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Abstract

Background: : The Insertable Cardiac Monitor (ICM) clinical pathway in Tampere Heart Hospital, Finland, did not correspond to the diagnostic needs of the population due to a lack of resources for insertion and follow-up. There has been growing evidence of delegating the insertion from cardiologists to specially trained nurses and outsourcing the remote follow-up. However, it is unclear if the change in the clinical pathway is safe and improves efficiency.

Objective: To describe and assess the efficiency of the change in the clinical pathway for patients eligible for an ICM.

Methods: Clinical pathway improvements included initiating nurse-performed insertions, relocating the procedure from the catheterization laboratory to a procedure room, and outsourcing part of the remote follow-up to manage ICM workload. Data was collected from EHR concerning all patients who received an ICM in the Tampere Heart Hospital in 2018 and 2020. Follow-up data was collected 12, 24, and 36 months after insertion for both groups.

Results: The number of inserted ICMs doubled from 74 in 2018 to 159 in 2020. In 2018, cardiologists completed all insertions, while in 2020, 70.4% were completed by nurses. The waiting time from referral to procedure was significantly shorter in 2020 (mean=36 days) compared with 2018 (mean=49 days), P=.02. The scheduled ICM procedure time decreased from 60 minutes in 2018 to 45 minutes in 2020. Insertions performed in the catheterization laboratory decreased significantly (18.9% in 2018; 1.9% in 2020, P=<.001). Patients receiving an ICM after syncope increased from 71 to 94 patients. Stroke and transient ischemic attack (TIA) as an indication increased substantially from 2018 to 2020 (2 and 62 patients, respectively). In 2018, nurses analyzed all remote transmissions. In 2020, the external monitoring service escalated only 11.2% of the transmissions (204 out of 1817) to the clinic for revision. This saved 296 hours of nursing time in 2020. Having nurses insert ICM in 2020 saved 48 hours of physicians' time and the shorter procedure additional 40 hours of nursing time compared with the process in 2018. Also, the catheterization laboratory was released for other procedures (27 hours per year). The complication rate did not change significantly (2.7% in 2018 and 3.1% in 2020, P=.85). The 36-month diagnostic yield for syncope remained high in 2018 and 2020 (45.1% and 38.3%, P<.005). The diagnostic yield for stroke patients with a procedure in 2020 was 43.5%.

Conclusions: The efficiency of the clinical pathway for patients indicated for an ICM can be increased significantly by changing to nurse-insertions in procedure rooms and to the use of an external monitoring and triaging service. Thereby, patient access to an ICM is increased while a significant amount of staff time and resources are saved without any compromise to treatment quality.

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Original Paper

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Conclusions: The efficiency of the clinical pathway for patients indicated for an ICM can be increased significantly by changing to nurse-insertions in procedure rooms and to the use of an external monitoring and triaging service. Thereby, patient access to an ICM is increased while a significant amount of staff time and resources are saved without any compromise to treatment quality.

Keywords: Insertable Cardiac Monitor; clinical pathway; nurse-led service; task shifting; efficiency improvement; remote monitoring

Introduction

Insertable Cardiac Monitors (ICMs) are indicated for long-term monitoring of heart rhythms, primarily for the indications of unexplained syncope and cryptogenic stroke or transient ischemic attack (TIA) [1-4]. For patients monitored with an ICM, a remote monitoring system transfers ICM data in most cases daily to hospital staff for analysis. The 2023 EHRA-HRS Expert Consensus on Remote Monitoring recommends remote monitoring as standard of care for ICMs [5]. However, remote monitoring can create a significant data-burden [6], which can be challenging in the current context of clinical staff shortage and disparities between different populations for access to services [7]. Recent studies have indicated that the in-office time to follow-up an ICM patient took approximately 39.9 minutes of staff time, while remote follow-up required only 11.3 minutes [8]. In addition, in studies regarding nurse-led ICM service, it has been confirmed that in an outpatient setting, ICM service by specially trained nurses can lead to significant savings without compromising the safety of the procedure [6].

Workforce challenges are well-known across countries. Therefore, the 2023 HRS EHRA Consensus statement recommends effective management of remote monitoring clinics to focus on adequate staffing with clear roles and responsibilities, on-going staff education, and efficient high-priority alert systems [5]. Nurse-led services play a particularly important role for efficient ICM services, as international case studies show that nurses can conduct both ICM insertions and remote follow-up effectively and safely [10].

Additionally, the use of third-party resources can be an opportunity to efficiently manage remote monitoring of ICM patients and a solution for dealing with increased device clinic volume [8,9]. ICMs are prone to produce a heavy workload for the remote monitoring clinic (25 % of all transmissions, 10 times more frequent than for a pacemaker) [11].

Also in Finland, health services are challenged due to the shortage of trained healthcare professionals and resources. In comparison to the average in the European Society of Cardiology member countries, Finland has fewer cardiologists per million people (Finland 50.5 vs. ESC countries 85.1) [7]. Furthermore, there is a growing need for nurses in Finland [12]. The Finnish government has launched the “Good Work Program” to ensure the sufficiency and availability of personnel in healthcare, social welfare, and rescue services. The Program aims to increase the attractiveness of working within the social- and healthcare sector by developing the structures and clarifying the tasks between the personnel [13].

At the Finnish Tampere Heart Hospital, both insufficient staff resources and a growing number of patients in need of ICM monitoring led to the restructuring of the clinical patient pathway. The changes centered around training nurses to perform ICM insertions, the inclusion of the neurology department in patient pathways, moving the remaining ICM procedures out of the catheter laboratory, and the use of third-party triaging services.

However, the impact of these changes in the clinical pathway from the perspective of efficient resource management and quality of care is unknown. Thus, we conducted an analysis of the changes in clinical pathways at the Tampere Heart Hospital, assessing the impact on patient pathway efficiencies and quality of care.

Analyzing the ICM Pathway in 2018

In 2018, the Tampere Heart Hospital began an analysis of the prevailing ICM workflow. The focus was on the clinical pathway and the way tasks were divided between professionals in each phase. The 2018 patient pathway was characterized by a cardiology-centric decision-making for ICM insertions. Only a few Cryptogenic Stroke (CS) patients were referred to the cardiology department in 2018 even though the neurologist could make a referral to Atrial Fibrillation (AF) monitoring therapy for secondary prevention of CS and Transient Ischemic Stroke (TIA). At the time, the ESC guidelines for AF management from 2016 were valid [3]. Unexplained syncope patients were referred by a general practitioner or the emergency department doctor to a cardiology clinic. Subsequently, a cardiologist assessed whether these patients required an ICM based on the ESC guidelines from 2018 [1]. If an ICM was recommended for CS, TIA, or unexplained syncope, the patient was placed on a waiting list for the procedure and later invited to an outpatient clinic for device insertion by a cardiologist in a catheterization laboratory (see Figure 1). Catheterization laboratory time was a highly demanded resource for performing more advanced interventional cardiological procedures.

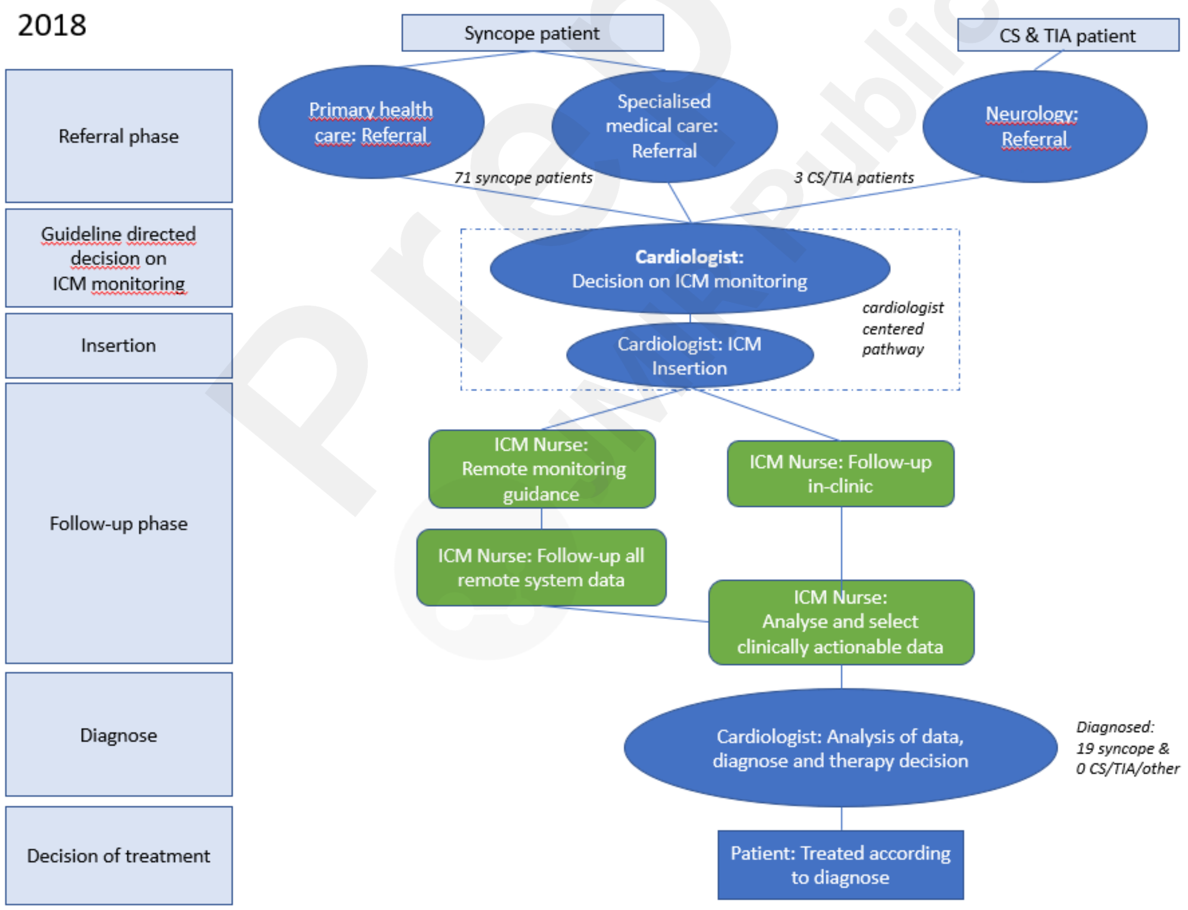

Figure 1. Patient pathways in 2018.

Changes in the ICM Pathway as of 2020

Increasing Access to ICM Monitoring for CS/TIA Patients

Based on the analysis of 2018, the clinical pathway was changed to improve its efficiency. As identified in 2018, the referral via cardiologist was a barrier for ICM monitoring for CS/TIA patients. To increase the access of CS patients, the neurologist could refer patients directly to an ICM procedure (see figure 2). Therefore, the decision on ICM insertions was transferred to the neurologist. This was in line with the updated 2020 ESC guidelines for AF management which had a stronger recommendation for IMC insertions for CS patients.

Increasing Patients' Access to ICM Insertion through Nurse-inserted ICM in Procedure Room

The initial change focused on solutions for increasing the ICM insertion capacity of the hospital as well as patients' access to diagnostic services. Drawing from experiences abroad [6,10,14] where nurses safely and effectively conducted ICM insertions, discussions were held with nursing education organizers and labor union representatives. These discussions led to the conclusion that training nurses to perform ICM procedures was safe and feasible.

The first ICM nurse-insertion training program was initiated in Finland in 2019. The content of the training was designed corresponding to the international, "Non-Physician Insert" (NPI) ICM training program [6]. On the organizational level, the trained specialized nurses were deemed comparable to advanced practice providers (APP) as defined in international literature and publications [10]. Registered nurses underwent specialized training to perform ICM insertions. Based on the training and monitoring of five patients' ICM insertions under the supervision of a cardiologist, the Tampere Heart Hospital authorized three nurses to perform independent ICM insertions. It can be concluded that some of the physicians' responsibilities were delegated to the nurses officially to redistribute the workload.

Limited availability of the catheterization laboratory and management of the ICM patient workflow in the hospital led to the decision to launch nurse-led ICM insertions in a clean follow-up room specifically equipped for this procedure. The improved ICM clinical pathway with nurses performing ICM insertion of smaller devices was launched in the beginning of 2020. Larger ICMs were still on the market as well and cardiologists implanted these devices (see Figure 2).

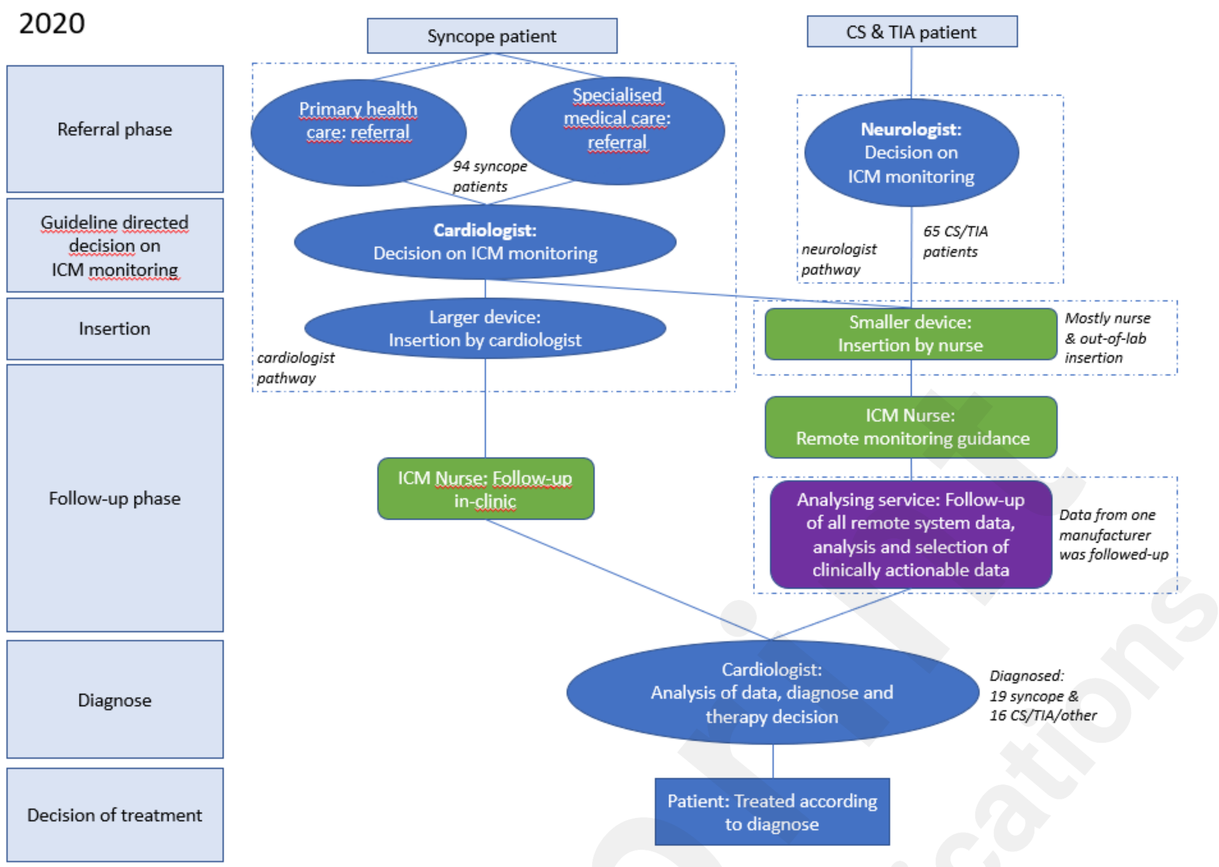

Figure 2. Patient pathways in 2020.

Outsourcing ICM Data Monitoring and Triaging

Another notable change pertained to managing the workload associated with ICM data, as most ICMs were monitored remotely. Considering that a significant portion of the remote monitoring data was not clinically actionable and given the limitations in staff time, it was decided to outsource the first line analysis and triaging of remote follow-up data to an external service provider (see figure 2).

The external monitoring service (FocusOn^{TM}, Medtronic) has been developed globally to cover the need of hospitals to facilitate the review and triaging of remote monitoring transmissions. A remotely located external team consisting of technicians and rhythm cardiology professionals analyzed the electrocardiogram (ECG) data from ICM patients followed up by remote monitoring. They determined the urgency of information and conveyed it to the hospital through phone calls, text messages, or emails, according to the order of priority established by the hospital. This approach enables efficient data management, allowing hospital staff to focus on patients needing immediate attention and allocate staff time to other tasks [21].

Therefore, the efficiency improvement of clinical pathways in the Tampere Heart Hospital included transferring the ICM data burden to outsourced monitoring and triaging service. This change allowed the trained nurses more time to perform additional ICM insertions by eliminating the need for routine non-actionable ICM transmission data reviews from the beginning of 2020.

Methods

Efficiency Assessment

A retrospective registry study was performed to assess the impact of the pathway changes. We computed key efficiency and safety metrics for the Tampere Heart Hospital before (2018) and after (2020) the change in the clinical pathways. Efficiency metrics included the number of patients treated with ICMs for unexplained syncope and cryptogenic stroke or unexplained TIA, the number of ICM insertions performed by nurses and cardiologists, procedure time, the number of insertions done in the catheterization laboratory, waiting time, and diagnostic yield. Clinically significant arrhythmia (brady or tachy) was included in the diagnostic yield for syncope patients. For stroke patients, the diagnostic yield was measured as the proportion of patients with AF > 6 minutes. Safety measures included the number of infections.

Patient Population and Data Collection

Data collection encompassed all consecutive ICM patients at the Tampere Heart Hospital, irrespective of their indications, in the years 2018 and 2020. The data collection process was established as part of the clinic's ongoing medical care quality improvement efforts. Data were retrospectively collected from the patient records and procedure registry and identified using procedure codes and device serial numbers.

Ethical Considerations

The study followed the ethical principles of the Declaration of Helsinki. TAYS Research Services of the Wellbeing Services County of Pirkanmaa provided the permissions for the patient-level data collection from the EHR (R23641X). To protect patient privacy, ICM patient-level data were pseudonymized and subsequently aggregated into an anonymized format to prevent the identification of individuals. The data was handled according to the EU's GDPR policy.

Statistical Analysis

Descriptive tabling of the quantitative variables was performed in Excel version 2302 (Microsoft 365 Apps for enterprise). For categorical variables, the X^2 -test was used to compare the distributions of two or more groups. For continuous variables, a t-test was conducted to test for statistically significant differences. All calculations were done according to the intention to treat principle.

Results

Participants

In 2018, 74 consecutive patients were included in the study and in 2020, 159.
The proportion of female patients was 43.2% and 51.6% in 2018 and 2020, respectively. As they were being treated in an adult cardiology department, all patients were over 15 years of age. Most of the patients were aged between 40 and 79 years (78.3%) in 2018, with a similar age distribution in 2020 (71.7%). The median age of the patients was 66 years in the 2018 patient population and 67 years in the 2020 population. Participants' characteristics are presented in table 1.

Table 1. Participants’ characteristics in 2018 and in 2020.

	2018 **% (n)**	**2020** **% (n)**
ICM Insertions (N)	100 (74)	100 (159)

Gender		*P=0.24*
Female	43.2 (32)	51.6 (82)
Age		*P=0.35*
0-39 years	5.4 (4)	15.1 (24)
40-59 years	29.7 (22)	20.8 (33)
60-79 years	48.6 (36)	50.9 (81)
80+ years	16.2 (12)	13.2 (21)

Increased Utilization of ICM According to Guidelines

In 2018, the indication for the ICM insertion was mainly unexplained syncope (95.9%) with 2.7% of the patients indicated with cryptogenic stroke. In contrast, in 2020, 59.1% were indicated with unexplained syncope and 39.0% with cryptogenic stroke. The number of patients receiving ICMs increased significantly from 2018 to 2020 (*P*<.001). For syncope patients, the increase was from 71 to 94. Notably, the use of ICMs in patients with SC or TIA substantially increased from 2018 (2 patients) to 2020 (62 patients). (See table 2.)

Shortened Waiting Time

A two-sample t-test was performed to compare the average waiting time from referral to insertion in 2018 and 2020. The average waiting time decreased significantly from 49 days in 2018 to 36 days in 2020 (*P*=.02). (See table 2.)

Improved Resource Utilization

In 2018, physicians conducted all insertions, while in 2020, 70.4% of the ICM insertions were performed by specially trained nurses. The number of inserted ICMs doubled from 74 in 2018 to 159 in 2020. Delegating the responsibility of ICM insertions to trained nurses allowed physicians to allocate their time to other essential procedures and interventions. This transition to nurse-performed insertions in 2020 resulted in a saving of 48 hours (more than six working days) of physicians' time, a noteworthy improvement from the process in 2018. (See table 2.)

Decreased Catheterization Laboratory Utilization

In 2018, 18.9% of the insertions were completed in the catheterization laboratory, whereas in 2020, this figure was reduced to 1.9% (*P*<.001). Additionally, the scheduled procedure time for ICM insertion decreased from 60 minutes in 2018 to 45 minutes in 2020. The streamlined procedure scheduling saved an additional 40 hours (1 week) of nursing time and released the catheterization laboratory for other critical procedures, amounting to 27 hours per year. (See table 2.)

Uncompromised Safety

All procedure-related complications were collected. Typical procedure-related complications were pain, infection erosion, and device migration. The complication rate remained consistent, with no significant change, at 2.7% in 2018 and 3.1% in 2020 (*P*=.85).

Enhanced Nurse Productivity

Remote monitoring was set up for 51.3% (38) of the patients in 2018 and for 67.9% (108) in 2020. In

2018, none of the remote-monitored ICM patients were followed up by an outsourced analyzing service, whilst in 2020, all ICM remote-monitored patients (108) were in the FocusOn-system. In 2018, nurses were responsible for analyzing all remote transmissions, consuming a substantial amount of time. The number of transmissions that needed analyzing from nurses was not available. In 2020, the initial review and triaging of remote transmissions were outsourced to an external monitoring center. This external service escalated 11.2% of the transmissions (204 out of 1817) to the clinic for review. Assuming an average of 11 minutes per transmission by a nurse [8,9,15], this external service saved 296 hours (approximately 40 working days corresponding to almost 2 months) of nursing time in 2020. (See table 2.)

Table 2. Results – change in clinical pathway and safety.

		2018 % (n)	2020 % (n)	P-values
Indication				*P*<.001
	Indication syncope	95.9 % (71)	59.1 % (94)	
	Indication cryptogenic stroke/ TIA	2.7 % (2)	39.0 % (62)	
	Other	1.4 % (1)	1.9 % (3)	
Waiting time to procedure		49 days	36 days	*P*=.02
Nurse insertions		0.0 % (0)	70.4 % (112)	*P*<.001
Scheduled procedure time		60 min	45 min	
Insertion in catheterization laboratory		18.9% (14)	1.9% (3)	*P*<.001
Complication rate		2.7% (2)	3.1% (5)	*P*=.85
Data burden				*P*<.001
	Patients on remote monitoring	51.3 % (38)	67.9 % (108)	
	Patients on analyzing service	0.0 % (0)	67.9 % (108)	

High Diagnostic Yield

Notably, the quality of the diagnostic pathway was high, with a high diagnostic yield despite the increase in inserted ICMs from 2018 to 2020 (see Table 3). The one-year diagnostic yield for patients with syncope remained high and exhibited no statistically significant difference between 2018 and 2020 (26.7% vs. 20.2%, *P*=.32). Furthermore, for cryptogenic stroke patients who received ICMs, the percentage of AF diagnoses in 2020 was 27.4%. The 36-month diagnostic yield for syncope patients was generally high, but statistically significantly lower in 2020 (45.1%) compared with 2018 (38.3%) (*P*<.05). The 36-month diagnostic yield for stroke patients was 43.5% for patients who received an ICM in 2020.

Table 3. Diagnostic yield -Intention to treat.

	2018	2020		2018	2020		2018	2020	
	12-month follow-up		P-	24-month follow-up		P-	36-month follow-		P-values

	% (N)		values	% (N)		values	up % (N)		
Overall	25.7 % (19)	22.0 % (35)	*P*=.54	41.9 % (31)	32.7 % (52)	*P*=.17	43.2 % (32)	39.6 % (63)	*P*=.60
Syncope	26.7 % (19)	20.2 % (19)	*P*=.32	43.7 % (31)	33.0 % (31)	*P*<.05	45.1 % (32)	38.3 % (36)	*P*<.05
Stroke	0.0 % (0)	27.4 % (17)	-	0.0 % (0)	33.9 % (21)	-	0.0 % (0)	43.5 % (27)	-

Discussion

Our study illustrated that the change from physician-led ICM insertions to a clinical pathway where nurses inserted the majority of ICMs released a substantial amount of staff time and resources without compromising the quality of the clinical pathway. The efficiency assessment showed that nurse insertion and the use of an external monitoring and triaging service significantly improved the utilization of hospital resources, such as patient access to ICM insertion, follow-up, and diagnosis.

The results correspond to findings from the UK's NHS healthcare system, where trained nurses have independently been taking care of the ICM patient care pathway with high quality and safety already since 2015 [6]. The literature also reports the benefits of an external monitoring and triaging service. According to [16], the introduction of such service offered efficiency and effectiveness in patient care safely compared with remote follow-up handled solely at hospital level. In addition, outsourcing the management of remote monitoring data was seen as a key tool for saving staff time, which is essential considering the current staff shortage [8,17].

Our study at the Tampere Heart Hospital showed both a decrease in the waiting time for the procedure and an increase in the number of patients receiving care in response to the implemented changes in the ICM care pathway and the introduction of an external monitoring and triaging service. Overall, the number of ICM insertions in 2020 doubled, with indications for cryptogenic stroke and transient ischemic attack (TIA) also increasing significantly from 2018 to 2020.

The new workflow enabled nurses to gain new skills and broader responsibilities, while physicians could refocus on specialized care. Physicians' time was released as most procedures were done by a nurse in 2020, while in 2018 these were all performed by physicians. Also, the shorter procedure released overall staff time in 2020 compared with 2018. These results correspond to the findings of Lim et al. (2019) with the study conducted in the NHS [6].
In addition, the Tampere Heart Hospital catheterization laboratory was also released for other procedures, as the insertions performed in this setting decreased significantly. Rogers et al. (2020) showed similar results for insertions performed outside the catheterization laboratory. Moving the procedure to office settings saved time spent by patients in hospital, space and resources used, clinical staff time, and, thus, the total costs of the procedure [15]. When aiming to increase efficiency in the clinical pathway, a detailed analysis of all resources supports optimizing the process.

In this study, only cardiac diagnoses were included in the reporting of the diagnostic yield. Furthermore, an "intention to treat" principle was used, hence all patients were included with full follow-up time, even though they were diagnosed, deceased, or exited the population earlier for any other reason.

In a meta-analysis from 2017 (Solbiati et al.), the overall diagnostic yield was 43.9%, and around 50% of these were arrhythmic syncope [17]. The cardiac diagnostic yield found in this study was high both in 2018 and 2020 although slightly lower in 2018 (45.1% and 38.3%, $P<.005$).

In an earlier study by Sanna et al. (2014), the AF detection rate for stroke patients was reported to be 12.4% at the 12-month follow-up and 30.0 % at the 36-month follow-up. However, the present study showed an even higher diagnostic yield of 43.5% at 36 months. Notably, the patient population in the initial care pathway only included a very low number of CS or TIA patients which prevents a comparison between 2018 and 2020 for this indication [18].

Importantly, the changes in the ICM pathway did not compromise patient safety. The safety of the procedure in this study remained high regardless of whether it was performed solely by a physician in the catheterization laboratory or a procedure room (2.7%) or mainly by a nurse in a procedure room (3.1%), as the complication rate did not change significantly. In earlier studies, procedure-related adverse events have been between 1.1%-2.6% depending on the location of the procedure [19,20], and the complication rate has been 1.0% for nurse-performed ICM insertions and 2.2% for physician-performed insertions [6]. Therefore, it can be concluded that task shifting the procedure to be performed by specially trained nurses in a procedure room increases the efficacy of the clinical pathway.

Regarding the patient follow-up, while in 2018 nurses were analyzing all remote monitoring data, in 2020 that part of the workflow was outsourced to an external monitoring and triaging service, seeking improvement in the quality and efficiency of care through the redistribution of work. As nurses in 2020 monitored only the remote transmissions that were escalated after initial review and triaging by the external platform, they could perform more ICM insertions and actionable patient follow-ups. Similar efficiency benefits of outsourcing part of the workflow have previously been reported [9,16]. In addition, Biundo et al. highlighted the need for appropriate staff resources to support patient management activities, including remote monitoring [8]. Considering the heterogeneity in the infrastructure and staff capacity of hospitals managing ICM patients, different organizational models should be considered locally to achieve efficient patient management, including outsourcing part of the remote monitoring workflow [21].

Limitations

This study has several limitations. This study is a single center study with a small number of consecutive ICM patients without randomization. Nonetheless, they represent patients from a tertiary level cardiac hospital that serves a population of 520 000 inhabitants [22]. However, the real-world setting helps to describe how a clinical pathway change is made in practice. One of the limitations is that the retrospective analysis uses data that was documented and/or available in the EHR. For example, the working time that the nurses used to analyze the data for the seventy-four patients was not recorded at that time. Therefore, for the efficiency estimation concerning the saved working time of nurses, we used only the 2020 data in comparison with earlier research. At the time of launching this study, there was only one other clinic in Finland that had nurse-led insertion in place. At the time of publishing the results, there are nine clinics running a nurse-led ICM process in Finland. In the future, with a multi-center study in Finland we could increase the generalizability of our findings.

Conclusions

The change in the clinical pathway to nurse-insertion in a procedure room and the use of an external monitoring and triaging service significantly improved the efficiency of the pathway for patients indicated for an ICM. In addition, nurse-insertion released a significant amount of staff time and resources without compromising the quality of the treatment. It can be stated that clinical pathway improvements enable offering ICMs to a greater number of patients to meet the diagnostic demand.

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Data Availabilities

The data of this study is owned by and only available internally to the Tampere Heart Hospital. For external researchers, ethical approval may be obtained via formal application for a specific research project, such as in this case. Interested parties are advised to contact the corresponding author.

Authors Contributions

Change in pathway: VV, VM, PK, OS
Collection of data: VM, OS, MLJ
Study design and writing of the first draft of the manuscript: OS
Analyzing the anonymized data: MLJ, OS
Revised the manuscript: VV, PK, OS, JH, MLJ
All authors reviewed and contributed to the final manuscript.

Conflicts of Interest

OS, MLJ, JV and EN are Medtronic employees and shareholders.

Abbreviations

ICM Insertable Cardiac Monitor
EHR Electronic Health Record
TIA Transient Ischemic Stroke
EHRA-HRS European Heart Rhythm Association – Heart Rhythm Society
ESC European Society of Cardiology
CS/TIA Cryptogenic Stroke/ Transient Ischemic Stroke
NPI Non-Physician Insertion
ECG Electrocardiogram
AF Atrial Fibrillation
GDPR General Data Protection Regulation
EU European Union
NHS National Health Trust

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