

A Physiological Closed Loop System to Prevent Intradialytic Hypotensive Episodes

Dissertation

submitted to obtain the grade of
Doctor of Philosophy

submitted to the Faculty of Computer Science and Automation
Ilmenau University of Technology

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Submission date
2016-03-08

Rigorosum dates
non-public part: 2016-09-28
public part: 2016-09-28

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Bibliographic information published by the Deutsche Nationalbibliothek.

The Deutsche Nationalbibliothek lists this publication in the Deutsche Nationalbibliografie; detailed bibliographic data are available in the Internet at <http://dnb.d-nb.de>.

Atallah, Richard:

A Physiological Closed Loop System to Prevent Intradialytic Hypotensive Episodes

ISBN 978-3-86376-192-2

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1. Edition 2016

© Optimus Verlag, Göttingen

© Pictures: stockphoto-graf - Fotolia (*Frontcover*)

© Logo: TU Ilmenau

URL: www.optimus-verlag.de

Printed in Germany

Paper is FSC certified (wood-free, chlorine free and acid-free, and resistant to aging ANSI 3948 and ISO 9706)

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Acknowledgements

This work would not have been possible without the support of colleagues, for whom I would like to express my acknowledgments. I would like to express my gratitude to Prof. Dr. Jens Haueisen for his guidance and support, and for giving the possibility to repeatedly present my work in the field of the research seminar in the institute of Biomedical Engineering and for his appreciable feedback. I would like to thank B. Braun, which gave me the possibility to write my work in a very interesting live-saving field - Dialysis. Furthermore, I would like to acknowledge Dr. Christof Strohhofer, who accompanied me throughout this complete work, and for his valuable guidance on the scientific track. Not to be forgotten, I would like to express my acknowledgments to every single person at B. Braun and at TU-Ilmenau who contributed to perform this work, especially the in vivo and in vitro validation. Finally, I would like to warmly thank my father Gaby, my mother Agathe, my brothers Elie, Paul and Roland, and my wife Valentina for their support and their encouragement to finalise this work.

Abstract

Intradialytic hypotensive episodes are still the most frequent complications in dialysis treatments. One of the reasons that causes hypotensive episodes is the application of a non-adequate net fluid removal rate.

This work presents the development of a physiological closed loop system, which is applied during a dialysis treatment with the aim to prevent hypotensive episodes. This system is based on two physiological parameters that reflect a patient's cardiovascular condition: the systolic blood pressure and the relative blood volume. From the evaluation of these two parameters an adequate net fluid removal rate is calculated.

The physiological closed loop system is based on fuzzy logic and was developed modularly. It consists of one module each to monitor the short and long time trend of systolic blood pressure, and one module to monitor the relative blood volume. These modules evaluate the trend of their respective parameter and calculate a value that represents a patient's cardiovascular stability every five minutes. These three values are weighted and combined into a single value representing a patient's momentary cardiovascular stability. Based on this value and the withdrawn net fluid removal volume, the system calculates an adequate net fluid removal rate that is then applied to the patient for the next five minutes.

The physiological closed loop system was verified and validated using the knowledge of medical experts, a laboratory test setup and a clinical pilot study. All three evaluation methods showed that the closed loop system is able to stabilise a patient's cardiovascular condition, and therefore to prevent and reduce hypotensive episodes. The pilot study comprised 106 treatments on six patients and showed that 83 % of all patients had higher cardiovascular stability when using the developed physiological closed loop system than when using a constant net fluid removal rate.

A product based on the physiological closed loop system is currently under development and will be incorporated into dialysis machines.

Zusammenfassung

Intradialytische hypotensive Episoden bleiben weiterhin die häufigsten Komplikationen aller Dialysetherapien. Die Ursachen von hypotensiven Episoden sind multifaktoriell. Dazu gehört unter anderem das Applizieren einer nicht adäquaten Ultrafiltrationsrate.

Im Rahmen dieser Arbeit wurde ein für Dialysetherapien bestimmter physiologischer Regelkreis entwickelt, der hypotensive Episoden reduziert beziehungsweise verhindert. Der Regelkreis regelt zwei physiologische Parameter, die den physiologischen Zustand des Patienten während einer Dialysetherapie widerspiegeln. Diese zwei physiologischen Parameter sind der systolische Blutdruck und das relative Blutvolumen. Der Regelkreis evaluiert diese Parameter und stellt eine adäquate Ultrafiltrationsrate ein.

Der physiologische Regelkreis basiert auf einer Fuzzy Logik und wurde modular entwickelt. Der Regelkreis enthält je ein Modul zur Überwachung des Kurzzeit- und Langzeittrends des systolischen Blutdruckes, und zusätzlich noch ein Modul zur Überwachung der Veränderung des relativen Blutvolumens. Diese Module überwachen den Trend ihrer entsprechenden Parameter und berechnen alle fünf Minuten je eine Variable, die den aktuellen kardiovaskulären Zustand des Patienten widerspiegelt. Die drei berechneten Variablen werden in einer Gewichtungseinheit gewichtet und zu einem Wert kombiniert, der den aktuellen kardiovaskulären Zustand des Patienten wiedergibt. Diese kombinierte Variable wird mit dem zum aktuellen Zeitpunkt der Therapie entzogenen Ultrafiltrationsvolumen abgeglichen und für die Berechnung der Ultrafiltrationsrate für die nächsten fünf Minuten angewendet.

Der physiologische Regelkreis wurde mit Hilfe von medizinischen Experten, eines Laboraufbaus und einer Pilot-Studie verifiziert und validiert. Die aus 6 Patienten und 106 Therapien bestehende Pilotstudie zeigte, dass 83% aller Dialysepatienten einen besseren kardiovaskulären Zustand erreichten, wenn sie mit dem entwickelten physiologischen Regelkreis behandelt wurden, verglichen mit einer konstanten Ultrafiltrationsrate.

Ein auf dem physiologischen Regelkreis basiertes Produkt ist derzeit in Entwicklung und wird in Dialysemaschinen implementiert.

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