OP142 Progression Analysis Versus Traditional Methods To Quantify Slowing Of Disease Progression In Alzheimer's Disease

Linus Jönsson, Milana Ivkovic (mqiv@novonordisk.com), Ron Handels, Anders Gustavsson, Teresa León, Julie Hviid Hahn-Pedersen and Lars Lau Raket

Introduction: New statistical methodology, known as progression models for repeated measures (PMRM), can estimate the slowing of progression (percentage slowing or time delay) of Alzheimer's disease from trial data on disease-modifying therapies. We compared the PMRM methodology with mixed models for repeated measures (MMRM) and Cox time-to-event analysis on simulated trial data with respect to their power and interpretability of estimates.

Methods: Two novel models were included: PMRM (estimating slowing of progression and allowing different rates across visits) and proportional-slowing PMRM. Clinical Dementia Rating (CDR) Sum of Boxes score and progression to dementia as assessed by CDR global score were the primary outcomes for MMRM/PMRM and the Cox model, respectively. Subject-level placebo arm trajectories were jointly simulated based on estimated CDR mean trajectories and joint temporal correlation structure of 538 amyloid-positive patients with mild cognitive impairment who met typical disease-modifying trial inclusion criteria from the Alzheimer's Disease Neuroimaging Initiative study. Active arm trajectories were simulated to show an average 20 percent slowing of disease progression, compared with placebo, at each visit. We conducted 1,000 simulations across multiple scenarios, varying the number of patients per arm (200 to 700) and clinical trial duration (18 to 36 months).

Results: The power of PMRM models was greater than that of MMRM, and much greater than that of the Cox model whose power never exceeded 45 percent. PMRM models accurately estimated the underlying treatment effect (median 20% slowed progression, which translated to a delay in progression of 5 and 7 months at trial durations of 24 and 36 months, respectively), unlike quantifications of the MMRM (median estimated 25% reduction in decline), and the Cox model (median estimated hazard ratio of 0.9).

Conclusions: For disease-modifying therapies, PMRM estimates may have a more intuitive clinical interpretation in terms of delayed progression than MMRM or Cox models and enable a description of the amount of time spent in less severe disease stages. Among all the methods studied, PMRM offered the best combination of interpretability and power.

OP143 Association Of Different Venous Access Device With Health-Related Quality Of Life Among Patients With Breast Cancer In China

Liu Liu (20111020056@fudan.edu.cn), Zhiyuan Xia, Yingyao Chen and Shimeng Liu

Introduction: Few studies have explored the relationship between different venous access devices and health-related quality of life (HRQoL) among patients with breast cancer in China. This study aimed to evaluate the HRQoL of patients with breast cancer in China who underwent different venous access devices and to estimate the association between type of venous access device and HRQoL.

Methods: A multicenter cross-sectional study was conducted in three tertiary hospitals from three major geographical regions in China. The final sample consisted of 472 patients aged from 18 to 78 years. The HRQoL was measured with the EQ-5D-5L scale and the EuroQoL Group visual analog scale. The venous access devices were divided into totally implantable venous access devices (TIVAD), peripherally inserted central catheters (PICC), and other devices. The multivariate regression analyses were used to explore the association between type of venous access device and HRQoL.

Results: Of 472 participants, 352 (75%) used the TIVAD device, 89 (19%) used the PICC device, and 31 (7%) used other devices. The TIVAD group had the highest EQ-5D-5L values (mean 0.89, standard deviation [SD] 0.178), while the PICC group had the lowest values (mean 0.85, SD 0.239). The EQ-5D-5L values for the other venous access device group was in between (mean 0.88, SD 0.127). However, the multivariate analysis indicated that the VAS and EQ-5D-5L scale dimension scores among patients were not significantly different (P>0.05) for the various central venous access devices.

Conclusions: This study demonstrates a non-significant association between the type of venous access device used and the HRQoL of patients with breast cancer in China. Although patients with a TIVAD experienced more pain during device insertion and access for chemotherapy, the negative effect on HRQoL scores was smaller than for PICCs.

OP144 Impact Of A Training Program For The General Population On Knowledge Of Aortic Valve Stenosis

Carla Fernández-Barceló (cafernandez@clinic.cat), Bàrbara Vidal, Ismail Abbas, Paloma Gonzalez, Marc Trilla, Marta Sitges Carreño and Laura Sampietro-Colom