UNLOCK EP LAB CAPACITY WITH MEDTRONIC CRYOBALLOON

TREAT MORE PATIENTS. SAVE TIME. REDUCE STRESS.

University Clinical Centre Rijeka, Croatia
Atrial fibrillation (AF) is the most common sustained cardiac arrhythmia, affecting 1–2% of the general population around the world. In Europe, there are over six million people diagnosed with AF, although the actual number is estimated to be much higher since so many cases remain undiagnosed. With the ageing population and increasing life expectancy across Europe, it is estimated that there will be 14-17 million people with AF in Europe by 2030. This is based on the fact that the prevalence of AF increases with age, from 0.3% at 40–50 years of age to 5–15% at 80 years of age. Given the comparable demographic landscape in Croatia and the assumption that the prevalence of AF is similar to that of the rest of Europe, it is estimated that there are currently 40–50 thousand patients with AF in Croatia.

Today, there are seven centres in Croatia treating atrial fibrillation patients with pulmonary vein isolation (PVI) via catheter ablation. In 2017, there were 778 AF ablations performed in Croatia, 23% of which were performed with Cryoballoon ablation and 77% with point-by-point radiofrequency (RF) ablation.

The 2016 European Society of Cardiology (ESC) guidelines recommend PVI with catheter ablation, without further substrate modification, as first-line therapy to treat patients with AF. Catheter ablation can be performed with radiofrequency (RF) or cryothermal energy. An alternative to catheter ablation is antiarrhythmic drug therapy. Results from CABANA, a large multicentre, randomised controlled trial comparing catheter ablation to drug therapy for the treatment of AF, did not demonstrate a significant difference in the primary composite endpoint of disabling stroke, serious bleeding, or cardiac arrest, or on all-cause mortality. However, a per-protocol analysis censoring the 9.2% of ablation patients who did not get the procedure and the 27.5% of the drug group who crossed over to ablation shows substantial advantages to the ablation procedure: 33% relative reduction in the primary composite endpoint, and 40% relative reduction in all-cause mortality. Both analyses showed a significant 17% relative reduction in death or cardiovascular hospitalisation associated with catheter ablation.

FIRE AND ICE, the largest multicentre, prospective, randomised trial that compared the efficacy and safety of Cryoballoon ablation and RF ablation, met its primary safety and efficacy endpoints with shorter, more consistent procedure times. Secondary analyses results highlight clinically meaningful outcomes that are highly impactful to patients. Relative to RF ablation, Cryoballoon ablation demonstrated 21% fewer all-cause hospitalisations, 34% fewer cardiovascular hospitalisations (including AF hospitalisations), 50% fewer direct current cardioversions and 33% fewer repeat ablations. Studies also demonstrate that Cryoballoon ablation procedures are more reproducible and have more consistent outcomes compared to RF. For instance, a French prospective multicentre survey comparing the safety and efficacy of Cryoballoon and RF ablation demonstrated that both techniques resulted in similar rates of freedom from AF (68–80% at 18 months), although the Cryoballoon procedure outcomes were less operator and volume-dependent. Cryoballoon ablation results were more consistent regardless of centre or operator experience. As a result, the outcomes in less experienced centres favoured cryoablation, reflecting its shorter learning curve and greater reproducibility. A single-centre study also demonstrated that RF ablation procedure durations are more variable than Cryoballoon ablations. In absolute terms, 28.6% of RF procedures proved to be more than 30 minutes longer than the median duration, while for Cryoballoon ablation procedures, only 4.4% of procedures exceeded the median by over 30 minutes. Since a procedure with increased variability can lead to less efficient resource planning related to cath lab space and staffing, it can be presumed that procedure duration variability results in more resource requirements and therefore, higher costs. Cryoballoon ablation can thus be considered more resource efficient than RF ablation.
CATH LAB MANAGEMENT AT UNIVERSITY CLINICAL CENTRE RIJEKA

EP RESOURCES
The cardiology department at University Clinical Centre (UCC) Rijeka is comprised of two cath labs, one of which is also an EP lab. The EP team at UCC Rijeka consists of three nurses, one radiology technician, one experienced EP specialist who is performing AF ablations, and two EP fellows who are still in training. Together, this team performs diagnostic coronaryography, PCI, endovascular valve implantation or repair, EVAR, TEVAR, LA appendage occlusion, device implantation and extraction, electrophysiology and catheter ablation procedures. Given the diversity of the procedures performed and the department resource constraints, it is essential that procedures are managed efficiently and according to a strict schedule.

THE GROWING DEMAND FOR AF ABLATIONS
The EP team at UCC Rijeka started performing AF ablations two and a half years ago. To support access to AF ablations for the increasing number of people with AF, the hospital team hosts educational events for general practitioners and cardiologists about AF ablation therapy and the types of patients who are indicated for the treatment. With growing awareness of the AF ablation outcomes in the local medical community, and as word of mouth from patients spreads, more and more patients are being referred to UCC Rijeka for AF ablations every year. To meet the growing demand for AF ablations, UCC Rijeka has been steadily increasing the number of AF ablation procedures performed per year. Given this context, it is extremely important to manage EP procedures efficiently and to thoughtfully plan the procedure schedule in advance and in detail. Any changes in procedure durations affect the schedule, which can then cause increased idle time, longer cath lab occupancy time per procedure, or the need to postpone or cancel procedures altogether. Therefore, in addition to the need for a procedure that is effective, with a low complication and repeat ablation rate, it is also very important for the selected method to have a predictable procedure duration. This helps to ensure optimal utilisation of hospital resources and prevents unforeseen overtime hours for staff. To optimise cath lab time and reduce operator idle time, block scheduling is used by the arrhythmologic team. Four days per week, one cath lab is reserved for the arrhythmologic team performing catheter ablation or device-related procedures. Usually two days are reserved for catheter ablation and the other two days for device-related procedures. Depending on the waiting list and resource availability, both catheter ablations and device-related procedures can be performed on the same day. By planning ahead, any unexpected changes to the schedule can be addressed in time. Knowing the schedule in advance also gives teams enough time to perform any additional tests required for patients undergoing AF ablation before their scheduled procedure to avoid any unnecessary complications or delays.

THE PATIENT PATHWAY
The patient admission protocol is as follows:
- Physical examination
- ECG
- Routine blood tests
- Blood coagulation tests
- Blood type (in case of complications requiring urgent blood transfusion)
- Transesophageal echocardiography
- Adequate preprocedural anticoagulation therapy planning

To improve pathway and workflow efficiency, effective communication among ward personnel is very important. For instance, it can significantly reduce patient changeover time and reduce idle time in the cath lab when the next patient is brought from the ward to the preparation room next to the cath lab where final preparations are made, at the final stage of the preceding patient. Patient turnover efficiency is also supported by the fact that Cryoballoon ablation procedures are performed with analgesedation, rather than general anesthesia.

THE CRYOBALLOON ABLATION LEARNING CURVE
The first AF ablation at UCC Rijeka was performed on the 11th of April 2016 using Cryoballoon and since then, 167 AF ablations have been performed with either cryoablation or point-by-point RF ablation. Although both technologies are used at the hospital, the learning curve was different for each technology. New operators at UCC Rijeka began performing Cryoablation procedures independently after only two proctorship sessions. The straightforwardness of the Cryoballoon ablation procedure together with the fact that the safety of the patient was not compromised even in the early learning phase helped to save time, reduce costs, and enable an efficient adoption process. This is supported by findings from a single-centre study in which new operators were able to perform PVIs successfully and with short procedure and fluoroscopy durations after performing 20–30 procedures.10
Despite limitations including limited available cath lab time and a lack of staff, the arrhythmology team initiated a project of performing four AF ablations and four complex device-related procedures in one cath lab in a single day. The planning process was extremely important, as the team needed to ensure that the procedures were completed in a limited time frame with the same level of efficacy and safety for the patients. This included detailed planning of the patient preparation process, respecting standardised procedure steps, and carefully coordinating patient turnover post-procedure. It was also very important to know the expected duration and cath lab occupation time for each procedure in order to minimize possible setbacks and procedure duration variations. Because of the simplicity and the short, predictable procedure duration and lab occupation time, cryoablation was the method chosen for AF ablation. The simple setup of the CryoConsole™, and the fact that cryoablation does not require a complex mapping system, made it possible to switch between AF ablations and device-related procedures without setbacks and procedure duration variations.}

**THE AF ABLATION WORKFLOW AT UCC RIJeka**

**OPTIMISING LAB OCCUPANCY TIME**

At UCC Rijeka, Cryoablation procedures are managed efficiently, with a protocol that seeks to reduce or eliminate potential idle time in the cath lab. The average time from the point when the patient enters the EP lab, until the procedure begins with the injection of local anaesthetics, is 28 minutes for cryoablation and 42 minutes for RF ablation. The variation in duration between the two approaches is largely due to the time needed to set up the 3D mapping system used for RF ablation. Due to the complex setup required for the 3D mapping system, it is very difficult and time consuming to switch between procedures using the mapping system and those which are performed without it, forcing the EP team to reserve days in the EP lab for procedures using the mapping system. On the other hand, the set-up for Cryoballoon ablation is much simpler and can be easily performed before or after different types of procedures without significant patient turnover prolongation, which is extremely important for the hybrid cath lab.

**CRYOBALLOON ABLATION PROTOCOL**

The average procedure time for cryoablation was 82 minutes, with the shortest procedure time being 57, and the longest 105 minutes. The average RF ablation procedure time was 121 minutes, with a shortest procedure time of 76 minutes, and a longest of 163 minutes. However, the average fluoroscopy time for Cryoballoon ablation was 18 minutes, while the average fluoroscopy time for RF ablation was 9 minutes.

**THE FOLLOWING PROTOCOL IS IMPLEMENTED FOR CRYOBALLOON ABLATION PROCEDURES:**

1. Two nurses work together to prepare the procedure material before each case.
2. The patient is prepared for the procedure by the ward nurses in a room next to the EP lab toward the end of the previous procedure. This is done while the EP nurses prepare the procedure material to optimise EP lab time per procedure.
3. Once the material is prepared, the patient is brought into the EP lab and the nurse administers the analgesia in predetermined doses.
4. The procedure is usually started by an EP fellow, with procedure support from the radiology technician and an EP specialist present at the bedside. The EP nurse is at the EP recording station while another nurse assists with the procedure, as needed. Once the initial procedure steps are complete, the EP specialist proceeds with the more complex procedure steps, while the EP fellow assists him at the bedside.
5. When the Cryoballoon is inserted, the radiology technician leaves the bedside and works at the EP station while an EP nurse operates the CryoConsole. It is important to stress out that our nurses and radiology technician are both educated in every step of the procedure and can share duties.
6. A nurse in the EP lab informs the ward nurse who is with the next patient to begin preparing the patient for the next procedure during the final steps of the ongoing procedure (catheter removal).
7. The groin puncture site is closed with a figure-of-eight suture.
8. A transthoracic echocardiogram (TTE) is performed to exclude pericardial effusion.
9. The patient is then transferred to the ward where he or she is continuously monitored by a central monitoring system for the next eight hours and regularly checked by nurses and physicians.

For both ablation methods, the same medications are used with the same starting doses: 1 mg of Midazolam and 100 µg of fentanyl. 70% of patients undergoing cryoablation required additional dose of 100 µg of fentanyl, while every patient undergoing RF ablation required additional doses with a cumulative additional dose varying from 100 to 500 µg of fentanyl.

The duration of hospitalisation for patients undergoing AF ablation in UCC Rijeka is 2-3 days with the duration varying slightly depending on the type of ablation. The hospitalisation time is usually slightly longer for patients with persistent and longstanding persistent atrial fibrillation due to the higher incidence of AF recurrence and therefore sometimes the need for cardioversion and additional antiarrhythmic drug assessment.

**CONCLUSION**

UCC Rijeka has been performing AF ablation procedures with both point-by-point RF ablation and Cryoballoon ablation for the past two and a half years. With limited resources available for catheter ablation and an increased demand for the procedure, the arrhythmology team is facing many challenges, which they can help to address with precise planning, efficient cath lab utilisation, and procedure duration predictability. Cryoballoon ablation has proven to be an effective procedure with a low complication rate, short preparation time and a short, predictable procedure duration. At UCC Rijeka, AF ablation using Cryoballoon has proven to be a relatively simple procedure with a short learning curve. With thoughtful planning, efficient patient preparation and operational protocols, a significant number of procedures can be performed, even in a context with resource and time limitations. With only four days per week when the cath lab is available, the arrhythmology team performs approximately 500 device implantations, 25-30 lead extraction procedures which are complex and time consuming, and 250-300 catheter ablations, including AF ablations, annually.
REFERENCES


See the device manual for detailed information regarding the instructions for use, indications, contraindications, warnings, precautions, and potential adverse events. For further information, contact your local Medtronic representative or consult the Medtronic website at www.medtronic.com.