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ORIGINAL ARTICLE

Monitoring left ventricular assist device parameters to detect flow- and power-impacting complications: a proof of concept

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Aims The number of patients on left ventricular assist device (LVAD) support increases due to the growing number of patients with end-stage heart failure and the limited number of donor hearts. Despite improving survival rates, patients frequently suffer from adverse events such as cardiac arrhythmia and major bleeding. Telemonitoring is a potentially powerful tool to early detect deteriorations and may further improve outcome after LVAD implantation. Hence, we developed a personalized algorithm to remotely monitor HeartMate3 (HM3) pump parameters aiming to early detect unscheduled admissions due to cardiac arrhythmia or major bleeding.

Methods and results The source code of the algorithm is published in an open repository. The algorithm was optimized and tested retrospectively using HeartMate 3 (HM3) power and flow data of 120 patients, including 29 admissions due to cardiac arrhythmia and 14 admissions due to major bleeding. Using a true alarm window of 14 days prior to the admission date, the algorithm detected 59 and 79% of unscheduled admissions due to cardiac arrhythmia and major bleeding, respectively, with a false alarm rate of 2%.

Conclusion The proposed algorithm showed that the personalized algorithm is a viable approach to early identify cardiac arrhythmia and major bleeding by monitoring HM3 pump parameters. External validation is needed and integration with other clinical parameters could potentially improve the predictive value. In addition, the algorithm can be further enhanced using continuous data.

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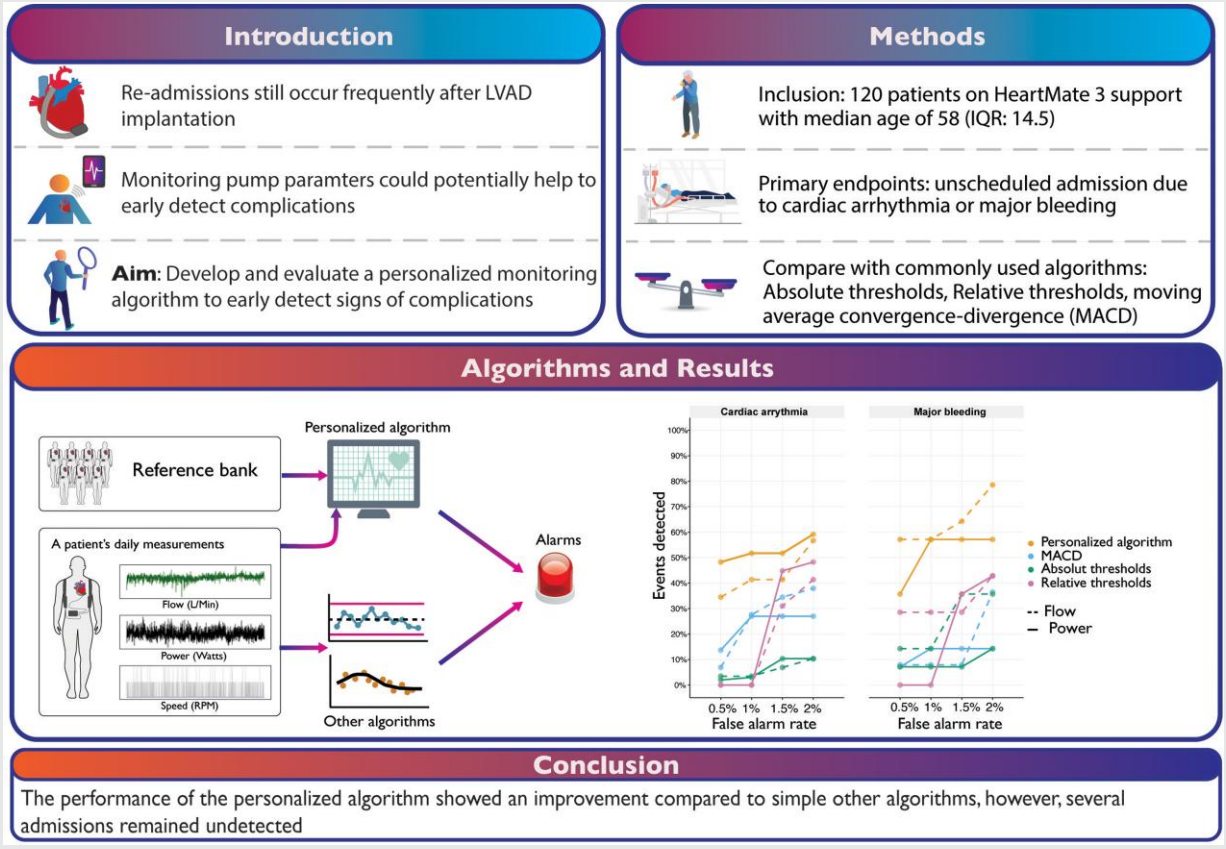
Graphical Abstract



Keywords Patient-specific monitoring • LVAD • Intensive longitudinal data • Remote patient monitoring

Introduction

Left ventricular assist device (LVAD) implantation is an established treatment for patients with advanced heart failure. Left ventricular assist devices are primarily implanted as a bridge to transplant, but are also used as destination therapy in patients not eligible for heart transplant.[1] Despite improving survival rates after third generation LVAD implantation, with a 5-year survival of 58.4%, patients frequently suffer from adverse events such as cardiac arrhythmia and major bleeding.[2–4] Between 20 and 60% of all patients experience ventricular arrhythmia after LVAD implantation and major bleeding occurs at a rate of 0.48 per patient-year,[5] LVAD care is complex and patients frequently suffer from adverse events. Hence, LVAD patients visit the outpatient clinic multiple times per year for a clinical and technical assessment and the surveillance between those visits relies purely on an alarm in case of a low flow (flow < 2.5 L/min) and self-management of the patient. This may lead to late detection of complications. Therefore, remote monitoring tools that enable early detection of LVAD-related complications are desired to start early treatment.[6,7] So far, some work has been done on remote monitoring of pump parameters.[6,8–13] Earlier studies have indicated that monitoring power to identify pump thrombosis (PT) in patients on HeartWare ventricular assist device (HVAD) support can provide results with high sensitivity (ranging from 85 to 100%) and high specificity with a low rate of false alarms (0.15 events per patient-year).[10,14,15] However, due to the global market withdrawal of HVAD, HeartMate 3 (HM3) has become the most implanted LVAD underscoring the necessity for investigations into algorithms applicable for HM3. Since PT is a very scarce complication in HM3 patients, occurring in 1.4% of HM3 patients within 2 years after implantation, algorithms should also be able to detect other more common complications such as cardiac arrhythmia and major bleeding as well.[16] As these complications may affect power or flow values, monitoring of these parameters provide the opportunity for timely diagnosis and treatment.[8]

Therefore, we aimed to develop and test a remote personalized monitoring algorithm to early detect the admission due to common adverse events (cardiac arrhythmia and major bleeding), based on the HM3 pump power and flow values.

Materials and methods

This single-centre retrospective study was approved by the local ethics committee of the University Medical Centre Utrecht (UMCU) in the Netherlands (METC:20-195) who waived the need for informed consent. The study was conducted in accordance with Good Clinical Practice and the 2002 Declaration of Helsinki.

Patient cohort

Between December 2015 and December 2021, 157 patients were implanted with HM3 in the UMCU. The follow-up was until February

2022. Measurements during index admission were removed from the analysis. Patients with a follow-up of less than 180 days were excluded, in addition to patients with more than 25% missing pump parameter data during follow-up. The number of 180 days was selected to allow for a minimum of 90 days to evaluate the algorithm while testing the maximum number of calibration phase of 90 days (see below). The maximum percentage of missingness of 25% was selected to allow for some missingness while retaining a sufficient amount of information per patient.

Primary endpoint

The primary endpoint was unscheduled admission due to either cardiac arrhythmia or major bleeding. Major bleeding was defined as any suspected internal or external bleeding that results in death, re-operation, hospitalization, or transfusion of red blood cells. Cardiac arrhythmias were defined as any arrhythmia that results in clinical compromise (e.g. diminished LVAD flow or suction events, oliguria, pre-syncope or syncope, angina or dyspnea) or requires hospitalization or treatment (drug therapy, defibrillation, cardioversion, implantable cardioverter-defibrillators (ICD) therapy, or ablation procedure). Cardiac arrhythmias were classified as sustained ventricular arrhythmia or sustained supraventricular arrhythmia.[17] For the development and evaluation of the algorithm, the patients were split into groups. Patients without any unplanned LVAD-related admission were called the 'stable-LVAD patient' group. Patients with admissions due to cardiac arrhythmia or major bleeding were called the 'non-stable patients' group. Patients with unplanned LVAD-related admissions other than cardiac arrhythmia or major bleeding were excluded. For the analysis, data on 180 days preceding the cardiac arrhythmia or major bleeding admissions were included. Patients with co-occurring events (i.e. both LVAD and LVAD unrelated events) in addition to the primary endpoint within this 180-day timeframe were also excluded. Co-occurrence events refer to any events other than the primary endpoints, which are cardiac arrhythmia or major bleeding. These co-occurrence events occurred within a span of 14 days from the primary endpoints.

Pump data

HM3 pump parameter data were manually retrieved during outpatient visits and admissions. These files contain pump speed (RPM), motor power (Watts), pulsatility index, flow (L/min), and haematocrit. HM3 can store 256 measurements before data is overwritten. At our centre, pump parameters are usually stored every 12 h. In some hospitalized patients, data was retrieved at a higher frequency. Hence, measurement frequency varies between patients. Therefore, data was downsampled to two samples per day with an interval of 12 h for each patient to reach agreement between patients. Logfiles were converted to comma-separated values and compiled into a database.

Personalized algorithm

A summary of the steps in the personalized algorithm is provided in this section, an implementation of the algorithm in R is made publicly available at Moazeni *et al.*[18] The algorithm screens for irregular observations in power and flow by patient-tailored thresholds. Initially, a linear mixed effects model is employed, which incorporates both the short segments of longitudinal pump parameters of 'stable-LVAD patients' and the patient-specific intense longitudinal data. This produces a personalized mean pump value that is dynamic and reflective of the patient's stable historical baseline. Our study included 53 patients from the 'stable-LVAD patient' group in our general cohort. We hypothesize that this group provides a precise estimation of the mean and variance of stable situation in LVAD patients.

During the calibration period (30 days), data from 'stable-LVAD patients' is used, and thresholds are continuously updated and tailored to the patient. In addition, patient-specific thresholds are updated after LVAD pump speed change. We chose a 30-day calibration period as it aligns with the time needed for the model to fine-tune its estimates for individual patient parameters (e.g. residual of the model varies around 0). Further insights into varying calibration sizes are elaborated in Supplementary material online, *Appendix 1*. In the final step, real-time measurements are subtracted from the patient-specific mean. These residuals show how much a pump parameter deviates from the predicted value. The residuals are smoothed using an exponentially weighted moving average (EWMA). The EWMA control chart determines the lower control limit and upper control limit. If the smoothed values exceed control limits, the algorithm alarms. An illustration of how the personalized algorithm operates is depicted in *Figure 1*.

The following parameters in the personalized algorithm need to be tuned: coefficient of the width of the control limits during the calibration phase and after the calibration varied between 1 and 5, with steps of 1. The smoothing parameter varied between 0.2 and 0.8 with step of 0.2. More elaborate exposé of the personalized algorithm can be found in Supplementary material online, *Appendix 1*.

Comparison with other algorithms

Since HM3 data is overwritten after 256 rows, it was not possible to retrieve all low flow alarms. Therefore, we could not compare out algorithm with the current situation (low flow alarms). Hence, we compared the personalized algorithm with three 'simple' algorithms, namely absolute and relative thresholds, and the moving average convergence-divergence (MACD) algorithm.

Absolute and relative thresholds

Absolute thresholds were determined by calculating the average of each pump parameter during the calibration period. The absolute thresholds are determined with a variation from the mean. An alarm is raised when real-time measurements exceed the thresholds. Patient-specific thresholds for each pump parameter fixed over time. To obtain the thresholds:

$$\text{Absolute threshold} = \mu_{i,\,1:c} \pm K$$

where $\mu_{i,\,1:c}$ is the mean for patient i in the calibration period (14 days) and K varied between 0.1 and 2 with steps of 0.1 L/min for flow 0.01 W for power.

The relative threshold method considers previous pump measurements during a specified time window (varying from 2 to 14 days with a step of 1 day).[11] In contrast to the absolute thresholds, the standard deviation (sd) is updated after each new measurement. The threshold solely relies on the sd of each patient, and it is equal to

$$\text{threshold}_j = \text{sd}_j \times n$$

where i is the ith patient and j is the jth relative threshold. n was varied of 0.1–3 with a step of 0.1. If the absolute daily difference of the flow/power measurements exceeds the thresholds, the algorithm will trigger an alarm.

Moving average convergence-divergence algorithm

The third algorithm is the MACD. Moving average convergence-divergence considers deviation between two exponentially weighted moving averages, a short- and long-time span. The algorithm is sensitive to trends instead of short increases, and it triggers an alarm once the MACD line exceeds a predefined threshold. Moving average convergence-divergence has been implemented for monitoring heart

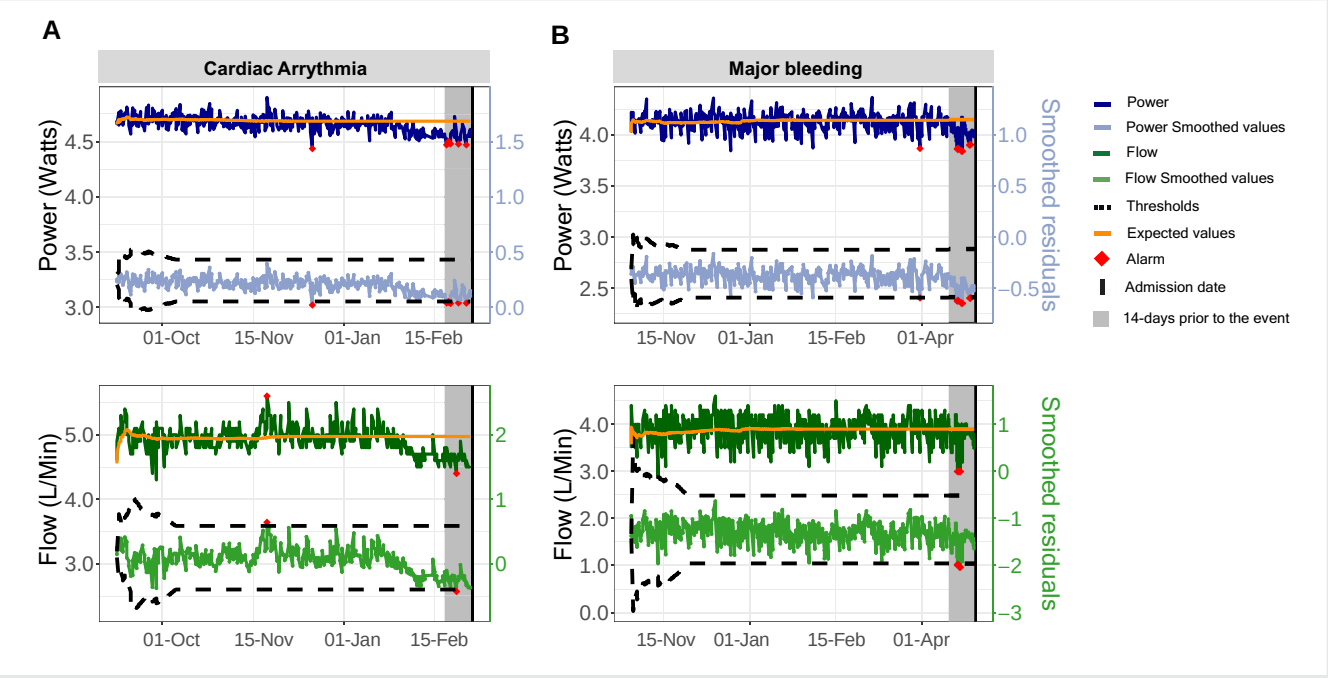


Figure 1 Personalized thresholds and out-of-control measurements for two patients with cardiac arrhythmia (*A*) and major bleeding (*B*) when monitoring flow and power is considered. Fourteen days prior to the admission is visualized as shaded area. Both events were detected when monitoring flow or power.

Table 1 Baseline characteristics of all patients ($n = 120$)

	All HeartMate 3 implants ($n = 120$)	Stable-LVAD patients ($n = 53$)	Cardiac arrhythmia or major bleeding patients ($n = 29$)
Age (years) (IQR)	55.0 (14.5)	54.6 (14)	60.1 (6)*
Sex *n* (% male)	79.0 (65.8%)	37 (69.8%)	21 (72.2%)
Ischaemic aetiology *n* (%)	31 (25.8%)	17 (32.0%)	4 (13.7%)
BSA (m^2) (IQR)	2.0 (0.30)	1.98 (0.25)	1.98 (0.27)
BMI (kg/m^2) (IQR)	24.9 (6.0)	24.9 (5.3)	24.5 (5.5)
Pre-operative characteristics of primary HeartMate3 implants ($n = 114$)		$N = 49$	$N = 28$
eGFR (mL/min/1.73 m^2) (IQR)	64.8 (40.0)	66.3 (27.0)	57.8 (38.5)
Bilirubin (μmol/L) (IQR)	24.9 (18.0)	27.7 (19.0)	25.5 (17.8)
Right ventricle function			
Poor *n* (%)	13 (11.4%)	9 (18.3%)	5 (17.8%)
Moderate *n* (%)	58 (50.9%)	23 (47.0%)	14 (50.0%)
Good *n* (%)	43 (37.8%)	20 (40.9%)	9 (32.1%)
Temporary support *n* (%)	12 (10.5%)	7 (14.3%)	1 (3.5%)
INTERMACS			
1 *n* (%)	7 (6.1%)	1 (2.0%)	2 (7.1%)
2 *n* (%)	37 (32.4%)	15 (30.6%)	11 (39.3%)
3–7 *n* (%)	58 (50.9%)	26 (53.0%)	14 (50.0%)
Diabetes mellitus *n* (%)	16 (14.0%)	1 (2.0%)	2 (7.1%)

Patients with other admissions than arrhythmia or major bleeding group ($n = 38$) were omitted from the subgroup analysis for conciseness.
IQR, inter-quartile range; LVAD, left ventricular assist device; BSA, body surface area; BMI, body mass index; INTERMACS, Interagency Registry for Mechanically Assisted Circulatory Support; eGFR, estimated glomerular filtration rate.
*P-value < 0.05.

failure patients.[19,20] Short- and long-term time windows were varied between 1–10 and 10–14, respectively, with thresholds of 0.1–1 L/min and Watts for flow and power, respectively.

Evaluation and definition of alarms

The performance was evaluated on 150 days preceding an event and after the 30-day calibration phase. The performance indices to evaluate and compare the algorithms were the percentage of detected events and false alarm rate (FAR) for power and flow. All algorithms were applied to power and flow of the 'non-stable group' patients. The following definitions were used:

- *True-Positive (TP)*: An alarm is labelled as a TP alarm if it is triggered 14 days before an admission.
- *False-Positive (FP)*: An alarm is labelled as a FP alarm if it is triggered more than 14 days before an admission.
- *Detection rate/Recall*: Fraction of events detected among all admissions.
- *False alarm rate (FAR)*: It is defined as the number of FP per patient using:

$$\text{FAR} = \frac{\text{FP}}{\text{Follow-up period}}$$

Alarms within the first 14 days were ignored for all algorithms because of calibration of the parameters. For false positives, we considered four different scenarios, where the average FAR ranged between 0.5 and 2%.

During evaluation, we can allow for a higher rate of missingness, as the algorithm has already 'learned' the personalized parameters and is only monitoring. As such, we increase the maximum missingness rate to 75% during the 45 days preceding the true alarm phase of 14 days, which leaves a minimum of 22 observations to assess the FAR within this time window. Within the true alarm phase of 14 days preceding the event, we allow for a maximum of 50% missingness, relating to a minimum of 14 observations available for evaluation.

Statistical analysis

Data analysis was conducted using R (version 4.2.0), adopting a significance threshold of 0.05. We employed the Shapiro–Wilk test to assess the normality of numeric datasets. Continuous data with a normal distribution were described using their mean and sd, and non-normally distributed continuous data were described using median and interquartile range (IQR). Categorical data were represented either numerically or as percentages. The χ^2 test facilitated comparisons among categorical variables. For continuous data with a normal distribution, we used the independent *t*-test, whereas the Mann–Whitney *U* test was chosen for data with non-normal distributions. To statistically compare the performance of the personalized algorithm against other methods, we employed DeLong test.

Results

Of the 157 patients, 23 patients on HM3 support had more than 25% missing data and were therefore excluded from the analysis, and 14 patients were excluded because of having less than 180 days of measurement when only two samples per day were selected. In total, 120 patients were included containing $n = 53$ from 'stable-LVAD' patient group and 67 patients from 'non-stable patients' group, yielding total patient-year of approximately 354. *Table 1* shows the baseline characteristics of all patients with HeartMate 3 implants, and for the subgroups stable-LVAD patients and patients with cardiac arrhythmia or major bleeding. There were no differences in clinical characteristics between stable and non-stable-LVAD patients with primary endpoint, except for age $W = 992$ (Mann–Whitney *U* test), $P = 0.03$. The median age of the patient cohort was 58 (IQR: 73) years and 65.8% were male. For the evaluation of all algorithms, 29 admissions related to cardiac arrhythmia and 14 admissions because of major bleeding were included for evaluation (*Figure 2*).

The personalized algorithm in cardiac arrhythmia detected around half of admissions when monitoring power and 35% when monitoring flow in cardiac arrhythmia with an FAR of 0.5%. For an FAR of 2%, the detection rate of the personalized algorithm increased to 59 and 57%, for power and flow monitoring, respectively (*Figure 3*). Comparing the performance of power and flow in detecting cardiac arrhythmia admissions, the personalized algorithm revealed that power surpasses flow throughout the FAR scenarios. Flow monitoring with MACD achieved a detection rate of 37%, which was higher when compared to absolute. Using relative thresholds was more effective in detecting cardiac arrhythmia admissions for both power and flow (48 and 42%, respectively) in scenarios with higher FARs in comparison to the absolute thresholds (31 and 37%, respectively). The DeLong test indicated that the difference between performance of the personalized algorithm and other methods was statistically significant ($Z = 2.72$, $P < 0.05$). Thus, personalized algorithm had outperformed other methods.

The highest rate attained by the personalized algorithm in detecting major bleeding admissions was in flow monitoring (79%), whereas with power the detection rate was lower (57%). The performance of the other algorithms was lower than the personalized algorithm regarding major bleeding admissions. The associated DeLong test for comparing personalized algorithm and other methods in the major bleeding was statistically significant ($Z = 3.26$, $P < 0.05$).

The median number of days of the first alarm before the admission due to cardiac arrhythmia or major bleeding was 6.5 (IQR: 7.0) days and 7.0 (IQR: 7.5), respectively. Supplementary material online, *Figure S2A* displays the first alarm in the 14 days window prior to the admission for personalized algorithm.

Supplementary material online, *Figure S3A* shows the FAR of all patients for an average FAR of 2% for power and flow, split-up in admissions due to cardiac arrhythmia and major bleeding. A large variation in the number of false alarms per patient was found (range 0.005–18%). Of the 22 patients, 10 patients in the cardiac arrhythmia group had a high FAR of more than 2%. The FAR for the 'stable-LVAD' patient group was 1.62%.

Discussion

Remote monitoring of LVAD pump parameters, as a supplement to outpatient clinic visits, may improve clinical outcomes by early detection of adverse events. In this proof-of-concept study, we developed and tested a personalized algorithm on HM3 parameters; 59 and 79% of the cardiac arrhythmia and major bleeding admissions were detected by the algorithm, with an FAR of 2%.

The performance of the personalized algorithm was evaluated by the number of true and false alarms. Alarms within 14 days before an endpoint were assigned as a TP alarm. The definition of this 2-week window was determined by a clinical expert team and was needed because of the retrospective nature of the study. Alarms prior to this window were labelled as false positives but could be related to the admission. On the other hand, an alarm during this window can be unrelated to the admission but is counted as a true positive. Hence, prospective testing is needed to confirm the algorithm's performance. There is a trade-off between detection power and number of false alarms. Wider thresholds increase detection power but come along with more false alarms. The detection power was shown for various false alarm rates. It is important to reduce nonactionable alarms to prevent alarm fatigue, which can increase health care professionals' and jeopardize patient safety.[21]

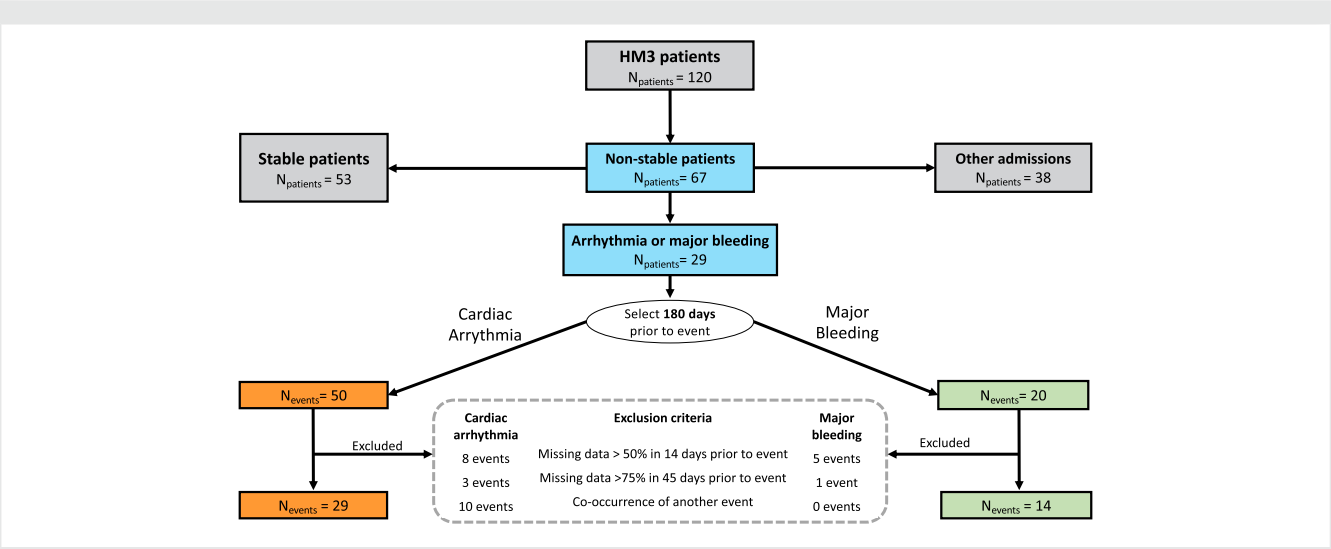


Figure 2 Flowchart of included patients and admissions due to cardiac arrhythmia and major bleeding. Co-occurrence events refer to any events other than the primary endpoints, which are cardiac arrhythmia or major bleeding. These co-occurring events took place within 14 days of the primary endpoints.

Several patients had a relatively high number of false alarms, which may occur after a shift in pump parameters. For example, power and flow shift in their baseline after a pump speed change. Therefore, the personalized algorithm recalibrates patient-tailored thresholds after a change in pump speed. In addition, progressive worsening or medication changes that affect pre-load or afterload of the heart can affect the baseline of a patient's pump parameters. A ventricular assist device (VAD) co-ordinator may update the personalized algorithm in such situations, in case of a stable patient. This could reduce the number of false alarms during prospective usage. The personalized algorithm is not updating continuously, i.e. at every new data-point, as slow upward or downward trends in the pump parameters remain undetected.

The primary endpoint used to evaluate the personalized algorithm was defined as admissions due to cardiac arrhythmia or major bleeding. Possibly, not all these admissions were accompanied by detectable changes in power or flow. Hence, the performance of the personalized algorithm may be interpreted as relatively low. However, the current situation, where the LVAD alarms in case of a low flow (i.e. 2.5 L/min), can be improved by patient-tailored thresholds that help to detect trends.

Comparison with existing literature

Previous research on the prediction of complications after LVAD implantation using pump parameters mainly focused on PT only in HVAD patients.[10,15,22,23] Slaughter *et al.* tested a power tracking algorithm yielding a high sensitivity of 85.7%.[10] Krysiński *et al.* achieved high sensitivity and specificity of 100% in detecting PT events by monitoring power.[15] The sensitivity and specificity of these studies are high since PT events drastically affect pump power. In addition to the LVAD power itself, the circadian rhythm of the power was of interest in previous literature. The circadian rhythm HVAD power is diminished at early stages of PT, unlocking the potential to early identify PT prior to clinical symptoms.[22,23] It was not possible to incorporate the circadian rhythm in the personalized algorithm due to HM3's limited data storage.

Strengths and limitations

We were the first to retrospectively test a patient-tailored monitoring algorithm for HM3 pump parameters considering two common adverse events: cardiac arrhythmia or major bleeding. It is an important addition to the current literature, as previous research mainly focused on the detection of PT. The current study has several limitations. At first, our method was evaluated using two daily samples and must be fine-tuned to higher frequency or continuous data -streams. Second, the study included a relatively small patient cohort using retrospective analysis. Third, we were not able to compare the performance of the personalized algorithm with the current monitoring system (low flow alarms) since all low flow alarms were overwritten after 256 rows. Hence, we compared our algorithm to other algorithms.

Future research

Several steps are required before clinical application of the personalized algorithm. First, higher frequency pump data for HM3 is needed to fine-tune the algorithm. Consolo *et al.* showed that during post-operative recovery, HVAD patients develop circadian rhythmicity, which remains stable in the long term.[22] Their findings suggested that including circadian variability provides unprecedented prediction power to detect PT events. Possibly, the circadian rhythm in pump parameters is informative as well with respect to cardiac arrhythmia or major bleeding events. To test this hypothesis, we need higher frequency data. The Snoopy HM3, a non-invasive device, was developed to retrieve high-frequency HM3 data (1 sample per second).[24] This allows optimization of the algorithm applicable for online monitoring. Moreover, these high-frequency datasets enable the possibility to incorporate the circadian rhythm, as power and flow show a nocturnal decrease.[25] In addition to varying thresholds throughout the day, the circadian rhythm itself may be used as a predictive tool.[22,23]

Additional clinical data can be used to further improve the detection power of monitoring algorithms for LVAD patients, since not all admissions are preceded by a substantial change in pump parameters.[8] Clinical data such as mean arterial pressure, lab values (i.e. sST2[26]) could be used to provide additional clinical context. Moreover, either non-invasive (i.e. activity trackers, heartrate monitoring) or invasive devices (i.e. CardioMEMS, ICDs, and pacemakers) may provide valuable data.[8] Other data sources could be used to influence the strictness of the personalized algorithm. A VAD co-ordinator may also decide to influence the strictness of the personalized algorithm in specific patients.

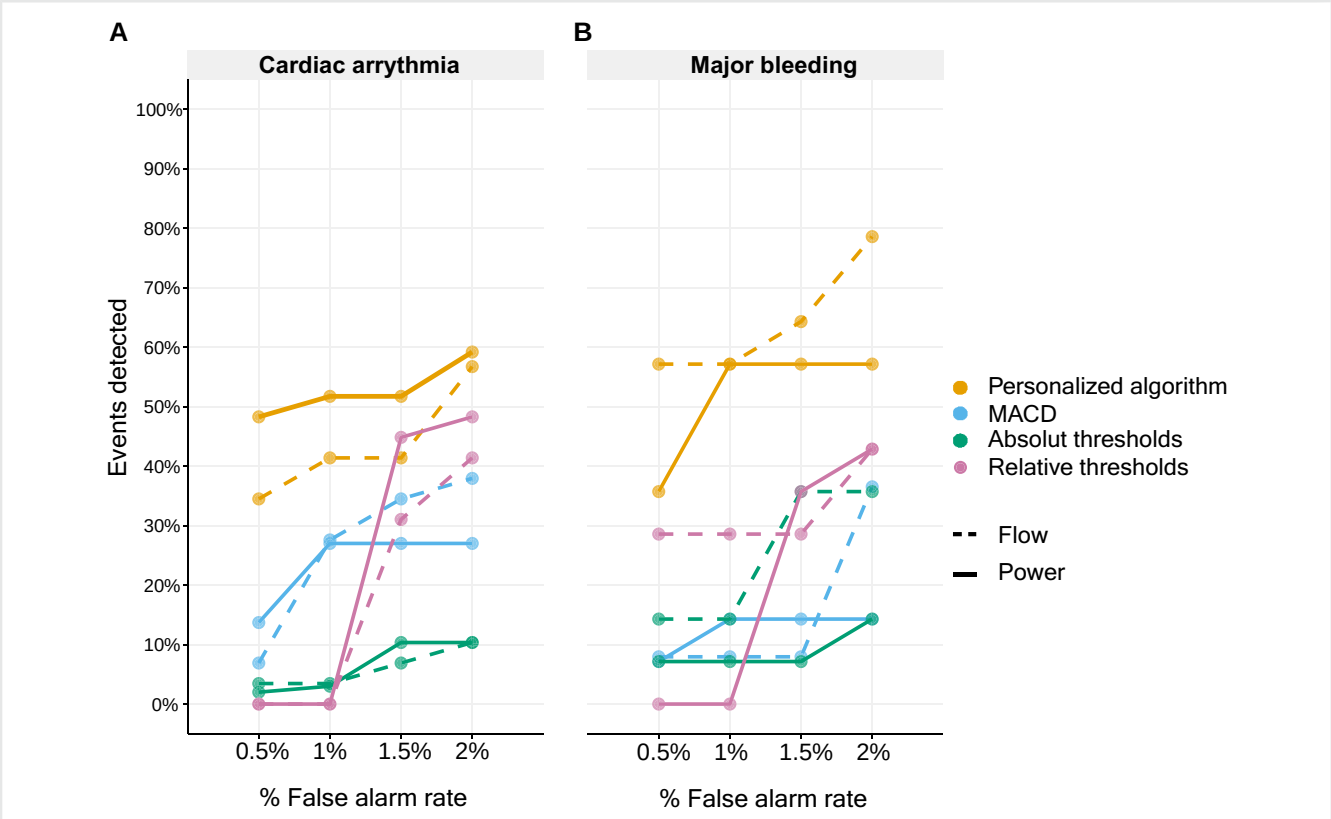


Figure 3 Detection rate comparison of the methods based on different FAR for cardiac arrhythmia (*A*) and major bleeding (*B*). Dashed lines represent flow and solid lines represent power monitoring.

The personalized algorithm developed in our research can be used for early detection of other type of adverse events that might change the pump parameters prior to a hospitalization.[8]

Importantly, infrastructure of the telemonitoring approaches must be set-up, which can hamper clinical implementation.[8] Ideally, the algorithm is incorporated into the HM3 enabling 'online monitoring' of continuous data-streams. Additionally, data should be transferred to the hospital, enabling remote assessment of the patient by the VAD co-ordinators.

Conclusion

Remote monitoring of pump parameters in patients on HM3 support is a potential powerful tool to early detect adverse events. This proof-of-concept study proposes a personalized algorithm applied to HM3 parameters to detect cardiac arrhythmia and major bleeding. The performance of the developed algorithm showed an improvement compared to other simple algorithms; however, several admissions remained undetected. Using higher frequency data accommodating circadian fluctuation may result in algorithm improvements. External validation within a larger sample and ultimately a prospective study is needed before clinical application.

Supplementary material

Supplementary material is available at *European Heart Journal—Digital Health*.

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Conflict of interest: M.M., L.N., M.S., N.K., F.W.A, and E.A. report no competing interests. L.W.L. received consultancy fees from Medtronic, Abbott Vifor, Novartis, outside the submitted work.

Data availability

An openly available implementation of the personalized algorithm in R is published on Zenodo[18] and can be accessed via https://zenodo.org/record/8307993. Synthetic datasets have also been developed for the purpose of testing the algorithm, which can be accessed publicly. However, the underlying data used in this study cannot be shared publicly, as it pertains to the privacy of the individuals who participated in the study. Access to this data can be granted upon reasonable request to the corresponding author. It is important to note that no new data were produced or analysed in the course of this research.

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