

**DOES EVAR SUITABILITY
IMPACT OUTCOMES OF
AAA & RAAA REPAIR ?**

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**CRITICAL ISSUES IN AORTIC
ENDOGRAFTING - 2012**

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**DOES EVAR SUITABILITY
IMPACT OUTCOMES OF
AAA & RAAA REPAIR ?**

SHORT ANSWER

YES – WHY?

**BECAUSE EVAR HAS BETTER
OUTCOMES THAN OPEN REPAIR
(OR)–IF PT HAS SUITABLE ANAT**

EVAR BETTER THAN OR

**THE PROBLEM IS THE
LEVEL 1 EVIDENCE
DOEN'T SHOW IT**

**FOR ELECTIVE AAAs - IN FIT &
UNFIT PTS - EVAR 1 & 2 TRIALS
FOR RAAAs - NO RC TRIALS**

SO WHAT I HAVE TO DO

- SHOW THE FLAWS IN
EVAR 1 & EVAR 2
- SHOW HOW EVAR IS
BETTER THAN OR
FOR RAAAs

**BUT
EVAR 1 & 2 ARE
LEVEL 1 EVIDENCE**

RCTs - LEVEL I EVIDENCE (THE HOLY GRAIL)

SHOW : NOT ALWAYS SO HOLY

**NOT ABSOLUTE
INVIOULATE OR
TIMELESS**

**BECAUSE RCTs CAN HAVE
FLAWS & WEAKNESSES
DUE TO PROBLEMS WITH:**

- 1. TIMELINESS – APPLICABILITY
TO PRESENT STATE OF ART**
- 2. DESIGN FLAWS IN RCTs**
- 3. MISINTERPRETATION BY
AUTHORS & OTHERS**

SO

LET US CONSIDER

EVAR FOR ELECTIVE

AAA REPAIR

&

RC EVAR TRIALS

EVAR TRIALS

EV 1 & DREAM - GOOD RISK PTS

AAAs >5.5 CM

OPEN VS. ENDO REPAIR

EV 2 - HIGH RISK UNFIT PTS

AAAs >5.5 CM

ENDO VS. NO Rx

EVAR 1

EVAR 1

HAS SOME FLAWS & BIASES

LET US LOOK AT

ITS LONG-TERM RESULTS

& ITS WRONG CONCLUSION

LONG-TERM – 10-YR RESULTS OF EVAR 1 NEJM 2010

IN EVAR 1

ALL CAUSE MORTALITY

BECAME = BY 2 YEARS

➤ BECAUSE OF THIS **CATCH-UP** PHEN &
HIGHER REINTERV & COST FOR EVAR 1

CONCLUSION:

“EVAR NOT BETTER THAN OR”

LONG-TERM RESULTS – 10 YEARS

CONCLUSION WRONG!

FOR SEVERAL REASONS

**1.* THIS CATCH-UP REPRESENTS
INCREASED PATIENT SURVIVAL IN THE
EVAR GROUP**

**– THIS IS THE MAIN PURPOSE
OF AAA REPAIR, ISN'T IT ?**

**IF YOU HAD YOUR AAA FIXED, WHO
WOULD NOT WANT TO LIVE LONGER ???**

SECOND REASON

CONCLUSION WRONG!

**2. OLD ENDOGRAFTS, INEXPERIENCED
OPERATORS AND OUTDATED
SECONDARY TREATMENT IN EVAR 1
& MANY RUPTURES AFTER EVAR LIKELY
WOULD NOT HAPPEN NOW
THEREFORE EVAR RESULTS TODAY
WOULD BE FAR SUPERIOR !**

THIRD REASON

NEJM 2010 – CONCLUSION WRONG!

3. UNFAIR COST COMPARISONS

BETWEEN EVAR & OR - IN EVAR 1

ALL OPEN REPAIR COMPLICATIONS NOT
REPORTED (ABD WALL AND SB OBSTR);

- CHEAPER SURVEILLANCE TODAY

THEREFORE REAL EVAR RESULTS TODAY

WOULD BE FAR SUPERIOR !

**THUS CONCLUSION OF EVAR 1
(10-YR RESULTS IN NEJM THAT)**

**“EVAR NOT BETTER THAN OR”
IS NOT CORRECT**

**CONCLUSION SHOULD BE: ‘EVAR IS BETTER
THAN OR’ & EVAR TODAY SHOULD
BE FIRST CHOICE FOR ELECTIVE
AAA REPAIR IN ANATOMICALLY SUITED
FIT PATIENTS**

**WHAT ABOUT EVAR 2
IN PATIENTS DEEMED
UNFIT FOR OPEN REP?**

EVAR 2 TRIAL

RESULTS

- EVAR **NOT** IMPROVE SURVIVAL OVER NO INTERVENTION & HAD BIG NEED FOR SURVEILLANCE & REINTERVENTIONS & ↑ COST

CONCLUSION OF EVAR 2:

DON'T Rx PATIENTS UNFIT FOR OR
BY EVAR

AGAIN THAT IS INCORRECT

EVAR 2

REACHES WRONG

CONCLUSION

BECAUSE OF FLAWS

IN THE TRIAL

TRIAL FLAWS IN EVAR 2 THAT RENDER IT MISLEADING

1. **LONG DELAY (AV 57 DAYS) BETWEEN RANDOMIZATION & EVAR & 9 PTS IN EVAR GROUP RUPTURED BEFORE EVAR (AV 98 DAYS) (9/20 DEATHS)**
2. **9% 30-D EVAR MORT NOT IN KEEPING WITH OTHER HIGH RISK RESULTS**

OTHER EVAR 2 FLAWS MAY RENDER ITS FINDINGS MISLEADING

**3. BEGAN IN 1999 – IMPROVED SKILLS,
ENDOGRAFTS, ETC COULD IMPROVE
EVAR RESULTS & CHANGE OUTCOME**

**4. DETERMINATION OF HIGH RISK UP
TO SURGEON – SUBJECTIVE
(34 PTS X-OVER TO EVAR WITH 3% MORTALITY)**

THUS IN EVAR 2

**IF WE ELIMINATE DELAY IN EVAR Rx,
& ELIMINATE OTHER FLAWS,
THE OUTCOME OF EVAR 2 COULD
& WOULD HAVE BEEN
TOTALLY DIFFERENT**

**SO THE VALUE OF EVAR 2
IS THAT IT JUSTIFIES
THESE CONCLUSIONS**

EVAR 2 JUSTIFIES

- **NON-OP Rx IN THE WORST RISK PTS WITH 5.5 - 6 CM AAAs**
- **NON-OP Rx IN VERY HIGH RISK PATIENTS WITH BAD ANATOMY FOR EVAR**

HOWEVER - EVAR 2

- **NOT APPLICABLE
GENERALLY**
- **EVAR IS STILL INDICATED
& IS BEST Rx IN MANY PTS
WITH >6 CM AAAs WHO ARE
UNFIT FOR OPEN REPAIR**

**WHAT ABOUT
RUPTURED AAAs
(RAAAs) ?**

**OUR AND OTHERS'
RESULTS SUGGEST
THAT EVAR IMPROVES
Rx OUTCOMES
FOR RAAAs**

HOWEVER

**SOME GROUPS
HAVE HAD POOR
RESULTS WITH
EVAR FOR RAAAs
& NO GOOD RCT**

**AND SOME CLAIMED
THE GOOD RESULTS
WITH EVAR WERE IN
SELECTED RAAA
PATIENTS**

**COLLECTED WORLD EXPER
WITH ENDOVASCULAR Rx
(EVAR) FOR RUPT AAAs**

**FJ VEITH, M LACHAT, M MEHTA
E VERHOEVEN, G COPPI, T LARZON
M MALINA & RAAA INVESTIGATORS**

**ANN SURG -- NOV 2009;
250 : 818-824**

RESULTS – UPDATED THROUGH 2009

- FROM 13 CTRS – EVAR ON
ALL ANAT POSS RAAA PTS

680 RAAA PTS R_xS BY **EVAR**

763 RAAA PTS R_xD BY **OR**

30-DAY MORTALITY

EVAR

OR

19.7% VS 36.3% (P < .0001)

MAYER, LACHAT, LARZON, ET AL

**2 CENTER EXPERIENCE WITH
100% Rx OF RAAAs WITH EVAR**

- 24% 30-DAY MORTALITY**
- <4% TURN DOWN RATE**

CONCLUSION

**EVAR IS BETTER THAN OR FOR
ELECTIVE AAAs & RAAAs
IN FIT & UNFIT PATIENTS
WITH SUITABLE ANATOMY
DONT NEED MORE RCTs TO SHOW
EVAR SUITABILITY IMPACTS
FAVORABLY ON OUTCOMES
OF AAA & RAAA REPAIR**

THANKS FOR YOUR ATTENTION



