crossover design study. Seventy men and women with moderate to severe rosacea of the nose were included. Subjects were randomized 1:1 to either AG once daily or BG twice daily for 15 days. After a washout period, subjects were given the other treatment for 15 days. The primary efficacy endpoint was composite success defined as a 2-grade improvement in both the CEA and PSA 6 hours after application on day 1 and 2. A treatment was defined as a success if at least a 2-grade improvement in both CEA and PSA was achieved. The second endpoint was change in chromator readings 6 hours after application on day 15. All outcomes were in comparison to baseline (Day 0). RESULTS: Per the protocol, the results of the second period were not included as the study did not have treatment crossover from the first period. The percentage of subjects with composite success in period 1 was 14.3% and 5.7% for BG and AG, respectively. The percentage of subjects with a 2-grade improvement for CEA was 31.7% and 11.4% for BG and AG, respectively and 39.4% and 18.2% for PSA. The log scale (VAS) for pain, patient satisfaction, and response to treatment in period 2 was statistically significant for BG and AG, respectively. Chromator readings decreased by 9.64% and 2.38% for BG and AG, respectively. CONCLUSIONS: Improvements were larger and more pronounced with the CEAG regimen compared with the AG alone regimen. The study is the first trial that has shown the impact of rosacea severity and improvements with treatment differently than either a clinician or objective instrumentation.

PRM4

A SCORING LITERATURE REVIEW ON THE EXTERNAL VALIDITY OF RANDOMIZED CONTROLLED TRIAL POPULATIONS

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OBJECTIVES: The aim of this scoring literature review was to report the findings of studies that have attempted to quantify external validity by comparing the patient population included in randomized controlled trials (RCTs) with patients from everyday clinical practice. METHODS: We conducted a literature review of English language journals from January 2003 to present. Studies that compared RCT populations with ‘real-life’ patient population. Studies were limited to pharmaceutical interventions undertaken in adults. A protocol was developed that outlined the search approach. A random selection of 23 studies was appraised (MEDLINE, EMBASE, Scielo, Cochrane Methodology Register). Double abstract review and data extraction were performed in line with protocol specifications. RESULTS: Out of 5456 de-duplicated abstracts, there were 73 studies that met the inclusion criteria. Studies covered a range of conditions and therapies, with the majority undertaken in mental health (n=18), cardiology (n=16), and oncology (n=13). Studies either assessed the proportion of people from a clinical setting that would be eligible for an RCT or undertook a post-hoc analysis of RCT patient characteristics compared with the real-world population. A range of comparisons were made, including demographic, socioeconomic, and clinical parameters. The vast majority of studies (n=59) concluded that study selection criteria excluded many patients from clinical practice; most commented on how bias limited generalizability. A number of recommendations were made to improve the generalizability of RCTs or facilitate better understanding of their limitations. CONCLUSIONS: RCTs designed to maximize internal validity frequently result in a loss of external validity. Designers of RCTs should carefully weigh inclusion/exclusion criteria to ensure study objectives are met without unnecessarily sacrificing external validity, and the extent to which generalizability is compromised should be reported. Ultimately, a combination of explanatory and pragmatic studies is necessary to meet the diverse needs of regulators, prescribers, payers, and patients.

PRM7

ESTIMATION OF LONG-TERM CARE NEEDS FOR 9 MAJOR CANCER IN TAIWAN

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OBJECTIVES: The lifetime functional disabilities associated with cancer have never been paid a great attention in the literature. This study determines the dynamic changes of different physical functional disabilities over time and their total duration after cancer diagnosis to understand their potential long-term care needs. METHODS: A convenience sample of 6,189 measurements of patient’s functional disability with EQ-5D was collected for measuring improvement levels and care needs. Lifetime functional disabilities were obtained by extrapolating the gender and age-stratified survival functions to lifetime, and multiplying them with the proportions of different kinds of functional disability over time. RESULTS: The common core needs for cancer patients were mobility and usual activity, the older the patient, the higher the prevalence of functional disabilities and care needs; the shorter the life expectancy (IL), the higher the proportion of expected years of living with disability (LE). The percentage of subjects with 2-grade improvement in CEA and PSA are 21.7% and 14.5% for BG and AG, respectively. Chromator readings decreased by 9.64% and 2.38% for BG and AG, respectively. CONCLUSIONS: Improvements were larger and more pronounced with the CEAG regimen compared with the AG alone regimen. The study is the first trial that has shown the impact of rosacea severity and improvements with treatment differently than either a clinician or objective instrumentation.

PRM8

DIFFICULTY IN ESTABLISHING THE IMPACT OF DRUGS ON QUALITY OF LIFE IN CONVENTIONALLY IMPAIRED PATIENTS: EXAMPLE OF IPAQ (INTERNATIONAL PROSTATE SYMPTOMS QUESTIONNAIRE) IN PATIENTS WITH URINARY INCONTINENCE

Role of Utility in Patients Treated with Rifaximin-α for the Reduction of Recurrence of Episodes of Hepatic Encephalopathy

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OBJECTIVES: Hepatic encephalopathy (HE) is a serious complication of liver disease. HE presents as a spectrum of neurocognitive impairments, from mild HE to coma. Direct measurement, or derivation of utility values related to treatment using a generic QoL mapping procedure may not provide the most valid measures, given the nature of the condition. Rifaximin-α is a treatment for HE that has been shown to reduce the recurrence of HE and related hospitalization. Following an exercise using a disease specific instrument that yielded a utility difference of 0.155 units, here we attempted to indirectly estimate the utility impact of Rifaximin-α in patients following total knee arthroplasty (TKA). This systematic literature review aims to evaluate the effectiveness of home telerehabilitation in patients who underwent TKA. The evidence from this systematic literature review will hopefully demonstrate telerehabilitation to be a practical alternative to conventional face-to-face rehabilitation therapy in patients who underwent TKA.

PRM8

The Implementation of the Extract of Centaria Islandica in Patients Suffering from Ejaculation of Chronic Pharyngitis

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OBJECTIVES: The objective of this paper is to establish if the implementation of Isla lozenges influences the intensity of sore throat sensation in patients suffering from chronic pharyngitis and whether their use influences the need of antibiotic therapy administration. METHODS: The study included 60 patients with ejaculation of chronic pharyngitis who has been observed. 30 of them used Isla lozenges during 10 days /6 times a day, while the remaining 30 did not take any. According to the VAS scale (0-10 cm) the intensity of sore throat sensation was determined at the beginning of the disease and after 10 days. Also, it was determined in how many patients it was necessary to introduce antibiotic therapy. RESULTS: The average value of sore throat sensation in the initial stage in the group in which Isla lozenges were administered was 6.80, while in the group that did not take them was 6.60; p > 0.05. After ten days of trial, the average value of sore throat sensation in the group that used Isla lozenges was lower (5.90 ± 0.82) than in the group that did not take the lozenges, the average sore throat sensation was 5.90 after ten days; p > 0.05. The average values of sore throat sensation after 10 days of Isla lozenges was significantly lower than in the group that did not take any of the measures to evaluate the effectiveness to the second group, p < 0.05. The group in which Isla lozenges were given for 10 days, 5 patients needed additional antibiotic therapy, whereas it was 14 patients in the second group, p < 0.05. CONCLUSIONS: Implementation of Isla lozenges in patients with ejaculation of chronic pharyngitis significantly lowers the intensity of sore throat sensation as well as the need for antibiotic therapy administration. This research was supported by Provincial Secretariat for Science and Technological Development, Autonomous Province of Vojvodina project No 114-451-3551/2013-01.