

Non-invasive Lung IMPEDANCE-Guided Preemptive Treatment in Chronic Heart Failure Patients: a Randomized Controlled Trial (IMPEDANCE-HF trial)

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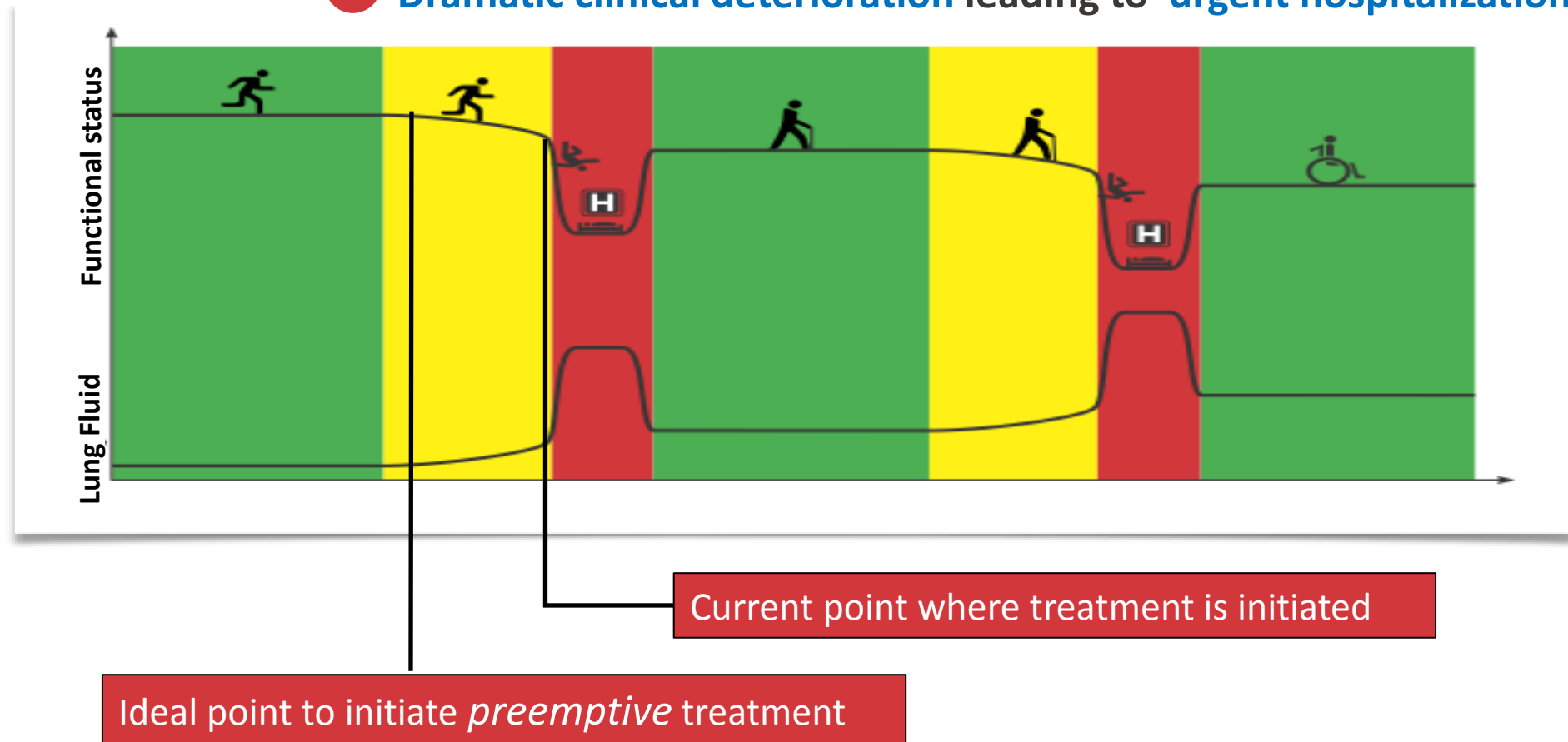
Presenter – Prof. Michael Kleiner Shochat

Conflict of interest: Michael Kleiner Shochat is a co-founder and member of the board of directors of the RSMM Company that manufactured and supplied the devices for the study

Process of Lung Fluid Accumulation

3 STAGES OF HEART FAILURE:

- **Stable stage:** No fluid accumulation in lung
- **Lung fluid accumulation** - without clinical signs
- **Dramatic clinical deterioration** leading to **urgent hospitalization**



The Solution: Edema Guard Monitor/EGM

The background of the slide features a blurred image of a hand holding a medical device. Overlaid on this is a large red heart and a white ECG line that passes through the heart.

Each year 20-25% of HF patients are being emergently hospitalized.

In the US alone: >1.1 Million hospitalization a year
Costing the healthcare system more than 40 billion \$

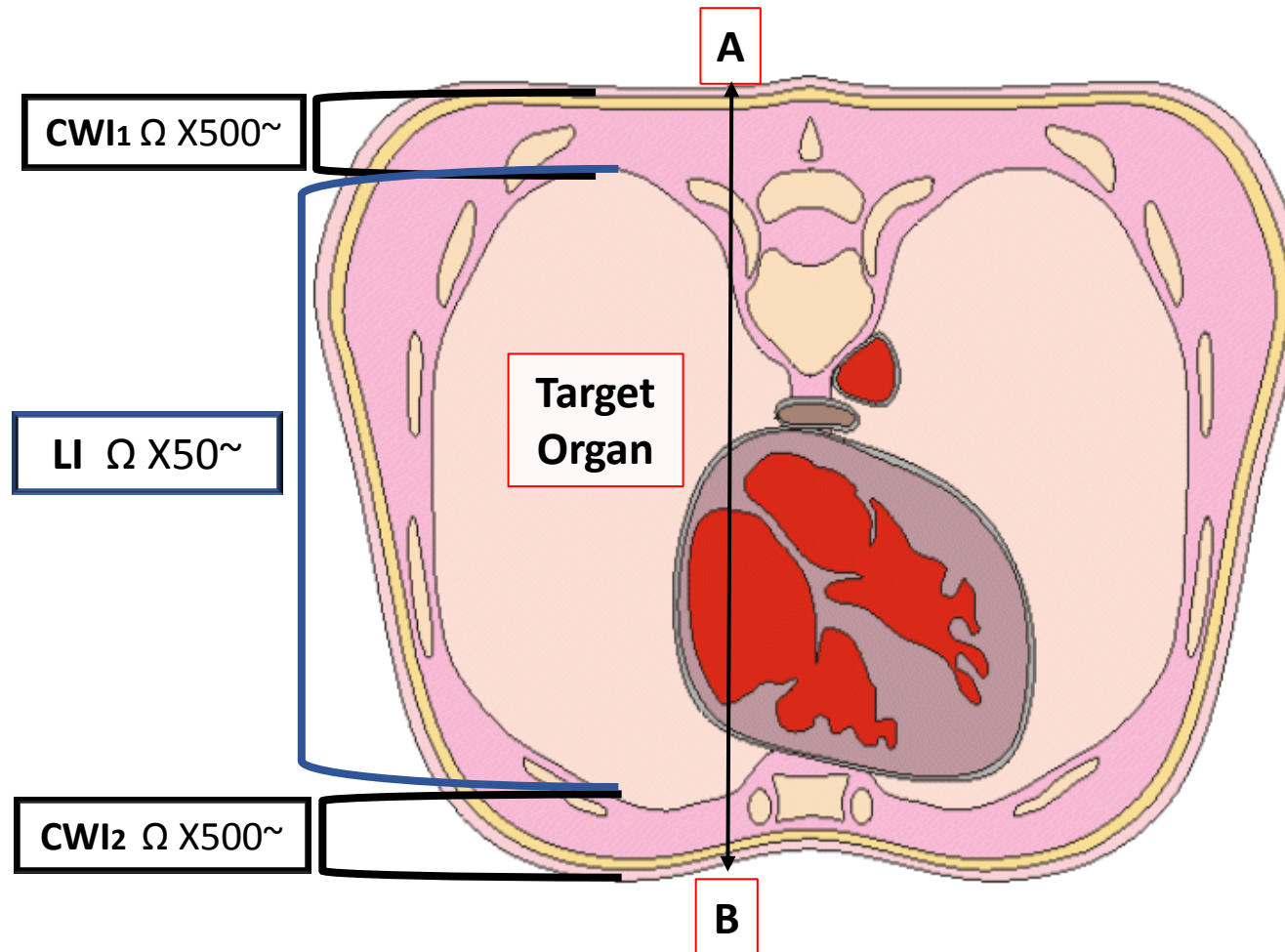
RSMM developed the EGM, a non-invasive device able to register very small changes in lung fluid content of NYHA class I-IV patients and prompt preemptive treatment at an early & critical stage

RS MEDICAL MONITORING Ltd.

The Technology

Transthoracic Impedance A-B (TTI_{AB}) = Chest Wall Impedance 1 + Lung Impedance + Chest Wall Impedance 2

CWI = "NOISE" Impedance



The Challenge:

Identifying small changes in the Lung Impedance as 1-3 Ω from the total TTI which is 1050 Ω

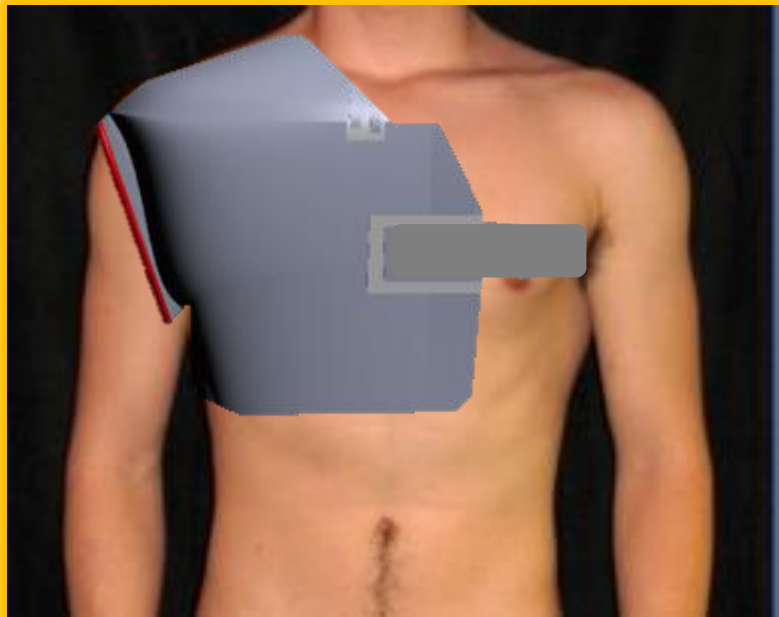
Impossible

The Solution:

RSM TECHNOLOGY helps to eliminate the NOISE Chest Wall Impedance (500 Ω +500 Ω) from TTI (1050 Ω), enabling to identify small changes in the Lung Impedance

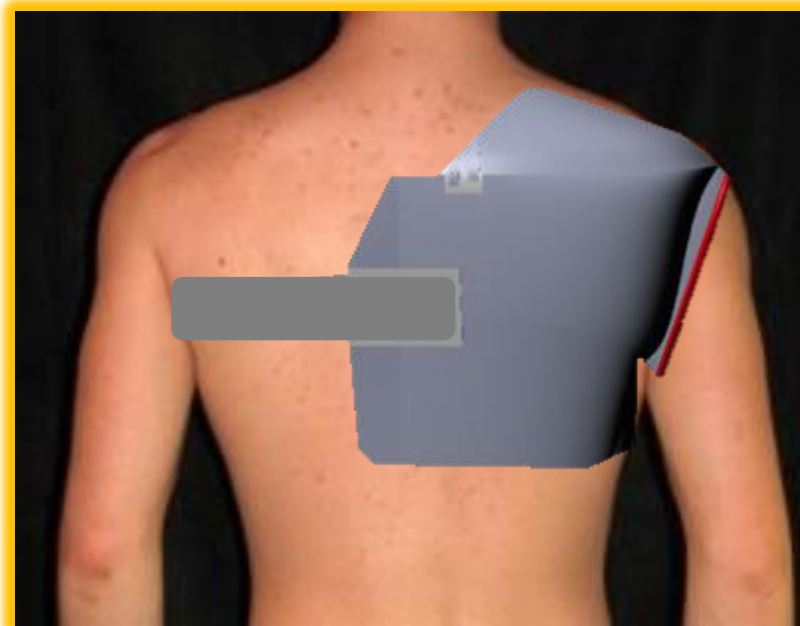
Possible

Measurement using the EGM Device



*Placing the vest with contact points
on the chest and back*

Measurement takes a few seconds



Comment: Vest still in concept phase

Publications and Events up to date

>1200
Patients!

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ORIGINAL ARTICLE
Congestive Heart Failure

A novel radio

acute heart fa

Michael Shochat¹,
Vladimir Gurovich²

¹Heart Institute and ²Ros
Wolfson Medical Center,

Background: Monitoring to
predict acute heart failure
(AHF) is an unmet clinical
Aim: To evaluate in AMI pa
tients the use of a novel ph
ysiological score (RS), which i
of congestion, to reflect o
physical examinations an
Methods: Chest X-rays we
detected, whenever indic
RS grading for LFC assess
RS = 2–4 for interstitial c
and 9–10 signified mild, a
respectively.

Results: 624 AMI patients
(94 ± 42 h), 476 patients i
not develop AHF. Overt AH
during monitoring: baseli
7.0 ± 0.8, and 9.8 ± 0.5 a
severe alveolar edema, re
RS decreased to 1.5 ± 1.3
examination ($r = 0.6$, $P <$
Conclusion: RS correlated
tion during AHF and clo

Keywords: Acute heart f
radiograph, lung imped

Introduction

Acute heart failure (AHF)
change or rapid onset in
manifesting mostly as a
result of accumulation o
space. AHF is a life-th
therapy (1). A fifth to a
myocardial infarction (A
fluid content (LFC) inc

Correspondence: Michael S
(Received 6 November 2010)

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DOI: 10.1007/s10877-014-9610-6

ORIGINAL RESEARCH



Intensive Care Med
DOI 10.1007/s00134-006-0237

Michael Shochat
Gideon Charach

Usefulness of Lung Impedance-Guided Pre-Emptive Therapy to Prevent Pulmonary Edema During ST-Elevation Myocardial Infarction and to Improve Long-Term Outcomes

S. Blondheim, MD*,
Ilia Shochat, BSc*,
Ilia R. Meisel, MD, MSc*

(STEMI) frequently
previously showed that
during admission for
alveolar edema and
study was to prove that
clinical outcomes. Five
tervent LI monitoring
not exceed 12% in 347
ed the threshold level
then randomized to
pre-emptive therapy. In
0.6%). In contrast,
of dyspnea occurring
All patients in group
IV PED ($p < 0.001$).
rate, 6-year mortality,
Multivariate analysis
creatinine kinase, and
outcome in group 3
ents with STEMI de
short- and long-term
(2012;110:190–196)

predicts evolution to PED.³ Likewise,
available impedance devices has shown
ly 8% to 13% during the asymptomatic
of evolving PED.^{4,5} However, im
available in the course of AMI,
invasive impedance devices are disad
sensitivity to detect small LI
ing the interstitial stage of PED. In
noninvasive device that is 50-fold more
sensitive. The aim of this study was to
pre-emptive therapy initiated at the
of evolving PED (Killip class I) in
stent elevation MI (STEMI) may pre
more advanced stages of PED (Killip
thus result in better outcomes.

center study included patients admit
unit for STEMI without signs of
admission, i.e., with no dyspnea, at
Killip class I with a normal chest x-ray, and without previ
ous heart failure. During hospitalization, repeated lung aus
cultations were done, and respiratory rate, heart rate, blood
pressure, and oxygen saturation were recorded every hour.

www.sciencedirect.com

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Israel

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doi:10.1016/j.amjcard.2005.10.005

Introduction

Early recognition and treat
edema might prevent its
methods can detect cardiac
when its clinical signs hav
capillary wedge pressure
for early detection of ca
but this is an invasive and

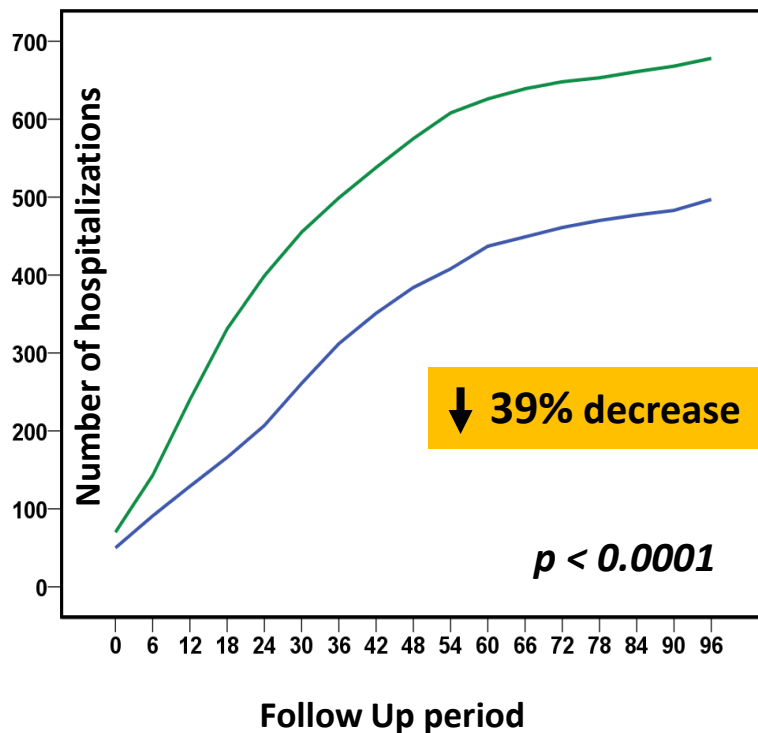
Dr. Shochat and Dr. Gurovich are members of the advisory board of
the RSMM Company, Tel Aviv, Israel.

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E-mail address: shochat1@yahoo.com (M. Shochat).

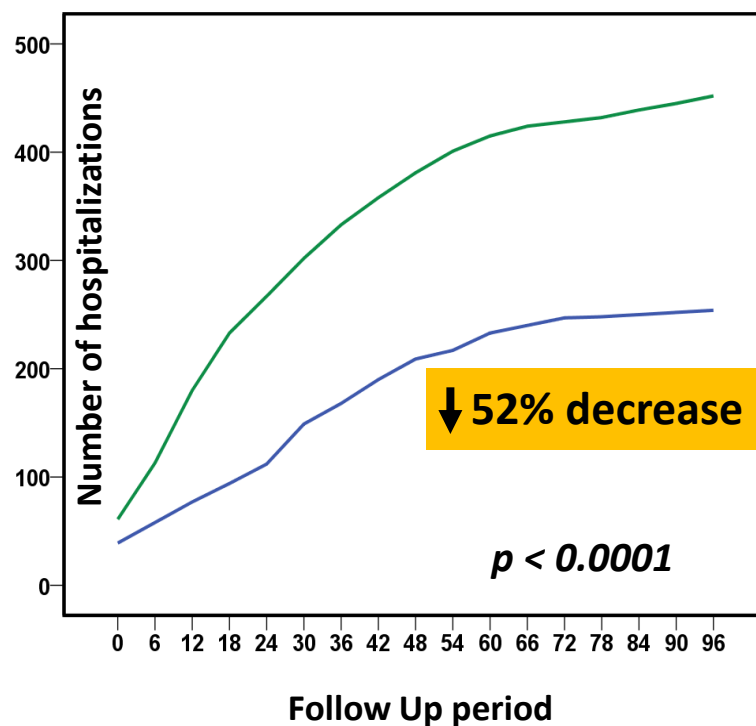
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doi:10.1016/j.amjcard.2012.03.009

Main Results from IMPEDANCE-HF trial

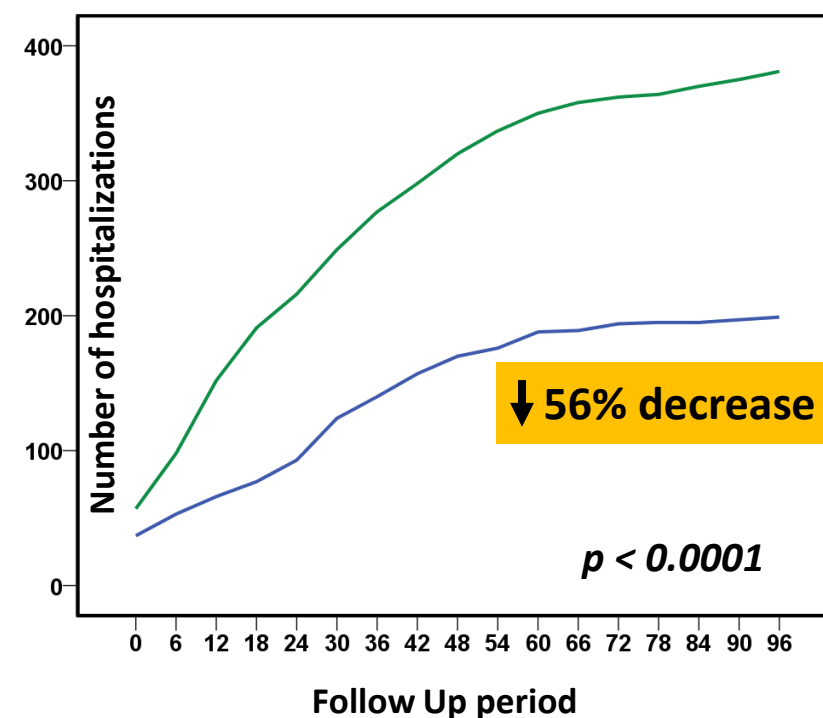
Hospitalizations by Cox regression analysis



All-cause Hospitalizations



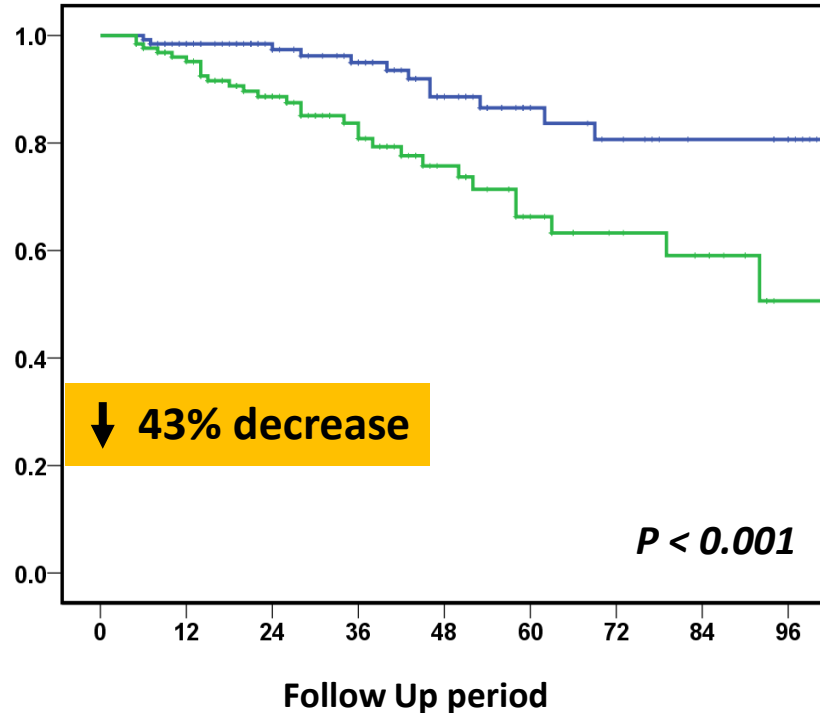
Cardiac Hospitalizations



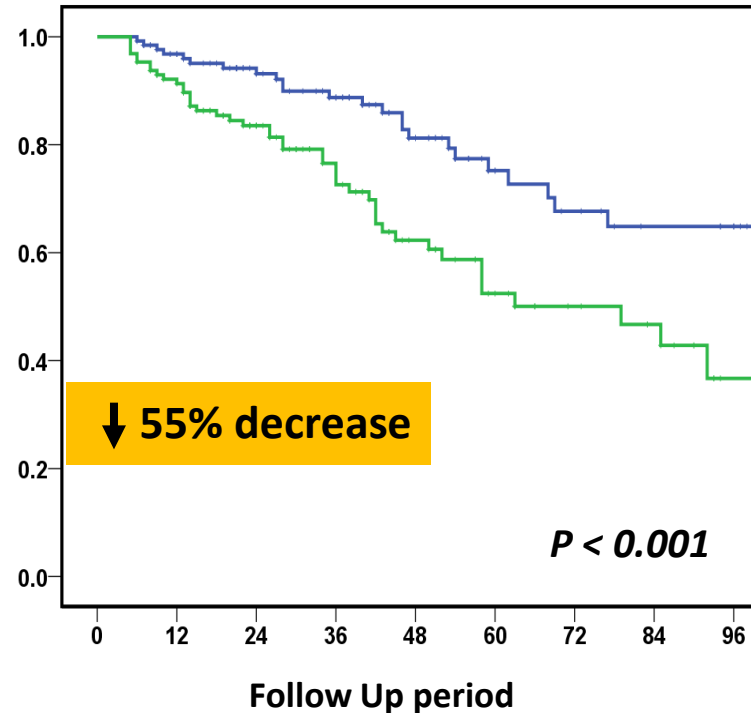
Heart Failure Hospitalizations

Main Results from IMPEDANCE-HF trial

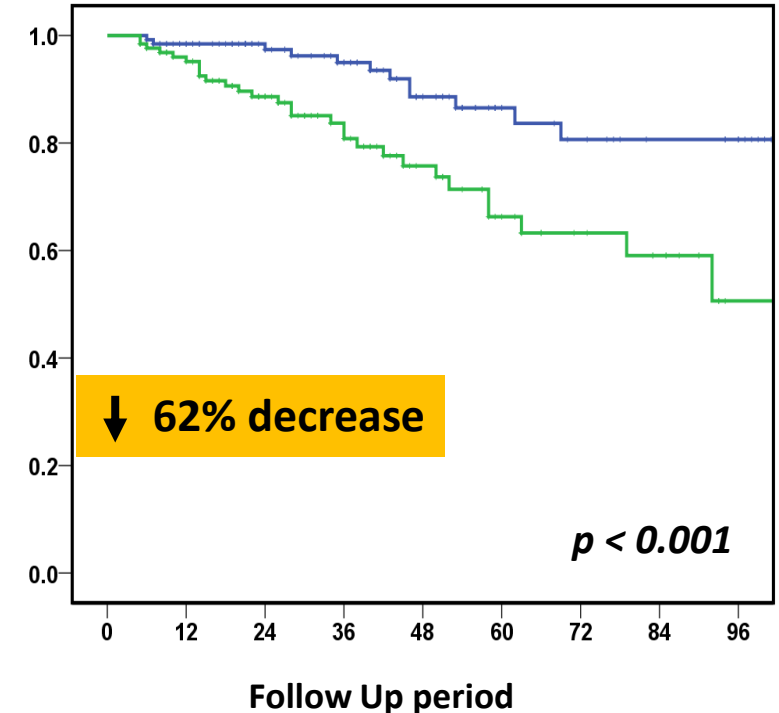
Mortality by Kaplan Meyer analysis



All-cause Death



Cardiac Death

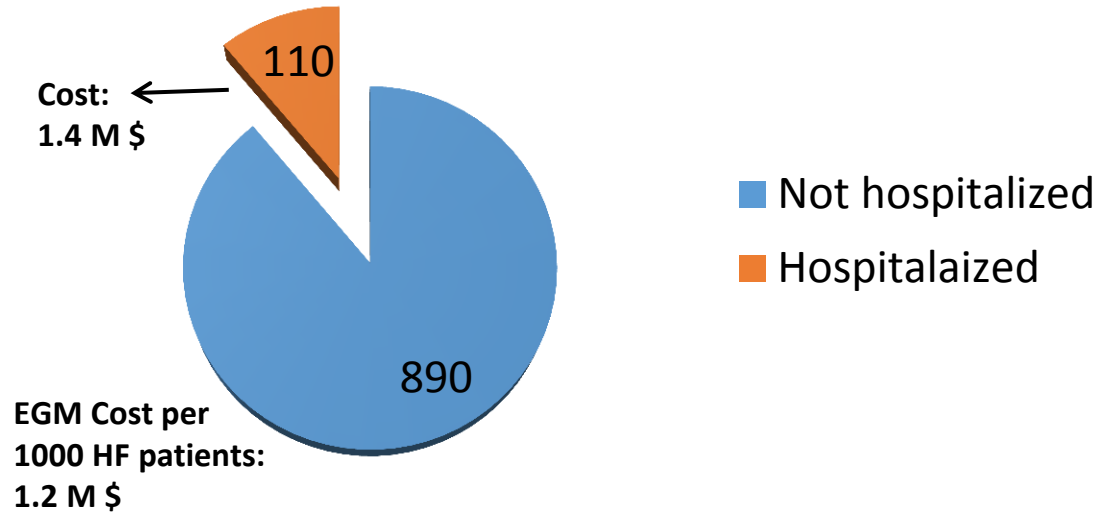


Heart Failure death

— Monitored group
— Control group

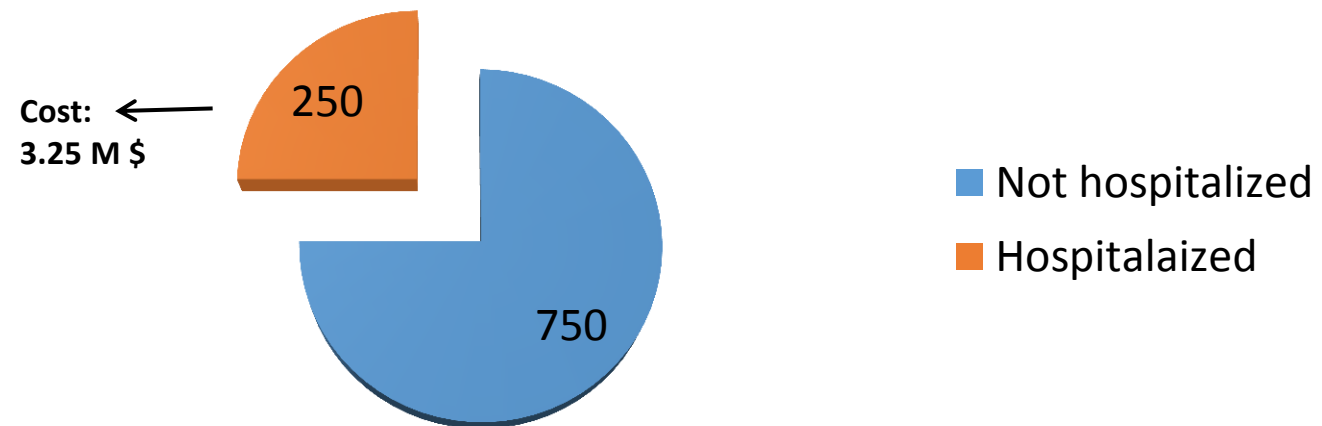
1000 Patients Model

EGM Use



Total expense: 2.6 M

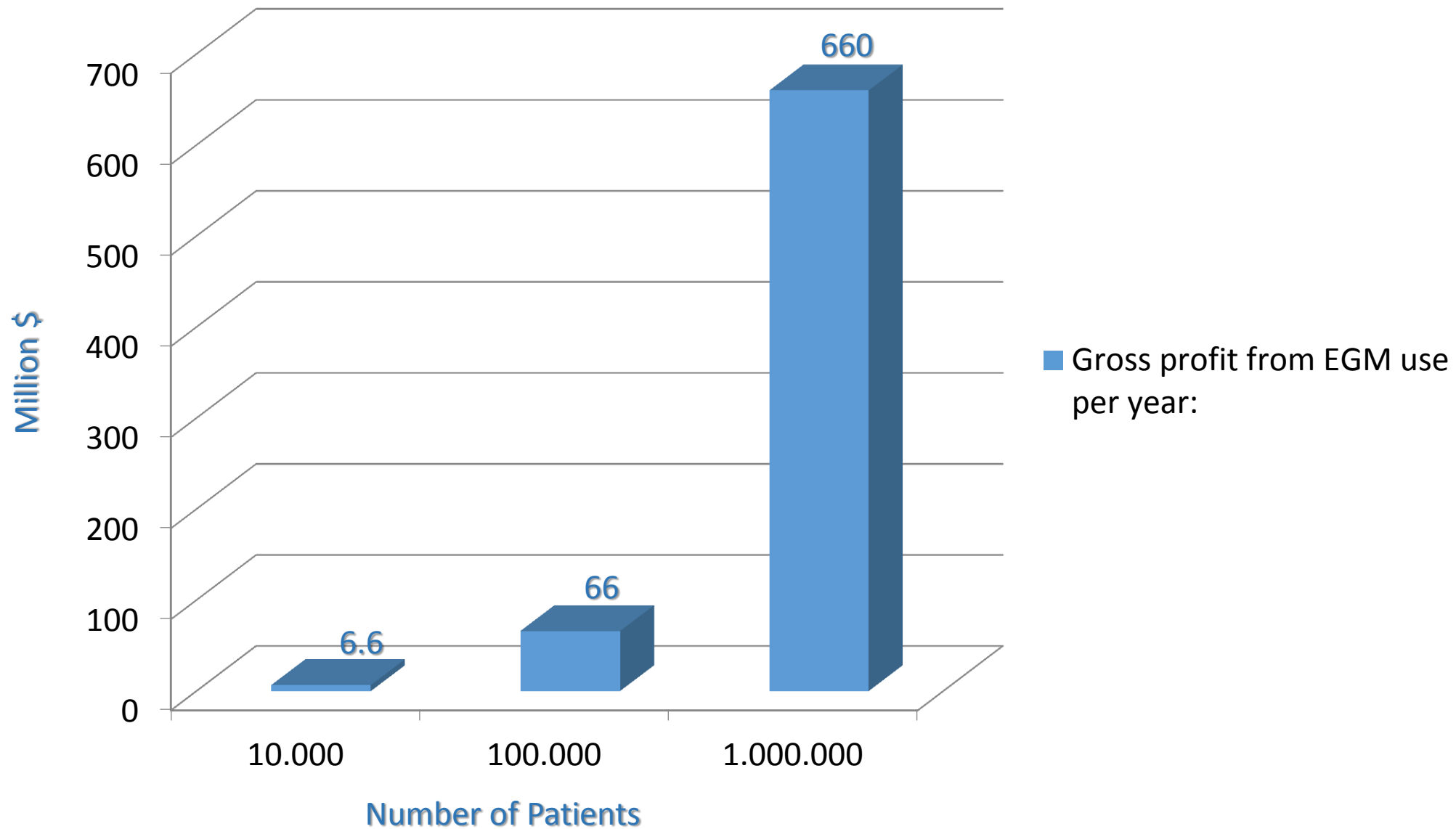
Current Status



Total expense: 3.25 M

$3.25 \text{ M \$} - 2.6 \text{ M \$} (1.4 + 1.2) = 0.66 \text{ M \$ Gross Profit}$

Gross Profit Potential



Summary

Study Conclusions: Treatment protocol using EGM will Decrease

- **Heart failure hospitalization by 56%**
- **Mortality from heart failure by 62%**
- **All cause of mortality by 43 %**

Data based on studies which include more than 1200 patients supports the following claims regarding use of EGM device :

- **Can considerably reduce risk of mortality and hospitalization**
- **Can considerably lighten the economic burden of the healthcare system**