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

- 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
Its main conclusion was that: “A strategy of endovascular repair was not associated with significant reduction in 30 day, 1 or 3-year mortality”
IMPROVE TRIAL

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

“NO DIFFERENCE BETWEEN ENDOVASC & OPEN REPAIR” !!!
IMPROVE TRIAL 30-DAY RESULTS

No difference between endovascular and open repair for ruptured aneurysms

Thirty-day mortality results from the IMPROVE trial show no difference between an endovascular strategy and open repair in the treatment of ruptured abdominal aortic aneurysms. In the study, the endovascular strategy arm had an overall 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 some of our patients would 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 Greenhalf—presented urgent CT scans and had EVAR if the modality was suitable, 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 Rx'D 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
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