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The Burden of Therapy©* [BOTh©*] - A novel method to evaluate the impact of therapeutic agents on patient safety

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BOTh analyses daily patient safety in a clinical study. It provides a more accurate reflection of the burden of treatment than current safety methods and facilitate informed treatment selection. Patient-level safety data was utilized to quantify the daily burden of adverse events by severity on a per patient and per day basis, and presented using a chart. Data from two published studies in peripheral neuropathic pain (PNP) and overactive bladder (OAB) were utilized. In the PNP study, the overall BOTh graph showed a difference in AEs in the two treatment groups. The topical TRPV1 agonist group showed an initial peak followed by a rapid decline in AEs per day, due primarily to transient application site reactions. The oral anticonvulsant group, showed a gradual increase, followed by a consistent number of AEs to the the study end. The overall burden (area under the curve) was 61.2 for the oral anticonvulsant and 23.5 for the topical TRPV1 agonist (p<0.0001). The integration of safety and efficacy into the graph allowed the safety burden comparison with the median time to treatment response. In the OAB study, the overall burden were similar between the two groups. An analysis of patients with dry mouth revealed that more patients reported it in the antimuscarinic group p=0.02. BOTh provides visual representation and statistical analyses of the burden of medication in individual patients or subgroups combining tolerability and efficacy. BOTh allows sensitive, clinically relevant analysis than current methods, which show an overall summary not reporting pateints with more than one AE over time.

Biography

Ayad K Abdul-Ahad continued his speciality training in the UK in Immunology and Oncology after obtaining his medical degree. He obtained PhD, MSc, MRCPath and FRCPath. His areas of interest included Immunotherapy and BMT. Over the past 24 years, he worked in the Biopharmaceutical industry, across the US and Europe, during which he built and lead Medical Affairs and Clinical Development in companies, such as Serono, Berlex, Biogen and Astellas. He also pioneered cancer immunotherapy by treating the first ever patient with a therapeutic antibody for cancer. He is regarded as a Medical Leader by the world leading experts in MS.

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Notes:

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