

**LESSONS I HAVE  
LEARNED FROM  
RCTs ON RAAA  
MANAGEMENT**

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**MEET - 2015**

**NICE – JUNE 9, 2015**

**I HAVE NO  
FINANCIAL CONFLICTS  
ALTHOUGH I HAVE  
LOTS OF **BIASES****

# MY CONCLUSION

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IMPROVE & OTHER RECENT  
RCTs COMPARING EVAR TO  
OPEN REPAIR FOR RAAAs ARE  
MISLEADING

EVAR IS STILL THE BEST Rx FOR  
RAAAs IF IT CAN BE DONE

NOW I HAVE TO TELL YOU WHY

**ENDO VASCULAR  
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**

**MANY SAY THESE GOOD  
RESULTS ARE DUE TO  
CASE SELECTION**

**AND**

**SOME GROUPS  
HAVE HAD POOR  
RESULTS WITH  
EVAR FOR RAAAs**

# **3 CONTROLLED STUDIES SHOWED EVAR NO BETTER THAN OPEN REPAIR**

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- **PEPPELENBOSCH, BUTH ET AL  
J VASC SURG 43:1111, 2006**
- **HINCHLIFFE, ET AL  
EUR J VASC ENDOV SURG  
32:506, 2006**
- **CHO – U PITTSBURG – JVS 2012**



# **FAIR TO SAY EVAR FOR RUPT AAAs**

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- **REMAINS CONTROVERSIAL**

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

**AND THE RESULTS OF**

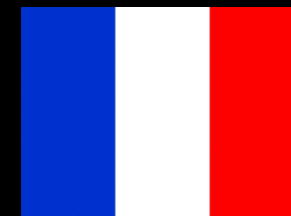
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**3 RCTs OF EVAR vs OR  
FOR RAAAs**

**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**

**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



CAREFULLY

LARGE MULTICENTER RCT - DONE

30-DAY RESULTS IN BMJ - JAN 2014

**Its main conclusion was that:**

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

**THIS CONCLUSION WAS...**

# IMPROVE TRIAL



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

**“NO DIFFERENCE BETWEEN  
ENDOASC & OPEN REPAIR” !!!**



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

# IMPROVE TRIAL



RDMIZD **316** PTS TO ENDOASC  
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  
ENDOASCULAR 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

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## 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**

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**DESCRIBED A 2 CENTER STUDY  
IN SWEDEN & ZURICH  
100% OF 70 RAAAs WERE  
TREATED BY EVAR – ALTHOUGH  
24% REQUIRED A CHIMNEY  
OR PERISCOPE GRAFT**

# **THIS 100% EVAR STUDY**

**ANN SURG 2012**

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**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**



**IMPROVE: 1 YEAR RESULTS**

**European Heart Jour, April 2015**

**doi:10.1093/eurheartj/ehv125**

**AJAX: Ann Surg 2013;258:248-56**

**Reimerink JJ, et al**

**ECAR: Eur J Vasc Endovasc Surg**

**2015 May 20: S1078-5884:doi: 10.**

**1016/j Desgrange P, et al**