Poster Presentations

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

Paola Andrea Rivera (p_rivera_ramirez@hotmail.com) and Fabián Fiestas

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

Linn Nathalie Støme (linast@ous-hf.no), Tone Vaksvik, Christian Ringnes Wilhelmsen and Kari Jorunn Kværner

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

Christine Maltais (christine.maltais.ccsmtl@ssss.gouv.qc.ca), Akram Djouini, Frédéric Messier, Karine Bélanger, Nadia Lespérance and Élaine Deguise

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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studies. Findings resulting from the systematic review were contextualized with information collected from administrative databases, clinical program documentation, and experiential data obtained from rehabilitation professionals. Recommendations were elaborated based on the aggregated data sources and informal deliberations by a committee involving researchers and clinicians.

Results. Out of 5014 selected references, 14 studies examining 13 interventions which targeted social integration of the management of PAS were included. Interventions with the strongest evidence base are user-centered (i.e., support individual choices and personal autonomy), individualized (i.e., considered individual needs and characteristics), and educational (i.e., support the acquisition of strategies and abilities). The evidence base was considered "emerging" for interventions which are systemic in nature (i.e., relate to familial, social, cultural, educational or professional environments), interdisciplinary (i.e., involve clinicians with distinct training, competences and expertise), and ecological (i.e., which involve interventions in the client's living settings). While additional research is necessary to better support their efficacy, these interventions exhibited promising effects on various outcomes.

Conclusions. The analysis and synthesis of three streams of information resulted in five clinical practice recommendations relating to integration to school and productive activities, psychological adaptation, integration in living settings and independence, social life and sense of belonging, and finally, use of PAS. Recommendations should help support clinicians in rehabilitation settings.

PP05 Effect Modifiers In Indirect Treatment Comparisons: Guidance Is Needed To Ensure An Unbiased Identification In Decision-Making

Andreas Freitag (andreas.freitag@cytel.com), Laura Gurskyte, Maria Rizzo and Grammati Sarri

Introduction. Unadjusted effect modifiers (EM) in indirect treatment comparisons (ITC) can produce biased and uncertain results in health technology assessments (HTA). Even though research on advanced ITC methods to adjust for EMs has attracted much attention, less emphasis has been placed on how these EMs are identified and assessed in the first place. This is surprising given the evidence-based approach underpinning all analyses supporting HTAs. To address this gap, our aim was to identify what HTA guidance exists on the selection process for EMs, and how the selection of EMs has been justified in the context of published ITCs.

Methods. A pragmatic review of HTA guidance documents was conducted in 2021 to describe current requirements for the selection of EMs for ITCs. A supplementary Embase and Medline search was conducted to identify primary research on ITCs published between 2015-2021 presenting information on how EMs were selected to inform these analyses.

Results. Our review found that guidance on this topic focusses on developing and testing different methodologies to adjust for EMs. No detailed guidance was identified in any of the reviewed HTAs, although the National Institute for Health and Care Excellence (NICE) briefly mentioned that companies should identify EMs through a topical review or expert discussions. Similar findings were also revealed through the database search; few published ITCs included information on the EM selection process which was either based on evidence highlighted in the literature or findings from prior trial subgroup analyses. No reference to a systematic identification of EMs was found.

Conclusions. To fill the guidance gap identified in our review an extension of current ITC guidelines (including those from HTA bodies) is needed, including (i) indication on how EMs should be identified through systematic reviews, (ii) a quantitative assessment of the EM distribution and (iii) formal expert elicitation prior to the selection of ITC methods. Without these additional steps, ITC results may be biased, potentially negatively impacting decision-making and ultimately patient care.

PP06 Clinical Effectiveness Of Fluticasone Furoate Nasal Spray For Perennial Allergic Rhinitis In Children: A Systematic Review And Meta-Analysis

Paola Andrea Rivera (p_rivera_ramirez@hotmail.com)

Introduction. Although previous studies suggest that fluticasone furoate nasal spray (FFNS) is superior to placebo in reducing symptoms in adolescents and adults with allergic rhinitis (AR), there is still uncertainty about its clinical effectiveness in the pediatric population. The aim of this study was to assess the clinical effectiveness of FFNS, compared with placebo, in reducing nasal symptoms in children with perennial AR.

Methods. A systematic review was conducted of studies identified from the MEDLINE and Embase databases that were published up to January 2021. The population of interest was patients aged 2 to 12 years with perennial AR. Included studies were limited to randomized controlled trials (RCTs) comparing FFNS (110 µg once daily) with placebo. The outcomes of interest included the reflective Total Nasal Symptom Score (rTNSS) and safety. Meta-analyses were performed using RevMan 5.4. The Cohen's guideline was used to assess the minimum clinically important difference for rTNSS; that is, if the pooled standardized mean difference (SMD) and the lower limit of the 95 percent confidence interval (CI) exceed -0.5, the treatment effect was considered clinically significant.

Results. Three RCTs (959 pediatric patients) were included. One study evaluated the short-term use of FFNS, one evaluated the long-term use of FFNS, and the third evaluated both the short- and long-term use of FFNS. FFNS produced a statistically significant reduction in rTNSS (SMD -0.35, 95% CI -0.63, -0.08; $p<0.001$) relative to placebo in the long-term treatment studies, but not in the short-term studies. However, since the mean reduction did not reach the minimum clinically important difference (SMD -0.5), these results

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