WHY THE EVAR TRIALS ARE MISLEADING: EVAR BETTER THAN OR IN FIT & UNFIT PTS WITH LARGE AAAs & SUITABLE ANATOMY

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3rd INTERNATL MEETING ON AORTIC DISEASES

LIEGE, BELGIUM – OCT 6, 2012

SOME (FUNDAMENTALISTS)

BELIEVE PRACTICE CHANGES SHOULD NEVER OCCUR WITHOUT THE SUPPORT OF LEVEL I EVIDENCE & RCTs

- OTHERS (FLAMING LIBERALS) POINT OUT POTENTIAL FLAWS OF RCTs & SOME BELIEVE RCTs UNNECESSARY
- ESPECIALLY WITH ENDOVASC PROCEDURES - FUELED BY TURF ISSUES

BOTH LIBERALS AND FUNDAMENTALISTS ARE SOMETIMES RIGHT

NO RCT NEEDED FOR PROXIMAL CONTROL IN ARTERIAL BLEEDING

EFFECTIVENESS OF CEA SHOWN BY LANDMARK RCTs OF 1990s

so

RCTs - LEVEL I EVIDENCE (THE HOLY GRAIL)

NOT ALWAYS SO HOLY

NOT ABSOLUTE NECESSARY OR TIMELESS

BECAUSE OF FLAWS & WEAKNESSES IN RC TRIALS DUE TO PROBLEMS WITH:

1. TIMELINESS – APPLICABILITY TO PRESENT STATE OF ART
2. DESIGN FLAWS IN RCTs
3. MISINTERPRETATION – AUTH OTHERS

WHAT ABOUT EVAR AS THE BEST TREATMENT FOR ELECTIVE AAAs IN FIT & UNFIT PATIENTS ? (BASED ON EVAR TRIALS)

PROVISO

PATIENT HAS SUITABLE ANATOMY FOR EVAR

EVAR RC TRIALS

- EVAR 1
- DREAM
- OVER

GOOD RISK PATIENTS WITH AAAs

- EVAR 2 – HIGH RISK

AAA PTS UNFIT FOR OR

EVAR TRIALS

EV 1 - GOOD RISK PATIENTS

AAAs >5.5 CM

OPEN VS. ENDO REPAIR

EV 2 – OR UNFIT PTS

AAAs >5.5 CM

ENDO VS. NO Rx (MED Rx)

EVAR 1

IS VALUABLE STUDY & SHOWS THAT EVAR IS ACCEPTABLE Rx FOR AAAs IN GOOD RISK PATIENTS

BUT...

BUT EVAR 1
HAS SOME FLAWS & BIASES
LET US LOOK AT
ITS RESULTS
SHORT-TERM & LONG-TERM

SHORT-TERM 30-DAY RESULTS

EVAR VS OR IN FIT PTS-OK FOR BOTH

LANCET 2005

IN EVAR 1 (& DREAM & OVER)

30-DAY MORTALITY OF EVAR ~ 2.5 X LESS THAN FOR OPEN REPAIR (OR)

IN EVAR 1: 30-DAY MORTALITY WAS 4.3% FOR OR & 1.8% FOR EVAR, P=.02

MORE REINTERV, HIGHER COST

CONCL: EVAR BETTER IN SHORT-TERM

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

IN EVAR 1

ALL CAUSE MORTALITY BECAME = BY 2 YEARS & AAA RELATED MORT BECAME = BY 6 YEARS

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

CONCL: "EVAR NOT BETTER THAN OR"

LONG-TERM RESULTS – 10 YEARS

NEJM 2010 – CONCLUSION WRONG!

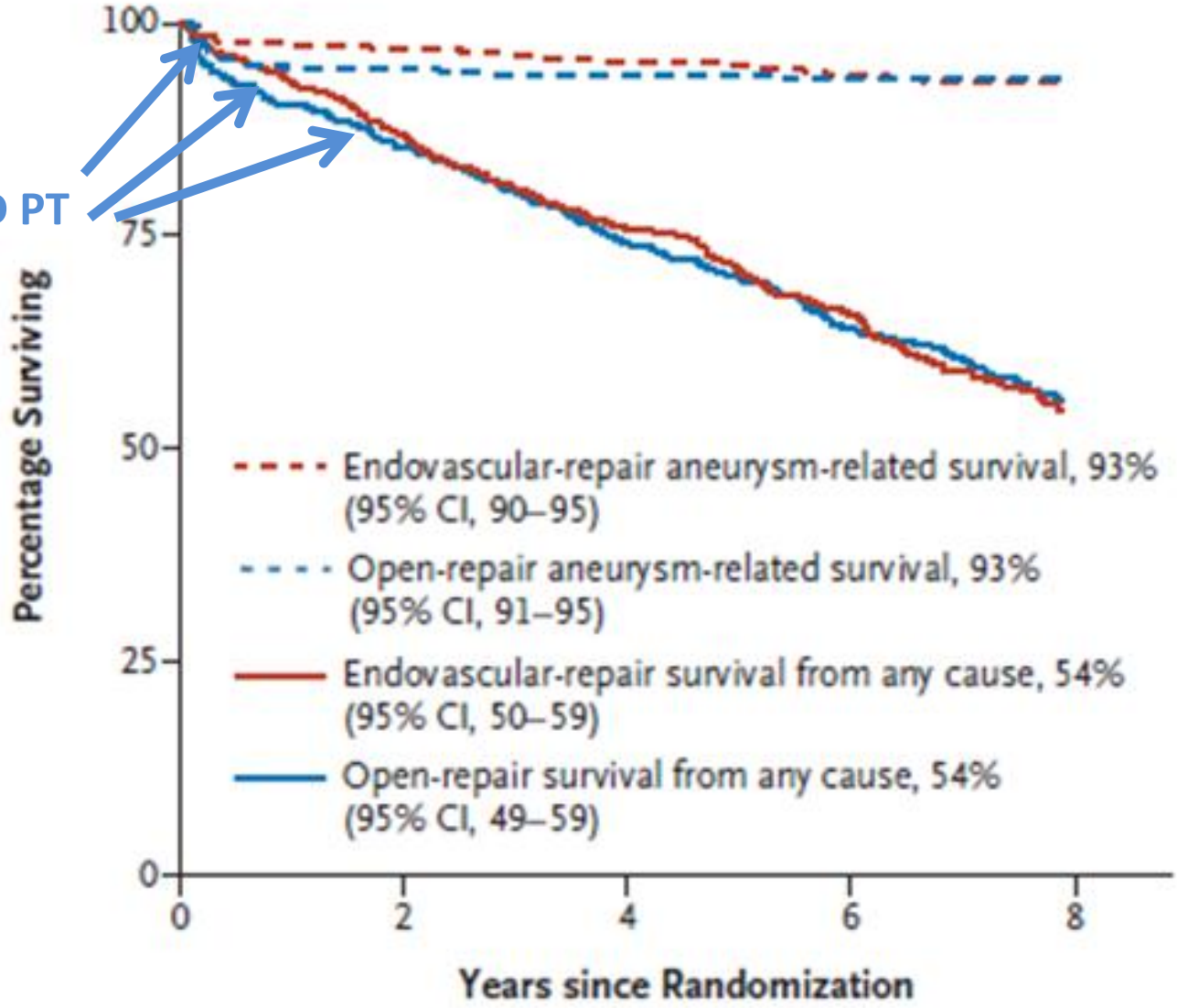
FOR SEVERAL REASONS

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 ???

INCREASED PT SURVIVAL



No. at Risk					
Endovascular repair	626	543	472	312	101
Open repair	626	534	461	301	109

SECOND REASON

NEJM 2010 – CONCLUSION WRONG!

2. OLD ENDOGRAFTS, INEXPERIENCED OPERATORS AND OUTDATED SECONDARY TREATMENT IN EVAR 1

e.g. MANY RAAAs AFTER EVAR LIKELY AVOIDED NOW

ALL TYPE 2 ENDOLEAKS RxD - ↑COST

THEREFORE EVAR RESULTS TODAY WOULD BE FAR SUPERIOR !

THIRD REASON

NEJM 2010 – CONCLUSION WRONG!

3. UNFAIR COST COMPARISONS

BETWEEN EVAR & OR - IN EVAR 1

e.g. ALL OPEN R COMPLICATIONS NOT REPORTED (ABD WALL AND SB OBSTR);

CHEAPER SURVEILLANCE TODAY

THEREFORE REAL EVAR RESULTS TODAY WOULD BE FAR SUPERIOR !

THUS ALTHOUGH
EVAR 1 WAS A WELL
CONDUCTED RANDOMIZED
TRIAL WHICH PROVIDED USEFUL
INFORMATION SUPPORTING EVAR
IT UNFORTUNATELY REACHED
THE WRONG CONCLUSION

THUS CONCLUSION OF EVAR 1 10 YEARS RESULTS IN NEJM 2010

"EVAR NOT BETTER THAN OR" IS INCORRECT

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

WHAT ABOUT EVAR IN UNFIT PATIENTS ?

THE ONLY LEVEL 1 EVIDENCE IN UNFIT PATIENTS COMES FROM THE EVAR 2 TRIAL

HOWEVER WE KNOW RCTs CAN BE MISLEADING

EVEN IN LEADING JOURNALS

BECAUSE OF:

i FLAWS IN RCTs –TIMELINESS OR DESIGN FLAWS

ii MISINTERPRETATIONS

ERROR OR BIAS BY AUTHORS

OTHERS

EVAR 2 TRIAL

HIGH RISK PATIENTS W/ AAAs >5.5 CM DEEMED UNFIT FOR OR

EVAR VS. NO TREATMENT

EVAR 2 TRIAL

RESULTS & CONCLUSION

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

CONCLUSION

DON'T Rx PATIENTS UNFIT FOR OR

MY VIEW - CONTROVERSIAL

EVAR 2
REACHES WRONG
CONCLUSION &
MAY BE MISLEADING

EVAR 2 TRIAL FLAWS MAY RENDER ITS FINDINGS 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. 8% 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
HAVE BEEN TOTALLY DIFFERENT

EVAR 2 IS VALUABLE TRIAL
JUSTIFIES THESE CONCLUSIONS

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

HOWEVER - EVAR 2

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

RUPTURED AAAs
NO GOOD LEVEL 1 EVIDENCE

EVAR FOR RUPT AAAs

- **REMAINS CONTROVERSIAL**

- SOME STILL SAY WE

NEED RCT

- THREE ONGOING – i IN UK

i IN FRANCE; i IN NETHERLANDS

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

FJ VEITH, M LACHAT, M MALINA
E VERHOEVEN, G COPPI, T LARZON
M MEHTA & 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 RxS BY EVAR
  763 RAAA PTS RxD BY OR

30-DAY MORTALITY

EVAR OR

19.7% VS 36.3% (P <.0001)

CONCLUSION

THE LOW MORTALITY (< 20%) &
MANY INOPERABLE CASES
TREATED SUCCESSFULLY SHOW

EVAR IS A BETTER WAY TO TREAT RUPTURED AAAs IN ANATOMICALLY SUITED PTS

OVERALL CONCLUSION

IN FIT & UNFIT PATIENTS REQUIRING ELECTIVE AAA OR RAAA REPAIR EVAR SHOULD BE THE FIRST CHOICE FOR Rx IF THEY HAVE OK ANATOMY


THANKS FOR YOUR ATTENTION

EVAR FOR ELECTIVE (UNRUPTURED) AAA REPAIR

ELECTIVE AAAs
EVAR RC TRIALS

EVAR 1