# WHY THE RCTs COMPARING EVAR & OPEN REPAIR FOR RAAAs ARE MISLEADING & NOT GENERALLY APPLICABLE

## EVAR IS BEST IF IT CAN BE DONE

---

FRANK J. VEITH

LINC - 2019

LEIPZIG – JANUARY 25, 2019

# I HAVE NO FINANCIAL CONFLICTS

# ENDOVASCULAR TOOLS IN THE MANAGEMENT OF RAAAs

CONCEPT WE HAD SINCE WE DID FIRST US REVAR IN 1992

# OUR & OTHERS' RESULTS SUGGEST THAT EVAR IMPROVES Rx OUTCOMES FOR RAAAs

VEITH, ET AL, ANN SURG 2009

# HOWEVER

# MANY SAY THESE GOOD RESULTS ARE DUE TO CASE SELECTION

AND

SOME GROUPS HAVE HAD POOR RESULTS WITH EVAR FOR RAAAs

# 4 CONTROLLED STUDIES SHOWED EVAR NO BETTER THAN OPEN REPAIR

- PEPPELENBOSCH, BUTH, ET AL
  J VASC SURG 43:1111, 2006
- HINCHLIFFE, ET AL.
  EJVES 32:506, 2006
- CHO – U PITTSBURG – JVS 2012
- GUNNARSSON, ET AL. SWEDISH
  REGISTRY DATA – EJVES 2015

# FAIR TO SAY EVAR FOR RUPT AAAs

- REMAINS CONTROVERSIAL

  - SOME STILL SAY WE **NEED A RCT OF EVAR vs OR**

# AND THE RESULTS OF

## 3 RCTs OF EVAR vs OR FOR RAAAs

## HAVE BEEN PUBLISHED & WIDELY PRESENTED

# THESE RECENT RCTs ARE:

ECAR - FRENCH

AJAX – DUTCH

****IMPROVE** - UK**

ALL 3 RCTs CLAIMED NO DIFFERENCE IN 30-DAY MORT BETW EVAR & OPEN REPAIR

HOWEVER

THAT CONCLUSION OF ALL 3 RCTS IS MISLEADING!

# HERE IS WHY

# ECAR & AJAX RC TRIALS

BOTH SMALL TRIALS (116 & 107 PTS)

BOTH EXCLUDED HIGH RISK PTS IN SHOCK & TOO SICK FOR OR

i.e. THOSE PTS MOST LIKELY TO BENEFIT FROM EVAR &

BOTH DID NOT USE OPTIMALLY 3 ADJUNCTS FOR IMPROVING EVAR…

HYPO HEMO, AO BALLOON, ACS Rx

THUS BOTH ARE MISLEADING

# IMPROVE TRIAL

LARGE MULTICENTER RCT - CAREFULLY DONE

30-D, 1 & 3-YEAR RESULTS PUBLISHED

Its main conclusion was that:

"A strategy of endovascular repair was not associated with significant reduction in 30 day, 1 or 3-year mortality"

THIS CONCLUSION WAS…

# IMPROVE TRIAL

**THIS CONCLUSION WAS WIDELY QUOTED ON INTERNET & IN VASCULAR NEWS AS SHOWING:**

**"NO DIFFERENCE BETWEEN ENDOVASC & OPEN REPAIR" !!!**

vascularNEWS
INTERNATIONAL
Issue 61 January 2014

Piergiorgio Cao:
Hybrid arch rep[illegible]
Page 14

Juan Parodi:
Renal denervation
Page 16

Andrew Holden:
Profile
Page 22

IM[illegible]PROVE TRIAL 30-DAY RESULTS

# No difference between endovascular and open repair for ruptured aneurysms

**Thirty-[illegible] mortality results from the IMPROVE trial show [illegible] difference between an endovascular strategy and ope[illegible]air in the treatment of ruptured abdominal aort[illegible]rysms. In the study, the endovascular strategy arm had an [illegible] mortality rate of 35% against 37% in the open repair arm. The results also indicate that open repair patients seen out-of-hours had higher mortality than those seen in-hours, blood pressure control has an important role on outcomes, and EVAR shows better results when patients are treated under local anaesthesia**

arm, if they were not suitable, they would have open repair as part of the protocol. "We also anticipated that som[illegible] [illegible] end up with a final diagnosis that was not aneurysm related," said Powell.

**The trial team—Powell, Pinar Ulug, Rob Hinchliffe, Michael Sweeting, Manuel Gomes, Matt Thompson and Roger Greenhalgh—present-**

went urgent CT s[illegible]nd had EVAR if t[illegible]odality was [illegible]e; if not, they had open repair. In the open repair arm, CT scan was optional. A CT scan was performed in 97% of patients in the endovascular strategy group and 90% in the open repair group.

The baseline characteristics were similar for both groups. When comparing the endovascular strategy with the

**HERE IS WHY THIS CONCLUSION IS MISLEADING & WRONG**

# IMPROVE TRIAL

RDMIZD **316** PTS TO ENDOVASC STRATEGY & **297** TO OPEN REPAIR

## 30-DAY MORTALITY

EV STRAT GROUP – **35%**

OPEN REP GROUP - **37%**

NO SIGNIFICANT DIFFERENCE

**BUT MUST SEE DETAILS !!!**

# IN IMPROVE

OF 316 PTS RANDOMIZED TO ENDOVASCULAR STRATEGY ONLY

154 HAD EVAR - LESS THAN HALF !!!

112 HAD OR; 17 NO Rx

OF 297 RANDOMIZED TO OPEN REPAIR

220 HAD OPEN REPAIR - BUT

36 HAD EVAR; 19 NO Rx

# IMPROVE DETAILED RESULTS

OF PTS RANDOMIZED TO
ENDOVASCULAR STRATEGY

154 HAD EVAR: Mortality – 27%

112 HAD OP REP: Mortality – 38%

OF PTS RANDOMIZED TO OPEN REPAIR

36 HAD EVAR: MORTALITY 22%

220 HAD OP REPAIR: MORTALITY 37%

# WHEN THE 2 GROUPS WERE COMBINED

MORTALITY OF ALL PTS

TREATED BY EVAR = 25%

MORTALITY OF ALL PTS

TREATED BY OPN REP = 38%

MORT OF PTS RxD BY OR+NO Rx = 44%

OPEN REPAIR PTS MORE LIKELY TO GET NO Rx

WHICH Rx DO YOU THINK IS BETTER?

EVAR OR OPEN REPAIR ?

TO ME IT SEEMS THAT THE

IMPROVE TRIAL

CLEARLY SHOWS THAT EVAR IS THE BETTER TREATMENT FOR RAAA PATIENTS

- IF IT CAN BE DONE

THIS CONCLUSION IS STRONGLY SUPPORTED BY THIS - ANN SURG ART (256:688-695, 2012)

BY DIETER MAYER, THOMAS LARZON, MARIO LACHAT, FRANK VEITH, ET AL

---

DESCRIBED A 2 CENTER STUDY IN SWEDEN & ZURICH

100% OF 70 RAAAs WERE TREATED BY EVAR – ALTHOUGH 24% REQUIRED A CHIMNEY OR PERISCOPE GRAFT, ETC

# THIS 100% EVAR STUDY

ANN SURG 2012

SHOWED

ONLY 24% 30-DAY MORTALITY !

ONLY 4% TURN-DOWN RATE (vs 20-30+%)

SO THIS STUDY'S RESULTS

SUPPORTS SAME CONCLUSION

EVAR SUPERIOR TO OP RPR

FOR RAAAs - IF IT CAN BE DONE

# FINALLY THE LATE RESULTS FROM THE IMPROVE TRIAL ARE SHOWING

- EVAR HAS BETTER LONG-TERM SURVIVAL THAN OPEN REPAIR
- EVAR HAS BETTER QUAL OF LIFE, SHORTER LENGTH OF STAY & BETTER SURVIVAL IN WOMEN THAN OPEN REPAIR

# CONCLUSION I

ALL EVIDENCE & OPINION
NOW SHOW
EVAR IS THE BEST WAY TO
TREAT RUPTURED AAAS
IF EVAR CAN BE DONE

# CONCLUSION II

RCTs (LEVEL 1 EVIDENCE)
ARE NOT ALWAYS
THE INFALLIBLE
HOLY GRAIL THEY ARE
CRACKED UP TO BE

THANK YOU

# WHY THE RCTs COMPARING EVAR & OPEN REPAIR FOR RAAAs ARE MISLEADING & NOT GENERALLY APPLICABLE

EVAR IS BEST IF IT CAN BE DONE

---

FRANK J. VEITH

LINC - 2019

LEIPZIG – JANUARY 25, 2019