coolloop® Cryoablation for Treatment of Atrial Fibrillation

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Introduction

The coolloop® cryoablation system for treatment of atrial fibrillation (AF) is designed for wide area circumferential lesions at the pulmonary veins (PV) without interruption of the blood flow (Fig. 1A, B). Very fast adherence to the tissue is achieved due to cryogenic temperatures below -80°C in the loop. Thawing within seconds is also an extremely fast process (Fig 1C). The CooL-TreatS study (Treatment Success with the CoolLoop® Cryoablation System) evaluates for the first time safety and procedural parameters of the coolloop® cryoablation system in a routine setting. The second objective of the study was to evaluate the freedom from atrial arrhythmias over a 6-month follow-up period.

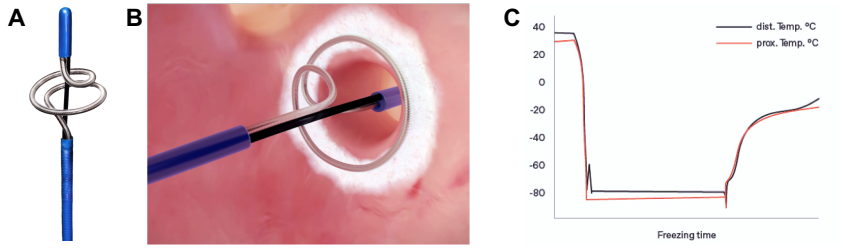

Fig. 1: A) Applicator of the coolloop® cryoablation catheter. B) Creation of wide circumferential lesions with distinct demarcations without occlusion of the pulmonary vein. C) Ultra-fast cooling, reaching temperatures below -80°C within just a few seconds.

Method

After establishing the coolloop® cryoablation system as one of the routine treatment regimens at our institution, 37 consecutive patients with AF were treated as part of the CooL-TreatS study. Three freezes of 180 seconds were applied per vein. For each application, the cryo-loop was rotated by approx. 120°. If the PV was not isolated, additional freezes of 90 to 180 seconds were applied. For a total of 32 patients, 6-months follow-up data are available.

Disclosure: F. H. is founder and shareholder of afreeze GmbH. D. S. and A. K. are employees of afreeze GmbH.

Results

37 consecutive patients (62.2% male, 37.8% female) with a mean age of 61.9 ± 6.8 years and first-diagnosed (5.4%) or paroxysmal (94.6%) AF (86.5% failed treatment with first line AADs) were included into the study (Table 1).

Out of 144 treated PVs, 135 PVs (94%) could be isolated with the coolloop®. No touch-up applications were performed. The median total procedure time was 161 min [range 97-275 min], the mean coolloop® procedure time was 122.6 ± 25 min. The mean fluoroscopy time was 25.8 ± 6.8 min with a mean fluoroscopy dose of 2769.1 ± 1466.9 µGy/m² (Table 2).

There were recorded 2 adverse events and 1 serious adverse event that were classified as procedure related, but without relation to the coolloop® cryoablation system (Table 3).

After a follow-up period of 6 months, 27 out of 32 patients (84%) were AF-free after a single procedure (Fig. 2).

Table 1: Patient demographic data. Table represents means (SD), % (n) or median [min, max].

	Total	Male	Female
Patient number	100% (37)	62.2% (23)	37.8% (14)
Age (years)	61.9 (6.8)	60.9 (6.5)	63.6 (7.1)
BMI (kg/m²)	26.4 [20.4, 36.9]	26.0 (1.7)	27.7 (5.5)
AF-type			
first diagnosed	5.4% (2)	4.3% (1)	7.1% (1)
paroxysmal	94.6% (35)	95.7% (22)	92.9% (13)
Failure of first line AADs			
Yes	86.5% (32)	87.0% (20)	85.7% (12)
No	13.5% (5)	13.0% (3)	14.3% (2)

Table 2: Procedure related parameters. Table represents % (n), median [min, max] or means (SD).

Measure	% (n) mean (SD) median [min, max]
Acute ablation success	94% (135)
Total procedure time [min]	161 [97, 275]
coolloop procedure time [min]	122.6 (25)
Total fluoroscopy time [min]	32.3 (7.7)
coolloop fluoroscopy time [min]	25.8 (6.7)
Fluoroscopy dose [µGy/m²]	2769.1 (1466.8)

Table 3: Overview on reported Adverse Events (AEs) and Serious Adverse Events (SAEs) indicating relation to the coolloop® cryoablation system or the ablation procedure.

Measure	% (n)
Adverse Events (AEs)	13.5 (5)
coolloop® related	0.0 (0)
procedure related	5.4 (2)
Serious Adverse Events (SAEs)	8.1 (3)
coolloop® related	0.0 (0)
procedure related	2.7 (1)

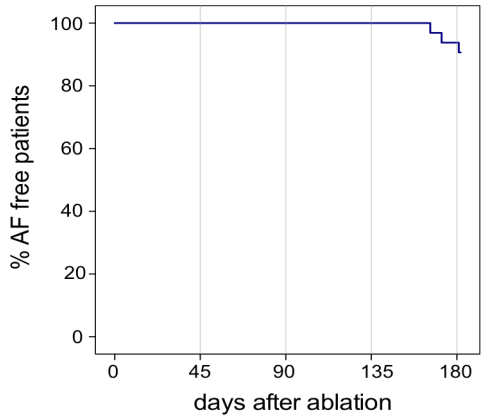

Fig. 2: Kaplan Meier curve showing AF free survival within the first 6 months after ablation (n=32).

Conclusion

Treatment of atrial fibrillation with the coolloop® catheter is safe. Procedural efficacy, procedural parameters, and 6-months follow-up data are comparable to similar devices and very promising for an ablation system that has just recently been introduced to clinical practice.