Remote Monitoring in the Management of Heart Failure

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Dedicated to my beloved

late father Fabio Maurizio Mirone –

I hope I have made you proud.

Abstract

Remote monitoring (RM) is increasingly being integrated in the management of patients with heart failure (HF) with cardiac implantable electronic devices (CIEDs). The aims were to identify benefits and challenges of RM and to assess the contribution of pulmonary fluid status RM in patients with HF.

A literature review was conducted using PubMed® and applying the search terms 'heart failure' AND 'digital health' AND 'remote monitoring' to identify benefits and challenges of RM in HF patients. Inclusion criteria were peer-reviewed articles, available as free full text, in English and published between 2012 and 2021. A cohort study was conducted at the Department of Cardiology of Mater Dei Hospital, including all patients (January 2015-December 2021) diagnosed with HF and with a CIED incorporating a pulmonary fluid status monitoring feature (OptiVol™ 2.0) which tracks intrathoracic impedance changes over time and has the possibility of being monitored remotely. A data collection sheet was developed and validated by an expert panel. Outcomes were assessed over one-year post-CIED implantation using hospital records.

From 54 articles screened in the literature review, 25 eligible articles were appraised. Benefits of RM included improved patient health status (n=11), new opportunities to identify and manage risk factors (n=5) and feasibility (n=3). Challenges included cost issues (n=1), data privacy concerns (n=1), maintenance of system efficiency and data quality (n=1). From the cohort of 45 patients assessed (35 male, 20 aged between 71 and 80 years, mean left ventricular ejection fraction 29%, 23 classified as New York Heart Association Class II), 21 patients had RM switched on. Alerts were recorded in 19 of these patients, which led to no action deemed necessary (n=12) or action taken (n=7) by the

cardiologist. Actions taken were increase in diuretic dose (n=5), hospital admission (n=3), limiting fluid intake (n=1) and/or increase in dose of disease-modifying drug (n=1).

The literature review showed that benefits of RM in patients with HF outweigh the challenges. In practice, pulmonary fluid status RM identified patients who required therapy optimisation in the outpatient setting or hospital admission. More than 50% of the patients opted to have RM switched off, indicating a need for more patient awareness on the benefits of RM.

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List of Abbreviations

ACC	American College of Cardiology
AI	Artificial Intelligence
ARNI	Angiotensin Receptor-Neprilysin Inhibitor
CABG	Coronary Artery Bypass Grafting
CIEDs	Cardiac Implantable Electronic Devices
CRT-D	Cardiac Resynchronisation Therapy Defibrillator
CVD	Cardiovascular Disease
CVIS	Cardiovascular Information Management System
ESC	European Society of Cardiology
HF	Heart Failure
ICD	Implantable Cardioverter Device
IF	Impact Factor
IT	Information Technology
NYHA	New York Heart Association
PCI	Percutaneous Coronary Intervention
POYC	Pharmacy Of Your Choice
PRISMA	Preferred Reporting Items for Systematic Reviews and Meta-Analysis
RM	Remote Monitoring
SGLT2i	Sodium-Glucose Co-Transporter 2 Inhibitors
USA	United States of America

Chapter 1 Introduction

1.1 Development of digital health in healthcare

Digitalisation in healthcare has progressed rapidly in recent years and is revolutionising healthcare systems (Whitelaw et al., 2021; Cuff, 2023).[1] Digital health involves the effective and efficient use of information technology (IT) systems for patient care, research, training of healthcare personnel, and disease and public health monitoring (Madhavan et al., 2021). Digital health may be regarded as a broad-spectrum term which encompasses the use of wearable devices, mobile applications, electronic health records, telehealth and telemedicine, which allow for the diagnosis and management of health conditions using artificial intelligence (AI), machine learning and remote monitoring (RM) (Abernethy et al., 2022). Although adopting innovation may be challenging, history has shown that it is essential for technological progress to occur in the medical and healthcare fields (Bond and Peace, 2021). As stated by the World Health Organization Director-General in a report published in 2019, "the creative use of digital health has the potential to close the gap of health access inequities, by improving medical outreach to patients and strengthening health systems".[2]

The variety, amount, speed, veracity, and importance of data has increased significantly over the years, and IT-based methods of practicing health care are creating a platform of data storage transformation and retrieval worldwide (Banerjee, 2017). Digital advancement is a vital tool for the modernisation of current healthcare systems and to improve overall patient

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[1] International Pharmaceutical Federation (FIP). Digital Health in pharmacy education: Global showcase of initiatives from pharmacy schools [Internet]. FIP; 2021 [cited 2024 Jul 1]. Available from: https://www.facebook.com/FIPpharmacists

[2] World Health Organization (WHO). WHO releases first guideline on digital health interventions [Internet]. Who.int. World Health Organization: WHO; 2019 [cited 2024 Jul 1]. Available from: https://www.who.int/news/item/17-04-2019-who-releases-first-guideline-on-digital-health-interventions

health, which further empowers patients and healthcare providers to be more involved in patients' progress and to achieve higher standards of care (Zwack et al., 2023).

In the era of the COVID-19 pandemic, the increased need and growth in value of digital services in healthcare demonstrated how healthcare can be optimised with the help of digital technology, and this experience could be imparted to future generations of practitioners (Mahajan et al., 2020). The transition to digital platforms which was beneficial during the COVID-19 pandemic (Antoniades et al., 2021) is advantageous today for busy working people, reducing issues related to traffic to and from hospital, parking and time spent waiting to receive an appointment with a specialist (Kumar et al., 2013), while allowing for earlier detection of conditions.[3] Digital Health allows for better communication between healthcare professionals and patients (Frederix et al., 2019).

1.2 Digital technologies for remote monitoring

The development of wearable devices has gained popularity over the past years (Schyvens et al., 2024). Smartwatches, bands, heart rate devices, and smart rings are examples of monitors which may be used in the management of chronic conditions. These non-invasive sensors lead to efficient and relatively low-cost remote monitoring of patient parameters such as blood pressure, heart rate, oxygen saturation and body temperature (Lu et al., 2024).

[3] Prescher S, Koehler J, Koehler F. e-Health in cardiology: remote patient management of heart failure patients. Escardio.org [Internet]. 2020 [cited 2024 Jul 1];18(26). Available from: https://www.escardio.org/Journals/E-Journal-of-Cardiology-Practice/Volume-18/e-health-in-cardiology-remote-patient-management-of-heart-failure-patients

As the most common means of communication, smartphones are the way forward for remote monitoring (Boulos et al, 2011). This is particularly important due to the global ageing population which poses a greater financial burden on healthcare systems due to increased risk of developing chronic conditions (Majumder et al, 2017). Real time data may be accessed by both the patient and clinician, and is particularly useful during medical appointments upon making a new diagnosis or when monitoring progression of the condition (Callum et al., 2021). These devices may encourage patient empowerment, whereby patients are more knowledgeable about their conditions and treatments, and are able to make more informed decisions and take a greater interest in their health (Andersen and Carlsen, 2024).

Mobile applications have become widely available for installation on smartphones. They are mostly free of charge or relatively cheap, easy to carry around and simple to use (Del Toro et al., 2023). They offer easy to follow, guided instructions on how to use the applications which facilitate their use even by patients who may be less technologically literate. Using mobile applications, patients can record and track their symptoms, as well as enhance medication adherence through the use of reminders and alarms for the management of chronic conditions (Pratiwi et al., 2023). These applications can further educate patients by explaining more about their condition and highlighting symptoms they should look out for and inform their clinician about. Such personalised care is an educational resource which provides relevant feedback regarding the patient's progress. Logged data may be easily displayed by the automatic generation of graphs and charts to display the patient's history and current status, allowing for easy analysis. A useful feature is the ability to share data from these applications with the healthcare provider to access real-time information allowing for swift interventions to occur (Jat and Morten Grønli., 2023).

1.3 Digital health in the cardiology specialty

Prevention is the most economically efficient intervention in cardiology (Saner and Van der Velde, 2016), and carries the greatest potential to reduce the financial burden of cardiovascular disease (CVD). CVD is a leading cause of mortality and morbidity globally (Jiang et al., 2019; Ogungbe et al., 2024) and is a major cause of reduced quality of life (Whitelaw et al., 2021). The outcomes of telehealth and digital health may contribute to different aspects of care in cardiology (Vervoort et al., 2020), including primary prevention along with acute care management of conditions and rehabilitation (Wade and Stocks, 2017).

According to results from the European Society of Cardiology (ESC) Atlas project, application of Digital Health could play a very important role in primary prevention, whereby solutions including online counselling by telemonitoring, telemedicine and telecardiology through mobile applications and instant messaging services, as well as monitors for self-tracking, can improve overall patient health and wellbeing (Timmis et al., 2017). Digital Health is currently being used to treat and follow up complex clinical syndromes and conditions such as heart failure (HF) (Kitsiou et al, 2021; Kwon et al., 2021). Digital Health is being used to prevent cardiac decompensation in ischaemic heart disease (Ibanez et al, 2017), to monitor automated electrocardiogram analysis to detect coronary occlusion (De Jaegere, 2021), and to monitor hypertension (Parati et al, 2019). Digital Health is proving to be useful in assuring adherence to essential medications (Campbell et al, 2021). Digital health technology is seen as an attractive powerful tool, especially amongst more IT literate patients, to increase awareness and empowerment in cardiovascular health management due to the rising popularity of owning smartphones and wearables, which in turn has led to more investment within this sector (Johnson et al., 2023).

Although the use of digital health in cardiology is still in its initial stages and is relatively slow-moving (Solberg, 2019; Martin, 2024), the notion of transforming cardiology onto a digitally driven platform through the convergence of science and technology is a promising one constituting very fertile ground for innovation (Ladejobi et al., 2020). The importance of home telemonitoring in HF in helping to maintain quality of care, facilitating rapid access to care when needed, reducing patient travel costs, and minimising frequency of clinic visits, is also emphasised in the 2021 European Society of Cardiology guidelines for the diagnosis and treatment of acute and chronic heart failure (McDonagh et al., 2021).

1.4 Applications of Digital Health in different countries

Over the past few years, medical call centres for use by patients have been set up in countries such as in the United States of America (USA), Australia and China. Most of these centres use non-invasive devices, such as blood pressure and pulse monitors. These devices are particularly effective when offering a 'round-the-clock' assistance and detection service, including during weekends and public holidays (Brahmbhatt and Cowie, 2019).

A study carried out in Australia introduced a telehealth cardiology pharmacist-led clinic. The study demonstrated that a cardiology pharmacist consultation carried out prior to consultation with the cardiologist significantly reduced the time spent by the cardiologist gathering medical information, decreased medication uncertainty, and provided the cardiologist with greater confidence in making treatment decisions. Patients who participated in the study and met with the pharmacists first, were more likely to attend their cardiologist consultation, lowering the rate of 'no show' missed appointments (Livori et al., 2021).

Artificial Intelligence (AI) is being incorporated in the digitalisation of cardiology healthcare (Ladejobi et al., 2020). One example is the development of an AI nurse launched in China in April 2020 (Robert, 2019). This technology served as a patient needs-led digital platform, supporting patients and healthcare workers in the management of HF in accordance with the 'Healthy China 2030' plan which has been implemented with the objective of improving health priorities, science, and technological innovations. [4]

A similar AI-based system introduced by the Japanese government was found to be capable of predicting one-year mortality for hospitalised patients suffering from HF (Tohyama et al., 2020). This AI-based system included a financial incentive mechanism which greatly encouraged healthcare professionals to use this platform. The outcome was that results collected did not require any further quantitative laboratory or physiological data, or any other additional information (Tohyama et al., 2020). This permits the evolution of cardiovascular medicine (Antoniades et al., 2021), promoting patient self-monitoring to the digitally engaged patient (Lupton, 2013), and increasing patient-centricity (Bhavani et al., 2016).

Another study carried out in rural areas in Italy on a sample of 200 people demonstrated that a high proportion (86%) of people expressed an interest in using telehealth and digital technologies for everyday health issues. While this survey indicated a favourable response for

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[4] Healthy China 2030 (from vision to action). World Health Organization [Internet]. 2023 [cited 2024 Jul 1]; Available from: https://www.who.int/teams/health-promotion/enhanced-wellbeing/ninth-global-conference/healthy-china

the use of telemedicine, it indicated that patient education and awareness on the matter is still limited (Dossi et al., 2020).

Many Digital Health companies in the USA have partnered with technological companies to introduce platforms to the health care delivery market. However, a number of barriers have hindered the smooth implementation of such systems. Barriers include clinicians' concern of increased workload, lack of a payment model, high demand for data which requires continuous physiological monitoring, and difficulty in determining which digital technologies to use.[5] Possibly as a result of these barriers, according to the American College of Cardiology (ACC), healthcare delivery to improve efficiency in the prevention of certain undesired health outcomes has not advanced in the same way as 'high tech' medicine that is currently being used in cardiovascular disorders (Sharma et al., 2018).

1.5 Remote monitoring for fluid status in heart failure patients

Remote monitoring (RM) offers an opportunity for enhancing healthcare (Meehan., 2024). RM is an aspect of digital health in cardiology which is increasingly being integrated in clinical practice in managing HF patients with cardiac implantable electronic devices (CIEDs) (Vandenberk and Raj, 2023). RM has the potential for identification of patients at risk of worsening HF and for efficient optimisation of therapy (Rosman et al., 2021). Patients with CIEDs need regular follow-up and RPM enables management of HF symptoms and provides

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[5] Roadmap For the Digital Transformation of Health Care: Lead, Facilitate and Partner - American College of Cardiology [Internet]. American College of Cardiology. 2019 [cited 2024 Jul 3]. Available from: https://www.acc.org/latest-in-cardiology/articles/2019/11/02/24/42/roadmap-for-the-digital-transformation-of-health-care-lead-facilitate-and-partner

an opportunity to facilitate such follow-up (Catalan Matamoros et al., 2022; Silvetti et al., 2022).

Through the use of CIEDs with RM, a continuous flow of information can be provided to clinicians, and clinically relevant outcomes may be identified pre-emptively to allow timely action to be taken for the benefit of patients (Cowie and Lam., 2021).

One aspect of RM in heart failure patients involves monitoring of intrathoracic impedance and fluid status. The OptiVol™ 2.0 fluid status monitoring feature in CIEDs can track intrathoracic impedance changes over time by means of electrical impulses to help in the assessment of congestion in heart failure patients by means of graphs and alerts (Yu et al., 2005; Yamokoski et al., 2007; Yang et al., 2013; Wintrich et al., 2021). However, conflicting results have been reported regarding its use. Data shows that changes in intrathoracic impedance and fluid increase in the thoracic cavity or lungs are inversely correlated (Yu et al., 2005). If the daily impedance (average of each day's multiple impedance measurements) falls below the relevant reference range (the average impedance calculated per patient), this may indicate that there is fluid accumulation in the thoracic cavity (inversely proportional). The clinician is able therefore to understand on a more accurate and precise level how the patient's fluid status reacts to changes in medications, new clinical events, and the overall status of patient's health.[6]

A study reported by the American Heart Association investigated the impact of RM based on measuring intrathoracic impedance using the OptiVol™ fluid status monitoring device.

[6] OptiVol Fluid Status Trend Feature. Medtronic Academy [Internet] 2024 [Cited 2024 Jul 9]. Available from: https://www.medtronicacademy.com/features/optivol-fluid-status-trend-feature#:~:text=The%20OptiVol™%20fluid%20trend,outcomes,%20and%20overall%20patient%20status.

Reactions to alerts were analysed to note if there was an improvement in patients with heart failure and CIEDs. Results of this study noted that appropriate timely reactions to RM alerts gave rise to significantly improved outcomes in HF patients (Wintrich et al., 2021).

1.6 Local relevance and study rationale

In Malta, comparable to global trends, an ageing population is noted. This factor, coupled with a high tendency for obesity, poses a higher risk for development of CVDs, which constituted the single largest cause of death in the Maltese community in 2022.[7] From slightly over 2,600 patients in 2017, over 4,300 patients were being treated at the HF clinic of Mater Dei Hospital in 2023.[8] Despite the significant improvement in prognosis for many HF patients due to increased availability of drugs, enhanced surgical techniques and specialised pacemakers, effective HF care and improved quality of life depends greatly on early detection, quick medication initiation and timely referral to specialists. The use of digital technology such as RM may help towards early detection and reduce the impact of CVDs identifying patients at higher risk of mortality and facilitating monitoring (Ahmed et al., 2022). It was deemed relevant to understand to what extent this opportunity is being availed of within the Maltese health sector, to analyse the factors which may hinder use of such technology and to discuss how challenges may be overcome.

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[7] Cardiovascular disease was Malta's leading cause of death in 2022. [internet] 2024. [Cited 2024 Jul 17]. Available from: https://www.maltatoday.com.mt/news/national/127818/cardiovascular_disease_was_maltas_leading_cause_of_death_in_2022#:~:text=old%20or%20older-,Cardiovascular%20disease%20was%20Malta's%20leading%20cause%20of%20death%20in%202022,1%2C080%20of%20the%20total%20victims.

[8] New cardiology consultants soon to be appointed as patients boom. [Internet] 2024. [Cited 2024 Sept 2]. Available from: https://timesofmalta.come/article/new-cardiology-consultants-soon-to-be-appointed-as-patients-boom.

1.7 Aims of the Study

The aims of the research were to:

1) Identify benefits and challenges of RM in heart failure

2) Assess the effect of fluid status RM in heart failure patients with CIEDs.

Chapter 2 Methodology

2.1 Study Design

The research design was divided into two phases. In phase 1, a literature review was conducted to understand the potential of RM in the management of HF, including studies that have already been carried out using OptiVol™2.0. This was followed by a cohort study in phase 2 which involved development and validation of a data collection sheet, ethics approval, patient identification according to inclusion criteria and data collection with data provided from hospital records by an identified intermediary. Patient follow up for specified outcomes was carried out over a one-year period at specified intervals from the date of CIED implantation using data from hospital records, followed by data analysis (Figure 2.1).

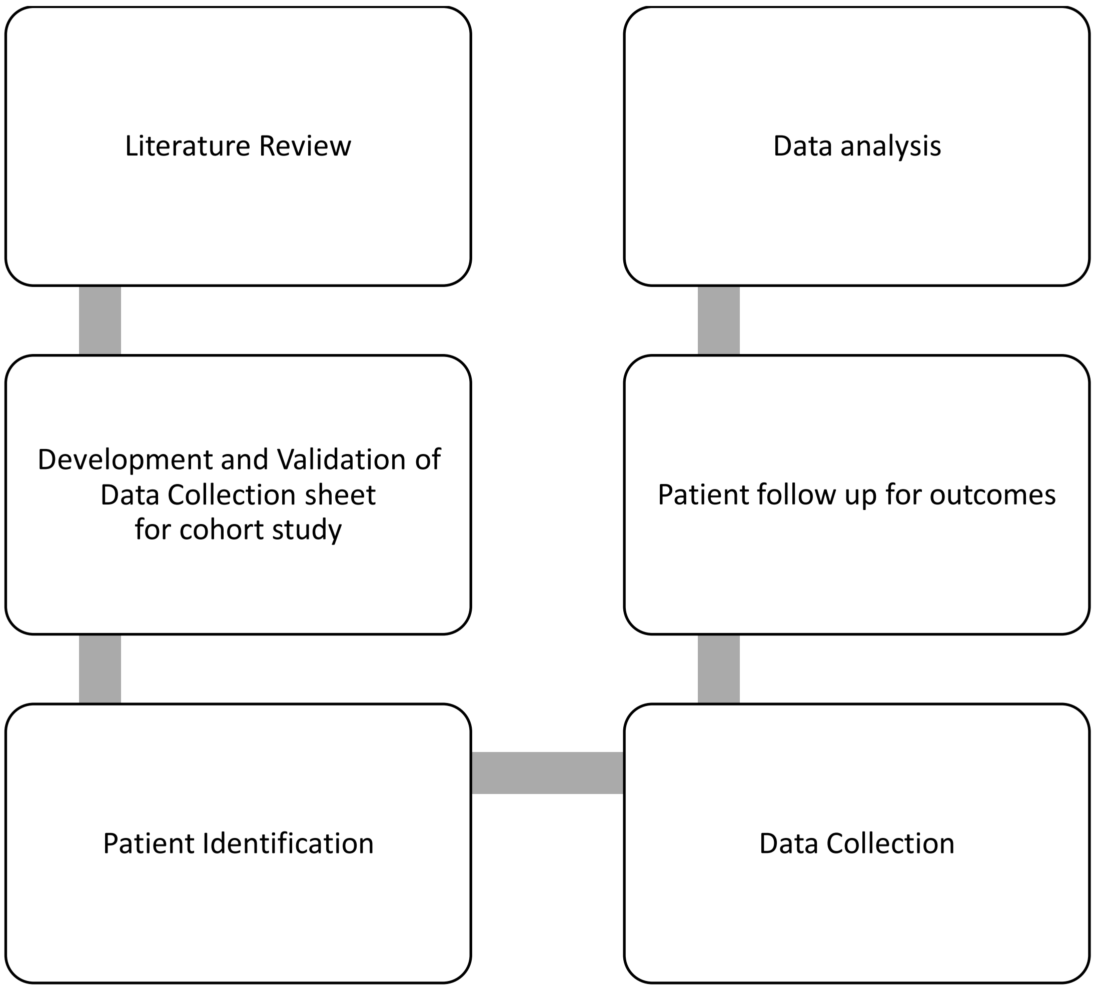

Figure 2.1: Methodology Overview

2.2 Ethics Approval

Ethics approval was obtained from the University of Malta Faculty of Medicine and Surgery Research Ethics Committee (MED-2022-00128) (Appendix 1).

2.3 Literature Review

Appraisal of relevant literature was carried out to identify the benefits and challenges of digital health and RM in HF. This was undertaken using the online research database PubMed® with the following search terms and Boolean operator: 'heart failure' AND 'digital health' AND 'remote monitoring'. Inclusion criteria were peer-reviewed articles, available as free full text, published between the years 2012 and 2021, and available in the English language. The results were filtered accordingly, using the 'Preferred Reporting Items for Systematic Reviews and Meta-Analysis' (PRISMA) guidelines as a reporting tool, and a PRISMA flow diagram was formulated. Microsoft® Office Excel® was used to categorise publications according to date, type, impact factor and country of publication.

2.4 Cohort Study

A cohort study was carried out to assess outcomes of pulmonary fluid status RM with the OptiVol™ 2.0 device in heart failure patients with CIEDs. The cohort study was conducted at the Department of Cardiology at Mater Dei Hospital (MDH).

2.4.1 Development and Validation of Data Collection Sheet

A data collection sheet (Appendix 2) was developed and validated for content, comprehensiveness and presentation by an expert panel consisting of 3 cardiologists, 2 pharmacists and 1 ECG technician. The data collection sheet included 7 sections covering patient details, risk factors and comorbidities, HF medications at CIED implantation, relevant investigations, outcomes, changes in medications during the follow-up periods, and a final section for patients who had RM switched on (Table 2.1).

Table 2.1: Sections of developed Data Collection Sheet

Section	Title	Content
1	Patient Details	Gender, Age at CIED implantation, Date of CIED implantation, NYHA Classification, Type of CIED, whether patient has RM
2	Risk Factors and Comorbidities	Cardiovascular, respiratory, metabolic, endocrine, smoking status, alcohol consumption and other relevant risk factors and comorbidities
3	HF Medications at CIED Implantation	Drug Class
4	Relevant investigations	LVEF, NT-proBNP, Blood Pressure, Heart rate, Potassium, eGFR, Sodium Creatinine, Urea, Haemoglobin, LDL Cholesterol, Weight, Height, BMI
5	Outcomes	Outcomes at each follow up:1-4 weeks, 3 months, 6 months, 12 months
6	Changes in Medications during follow-up	Drug Class
7	Patients with RM switched ON	Number of alerts, date or alert, false alarm, Action taken, Close monitoring at HF clinic, Change in treatment, Admission to hospital.

2.4.2 Patient Recruitment and Data Collection

Inclusion criteria for patient recruitment were a diagnosis of HF and having an implantable cardioverter device (ICD) or cardiac resynchronisation therapy defibrillator (CRT-D) device incorporating the pulmonary fluid status monitoring feature (OptiVol™ 2.0), which can be monitored remotely by the heart failure clinic at MDH. All patients meeting the abovementioned inclusion criteria in the period between 2015 and 2021 were identified by an intermediary using information from the Cardiovascular Information Management System (CVIS) and iSOFT at the Department of Cardiology, MDH. A total of 45 patients were identified and were included in the study. There was no contact with patients at any point during the study.

2.4.3 Patient Follow Up

Patients were followed up at intervals of 1-4 weeks, 3 months, 6 months, and 12 months post-CIED implantation for outcomes, including timely therapy optimisation, patient status, hospital admission and mortality. Any alerts were recorded for those patients with RM switched on, and any action taken following alerts were noted.

2.4.4 Data Analysis

All data collected was analysed using Microsoft® Office Excel® for Mac version 16.77.

2.5 Dissemination of findings

An abstract was accepted for poster presentation at the 82nd FIP World Congress of Pharmacy and Pharmaceutical Sciences 2024, Cape Town, South Africa in September 2024.

(See list of Publications and Abstracts)

Chapter 3 Results

3.1 Findings from the Literature Review

In the initial search, a total of 54 records were retrieved and screened. There were no duplicate publications. Upon applying the inclusion criteria, 14 publications were not available as full text, 14 were outside the specified date range and 1 article was excluded since it was not related to digital health and remote monitoring. A total of 25 records were included in the literature review (Figure 3.1).

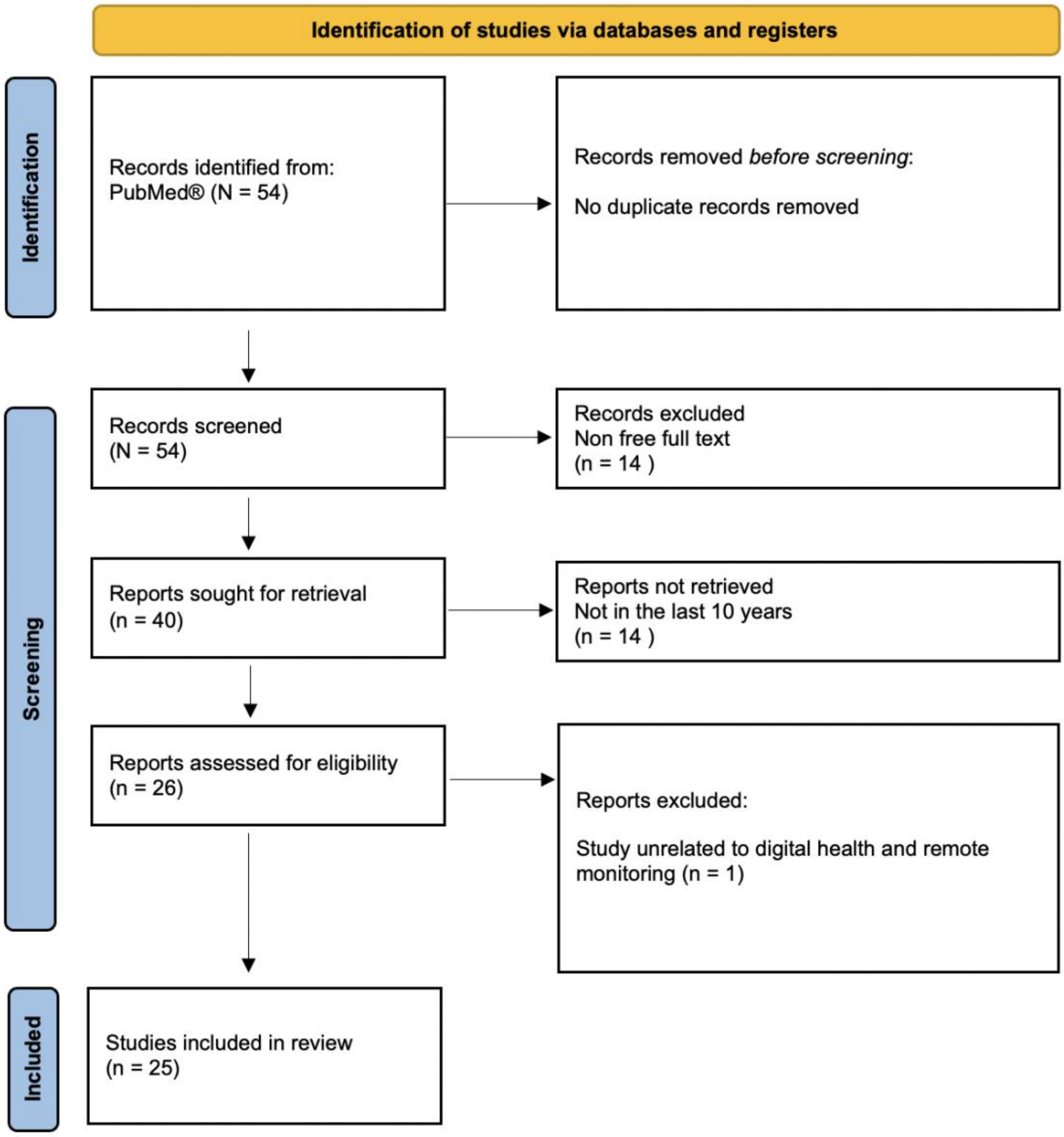

Figure 3.1: PRISMA flow diagram

The 25 records included in the review were categorised according to year of publication. An increase in records was seen with most articles published in 2020 (n=9) and 2021 (n=8) (Figure 3.2).

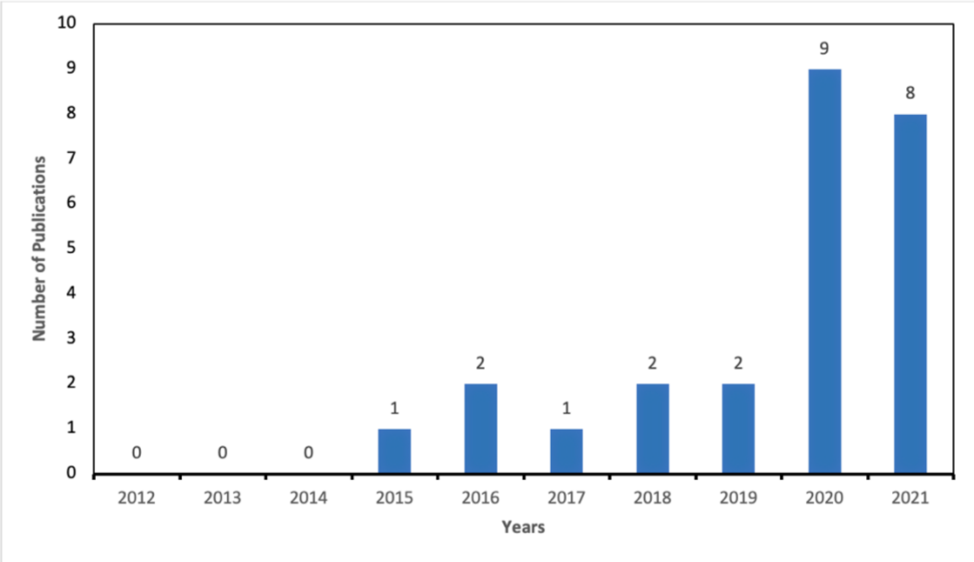

Figure 3.2: Number of publications according to year (N=25)

The publications were mostly review articles (n=12) (Figure 3.3).

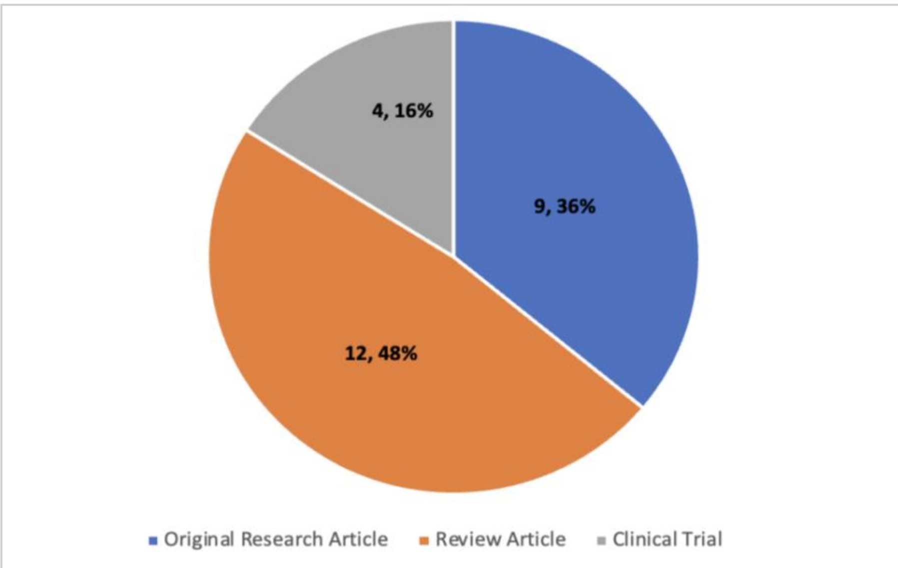

Figure 3.3: Types of Publications (N=25)

The publications were classified according to country of publication. The highest number of publications originated from the United Kingdom (n=7), followed by the United States of America (n=6) and Canada (n=6) (Figure 3.4).

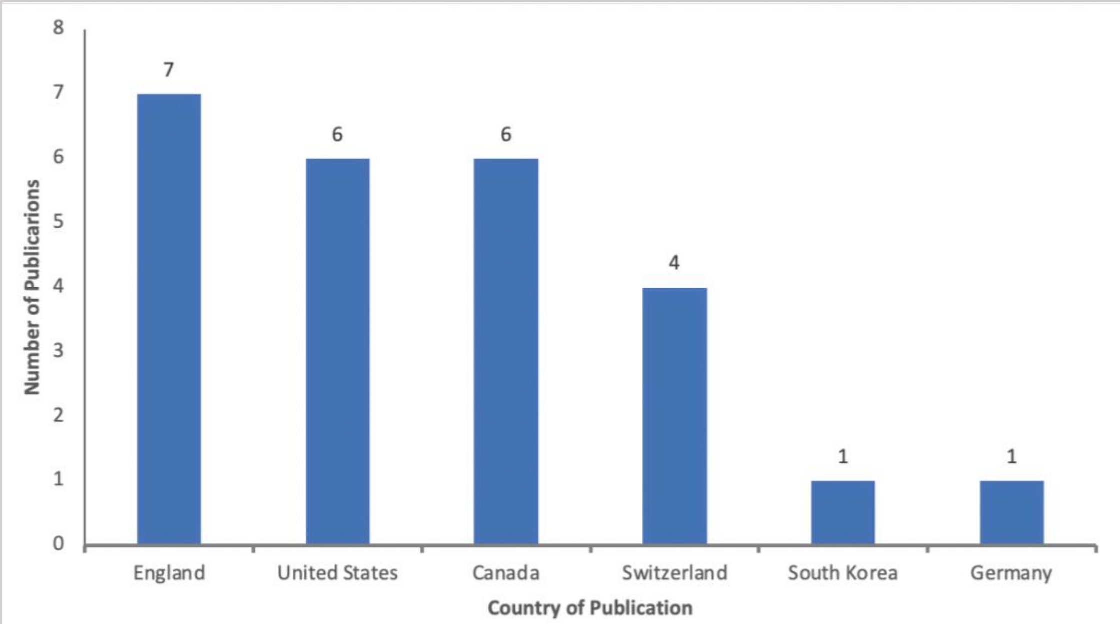

Figure 3.4: Number of publications according to the country of publication (N=25)

The impact factor for each journal was reviewed and tabulated from highest to lowest (Table 3.1). Impact factor ranged from 0.27 (*Journal of Community Hospital Internal Medicine Perspectives) to* 49.42 (*Nature Reviews Cardiology).*

Table 3.1: Journal Impact Factor of articles appraised (N=25)

Journal Name	Impact Factor, Year		Number of articles	References
Nature Reviews Cardiology	49.42	2021	1	Cowie & Lam, 2021
Journal of the American College of Cardiology	24.09	2020	1	Krishnaswami et al, 2020
American College of Chest Physicians	10.26	2021	1	Mackinnon & Brittain, 2020
European Journal of Heart Failure	7.91	2021	2	Koehler et al, 2018; Mullens et al, 2020
Journal of Medical Internet Research	7.08	2021	1	Ding et al, 2020
Digital Biomarkers	6.90	2021	1	Kramer et al, 2020
International Journal of Heart Failure	5.71	2022	1	Bhatia & Maddox, 2020
Telemedicine and E-Health	5.03	2021	1	Evans et al, 2016
Journal of Medical Internet Research for Mobile health and Ubiquitous health.	4.95	2022	1	Zan et al, 2015
Journal of Medical Internet Research for Aging	4.51	2021	1	Lefler et al, 2018
European Heart Journal Supplements	4.42	2022	1	Di Lenarda et al, 2017
Sensors	3.58	2020	2	Duncker et al, 2021; Bleda et al, 2019
The British Journal of Cardiology	3.49	2021	1	Sze, 2020
Journal of Medical Internet Research for Medical Informatics	3.23	2022	1	Park et al, 2019
Healthcare	3.16	2021	1	Sagaro et al, 2021
Yearbook of Medical Informatics	2.96	2022	1	Indraratna et al, 2021
Cardiac Failure Review	2.50	2022	1	Singhal & Cowie, 2021
Cardiovascular Digital Health Journal	2.00	2021	1	Toscos et al, 2020
Current Treatment Options in Cardiovascular Medicine	1.87	2022	1	Farwati et al, 2021
Journal of Medical Internet Research for Research Protocols	1.85	2021	2	Herkert et al, 2020; Ho et al, 2016
Health Informatics Journal	1.83	2017	1	Gjeka et al, 2021
Journal for Community Hospital Internal Medicine Perspectives	0.27	2019	1	Sattar et al, 2021

Of the 25 publications reviewed, all reported on the benefits/outcomes of digital health and remote monitoring in patients with heart failure. The most common outcome was improving the overall patient health (n=11) (Table 3.2).

Table 3.2: Benefits of digital health and remote monitoring in patients with heart failure (N=25)

Outcome	Number of Articles	References
Improve patient health	11	Mackinnon & Brittain, 2020; Krishnaswami et al, 2020; Farwati, Riaz & Tang 2021, Park et al, 2019; Gjeka, Patel, Reddy & Zatsche, 2021; Mullens, et al, 2020; Di Lenarda et al, 2017; Sattar et al, 2021, Di Lenarda et al, 2017, Ho et al, 2016, Herkert et al, 2020
New opportunities for identification and management of risk factors	5	Duncker et al, 2021, Koehler et al, 2018; Bleda et al, 2019, Farwati, Riaz & Tang, 2021, Kramer et al, 2020
Feasibility	3	Lefler et al, 2018; Zan et al, 2015, Gjeka, Patel, Reddy & Zatsche, 2021
High level of patient weight monitoring	2	Ding et al, 2020; Foreman et al, 2021
Older adults able to reside longer in their own homes	1	Evans et al, 2016
Ease of collecting data remotely	1	Cowie & Lam, 2021
Use of remote monitoring onboard ships	1	Sagaro, Canio, Talevi & Amenta, 2021
Patient empowerment	1	Toscos et al, 2020

Four publications reported on challenges in the implementation of digital health and remote monitoring in patients with heart failure (Table 3.3).

Table 3.3: Challenges of digital health and remote monitoring in patients with heart failure (n=4)

Challenges	Number of Articles	References
Cost issues	1	Singhal & Cowie, 2021
Data privacy concerns	1	Cowie & Lam, 2021
Achievement of effective care outcomes	1	Duncker et al, 2021
Maintenance of system efficiency and data quality	1	Sze, 2020

3.2 Findings from the Cohort Study

Patient characteristics, comorbidities, HF pharmacotherapy, investigations, outcomes during patient follow-up, RM alerts recorded and actions taken are reported in this section.

3.2.1 Patient Characteristics

From the cohort of 45 patients assessed, 35 were male and 10 were female. Patients were classified according to age, with most patients aged between 71 and 80 years (n=20) and 61 and 70 years (n=15) (Table 3.4).

Table 3.4: Age at CIED implantation (N=45)

Age Range in years	Number of Patients
41-50	2
51-60	6
61-70	15
71-80	20
>80	2

From the 45 patients assessed, 22 were classified as Class I and 23 patients as Class II according to the New York Heart Association (NYHA) classifications system.

The most common type of CIED was a cardiac resynchronisation therapy device (CRTD) (n=20), followed by an implantable cardioverter defibrillator (ICD) device (n=19). Most implantations took place in 2018 (n=12), 2021 (n=12) and 2015 (n=8).

3.2.2 Comorbidities and Risk Factors

The most common comorbidities were hypertension (n=37), hyperlipidaemia (n=23), diabetes mellitus (n=22) and coronary artery disease (n=18) (Table 3.5).

Table 3.5: Comorbidities and Risk Factors (N=45)

<table>
<tr><th>Comorbidity</th><th colspan="4">Number of Patients</th></tr>
<tr><td>Hypertension</td><td colspan="4">37</td></tr>
<tr><td>Hyperlipidaemia</td><td colspan="4">23</td></tr>
<tr><td>Diabetes</td><td colspan="4">22</td></tr>
<tr><td>Coronary Artery Disease</td><td colspan="4">18</td></tr>
<tr><td>Atrial Fibrillation</td><td colspan="4">10</td></tr>
<tr><td>COPD</td><td colspan="4">7</td></tr>
<tr><td>Liver Disease</td><td colspan="4">2</td></tr>
<tr><td>Previous MI</td><td colspan="4">2</td></tr>
<tr><td>Previous TIA</td><td colspan="4">2</td></tr>
<tr><td>Hypothyroidism</td><td colspan="4">2</td></tr>
<tr><td>Anaemia</td><td colspan="4">1</td></tr>
<tr><td>Hyperthyroidism</td><td colspan="4">1</td></tr>
<tr><td>Previous Stroke</td><td colspan="4">0</td></tr>
<tr><td>Previous Revascularisation</td><td colspan="4">11 (9 CABG, 2 PCI)</td></tr>
<tr><td>Regular Alcohol Consumption</td><td colspan="4">13
Not reported n=8</td></tr>
<tr><td>Smoker</td><td>7 (Current)</td><td>18 (Never)</td><td>15 (Past)</td><td>5 (Not reported)</td></tr>
</table>

3.2.3 Relevant Medications at CIED Implantation

The most common drug classes prescribed were beta-blockers (n=39) and statins (n=34) (Table 3.6).

Table 3.6: Relevant Medications at CIED Implantation (N=45)

Medication	Number of Patients
Beta-Blocker	39
Statin	34
Antiplatelet	31
Loop Diuretic	25
ACEi	24
Mineralocorticoid Receptor Antagonist (spironolactone)	22
ARB	6
Ivabradine	6
ARNI (sacubitril/valsartan)	3
Empagliflozin	3
Digoxin	1
Other	38

From the 45 patients assessed, 38 were taking other medications. The most common 'other' medications were metformin (n=18) and omeprazole (n=14).

3.2.4 Investigations

Relevant parameters taken close to the date of CIED implantation are presented as minimum, maximum and mean results (Table 3.7).

Table 3.7: Analysis of investigations (N=45)

Parameter	Minimum	Maximum	Mean
LVEF	10%	47%	29.17%
Blood Pressure mmHg Systolic Diastolic	 80 55	 180 80	 126.84 71.87
Heart rate	55	95	70.26
Serum Creatinine	57	465	108.42
LDL cholesterol	1.26	5.1	2.13
NTproBNP	106	8993	1611.22
Potassium	1.12	5.96	4.5
eGFR	8.0	134	69.60
Haemoglobin Males Females	 6.1 7.6	 17.4 13.5	 13.68 11.17
Weight	54.8	131	83.27

3.2.5 Outcomes during patient follow-up

A change in medication such as changing drug or dose was noted for 30 patients throughout the follow-up period. Outcomes for all patients were tabulated at each follow-up period, with the most common symptoms being shortness of breath (n=15), lower limb oedema (n=11) and fatigue (n=11) (Table 3.8). Lifestyle modifications such as increasing daily exercise and limiting fluid intake were documented for 6 patients.

Table 3.8: Outcomes (N=45)

	Number of Patients				
Outcomes	**1-4 weeks**	**3 months**	**6 months**	**1 year**	**Total**
Shortness of Breath	8	2	1	6	**15**
Lower Limb Oedema with weight gain	3	3	8	5	**11**
Fatigue	7	2	1	2	**11**
Hospital admission - Non-Cardiac	2	5	5	4	**10**
Hospital admission - Cardiac	2	2	1	4	**8**
Chest Pain	4	1	1	2	**8**
Palpitations	1	2	0	1	**4**
Syncope	1	2	2	0	**4**
Mortality	0				**0**

3.2.6 Alerts for Patients with RM

From the 45 patients assessed, 21 patients had the RM feature switched on. Alerts were recorded in 19 of these patients, which led to no action being deemed necessary by the cardiologist in 12 cases. Action was taken by the cardiologist in 7 cases. The main actions taken were to increase diuretic dose (n=5) and hospital admission (n=3) (Table 3.9).

Table 3.9: Alerts due to RM and action taken

Alerts (n=19) led to:	**Number of Patients**
No action deemed necessary by cardiologist	12
Action needed – Close monitoring at HF clinic	7
Close monitoring (n=7) led to:	**Number of Patients**
Increase in diuretic dose	5
Hospital admission	3
Increase in dose of disease modifying drug	1
Limit in fluid intake	1

Chapter 4 Discussion

4.1 Reflections on research findings

Positive outcomes and challenges identified in the research conducted are reflected upon and discussed in this chapter.

4.1.1 Points in favour of remote monitoring in patients with heart failure

The literature review showed that the benefits of remote monitoring (RM) in patients with heart failure outweigh the challenges. Improvement in patient health with RM was reported, achieving a positive effect on care outcomes due to better overall patient management. Remote patient monitoring systems and digital health platforms have been shown to be an asset in the hospital setting by improving patient monitoring and safety as well as alleviating staff workload. Furthermore, advantages included significant time savings on routine tasks and high satisfaction levels reported by both patients and staff (Pavithra et al., 2024).

In practice, the analysis of pulmonary fluid status RM in the cohort study led to the identification of patients requiring closer outpatient monitoring, pharmacological and non-pharmacological therapy optimisation and hospital admission. The small sample size studied, despite screening a six-year period, limited the extent of research that could be conducted and the conclusions that could be drawn. For instance, it could not be established whether RM led to a lower incidence of morbidity and mortality when compared to patients not availing themselves of the RM facility. Nevertheless, the research showed cases where medical interventions occurred in a timely manner as a result of RM, and which may have not been identified and managed in a timely way if constant monitoring was not in place. These results are comparable to a study carried out in 2013, whereby Optivol™ Fluid Index predicted worsening of heart failure with high sensitivity (Yang et al., 2013). The MOMOTARO study on the effectiveness of RM concluded that intrathoracic impedance decrease detected with OptiVol® alerts was indicative of HF deterioration (Nishii et al., 2015).

Apart from its ability to ensure more timely intervention in higher risk cases, RM offers a practical solution by reducing the frequency of physical visits to one's physician or to hospital for routine monitoring overcoming limitations caused by distance and/or the availability of transport (Claggett et al., 2024). However, this aspect was not assessed in the present study. Digital health and remote patient monitoring platforms can help in the reduction of day-to-day challenges related to waiting in traffic to and from hospital, parking issues and time spent waiting to receive an appointment, allowing for earlier detection of conditions, improving efficiency of patient monitoring, and easing communication between healthcare professionals and patients (Frederix et al., 2019). This observation is pertinent locally due to the increasing number of patients with CVD. Moreover, despite Malta's small size and short distance to hospital, the high degree of traffic congestion limits efficiency to attend hospital visits.

4.1.2 Challenges and facilitators of remote monitoring and digital health

There have been evidence-based medical and pharmacological advancements in the management of heart failure (HF), however, such management remains challenging, particularly in the ambulatory setting (Theuns et al., 2021). Telemonitoring in HF aims to predict and prevent worsening of HF, improve self-care through implementation of RPM and overall patient survival (Planinc et al., 2020).

The literature review identified challenges that hinder the more widespread use of RM namely achievement of effective care outcomes and health care professional perception, cost considerations, data privacy concerns and the maintenance of system efficiency and data quality, as well as patient considerations.

An impediment to the more widespread use of RM is that certain medical practitioners may harbour doubts about the general efficacy of RM or on its suitability in certain circumstances. The OptiLink HF study reported by the American Heart Association (Wintrich et al., 2021) investigated the impact of RM based on measuring intrathoracic impedance using the fluid status monitoring device OptiVol™. The study showed that after 20% of alerts given off, patients were not appropriately contacted and only 34% of the alerts resulted in medical intervention by the physician. It was concluded that the OptiVol™ device and RM did not directly improve clinical outcomes in heart failure patients, however served to ensure a timelier reaction due to the alerts generated. This emphasises the importance of intensifying the use of digital health, including within the cardiology area, which if handled correctly, could attain its full potential to help decrease hospitalisation and mortality rates (Cowie et al., 2016).

Another study consisted of a systematic review and interestingly evaluated the perception of remote monitoring from the healthcare professionals' point of view (Serrano et al., 2023). It was shown that health care practitioners are of the opinion that RM is a feasible option and that telemonitoring will grow in popularity in the future. Remote monitoring technologies are likely to play a significant role in areas such as personalised medicine, drug discovery and population health management (Abernethy et al., 2022).

At the same time there is no room for complacency in the drive to enhance the reliability and quality RM outcomes. Limitations of remote monitoring in cardiology may include the lack of accuracy and reliability of some of the available devices, whereby false alarms may be troublesome (Wang et al., 2017). A study reported inconsistencies in measurements obtained from wearable devices, such as heart rate monitors and activity trackers (Cadmus-Bertram et al., 2015). Due to the ongoing progress of new technologies, constant research and development are required to maintain and improve the functioning of any device used for RM. Improvement of the accuracy of all such devices is fundamental for patients and medical practitioners to accept and integrate RM systems into patient care (Kasoju et al., 2023).

Regarding cost related considerations, the introduction of RM based on CIEDs typically entails a high initial fixed investment in the technological and human resources required to set up the infrastructure. Furthermore, integration of remote monitoring technologies can be challenging and time-consuming, requiring significant resources and could possibly lead to workflow disruptions and challenges in data management (Jung et al., 2017; Simonson et al., 2023). Once the initial investment required has been made, the resultant system cost per patient would typically decrease as more patients make use of the system, while at the same time avoiding the cost related to alternative monitoring procedures that depend on for example repetitive visits to one's physician or to hospital (Simonson et al., 2023).

The cost of RM is likely to reduce moving ahead due to two other considerations. The first consideration is the constant pace of technological development that is continually serving to enhance the IT tools available to healthcare systems at a cheaper price. The second consideration is the advancement of artificial intelligence (AI) and its potential to reduce the need for human intervention in the RM process, also serving to reduce cost. The growing awareness of the various applications of AI has gained momentum. This innovative technology needs to be embedded in healthcare systems due to its ability to detect different events at earlier stages when compared to human reaction times (Nishii et al., 2024). AI has the ability of forming algorithms which can interpret and predict the worsening of certain conditions through alerts transmitted from CIEDs (Lazarus et al., 2023). AI can be employed into the development of mobile diagnostic clinics whereby certain consultations may be carried out by these advanced technology systems and reducing the need for face-to-face appointments to be set up in non-severe cases (Baron and Haick., 2024).

Patient attitudes have an impact on the extent of use of RM. With respect to patient considerations, the present study indicated that 24 out of the 45 patients assessed (53.3%) are not availing themselves of the RM opportunity. Possible reasons for apprehension towards RM reported in literature include anxiety due to alarms, feeling intimidated by the technology involved in RM systems, worry about the ability to understand results, or use the system effectively, concerns about privacy and security of health information transmitted through RM systems and some patients prefer face-to-face consultations with clinicians (Serafini et al, 2010; Walker et al., 2019). Noting more than 50% of the patients opting to have RM switched off, indicates a need for more patient awareness on the benefits of RM. The research carried out points towards possible room for improvement in the further development of RM as a means of improving health care. The need for more education on the benefits of RM was highlighted in recent studies (Middlemass et al., 2017; Dossi et al., 2020; Hareem et al., 2024).

Awareness efforts locally are ongoing such as by the Maltese Cardiac Society. During HF Awareness Week held in April/May 2024, the Society organised two events. The first event was directed to the public, where the HF team conducted a community talk focused on educating people about signs and symptoms of HF to ensure timely detection and treatment of the condition. The second event targeted general practitioners where various topics were discussed including recent HF guidelines, the role of the HF clinic at Mater Dei Hospital and the importance of encouraging HF patients to exercise and ensure good cardiac rehabilitation.[9]

Digitalisation allows for efficient data collection and analysis in large quantities, opening a new window for researchers to facilitate understanding of CVDs and to develop more effective treatments (Haleem et al., 2021). Following the increasing age of the global population having CVDs, there is a need for further studies and research on the topic to allow healthcare professionals to make better-informed and timely decisions regarding patient care to ensure optimal outcomes (Wongvibulsin et at., 2019).

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[9] Detecting the undetected: Recognising the signs and symptoms of heart failure. Times of Malta [Internet] 2024 [Cited 2024 Aug 27]. Available from: https://timesofmalta.com/article/detecting-undetected-recognising-signs-symptoms-heart-failure.1092477.

4.1.3 Pharmacotherapy for heart failure

In accordance with the latest European Society of Cardiology (ESC) guidelines for HF, the ‘four pillars’ of heart failure pharmacotherapy include ACE inhibitors/ARBs/Angiotensin Receptor-Neprilysin inhibitors (ARNI), Sodium-Glucose Co-Transporter 2 inhibitors (SGLT2i) such as empagliflozin, beta-blockers and mineralocorticoid receptor antagonists (McDonagh et al., 2023). The cohort study revealed that in line with the guidelines, most patients were prescribed a beta-blocker and an ACE inhibitor/ARB. However, only around half of the patients were taking spironolactone, only 3 patients were prescribed sacubitril/valsartan and only 3 patients were prescribed empagliflozin.

The lower number of patients on spironolactone may be attributed to side-effects such as risk of hyperkalaemia in renal impairment, particularly since most of the patients were elderly. The low number of patients on sacubitril/valsartan may be attributed to the drug not being currently available on the Maltese government formulary hence having to be purchased by costly out of pocket payment. Intolerance to sacubitril/valsartan due to side-effects such as hypotension may be another attributing factor. The low number of patients on empagliflozin may be since during the study period, which was until 2021, empagliflozin was not yet integrated into the Maltese government formulary and strong evidence favouring its use in HF patients irrespective of diabetes has increased over recent years. It is expected that the number of patients on empagliflozin has increased in the past two years. However, use of empagliflozin is still limited locally since it is currently available on the formulary only for diabetic patient with HF.

4.3 Study Limitations

A limitation of this study is that the total population of eligible patients was small, hence generalisability of data is limited. Since the data was collected from hospital records via an intermediary, patients opting to have RM switched off were not interviewed to identify possible reasons as to why this decision was made. Another limitation is that patient records indicate when a RM alert led to an intervention, however detailed documentation in the records that could indicate how crucial the intervention was is rarely available. Insufficient data documentation, such as patient weight and height was another limitation encountered, hence body mass index could not be calculated.

A limitation with regards to the literature review is that only one database was used. Using other databases and searching for reports from different countries using a Google search could have yielded more comprehensive data. Moreover, the articles selected were only screened and appraised by the researcher and not by other reviewers limiting systematic robustness of the review.

4.4 Recommendations for Future Studies

Assessing a larger sample over a longer study period is recommended to allow for better evaluation of the benefits of remote monitoring. The quality of the evaluation would be improved by carrying out a case control study comparing outcomes in patients with and without RM. Further study could explore reasons patients opted to have RM switched off, as well as patient expectations and experiences of RM by means of directly interviewing patients.

Following ongoing advancements in technology, the need for further studies and research on the topic to determine the long-term efficacy and impact of remote monitoring interventions on clinical outcomes in heart failure is warranted (Lee et al., 2019). Noting the significant rise in publications during 2020 and 2021, likely influenced by the COVID-19 pandemic, it would be interesting to investigate whether this trend persisted in the following years.

4.5 Conclusion

The literature review showed that benefits of RM in patients with HF outweigh the challenges. The research carried out indicates that pulmonary fluid status RM helps in the assessment of HF congestion and in the identification of patients requiring therapy optimisation, whether in the outpatient or inpatient hospital setting. More than half the patients opted to have RM switched off, reflecting a need for more patient awareness on the benefits of RM.

References

Abernethy A, Adams L, Barrett M, Bechtel C, Brennan P, Butte A. The promise of digital health: Then, Now, and the Future. Nam Perspect. 2022. Doi:10.31478/202206e.

Ahmed FZ, Sammut-Powell C, Kwok CS, Tay T, Motwani M, Martin GP, et al. Remote monitoring data from cardiac implantable electronic devices predicts all-cause mortality. Europace. 2022; 24(2): 245–55. doi: 10.1093/europace/euab160.

Andersen M, Carlsen J. Continuous heart monitoring in patients with pulmonary hypertension smartwatches and direct transmission to their electronic health records: A trial design. Contemp Clin Trials. 2024:142. Doi: 10.1016/j.cct.2024/107548.

Antoniades C, Asselbergs FW, Vardas P. The year in cardiovascular medicine 2020: Digital health and innovation. Eur Heart J. 2021;42(7):732–739. Doi:10.1093/eurheartj/ehaa1065.

Banerjee A. Bridging the Global Digital Health Divide for Cardiovascular Disease. Circ Cardiovasc Qual and Outcomes. 2017; 10(11): e004297. Doi:10.1161/CIRCOUTCOMES.117.004297.

Baron R, Haick H. Mobile diagnostic clinics. ACS Sens. 2024;9(6):2777-2792. Doi: 10.1021/acssensors.4c00636.

Bender BG, Cvietusa PJ, Goodrich GK, Lowe R, Nuanes HA, Rand C. Pragmatic trial of health care technologies to improve adherence to paediatric asthma treatment: a randomized clinical trial. JAMA Pediatr. 2015; 169(4): 317-323. Doi:10.1001/jamapediatrics.2014.3281.

Bhatia A, Maddox T. Remote Patient Monitoring in Heart Failure: Factors for Clinical Efficacy. Int J Heart Fail. 2020; 3(1): 31-50. Doi: 10.36628/ijhf.2020.0023.

Bhavnavi S, Narula J, Sengupta P. Mobile technology, and the digitization of healthcare. Eur Heart J. 2016; 37(18): 1428-1438. Doi:10.1093/eurheartj/ehv770.

Bleda AL, Melgarejo-Meseguer FM, Gimeno-Blanes FJ, Garcia-Alberola A, Rojo-Alvarez JL, Corral J, et al. Enabling heart self-monitoring for all and for AAL-portable device within a complete telemedicine system. Sensors (Basel). 2019;19(18):3939. Doi: 10.3390/s19183969.

Bond R, Peace A. Towards a digital future. Eur Heart J. 2021; 2(1): 60-61. Doi:10.1093/ehjdh/ztab023.

Boulos MN, Wheeler S, Tabares C, Jones R. How smartphones are changing the face of mobile and participatory healthcare: an overview, with example from eCAALYX. Biomed Eng online. 2011;10:24. Doi: 10.1186/1475-925X-10-24.

Brahmbhatt D, Cowie M. Remote Management of Heart Failure: An overview of Telemonitoring Technologies. Card Fail Rev. 2019; 5: 86-92. Doi:10.15420/cfr.2019.5.3.

Cadmus-Bertram L, Marcus BH, Patterson RE, Parker BA, Morey BL. Randomized trial of a Fitbit-based physical activity intervention for women. Am J Prev Med. 2015; 49(3):414-418. Doi:10.1016/j.amepre.2105.02.012.

Callum K, Graune C, Bowman E, Molden E, Leslie SJ. Remote monitoring of implantable defibrillators is associated with fewer inappropriate shocks and reduced time to medical assessment in a remote and rural area. World J Cardiol. 2021;13(3):46-54. Doi: 10.4330/wjc.v13.i3.46.

Campbell G, Auyeung V, Ismail T. Smartphone, and email capabilities of heart failure patients. Eur Heart J. 2021; 2(1): 5-6. Doi:10.1093/ehjdh/ztab008.

Catalan-Matamoros D, Lopez-Villegas A, Leal Costa C, Bautista-Mesa R, Robles-Musso E, Rocamora Perez P, et al. A non-randomized clinical trial to examine patients' experiences and communication during telemonitoring of pacemakers after five years follow-up. PLoS ONE. 2022; 17(3). doi: 10.1371/journal.pone.0265801.

Claggett J, Petter S, Joshi A, Ponzio T, Kirkendall E. An infrastructure framework for remote patient monitoring interventions and research. J Med internet Res. 2024;26. Doi: 10.2196/51234.

Cowie M, Bax J, Bruining N, Cleland J, Koehler F, Malik M, et al. E-Health: A position statement of the European Society of Cardiology. Eur Heart J. 2016; 37(1): 63-66. Doi:10.1093/eurheartj/ehv416.

Cowie MR, Lam CSP. Remote monitoring and digital health tools in CVD management. Nat Rev Cardiol. 2021; 18(7):457–8. doi: 10.1038/s41569-021-00548-x.

Cuff A. The evolution of digital health and its continuing challenges. BMC Digital Health. 2023; 1(3). Doi:10.1186/s44247-022-00004-x.

De Jaegere P. Artificial intelligence for automated ECG analysis: An experimental study revealing knowns and mysteries: still a long pathway ahead? Eur Heart J. 2021; 2(1): 125-126. Doi:10.1093/ehjdh/ztab024.

Del Toro MR, Leaño NM, Barahona-Correa J, Muñoz Velandia O, Ávila D, Peña AA. Effectiveness of mobile telemonitoring applications in heart failure patients: systematic review of literature and meta-analysis. Heart Fail Rev. 2023; 28(2):431-452. Doi: 10.1007/s1074-022-10291-1.

Di Lenarda A, Casolo G, Gulizia MM, Aspromonte N, Scalvini S, Mortara A, et al. The future of telemedicine for the management of heart failure patients: a Consensus Document of the Italian Association of Hospital Cardiologists (A.N.M.C.O), the Italian Society of Cardiology (S.I.C.) and the Italian Society for Telemedicine and eHealth (Digital S.I.T.). Eur Heart J Suppl. 2017;19:113-129. Doi: 10.1093/eurheartj/sux024.

Ding H, Jayasena R, Chen SH, Maiorana A, Dowling A, Layland J, et al. The effects of telemonitoring on patient compliance with self-management recommendations and outcomes of the innovative telemonitoring enhanced care program for chronic heart failure: Randomized controlled trial. J Med internet Res. 2020;22(7). Doi: 10.2196/17559.

Dossi F, Marini A, Sanna G, Saba P, Parodi G. M-Health and telemedicine: Are people ready for the future? A real-world survey. Eur Heart J. 2020; 41(2): 3460. Doi:10.1093/ehjci/ehaa946.3460.

Duncker D, Yew Ding W, Etheridge S, Noseworthy P, Veltmann C, Yao X, et al. Smart wearables for cardiac monitoring-real-world use beyond atrial fibrillation. Sensors (Basel). 2021; 21(7): 2539. Doi: 10.3390/s21072539.

Evans J, Papadopoulos A, Silvers CT, Charness N, Boot WR, Schlachta-Fairchild L, et al. Remote Health monitoring for older adults and those with Heart failure: Adherence and System Usability. Telemed J E Health. 2016;22(6):480-488. Doi: 10.1089/tmj.2015.0140.

Farwati M, Riaz H, Tang WH. Digital Health Applications in Heart Failure: a Critical Appraisal of Literature. Curr Treat Options Cardiovasc Med. 2021;23(2):12. Doi: 10.1007/s11936-020-00885-z.

Foreman J, Salim AT, Praveen A, Fonseka D, Wei Ting DS, Guang He M, et al. Association between digital smart device use and myopia: a systematic review and meta-analysis. The Lancet. 2021; 3(12):E806-E818. Doi: 10.1016/S2589-7500(21)00135-7.

Frederix I, Caiani EG, Dendale P, Anker S, Bax J, Böhm A, et al. ESC e-Cardiology Working Group Position Paper: Overcoming challenges in digital health implementation in cardiovascular medicine. Eur J Prev Cardiol. 2019; 26(11): 1166-1177. Doi:10.1177/2047487319832394.

Gjeka R, Patel K, Reddy C, Zetsche N. Patient engagement with digital disease management and readmission rates: The case of Congestive heart failure. Health Informatics J. 2021;27(3). Doi: 10.1177/14604582211030959.

Haleem A, Javaid M, Singh RP, Suman R. Telemedicine for healthcare: Capabilities, features, barriers, and applications. Sens Int. 2021; 2:100117. doi: 10.1016/j.sintl.2021.100117.

Hareem A, Stupans L, Park JS, Stevens JE, Wang K. Navigating digital health: perspectives of Australian community pharmacists – a short communication. JPHSR. 2024; 15(3). Doi: 10.1093/jphsr/rmae013.

Herkert C, Kraal JJ, Spee RF, Serier A, Graat-Verboom L, Kemps HM. Quality Assessment of an Integrated Care Pathway using telemonitoring in Patients with Chronic heart failure and Chronic obstructive pulmonary disease: Protocol for a Quasi-Experimental study. JMIR Res Protoc. 2020;9(11):e20571. Doi: 10.2196/20571.

Ho K, Kim-Sing C, Ackenhusen M, Wong H, Marsden J, Nasiopoulos P, et al. Supporting heart failure patient transitions from acute to community care with home telemonitoring technology: a protocol for a provincial random controlled trial (TEC4Home). JMIR Res Protoc. 2016; 5(4). Doi: 10.2196/resprot.5856.

Ibanez B, James S, Agewall S, Antunes MJ, Bucciarelli-Ducci C, Bueno H, et al. 2017 ESC Guidelines for the management of acute myocardial infarction in patients presenting with ST-segment elevation. Eur Heart J. 2017; 39(2): 119-177. Doi:10.1093/eurheartj/ehx393.

Jat A, Morten Grønli T. Harnessing the digital revolution: A comprehensive review of mHealth applications for remote monitoring in transforming healthcare delivery. Mobile Web and Intel Info System. 2023; 13977. Doi: 10.1007/978-3-031-39764-6-4.

Jiang X, Ming W, You J. The cost effectiveness of digital health interventions on the management of cardiovascular diseases: Systematic review. J Med Int Res. 2019; 21(6): e13166. Doi:10.2196/13166.

Johnson T, Chilazi M, Isakadze N, Desai K, Spaulding EM, Goyal A, et al. Bridging the digital divide. JACC Adv. 2023; 2(7):100587. Doi: 10.1016/j.jacadv.2023.100587.

Jung Y, Lee J, Lee JH. Real-time mobile healthcare system for continuous monitoring of physiological data and medication adherence in heart failure patients. Int J Med Inform. 2017(101): 65-75. Doi:10.1016/j.ijmedinf.2017.01.016.

Kasoju N, Remya N, Sasi R, Sujesh S, Soman B, Kesavadas C, et al. Digital health: trends, opportunities and challenges in medical devices, pharma, and biotechnology. CSI Transactions on ICT. 2023; 11: 11-30. Doi: 10.1007/s40012-023-00380-3.

Kitsiou S, Vatani H, Paré G, Gerber BS, Buchholz SW, Kansal MM, et al. Effectiveness of mobile health technology interventions for patients with heart failure: Systematic review and meta-analysis. Can J Cardiol. 2021; 37 pages. Doi:10.1016/j.cjca.2021.02.015.

Koehler F, Koehler K, Deckwart O, Prescher S, Wegscheider K, Winkler S, et al. Telemedical Interventional Management in heart failure II (TIM-HF2), a randomised, controlled trial investigating the impact of telemedicine on unplanned cardiovascular hospitalisations and mortality in heart failure patients: study design and description of the intervention. Eur J Heart Fail. 2018; 20(10); 1485-1493. Doi: 10.1002/ejhf.1300.

Kramer F, Butler J, Shah SJ, Jung C, Nodari S, Rosenkranz S, et al. Real-life multimarker monitoring in patients with heart failure: Continuous remote monitoring of mobility and patient-reported outcomes as digital end points in future heart-failure trials. Digit Biomark. 2020; 4(2): 45-59. Doi: 10.1159/ 000507696.

Krishnaswami A, Beavers C, Dorsch M, Dodson J, Creber R, Kitsiou S et al. Gerotechnology for older adults with Cardiovascular Diseases: JACC State-Of-The-Art Review. JACC. 2020;76(22) 2650-2670. Doi: 10.1016/j.jacc.2020.09.606.

Kumar S, Nilsen WJ, Abernethy A, Atienza A, Patrick K, Pavel M, et al. Mobile health technology evaluation. Am J Prev Med. 2013; 45(2): 228- 236. Doi:10.1016/j.amepre.2013.03.017.

Kwon J, Kim K, Eisen H, Cho Y, Jeon K, Lee SY, et al. Artificial intelligence assessment for early detection of heart failure with preserved ejection fraction based on electrocardiographic features. Eur Heart J. 2021; 2(1): 106-116. Doi:10.1093/ehjdh/ztaa015.

Ladejobi A, Cruz J, Attia Z, Van Zyl M, Tri J, Lopez-Jimenez F, et al. Digital health innovation in cardiology. Cardiovasc Digit Health J. 2020;1(1):6-8. Doi: 10.1016/j.cvdhj.2020.07.003.

Lazarus A, Gentils M, Klaes S, Ibnouhsein I, Rosier A, Moubarak G et al. Filtering of remote monitoring alerts transmitted by cardiac implantable electronic devices and reclassification of atrial fibrillation events by a new algorithm. Cardiovasc Digit Health J. 2023;4(5):139-154. Doi: 10.1016/j.cvdhj.2023.08.019.

Lee C, Gibbs H, Hooker EA, et al. Digital health interventions for the prevention and management of heart failure: a systematic review and meta-analysis. J AM Heart Assoc. 2019; 8(15). Doi:10.1161/JAHA.118.010840.

Lefler LL, Rhoads SJ, Harris M, Fuderburg AE, Lubin SA, Martel ID, et al. Evaluating the use of mobile health technology in older adults with heart failure: Mixed-methods study. JMIR Aging. 2018; 1(2):e12178. Doi: 10.2196/12178.

Livori AC, Bishop JL, Ping SE, Oqueli E, Aldrich R, Fitzpatrick AM, et al. Towards OPtimising Care of Regionally Based Cardiac Patients with a Telehealth Cardiology Pharmacist Clinic (TOPCare Cardiology). Heart Lung and Circ. 2021; 30(7): 1023-1030. Doi:10.1016/j.hlc.2020.12.015.

Lu Y, Zhou Z, Li X. Study on the relationship between technology, data and body isomorphism – The example of smartwatches. Tele and Inform Rep. 2024; 13. Doi: 10.1016/j.teler.2024.100118.

Lupton D. The digitally engaged patient: Self-monitoring and self-care in the digital health era. Soc Theor Health. 2013; 11: 256-270. Doi:10.1057/sth.2013.10.

MacKinnon G, Brittain E. Mobile Health Technologies in Cardiopulmonary Disease. Chest. 2020;157(3):654-664. Doi:10.1016/j.chest.2019.10.015.

Madhavan S, Bastarache L, Brown J, Butte A, Dorr D, Embi P. Use of electronic health records to support a public health response to the COVID-19 pandemic in the United States: A perspective from 15 academic medical centres. JAMIA. 2021; 48(2): 393-401. Doi:10.1093/jamia/ocaa287.

Mahajan V, Singh T, Azad C. Using Telemedicine During the COVID-19 Pandemic. Indian Pediatr. 2020; 57(7): 658-661. Doi:10.1007/s13312-020-1895-6.

Majumder S, Mondal T, Deen MJ. Wearable sensors for remote health monitoring. Sensors (Basel). 2017; 17(1):130. Doi: 10.3390/s17010130.

Martin SS. Centennial Collection: Health Applications of Digital Technologies. Circulation. 2024; 149(22):1701-1703. Doi: 10.1161/CIRCULATIONHA.124.068243.

McDonagh TA, Metra M, Adamo M, Gardner RS, Baumbach A, Böhm M, et al. 2021 ESC Guidelines for the diagnosis and treatment of acute and chronic heart failure. Eur Heart J. 2021; 42(36): 3599–726. doi: 10.1093/eurheartj/ehab368.

McDonagh T, Metra M, Adamo M, Gardner R, Baumbach A, Böhm M, et al. 2023 Focused update of the 2021 ESC guidelines for the diagnosis and treatment of acute and chronic heart failure: Developed by the task force for the diagnosis and treatment of acute and chronic heart failure of the European Society of Cardiology (ESC) with the special contribution of the Heart Failure Association (HFA) of the ESC. Eur Heart J. 2023; 44(37): 3627-3639. Doi: 10.1093/eurheartj/ehad195.

Meehan R. Health Informatics Workforce in the digital health ecosystem. Stud Health Technol Inform. 2024;1226-1230. Doi: 10.3233/SHTI231160.

Middlemass JB, Vos J, Siriwardena AN. Perceptions on use of home telemonitoring in patients with long term conditions – concordance with the Health Information Technology Acceptance Model: a qualitative collective case study. BMC Med Inform Decis Mak. 2017; 17(89). Doi:10.1186/s12911-017-0486-5.

Mullens W, Sharif F, Dupont M, Rothman AMK, Wijns W. Digital health care solution for proactive heart failure management with the Cordella heart failure system: results of the SIRONA first-in-human study. 2020; 22(10):1912-1919. Doi: 10.1002/ejhf.1870.

Nishii N, Baba K, Morooka K, Shirae H, Mizuno T, Masuda T, et al. Artificial intelligence to detect noise events in remote monitoring data. J Arrhythm. 2024 40(3): 560-577. Doi: 10.1002/joa3.13037.

Nishii N, Kubo M, Okamoto Y, Fujii S, Wantanabe A, Toyama Y, et al. Decreased intrathoracic Impedance Associated with OptiVol alert can diagnose increased B-Type Natriuretic peptide - MOMOTARO (Monitoring and Management of OptiVol Alert to Reduce Heart Failure Hospitalization study). Circ J. 2015; 79(6):1315-22. Doi: 10.1253/circk.CJ-15-0076.

Ogungbe O, Longenecker CT, Beaton A, De Loizaga S, Brant LC, Ocran RAN, et al. Advancing Cardiovascular Health Equity Globaly Through Digital Technologies. J Am Heart Assoc. 2024;13(2):e031237. Doi: 10.1161/JAHA.123.031237.

Parati G, Pellegrini D, Torlasco C. How digital health can be applied for preventing and managing hypertension. Curr Hypertens Rep. 2019; 21(5): 1-8. Doi:10.1007/s11906-019-0940-0.

Park C, Otobo E, Ullman J, Rogers J, Fasihuddin F, Garg S, et al. Impact on readmission reduction among heart failure patients using digital health Monitoring: Feasibility and Adoptability study. JMIR Med Info. 2019; 7(4). Doi: 10.2196/13353.

Pavithra LS, Khurdi S, Priyanka TG, Patrisia MS. Impact of remote patient monitoring systems on nursing Time, healthcare providers, and patient satisfaction in general wards. Cureus. 2024; 16(6). Doi: 10.7759/cureus.61646.

Planinc I, Milicic D, Cikes M. Telemonitoring in Heart Failure Management. Card Fail Rev. 2020; 6. doi: 10.15420/cfr.2019.12.

Pratiwi H, Kristina S, Widayanti AW, Prabandari Y, Kusuma I. A Systematic Review of compensation and technology-mediated strategies to maintain older adults' medication adherence. Int J Environ Res Public Health. 2023;21(1):803. Doi: 10.3390/ijerph20010803.

Robert N. How artificial intelligence is changing nursing. Nursing Management. 2019; 50(9): 30–39. Doi:10.1097/01.NUMA.0000578988.56622.21.

Rosman J, Rosenbaum M, Berkowitz E, Kloosterman M. Impact of Remote Monitoring on Hospitalizations for Heart Failure: A Five-year Single-center Experience. J Innov Card Rhythm Manag. 2021;12(8): 4621-4. doi: 10.19102/icrm.2021.120802.

Sagaro GG, Di Canio M, Talevi E, Amenta F. Telemedicine fir Pre-employment medical examinations and follow-up visits on board ships: A narrative review on the feasibility. Healthcare (Basel). 2021;9(1):69. Doi: 10.3390/healthcare9010069.

Saner H, Van der Velde E. eHealth in cardiovascular medicine: A clinical update. Eur J Prev Cardiol. 2016; 23(2): 5-12. Doi:10.1177/2047487316670256.

Sattar Y, Zghouzi M, Suleiman ARM, Sheikh A, Kupferman J, Sarfraz A, et al. Efficacy of remote dielectric sensing (ReDS) in the prevention of heart failure rehospitalizations: a meta-analysis. J Community Hosp Intern Med Perspect. 2021; 11(5): 646-652. Doi: 10.1080/20009666.2021.1955451.

Schyvens AM, Van Oost NC, Aerts JM, Masci F, Peters B, Neven A, et al. Accuracy of Fitbit Charge 4, Garmin Vivosmart 4, and WHOOP Versus Polusomnography: Systemic Review. JMIR Mhealth Uhealth. 2024; 27(12). Doi: 10.2196/52192.

Serafini G, Pompili M, Innamorati M, Lacorosssi G, Cuomo I, Della Vista M. The impact of anxiety, depression, and suicidality on quality of life and functional status of patients with congestive heart failure and hypertension: an observational cross-sectional study. Prim Care Companion J Clin Psychiatry. 2010; 12(6). Doi:10.4088/PCC.09m00916gry.

Serrano L, Maita K, Avila F, Torres-Gyzman R, Garcia J, Eldaly A, et al. Benefits and Challenges of remote patient monitoring as perceived by health care practitioners: A systematic review. Perm J. 2023; 27(4):100-111. Doi: 10.7812/TPP/23.022.

Sharma A, Harrington R, McClellan M, Turakhia M, Eapen Z, Steinhubl S, et al. Using digital health technology to better generate evidence and deliver evidence-based care. J Am Coll Cardiol. 2018; 71(23): 2680-2690. Doi:10.1016/j.jacc.2018.03.523.

Silvetti MS, Tamburri I, Porco L, Saputo FA, Di Mambro C, Righi D, et al. A decade of insertable cardiac monitors with remote monitoring in pediatric patients. Rev Cardiovasc Med. 2022; 23(1): 1. doi: 10.31083/j.rcm2301027.

Simonson J, Anderson M, Polacek C, Klump E, Haque S. Characterizing Real-World implementation of Consumer Wearables for the Detection of Undiagnosed Atrial Fibrillation in Clinical Practice: Targeted Literature Review. JMIR Cardio. 2023; 7. Doi: 10.2196/47292.

Singhal A, Cowie MR. Digital Health: implications for heart failure management. Card Fail Rev. 2021;11:7. Doi: 10.15420/cfr.2020.28.

Solberg L. Digital Health in Cardiology: Time for Action. Cardiology. 2020; 145(2):106–109. Doi: 10.1159/000504797.

Sze S. Rise of the machines: will heart failure become the first cyber-speciality?. Br J Cardiol. 2020;27(1):06. Doi: 10.5837/bjc.2020.006.

Theuns D, Radhoe SP, Brugts JJ. Remote Monitoring of Heart Failure in Patients with Implantable Cardioverter-Defibrillators: Current Status and Future Needs. Sensors (Basel). 2021; 21(11): 3763. doi: 10.3390/s21113763.

Timmis A, Townsend N, Gale C, Grobbee R, Maniadakis N, Flather M, et al. European Society of Cardiology: Cardiovascular Disease Statistics. Eur Heart J. 2017; 39(7): 508–79. Doi:10.1093/eurheartj/ehx628.

Tohyama T, Funakoshi K, Kahu H, Enzan N, Ikeda M, Matsushima S, et al. Artificial intelligence-based analysis of payment system data can predict one-year mortality of hospital patients with heart failure. Eur Heart J. 2020; 41(2): 3492. Doi:10.1093/ehjci/ehaa946.3492.

Toscos T, Daley C, Wagner S, Coupe A, Ahmed R, Holden RJ, et al. Patient responses to daily cardiac resynchronization therapy device data: A pilot trial assessing a novel patient-centred digital dashboard in everyday life. Cardiovasc Digit Health J. 2020;1(2): 97-106. Doi: 10.1016/j.cvdhj.2020.09.003.

Vandenberk B and Raj S. Remote patient monitoring: What have we learned and Where are we going?. Curr Cardiovasc Risk Rep. 2023;17(6):103-115. Doi: 10.1007/s12170-023-00720-7.

Vervoort D, Marvel FA, Isakadze N, Kpodonu J, Martin SS. Digital Cardiology: Opportunities for disease prevention. Curr Cardiovasc Risk Rep. 2020; 14(10): 1-7. Doi:10.1007/s12170-020-00644-6.

Walker RC, Tong A, Howard K, Palmer SC. Patient expectations and experiences of remote monitoring for chronic diseases: Systematic review and thematic synthesis of qualitative studies. Int J Med Inform. 2019;124:78-85

Wade V, Stocks N. The Use of Telehealth to Reduce Inequalities in Cardiovascular Outcomes in Australia and New Zealand: A Critical Review. Heart Lung Circ. 2017; 26(4): 331-337. Doi:10.1016/j.hlc.2016.10.013.

Wang R, Blackburn G, Desai M, Dermot P, Gillinov L, Houghtaling P, et al. Accuracy of wrist-worn heart rate monitors. JAMA Cardiol. 2017; 2(1):104-106. Doi:10.1001/jamacardio.2016.3340

Whitelaw S, Pellegrini D, Mamas M, Cowie M, Van Spall H. Barriers and facilitators of the uptake of digital health technology in cardiovascular care: a systematic scoping review. Eur Heart J. 2021; 2(1): 62-74. Doi:10.1093/ehjdh/ztab005.

Wintrich J, Pavlicek V, Brachmann J, Bosch R, Butter C, Oswalk H et al. Remote monitoring with appropriate reaction to alerts was associated with improved outcomes in chronic heart failure: Results from the OptiLink HF Study. AHA. 2021; 14(1). Doi: 10.1161/CIRCEP.120.008693.

Wongvibulsin S, Martin SS, Steinhubl SR, Muse ED. Connected Health Technology for Cardiovascular Disease Prevention and Management. Curr Treat Options Cardiovasc. Med. 2019 21(6): 29. Doi: 10.1007/s11936-019-0729-0.

Yamokoski LM, Haas GJ, Gans B, Abraham WT. OptiVol fluid status monitoring with an implantable cardiac device: A heart failure management system. Expert Rev Med Devices. 2007; 4(6): 775-80. doi: 10.1586/17434440.4.6.775.

Yang X, Hua W, Ding L, Wang J, Zheng L, Qiang Li C, et al. OptiVol fluid index predicts acute decompensation of heart failure with a high rate of unexplained events. 2013; 10(3): 253 – 257. Doi: 10.3969/j.issn.1671-5411.2013.03.012.

Yu CM, Wang L, Chau E, Chan R, Kong S, Tang M, et al. Intrathoracic Impedance Monitoring in Patients With Heart Failure. *Circulation*. 2005; 112: 841–8. doi: 10.1161/CIRCULATIONAHA.104.492207.

Zan S, Agboola S, Moore SA, Parks K, Kvedar JC, Jethwani K. Patient engagement with a mobile web-based telemonitoring system for heart failure self-management: a pilot study. JMIR Mhealth Uhealth. 2015;3(2). Doi: 10.2196/mhealth.3789.

Zwack CC, Haghani M, Hollings M, Zhang L, Gauci S, Gallagher R, et al. The evolution of digital health technologies in cardiovascular disease research. NPJ Digit. 2023; 6(1). Doi:10.1038/s41746-022-00734-2.

List of Publications and Abstracts

Abstract accepted for poster presentation at the 82nd FIP World Congress of Pharmacy and Pharmaceutical Sciences 2024, Cape Town, South Africa, 1- 4 September 2024.

Remote Monitoring in the Management of Heart Failure

Elena Mirone[1], Francesca Wirth[1], Christina Grima[2], Jeremy Fleri Soler[2], Mark A. Sammut[2], Robert G. Xuereb[2], Lilian M. Azzopardi[1]

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Background: Remote monitoring (RM) is increasingly being integrated in the management of heart failure (HF) patients with cardiac implantable electronic devices (CIEDs).

Purpose: The aim was to assess the contribution of pulmonary fluid status RM in HF patients.

Method: The study was carried out at the main acute general hospital in Malta. After ethics approval, all patients (January 2015-December 2021) diagnosed with HF and with a CIED incorporating a pulmonary fluid status monitoring feature (OptiVol™ 2.0) which tracks intrathoracic impedance changes over time and has the possibility of being monitored remotely, were included in the study. A data collection sheet was developed and validated by an expert panel. Outcomes were assessed over one-year post-CIED implantation using hospital records.

Results: From the cohort of 45 patients assessed (35 male, 37 aged ≥61 years, mean left ventricular ejection fraction 29%, 23 classified as New York Heart Association Class II), the most common comorbidities were hypertension (n=37), dyslipidaemia (n=23), diabetes (n=22) and coronary artery disease (n=18). Pharmacotherapy for heart failure included beta-blockers (n=39), loop diuretics (n=25), angiotensin converting enzyme inhibitors (n=24), mineralocorticoid receptor antagonists (n=22), angiotensin II receptor blockers (n=6), ivabradine (n=6), empagliflozin (n=3), sacubitril/valsartan (n=3), and digoxin (n=1).

Twenty-one patients had the RM feature switched on. Alerts were recorded in 19 of these patients, which led to no action deemed necessary (n=12) or action taken (n=7) by cardiologist. Actions taken were increase in diuretic dose (n=5), hospital admission (n=3), limit fluid intake (n=1), and/or increase in dose of disease-modifying drug (n=1).

Conclusions: Pulmonary fluid status RM helped in the assessment of congestion and identified patients requiring therapy optimisation in the outpatient setting or hospital admission. More than half the patients opted to have RM switched off, indicating a need for more patient awareness on the benefits of RM. It is recommended to explore reasons for patients preferring to have RM switched off. Since data was collected from hospital records, patients who opted to have RM switched off were not interviewed to identify reasons. Possible reasons for apprehension towards RM reported in literature include anxiety due to alarms, feeling intimidated by the technology involved in RM systems, worry about the ability to understand, or use the system effectively, concerns about privacy and security of health information transmitted through RM systems and some patients prefer face-to-face consultations with clinicians.[1]

Reference:

Walker RC, Tong A, Howard K, Palmer SC. Patient expectations and experiences of remote monitoring for chronic diseases: Systematic review and thematic synthesis of qualitative studies. Int J Med Inform. 2019;124:78-85.

Topic Area: Pharmacy Practice Research

Poster Presentation

L-Università ta' Malta | Faculty of Medicine & Surgery | Department of Pharmacy

Remote Monitoring in the Management of Heart Failure

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INTRODUCTION

Remote monitoring (RM) is increasingly being integrated in the management of patients with heart failure (HF) with cardiac implantable electronic devices (CIEDs).[1]

AIM

To assess the contribution of pulmonary fluid status RM in patients with HF

METHOD

- A data collection sheet was developed and validated by an expert panel.
- Following ethics approval, all patients diagnosed with HF and with a CIED incorporating the pulmonary fluid status monitoring feature OptiVol™ 2.0 during the period January 2015 to December 2021 were identified. OptiVol™ 2.0 tracks intrathoracic impedance changes over time and has the possibility to be monitored remotely.
- Outcomes including RM alerts and actions taken were assessed over one-year post-CIED implantation using hospital records.

RESULTS

- 45 patients were assessed (35 male, 37 aged ≥61 years, mean left ventricular ejection fraction 29%, 23 classified as New York Heart Association Class II).
- Most common comorbidities: hypertension (n=37), hyperlipidaemia (n=23), diabetes mellitus (n=22).
- Pharmacotherapy for HF: beta-blocker (n=39), loop diuretic (n=25), ACE inhibitor (n=24), spironolactone (n=22), ARB (n=6), ivabradine (n=6), empagliflozin (n=3), sacubitril/valsartan (n=3), digoxin (n=1).
- 21 patients had the RM feature switched on. Alerts and actions taken following RM alerts are presented in Tables 1 and 2.

Table 1: RM alerts and action taken (n=21)

Outcome of RM	Number of Patients
Alerts recorded	19
No action deemed necessary by cardiologist	12
Action taken by cardiologist	7

Table 2: Action taken following RM alerts (n=7)

Action taken	Number of Patients
Increase diuretic dose	5
Hospital admission	3
Limit fluid intake	1
Increase dose of disease modifying drug	1

CONCLUSION

Pulmonary fluid status RM helped in the assessment of congestion and identified patients requiring therapy optimisation in the outpatient setting or hospital admission. More than half the patients opted to have RM switched off, indicating a need for more patient awareness on the benefits of RM. A limitation of the study was that since data was collected from hospital records, patients opting to have RM switched off were not interviewed to identify reasons. Further study could explore these reasons, as well as patient expectations and experiences of RM.

REFERENCE

1. Vandenberk B, Raj S. Remote patient monitoring: What have we learned and Where are we going?. Curr Cardiovasc Risk Rep. 2023;17(6):103-115. Doi: 10.1007/s12170-023-00720-7.

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Appendices

Appendix 1: Ethics Approval

L-Università ta' Malta

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Ref No: MED-2022-00128

19 September 2022

Ms Elena Mirone,
40, il-Faro,
Triq il-Pruna,
Attard,
ATD2763

With reference to your application submitted to the Faculty Research Ethics Committee in connection with your research entitled:

Digital Health in Cardiology

The Faculty Research Ethics Committee is granting ethical approval for the above-mentioned application.

Professor Anthony Serracino Inglott
Chair
Faculty Research Ethics Committee

cc Dr Francesca Wirth

Appendix 2: Data Collection Sheet

Remote Monitoring in the Management of Heart Failure

Elena Mirone

Data Collection Sheet

To be completed using information from CVIS and iSOFT provided by the identified intermediary

Patient Study Number: _____________

Section A: Patient Details

Gender

☐ Male

☐ Female

☐ Other

Type of CIED

☐ ICD

☐ Single chamber

☐ Dual chamber

☐ CRT-D

☐ CRT-P

Age at CIED Implant (years)

☐ 18-30

☐ 31-40

☐ 41-50

☐ 51-60

☐ 61-70

☐ 71-80

☐ 80+

NYHA Classification

☐ Class I

☐ Class II

☐ Class III

☐ Class IV

Date of CIED implantation: __________________________

Patient has Optivol® fluid status monitoring feature

- ☐ Yes

  Patient also has Remote monitoring feature

  - ☐ Yes
  - ☐ No

Section B: Risk Factors and comorbidities

	Yes / No (✓/ ✗)
Anaemia	
Atrial Fibrillation	
Chronic Obstructive Pulmonary Disease	
Diabetes Mellitus	
Hyperlipidaemia	
Hypertension	
Coronary Artery Disease	
Liver Disease	
Previous Myocardial Infarction Date	
Previous Revascularisation Date	☐ PCI ☐ CABG
Previous Stroke	
Previous TIA	
Smoker	☐ Active ☐ Past ☐ Never
Thyroid disorders	☐ Hyperthyroidism ☐ Hypothyroidism

Alcohol	☐ Yes
	    ☐ Regularly (daily)
	    ☐ Socially (weekly)
	    ☐ Socially (occasionally)
	☐ No

Section C: Relevant Current Medications at CIED Implantation

Drug Class

Section D: Most Recent Investigations Near Date of CIED Implantation

Parameter ***(Reference Range)***	**Result**	**Date**
LVEF *(>50%)*		
NT-proBNP *(<125pg/ml 0-74yrs* *<450pg/ml 75-99yrs)*		
Blood Pressure **Systolic/ Diastolic** *(120/80 mmHg)*		
Heart rate (pulse)		
Potassium *(3.5-5.1mmol/L)*		
eGFR *(>60ml/min per 1.73m^2)*		
Serum Creatinine *(59-104umol/L)*		
Urea *(1.7-8.3mmol/L)*		
Haemoglobin *(14.1-17.2)*		
LDL Cholesterol *(0.1-3.88 mmol/L)*		

Weight (Kg)		
Height (cm)		
BMI (Kg/m^2) ☐ Underweight <18.5 ☐ Normal 18.5-24.9 ☐ Overweight 25-29.9 ☐ Obese 30+ ☐ Class I (30.0 – 34.9) ☐ Class II (35.0 – 39.9) Class III (>40)		

Section E: Outcomes (follow-up)

1-4 Weeks	3 Months	6 Months
Death ☐ Cardiac ☐ Non-cardiac	**Death** ☐ Cardiac ☐ Non-cardiac	**Death** ☐ Cardiac ☐ Non-cardiac

Hospital admission due to HF
 	
☐ Yes
    ☐ **Cardiac**
    ☐ **Non-cardiac**
☐ No
 	
Signs and symptoms of HF
 	
Respiratory Distress
 	
☐ Orthopnoea
☐ Paroxysmal Nocturnal Dyspnoea (PND)
☐ Shortness Of Breath (SOB)
 	
Oxygen Saturation <90%
 	
☐ Yes
☐ No
 	
Oedema
 	
☐ Lower Limb (LL)
☐ Pulmonary
 	
Fatigue
 	
☐ Yes
☐ No
	Hospital admission due to HF
	
	☐ Yes
	    ☐ **Cardiac**
	    ☐ **Non-cardiac**
	☐ No
	
	Signs and symptoms of HF
	
	Respiratory Distress
	
	☐ Orthopnoea
	☐ PND
	☐ SOB
	
	Oxygen Saturation <90%
	
	☐ Yes
	☐ No
	
	Oedema
	
	☐ LL
	☐ Pulmonary
	
	Fatigue
	
	☐ Yes
	☐ No
		Hospital admission due to HF
		
		☐ Yes
		    ☐ **Cardiac**
		    ☐ **Non-cardiac**
		☐ No
		
		Signs and symptoms of HF
		
		Respiratory Distress
		
		☐ Orthopnoea
		☐ PND
		SOB
		
		Oxygen Saturation <90%
		
		☐ Yes
		☐ No
		
		Oedema
		
		☐ LL
		☐ Pulmonary
		
		Fatigue
		
		☐ Yes
		☐ No

Chest Pain ☐ Yes ☐ No **Palpitations** ☐ Yes ☐ No **Syncope** ☐ Yes ☐ No **Stroke** ☐ Disabling ☐ Non-disabling **TIA** ☐ Yes ☐ No **Upgraded ICD to CRT-D** ☐ Yes ☐ No **Other Relevant** **Observations**	**Chest Pain** ☐ Yes ☐ No **Palpitations** ☐ Yes ☐ No **Syncope** ☐ Yes ☐ No **Stroke** ☐ Disabling ☐ Non-disabling **TIA** ☐ Yes ☐ No **Upgraded ICD to CRT-D** ☐ Yes ☐ No **Other Relevant** **Observations**	**Chest Pain** ☐ Yes ☐ No **Palpitations** ☐ Yes ☐ No **Syncope** ☐ Yes ☐ No **Stroke** ☐ Disabling ☐ Non-disabling **TIA** ☐ Yes ☐ No **Upgraded ICD to CRT-D** ☐ Yes ☐ No **Other Relevant** **Observations**

1 Year
Death ☐ Cardiac ☐ Non-cardiac

Hospital admission due to HF
 	
☐ Yes
  ☐ **Cardiac**
  ☐ **Non-cardiac**
☐ No
 	
Signs and symptoms of HF
 	
Respiratory Distress
 	
☐ Orthopnoea
☐ PND
SOB
 	
Oxygen Saturation <90%
 	
☐ Yes
☐ No
 	
Oedema
 	
☐ LL
☐ Pulmonary
 	
Fatigue
 	
☐ Yes
☐ No
 	
Chest Pain
 	
☐ Yes
☐ No

Palpitations

- ☐ Yes
- ☐ No

Syncope

- ☐ Yes
- ☐ No

Stroke

- ☐ Disabling
- ☐ Non-disabling

TIA

- ☐ Yes
- ☐ No

Upgraded ICD to CRT-D

- ☐ Yes
- ☐ No

Other Relevant

Observations

Changes to Medications during follow-up

For Optivol® group only

Number of Alerts Received: ____________________

Dates when alert was recorded: ____________________

____

Number of False Alarms: ____________________

Remote monitoring findings correspond with clinical picture:

- ☐ Yes
- ☐ No
- ☐ N/A

Action taken based on alert/s

- ☐ Yes
- ☐ No

Close monitoring (at the HF clinic)

- ☐ Yes
- ☐ No

Change in treatment

- ☐ Yes
  - ☐ Increase diuretic dose
  - ☐ Limit fluid intake
  - ☐ Other ____________________
- ☐ No

Admitted to hospital

- ☐ Yes
- ☐ No