WEIGHING TREATMENT BENEFITS AGAINST TREATMENT RISKS: CROHN’S DISEASE PATIENTS’ WILLINGNESS TO ACCEPT RISK-BENEFIT TRADEOFFS

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OBJECTIVE: Quantify Crohn’s disease (CD) patients’ maximum acceptable risk (MAR) of treatment-related serious adverse events (SAE) for improvements in daily symptom experience.

METHODS: An on-line panel of self-identified CD patients completed a series of choice-format conjoint tradeoff tasks. Patients selected between treatment alternatives with varying efficacy and risk levels. The treatment attributes included the daily symptom severity and activity limitations, the potential for serious complications (fistulas, abscesses, bowel obstructions), the time between flare-ups, oral steroid use and varying levels of SAE risks, including progressive multifocal encephalopathy (PML) death or disability, and death from serious infection or lymphoma. The questionnaire also contained items regarding demographics, disease and treatment history, and the short form of the Inflammatory Bowel Disease Questionnaire (SIBDQ). The maximum acceptable 10-year MAR was calculated for various clinical benefit levels. RESULTS: A total of 357 patients completed the survey. Improvements in daily symptom severity were the most important factor in treatment preferences. Higher MAR (greater risk acceptance) was observed for trade-off tasks involving higher levels of clinical benefit, patients with lower SIBDQ scores, and patients reporting a low level of worry about SAEs. For the PML SAE, mean MARs (SD) for an improvement from severe daily symptoms to remission and moderate daily symptoms to remission were 7.2% (0.26) and 4.7% (0.18), respectively. The lowest observed MAR for any of the three studied SAEs is well above the observed rates of SAE occurrence with natalizumab or any of the commonly used CD medications. CONCLUSIONS: Medical interventions carry risks of adverse outcomes that must be evaluated against their clinical benefits. CD patients indicated they are willing to accept a defined risk of death or disability in exchange for clinical efficacy. The patient perspective on the balance between potential benefits and risks can assist in making treatment and regulatory decisions.

A COST EFFECTIVENESS STUDY OF CARBETOCINE COMPARED TO OXYTOCIN FOR THE PREVENTION OF UTERINE ATONY IN PATIENTS WITH RISK FACTORS

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OBJECTIVE: To estimate cost-effectiveness of carbetocine compared to oxytocin in preventing uterine atony in patients with risk factors. METHODS: A randomized pragmatic clinical trial in patients with risk factors for uterine atony was performed in the Instituto Mexicano del Seguro Social (IMSS) in Mexico City. Two therapies were included: carbetocine and oxytocin. One hundred patients with fetal macrosomia, polyhydramnios, low insertion of the placenta, multiple gestation, prolonged labor, uterine myomata and chorioamnionitis were included in each group. The effectiveness was defined as the reduction of the number of patients with uterine atony. The use of resources was obtained from the clinical trial and the costs were gotten from financial information from IMSS, and are expressed in US 2006 dollars. Univariate and probabilistic sensitivity analyses were performed using Monte Carlo simulation. RESULTS: No statistically significant difference was found in general characteristics, obstetric background and risk factors distribution in both groups. Uterine atony was reported in 20% in the oxytocin group compared to 5% in the carbetocine one (p < 0.0001). Multiple gestation and fetal macrosomia were the most frequent diagnosis, 30% (p < 0.0001). Bleeding was less than 500 mL in the carbetocine group and 300 to 1000 mL in the oxytocin one (p < 0.0001). Mean cost per patient treated with carbetocine was $3468 vs. $4082 for oxytocine (p < 0.0001). Mean cost-effectiveness ratio for oxytocin was $5103, while for carbetocine $3651; ICER showed that carbetocine was dominant. Univariate analysis supported those results. A Monte Carlo microsimulation with 10,000 iterations was performed using probability distribution data from the clinical trial. The acceptability curve and health net benefits showed that carbetocine group was superior independently of WTP. CI 99% by ellipse method showed that carbetocine was dominant in 100% of cases. CONCLUSIONS: Carbetocine was the most cost-effective drug to prevent uterine atony in patients with risk factors.

THE EXCESS PREVALENCE OF COMORBIDITIES ASSOCIATED WITH ERECTILE DYSFUNCTION IN A LARGE STATE MEDICAID PROGRAM

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Erectile dysfunction (ED) affects approximately 10 million men in the US. ED has been associated with cardiovascular risk factors and depression in a managed care setting. However, similar data among Medicaid recipients is limited. OBJECTIVE: To estimate the excess prevalence of selected comorbidities in men diagnosed with ED in the California Medicaid (Medi-Cal) program. METHODS: This study employed a retrospective cross-sectional matched cohort design and administrative claims data for a 20% random sample of Medi-Cal recipients. Men selected were 18+ years of age, had a diagnosis of ED (ICD-9-CM 302.72, 607.84), or were dispensed a PDE5 inhibitor (i.e., sildenafil, tadalafil, vardenafil) between July 1, 2001 and June 30, 2002 ("study period"), and were eligible for non-capitated Medicaid-only coverage during the study period. The comparison cohort consisted of patients without ED and not dispensed a PDE5 inhibitor, matched on age, gender, and race. The excess prevalence of selected comorbidities was estimated as the ratio of proportions between the ED and comparison cohorts. RESULTS: A total of 332 patients with ED met study inclusion criteria. ED patients and their matched controls (n = 332) averaged 52 years of age; 43% were white, 18% were Asian, and 18% were African-American. Relative to matched controls, ED patients were 67% more likely to be diagnosed with hypertension, 74% more likely to be diagnosed or treated for dyslipidemia, 84% more likely to be diagnosed or treated for diabetes, and 153% more likely to be diagnosed with depression. ED patients (versus matched controls) were about two-thirds more likely to have at least one of the four conditions listed above during the study period. Prostate cancer also was 9.5 times as likely among ED patients. CONCLUSION: There appears to be higher rates of prevalence of hypertension, dyslipidemia, diabetes, depression, and prostate cancer among ED patients in the Medi-Cal program.