

#AHA21



DABIGATRAN VERSUS WARFARIN ON COGNITIVE OUTCOMES IN NONVALVULAR ATRIAL FIBRILLATION: RESULTS OF THE GIRAF TRIAL

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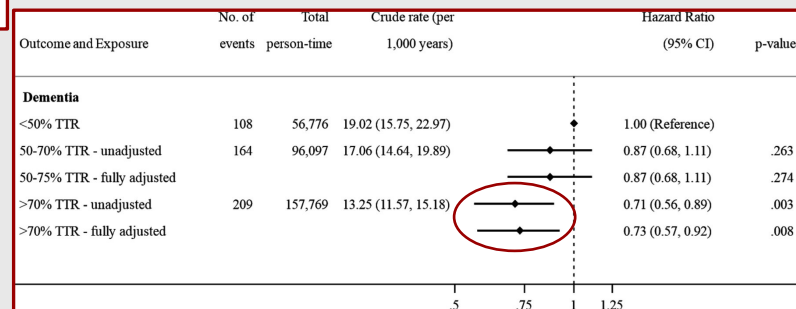
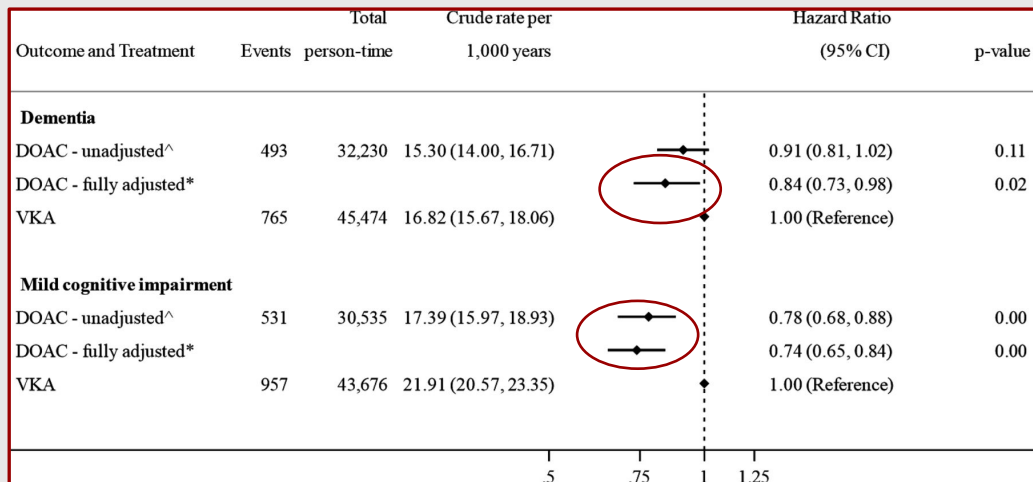


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DISCLOSURES

- ✓ **GIRAF PREVENTION TRIAL** IS AN INVESTIGATOR-INITIATED STUDY (IIS) THAT WAS PARTIALLY SUPPORTED BY BOEHRINGER INGELHEIM DO BRASIL QUÍMICA E FARMACÊUTICA
- ✓ THE SPONSOR HAD NO ROLE IN STUDY DESIGN, TRIAL EXECUTION, DATA ANALYSIS, WRITING/REVIEWING THE MANUSCRIPT OR IN THE DECISION TO SUBMIT FOR PUBLICATION.

ANTICOAGULATION IN AF PATIENTS AND THE RISK OF INCIDENT DEMENTIA HISTORICAL COHORT STUDY



Sharon Louise Cadogan et al. Heart doi:10.1136/heartjnl-2021-319672

THE GIRAF PREVENTION TRIAL

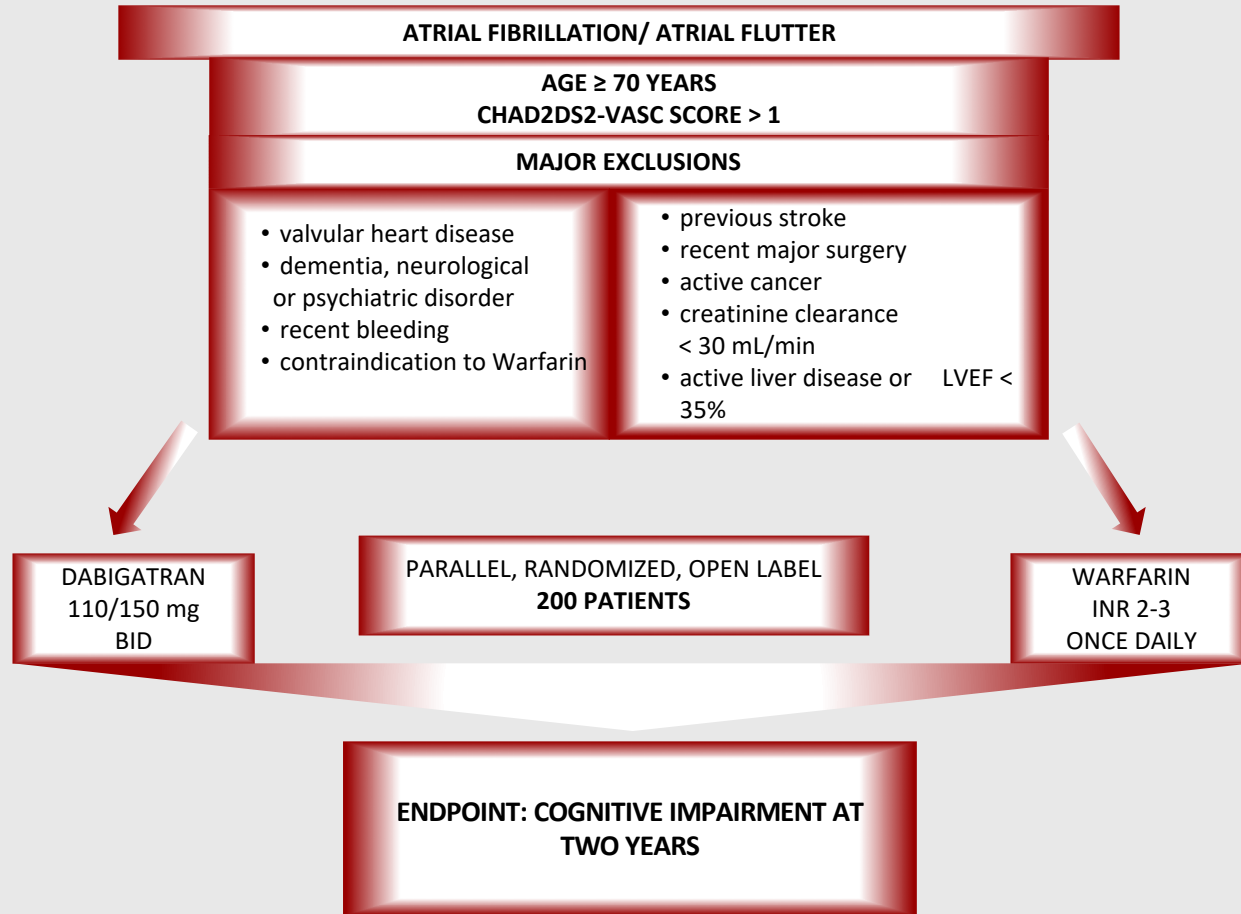
IIS TRIAL ADDRESSING COGNITIVE OUTCOMES IN AF PATIENTS

OBJECTIVE

- ✓ To investigate the effects of Dabigatran compared with Warfarin on cognitive outcomes in older adults with Atrial Fibrillation/Atrial Flutter

GIRAF TRIAL

STUDY DESIGN



METHODS

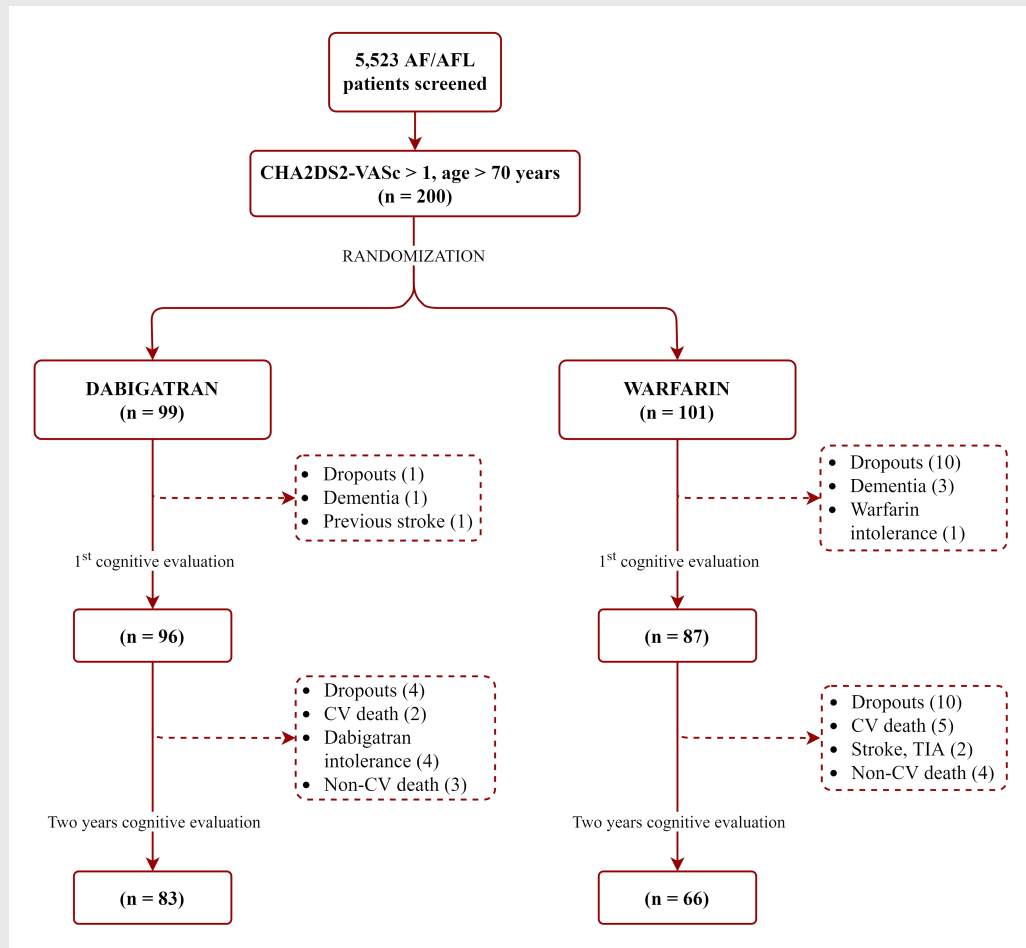
EXTENSIVE COGNITIVE EVALUATION AT BASELINE AND AFTER TWO-YEARS

TEST	ACRONYM	COVERAGE PATTERN
MONTREAL COGNITIVE ASSESSMENT	MOCA	GLOBAL
MINI-MENTAL STATE EXAM	MMSE	GLOBAL
NEUROPSYCHOLOGICAL BATTERY (DIGIT SYMBOL SUBSTITUTION TEST, FIGURE MEMORY TEST, SEMANTIC VERBAL FLUENCY, PHONEMIC VERBAL FLUENCY, BOSTON NAMING , TRAIL MAKING A&B, CLOCK-DRAWING)	NTB	ATTENTION MEMORY, LANGUAGE, EXECUTIVE FUNCTIONS
COMPUTER GENERATED NEUROPSYCHOLOGICAL MEASURING ACCURACY AND REACTION TIME	CGNT	SUSTAINED, SELECTIVE AND DIVIDED ATTENTION



- ✓ Tests performed by neurologists blinded to group assignments
- ✓ Modified Intention to Treat statistical analysis, no imputation
- ✓ Only patients that performed evaluations at baseline and after 2 years were considered.

PATIENT FLOW DIAGRAM



BASELINE CHARACTERISTICS

CHARACTERISTICS	DABIGATRAN (N=83)	WARFARIN (N=66)	P VALUE
AGE, MEAN (SD) IN YEARS	74 (71-77)	76 (72-77)	0.06
SEX (MALE)	51 (61.4%)	39 (59.1%)	0.90
EDUCATION YEARS, MEAN (SD)	7 (4-12)	4 (4-9)	0.21
MMSE SCORE, MEDIAN (IQR)	27 (26-29)	27 (26-29)	0.85
MoCA SCORE, MEDIAN (IQR)	23 (21 to 26)	22 (18-24.8)	0.03
NTB Z-SCORE, MEDIAN (IQR)	0.08 (0.60)	-0.12 (0.58)	0.04
CGNT Z-SCORE, MEDIAN (IQR)	0.24 (0.02-0.47) N=72	-0.04 (-0.27-0.31) N=57	0.004
CHA2DS2-VASC, MEDIAN (IQR)	4 (3-4)	4 (3-5)	0.24
HAS - BLEED, MEDIAN (IQR)	1 (1-1.25)	1 (1-1)	0.12

MMSE: Mini-Mental State Exam; **MoCA:** Montreal Cognitive Assessment; **NTB:** composite neuropsychological test battery consisting of the average of the z-scores for Boston naming test, semantics verbal fluency, phonemic verbal fluency, trail making tests, clock-drawing test, and digit symbol test; **CGNT:** a composite score composed of the average of the z-scores of the computer-generated neuropsychological tests.

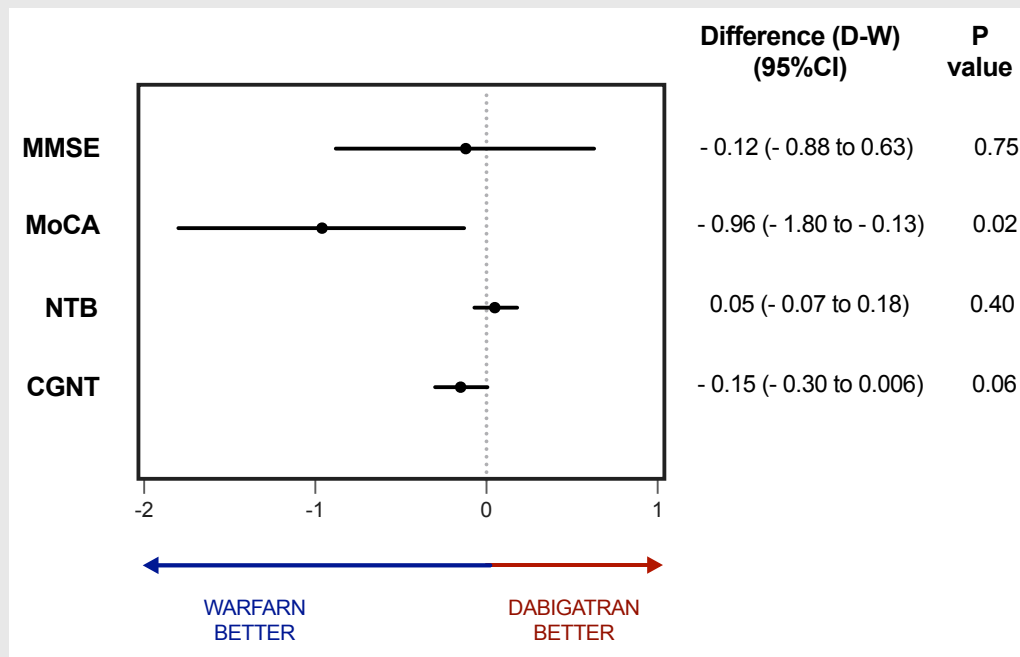
ADJUSTED MEAN CHANGES FROM BASELINE

HIGHER SCORES INDICATE BETTER COGNITIVE PERFORMANCE

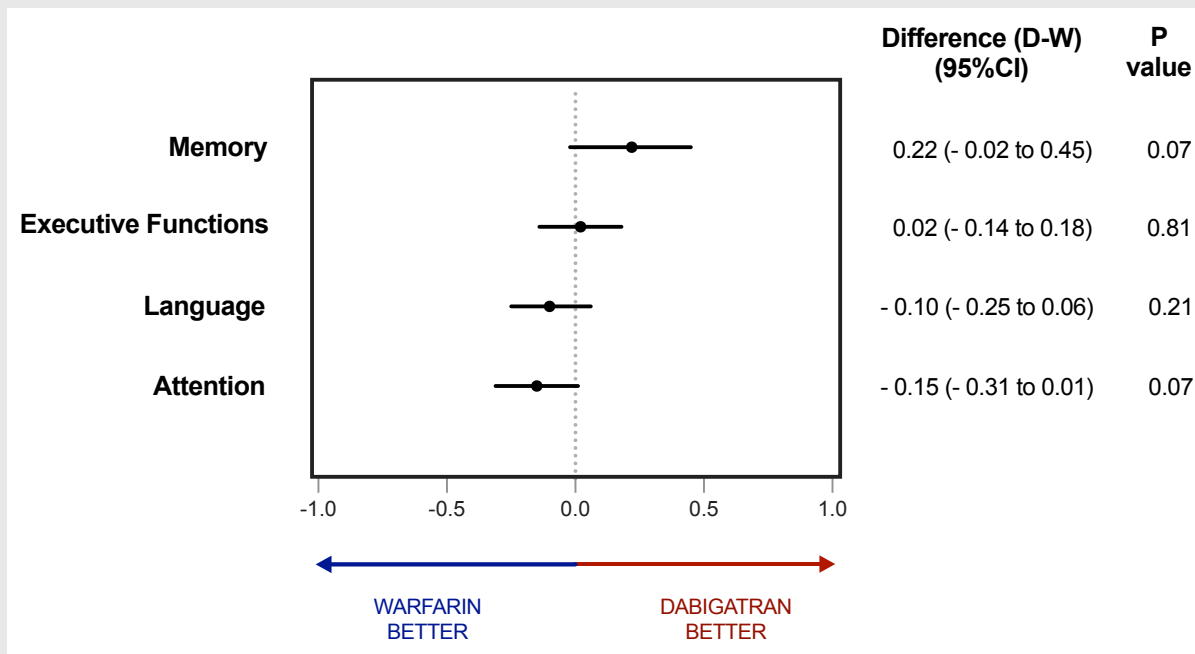
COGNITIVE ASSESSMENT	DABIGATRAN (N=83)	WARFARIN (N=66)	DIFFERENCE (D-W) (95% CI)	P VALUE	EFFECT SIZE COHEN'S D
MMSE SCORE	-0.69 (-1.18 to -0.2)	-0.57 (-1.12 to -0.01)	-0.12 (-0.88 to 0.63)	0.75	-0.06
MoCA SCORE	-0.39 (-0.94 to 0.16)	0.58 (-0.04 to 1.19)	-0.96 (-1.8 to -0.13)	0.02	-0.39
NTB SCORE	0.02 (-0.06 to 0.1)	-0.03 (-0.12 to 0.06)	0.05 (-0.07 to 0.18)	0.40	0.14
CGNT SCORE	-0.06 (-0.16 to 0.04) N=68	0.09 (-0.02 to 0.2) N=56	-0.15 (-0.3 to 0.006)	0.06	-0.36

ANTICOAGULATION QUALITY	WARFARIN (N=66)
TTR	69.86% ± 13.94

DABIGATRAN AND WARFARIN GROUPS IN THE 4 CO-PRIMARY OUTCOME TESTS



DABIGATRAN AND WARFARIN GROUPS IN COGNITIVE DOMAINS' TESTS



CONCLUSIONS

- ✓ IN OLDER PATIENTS WITH ATRIAL FIBRILLATION OR ATRIAL FLUTTER WHO DID NOT PRESENT MAJOR CEREBROVASCULAR EVENTS AND WERE ADEQUATELY TREATED WITH WARFARIN (TTR 70%) OR DABIGATRAN FOR 2 YEARS, THERE WAS NO DIFFERENCE IN THE MAJORITY OF THE COGNITIVE OUTCOMES.

ACKNOWLEDGEMENTS

INVESTIGATORS



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NITRINI R



CALDERARO D



PASTANA A



CARAMELLI B



RODRIGUES A



CARAMELLI P



ROJAS M



CARDOZO F



SPERRA R



FEITOSA R



TAVARES C



GUALANDRO D



YU P



TO THE PATIENT, TO THE BRAZILAN PUBLIC HEALTH SYSTEM AND TO THE BRAZILIAN PEOPLE, WHO RESIST DESPITE EVERYTHING