IMPACT OF UNCONTROLLED PEDIATRIC ASTHMA ON HEALTH-RELATED QUALITY OF LIFE (HRQOL)

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OBJECTIVE: To assess the burden of uncontrolled asthma (UA) on HRQOL of the child and their family.

METHODS: An internet-based survey was administered to caregivers of children aged 6–12 years with moderate to severe asthma (severity and control based on NAEP guidelines). The caregiver questionnaire assessed pediatric asthma symptoms, rescue medication use, activity limitation, and included the Child Health Questionnaire—Parent Form 28 (CHQ-PF28), a generic instrument measuring HRQOL in children and their family. Mean CHQ-PF28 scores were calculated (ranging from 0–100, with lower scores representing greater impairment) and compared between UA and controlled asthma (CA) groups using the two-sample t-test.

RESULTS: A total of 4,514 of 16,396 invited to participate responded. A total of 473 satisfied study inclusion criteria; 360 were caregivers of children with UA and 113 for children with CA. Seven out of 8 child-related CHQ-PF28 scale scores were significantly lower among children with UA versus CA with the greatest differences in physical functioning (mean difference = 26.8, P < 0.0001) and physical role limitations (mean difference = 20.0, P < 0.0001). Physical (mean difference = 11.7, P < 0.0001) and psychosocial (mean difference = 5.6, P < 0.0001) summary scales were both significantly lower among children with UA. Caregivers of children with UA had significantly lower scores on both parent-related scales of emotional (mean difference = 20.8, P < 0.0001) and time (mean difference = 16.3, P < 0.0001) impact, and 1 of 2 family-related scales (activities, mean difference = 19.3, P < 0.0001).

CONCLUSION: Uncontrolled asthma was associated with significant impairment in HRQOL, extending beyond the physical health of the child to their psychosocial development. Additionally, uncontrolled pediatric asthma had a significant HRQOL impact on the caregiver and family.

EVALUATION OF IMPACT OF ORAL TOPOTECAN ON HEALTH-RELATED QUALITY OF LIFE IN RELAPSED SMALL CELL LUNG CANCER

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OBJECTIVE: Relapsed small cell lung cancer (SCLC) carries a poor prognosis and is associated with poor health-related quality of life (HRQoL). This study assesses the impact of oral topotecan (OT) on HRQoL when used as second-line treatment for relapsed SCLC.

METHODS: Data from a randomized, open-label, multicenter clinical trial were analyzed, including 141 patients with relapsed SCLC receiving either OT plus best supportive care (BSC) or BSC alone. EQ-5D, a widely used measure of HRQoL that produces both a visual analogue scale (VAS) and an index-based utility score, was administered at baseline and subsequently at three-week intervals. Changes in HRQoL from baseline were compared between two groups by measuring 1) changes between baseline and last evaluation, and 2) changes between baseline and all on-treatment evaluations (pooled analysis). Published criteria for interpretation of minimally important differences (MID) in cancer, i.e., UK-based utility score changes of 0.10 or more and VAS score changes of 8 or more, were used to further interpret results (Pickard AS, et al. HQOL, 2007).

RESULTS: Patients receiving OT + BSC experienced better HRQoL outcomes compared to patients receiving BSC alone. Mean declines from baseline to the last evaluation were significantly smaller in the OT + BSC than BSC alone group in EQ-5D utility (−0.10 vs. −0.30, p = 0.0078) and VAS (−3.98 vs. −14.46, p = 0.0044) scores. Similarly, in the pooled analysis, the OT + BSC group exhibited significantly smaller declines from baseline than the BSC alone group in both EQ-5D utility (−0.04 vs. −0.18, p = 0.0045) and VAS (−0.71 vs. −8.83, p = 0.0035) scores. Using previously established criteria for MIDs, the differences in HRQoL decline between two groups were statistically significant and clinically meaningful.

CONCLUSION: Patients receiving OT + BSC experienced smaller declines in HRQoL from baseline than patients receiving BSC alone. Differences in change from baseline between groups exceeded MIDs from previous studies, indicating a meaningful clinical benefit.

WHI EXPOSURE TO CONTRAINDICATED AND OTHER POTENTIALLY DANGEROUS MEDICATIONS DURING PREGNANCY: A POPULATION BASED STUDY IN ITALY

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OBJECTIVE: To estimate the burden of exposure to medications associated with known or suspected risk of fetal harm among pregnant women in Regione Emilia-Romagna (RER), Italy.

METHODS: A prevalence study was conducted using the RER health care database, including data for the entire RER population of about 4 million inhabitants. Female residents of RER pregnant women in Regione Emilia-Romagna (RER), Italy. All prescription drug data were reviewed for the 270 days leading up to date of delivery. Drugs were grouped into pregnancy risk categories (A, B, C, D, X) using established classification systems. Contraindicated drugs were defined as category X drugs and potentially dangerous drugs were defined as category D drugs. Women exposed to contraindicated and potentially dangerous drugs in the 270 days prior to delivery were identified via ICD-9-CM codes. All prescription drug data were reviewed for the 270 days leading up to date of delivery. Drugs were grouped into pregnancy risk categories (A, B, C, D, X) using established classification systems. Contraindicated drugs were defined as category X drugs and potentially dangerous drugs were defined as category D drugs. Women exposed to contraindicated and potentially dangerous drugs in the 270 days prior to delivery were identified. RESULTS: Among the 33,343 deliveries identified in 2004, 70% were exposed to at least one prescription medication in the 270 days prior to delivery. Approximately 1% of women were exposed to drugs contraindicated in pregnancy (category X), including 189 women (0.6%) receiving these drugs during the first trimester. Approximately 1.5% of women were exposed to potentially dangerous (category D) drugs. Measurable proportions of women were exposed to ACE-inhibitors (0.79%) and HMG-CoA reductase inhibitors (0.28%), which have recently been linked to risk of fetal malformations.

CONCLUSIONS: For the entire RER population,