short period for the gathering of data leads to an underestimation of the cost-effectiveness ratio of HAART.

WOMEN’S HEALTH/DIABETES STUDIES

NHP AND 15D PERFORM WELL IN ASSESSMENT OF THE HRQOL OF HEALTHY WOMEN WITH HORMONE REPLACEMENT THERAPY

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OBJECTIVES: To compare 2 generic health-related quality of life (HRQoL) measures, 15D and Nottingham Health Profile (NHP), in hormone replacement therapy.

METHODS: Two hundred and eight Finnish postmenopausal women (aged 57–67 years), treated with continuous combined E2V/MPA for 6 years, participated. Age- and sex-matched normal controls had randomly been selected from the National Population Register of Finland. HRQoL was measured cross-sectionally with the 15D and NHP; two generic, validated and self-administered measures of HRQoL. The 15D, a profile and single index measure, includes 15 dimensions: mobility, vision, hearing, breathing, sleeping, eating, speech, elimination, usual activities, mental function, discomfort and symptoms, depression, distress, vitality, and sexual activity. The NHP is a profile including six dimensions: energy, sleep, pain, emotional reactions, social isolation, and physical mobility. The performance of the measures was compared in terms of feasibility and discriminatory power.

RESULTS: With both measures the HRQoL of women on continuous combined hormone replacement therapy with E2V/MPA was significantly better than that of normal controls. The response rate with the 15D (96%) was slightly higher than with the NHP (93%). The completion rates by dimensions varied from 94% to 96% with the exception of sexual activity (87%) for the 15D, and from 88% to 92% for the NHP. Each NHP dimension, except social isolation, correlated significantly with comparable 15D dimensions (p < 0.001). The proportion of patients with the best possible score on different dimensions varied from 56% to 95% for the NHP and from 47% to 100% for the 15D. CONCLUSIONS: Both the 15D and NHP perform well in assessment of the HRQoL of women on continuous combined hormone replacement therapy with E2V/MPA. However, the 15D gives information on more dimensions, e.g., sexual activity, which is relevant for postmenopausal women. Furthermore, only the 15D provides utility and therefore can be used in economic evaluations.

PRE-TERM PREGNANCY TERMINATIONS FOLLOWING EXPOSURE TO ANTIDEPRESSANTS: A META-ANALYSIS

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OBJECTIVES: Counseling pregnant women on the hazards of drugs requires valid data. No study has definitively established the baseline risk for spontaneous (SA) or therapeutic (TA) pregnancy termination in pregnant women taking antidepressants. Our objectives were to estimate the baseline risk for SAs and TAs and determine whether antidepressants increase those risks.

METHODS: We used a random effects meta-analytic model. MEDLINE, EMBASE, Healthstar, and Cochrane databases were searched by 2 independent reviewers for cohort studies published from 1966 to the present (2002) reporting rates of spontaneous and therapeutic abortions in women taking antidepressants in therapeutic doses to treat any depression. Up to 10% of patients could have comorbidities, but could not have exposure to other known abortifacients. Data were extracted by two reviewers; all differences were resolved through consensus. Rates, risk differences, and risk ratios, along with 95% confidence intervals (CI95%) were summarized across studies. Sub-analyses were done by class (TCAs, SSRIs, and dual action agents).

RESULTS: We identified 15 potential studies; 6 prospective cohort studies with 11 treatment arms provided extractable data for SA and 6 for TA. All of those studies matched exposed and comparison groups on important confounders such as age, smoking, and alcohol consumption. The baseline risks (CI 95%) were 8.7% (7.5%–9.9%, n = 2033) and 6.0% (3.3%–8.7%, n = 2033) for SA and TA, respectively. Antidepressants had baseline risks of 12.4% (10.8%–14.1%) and 8.5% (6.0%–11.1%) and were associated with increases in risk of 3.9% (1.9%–6.0%) and 2.9% (0.5%–5.3%), respectively. RRs was 1.52 (1.22–1.89, n = 3567) for SA and 1.47 (1.14–1.89, n = 3552) for TA. No differences were found among antidepressant classes.

CONCLUSIONS: Maternal exposure to antidepressants is associated with a small but significant increased risk for both spontaneous and therapeutic abortions. This risk must be considered when counseling patients. Further research is required to rule out depression or other indications as confounders.