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Requirements for a Telemedicine Center to Monitor LVAD Patients

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Abstract. E-health, especially telemedicine, has undergone a remarkably dynamic development over the last decade. Most experience is currently in the field of telemedical care for heart failure (HF) patients. However, HF patients with an implanted left-ventricular assist device (LVAD) have been more or less excluded from consistent telemonitoring until now. The majority of complications associated with LVAD therapy occur during the post-implantation phase. Effective outpatient management is therefore the key to improving long-term outcome of LVAD patients. Thereby, implementation of a telemedicine center for close monitoring could play an important role, e.g. through early detection of complications. This study provides insights into structural, staff and spatial requirements for a telemedicine center to monitor the special group of LVAD patients, based on comprehensive literature research and expert interviews.

Keywords: heart failure, left-ventricular assist device, telemonitoring, remote monitoring, disease management

1. Introduction

LVAD implantation as an alternative to heart transplantation is known to improve survival, functional capacity, and quality of life in heart failure patients [1, 2]. Today it is possible for LVAD patients to be discharged home. Survival following LVAD implantation can now be 10 years or more [3].

Despite all the technological progress, a significant number of severe complications remain, with a high rate of readmission to the implanting center in the long-term follow-up [4–10]. The most frequent complications are renewed heart failure, thromboembolism, hemorrhage, infection (especially driveline infections) and right-heart failure [4–10].

Nowadays, aftercare for this special patient group usually comprises outpatient visits every 3 months [11, 12]. Between these visits, patients are predominantly left to their own devices and largely manage the LVAD system (**Figure 1**) themselves. The quality of this self-management crucially depends on patient compliance [13]. Should

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patients have questions or problems, they can contact staff at the implanting center by telephone at any time. Ultimately, however, aftercare in the post-hospital phases is insufficient and urgently in need of improvement.

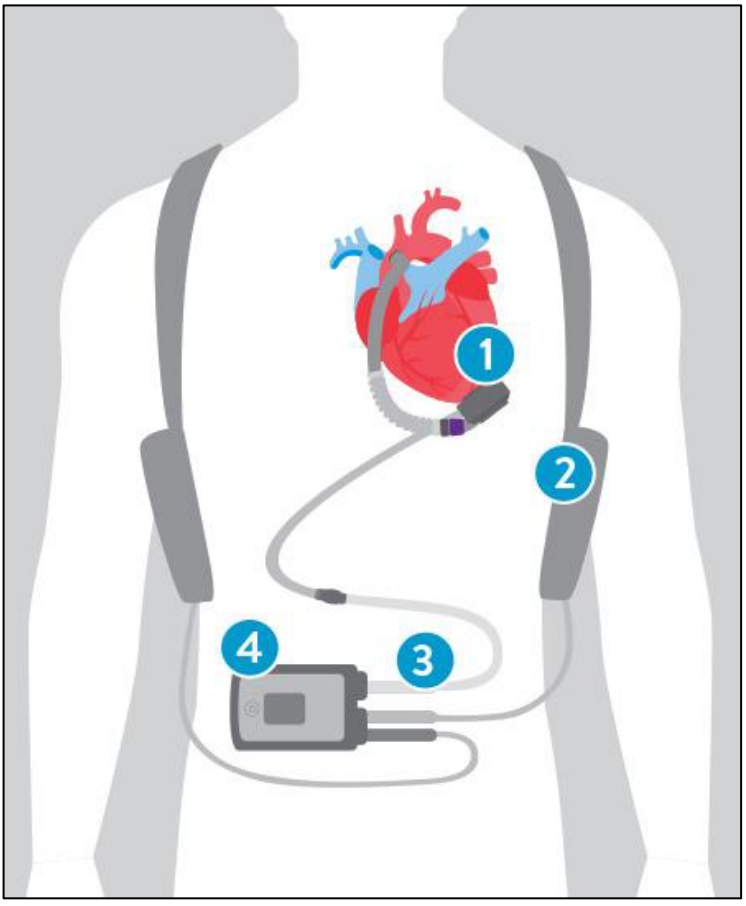

Figure 1. LVAD patient with internal and external equipment [14] (1- pump, 2- batteries, 3- driveline, 4- controller, with permission of Abbott®).

In the field of heart failure therapy (without LVAD), first experiences have been made with telemonitoring approaches in the last few years [15–19]. Implementation of telemedicine centers facilitates remote medical services. Telemedicine centers improve the efficiency of treatment and provide patients with a greater sense of safety by assuring permanent contact with qualified medical staff. However, the approaches applied so far are insensitive to LVAD patients, and new strategies are indispensable for this patient group [20, 21]. To date, there are no telemedicine centers available for monitoring heart failure patients supported by LVAD.

In the following paper, structural, staff and spatial requirements for a telemedicine center to monitor the special group of LVAD patients are described, based on comprehensive literature research and expert interviews.

2. Methods

2.1. Comprehensive literature research

For the systematic recording, organization and administration of all relevant literature sources, a systematic literature search was carried out at the beginning of the study. In order to select relevant studies, inclusion and exclusion criteria were established using the PICO schema [22] and advanced elements. Based on the PICO schema, the following parameters were considered in more detail in order to subsequently define corresponding inclusion or exclusion criteria (**Table 1**).

Table 1. Inclusion and exclusion criteria for systematic literature search.

Inclusion (I) - and Exclusion(E) -Criteria			
I1		Population	Adult heart failure patients treated by LVAD
	E1		Children and adolescents < 18 years
I2		Intervention	Telemonitoring by Telemedicine Center
	E2	Language	Non-German and non-English language publications
I3		Type of study	Without restriction
I4		Study duration	Without restriction

2.2. Expert interviews

A qualitative investigation based on guided interview and focus group techniques was conducted at three German heart centers with caregiver experts. The expert interviews were conducted as openly as possible since the goal of this method was a comprehensive survey of expert knowledge regarding the research topic. Guidance interviews are non-standard interviews that work with given topics and a list of questions – known as the guide.

In line with the research question of the present work, a guideline was developed for the expert interviews with corresponding topics and questions. The guide was subdivided into five subject blocks with a total of 14 principal questions and 9 subordinate questions, corresponding to 23 categories. The 5 blocks were:

- Initial questions (8 categories)
- Structural requirements (6 categories)
- Personnel requirements (3 categories)
- Spatial requirements (2 categories)
- Final questions (4 categories)

The expert interviews were intended to provide a first insight into the field of structural, personnel and spatial requirements in order to derive conclusions for the practical implementation of a telemedicine center.

The selection of experts is an essential decision in research design because it decides the nature and quality of the information. Experts are in this scenario people who, based on their work with LVAD patients, have the expertise to make statements about the requirements of planned centers. The selected group of experts thus includes

persons who work closely with LVAD patients, who have the required experience, and who have a comprehensive overview of the overall care situation of this patient clientele.

These include, on the one hand, implanting physicians and physicians with pre- and aftercare patients. On the other hand, VAD coordinators and VAD nurses with appropriate specialist training, working intensively with LVAD patients, are also involved.

The interviews were conducted personally, face-to-face, by the same interviewer. Face-to-face interviews are characterized by high information content and a good controllability of the conversation. The individual expert interviews were transcribed promptly after implementation using the transcription program f5 in order to fully map and capture the information received. The transcripts of the expert interviews were used as base material for the data analysis and evaluated using the qualitative content analysis according to Mayring [23].

3. Results

3.1. Literature research

In summary, there were no published studies available to answer the questions posed by the research topic. Thus, the current state of research must be assessed as bad or non-existent, clarifying the crucial importance of research regarding this topic.

A reduced search strategy was therefore then used, with 450 hits achieved in total (**Table 2**). By means of the systematic literature research or the reduced search strategy and the supplementary unsystematic research by hand, publications on individual elements of the search strategy were found. These were helpful for development of the guideline and provided information which had an impact on the topic.

Table 2. Research strategy PubMed.

Source: PubMed
Date: 30.04.2018
Filter: humans, english or german, adult

#	Term	Result
1	"left ventricular assist device*"	4.768
2	LVAD	3.460
3	#1 OR #2	5.694
4	telemonitoring	1.140
5	"remote monitoring"	1.420
6	"telemedical monitoring"	20
7	#4 OR #5 OR #6	2470
8	"telemedical service cent*"	27
9	"telemedicine cent*"	4.985
10	"telehealth cent*"	5.286
11	#8 OR #9 OR #10	5290
12	#3 AND #7 AND #11 Filters: Humans; English; German; Adult: 19+ years	0
13	#3 AND #11 Filters: Humans; English; German; Adult: 19+ years	0
14	#3 AND #7 Filters: Humans; English; German; Adult: 19+ years	450

3.2. Expert interviews

The multicenter interviews were carried out at three different German clinics in Lower Saxony and North Rhine-Westphalia. All clinics had been implanting LVAD systems for many years and also offered aftercare for discharged patients. From the 3 hospitals, a total of 11 experts (6 physicians and 5 VAD coordinators or VAD nurses, 91% male) took part in the interviews. The mean experience of the interviewed experts with LVAD patients can be assessed as very good, spanning 12.9 ± 7.5 years (**Table 3**). All interviews could be conducted through to the end without interruption. Overall, the interviews led to a total of 04:29:09 hours of soundtrack and spoken data, and single interviews lasted between 00:14:15 and 00:42:32 hours (mean 00:24:28 hours).

Table 3. LVAD experiences of the individual clinics and interviewed experts.

	Clinic 1	Clinic 2	Clinic 3
LVAD implantations per year	~ 45-50	~ 100-120	~ 30-40
LVAD outpatient treatment (pts)	~ 100	~ 250	~ 45
LVAD experience of the interviewed experts (yrs)	11.5	20	11

The expertise and experience in the field of telemedicine varied among the LVAD experts interviewed, ranging from no knowledge to expert knowledge. The median was within the range of basic knowledge of telemedicine (**Figure 2**).

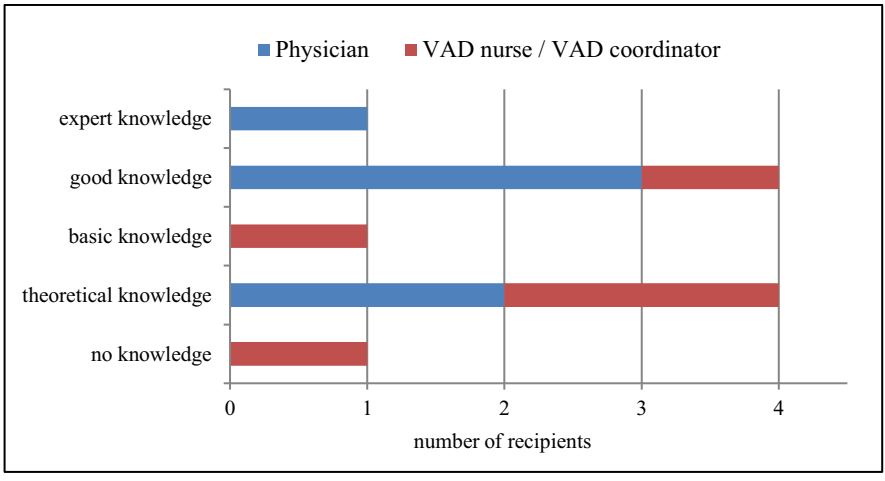

Figure 2. Knowledge of individual experts in the field of telemonitoring (n=11).

3.3. Generated hypothesis

Based on the findings from the five interview blocks mentioned, corresponding to 23 categories, 10 hypotheses were generated according to the answers given by the experts (**Table 4**). The first hypothesis is that each LVAD-implanting clinic should monitor its LVAD patients via its own telemedicine center. The second hypothesis is as follows: in order to better interpret the transmitted data and parameters, patients should be known to the telemedicine center. In addition, based on the findings of this thematic block, a

third hypothesis is that a minimum of 50 LVAD patients is necessary to implement a telemonitoring program. The fourth hypothesis is that telemonitoring of LVAD patients by a telemedicine center leads to a reduction in operating expenses in other areas of LVAD patient aftercare. Nonetheless, the fifth hypothesis is that routine outpatient appointments could not be completely avoided, although the sixth hypothesis indicates that after implementation of a telemedicine center routine outpatient appointments could be reduced.

The subject block "personnel requirements" also gave rise to extensive insights during the expert interviews. First of all, based on the interpreted findings, it is hypothesized that the professional groups physicians, VAD coordinators and VAD nurses must be involved. Physicians and VAD coordinators are called for by all the experts, with the majority of experts further calling for VAD nurses. This consensus makes it clear that, ideally, the occupational groups should be involved which are currently also involved in the care and aftercare of LVAD patients. Moreover, the hypothesis is put forward that additional staff needs to be hired to monitor LVAD patients through a telemedicine center. In the thematic block "personnel requirements", it is hypothesized that the telemedicine center does not have to be occupied 24/7 and can be covered by staff on call. This hypothesis is based on that an access to the patient data is possible from the staff´s home. Furthermore, alerts can be sent to the smartphone of staff members regardless of where their whereabouts are.

The thematic block "spatial requirements" gave rise to the following hypothesis: the telemedicine center must be spatially connected to the implanting center.

In summary, all experts agreed that close telemonitoring of LVAD patients should lead to improvements in quality of life and quality of aftercare in this special patient group. According to this expert opinion, telemonitoring of LVAD patients should be feasible. The overall results confirm the potential of this form of care.

Table 4. Generated hypotheses.

Hypothesis	Thematic block	Hypothesis
H1	Structural requirements	Each LVAD implanting center should have a telemedicine center to monitor LVAD patients.
H2	Structural requirements	For interpretation of transferred data and parameters, LVAD patients should be known to the physicians.
H3	Structural requirements	A minimum number of 50 LVAD patients is necessary for the implementation of a telemonitoring program.
H4	Structural requirements	Telemonitoring of LVAD patients by a telemedicine center leads to a reduction in operating expenses in other areas of LVAD patient aftercare.
H5	Structural requirements	Outpatient appointments for LVAD patients cannot be completely avoided through telemonitoring.
H6	Structural requirements	Outpatient appointments for LVAD patients can be reduced through telemonitoring.
H7	Personnel requirements	Physicians, VAD coordinators and VAD nurses should all be involved in the running of a telemedicine center for LVAD patients.
H8	Personnel requirements	For telemonitoring of LVAD patients through a telemedicine center, additional staff must be hired.
H9	Personnel requirements	A telemedicine center does not have to be occupied 24/7 and can be covered by staff on call.
H10	Spatial requirements	A telemedicine center must be spatially connected to the implanting center.

Qualitative investigation is a sufficient tool for learning about user requirements (clinical experts; physicians, VAD coordinators or VAD nurses) when setting up a telemedicine center. The results achieved in this study gave rise to 10 hypotheses which could/should be taken into account when implementing telemedicine centers for LVAD patients in the future. The telemonitoring of LVAD patients seems to be particularly suited to close monitoring because the patients already have numerous sensors as a result of the implanted devices. This means that significantly more conclusive parameters can be generated than in the group of heart failure patients without such devices. The quality of aftercare should be elevated to a different level as a result. The early detection of potentially severe complications in the early stages should lead to a reduction in invasive treatments and as a consequence also to a reduction in treatment costs.

Nevertheless, there are still obstacles which must be overcome before telemedicine centers can be implemented. There are many issues of concern regarding the legal and ethical aspects of telemedicine (confidentiality and privacy). Finally, reimbursement for care provided using a telemedicine service still requires clarification.

Future studies are needed in order to demonstrate the extent to which the elaborated (still theoretical) requirements hold true in practice, and which aspects need additional attention.

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