A survey on requirements for safety and control concepts of artificial implantable lungs

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Abstract: There are endeavors for the development of an artificial implantable lung as a long-term lung support, even in an ambulatory setting. In the present work, we report on a survey with domain-experts on requirements for safety and automation concepts of an artificial (partially) implanted lung. The results of the study indicate that there are significant concerns regarding the safety, especially in the ambulatory setting. Further technological advances are necessary to prevent complications that currently occur and to reduce the required supervision to the most important parameters.

I. Introduction

Today the extracorporeal lung assist (ECLA) is used as an artificial lung for patients with acute respiratory distress syndrome (ARDS). While the present solutions allow for a short-term use, a long-term support is currently not feasible [1]. In the priority program SPP 2014 "Towards an Implantable Lung" by the German Research Foundation (DFG), several different projects address research towards the development of an implantable artificial lung as long-term support. While current lung support is performed in the intensive care unit, such an artificial lung will also be used outside of the intensive care unit and eventually even in an ambulatory setting. Therefore, an implantable artificial lung also requires completely revised safety and automation concepts. To determine the requirements for the development of these safety and automation concepts, we need expert experience and knowledge. In this paper we present a survey on the requirements for an artificial (partially) implanted lung sent to experts in the field known to the authors and discuss the results.

I.I. Current state of an artificial lung

Recent developments in ECLA systems and technical aspects result in broader indication, which are defined as "any potentially reversible condition in which the lungs are unable to ventilate and oxygenate despite the use of optimal mechanical ventilation and treatment" [2], emphasizing the wider spectrum of use (e.g. bridge to lung transplant, CO_2 removal) [3]. Today, in contrast to former settings, the target is a minimal sedated or awake, spontaneously breathing, mobilized patient with moderate or without anticoagulation, which implies increased survival rate and the opportunity of longer operation of ECLA therapy [3–5]. Even though ECLA therapy has become more effective, safer and easier in use and allows for longer therapy scopes due to many technical developments, it still remains a very complex system with the need for specific qualified personnel and highly frequent monitoring [6,2]. Nevertheless, there is only discontinuous clinical control and regulation of ECLA parameters [6]. Modern ECLA systems are able to continually measure blood flow, different system pressures, pre-oxygenator saturation, temperatures of blood and pump, hematocrit and amount of hemoglobin and can detect air bubbles, but there is no continuous self-regulation of blood flow or gas exchange [6]. Merely some automatic security functions can be activated in some systems. For reaching further goals of development like managing patients in standard care units or ambulant settings up to (partially) implantable lung assist systems, further technical and regulatory developments are necessary. An automatic regulation and model-based security concept would increase safety and enhance therapy success by continuously supervising and regulating ECLA therapy - in context of each mentioned setting in consideration of ventilation, hemodynamics and other parameters - to reach predefined target parameters at any time [6]. In the last years the lack of development in regulatory aspects of ECLA therapy comes more and more into focus of research. By now there are several approaches for self-regulatory ECLA like "SmartECLA" [7,8] or "AR-ECMO" [9] which were successful in animal testing but additional research and development is still necessary.

II. Material and methods

In the survey (conducted in German) on requirements for the development of safety and automation concepts of an (partially) implanted artificial lung we focused on two different settings. On one side the stationary setting where a patient is in the hospital, either in intensive care or general ward. On the other as an outpatient for multiple weeks or even month. The survey was structured into 5 parts. In each

part different questions addressed the stationary and ambulatory setting. The first part contained questions on the professional field and experience with ECLA for a better classification of the results. The next part consisted of adaption and control questions to determine how the system should adapt to the physiological needs of the patient. This included the capabilities of the adaption and its possible actions. In the third part of the survey the setting options of the system were addressed to determine how a caregiver should be able to adjust the system in different settings. In the ambulatory setting the question was, among others, if and how the patient should be allowed to adjust settings of the system. The fourth part contained questions on other related automated medical systems, which already include (partly) comparable concepts for automation, safety, and supervision. The final part of the survey dealt with the safety and supervision of the system and included questions about the measurements and alarms required. This included questions on the importance of different measurement values for an artificial lung, which measurements need to be recorded and displayed and which alarms are required for such a system. A central part of this section was the relevance of different complications that can occur for an artificial lung and whether other complications are to be expected.

III. Results and discussion

The survey was sent to experts in the field of intensive care including ECMO, as well as out of hospital emergency medicine known by name. For the survey we addressed 28 participants in total. The complete survey and anonymized results can be found in [10]. Due to space constraints, we will only highlight certain topics and discuss the overall results of the study. Most experts in the survey came from the field of anesthesia. The experience of the experts with ECMO ranged from 1 year to over 10 years with most experts having at least 5 years of ECMO experience. For the adaption of an artificial lung all experts agreed on the importance of the system's ability to adapt to the physiological needs of the patients even during changes in physical activity. In addition, the system needs to detect complications like cannula suction events or blood clots and adapt accordingly. For the setting options of an artificial lung a manual modus for the stationary setting was considered to be very important. In an ambulatory setting the patient should only be able to choose predefined profiles for different stress levels, like sleeping or sports. For the safety and supervision of an artificial lung, the experts were mostly in agreement that all presented measurements were at least "rather important", with greater uncertainty for the pump speed, heartrate and temperature of components. Furthermore, all listed complications were classified as very important. For all complications the experts considered alarms to be necessary. The results of the survey indicate that concerns regarding the safety of an artificial (partially) implanted lung are significant. This is further emphasized by the complexity of an ECLA. The survey findings indicate a consensus that monitoring and regulating all aspects of an artificial lung system is necessary. In particular, the high requirements for safety in the ambulatory setting are seen as very important. Further research will be required to reduce the number of monitored parameters without compromising patient safety. Moreover, there is uncertainty regarding the capabilities of new materials and technologies in addressing current challenges. For example, improved coatings to reduce anticoagulation requirements, new oxygenator designs to prevent thrombosis, and new cannulae technologies to prevent recirculation are crucial areas for future development. Therefore, there is a clear need for further research to overcome existing limitations and allow for the vision of a long-term artificial lung in the ambulatory setting.

IV. Conclusions

In this work, we conducted a survey on the requirements for safety and automation concepts of an artificial (partially) implanted lung. The participants of the survey were experts in the field of ECLA. The results of the survey show, that there are major concerns regarding the safety of an artificial lung, especially in the ambulatory setting. It became clear, that medical experts are accustomed to a multitude of parameters for the supervision of an ECLA in intensive care. This habit is transferred to the anticipation for an ambulant setting of an artificial lung. We conclude that further developments by research are necessary to obtain a concept regarding which parameters are relevant for a safe (partly) implantable lung and how to implement this concept in an ambulatory device.

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