From Evidence to Practice: CardioMEMS Implementation strategy in real-world practice

Sun Min Kim, DNP, FNP-BC, Geir Frivold, MD, FACC, Marriyam Moten, MD, FACC
VA Loma Linda Healthcare System, CA

Background

- ❑ Heart failure (HF) is global epidemic and complex clinical syndrome.
- ❑ Despite guideline-directed medical therapy (GDMT) and device therapy, HF mortality and morbidity remain a burden to patients, caregivers, and healthcare systems.
- ❑ New strategy, CardioMEMS HF system, implantable pulmonary artery pressure sensor monitoring technology recently received FDA approval for patients with NYHA HF functional class III who had been hospitalized related to HF at once within past 12 months, regardless of left ventricular ejection fraction (LVEF).

Objectives

The objectives of this presentation are:

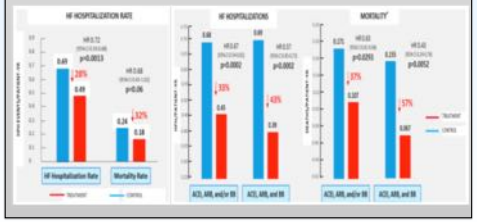
- ❑ To identify and critically evaluate the new evidence in HF management.
- ❑ To explore the implementation strategies of CardioMEMS HF system in real-world practice.
- ❑ To address how to sustain this new program in real clinical setting.

From Evidence to Practice

Evidence on CHAMPION Trial

- ❑ **Study Design:**
  - Prospective, multicenter, randomized, single -blind clinical trial.
- ❑ **Population**
  - HF NYHA III (HFrEF or HFpEF), 550 patients
  - At least a HF-related hospitalization within 12-months
- ❑ **Intervention**
  - Pulmonary Artery pressure monitoring system for HF management
- ❑ **Outcomes**

	Treatment (n=270)	Control (n=280)	Risk (95% CI)	p value
HF related hospitalization for 6 months	84	120	0.72	0.0002
HF related hospitalization during entire f/u (average 15 months)	158	254	0.63	<0.0001
Changes from baseline in PA mean pressure at 6 months (mmHg x days)	-156	33		0.008
Patients admitted to hospital for HF admission at 6 months	55 (20%)	80 (29%)	0.71 (0.53-0.96)	0.03
Days alive outside hospital at 6 months	174.4	172.1		0.02
Minnesota Living with HF questionnaire at 6 months	45	51		0.02



Evidence of CHAMPION

- ❑ Sub-group analysis
- ❑ Post Hoc analysis
- ❑ General Practice Use
  - Retrospective analysis of data
  - 2000 general- use patient group
  - Mean pulmonary artery pressure trends
  - Adherence to daily transmission

- ❑ **Cost Analysis**

- CardioMEMS reduced lifetime hospitalization (2.18 vs. 3.12)
- Increased quality-adjusted life-years (QALYs) (2.74 vs. 2.46)
- Increased costs ($176, 648 vs. $156,569)
- $71,462 per QALY gained and $48, 054 per life-year gained

5-year Costs and Outcomes	CardioMEMS	Standard of Care
Total costs	$188,880	$162,772
Implant: device, procedure, complications	$19,111	$0
Inpatient Costs	$108,124	$113,199
Outpatient Costs (including monitoring)	$61,645	$49,573
Total accumulated QALYs	2.509	1.926
Incremental cost-effectiveness ratio (cost per QALY gained)		**$44,482**

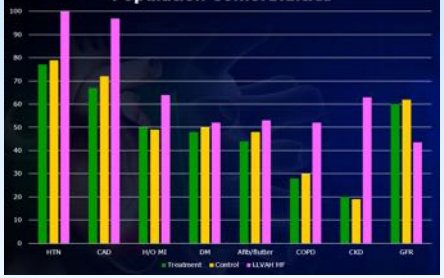
- The device is much less cost-effective if duration of effect is shorter.
- The values decrease in lower-risk patients.

Population Analysis

Baseline Demographic Characteristics

	Treatment (n=270)	Control (n=280)	LLVAH HF (n=87)
Age	61 (13)	62(13)	**68.7**
Male sex	194 (72%)	205 (73%)	**87 (100%)**
White	196 (73%)	205 (73%)	NA
Body-mass index (Kg/m2)	31 (7)	31 (7)	**36.2**
LVEF (≥ 40%)	62 (23%)	37 (20%)	15 (17%)
Ischemic cardiomyopathy	158 (59%)	174 (62%)	**62 (71%)**
CRT or CRT-D Device	91 (34%)	99 (35%)	**21 (24%)**
ICD only device	88 (33%)	98% (35%)	**26 (30%)**

Population Comorbidities



Conclusion/ Recommendation

Critical evaluation and synthesis of the new evidence, cost analysis, appropriate patient selection and compliance evaluation through population analysis are imperative strategies for successful implementation of new evidence to real-world practice setting and sustaining program in its facility.