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FROM THE ALZHEIMER'S ASSOCIATION INTERNATIONAL CONFERENCE 2018

STUDY SHOWS INTENSIVE BLOOD PRESSURE CONTROL REDUCES RISK OF MILD COGNITIVE IMPAIRMENT (MCI) AND THE COMBINED RISK OF MCI AND DEMENTIA

Plus: – Genomic Analysis of Alzheimer's Study May Enable a Precision Medicine Approach

CHICAGO, July 25, 2018 – Significant reductions in the risk of mild cognitive impairment (MCI)*, and the combination of MCI and dementia**, have been shown for the first time through aggressive lowering of systolic blood pressure in new research results from the federally-funded SPRINT MIND Study reported at the Alzheimer's Association International Conference (AAIC) 2018 in Chicago.

"This is the first randomized clinical trial to demonstrate a reduction in new cases of MCI alone and the combined risk of MCI plus all-cause dementia," said Jeff D. Williamson, MD, MHS, Professor of Internal Medicine and Epidemiology and Chief, Section on Gerontology and Geriatric Medicine at Wake Forest School of Medicine. Williamson reported these results at AAIC 2018.

The results of this large-scale, long-term clinical trial provide the strongest evidence to date about reducing risk of MCI and dementia through the treatment of high blood pressure, which is one of the leading causes of cardiovascular disease worldwide.

"This study shows more conclusively than ever before that there are things you can do — especially regarding cardiovascular disease risk factors — to reduce your risk of MCI and dementia," said Maria C. Carrillo, PhD, Alzheimer's Association Chief Science Officer. "To reduce new cases of MCI and dementia globally we must do everything we can — as professionals and individuals — to reduce blood pressure to the levels indicated in this study, which we know is beneficial to cardiovascular risk."

Carrillo pointed out that these results fit well with recent population data showing reductions in new cases of dementia in developed Western cultures. These lower rates of dementia may be occurring as these societies have begun to improve control of cardiovascular disease risk factors through medication management, reducing smoking, and greater awareness of healthy lifestyle.

The Alzheimer's Association offers 10 Ways to Love Your Brain, based on the latest research evidence.

"The future of reducing MCI and dementia could be in treating the whole person with a combination of drugs and modifiable risk factor interventions — as we do now in heart disease," Carrillo suggested. "These new blood pressure findings raise our level of anticipation for the U.S. POINTER Study, which includes managing cardiovascular disease risk factors as part of the multi-component lifestyle intervention."

The Alzheimer's Association U.S. Study to Protect Brain Health Through Lifestyle Intervention to Reduce Risk (U.S. POINTER) is a two-year clinical trial funded by the Alzheimer's Association to evaluate whether lifestyle interventions can protect cognitive function in older adults at increased risk for cognitive decline. The interventions include physical exercise, nutritional counseling and modification, cognitive and social stimulation, and improved self-management of health status.

Intensive Blood Pressure Control Significantly Reduces New Cases of MCI, and Combined Risk of MCI and Dementia: SPRINT MIND Study

At AAIC 2018, Williamson and colleagues reported preliminary results related to risk of dementia and cognitive decline from the Systolic Blood Pressure Intervention Trial (SPRINT). SPRINT is a randomized clinical trial that compared two strategies for managing high blood pressure (hypertension) in older adults: an intensive strategy with a systolic blood pressure goal of less than 120 mm Hg versus a standard care strategy targeting a systolic blood pressure goal of less than 140 mm Hg. Previously, SPRINT demonstrated that more intensive blood pressure control reduced the risk for cardiovascular morbidity and mortality (NEJM, 11-26-15). SPRINT helped inform the 2017 American Heart Association and American College of Cardiology high blood pressure clinical guidelines.

SPRINT Memory and Cognition IN Decreased Hypertension (SPRINT MIND) examined whether treating to the lower blood pressure target reduces the risk of developing dementia and/or MCI, and reduces the total volume of white matter lesions in the brain as shown by magnetic resonance imaging (MRI).

Study participants were 9,361 hypertensive older adults with increased cardiovascular risk (based on the Framingham risk score) but without diagnosed diabetes, dementia or prior stroke. Participant mean age was 67.9 years (35.6% women) and 8,626 (92.1%) completed at least one follow-up cognitive assessment. In SPRINT MIND, the primary outcome was incident probable dementia. Secondary outcomes included MCI and a composite outcome of MCI and/or probable dementia. Each outcome was adjudicated by an expert panel blinded to who was in each treatment group.

Recruitment for SPRINT began in October 2010. At one year, mean systolic blood pressure was 121.4 mmHg in the intensive-treatment group and 136.2 mmHg in the standard treatment group. Treatment was stopped in August 2015 due to cardiovascular disease (CVD) benefit after a median follow up of 3.26 years, but cognitive assessment continued until June 2018.

> Intervention — According to NEJM, 11-26-15, "All major classes of antihypertensive agents were included in the formulary and were provided at no cost to the participants. SPRINT investigators could also prescribe other antihypertensive medications (not provided by the study). The protocol encouraged, but did not mandate, the use of drug classes with the strongest evidence for reduction in cardiovascular outcomes, including thiazide-type diuretics (encouraged as the first-line agent), loop diuretics (for participants with advanced chronic kidney disease), and beta-adrenergic blockers (for those with coronary artery disease)."

> "Participants were seen monthly for the first 3 months and every 3 months thereafter. Medications for participants in the intensive-treatment group were adjusted on a monthly basis to target a systolic blood pressure of less than 120 mm Hg. For participants in the standard-treatment group, medications were adjusted to target a systolic blood pressure of 135 to 139 mm Hg, and the dose was reduced if systolic blood pressure was less than 130 mm Hg on a single visit or less than 135 mm Hg on two consecutive visits. … Lifestyle modification was encouraged as part of the management strategy."

In SPRINT MIND, the researchers found a statistically significant 19 percent lower rate of new cases of MCI (p=0.01) in the intensive blood pressure treatment group. The combined outcome of MCI plus probable all-cause dementia was 15 percent lower (p=0.02) in the intensive versus standard treatment group. There was a non-significant reduction in probable dementia alone (HR=0.83, p=0.10).

> Adverse events — According to NEJM, 11-26-15, "Serious adverse events occurred in 1793 participants in the intensive-treatment group (38.3%) and in 1736 participants in the standard-treatment group (37.1%) (hazard ratio with intensive treatment, 1.04; P=0.25). Serious adverse events of hypotension, syncope, electrolyte abnormalities, and acute kidney injury or acute renal failure, but not injurious falls or bradycardia, occurred more frequently in the intensive-treatment group than in the standard-treatment group. Orthostatic hypotension as assessed during a clinic visit was significantly less common in the intensive-treatment group. A total of 220 participants in the intensive-treatment group (4.7%) and 118 participants in the standard-treatment group (2.5%) had serious adverse events that were classified as possibly or definitely related to the intervention (hazard ratio, 1.88; P<0.001) [but overall number of SAEs by group did not differ]. The magnitude and pattern of differences in adverse events according to treatment assignment among participants 75 years of age or older were similar to those in the overall cohort."

"These results support the need to maintain well-controlled blood pressure, especially for persons over the age of 50," said Williamson. "A particular strength of SPRINT-MIND is that 30 percent of the participants were African American and 10 percent were Hispanic."

"This is something doctors and the majority of their community-dwelling patients with elevated blood pressure should be doing now to keep their hearts — and brains — healthier. These new results for maintaining cognitive health provide another strong rationale for starting and maintaining healthy lifestyle changes in mid-life," Williamson added.

SPRINT MIND MRI Results

In a related abstract reported at AAIC 2018, Ilya Nasrallah, MD, PhD, of the University of Pennsylvania, Philadelphia, reported preliminary results from 673 participants in SPRINT MIND who were recruited for brain magnetic resonance imaging (MRI). Primary outcomes included change in total white matter lesion (WML) volume and total brain volume (TBV). Follow-up MRIs were obtained for 454 (67.4%) participants at a median of 3.98 years post-randomization.

In this sub-study, WML volume increased in both treatment groups, however the increase was significantly less in the intensive treatment group. There was no significant difference in total brain volume change.

- In the intensive treatment group, WML volume increased by 0.28 cm^3 compared to 0.92 cm^3 in the standard treatment group (mean difference=0.64 cm^3, p=0.004).

- TBV decreased by 27.3 cm^3 in the intensive treatment group versus 24.8 cm^3 in the standard treatment group (mean difference=2.54 cm^3, p=0.16).

White matter lesions are frequently indicative of small vessel disease and linked to higher risk of stroke, dementia and higher mortality. While white matter lesions are thought to increase the risk of vascular dementia, they also may be a risk factor for Alzheimer's disease. People living with dementia may have Alzheimer's disease and white matter lesions at the same time. Research has demonstrated that when people have more than one type of disease-related brain changes, the cognitive consequences are greater.

Genomic Analysis of Phase 2a Alzheimer's Study with ANAVEX®2-73 May Enable a Precision Medicine Approach

"Precision medicine involves giving the right therapy to the right patient at the right time, customized to his or her specific biological makeup," says Professor Harald Hampel, MD, PhD, MA, MSc, AXA Research Fund & Sorbonne University Excellence Chair, Department of Neurology, Sorbonne University, Paris.

Precision medicine emphasizes the customization and individualization of healthcare, with treatments and practices tailored to the specific patient's situation and needs, often taking into account genes, environment, and lifestyle. Sometimes called personalized medicine, it is a common approach in cancer and respiratory diseases.

At AAIC 2018, Hampel and colleagues reported results of an innovative attempt to move a step closer to precision medicine in Alzheimer's therapy trials. Anavex Life Sciences (AVXL) conducted a 57-week Phase 2a study with ANAVEX®2-73, a selective sigma-1 receptor agonist, in 32 people with mild to moderate Alzheimer's disease and analyzed the entire genome DNA and RNA of all study participants, resulting in the analysis of 33,311 genes and 860 pathways.

The company identified several genetic variants that impacted response to the drug, including SIGMAR1, which is ANAVEX®2-73's target, and COMT, a gene involved in memory function. They found further that excluding people with these variants (~20% of the study group) — leaving about 80% of the population — resulted in improved scores on gold standard tests of cognition (MMSE) and activities of daily living (ADCS-ADL) ($p<0.05$).

- Including participants with milder disease (baseline MMSE≥20) and excluding those with a SIGMAR1 variant resulted in improvement of 1.7 MMSE and 3.9 ADCS-ADL at week 57.
- The additional exclusion of the COMT variant resulted in a score improvement of 2.0 MMSE and 4.9 ADCS-ADL at week 57.

"This study represents an exciting step forward, away from the 'magic bullet, one-size-fits-all' drug development in Alzheimer's, following the targeted therapy successes in the field of oncology," Hampel said. "Our vision is that a precision medicine approach will allow us to more precisely treat and prevent key features of the cause and progression of Alzheimer's. We are intrigued that several studies with this novel approach are now planned or underway."

According to the company, these patient selection markers will be implemented in an upcoming Phase 2b/3 study of ANAVEX®2-73.

The Alzheimer's Association International Conference® (AAIC®)

The Alzheimer's Association International Conference (AAIC) is the world's largest gathering of researchers from around the world focused on Alzheimer's and other dementias. As a part of the Alzheimer's Association's research program, AAIC serves as a catalyst for generating new knowledge about dementia and fostering a vital, collegial research community.
AAIC 2018 home page: alz.org/aaic
AAIC 2018 newsroom: alz.org/aaic/press

About the Alzheimer's Association®
The Alzheimer's Association is the leading voluntary health organization in Alzheimer's care, support and research. Our mission is to eliminate Alzheimer's disease through the advancement of research, to provide and enhance care and support for all affected, and to reduce the risk of dementia through the promotion of brain health. Our vision is a world without Alzheimer's. Visit alz.org or call 800.272.3900.

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*Mild cognitive impairment (MCI) — MCI causes a slight but noticeable and measurable decline in cognitive abilities, including memory and thinking skills, but the changes are not severe enough to interfere with daily life or independent function. A person with MCI is at an increased risk of developing Alzheimer's or another dementia. However, MCI does not always lead to dementia. In some people, MCI reverts to normal cognition or remains stable.

**Dementia — A general term for memory loss and other cognitive abilities serious enough to interfere with daily life. Dementia is not a specific disease. It's a term that describes a group of symptoms. Alzheimer's disease accounts for 60 to 80 percent of dementia cases. Vascular dementia, which occurs after a stroke, is the second most common dementia type. There are many other conditions that can cause dementia symptoms, including some that are reversible, such as thyroid problems and vitamin deficiencies.

***Alzheimer's disease and Alzheimer's disease dementia — Alzheimer's is a type of dementia that causes problems with memory, thinking and behavior. Symptoms usually develop slowly and get worse over time, becoming severe enough to interfere with daily tasks. Two abnormal structures called plaques and tangles are prime suspects in damaging and killing nerve cells in Alzheimer's disease. Plaques are deposits of a protein fragment called beta-amyloid that build up in the spaces between nerve cells. Tangles are twisted fibers of another protein called tau that build up inside cells. It's the destruction and death of nerve cells that causes memory failure, personality changes, problems carrying out daily activities and other symptoms of Alzheimer's disease dementia.

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- Jeff Williamson, MD, MHS, et al. A Randomized Trial of Intensive Versus Standard Systolic Blood Pressure Control and the Risk of Mild Cognitive Impairment and Dementia: Results from SPRINT MIND. Funder(s): U.S. National Institutes of Health (NIH), including the National Heart, Lung and Blood Institute (NHLBI), National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), National Institute on Aging (NIA), and National Institute of Neurological Disorders and Stroke (NINDS); U.S. Department of Veterans Affairs.
- Ilya Nasrallah, MD, PhD, et al. A Randomized Trial of Intensive Versus Standard Systolic Blood Pressure Control on Brain Structure: Results from SPRINT MIND MRI. Funder(s): U.S. National Institutes of Health, including the National Heart, Lung and Blood Institute, National Institute of Diabetes and Digestive and Kidney Diseases, National Institute on Aging, and National Institute of Neurological Disorders and Stroke; U.S. Department of Veterans Affairs.
- Harald Hampel, Prof., MD, PhD, et al. Full Genomic Analysis of ANAVEX®2-73 Phase 2a Alzheimer's Disease Study Identifies Biomarkers Enabling Targeted Therapy and a Precision Medicine Approach. Funder: Anavex Life Sciences Corp.
- Harald Hampel, Prof., MD, PhD, et al. Systematic Processing of Full Genomic Analysis of ANAVEX®2-73 Phase 2a Alzheimer's Disease Study Identifies Biomarkers Enabling a Precision Medicine Approach. Funder: Anavex Life Sciences Corp.

Proposal ID: DT-02-02
Weds., July 25, 2018, 4:30 pm

A Randomized Trial of Intensive Versus Standard Systolic Blood Pressure Control and the Risk of Mild Cognitive Impairment and Dementia: Results from SPRINT MIND

Background: Proven treatments for reducing the risk of mild cognitive impairment (MCI) and dementia are lacking. The impact of intensive treatment of hypertension on brain health remains uncertain. Our objective was to evaluate the effect of intensive blood pressure control to a target systolic blood pressure of <120 mmHg versus a standard target (<140 mmHg) on the risk of MCI and probable dementia in hypertensive older adults and increased cardiovascular risk but without diabetes.

Methods: Participants in the Systolic Blood Pressure Intervention Trial (SPRINT, n=9,361) were randomized to a SBP target of <120 mmHg (intensive treatment) versus <140 mmHg (standard treatment). The primary outcome was incident probable dementia. Secondary outcomes included MCI and a composite outcome of MCI or probable dementia. Each outcome was adjudicated by an expert panel blinded to treatment group.

Results: Recruitment began 10/20/2010. At one year, mean systolic blood pressure was 121.4 mmHg in the intensive-treatment group and 136.2 mmHg in the standard treatment group. Treatment was stopped on 8/20/2015 due to cardiovascular disease (CVD) benefit after a median follow up of 3.26 years, but cognitive assessment continued until 6/29/2018. Participant mean age was 67.9 years (35.6% women) and 8,626 (92.1%) completed at least one follow-up cognitive assessment.

There was a significantly lower rate of adjudicated incident MCI (HR = 0.81, 95% CI: 0.70 to 0.95, p=0.01) and a non-significant reduction in probable dementia (HR = 0.83, 95% CI: 0.67 to 1.04, p=0.10). The combined outcome of MCI plus probable all cause dementia was significantly lower (HR = 0.85, 95% CI: 0.74 to 0.97, p=0.02) in the intensive versus standard treatment group.

Conclusions: Among ambulatory adults at increased risk for CVD but without diabetes, treating to a SBP target <120 mmHg compared to a target of <140 mmHg reduces the risk of MCI, the combination of MCI/probable dementia, but not probable dementia alone.

TRIAL REGISTRATION: clinicaltrials.gov Identifier: NCT01206062

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Proposal ID: DT-02-03
Weds., July 25, 2018, 4:45 pm

A Randomized Trial of Intensive Versus Standard Systolic Blood Pressure Control on Brain Structure: Results from SPRINT MIND MRI

Background: Proven treatments for reducing the risk of mild cognitive impairment (MCI) and dementia are lacking. The impact of intensive treatment of hypertension on brain health remains uncertain. Our objective was to evaluate the effect of intensive blood pressure control to a target systolic blood pressure (SBP) of <120 mmHg versus a standard target (<140 mmHg) on brain structure in hypertensive older adults with increased cardiovascular risk but without diabetes.

Methods: 673 participants in the Systolic Blood Pressure Intervention Trial (SPRINT) were recruited for brain magnetic resonance imaging (MRI). Randomization to a SBP target of <120 mmHg (intensive treatment) versus <140 mmHg (standard treatment). Primary outcomes included change in total white matter lesion (WML) volume and total brain volume (TBV).

Results: Recruitment began 10/20/2010. With follow-up until the decision to stop the SPRINT intervention due to cardiovascular disease (CVD) benefit (8/20/2015), SBP averaged 120.7 mmHg in the intensive treatment group and 134.9 mmHg in the standard treatment group (mean difference = 14.2 mmHg, 95% CI: 13.1 to 15.3 mmHg). Follow-up MRIs were obtained for 454 (67.4%) participants at a median of 3.98 years post-randomization. In the intensive treatment group, WML volume increased by 0.28 cm3 (95% CI: -0.03 to 0.58) compared to 0.92 cm3 (95% CI: 0.59 to 1.24) in the standard treatment group (mean difference = 0.64 cm3, p=0.004). TBV decreased by 27.3 cm3 (95% CI: 24.8 to 29.8) in the intensive treatment group versus 24.8 (95% CI: 22.0 to 27.5) in the standard treatment group (mean difference = 2.54 cm3, p=0.16). Sensitivity analyses using multiple imputation did not appreciably alter these results.

Conclusions: Among ambulatory adults at increased risk for CVD but without diabetes, treating to a SBP target <120 mmHg, compared to treating to a target of <140 mmHg, resulted in significantly lower increases in cerebral WML, and no significant difference by treatment group in total brain volume change.

TRIAL REGISTRATION: clinicaltrials.gov Identifier: NCT01206062

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Proposal ID: P4-206
[Posters Wed] Developing Topics: Poster Presentations, 9:30 am

Full Genomic Analysis of ANAVEX®2-73 Phase 2a Alzheimer's Disease Study Identifies Biomarkers Enabling Targeted Therapy and a Precision Medicine Approach

Background: ANAVEX®2-73, a selective sigma-1 receptor agonist was studied in a Phase 2a trial with 32 mild-to-moderate Alzheimer's disease patients for 57 weeks. MMSE baseline range was 16-28. ANAVEX®2-73 demonstrated a favorable safety profile. An ANAVEX®2-73 concentration-response relation was observed using exploratory endpoints MMSE (Mini-Mental State Examination) and ADCS-ADL (Alzheimer's Disease Co-operative Study – Activities of Daily Living).

Methods: The full exome (DNA) and transcriptome (RNA) of attainable AD patients were sequenced using Illumina HiSeq 2500 with an average sequencing depth of 70x, resulting in the analysis of 33,311 genes and 860 pathways, using non-linear rule based Formal Concept Analysis as implemented in KEM.

Results: Systematic analysis identifies several genetic variants impacting the response including SIGMAR1(rs1800866), ANAVEX®2-73 putative target, and COMT(rs113895332/rs61143203), a gene involved in memory function. Excluding these variants from the study population, still leaving about 80% of the population, results in improved MMSE and ADCS-ADL scores ($p<0.05$, Cohen's d effect size >0.5 and Specificity=100%). In addition, we observe that high RNA expression levels for SIGMAR1 are associated with improved outcome as measured by MMSE and ADCS-ADL. Including patients with milder disease stage (baseline MMSE $\geq$20) and the exclusion of AD patients carrying SIGMAR1 mutation results in a score improvement of 1.7 MMSE and 3.9 ADCS-ADL, respectively at week 57. The additional exclusion of the COMT mutation results in a score improvement of 2.0 MMSE and 4.9 ADCS-ADL, respectively for the same period. Both effects would be clinically meaningful.

Conclusions: This is the first full genomic analysis of ANAVEX®2-73 in AD patients resulting in the identification of actionable genetic variants. Consistent results were found using both DNA and RNA and multiple endpoints and time points. The data provides support to further precision medicine clinical development of ANAVEX®2-73 utilizing genetic biomarkers leading to a pre-specified population, who demonstrated a confirmed response with ANAVEX®2-73. Further larger clinical studies in several indications are planned or underway. Detailed results will be presented at the conference.

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Proposal ID: DT-02-05
Wednesday, July 25, 2018, 5:15 pm

Systematic Processing of Full Genomic Analysis of ANAVEX®2-73 Phase 2a Alzheimer's Disease Study Identifies Biomarkers Enabling a Precision Medicine Approach

Background: The selective sigma-1 receptor agonist ANAVEX®2-73 was studied in a 57-week Phase 2a with 32 mild-to-moderate AD patients. This study showed favorable safety profile and concentration-response relationship using cognitive (MMSE) and functional (ADCS-ADL) endpoints. Delta MMSE and ADCS-ADL were calculated for the difference between values collected at week 57 and baseline. All 21 patients in a 104-week extension study agreed to full exome (DNA) and transcriptome (RNA) sequencing.

Methods: Blood samples were collected with Paxgene tubes. Next-generation sequencing was run at Eurofins Genomics. RNA strand-specific libraries were created with commercially available kits (TruSeq Stranded mRNA Library Prep Kit, Illumina). PolyA-RNA was extracted from total RNA (oligo dT-bead based method). First-strand and dUTP-based second strand synthesis was after fragmentation of the mRNA, followed by end-repair, A-tailing, ligation of the indexed Illumina Adapter, and digestion of the dUTP-strand. A bead-based method was used for size selection. After PCR amplification, resulting fragments were processed and used for cluster generation. Library generation was with Agilent SureSelectXT Reagent Kit for 200ng starting material. Enrichment was with Agilent's SureSelect Exome V6+UTR Capture Library Kit. Pooled libraries cluster generation was on the cBot (Illumina). Paired-end sequencing with 100bp read length was on a HiSeq2500 (HiSeq Control Software 2.2.58) with HiSeq Flow Cell v4 and TruSeq SBS Kit v4. Raw data was processed with RTA version 1.18.64. FASTQ-files were generated with CASAVA 1.8.4. Reads were mapped to reference sequence(s) (GRCh37.p13). BAM and BAI files (Binary Sequence Alignment/Map and Index) were generated with mapping statistics. Mapping and variant analysis (BWA/GATK) followed by complete SNP/InDel positions and variant statistics, and variant annotation and comparison, with dbSNP.

Results: A total of 33,311 genes and 860 pathways were identified in AD patient sequences. Systematic analysis showed several response-linked gene variants, including SIGMAR1 (rs1800866), ANAVEX®2-73 putative target, and COMT (rs113895332/rs61143203), a gene involved in memory function.

Conclusions: This genomic analysis of ANAVEX®2-73-treated AD patients identified actionable genetic variants, and support enrichment with genetic biomarkers in the clinical development of ANAVEX®2-73. These mutations are found at frequencies of approx. 20%. If patients with these are excluded, clinically meaningful effects on cognition and function would be expected on the remaining AD population (approx. 80%).

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