0.9±0.1	0.126
Albumin (g/dL)[1]	2.9±0.3	2.5±0.1 *	3.0±0.2 §	<0.001
LDH (U/L)[1]	52±30	156±47 *	54±14 §	<0.001
BILI (mg/dL)[1]	0.1±0	0.1±0.1	0.1±0	0.402
CK (U/L)[1]	203±47	1362±537 *	467±693 §	<0.001

FH= free hemoglobin, HGB= hemoglobin, LDH = lactate dehydrogenase; BILI = bilirubin; CK = creatine kinase

[1] One Way Repeated Measures Analysis of Variance

[2] Plasma FH results only available for N=5 animals

[3] p-value < 0.05 indicates the differences in mean values among timepoints are greater than would be expected by chance. Multiple comparison procedure (Bonferroni t-test) used to isolate timepoints that differed.

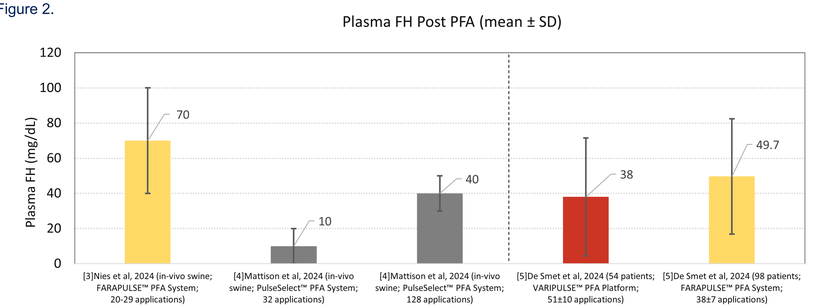
§ Statistically different ($p<0.05$) vs. T1, based on Bonferroni t-test for pairwise comparisons

* Statistically different ($p<0.05$) vs. T0, based on Bonferroni t-test for pairwise comparisons

Conclusion

Small amounts of hemolysis were noted after very high numbers of PFA applications using the VOLT™ PFA system. The amounts seen are less than those reported by some other PFA systems (see Figure 2).

Figure 2.



Disclosures

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Study was conducted at NAMSA, Minneapolis, MN

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