ESC European Society of Cardiology

Europace (2022) **24**, 1763–1768
https://doi.org/10.1093/europace/euac048

Process optimization for atrial fibrillation ablation

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Received 24 January 2022; accepted after revision 27 February 2022; online publish-ahead-of-print 22 August 2022

Aims In the light of an increasing prevalence of atrial fibrillation (AF) and growing evidence for the superiority of early invasive rhythm control, the demand for ablation therapy is rising. Accordingly, ablation centres will have to maximize their capacity by either adding electrophysiology laboratory resources or optimizing process management. In order to optimize process management, we applied "Lean Six Sigma" method to a single ablation center. We compared procedural parameters, acute efficacy and safety of cryoballoon pulmonary vein isolation (cryoPVI) before and after modifications.

Methods and results Patients ($n = 713$) undergoing cryoPVI (108 before and 605 after process optimization) were analysed. Within 3 years of process optimization, electrophysiology laboratory occupancy time (150.7 ± 44.4 vs. 94 ± 22.1 min, $P < 0.001$), procedure time (84.5 ± 21–47.4 ± 12 min, $P < 0.001$), left-atrial dwell time (53.9 ± 18.4–31.9 ± 9.9 min, $P < 0.001$), and fluoroscopy time (15.8 ± 5.1 vs. 6.2 ± 2.8 min, $P < 0.001$) decreased. Contrast dye use (116 ± 35 vs. 27 ± 15 mL, $P < 0.001$) and radiation dose (893 ± 1078 vs. 253 ± 249 cGy cm^2, $P < 0.001$) were reduced by ∼77 and ∼72%, respectively. There was no difference in safety endpoint occurrence (3.7 vs. 1.5%, $P = 0.11$).

Conclusion The process optimization of cryoPVI for AF therapy using the 'Lean Six Sigma' method significantly increases efficiency without compromising patient safety.

Keywords Pulmonary vein isolation • Process optimization • EP laboratory capacity

Introduction

Atrial fibrillation (AF) is the most common cardiac arrhythmia and is associated with increased morbidity and mortality.[1] In the context of an ageing population, there is evidence of a steadily increasing AF prevalence of currently ∼5.5% for the overall population (≥55 years) and 17.8% for those aged 85 years and above. Recent analyses suggest that at the index age of 55 years, the lifetime risk for AF development is 37% for individuals of European ancestry.[2] Atrial fibrillation is predicted to affect 15.3 million people in Europe by 2040.[3] In this regard, AF represents a major public health burden with increasing healthcare costs of an estimated €660 million annually to the German[4] and $26 billion to the US-American[5] healthcare system.

Pulmonary vein isolation is an established treatment for symptomatic AF and has demonstrated its superiority over anti-arrhythmic drug therapy in terms of rhythm control.[6] Cryoballoon pulmonary vein isolation (cryoPVI) is equivalent to radiofrequency ablation in terms of safety and efficacy for the treatment of paroxysmal AF,[7] but has significant advantages in terms of laboratory resource utilization due to shorter procedure times and substantial cost savings.[8]

Against the background of rising costs for healthcare systems worldwide, increased demand and limited electrophysiology (EP)

What's new?

- Lean Six Sigma–driven process optimization (PO) [without adding new electrophysiology (EP) resources] can almost double EP capacity without compromising patient safety.
- Structured PO can reduce radiation dose, time, and contrast media consumption by ± 70%.

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lab occupancy time, we sought to prospectively analyse the effect of process optimization (PO) using the 'Lean Six Sigma' method[9] on procedural parameters, safety, and acute procedural efficacy in a large single-centre approach.

Methods

Process optimization using the 'Lean Six Sigma' method

Lean Six Sigma describes an approach that combines the principles of *Lean* and *Six Sigma*. Lean (introduced by Taiichi Ohno's articulation of Toyota Production System in 1978[10]) describes 'accelerating' by improving efficiency by eliminating unneeded process steps, errors that need to be fixed, material or people movement without purpose, and unnecessary waiting time because an upstream action/activity was not performed on time. By comparison, Six Sigma [which helped Motorola achieve commercial success in the 1980s and refers to errors only occurring at 6 SDs from the mean, i.e. six sigma] is about improving quality by making processes more consistent and precise.[11] Nowadays, different combinations of Lean and Six Sigma can be found: the need to optimize procedural management of cryoballoon procedures was met together with Medtronic (Dublin, Ireland) based on the 'Lean Six Sigma' problem-solving DMAIC approach.[9]

DMAIC

(1) **D**EFINE: Define the scope of the project with an internal process mapping.
(2) **M**EASURE: Measure the problem via process cycle analysis.
(3) **A**NALZYE: Analyse the root causes of the problem.
(4) **I**MPROVE: Implement the solution.
(5) **C**ONTROL: Maintain the solution.

Study design

The present study was a prospective observational single-centre study conducted at St Josefs-Hospital, Wiesbaden, Germany. Data were collected from January 2016 to December 2020. Prospective data are available for a time after PO (2018–20). Data before PO were analysed retrospectively. Patients provided written informed consent for study participation. The study was approved by the local ethics committee and institutional review board.

Inclusion and exclusion criteria

Patients aged >18 years affected by symptomatic paroxysmal or persistent AF and indication for cryoPVI were eligible for inclusion. Pregnant patients or patients unable to consent were not treated and accordingly excluded from study participation.

Endpoints

The primary endpoints were EP laboratory occupancy time (time from the arrival of a patient in the EP laboratory to the arrival of the next patient, i.e. including the ablation procedure, post-procedure cleaning, and preparation for the next procedure), procedure time (time from the start of the procedure with the first venipuncture to the end of the procedure with the application of the bandage), left-atrial dwell time, total fluoroscopy time, contrast dye use, and radiation dose.

The safety endpoint was defined as a composite of procedure-associated complications (procedure-related death, major groin site complications, pericardial effusion, cerebrovascular or systemic embolism, phrenic nerve palsy, non-fatal or fatal stroke/transient ischaemic attack).

Procedure

Cryoballoon pulmonary vein isolation procedure was standard. In brief, a 12 Fr (ID 12 Fr/OD 15 Fr) steerable sheath (FlexCath Advance, Medtronic) was introduced into the left atrium after a single transseptal puncture (TSP). Then the second-generation Arctic Front (Medtronic) balloon was introduced in the sheath, inflated, and advanced to the ostium of each pulmonary vein and ablation was performed with a freeze cycle duration of 180 s per pulmonary vein. The 28 mm balloon was used in all cases. Pulmonary vein signals were recorded with the help of an octapolar, circular mapping catheter (Achieve, Medtronic). The occlusion of each vein was assessed with venous angiography. The right-sided veins were ablated during phrenic nerve stimulation with a decapolar catheter (BARD Dynamic, Boston Scientific). Classes I and III antiarrhythmic drugs were discontinued after the end of the 90-day blanking period and oral anticoagulation was performed according to the CHA_2DS_2-VASc score as per current guidelines.[12] All procedures were performed by two experienced electrophysiologists (>100 cryoPVI before PO). There was no additional training for younger physicians, so we consider the effect of a learning curve to be minor.

Statistical analysis

Procedural data were compared after testing for normal distribution using ordinary one-way analysis of variance (in case of normal distribution) or Mann–Whitney/Kruskal–Wallis test (in case of non-normal distributed variables). The mean values are presented with standard deviation. Statistical analyses were performed using GraphPad PRISM software version 9 (San Diego, CA, USA) and SPSS software version 27 (IBM, Armonk, NY, USA).

Results

Patient population and acute procedural success

A total of 713 patients with symptomatic AF undergoing cryoPVI were analysed. Of these, 108 patients underwent cryoPVI before PO and 605 between 2018 and 2020 after PO (*Figure 1*). Baseline characteristics were similar between the two groups and are listed in *Table 1*. Acute electrical isolation was achieved in 100% of pulmonary veins by cryoPVI irrespective of the type of AF (paroxysmal/persistent).

Components of 'Lean Six Sigma' and DMAIC for periprocedural efficiency

(1) *DEFINE*: Define the scope of the project with an internal process mapping.
   (a) Target: Reduction of EP laboratory time required per cryoPVI procedure to <120 min within 1 year.

(2) *MEASURE*: Measure the problem via process cycle analysis.
   (a) Average EP laboratory occupancy time before PO was 151 ± 44 min.

(3) *ANALZYE*: Analyse the root causes of the problem (*Figure 2*).

Time delays were caused by:

(a) Time needed for laboratory preparation, patient transfer from ward to laboratory, positioning on the table for procedure, delay of physicians, and delays in laboratory cleaning.
(b) Transoesophageal echocardiography (TEE) for thrombus exclusion and TSP during EP study.

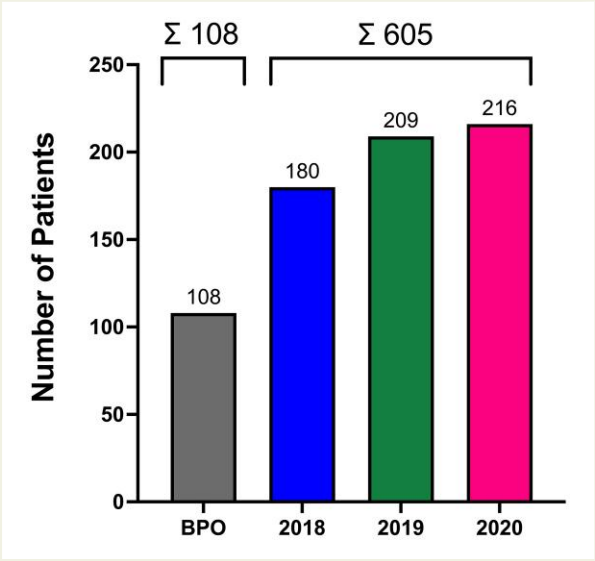

Figure 1 Number of patients undergoing cryoPVI before and after PO.

(c) Non-standardized dosing protocol.
(d) Inefficient haemostasis.

(4) *IMPROVE*: Implement the solution (*Figure 3*).
   (a) Shortening of EP laboratory preparation and patient transfer time were optimized through better lines of communication within the team and by adding a second EP nurse to the team. The next patient transfer was initiated during the ablation of the right pulmonary vein of the current patient. The cleaning staff was informed with sufficient lead time.
   (b) *Routine:* Transoesophageal echocardiography-guided TSP was declared unnecessary and thrombus exclusion was performed in the echo laboratory on the day of the procedure before ablation.
   (c) *Cryoballoon procedure:* Standardized dosing protocol was implemented reducing the duration of cryo-applications from an average of 240 to 180 s and eliminating the need to apply additional cryo-applications if the pulmonary vein was isolated in <1 min. Propofol infusion was stopped before isolating the last pulmonary vein.

The implementation of these modifications identified during the PO reduced EP laboratory occupancy time for cryoPVI by 23%

Table 1 Baseline characteristics

Characteristic	Before PO ($n = 108$)	2018 ($n = 180$)	2019 ($n = 209$)	2020 ($n = 216$)	*P*-value
Age (years)	65 ± 12	68 ± 9	69 ± 10	69 ± 11	0.008
Male sex	62 (57%)	101 (56%)	115 (55%)	133 (62%)	0.55
Body mass index (kg/m^2)	27.9 ± 5.2	27.8 ± 4.7	27.9 ± 4.3	27.4 ± 4.8	0.75
CHA_2DS_2-VASc score	2.2 ± 1.5	2.5 ± 1.3	2.8 ± 1.5	2.7 ± 1.6	0.02
Paroxysmal AF	78 (71%)	107 (69%)	133 (63%)	126 (68%)	0.1
Coronary artery disease	21 (20%)	35 (19%)	42 (20%)	38 (18%)	0.99
Heart failure (LVEF ≤ 40%)	2 (2%)	20 (11%)	19 (9%)	28 (13%)	0.04
Hypertension	68 (64%)	117 (64%)	140 (67%)	138 (64%)	0.94
Hyperlipidaemia	23 (22%)	14 (13%)	27 (13%)	48 (23%)	0.01
Diabetes	4 (8%)	16 (8%)	21 (10%)	27 (13%)	0.26
Previous stroke	8 (4%)	5 (3%)	13 (6%)	21 (10%)	0.005

AF, atrial fibrillation; CHA_2DS_2-VASc: C, congestive heart failure; H, hypertension; A_2, age ≥ 75 years; D, diabetes mellitus; S_2, stroke; V, vascular condition; A, age ≥ 65 years; Sc, sex category (female); LVEF, left ventricular ejection fraction.

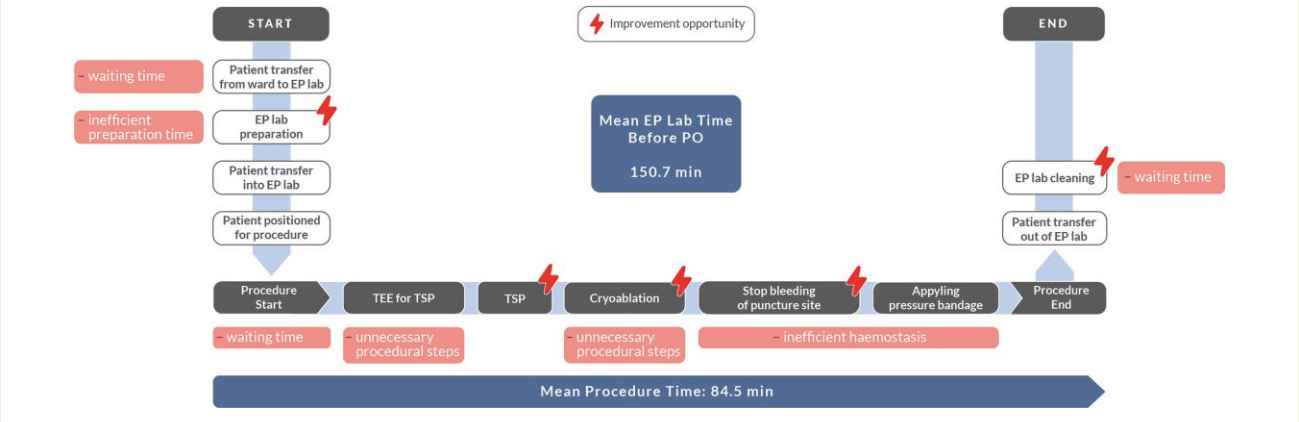

Figure 2 Standard operating cycle of cryoPVI before PO.

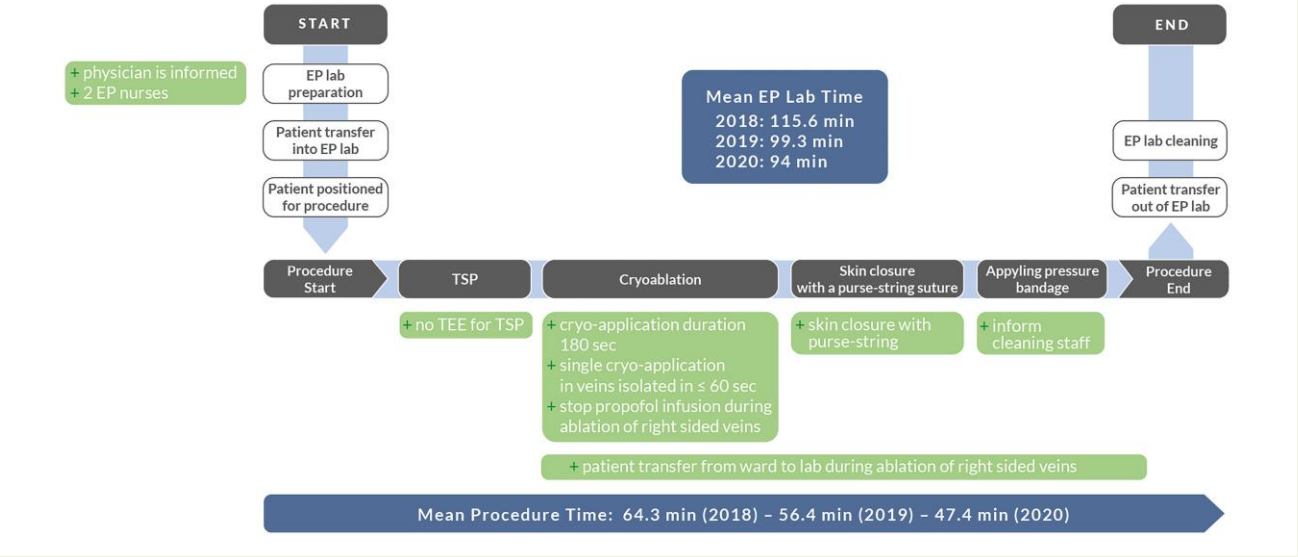

Figure 3 Operating cycle of cryoPVI after PO.

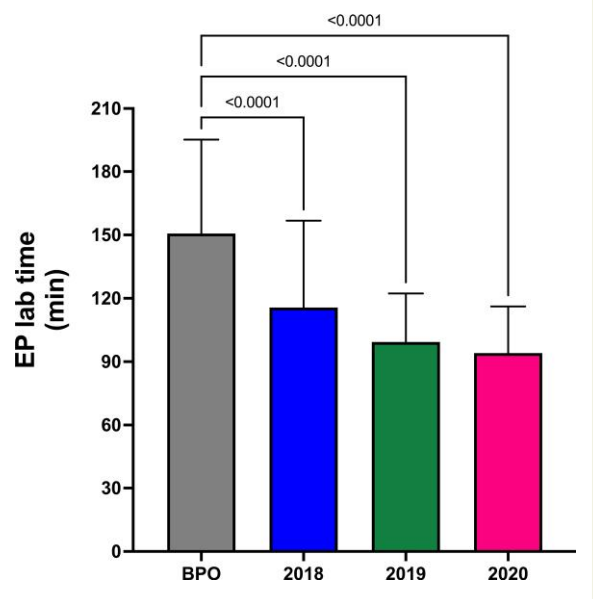

Figure 4 Comparison of laboratory occupancy time per cryoPVI before and after PO.

from 150.7 ± 44.4 to 115.6 ± 41.2 min (2018) within 1 year ($P <$ 0.0001) and by 38% within 3 years (94 ± 22.1 min, $P < 0.0001$, *Figure 4*).

The total procedure time became shorter from year to year [84.5 ± 21 (before PO) vs. 64.3 ± 17.9 (2018) vs. 56.3 ± 14.6 (2019) vs. 47.4 ± 12 min (2020), $P < 0.001$ for all values compared with before PO and for all values compared with previous year, *Figure 5A*]. Similar findings were seen for left-atrial dwell time [53.9 ± 18.4 (before PO) vs. 47.2 ± 17 (2018) vs. 41.1 ± 15.3 (2019) vs. 31.9 ± 9.9 min (2020), $P < 0.001$ for all values compared with before, *Figure 5B*], fluoroscopy time [15.8 ± 5.1 (before PO) vs. 9.8 ± 4.4 (2018) vs. 6.7 ± 2.9 (2019) vs. 6.2 ± 2.8 min (2020), $P < 0.001$ for all values compared with before PO, *Figure 5C*], contrast dye amount [116 ± 35 (before PO) vs. 91 ± 28 (2018) vs. 71 ± 32 (2019) vs. 27 ± 15 mL (2020), $P < 0.001$ for all values compared with before PO, *Figure 5D*] and radiation dose [893 ± 1078 (before PO) vs. 488 ± 676 (2018) vs. 230 ± 196 (2019) vs. 253 ± 249 cGy × cm^2 (2020)], and contrast dye amount [116 ± 35 (before PO) vs. 91 ± 28 (2018) vs. 71 ± 32 (2019) vs. 27 ± 15 mL (2020),
$P < 0.001$ for all values compared with before PO, *Figure 5E*].

(5) *CONTROL*: Maintain the solution.

By 2020, the average overall laboratory time could continuously be reduced by 38% from 150.7 ± 44.4 to 94 ± 22.1 min. The procedure time was reduced by 44%.

Safety endpoints before and after process optimization

The primary safety endpoint occurred in four patients (3.7%) before PO (two transient phrenic nerve injuries, one haemoptysis) and nine after PO (1.5%) (three pericardial effusions, three transient phrenic nerve injuries, two air embolism, one femoral pseudoaneurysm). Only one of the pericardial effusions was associated with difficult TSP while the others were not. No procedure-related death or stroke was observed in either group.

Discussion

This study compared procedural efficiency as well as safety of cryoPVI in patients who underwent ablation before and after PO through 'Lean Six Sigma' methodology in a large single-centre cohort. Our main findings were two-fold.

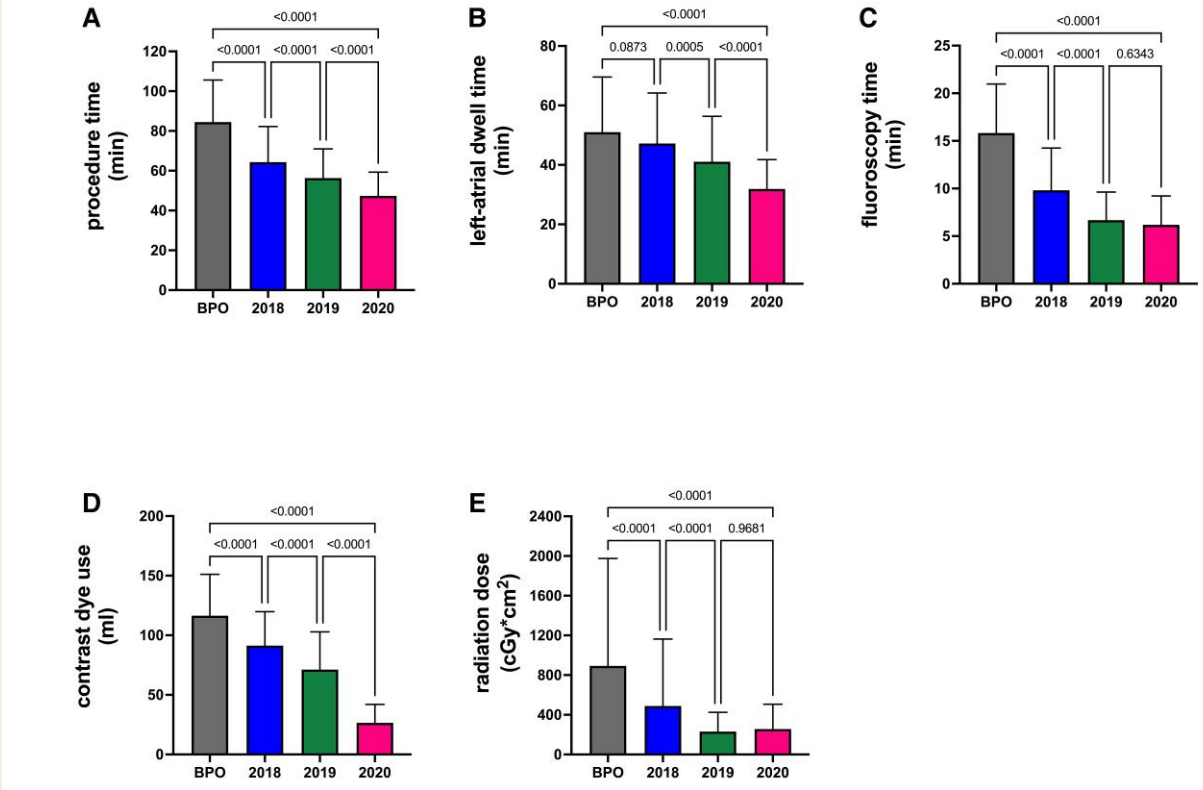

Figure 5 Comparison of procedural parameters per cryoPVI before and after PO.

Firstly, a significant and progressive optimization of resource utilization was achieved by PO. Within 3 years of successful PO implementation, EP laboratory, procedure, and fluoroscopy times were reduced by ∼38, 44, and 61%, while contrast dye and radiation dose were reduced by 77 and 72%, respectively.

The implementation of PO resulted in an immediate improvement in all variables (2018 compared with PO). Increasing standardization over time led to continuous amelioration (2019 and 2020 compared with 2018).

Secondly, the procedure was equally safe regardless of the cohort.

Use of 'Lean Six Sigma' methodology in healthcare

Among others, the application of 'Lean Six Sigma' has significantly reduced waiting times and thus improved patient satisfaction in vascular interventional radiology and hospital emergency department organization.[13,14] The Recycling in the operating room (RECOR) project demonstrated a halving of waste generated in the operating room by using 'Lean Six Sigma' method.[15] Furthermore, the application of 'Lean Six Sigma' reduced the length of hospital stay and thus the median hospital direct cost per case in patients with prolonged mechanical ventilation.[16] Improta *et al.*[17] demonstrated almost halving in healthcare-associated infections through 'Lean Six Sigma' and in accordance with our findings, Agarwal *et al.*[18] found a significant improvement in efficiency at their catheterization laboratory (increase in cases with optimal turn-time from 44 to 57%, $P < 0.001$) after application of 'Lean Six Sigma' methodology.

Growing demand for atrial fibrillation ablation and use of cryoballoon pulmonary vein isolation for procedure optimization

Recent data suggest not only a growing demand for AF ablation because of ageing population and improved detection of arrhythmias,[12] but also increasing evidence for beneficial effects of early ablation therapy. The Early Rhythm-Control Therapy in Patients with Atrial Fibrillation (EAST-AFNET 4) trial showed that in patients with early AF and cardiovascular conditions, early rhythm-control therapy was associated with a lower risk of adverse cardiovascular events than usual care.[19] In 2021, both Wazni *et al.*[20] (Cryoballoon Ablation as Initial Therapy for Atrial Fibrillation, STOP-AF First) and Andrade *et al.*[21] (Cryoablation or Drug Therapy for Initial Treatment of Atrial Fibrillation, EARLY-AF) independently reported superiority of cryoPVI as initial therapy for prevention of atrial arrhythmia over drug therapy in patients with paroxysmal AF.

These results support a regimen of early rhythm control, particularly by catheter ablation, and also raise again the question of ablation in asymptomatic patients, which has not yet been adequately answered. Nevertheless, these results show that therapy options for AF patients need to be expanded and that existing ablation centres

will have to further optimize their performance and capacities in the future.

Summary

The process optimization of cryoPVI for AF therapy using the 'Lean Six Sigma' methodology significantly increases efficiency without compromising patient safety and thus may help to address the rising demand for AF ablation.

Funding

No funding declared.

Conflict of interest: The authors' department is an international training centre for cryoballoon ablation by Medtronic. S.V. is a full-time employee of Medtronic; J.R.E. is an advisor to and speaker for Medtronic.

Data availability

The data underlying this article will be shared on a reasonable request to the corresponding author.

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