ReSEARCH ON METHODS – Patient-Reported Outcomes Studies

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RESEARCH ON METHODS – Patient-Reported Outcomes Studies

their disease stage. The methodological framework here presented uses prevalent cohort data to reconstruct stage-specific survival rates, as they would be if obtained from an incident cohort. METHODS: This approach assumes identical precursors and, under certain conditions, can be generalized to non-proportional hazards. Through a piece-wise back calculation approach recent survival data are fed and integrated into the model to calculate survival at earlier time points. As an example, this allows the construction of the probability as a function of the time elapsed from the onset of illness. This method is then generalized to allow comparison between ‘placebo’ and ‘treatment’ prevalent-cohorts. RESULTS: The method is very general and can be applied to any scenario. As an example, the only published data on an untreated tuberculosis prevalent cohort is used to infer the actual mortality rates of untreated tuberculosis through the course of the illness. The results show that mortality among hospitalizations for the first two years of illness, declining dramatically immediately after and increasing again to intermediate rates after one year, suggesting population heterogeneity with respect to the risk of dying from tuberculosis.

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outcomes. METHODS: Nine clinicians and 43 patients with linear surgical scars participated in a photograph sorting exercise. Patients sorted approximately 50 scar photographs consistent with their own skin type (light, medium or dark skin), without previously trained all the skin types photographs (n=151) to select photographs (n=51). All participants arranged the photographs into 5 categories of perceived scar severity (least to most severe) and 5 photographs were considered for inclusion in the consensus. Based on analysis of inter-rater reliability, consistency, redundancy, and variability. When photographs yielded similar results, clinical judgment was used to select the best photo. Instruction and response dichotomized for the 5 scar photographs and the final guide was cognitively debriefed for relevance, comprehensibility, and acceptability in 24 additional scar patients. RESULTS: Based on the pre-specified criteria for inclusion and exclusion, 5 light skin and 5 dark skin photographs were included in the guide. A "medium" guide was not developed because of significant overlap between it and the light skin guide rendering it superfluous. Inter-rater reliability of the 52 subject cohort was strong (0.95±0.06) across all groups. The photographs in the final guide demonstrated goodness-of-fit (infit mean-square < 1.4 and > 0.6), low variance in severity ratings (SD < one category change), and strong agreement between patients and clinicians. CONCLUSIONS: The Patient and Clinician Reported Scar Severity Scales were systematically developed to easily assess scar severity outcomes in clinical trials. Continued psychometric evaluation of the guide is planned to ensure the scales meet regulatory standards for labeling purposes.

FRM107 MAPPING RELATIONSHIPS AMONG PAIN DESCRIPTORS USED BY PATIENTS: EVIDENCE FROM QUALITATIVE INTERVIEWS IN FOUR CHRONIC PAIN CONDITIONS

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OBJECTIVES: To describe how pain descriptors are used to represent patients' pain experiences by mapping word clusters identified by patients as synonyms for the same pain sensation. METHODS: Subjects were recruited by web posting and telephone screening. Those self-reporting current pharmacological treatment for Migraine, Low Back Pain (LBP), Osteoarthritis (OA), or Rheumatoid Arthritis (RA) were enrolled and completed in-person interviews using card sort exercises with 93 different pain descriptors. Subjects were asked to identify the descriptors they commonly used to describe their pain associated with their condition, and to isolate any pairs of words that describe the same pain sensation ("linked" descriptors). Network maps that diagrammed subject-identified linked descriptors were created for each condition. Scranion N etdraw (Borgatti 2002) and compared. RESULTS: The 72 subjects ranged in age between 19 and 84 years (mean=45). Sixty-eight percent were female, 63% were working full- or part-time, and 61% were Caucasian. OA and Migraine subjects used more synonyms to describe similar pain experiences (14% and 10% of all linked synonyms, respectively) than the LBP and RA groups (at 7% and 6%). For Migraine, most linked descriptors formed a single group of connections, or single integrated relationship. For the OA group, several smaller, lower linked nodes and indegree QoD were found. Some synonyms were common to all four groups (e.g., STIFFNESS-TIGHTNESS), but others were condition-specific (e.g., SPREADING-RADIATING for OA, but SPREADING-SPREAD for Migraine). CONCLUSIONS: While some descriptors were condition-specific, others linked descriptors' synonyms varied by condition, demonstrating condition-specific meaning. These findings emphasize the importance of tailoring item language to the specific population of interest when assessing pain with PRO instruments.

FRM108 CONSTRUCT VALIDITY OF THE SF-12 IN TYPE-1 DIABETES

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OBJECTIVES: To assess the construct validity of the Short Form-12 (SF-12) in type-1 diabetes (T1D). METHODS: This analysis used data from a study investigating factors affecting setting and attainment of HbA1c targets. A total of 1,918 patients were recruited from the T1D exchange registry and completed a web-based survey. 1,866 patients reliably linked the SF-12 to another descriptor. The physical component score (PCS) and the mental component score (MCS) from SF-12 were compared between known groups. The known groups were defined by treatment intensity, duration with disease, complication, hospitalization, employment status, education, glycemic control, insurance status, and whether patients had end-stage renal disease (ESRD). PCS and MCS were compared between patients with 0- vs 13+ years of diabetes, and whether or not they had a negative correlation (r<0.07, p>0.05). Patients with depression or anxiety had lower PCS (difference: 3.5 and 3.7, p<0.05) and MCS (8.4 and 6.8, p<0.05). Patients who had hospitalization due to diabetic ketoacidosis (DKA) reported significantly lower PCS (difference: -2.8, p<0.005) and MCS (difference: -2.0, p<0.005). Probable depression was associated with lower PCS (Spearmann r=-0.05, p<0.05), but not MCS. Patients with an A1C value greater than 9% had lower PCS (2.3, p<0.05) and MCS (3.6, p<0.05). Working patients had higher PCS (4.2, p<0.05) and MCS (1.1, p<0.05). Finally, both PCS (r=-0.38, p<0.05) and MCS (r=-0.53, p<0.05) had very strong negative correlations with QoD score. CONCLUSIONS: This study contributed some evidence of construct validity of the SF-12 in patients with TID.