Poster Presentations

PP02 Is Glycated Hemoglobin A Valid Surrogate Endpoint To Evaluate The Effectiveness Of Drugs In Diabetes Mellitus Studies?

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Introduction. In the field of drug development and effectiveness evaluation, the use of surrogate endpoints is acceptable if they reliably predict a positive effect on clinical outcomes such as mortality or morbidity. Hemoglobin A1c (HbA1c) is a widely used surrogate endpoint in phase 3 and 4 clinical trials evaluating drugs in patients with diabetes mellitus (DM). The objective of this study was to investigate whether HbA1c is a valid surrogate endpoint for evaluating the effectiveness of antihyperglycemic drugs in DM trials.
Methods. We conducted a systematic review of randomized placebo-controlled trials evaluating the effect of a treatment on levels of HbA1c and clinical outcomes in patients with DM. The association between the effects of treatment on HbA1c levels and clinical outcomes was then investigated using regression analysis at the trial level. The correlation coefficients (R) were interpreted using the cut-off points suggested by the German Institute for Quality and Efficiency in Health Care (IQWiG). HbA1c was considered a valid surrogate endpoint if it demonstrated a strong association with clinical outcomes (i.e., the lower limit of the 95% confidence interval [CI] of $R \geq 0.85$).
Results. Nineteen phase 3 or 4 randomized controlled trials (RCTs) were identified. All studies included adults with type 2 DM. None of the associations evaluated was strong enough to validate HbA1c as a surrogate endpoint for any clinical outcome: mortality (R 0.34, 95% CI: -0.14, 0.69); myocardial infarction (R 0.20, 95% CI: -0.30, 0.61); heart failure (R 0.08, 95% CI: -0.40, 0.53); kidney injury (R -0.04, 95% CI: -0.52, 0.47); and stroke (R 0.81, 95% CI: 0.54, 0.93).
Conclusions. The evidence from multiple placebo-controlled RCTs of antihyperglycemic drugs in patients with type 2 DM suggests that a reduction in levels of HbA1c does not meet the IQWiG criteria for a valid surrogate endpoint. Consequently, the risk-benefit ratio of antihyperglycemic drugs in terms of patient relevant clinical outcomes, regardless of their hypoglycemic effect, should be the focus of therapeutic, regulatory, and reimbursement decisions.

PP03 Early Assessment Of Video Consultations In Rehabilitation After Hand Injury

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Introduction. With the aim of reducing patient travel and related costs, physiotherapists and occupational therapists at the Oslo University Hospital began offering video consultations to patients with hand and arm injuries in March 2020. A feasibility study was initiated to describe the first year of using video consultations in the rehabilitation of upper extremity injuries in children and adults, and to assess the acceptability of the service from the perspective of hand therapists. The secondary objective of the study was to investigate the economic effects of using video consultation for this patient group.
Methods. The therapists documented the individual consultations in an Excel spreadsheet. Utility and acceptability were analyzed based on the content of each video consultation. The therapists also registered the patient's municipality in order to calculate costs related to travel, accommodation, and other costs related to in-person consultation. Utility was analyzed using an early economic model based on scenario analysis to compare the costs of video consultations with in-person consultations.
Results. Based on the content analysis from 89 consultations, video consultations were deemed acceptable by the therapists. The total travel distance from patients' homes to the hospital was 20,190 km, as hand rehabilitation is a national service. The video consultations that replaced the consultations at the hospital were potentially more time efficient, reduced patients' travel time and absence from home and work, and saved costs for the Oslo University Hospital and society.
Conclusions. Based on early decision support provided by this study, adaptions were made to the delivery of video consultations to improve the cost effectiveness of the service. The findings from this study provided an indication of the potential value of the new service, which may be used for benchmarking purposes to ensure that it meets the needs of users, the health service, and society.

PP04 Supporting The Social Integration Of Persons With Brain Injury Using Psychoactive Substances: A Health Technology And Intervention Assessment

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Introduction. People with a traumatic brain injury and who present with an unsafe or problematic substance use of psychoactive substances (PAS) face specific challenges in social integration resulting from the negative impacts of substance use on the benefits of rehabilitation services and treatments.
Methods. A systematic review of grey and scientific literature was conducted. The selection and coding of the included interventions (according to their characteristics), as well as descriptive analyses, resulted in findings which describe the interventions under study. Grades of evidence strength were attributed to the findings based on a range of factors including the methodological characteristics of the

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