Longer Term Results from a Phase I/II Study of EP-guided Noninvasive Cardiac Radioablation for Treatment of Ventricular Tachycardia (ENCORE-VT)

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Disclosures for Dr. Robinson

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- **Speaking:** Varian, ViewRay

- Results discussed here involve off-label use of linear accelerators outside of their current 510(k) intended use

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Background

**TOP TWO KILLERS**

*By AMERICAN HEART ASSOCIATION NEWS*

The total number of Americans dying from heart disease rose in recent years following decades in decline. Cancer deaths have nearly tripled since 1950 and continue to climb.

- **Heart disease**
  - 2014: 614,346
  - 2011: 596,577
  - 2001: 516,740
- **Cancer**
  - 2014: 581,680
  - 2011: 578,551
  - 2001: 556,577

Source: Centers for Disease Control and Prevention

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- **Implantable Cardiac Defibrillator (ICD)**
- **Medications (Amiodarone)**
- **Catheter Ablation**
5 patients with refractory VT treated off-label for clinical need in 2015
Single SBRT treatment, 25 Gy
Average treatment time 14 min

3 month pre treatment = 6577
6 week blanking = 680
Next 10.5 months = 4
Phase I/II Trial – “ENCORE-VT”

• **Inclusion**
  • ≥3 VT episodes over 6 months
  • Failed medication
  • Failed (or too sick for) at least one catheter ablation

• **Phase I - Safety**
  • Serious toxicity in first 90 days

• **Phase II – Efficacy**
  • Any reduction in VT, 6 months before vs after

• **19 patients** - 90% Male and Caucasian

• **Significant cardiac impairment** – Average heart function (EF) less than half of normal

• **High burden of VT** – 53% presented in “storm”

• **Heavily medicated** – 58% on 2+ drugs and >300 mg of amiodarone

• **Average treatment time** - 15 min as outpatient
Phase I – Safety

Serious adverse events, probably or definitely related to SBRT

<90 days
• Grade 3
  • 1 pericarditis (80d)

>90 days
• Grade 3
  • 2 pericardial effusions (2.2y and 2.4y)
• Grade 4
  • 1 gastropericardial fistula (2.4y)

Median follow-up, 23.5 mo (range, 0.6-36.1)
Phase II – Primary Efficacy Endpoint (n=18)

94% of patients met primary endpoint

VT episodes
Phase II – Efficacy over time

78% of patients continued to meet primary endpoint

VT episodes

0 50 100 150

Deceased

2019 AMERICAN SOCIETY FOR (ASTRO) ANNUAL MEETING
Medications and QoL

Nine quality of life (SF-36) modules:
- 5 improved
- 4 maintained
- 0 worsened

N=14
Conclusion

We were able to **significantly reduce VT** using a workflow combining **noninvasive** imaging with a single noninvasive radiation therapy treatment.

The **effect persisted for 2 years** in most patients.

**Serious toxicity was low, but may occur after 2 years.** Long term follow-up is needed.

ENCORE is currently **best suited for high-risk patients** who have failed conventional treatments for VT, and ideally on study.