MEETING THE GROWING DEMAND FOR ATRIAL FIBRILLATION ABLATION: ST. JOSEFS-HOSPITAL WIESBADEN, GERMANY
Atrial fibrillation (AF) is the most common arrhythmia of clinical significance, with increased prevalence associated with demographic trends and lifestyle changes. It is estimated that one in four middle-aged adults in Europe will develop AF by 2050, with 14–17 million patients. By 2030, it is anticipated that there will be 14–17 million patients with AF in the European Union, with 120 000–215 000 newly diagnosed patients each year.

AF is associated with increased morbidity, such as stroke and heart failure. Studies show that 20–30% of patients with an ischaemic stroke have AF diagnosed before, during, or after the initial event.

The rising incidence of AF is a growing burden on healthcare systems, with an estimated annual cost of €660 million to the German healthcare system, and 1% of the National Health Service budget in the United Kingdom.

Pulmonary vein isolation (PVI) with catheter ablation has been proven to be an effective treatment option for patients with AF. Studies have also demonstrated that PVI using cryoballoon ablation, rather than radiofrequency (RF), has been associated with reduced resource needs. This is due in part to the fact that cryoballoon procedures tend to be shorter and more predictable compared to RF procedures.

The hospital's cardiology department had one hybrid operating room for TAVI procedures and a second cath lab for coronary angiography and device implantation. A third cath lab was operated by cardiologists in private practice and could be typically used by the hospital two days per week.

The hospital EP division was created in January 2015, when Prof. Dr. Joachim Ehrlich joined the cardiology department. To support EP procedures, one of the cath labs was initially turned into a mobile EP lab for EP studies and AF ablations.
Cryoballoon was adopted as an index procedure for patients with paroxysmal AF, since it was proven to be a safe and effective approach to PVI, with shorter and more reproducible procedures compared to radiofrequency (RF).

Prior to the implementation of the process optimisation project in August 2016, the roles and responsibilities for performing cryoballoon ablation procedures were as follows:

- One nurse to prepare the procedure and monitor the patient
- Two electrophysiologists (EP) to perform the cryoballoon procedure and manage the EP recording system

Nurses available for cryoballoon ablations supported both EP lab and cath lab procedures. When the EP division was first created, Prof. Ehrlich was the only EP on staff, until he was joined by Dr. Kaess in April 2016.

The EP lab was dedicated to cryoballoon procedures one day per week and the team performed an average of three procedures on such days.

Prof. Ehrlich became the head of the cardiology department in August 2016, gaining the opportunity to optimise EP lab procedure management. In this capacity, he identified the potential to increase the hospital’s EP lab efficiency to meet the growing demand for AF ablations.

Given the recognised need to better optimise the management of cryoballoon procedures, the decision was made to work together with Medtronic to implement a process optimisation project based on Lean Six Sigma methodology.

In accordance with Lean Six Sigma methodology, the project steps were as follows:

1. Define the project scope with an internal process review
2. Measure the problem via process cycle analyses
3. Analyse the sources of the problems
4. Implement the solution
5. Sustain the solution

The goal defined for this project was to double the number of AF procedures performed per allocated day from three to six in a single year.

To do so, there was a recognised need to address inefficiencies associated with patient transfers, procedure preparation, lab cleaning, and staff availability, given the impact of such factors on lab occupancy time.

2. Measure the problem

To clearly identify and assess the inefficiencies delaying lab occupancy time per patient, all pre and post-procedure steps were timed and outlined on a value stream map.

The available EP lab time and average lab occupancy time was as follows:

- Available EP lab time: 10 hours per day
- Lab occupancy time for cryoballoon procedures: 3 hours per patient

Given the available lab time and the average lab occupancy time per patient, the hospital had the capacity to perform three cryoablation procedures per allocated cryoballoon day (3.33 patients).

At the time, the average daily demand was for five procedures per cryoablation day. To meet their established objective, the team needed to reduce lab occupancy time per cryoballoon procedure from 180 minutes to 100 minutes. To sustain this change, there was also the need to increase demand for the procedure.

3. Identify the sources of delay

The process map on the following page (figure 1) outlines the current lab occupancy time required for each step of the procedure cycle. Lab occupancy times for each step of the procedure process are listed in dark blue and cycle durations without waiting time are listed in light blue.

Opportunities for improvement are highlighted in green, to illustrate where there were gaps between the current lab occupancy time and the cycle time per patient without waiting time.
### 3.1 Analyse and address the problems

In accordance with the findings from the value stream map analysis (figure 1), the following delays were identified throughout the procedure cycle:

#### A) Lab preparation

Time wasted during the procedure preparation stage often resulted from a shortage of nurses available to prepare the procedure material on time. This was due in part to resource constraints and to a lack of effective communication within the team, which resulted in nurses not being informed that they were needed to prepare the next procedure in due time.

To address this issue, efforts were made to improve lines of communication within the team and to allocate a second nurse to material preparation for each procedure.

#### B) Patient transfer from the ward to the lab

Inefficiencies associated with patient transfers typically resulted from a lack of effective communication within the team and insufficient lead time for the initiation of the patient transfer. Given this challenge, the team concluded that nurses responsible for the management of patient transfers required a lead time of at least 27 minutes.

To better optimise this step of the procedure cycle, a process was implemented wherein the next patient is transferred to the lab during the ablation of the current patient’s right pulmonary veins.

#### C) Patient positioned on the table for the procedure

Delays related to patient positioning were generally associated with a lack of coordinated communications between the nurses and EPs. As a result, nurses often had to wait in the EP lab for physicians to arrive so that the team could begin the procedure.

To address this issue, the expectation was set for physicians to remain in the lab as much as possible during allocated cryoballoon days. A process was also implemented wherein nurses are expected to provide EPs with at least 5-10 minutes notice before they are needed for the procedure.

#### D) Transesophageal echocardiography (TEE) for thrombus exclusion and transseptal puncture (TSP)

To further optimise lab occupancy time, the EPs decided that performing TEE-guided TSP was unnecessary, and that thrombi could be excluded in the echo lab on the day of the procedure, prior to ablation.

Therefore, the decision was made to stop routinely performing TEEs for TSPs. To further optimise this step of the procedure, the decision was made to have a second EP prepare the cryoballoon material during the TSP. These changes reduced the time required for each procedure by an average of 11 minutes.

#### E) Cryoablation procedure

Procedure reproducibility and patient turnover were identified by the team as areas for improvement.

To help reduce the variability of procedure times, which was particularly relevant when a new EP was being trained, the hospital implemented a standardised dosing protocol. This protocol reduced the duration of cryoapplications from an average of four minutes to three minutes and eliminated the need to apply additional cryoapplications if the pulmonary vein was isolated in less than one minute.

To help facilitate the efficiency of the patient turnover process at the end of each procedure, the decision was also made to stop propofol infusions before isolating the last pulmonary vein.

#### F) Lab cleaning process

The process optimisation project helped to spotlight the fact that lab cleaning was not being performed as efficiently as it could be. This was due in part to the fact that there was a lack of cleaning staff dedicated to the cath labs and EP lab and to the fact that they were not consistently informed of when they would be needed in the lab sufficiently in advance.
To address this problem, the hospital added a second cleaner for the labs and required that they be given sufficient notice before they are needed to clean a lab.

Resulting time savings

Since implementing the solutions identified via the process optimisation project, the lab occupancy time for cryoballoon ablation procedures was decreased from 180 minutes to 100 minutes per patient. Such time savings enabled the team to meet their goal of performing six procedures in a single day, which they continue to do consistently. The hospital even managed to perform eight procedures in a single lab, in a single day (07.30 to 18.00) by reducing the lab occupancy time to 90 minutes.

4. Sustain the solution

To maintain the efficiency gains derived from the process optimisation project, a material preparation checklist was created and processes related to the procedure were formalised. A team of four nurses was designated to EP procedures as well, enabling the creation of a specialised team who could collaborate and communicate effectively and support procedures efficiently. Based on the learnings from the process optimisation project, subsequent cryoablation procedures were consistently performed according to the following steps:

1. Patients are seen in the outpatient clinic for bloodwork a few weeks before the procedure to have the procedure explained, to sign the consent form and to have necessary medication prescriptions.

2. On the morning of the procedure, patients are taken for an ECG. If the patient is in atrial fibrillation, a TEE is performed.

3. Two nurses work together to prepare the procedure material before each case.

4. The patient is prepared for the procedure in a room on the same floor as the EP lab.

5. Once the procedure material is prepared, the patient is brought into the lab and the nurse informs the EP that the procedure is nearly ready to begin. The nurse administers the propofol to the patient before the physicians arrive.

6. During the procedure, there is typically one electrophysiologist at the EP recording system and two EPS at the bedside for the cryoballoon preparation. Once the cryoballoon is inserted, the second EP leaves the EP lab. Two nurses will monitor the patient and support the procedure, as needed. An automated pump is used for contrast delivery to optimise and standardise the process as precisely as possible (adjusts contrast very precisely at a predefined speed).

7. A nurse in the EP lab informs the nurse who is with the next patient to begin preparing the patient for the next procedure during the isolation of the right pulmonary veins. Propofol perfusion is stopped before the last PVI (unless cardioversion is required) to help facilitate an efficient patient turnover.

8. The groin puncture site is closed with a purse-string suture.

9. A TEE is performed to exclude pericardial effusion.

10. The patient is then transferred to the nearby recovery room on the same floor.
AWARENESS EFFORTS

In parallel with the process optimisation project, Prof. Ehrlich collaborated with Medtronic to organise educational events for referring physicians.

Such events sought to promote the benefits associated with AF ablation and to build awareness of EP expertise and activities at St. Josefs-Hospital Wiesbaden.

Such efforts have resulted in a consistently higher demand for AF ablation procedures and establishing stronger relationships with referring physicians in the area.

To meet this increased demand, the hospital has since trained a third electrophysiologist and established a second cryoablation day. A new EP lab is also planned for 2024.

CONCLUSION

The process optimisation project and referral physician awareness efforts proved to be very successful, enabling St. Josefs-Hospital Wiesbaden to increase AF ablation demand and capacity. Prof. Ehrlich and his team perform an average of six procedures per cryoablation day, with the capacity to reach up to eight procedures per day.

The number of cryoballoon procedures performed per year also increased from 33 in 2015 to 125 in 2016 and to 210 in 2017.

Since the process optimisation measures were put in place, the EP team has hosted physicians from across Europe who are interested in optimising their AF ablation procedure management and applying learnings to their own EP labs. The EP lab management at St. Josefs-Hospital Wiesbaden is thus serving as a model to derive learnings from Germany and across much of Europe.
References:


