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Electrophysiology lab efficiency using cryoballoon for pulmonary vein isolation in central and eastern Europe: A sub-analysis of the Cryo Global Registry study

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Abstract

Background: *Cryoballoon ablation for treatment of atrial fibrillation (AF) reduces procedure times, but limited data is available about its impact on electrophysiology (EP) lab efficiency in Central and Eastern Europe (CEE). Using CEE-specific procedure data, the present study modeled cryoballoon ablation procedures on EP lab resource consumption to improve efficiency.*

Methods: *A discrete event simulation model was developed to assess EP efficiency with cryoballoon ablation. Model inputs were taken from CEE sites within the Cryo Global Registry, namely Czech Republic, Hungary, Poland, Serbia, and Slovakia. The main endpoints were percentage of days that resulted in overtime and percentage of days with time for one extra simple EP procedure. Use of the 'figure of 8' (Fo8) closure technique to reduce procedure time was also examined.*

Results: *The mean lab occupancy time across all CEE sites was 133 ± 47 minutes (min: 104 minutes, max:181 minutes). Cryoballoon ablation in the base-case scenario resulted in 14.6% of days with overtime and 64.8% of days with time for an extra simple EP procedure. Use of the Fo8 closure technique enhanced these values to 5.5% and 85.3%, respectively. Model endpoints were most sensitive to changes in lab occupancy times and overtime start time.*

Conclusions: *In this CEE-specific analysis of EP lab efficiency it was found that 3 cryoballoon ablation procedures could be performed in 1 lab day, leaving time for a 4th simple EP procedure on most days. As such, use cryoballoon ablation for PVI is an effective way to improve EP lab efficiency.* (Cardiol J 2024; 31, 5: 656–664)

Keywords: cryoballoon, catheter ablation, pulmonary vein isolation

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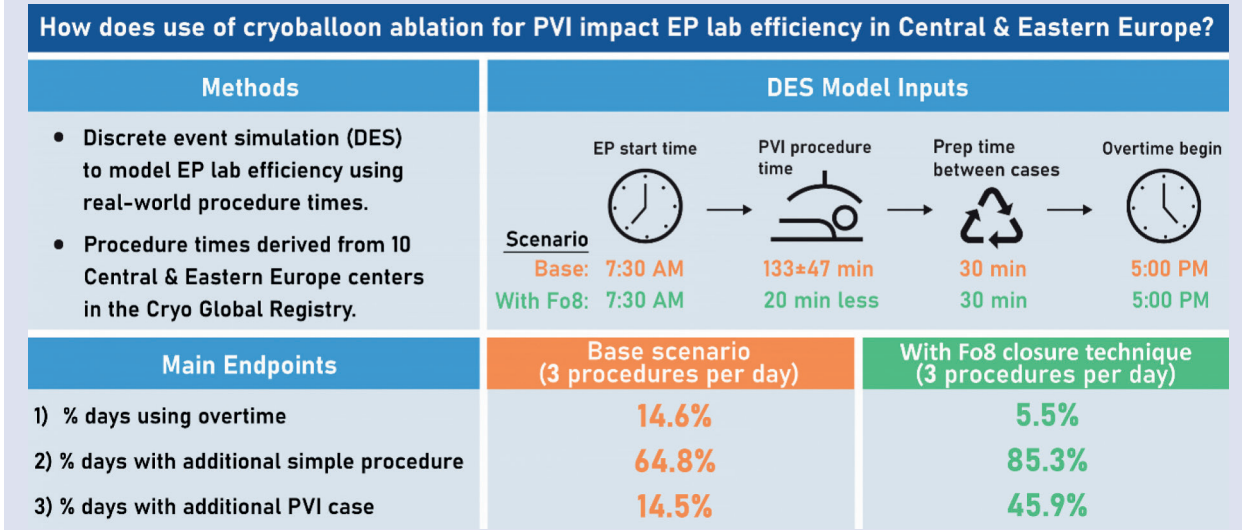
Central illustration

The impact of cryoballoon for PVI ablation on EP lab efficiency in central and eastern Europe



Introduction

The incidence of atrial fibrillation (AF) continues to surge globally spurned by an increase in the aging population and in individuals (regardless of age) with AF risk factors [1]. As a result, catheter ablation procedures used to terminate abnormal AF rhythms are also on the rise [2]. For example, in Europe from 2007 to 2016, the number of catheter ablation procedures doubled from 156 to 378 per million people [3].

The cornerstone of all AF ablation strategies is electrical isolation of the pulmonary veins (PVs) [4]. Since the PVs have been identified as the major trigger for initiation and perpetuation of AF, different strategies and technologies were developed aiming at durable PVI [5, 6]. Cryoballoon ablation was developed specifically for PVI and several clinical trials have demonstrated its safety and efficacy in treatment of paroxysmal and persistent AF patients [7–10]. In addition, utilization of cryoballoon ablation as an initial rhythm control strategy in patients with paroxysmal AF resulted in significantly improved outcomes compared to antiarrhythmic drugs in terms of AF symptom control, quality of life and healthcare utilization in different healthcare settings [7]. Ablation for PVI is generally a complex procedure that requires skilled physicians and technologically tailored electrophysiology (EP) labs. Thus, with increasing numbers of ablation procedures and expanding indications for ablation, deliberate management of EP lab resources will be paramount to maximize the number of procedures performed in a day.

Cryoballoon ablation has improved EP lab efficiency compared to conventional point-by-point radiofrequency ablation by decreasing procedure times and providing a shorter learning curve for operator mastery [11–14]. Optimizing EP lab efficiency will require region-specific data, but data is lacking in several regions across the globe including Central and Eastern Europe (CEE). Thus, more research is needed to determine how newer cryoablation technology, operator experience, and increased patient burden will impact EP lab efficiency in CEE. Using CEE-specific data derived from the Cryo Global Registry, the current study modeled the effect of cryoballoon ablation on EP lab resource consumption to determine pathways that can minimize hospital and EP lab burden in CEE.

Methods

Cryo Global Registry cohort and procedural details

The Cryo Global Registry (NCT02752737) is an ongoing, prospective, global, post-market registry examining the effectiveness and safety of cryoablation using Medtronic ablation tools [9–16]. The registry also collects operational data including procedure and lab occupancy times, which were used for this analysis. Procedure time was defined as the duration from initial venous access to removal of the last sheath. Lab occupancy time was classified as the duration from the patient entering

the EP lab to when they exited the lab. For the purposes of this study, the data used was made available from CEE countries including the Czech Republic, Hungary, Poland, Serbia, and Slovakia. Patients aged 18 years or older with a planned cryoballoon ablation procedure was included in the registry.

The cryoablation procedure has been described previously [17, 18]. Briefly, the patients first received an optional trans-esophageal echocardiogram (dependent on patient heart rhythm and anticoagulation status). Following transseptal puncture, a FlexCath advance sheath (Medtronic) was guided into the left atrium. The cryoballoon (Arctic Front Advance, Medtronic) was then inserted into the pulmonary veins using either a guidewire or dedicated mapping catheter (Achieve, Medtronic). At the discretion of the operating physician, a Freezor focal cryoablation or other focal radiofrequency (RF) catheter could be used for PVI touch-up and/or, in qualifying patients, a cavotricuspid isthmus line was created.

Discrete event simulation model operation

To assess EP lab utilization during days when performing PVI ablation procedures, a discrete event simulation (DES) model was created using the lab occupancy times from the Cryo Global Registry. A DES model is intended to analyze complex systems over time based on discrete events while focusing on interactions between entities (objects that move through the system), and this type of model is especially useful in analyzing efficient use of resources in a healthcare setting [19, 20].

The model structure used for this analysis has been previously described [13]. To summarize, direct entities of the model included physicians, support staff, patients, and the EP lab, all of which impact lab occupancy times. Both the physician and patient contributed to delaying the PVI procedure by drawing from defined distributions of delay time (Table 1). A PVI procedure in the DES model could not begin until physician and patient were available, and total procedure time was derived from a probability distribution of lab occupancy times. For each day, once the lab occupancy time was up, the entities were entered back into the model where the process would start again. The model was run for 1,000 days to account for daily variation. Also tracked were the percentage of days that resulted in: 1) overtime, or 2) enough extra time for 1 additional simple EP procedures (e.g. pacemaker implant, defibrillator replacement), which was defined as 1 hour. A flow chart depicting the model overview can be found in Figure 1. The SIMUL8 professional version 30.0 (SIMUL8 Corporation) program was used to run the DES model.

Table 1. Model inputs

	Current		
Model parameter	**Base case**	**High**	**Low**
Lab occupancy time (minutes)	133 ± 47	146 ± 47	120 ± 47
PVI cases per day	3	N/A	N/A
First case start times	7:30am	8:00am	7:15am
Overtime begin time	5:00pm	5:30pm	4:30pm
Time for additional simple EP case (minutes)	60	75	45
Time for additional PVI case	165	180	150
Room turnover time (minutes)	30	40	20
Delays (minutes)			
Physician	0–20	0–40	0–10
Patient operational	0–10	0–20	0

EP — electrophysiology; PVI — pulmonary vein isolation

DES model inputs

The model assumed that three PVI procedures could be performed in one day and that the EP lab had PVI-dedicated days. Lab occupancy times for PVI procedures or PVI-equivalent procedures were taken from the Cryo Global Registry and supplemented with additional EP lab management information (time between procedures, shift scheduling, etc.) that was gathered by surveying of CEE sites that participated in the Cryo Global Registry. Delays during an operation were based on qualitative research, including 1) standardized 30 minutes for EP lab turnover time, 2) 0 to 10-minute distribution for patient delays, and 3) 0 to 20-minute distribution for physician delays. The first procedure of the day was assumed to begin at 7:30 AM, and the consecutive procedure began once EP lab turnover time between procedures was accounted for. Overtime was assumed to begin at 5:00 PM. Details on all model inputs are listed in Table 1.

Model validation, scenario, and sensitivity analysis

Model validation was performed by comparing procedure and lab occupancy times from the simulation to those from the Cryo Global Registry.

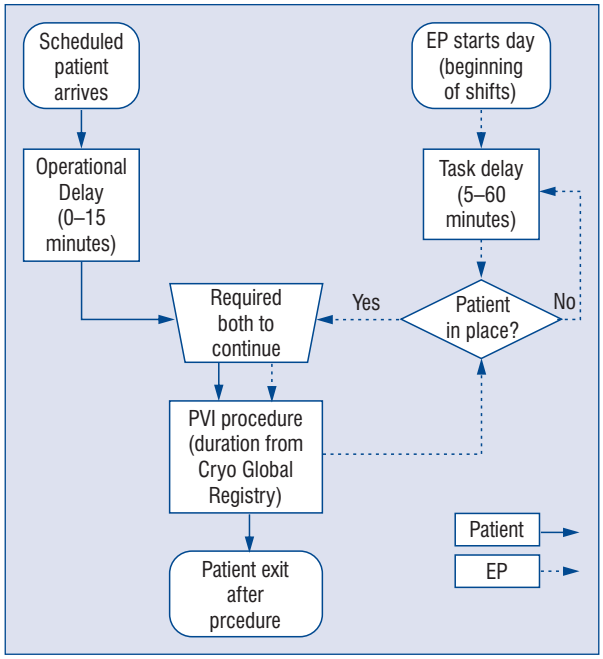


Figure 1. Discrete event simulation model operation. The key entities in the model are the patient, the physician, and the EP lab. When the patient (solid line) and physician (dashed line) arrive at an empty lab, the PVI procedure commences within the model using a time drawn from the probability distribution derived from the Cryo Global Registry. This is repeated for the prescribed number of cases in each lab day

A separate Figure of Eight scenario was simulated to explore the potential impact of using a "figure of eight" (Fo8) closure technique, which is modeled by assuming the same PVI procedure time but reducing the total PVI procedure lab occupancy time by 20 minutes [21, 22]. Additionally, a deterministic sensitivity analysis was performed by individually varying each duration input (mean lab occupancy time, turnover time, and lab shift end) to a "High" end-of-the-range value and a "Low" end-of-the--range value which represented the outer edge scenarios on either side of the base-case scenario (Table 1). Given that the DES model is already random in nature, a probabilistic sensitivity analysis was not performed.

Statistics

Descriptive raw data taken from the Cryo Global Registry was reported as the mean and standard deviation with 10th and 90th percentile values. Primary outputs from the model were reported as percent days that resulted in overtime or percent resulting in time for additional simple EP procedures. Best fit distributions were used to define variability in lab occupancy time. By running the model for 1,000 days, the mean simulated lab occupancy time fell within 3% of the expected mean, derived from the clinical trial, with 95% confidence. All graphs, plots and tables were created using Tibco Spotfire Analyst version 7.14.

Results EP lab occupancy time distributions

The range of lab occupancy times used in this analysis were derived from the Cryo Global Registry dataset specifically for procedures performed in the CEE region. This data included procedure data from 538 patients across 10 study sites including the Czech Republic (n = 32), Hungary (n = 128), Poland (n = 165), Serbia (n = 92), and Slovakia (n = 121). The patient baseline characteristics, treatment details, and clinical outcomes of the full cohort of patients were previously published [15].

Mean lab occupancy times ranged from 104 to 181 minutes across sites from CEE (Fig. 2A). The average lab occupancy time for CEE overall was 133 ± 47 minutes, with a 10th percentile of 81 minutes and a 90th percentile of 190 minutes (Fig. 2B). Detailed procedure times from the study were fit to a Gamma distribution as input to the DES model.

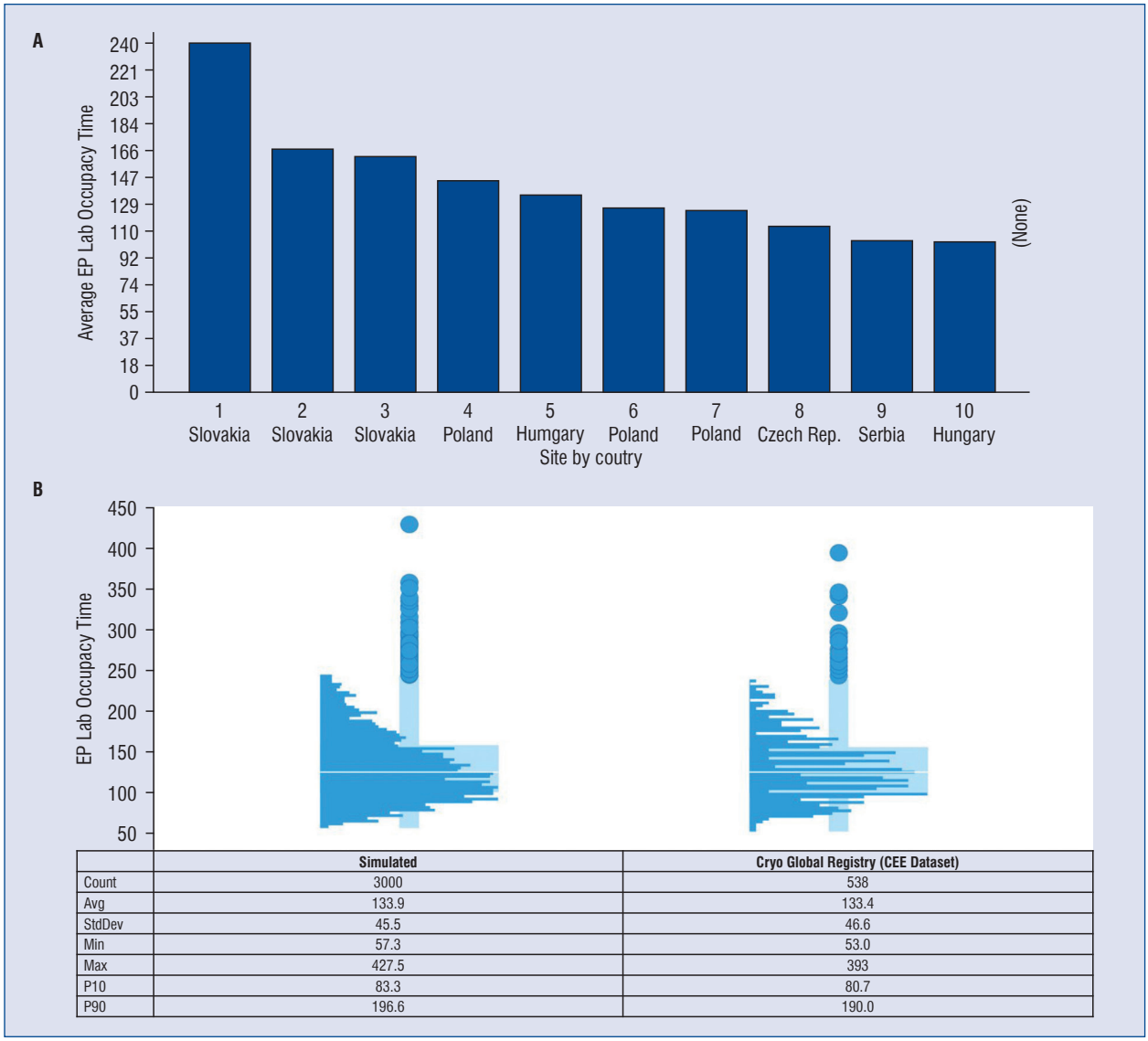
EP lab efficiency outcomes

A simulation of cryoballoon PVI procedures over the course of 1,000 EP lab days was performed. The simulation represented 3,000 total PVI procedures and resulted in cases that required overtime work in 146 (14.6%) of the simulated days, while 648 (64.8%) of the simulated days finished PVI cases early enough to allow time for an extra simple EP procedure without overtime (Table 2).

Validation, scenario and sensitivity analyses

Model validation was performed by comparing the EP lab occupancy time distribution assigned by the model to the actual lab occupancy time distribution from the study (Fig. 2B). Representative simulated case procedure times in the context of a full EP lab day are included in Figure 3.

When the model was configured to represent the Fo8 scenario, a simulation of 1,000 EP lab days with three cases per day showed a further minimization of overtime (overtime was required in 5.5% of days), and more consistently allowed



	Simulated	Cryo Global Registry (CEE Dataset)
Count	3000	538
Avg	133.9	133.4
StdDev	45.5	46.6
Min	57.3	53.0
Max	427.5	393
P10	83.3	80.7
P90	196.6	190.0

Figure 2. Lab occupancy times derived from the Cryo Global Registry and distribution compared to simulated model. **Panel A** shows average lab occupancy times for each of the Cryo Global Registry sites. **Panel B** The left distribution includes all individual lab occupancy times assigned by the DES model. The right distribution includes all individual lab occupancy times from CEE sites in the Cryo Global Registry

Table 2. Key metrics

Metric	Base case	Fo8 scenario
Total Days (Cases)	1,000 (3,000)	1,000 (3,000)
Overtime Days	146 (14.6%)	55 (5.5%)
Days with time for 1 additional simple EP case	648 (64.8%)	853 (85.3%)
Days with time for additional PVI case	145 (14.5%)	459 (45.9%)

EP — Electrophysiology; Fo8 — Use of "figure of eight" closure technique

for an extra simple EP procedure (extra procedure was possible in 85.3% of days). The Fo8 scenario also had enough time for a fourth PVI procedure in nearly half (45.9%) of the simulated days (Table 2, **Suppl. Fig. 1**).

The results of the sensitivity analysis for the overtime days, days with enough time for 1 additional simple EP case or 1 extra PVI are shown in Figure 4. The DES model was most sensitive to changes in lab occupancy time and the length of the lab day (overtime begin time). There was a higher incidence of overtime and fewer days with additional simple EP procedures when lab occupancy

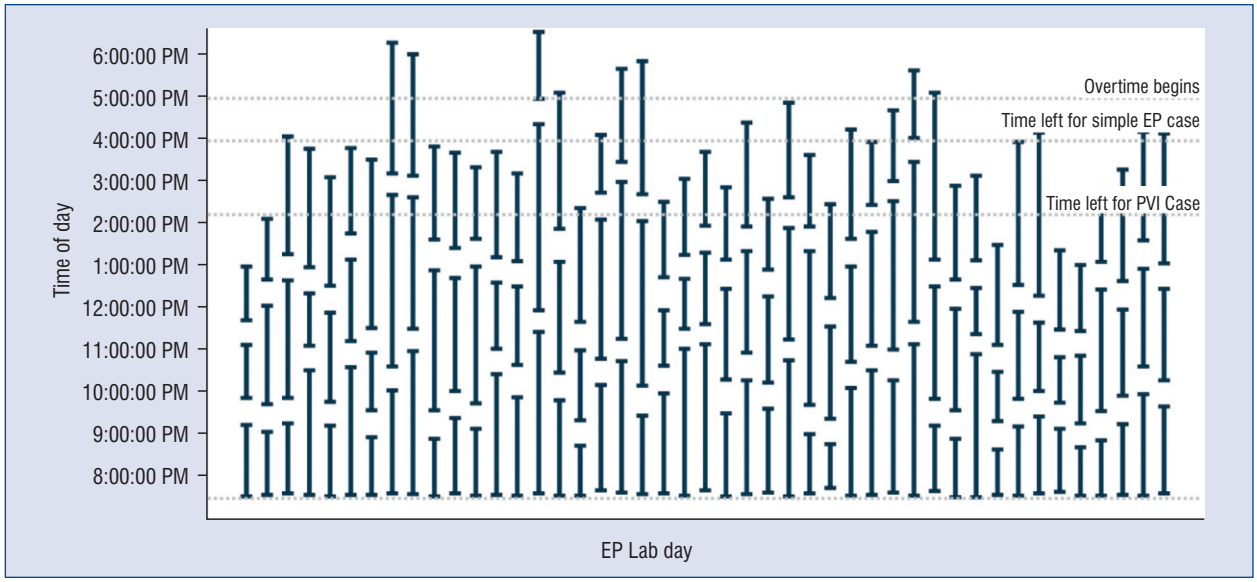


Figure 3. PVI case begin and end times per day. Represents the begin and end wall times for a sampling of days from the simulation, with each contiguous vertical line indicating the time of lab occupancy (the bottom end indicating the case begin time and the top end indicating the case end time). Cases were scheduled to start at 7:30 AM, and overtime began at 5:00 PM. Adequate time for an adjunctive simple EP procedure is represented between the labeled horizontal dashed lines

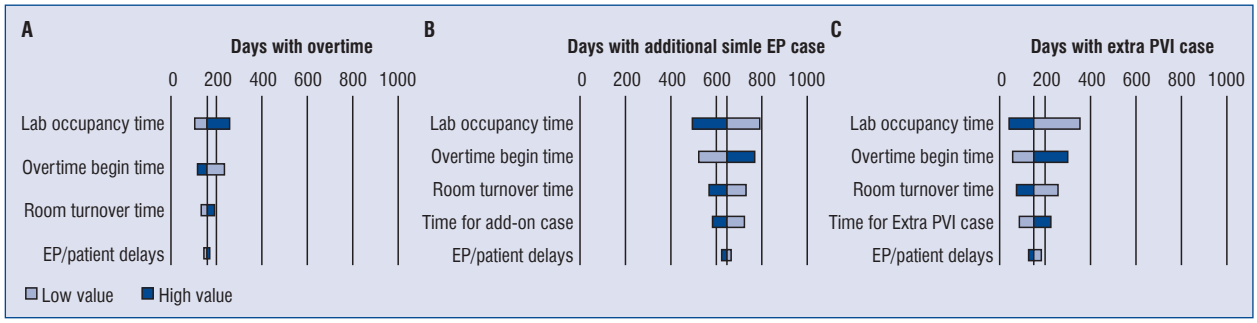


Figure 4. Sensitivity analyses. Each panel contains tornado charts showing the impact of varying the model inputs according to the High and Low values from Table 1. The x-axis represents the number of lab days that require overtime (**Panel A**), that allow time for an additional simple EP case (**Panel B**), or that allow time for an additional PVI case (**Panel C**) according to the model. The limits of the horizontal bar associated with each variable indicate the number of simulated overtime days when the indicated parameter is changed to the low value (light blue) or high value (dark blue) while holding the other variables constant

time was increased, the length of the lab day was shorter, or when room turnover time was longer.

Discussion

This analysis represents a contemporary picture of the efficiencies of an EP lab to perform PVI ablation procedures using cryo technology in a setting specific to centers in CEE. The findings make it clear that performing 3 PVI procedures per day is attainable with reasonable operational parameters, and on most days, there is enough time left to perform additional simple EP procedures. Days where staff overtime was necessary were rare (< 15% of days), and the amount of overtime was relatively small. The efficiency metrics were most sensitive to changes in lab occupancy time and end-of-day times (overtime start time). Additionally, there are opportunities for EP labs to further optimize procedural workflows and improve efficiency by adopting safe, effective and time-saving techniques at multiple stages of the ablation procedure, such as Fo8 closure technique or by utilizing "zero-exchange" integrated transseptal crossing device to achieve transseptal puncture [23, 24].

This analysis shows that EP labs in CEE can perform PVI ablation procedures as efficiently as other regions around the world and underscores the fact that cryoballoon ablation can support efficient EP lab management irrespective of location worldwide. In an early (2016) efficiency analysis in the United States (US), use of cryoballoon technology enabled the near elimination of staff overtime in the context of a lab performing two PVI procedures per day for paroxysmal AF as compared to RF ablations [13]. Procedure times steadily reduced over time, with a more contemporary (2021) single arm analysis of cryoballoon technology proving that three PVI cases per day for persistent AF were attainable in the US [25]. In the German healthcare system in 2023, the use of cryoballoon technology enabled three PVI cases per lab day and reduced the number of days requiring staff overtime from 70.7% to 25.7% with cryoballoon as compared to radiofrequency ablation, also increasing days with time for extra simple EP procedures [14].

The data from the Cryo Global Registry and supplied EP lab management information shows variations in EP lab efficiency between different CEE centers included in the registry. For example, the use of the Fo8 suture has been shown to reduce the EP lab occupancy time and improve the EP lab workflow [21]. The use of the Fo8 suture led to a further reduction of overtime and an increase in the number of days a simple EP procedure or even a fourth PVI procedure could be performed. Looking beyond the registry, variations in lab efficiency across different countries and also at different sites within the countries may be even greater. Differences may stem from a confluence of factors, including the unique historical trajectory and organizational dynamics of each institution, alongside the nuanced work practices prevalent within EP labs. Moreover, the center's cumulative experience, bolstered by the efficacy of its support staff and their specialized training as well as the work culture, supervision, and motivational frameworks also play a crucial role. To address these considerations, EP centers across CEE should employ comparative assessments, utilize benchmarking strategies and adopt best practices to optimize operational efficacy and enhance patient access to care.

CEE countries, like many other geographies [26], are facing challenges related to an overwhelmed healthcare system, healthcare staff shortage, and long waiting times for AF ablation procedures. Considering this, as well as the expected rise in AF patients, it will be crucial for healthcare systems to adopt efficient strategies in EP labs, such as the use of cryoballoon for AF PVI ablation, to optimize resources, procedural workflows, and improve patient access to care.

There were limitations associated with this analysis. While the Global Cryo Registry was designed to prospectively collect information on EP lab occupancy times, this analysis was not specified as a prospective objective of the registry. PVI ablation procedure data was only available for cryoballoon technology, thus there is no attempt to compare it to other technology options. Data on EP lab operational parameters (for example begin and end time of day) were not available directly from the registry, but were estimated using qualitative research with the sites involved in the registry. While acknowledging variations in standard of care, procedural characteristics, and EP lab management among CEE centers in the registry, the primary aim of this analysis was to evaluate efficiency at a typical center in the region, rather than to conduct direct comparisons between centers or seek correlations between procedural characteristics and EP lab efficiency. Instead, sensitivity analyses were performed that explore how changes in procedure times and EP lab management (model inputs) impacts efficiency. The economic implications of EP lab efficiency were not quantified as such an attempt would be confounded by variability in cost accounting between different healthcare systems in the region. However, these data could potentially be combined with site specific information to attempt such a quantification.

Conclusions

In this analysis of CEE-specific centers, cryoballoon ablation allowed for three procedures on most simulated days with minimal overtime, with two-thirds of days having enough time for a fourth simple EP procedure. Implementing the Fo8 closure technique further streamlined EP lab efficiency by leaving time for a fourth procedure on nearly 90% of simulated days. Use of cryoballoon ablation for PVI can reliably reduce lab occupancy time to allow for more procedures, which will help ease the growing burden of ablation procedures in CEE.

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Ethical approval: Data collection for the Cryo Global Registry adhered to Good Clinical Practice guidelines and the principles outlined in the Declaration of Helsinki. The Cryo Global Registry was approved by each site's institutional review board and local ethics committees, and each patient provided written informed consent for participation in the study.

Author contributions: The authors confirm contribution to the paper as follows: study conception and design: CF, RH, MSt, ASa; data collection: RH, MSt. Author; analysis and interpretation of results: CF, DK, AS, MK, PN, ZC, MŠ, JR, RH, MSt, ASa, TH, PP; draft manuscript preparation: CF, RH, MSt, TH. All authors reviewed the results and approved the final version of the manuscript.

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