PSY10

A NOVEL APPROACH TO ADJUST FOR THE IMPACT ON SURVIVAL RESULTING FROM PATIENT CROSS-OVER FROM CONTROL TO EXPERIMENTAL TREATMENT IN CLINICAL TRIALS

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OBJECTIVE: Clinical trials are often the best source of efficacy data for economic evaluations of medical interventions. However, their reliability can be compromised when patients cross-over from control to experimental treatment. In two trials evaluating lenalidomide (Len) plus high-dose dexamethasone (Dex) vs Dex alone (MM-009/010) in patients with multiple myeloma (MM), 47% of patients in the Dex alone group were switched to Len +/– Dex at disease progression or following study unblinding. Given the significant efficacy benefits of Len + Dex over Dex alone, the trial data will overestimate the survival with Dex alone biasing the results. **METHODS:** External data from the UK Medical Research Council (MRC) MM-IV, V, VI, and VIII trials enrolled between 1980 and 1997 were used to derive an equation reflecting survival without lenalidomide, including prognostic variables to enable adjustment for differences between the MRC and MM-009/010 trials. Applying the MRC equation to the MM-009/010 Dex patient characteristics yielded expected median survival time without cross-over to Len +/– Dex. This was used to calibrate the economic model for the Dex alone group by correcting the scale parameter of the underlying Weibull survival equation, estimated from MM-009/010, assuming the shape parameter remained the same. **RESULTS:** Of 873 MRC patients, 826 died. Exponential survival fit the data, with age, MM performance status, M-protein level, B2M level and time to progression as predictors. Applied to MM-009/010 Dex patient characteristics, this yielded a median survival of 14.9 months (95%CI: 12.3–18.0) (compared to 31 months (95%CI: 25.7–35.1) observed with cross-over in MM-009/010). Incorporating the corrected survival function into the economic model resulted in an estimated incremental 2.8 life-years and 1.9 QALYs gained per patient treated with Len + Dex vs Dex alone. **CONCLUSION:** Using external data to adjust estimation equations can mitigate the impact on economic evaluations resulting from cross-over or other distorting factors in clinical trials.

PSY11

EVALUATION OF ACETAMINOPHEN EXPOSURES REPORTED TO A REGIONAL POISON CONTROL CENTER FOR ADULT PATIENTS

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OBJECTIVE: To describe patient characteristics, doses taken, reason for exposure, time of exposure, treatment and severity of poisoning in adults with acetaminophen-related exposures reported to a regional poison control center (RPCC). **METHODS:** A retrospective review was conducted of all acetaminophen exposures that occurred between October 31, 2000 and October 31, 2003 in adults over 18 years of age who were managed by a RPCC. Data collected included patient demographics, amount ingested, severity of exposure, time since exposure, treatment, reason for exposures, exposure site, and caller site. **RESULTS:** There were 175 exposures to acetaminophen; 72% were females and 28% were males in the study population. There was no significant difference between the mean age of females (31.2 ± 14.0) and males (30.9 ±12.3) in years. The mean dose of acetaminophen taken was 18.7 ± 20.4 grams and no significant difference in the amount ingested between males and females. The majority of the callers seeking information on acetaminophen ingestion were health care professionals (68%). The mean time between the exposure and the call made to the RPCC was 11.27 ± 18.54 hours. Fifty percent of the patients received acetylcysteine therapy, 27.4% received decontamination (e.g., activated charcoal), and 22.3% received other interventions for the treatment of acetaminophen poisoning. Females (72.4%) were more likely ($p < 0.001$) to take intentional overdoses than males (27.6%). The most common acetaminophen exposure site was patient's own residence (96%). The majority of the exposures were acute (86.9%) rather than chronic poisoning. **CONCLUSION:** The main reason for acetaminophen exposure was intentional and females were more likely to ingest intentionally than males. Contacting the RPCC for advice generally occurred beyond the time for optimal acetylcysteine effectiveness. The majority of the exposures were due to acute poisoning.

SYSTEMIC DISORDERS/CONDITIONS—Cost Studies

PSY12

PROJECTED COST OF CARDIOMETABOLIC RISK FACTORS IN COMMERCIALLY INSURED NORMAL AND OVERWEIGHT PRIMARY CARE PATIENTS

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OBJECTIVE: To determine the economic impact of increased prevalence of cardiometabolic risk (CMR) factors including high blood pressure (BP), loss of glycemic control (DB), high triglycerides (TG) and decreased high density lipoproteins (HDL) in commercially insured overweight patients [Body Mass Index (BMI) > 27 kg/m2] compared to normal weight (18 ≥ BMI < 27 kg/m2). **METHODS:** Patients 18–65 years old were identified from an electronic medical record database (EMR) with CMR factors designated by prescription orders or ICD-9 codes and grouped into normal or overweight categories. Similar patients with CMR factors were identified in Medstat MarketScan® administrative claims database. Using a multivariate two-part regression model, costs from this database were estimated for CMR factors. Probabilities of being normal or overweight from the EMR database were applied to the estimated costs to obtain per patient total annual medical costs for CMR factors stratified by normal and overweight groups. **RESULTS:** A total of 75,578 patients with CMR factors were identified in the EMR. Normal [18,213 (24%)] versus overweight patients [57,365 (76%)] were distributed as follows: BP, 29% vs. 71%; DB, 19% vs. 81%; TG, 25% vs. 75%; HDL, 37% vs. 63%; any 2 CMR factors, 13% vs. 87%; any 3 CMR factors, 9% vs. 91%; and all 4 CMR factors, 6% vs. 94%. Estimated costs from the claims database were: high BP, $1630; DB, $1748; high TG's, $638; low HDL, $1474; and $2606, $2801, $3191 for 2, 3, and 4 CMR factors, respectively. Applying the probability of normal or overweight and the estimated costs to the distribution of CMR factors resulted in an