

the Lawton Index (basic and instrumental activities of daily living). A comparative analysis between patients' groups (with and without DM) was performed using the Mann-Whitney and Chi-Square tests.

Results: The final sample included 202 older adults (99 diabetics and 101 non-diabetics), with a mean age of 77 (± 7) years, mostly (69.8%) women. Comparing the patients with and without DM, the first group had more dyslipidemia (97% vs. 62.1%, $p < 0.001$) and osteoporosis (97% vs. 67%; $p < 0.001$), as well as more comorbidities (6 vs. 5; $p < 0.001$) and daily medication (9 vs. 7; $p < 0.001$). Moreover, DM patients had more cognitive impairment (52.5% vs. 34.0%; $p = 0.008$) and greater dependence on instrumental activities of daily living (57.6% vs. 37.6%; $p = 0.009$). A tendency was found regarding the presence of a caregiver for those with diabetes (75.8% vs. 63.1%; $p = 0.051$).

Conclusion: Patients with diabetes had more associated diseases and prescribed medicines, presented more cognitive impairment, greater dependence on instrumental activities of daily living, and were more likely to have a caregiver. This study will contribute to a better knowledge about the clinical and psychosocial characterization of older adults with DM in a specific context, allowing the development of future care plans and the adoption of better strategies for this group's specificities.

P170: Safety and Tolerability of Brexpiprazole for the Treatment of Agitation in Alzheimer's Dementia: Pooled Results From Three Phase III Trials

Authors: Anja Farovik, Maia Miguelez, Daniel Lee, Mary Slomkowski, Nanco Hefting, Dalei Chen, Klaus Larsen, Eva Kohegyi, Mary Hobart, Alpesh Shah, Alvin Estilo, Moeen Panni, Pedro Such, George T. Grossberg

Objective: Agitation in Alzheimer's dementia (AAD) is prevalent, distressing, and burdensome. Medications for agitation are commonly prescribed off-label, although use is hindered by safety and tolerability concerns. This pooled analysis evaluates the safety and tolerability of brexpiprazole in patients with AAD.

Methods: Data were pooled from three Phase 3, 12-week, placebo-controlled trials (NCT01862640, NCT01922258, NCT03548584) (overall, and by brexpiprazole dose). The primary objective of each trial was to assess the efficacy of brexpiprazole on agitation. Safety was a secondary objective.

Results: 658 patients were randomized to brexpiprazole (0.5–3 mg/day, depending on the trial; $n = 655$ treated), and 389 patients were randomized to placebo ($n = 388$ treated). Mean baseline age was 73.5–74.2 years, and mean time since diagnosis of Alzheimer's disease was 28.2–35.6 months. The pooled incidence of treatment-emergent adverse events (TEAEs) was 51.1% with brexpiprazole, with no notable differences between doses, and 45.9% with placebo. The incidence of serious TEAEs was 6.4% (brexpiprazole) versus 4.1% (placebo), and the incidence of TEAEs leading to discontinuation was 6.3% versus 3.4%, respectively. TEAEs that occurred in $\geq 2\%$ of patients receiving brexpiprazole and more than in placebo-treated patients were insomnia (3.7% versus 2.8%), somnolence (3.4% versus 1.8%), nasopharyngitis (2.7% versus 2.6%), and urinary tract infection (2.6% versus 1.5%). Other TEAEs of interest included falls (1.7% versus 2.6%) and sedation (0.3% versus 0.0%). TEAE categories of interest included extrapyramidal symptom (EPS)-related TEAEs (5.3% versus 3.1%), cardiovascular TEAEs (3.7% versus 2.3%), and cerebrovascular TEAEs (0.5% versus 0.3%). The mean change from baseline to last visit in Mini-Mental State Examination score was 0.21 (brexpiprazole) and 0.14 (placebo). Six patients receiving brexpiprazole (0.9%) and one patient receiving placebo (0.3%) died; none of the deaths was considered related to brexpiprazole.

Conclusion: Based on pooled data, brexpiprazole was well tolerated in patients with AAD, and had a clinical safety profile consistent with that of brexpiprazole in other indications. Patients receiving brexpiprazole had a similar incidence of sedation, EPS events, falls, cardiovascular events, and cerebrovascular events compared with placebo, and no worsening of cognition. The incidence of death was low, and no deaths were considered related to study treatment.

P171: Identifying pre-agitation biometric signature in dementia patients: A feasibility study

Authors: Samira Choudhury, Abeer Badawi, Mervin Blair, Sarah Elmi, Khalid Elgazzar, Amer M. Burhan

Objectives: Agitation and aggression (AA) occur frequently in patients with dementia (PwD), are challenging to manage, and are distressing for PwD, families, caregivers, and healthcare systems. Physiological parameters, such as Actigraphy, Heart Rate Variability, and Electrodermal Activity, measured via wearable sensors are correlated with AA in PwD. It is unclear whether these parameters could be compiled into an operational algorithm to create a pre-agitation biometric marker (i.e. parameters of Autonomous Nervous System's arousal: elevated EDA, more frequent HR, lower heart rate variability (HRV), as well as higher motor activity) capable of predicting episodes of AA. This study will assess the feasibility and clinical utility of collecting physiological parameters via wearable multi-sensor Empatica E4 device in relation to clinically recorded episodes of AA in PwD.

Methods: This study is leveraging a clinical trial (ClinicalTrials.gov/NCT04516057) taking place at Ontario Shores Centre for Mental Health Sciences. Participants are inpatients, males and females, 55-years old or older, with clinically significant AA, and a diagnosis of a Major Neurocognitive Disorder due to Alzheimer's disease or multiple aetiologies. Participants wear the E4 device for 48 to 72 hours on three occasions during the 8-week study period. Participant demographics, and clinical measures used to assess behavior are collected at specific time intervals during the study period.

Results: The study is ongoing and currently to-date we have been able to acquire approximately 240 hours of recordings from patients. We will be presenting feasibility data (proportion of participants successfully completing a minimum 48-hours of recordings), correlation analysis between physiological measures and clinical measures to identify pre-agitation triggers. Further, we will use generalized linear models to test whether physiological measures can predict pre-agitation triggers. This study will allow estimation of sample size needed to detect a meaningful effect size, which will be determined from the prediction model. Deep learning using Python will be used to create a predictive algorithm using the physiological data to profile participants' behaviors and detect pre-agitation triggers.

Conclusion: Early detection of AA in PwD will allow caregivers to offer timely, 260ndividualized, non-medical or medical interventions which will help avoid crises and critical incidents and improve quality of life of the PwD and their caregivers.

P174: Project Connect 80+

Authors: Sergio Alexandre Alfonso Silguero, Enrique Arriola Manchola, Leticia Crespo, Yadira Bardales Mas, Kevin O'hara Ventimilla, Petra Peña Labour, Arlovia Herasme Gullón

Introduction: -Patients with a memory deficit, as well as patients with small deficits in various cognitive areas, with the requirement that there is no functional impairment in their domestic or work life, do not meet the