EVALUATION OF THE 3 RCTs (RANDOMIZED CONTLD TRIALS) COMPARING EVAR TO OPEN REPAIR FOR RUPTURED AAAs
EVAR IS STILL THE BEST Rx

FRANK J. VEITH
CX AT LINC - 2015

LEIPZIG – JANUARY 29, 2015
FRANK J. VEITH
I HAVE NO FINANCIAL CONFLICTS
BUT I HAVE LOTS OF BIASES
ENDOVASCULAR TOOLS IN THE MANAGEMENT OF RAAAs CONCEPT WE HAD SINCE WE DID FIRST US EVAR IN 1992
OUR & OTHERS’ RESULTS SUGGEST THAT EVAR IMPROVES Rx OUTCOMES FOR RAAAs

VEITH, ET AL, ANN SURG 2009
HOWEVER
SOME GROUPS HAVE HAD POOR RESULTS WITH EVAR FOR RAAAs
3 CONTROLLED STUDIES SHOWED EVAR NO BETTER THAN OPEN REPAIR

- PEPPELENBOSCH, BUTH ET AL
  J VASC SURG 43:1111, 2006
- HINCHLIFE, ET AL
  EUR J VASC ENDOV SURG 32:506, 2006
- CHO – U PITTSBURG – JVS 2012
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 RAAAAs HAVE RECENTLY BEEN PUBLISHED OR 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

ALL 3 RCTS ARE FLAWED & 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 BALOON, ACS Rx

THUS FLAWED & MISLEADING
The main conclusion of the IMPROVE TRIAL was that:

“...A strategy of endovascular repair was not associated with significant reduction in 30 day mortality...”
IMPROVE TRIAL

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

“NO DIFFERENCE BETWEEN ENDOVASC & OPEN REPAIR” !!!
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 !!!
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%
IMPROVE DETAILED RESULTS

ALL EVAR MORTALITY = 25%

ALL OP RP MORTALITY = 38%

ALL OR+NO Rx MORTALITY = 44%

OPEN REPAIR PTS MORE LIKELY TO GET NO Rx

WHICH Rx DO YOU THINK IS BETTER?

EVAR OR OPEN REPAIR?
I BELIEVE 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 RAAs were treated by EVAR – although 24% required a chimney or periscope graft.
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 THE CONCLUSION
EVAR SUPERIOR TO OP RPR FOR RAAAs - IF IT CAN BE DONE
THANK YOU
DISCUSSION