

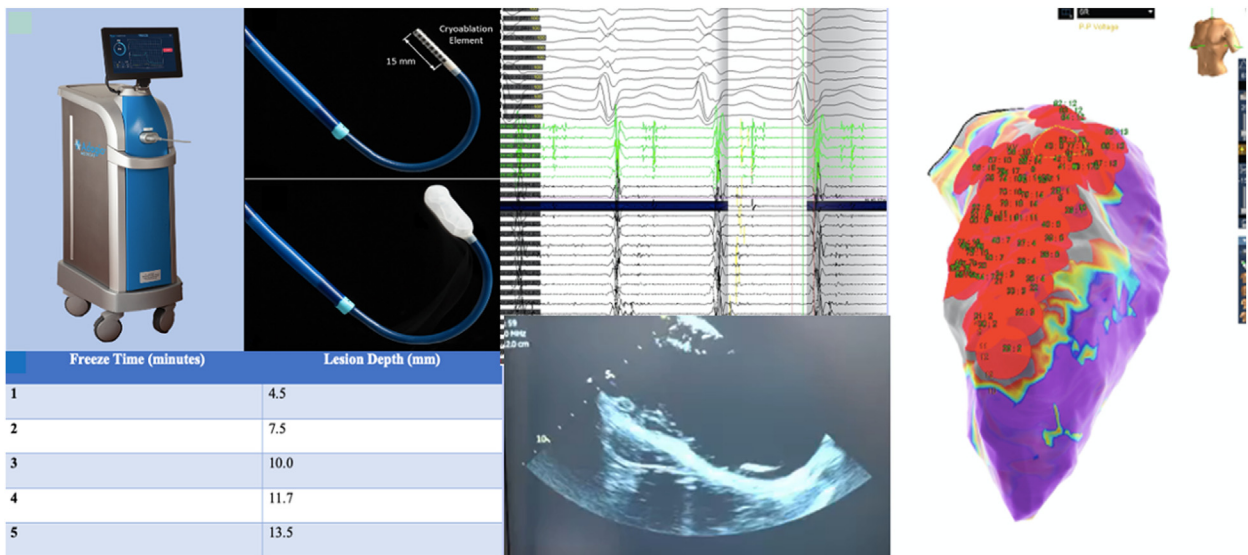
Original Article

# Ultra-Low—Temperature Cryoablation for Ventricular Tachycardia: An Early Single-Centre Report of Acute Results

Paula Sanchez-Somonte, MD,<sup>a,b,†</sup> Atul Verma, MD,<sup>a,†</sup> Luiz-Gustavo Bravosi Da Rosa, MD,<sup>a</sup> Valeria Anglesio, MD,<sup>a</sup> Vladimir Poletaev, MD,<sup>a</sup> Ahmed Alturki, MD,<sup>a</sup> Martin Bernier, MD,<sup>a</sup> Jacqueline Joza, MD, MSc,<sup>a</sup> and Vidal Essebag, MD, PhD<sup>a</sup>

<sup>a</sup> Division of Cardiology, McGill University Health Centre, McGill University, Montréal, Québec, Canada

<sup>b</sup> Departament de Medicina, Universitat de Barcelona (UB), Barcelona, Spain



**ABSTRACT**

**Background:** Endocardial catheter ablation for ventricular tachycardia (VT) may fail because of the inability to deliver transmural lesions. Ultra-low-temperature cryoablation (ULTC) uses near-critical nitrogen and can generate temperatures as low as  $-196\text{ }^{\circ}\text{C}$ . We report a series of 18 patients who underwent ULTC at the McGill University Health Centre (MUHC), representing the largest single-centre experience to date.

**Methods:** Eighteen patients with monomorphic drug-refractory VT underwent VT ablation with ULTC at our institution as part of the first-in-human CryoCure-VT trial (NCT04893317). After voltage map, the mapping catheter was replaced with the ULTC catheter, and lesions were applied over a fixed duration of time (60–180 seconds), followed by a 60-second thaw and another application at the original duration (freeze-thaw-freeze). Duration of ablation time was selected depending on the wall thickness of the left ventricle monitored with intracardiac echo to achieve tissue depths of 4.5 to 7.5 mm.

**RÉSUMÉ**

**Contexte :** L’ablation endocardique par cathéter pour traiter la tachycardie ventriculaire (TV) peut être un échec, en raison de l’incapacité à créer des lésions transmurales. La cryoablation à ultra-basse température (ULTC, pour *ultra-low-temperature cryoablation*) réalisée au moyen d’azote près de son point critique liquide-vapeur peut produire des températures aussi basses que  $-196\text{ }^{\circ}\text{C}$ . Nous faisons état d’une série de 18 patients ayant subi une ULTC au Centre universitaire de santé McGill (CUSM), ce qui représente la plus importante expérience menée dans un seul établissement jusqu’à ce jour.

**Méthodologie :** Au total, 18 patients atteints de TV monomorphe pharmacorésistante ont subi une ablation de la TV par ULTC à notre établissement, dans le cadre du premier essai mené chez l’humain sur la guérison par cryothérapie de la TV (NCT04893317). Après l’obtention de la carte électrophysiologique, le cathéter de cartographie a été remplacé par le cathéter d’ULTC, qui a permis de créer des lésions par

**Results:** Baseline left ventricular ejection fraction was 32%, mean age 71 years, 94% were male. A total of 32 sustained VTs were induced in 16 of 18 patients. A total of 177 cryoablation lesions were delivered (9.8 lesions per patient). Of the 16 patients with inducible VT, 15 (94%) were rendered noninducible postablation, and 1 was inducible only for a nonclinical VT. Complications included 1 pericardial effusion that required drainage. From 18 patients, 16 (89%) were discharged within the first 24 hours postablation.

**Conclusions:** ULTC is feasible and permits acute control of monomorphic VT during VT ablation procedures in drug-refractory patients.

l'application de froid pendant une durée fixe (de 60 à 180 secondes), suivie d'une période de dégel de 60 secondes, puis d'une autre application de froid pendant la même durée que la première application (cycle gel-dégel-gel). La durée de l'ablation a été déterminée en fonction de l'épaisseur de la paroi du ventricule gauche surveillée par échocardiographie endocavitaire afin d'obtenir des profondeurs tissulaires de 4,5 à 7,5 mm.

**Résultats :** La fraction d'éjection du ventricule gauche initiale était de 32 %, l'âge moyen des sujets était de 71 ans et 94 % d'entre eux étaient de sexe masculin. Au total, 32 TV soutenues ont été induites chez 16 patients sur 18. Dans l'ensemble, 177 lésions de cryoablation ont été créées (soit 9,8 lésions par patient). Après l'ablation, nous avons été incapables d'induire une TV chez 15 (94 %) des 16 patients chez qui nous en avons induit avant l'intervention et, chez le patient restant, nous avons pu induire une TV non clinique seulement. Les complications comprenaient un cas d'épanchement péricardique ayant nécessité un drainage. Au total, 16 (89 %) des 18 patients ont reçu leur congé de l'hôpital dans les 24 heures suivant l'ablation.

**Conclusions :** L'ULTC est réalisable et permet une maîtrise rigoureuse de la TV monomorphe lors des interventions d'ablation de la TV chez les patients dont la TV est pharmacorésistante.

Catheter ablation (CA) has become an effective strategy for the treatment of drug-refractory ventricular tachycardia (VT),<sup>1-6</sup> but despite the advances in the field, recurrences postablation still remain high.<sup>7,8</sup> Some substrates are complex and transmural or are located mid-myocardial, and 1 of the main limitations of endocardial CA is the inability to create lesions deep enough to reach these substrates. In these cases, epicardial access is often needed, especially in nonischemic patients in whom epicardial substrate is common, but epicardial access can sometimes be limited (cardiac surgery, inaccessibility, coronary arteries, etc).

If CA and antiarrhythmic drugs (AADs) fail, patients are at risk of having recurrent implantable cardioverter defibrillator (ICD) shocks, which are associated with an increase morbidity and mortality.<sup>9</sup> To overcome this problem, in the last years, efforts have been focused on the development of new techniques that allow the delivery of deeper lesions. Ultra-low-temperature cryoablation (ULTC) uses near-critical nitrogen instead of conventional nitrous oxide, allowing the temperature to drop as low as  $-196^{\circ}\text{C}$ . In vivo sheep and swine models showed how ULTC was able to create deep and contiguous atrial and ventricular lesions.<sup>10</sup> De Potter et al.<sup>11-13</sup> recently published the first-in-human experience of ULTC in the ventricle, demonstrating its feasibility to ablate VT in a multicentre series of 13 patients. The purpose of this paper is to describe a single-centre experience on the largest series of patients worldwide undergoing ULCA for VT ablation.

## Methods

This is a prospective, single-arm, single-centre experience. All patients were recruited and ablated at McGill University Health Centre (MUHC) from July 2022 to April 2023, as part of the first-in-human **Cryoablation for Monomorphic Ventricular Tachycardia** (CryoCure-VT; NCT04893317) clinical trial. The study protocol was approved by the ethics committee, and all patients signed informed consent forms. Data collection and trial procedure were in accordance with Declaration of Helsinki.

## Inclusion criteria

Patient population included men and women with ischemic or nonischemic cardiomyopathy with symptomatic monomorphic VT scheduled for an endocardial ablation if  $\geq 18$  years of age, refractory to at least 1 AAD (refractory was defined as occurrence of VT despite the AAD or inducing unwanted side effects), has or will be receiving an ICD before hospital discharge postprocedure, with left ventricle ejection fraction (LVEF)  $> 20\%$  confirmed by echo or comparable technique during baseline evaluation and willing to give informed consent and participate in baseline and follow-up visits.

## Exclusion criteria

The exclusion criteria included contraindication for VT ablation, polymorphic VT, any VT ablation within 4 weeks before enrollment; more than 1 previous ( $> 4$  weeks) VT ablation or previous surgical treatment for VT, VT secondary to electrolyte imbalance, active thyroid disease, or any other reversible or noncardiac cause, structural heart disease, history of cryoglobulinemia, history of blood clotting or bleeding disease, history of documented cerebral vascular accident (CVA), transient ischemic attack (TIA) or systemic embolism within 6 months, pregnancy, or enrollment in any other study

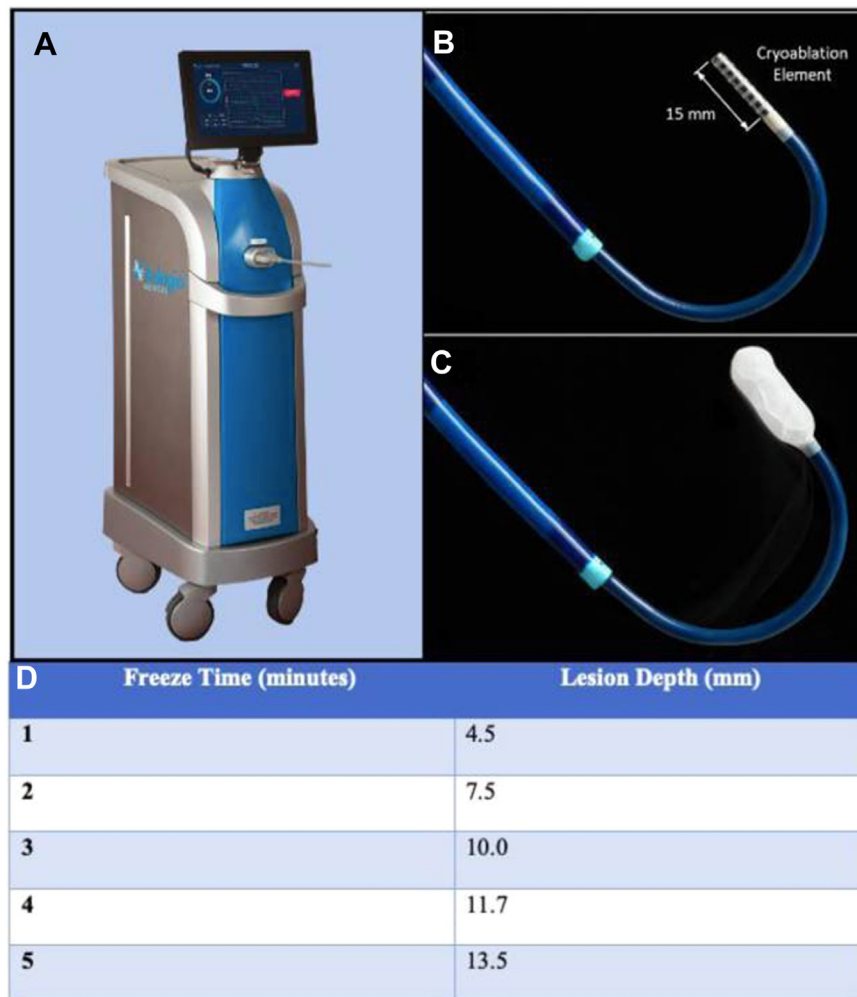
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<sup>†</sup>These authors contributed equally to this manuscript as first authors.

Corresponding author: Dr Atul Verma, Division of Cardiology, McGill University Health Centre, D13.173, 1650 Cedar Avenue, Montréal, Québec H3G 1A4, Canada. Tel.: +1-514-934-1934, ext 34630.

E-mail: [atul.verma@mcgill.ca](mailto:atul.verma@mcgill.ca)

See page 567 for disclosure information.



**Figure 1.** (A) Cryoablation console. (B) Cryoablation catheter before freezing. (C) Cryoablation catheter with the ice ball forming on cryoablation element. (D) Ventricular lesion depth as a function of freeze time using first freeze-1 minute thaw-second freeze. Image adapted from Sanchez-Somonte et al.,<sup>13</sup> with permission from Adagio Medical, Inc.

protocol in which testing or results may interfere with the procedure or outcome.

### Ablation protocol

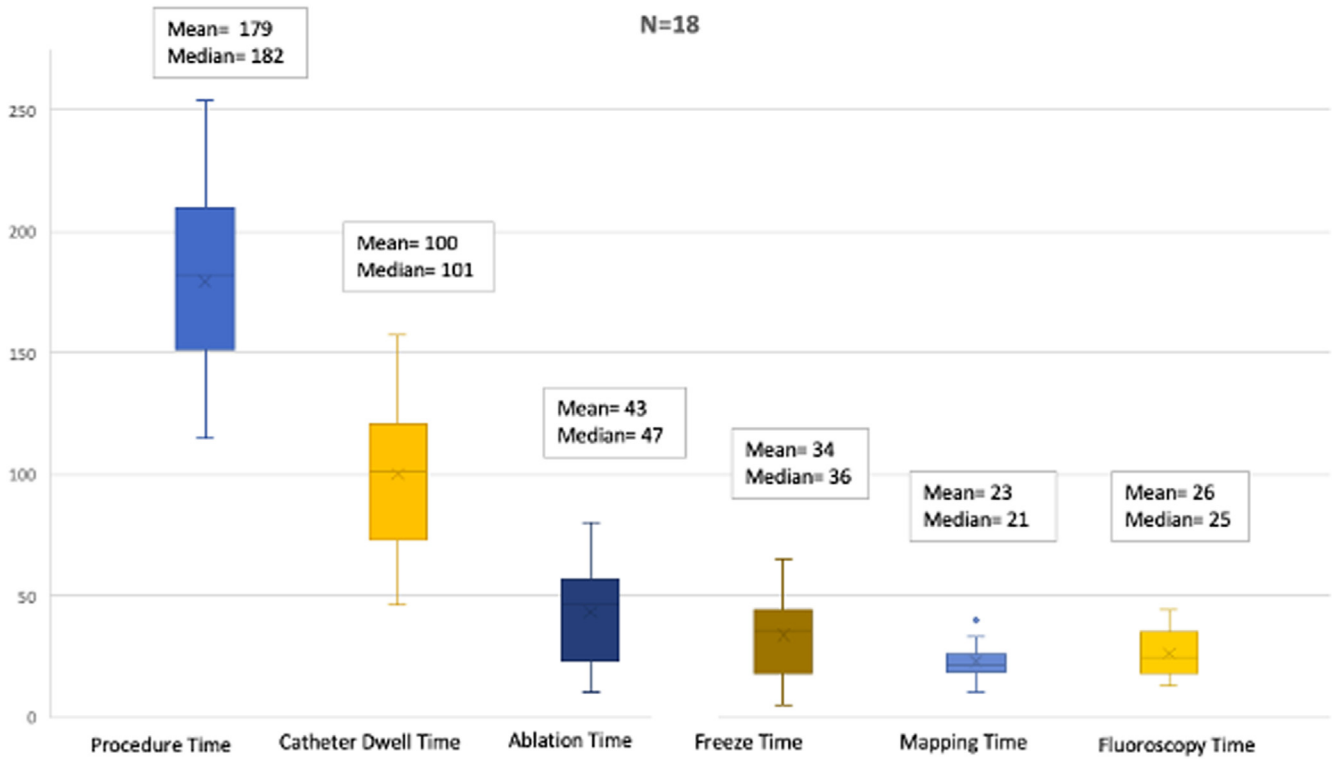
All ablations were performed with the Adagio Medical VT Cryoablation System (Adagio System, Adagio Medical, Laguna Hills, California, USA) that includes the cryoablation console and the VT cryoablation catheter. The console consists of a reusable electromechanical device that contains an internal reservoir for the liquid nitrogen. The nitrogen is pressurized and delivered to the cryoablation catheter, creating the cryogenic temperatures ( $-196^{\circ}\text{C}$ ) to ablate cardiac tissue. The cryoablation catheter is a single-use, sterile, 9-Fr device that has freezing distal tip that can be used for focal ablation. It has 8 electrodes strategically positioned along the freezing section and is compatible with commercially available 10-Fr steerable or nonsteerable guide sheaths (Fig. 1).

All procedures were done under general anesthesia. Arterial blood pressure was monitored in all cases. Access to the left ventricle (LV) was obtained via transeptal access, retroaortic access or both. Intracardiac echo (ICE) was used

to guide transeptal puncture, identify the LV wall thickness, and monitor for pericardial effusion. Ensite Precision (Abbott, Minneapolis, Minnesota, USA) was used for all cases, and electroanatomic mapping of the LV was performed with the high-density (HD) grid catheter (Abbott). Baseline voltage map was performed during sinus rhythm or right ventricle (RV) pacing. Peak-to-peak amplitudes of 0.5 mV to 1.5 mV and  $< 0.5$  mV were used to define the low-voltage zone and the dense scar zone, respectively. Regions of interest (diastolic potentials and local abnormal ventricular activities [LAVAs]) were identified and labelled into the map as target sites. In addition to LAVAs and diastolic potentials in the scar area, pace mapping, entrainment mapping, or relatively early activation during VT were used to identify the target sites.

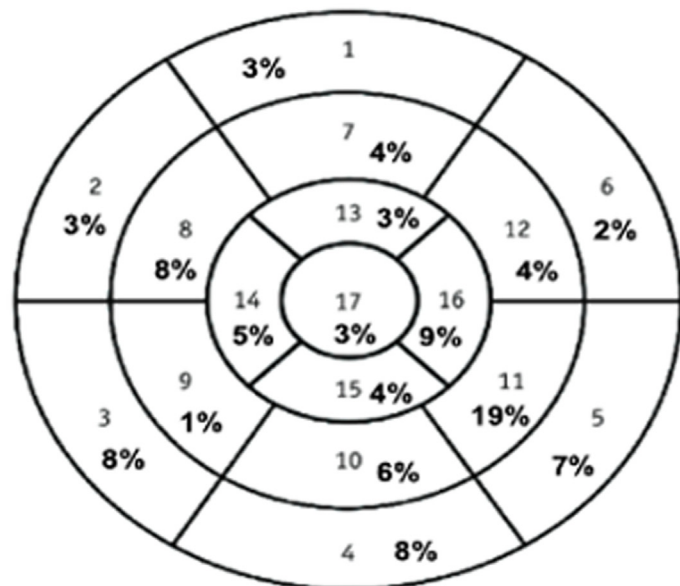
Once the map was completed, VT was induced with the use of programmed ventricular pacing. Our standard protocol consisted of a 6- to 8-beat drive train at the RV apex or outflow tract at cycle length of 600 ms and 400 ms. When a single extrastimulus did not induce VT, a second was added—and up to a third—if needed, until refractoriness. If

### A Procedure related times



### B Percentage of lesions delivered in each AHA segment of the heart

1. Basal anterior
2. Basal anteroseptal
3. Basal inferoseptal
4. Basal inferior
5. Basal inferolateral
6. Basal anterolateral
7. Mid anterior
8. Mid anteroseptal
9. Mid inferoseptal
10. Mid inferior
11. Mid inferolateral
12. Mid anterolateral
13. Apical anterior
14. Apical septal
15. Apical inferior
16. Apical lateral
17. Apex

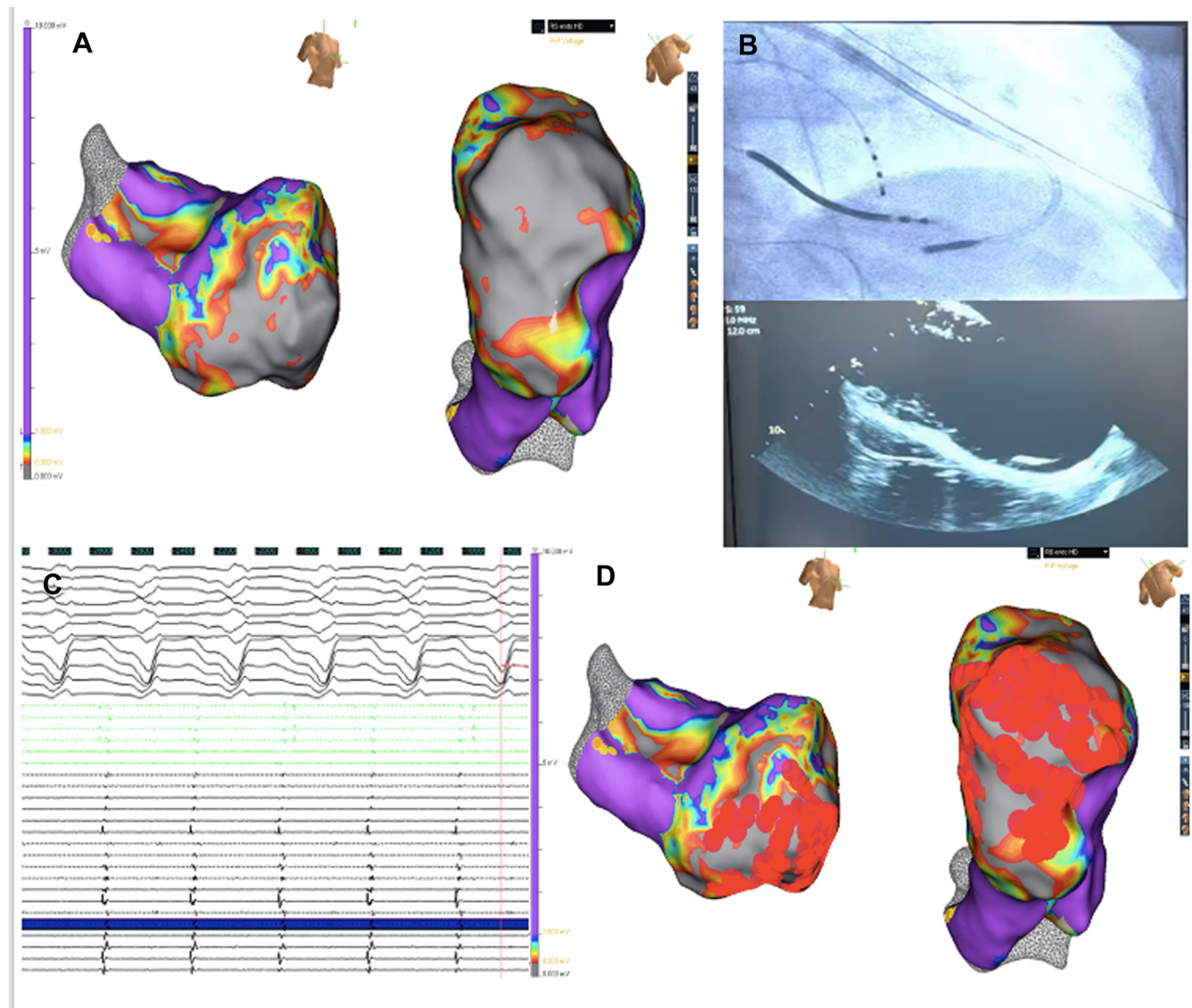


**Figure 2.** (A) Procedure related times (minutes). (B) The 17-segment American Heart Association (AHA) model<sup>14</sup> showing the percentage of lesions delivered in each segment. The total number of lesions delivered was 177, and the area most commonly ablated was the mid-inferolateral wall.

VT could not be induced, the same protocol was repeated from the LV.

If the target VT was stable, activation mapping was performed. If not, VT was terminated. The HD grid was

exchanged for the cryoablation catheter and voltage-based ablation, substrate-based ablation, and scar homogenization (complete elimination of all abnormal potentials) were performed.



**Figure 3.** (A) Endocardial bipolar substrate map showing scar involving the inferior and inferoseptal wall (voltage scale 0.3–1 mV). (B) Fluoroscopic and intracardiac echocardiographic (ICE) images of the ultra-low-temperature cryoablation catheter positioned in the inferior wall during ablation. (C) Ventricular tachycardia induced after programmed stimulation originating from the inferoapical wall. (D) Endocardial bipolar substrate map with cryoablation lesions in red, covering all scar area.

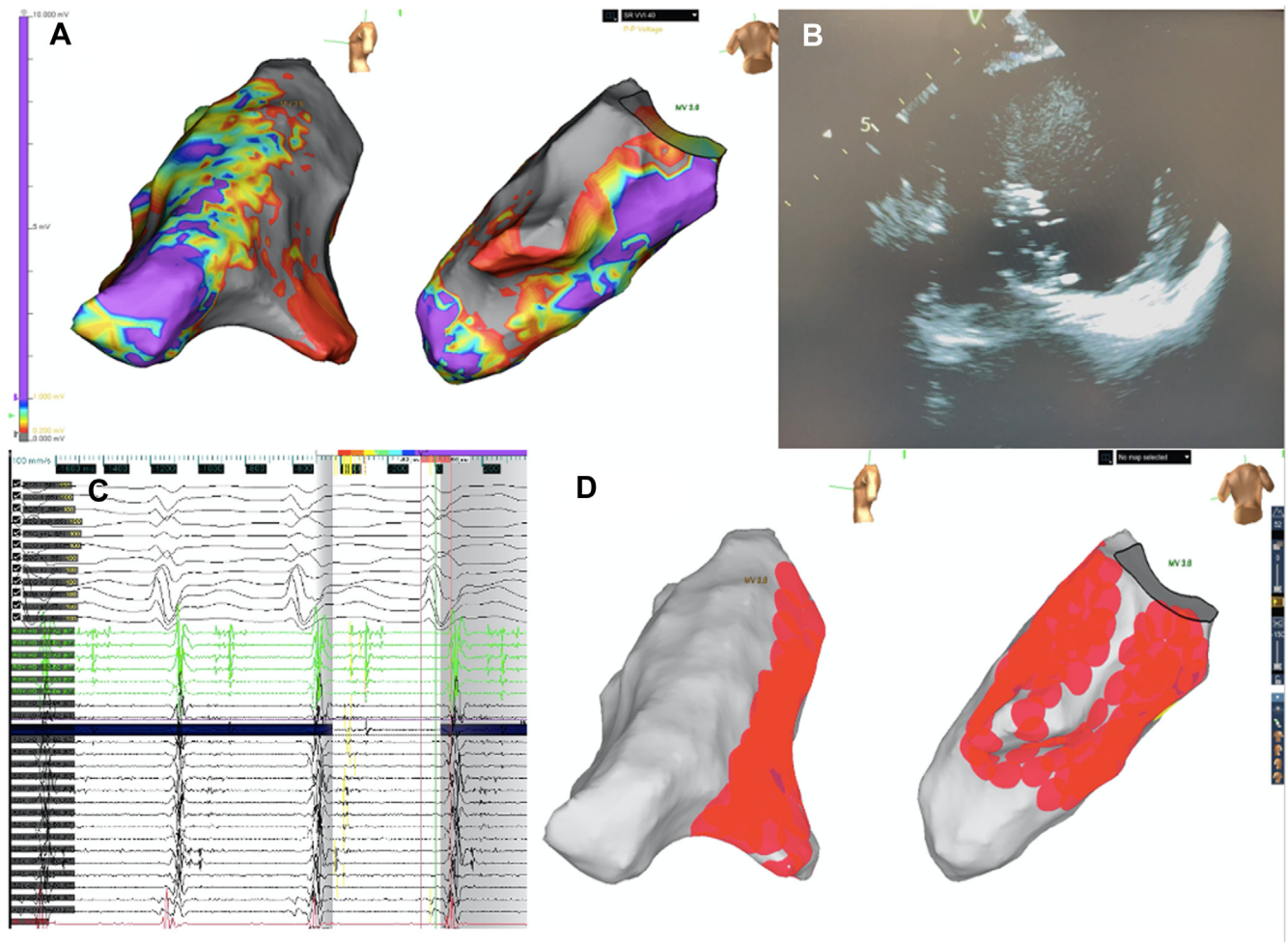
To create 1 ULTC lesion, all patients received 2 ablations in a freeze-thaw-freeze ablation cycle fashion. The duration of the freeze was chosen depending on the desired depth of the lesion. Operators chose the depth based on wall thickness measured by ICE. Figure 1 shows the freeze time manufacturer recommendations based on the lesion depth desired. These recommendations derived from preclinical data.<sup>10</sup> Once ablation was considered to be complete, programmed stimulation was performed again, following the same pre-ablation protocol, and if VT still was inducible, additional cryolesions were delivered, if needed. Average procedural times are shown in Figure 2. Figures 3 and 4 show examples of 2 different cases (substrate maps preablation, ICE images, and anatomic maps with cryolesions postablation).

### Statistical analysis

Descriptive statistics for all variables were applied, continuous data are reported as mean  $\pm$  standard deviation (SD), and categorical variables are presented as frequency (percentage).

### Results

A total of 18 patients with ischemic and nonischemic cardiomyopathy with previous ICDs and documented monomorphic VT resistant to antiarrhythmic drugs were prospectively enrolled. None of the patients enrolled was in cardiogenic shock or required mechanical support. Two



**Figure 4.** (A) Endocardial bipolar substrate map showing scar involving the inferolateral wall (voltage scale 0.2–1 mV). (B) Intracardiac echocardiographic (ICE) images of the left ventricle with a large inferior aneurysm. (C) Ventricular tachycardia induced after programmed stimulation with diastolic potentials noted on the diagnostic mapping catheter. (D) Three-dimensional anatomic map of the left ventricle with cryoablation lesions in red, covering the inferior basal scar and aneurysm. (Each ablation was tagged with 3 overlapped red dots. Furthermore, each ultra-low-temperature cryoablation (ULTC) lesion required a second ablation (ie, 2 ablations per lesion), which was marked with a second set of superimposed lesion tags).

patients had history of VT storm within 1 month of preablation, but both of them were stable at the moment of the procedure.

Mean LVEF was 32%, mean age 71 years, 94% were male, and 72% had coronary artery disease. Mean number of sustained or ICD-treated VT episodes per patient before ablation was  $21 \pm 62$  (minimum 1 and maximum 270 VT episodes; median = 5.5 VT episodes; interquartile range [IQR] = 9). Baseline characteristics are listed in Table 1.

### Procedure characteristics

Before ablation, sustained VT was induced in 16 of 18 patients. One patient was noninducible at baseline, and 1 patient was only inducible with a nonsustained clinical VT. Among those 16 patients, a total of 32 VTs were induced during the procedure (mean of  $2.0 \pm 1.7$  VT per patient, median = 1; IQR = 1). Of the 32 VTs, 28 were clinical VTs (87.5 %).

Mean ablation strategy per patient was  $1.6 \pm 0.5$  (median = 2; IQR = 1). Substrate mapping was performed in 12 patients (66.7%), activation mapping in 7 patients (38.9%), entrainment mapping in 2 patients (11.1%), and pace mapping in 3 patients (16.7%). The mean procedure time was 173 minutes, mean ablation time 44 minutes, and mean fluoroscopy time 26 minutes. Procedure characteristics are summarized in Table 2.

A total of 177 cryoablation lesions were delivered (mean of  $9.8 \pm 5$  per patient; median = 9.5; IQR = 8.5). Figure 2 summarizes the 17-segment American Heart Association model<sup>14</sup> in which the lesions were delivered. The area most commonly ablated was the mid-inferolateral wall (19%), followed by the apical lateral wall (9%). Mean freezing time was  $9.8 \pm 5$  minutes (median = 35.5 minutes; IQR = 26).

All 16 patients with inducible VT previous ablation were rendered noninducible for their clinical VT by the end of the case (Table 3). Only 1 patient had inducible nonclinical VT postablation after successful ablation of the clinical VT. In this

**Table 1. Baseline characteristics**

Demographics	n = 18
Age (years)	71 ± 11
Male gender	94.4% (17/18)
LVEF, %	32% ± 9%
Coronary artery disease	72.2% (13/18)
Previous myocardial infarction	88.9% (16/18)
Hypertrophic cardiomyopathy	5.6% (1/18)
Congestive heart failure	50% (9/18)
Valvular disease	16.7% (3/18)
ICD before ablation	94.4% (17/18)
Previous VT ablations	0%

ICD, implantable cardioverter defibrillator; LVEF, left ventricular ejection fraction; VT, ventricular tachycardia.

case, the procedure was terminated after 2 additional ablation lesions were delivered, without repeating inducibility testing postablation. No other nonclinical VT were induced postablation in other patients. Ablation parameters per-patient bases are summarized in [Supplemental Table S1](#).

In all cases, VTs were eliminated with the cryoablation catheter alone, and no patients required the use of a standard radiofrequency catheter to complete the ablation.

## Complications

Complications included 1 pericardial effusion that required drainage. This patient had a very thin apical aneurysm (4-mm wall thickness). Five cryolesions were delivered in this area. Freeze time per lesion was 1 minute; 3 of them were delivered in the septoapical wall, 1 in the inferoapical wall, and 2 in the lateroapical wall). During ablation, first a small effusion was seen with no hemodynamic repercussion. After completion of the ablation, it was decided to place a pericardial drain because the effusion appeared to have increased in size in the context of a decrease in blood pressure. The pericardiocentesis was complicated with a hepatic laceration resulting in bleeding that required blood transfusion. The patient recovered with conservative medical management and was discharged 14 days postablation. No other complication was seen. Sixteen patients (89%) were discharged within the first 24 hours postablation.

## Discussion

This report represents the largest series of patients undergoing ULTC for VT ablation worldwide. ULTC has demonstrated its feasibility to control drug refractory VT during VT ablation with a high acute success rate and an acceptable safety profile and may be an effective ablation modality for formation of deep ventricular lesions.

Conventional radiofrequency (RF) ablation for VT already proved its superiority to escalation of AADs in patients with ischemic cardiomyopathy.<sup>3</sup> However, contact-force open-irrigated catheters still have limited tissue penetration, and this acquires special relevance when substrates are transmural or located mid-myocardial. With the purpose of overcoming this limitation, and to reduce the currently high recurrence rate post-VT ablation,<sup>3,15</sup> other technologies have been developed and tested.<sup>16</sup> The use of low irrigants, impedance modulation, bipolar ablation, or infusion RF needle ablation have

**Table 2. Procedure characteristics**

VT inducibility data	(n = 18)
Total number of VT induced	32
VTs induced per patient*	2.0 ± 1.7
Patients according to number of induced VTs	
n = 0	2 (11.1%)
n = 1	8 (44.4%)
n = 2	6 (33.3%)
n = 3	0 (0%)
n = 4+	2 (11.1%)
% Clinical VTs	87.5% (28/32)
Cycle length (CL) of clinical VTs	391 ± 84 ms
% Hemodynamically stable VTs	56.3% (18/32)
<b>Mapping strategies</b>	<b>(n = 18)</b>
Substrate mapping	12 (66.7%)
Activation mapping	7 (38.9%)
Entrainment mapping	2 (11.1%)
Pace mapping	3 (16.7%)
<b>Ablation strategies</b>	<b>(n = 18)</b>
Substrate-based ablation (scar homogenization)	18 (100%)
VT isthmus	1 (5.6%)
VT exit sites	3 (16.7%)
Scar dechanneling	6 (33.3%)
Slow conduction channel	1 (5.6%)
LAVA elimination	2 (11.1%)
Average number of strategies per patient	1.7
Average lesions per patient	9.8 ± 5.0
Minimum lesions per patient	3
Maximum lesions per patient	21
Freeze time per lesion including second freeze per site (minutes)	3.6 ± 1.0

LAVA, local abnormal ventricular activities; VT, ventricular tachycardia.

\* From 18 patients ablated, 1 patient was noninducible at baseline, and 1 was inducible with nonsustained clinical VT. The number of VTs induced per patient is reported for the 16 patients with inducible sustained VT.

demonstrated increasing lesions size but also have the potential to increase the risk for complications.<sup>17-21</sup>

ULTC uses near-critical nitrogen, and—compared with traditional cryoablation, which uses gaseous nitrous oxide—near-critical nitrogen has a much more favourable cryogenic properties and is able to generate temperatures as low as -196 °C, thus creating a more transmural lesion.<sup>10</sup> The cryoablation catheter consists of a 9-Fr deflectable device with a 15-mm cryoablation element and 8 electrodes equally positioned along the freezing section. Manipulation of the catheter is similar to a conventional deflectable RF tip irrigated catheter and has the advantage to provide a better stability during creation of lesions because of cryo-adhesion to the myocardium. Another potential advantage is the ability to deliver substrate-tailored lesions by titrating ablation duration according to desired lesion depth for each location targeted during VT ablation.

De Potter et al.<sup>11</sup> already demonstrated results of ULTC for VT in a multicentre series of series of 13 patients. Among the 12 patients with inducible VT at baseline, 11 underwent repeat inducibility testing postablation; 7 (64%) had full success (no inducible VT), and 3 (27%) had partial success (inducible nonclinical VTs). The current study reports on a mutually exclusive series of 18 patients who underwent ULTC for VT ablation at a single centre in Canada. Among the 16 patients with inducible sustained

**Table 3. Acute success based on patients undergoing reinduction postablation\***

	(n = 16)
Failure (inducible clinical VTs)	0
Partial success (inducible nonclinical VTs) <sup>†</sup>	6% (1/16)
Full success (noninducible)	94% (15/16)
% of clinical VTs eliminated	100% (28/28)

VT, ventricular tachycardia.

\*From 18 patients, 1 patient was noninducible at baseline (and repeat inducibility testing was not performed postablation), and another patient was inducible only for nonsustained clinical VT (which was no longer inducible with repeat inducibility testing postablation). This table includes only the 16 patients with inducible sustained VT at baseline.

<sup>†</sup>One patient had inducible clinical VT at baseline that was successfully ablated. Repeat inducibility testing postablation failed to reinduce the clinical VT but induced a faster nonclinical VT requiring pace termination. The procedure was terminated after 2 additional ablation lesions were delivered, without repeating inducibility testing post ablation.

VT at baseline, acute full success (elimination of all inducible VT) was achieved in 15 (94%) patients and partial success (elimination of the clinical VT but inducible nonclinical VT) in 1 (6%) patient. Although long-term follow-up data are not yet available, previous clinical trial data has shown that noninducibility post-VT ablation correlates with favourable clinical outcomes.<sup>22</sup> Based on these early acute clinical outcomes, ULTC appears to be a potentially effective modality for VT ablation.

Regarding the complication rate, 1 patient (5.6%), had pericardial effusion that required drainage. There were no other complications, and 89% of the patients were discharged within the next 24 hours postablation.

The patient who required pericardiocentesis had a very high VT-burden previous ablation originating from a very thin apical aneurysm. The wall thickness of the aneurysm was 4 mm, and 5 lesions were delivered (total freeze time of 1 minute each lesion). This may suggest that manufacturer recommendations (based on the lesion depth desired and selected based on wall thickness) may not apply as well for this kind of very thin, scarred, and aneurysmal tissue. In this context, recommendations to perform ULTC following manufacturer recommendations among these patients should be taken cautiously, and lesions may need to be shorter and less aggressive.

In any case, the complication rate is comparable with rates reported in the literature for conventional VT ablation<sup>23</sup> and lower than those reported for other advanced approaches.<sup>17-21</sup> In this sense, ULTC appears relatively safe and effective, but, ultimately, larger trials assessing long-term recurrences post-VT ablation will be required.

### Limitations

This was a single-centre study; there was absence of a control group; and there was a moderate number of patients. This study is limited to acute efficacy and safety outcomes, with longer-term outcomes to become available upon completion of the CryoCure-VT (NCT04893317) clinical trial.

### Conclusions

ULTC is feasible and permits control of monomorphic VT during VT ablation procedures in drug-refractory patients with a very high acute success rate and an acceptable safety profile. Further research regarding long-term outcomes is required and is ongoing.

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### Ethics Statement

The study protocol was approved by the ethics committee and all patients signed the informed consent. Data collection and trial procedure were in accordance with Declaration of Helsinki.

### Patient Consent

The authors confirm that patient consent forms have been obtained for this article.

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### Supplementary Material

To access the supplementary material accompanying this article, visit *CJC Open* at <https://www.cjopen.ca/> and at <https://doi.org/10.1016/j.cjco.2023.11.009>.