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In partnership with:

Top Clinical Trials of 2018

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Blood-Pressure Reduction in Black Barbershops

Non-Hispanic black men

- Highest HTN-related death rate in the U.S.
- Less physician interaction with lower HTN treatment & control rates than black women, thus necessitating community outreach

Health outreach to barbershops

- Prior RCT: marginally lower BP when barbers checked BP and referred patrons with high readings to primary care, compared with when they distributed HTN pamphlets *

Victor RG et al,. Arch Intern Med, 2011; Rader F et al. , Am J Cardiol, 2013

Aim- to develop an effective intervention which links health promotion by barbers to drug therapy by pharmacists, and evaluate efficacy in a cluster RCT.

Randomized black male patrons with uncontrolled HTN by barbershop

Intervention Group

- Barbers promoted follow up w/ specialty-trained pharmacists.
- Pharmacists met patrons monthly at the barbershops:
  - Checked BP
  - Prescribed medications (collaborative practice)
  - Monitored electrolytes
  - Sent progress notes to PCPs

Control Group

- Barbers promoted:
  - follow up w/ PCPs
  - lifestyle modification

Primary Outcome:

$\underline{\Delta}$ systolic BP at 6 months

Intervention Group Medication Protocol

Goal: in-barbershop BP < 130/80 mmHg
= new 2017 ACC/AHA/ASH guidelines

Step 1. CCB *plus* ARB or ACEI
- amlodine *plus* irbesartan

Step 2. *add* thiazide-type diuretic
- indapamide

Step 3. *add* aldosterone antagonist
- spironolactone

Plasma electrolytes at the point of care

Primary Outcome: Systolic BP

	Intervention N = 132	**Control** N =171	**Intervention Effect**	
			Group Difference* (95% CI)	p-value*
Systolic BP, mmHg				
Baseline	152.8	154.6		
6-months	125.8	145.4		
Change	-27.0	-9.3	**-21.6** (-14.7 to -28.4)	<0.001

Secondary Outcome

BP goal attained at 6 months, n(%)	**Intervention**	**Control**	**RR** (95% CI)	**P value**
BP < 130/80	84 (**63.6 %**)	20 (**11.7%**)	**5.7** (2.5 to 12.8)	<0.001

BP Drugs at 6 Months

	Intervention, N = 132	**Control ,** N = 171		
# of BP Drug Classes/Pt			Mean Difference (95% CI)	p-value
Mean ± SD	2.6 ± 0.9	1.4± 1.4	**1.9** (1.3, 2.4)	<0.001

Conclusions

- Medication management delivered in barbershops by specialty-trained pharmacists, as compared with standard management by PCP, resulted in much larger BP reductions in patrons of those shops who had hypertension.
- Because hypertensive black men often have many CVD risk factors, marked reductions in BP—if sustained using our approach and then initiated widely—might reduce high HTN-related disability & death among black men in the US.

Vest Prevention of **E**arly **S**udden Death **T**rial (VEST)

Background: Guideline recommendations

JACC
JOURNAL OF THE AMERICAN COLLEGE OF CARDIOLOGY

Al-Khatib SM, et al.
2017 VA/SCD Guidelines

6.1.2. Primary Prevention of SCD in Patients with Ischemic Heart Disease

Recommendations for Primary Prevention of SCD in Patients With Ischemic Heart Disease		
COR	**LOE**	**Recommendations**
I	A	1. In patients with LVEF of 35% or less that is due to ischemic heart disease who are at least 40 days post-MI and at least 90 days post revascularization, and with NYHA class II or III HF despite GDMT, an ICD is recommended if meaningful survival of greater than 1 year is expected (1,2).

2017 ACC/AHA/HRS Guideline for Management of Patients With Ventricular Arrhythmias. JACC 2017

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VEST & VEST REGISTRY

Methods: Study design

- **Multi-center, randomized, open-label trial**
- **Participants enrolled within 7 days of hospital d/c with acute MI and EF≤35%**
- **Randomized 2:1 to receive:**
  - Wearable cardioverter defibrillator (WCD) + guideline-directed therapy **or**
  - Guideline-directed medical therapy alone
- **MD's & sites blinded to detected arrhythmias**
- **Crossovers & ICDs prohibited (except for secondary prevention during follow-up)**

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Methods: Outcomes

- **Follow-up at 1 month & 3 months**
- **Search NDI at end of study**
- **Primary Outcome: SCD & death due to ventricular arrhythmias**
- **Secondary outcomes**
  - Total mortality & Non-sudden death
  - Cause-specific death
  - Non-fatal outcomes
    - CV Hospitalizations
    - WCD compliance
    - Adverse events

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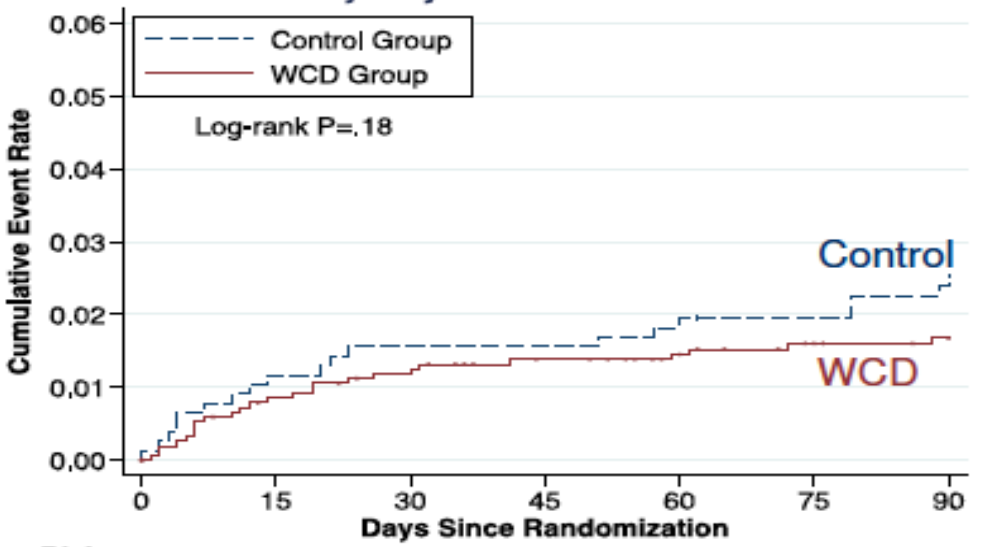
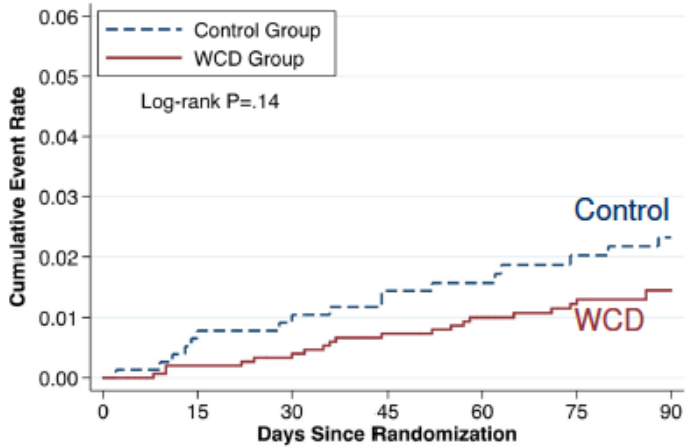
Results: Outcomes, intention-to-treat

A Sudden + Ventricular Tachyarrhythmia Death



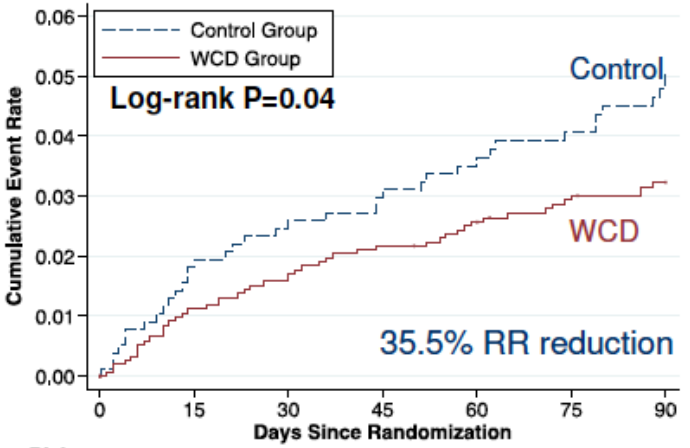
No. at Risk							
Control Group	778	759	754	746	742	657	650
WCD Group	1524	1502	1495	1486	1479	1314	1309

B Non-sudden Death



No. at Risk							
Control Group	778	759	754	746	742	657	650
WCD Group	1524	1502	1495	1486	1479	1314	1309

C Death from Any Cause



No. at Risk							
Control Group	778	759	754	746	742	657	650
WCD Group	1524	1502	1495	1486	1479	1314	1309

Conclusions

- **The WCD did not statistically significantly reduce sudden death mortality**
- **The WCD did reduce total mortality in the first 90 days post-MI in patients with LVEF ≤35%**
  - Relative risk reduction of 35.5%
- **VEST represents the first randomized, controlled trial of the WCD**
- **Prescribing the WCD is reasonable to protect high-risk patients with a low LVEF post-MI until evaluation for an ICD at 40-90 days**

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