CONCLUSIVE VALIDATION OF THE BRIEF QUESTIONNAIRE OF SMOKING URGES
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OBJECTIVES: The 10-item version of the 32-item Questionnaire of Smoking Urges (the QSU-brief) provides a multidimensional measure of craving to smoke. Previous research from a factor analysis of the QSU-brief supported a two-factor structure with Factor 1 measuring “a strong desire and intention to smoke with smoking perceived as rewarding” and Factor 2 measuring “demonstrating anticipation of relief from negative affect and an urgent desire to smoke”. We conducted an independent investigation of the QSU-brief to assess the validity and reliability of the proposed two-factor structure. METHODS: Data came from a seven-week Phase II clinical trial (n = 626) of varenicline developed for smoking cessation. The two pre-specified domains from previous research were Factor 1 (5 items) and Factor 2 (3 items). Factor analyses and internal consistency reliability analyses (Cronbach’s alpha) were conducted during occasions when varying levels of craving intensity might be expected (baseline, Week 2, and Week 4). RESULTS: The hypothesized multidimensional framework of the QSU-brief was supported by confirmatory factor analysis at each of the three occasions (baseline, Week 2, and Week 4). Comparative fit indexes (CFI) and non-normed fit indexes (NNFI) exceeded 0.90 (CFI = 0.97, 0.95, 0.96; NNFI = 0.96, 0.93, 0.95). Values of Cronbach’s alpha exceeded 0.75 on Factor 1 (0.90, 0.89, 0.90) and Factor 2 (0.76, 0.78, 0.85), as well as on the Total Score of 10 items (0.92, 0.93, 0.93). CONCLUSION: The validity and reliability of the postulated two dimensional structure of self-reported craving as measured by the QSU-brief is confirmed.

STROKE

EVALUATING THE POTENTIAL COST-EFFECTIVENESS OF FUTURE ANTICOAGULANT DRUGS VS. WARFARIN IN THE PREVENTION OF STROKE AND MAJOR BLEEDS IN ATRIAL FIBRILLATION PATIENTS
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OBJECTIVES: To determine the attributes of future anticoagulation drug candidates necessary to demonstrate cost-effectiveness versus traditional warfarin therapy in the prevention of stroke and major bleeds in Atrial Fibrillation (“AF”) patients. METHODS: A decision-analytic model was constructed to simulate the population of individuals using warfarin therapy versus a proxy (future) anticoagulation drug in patients with AF. Exposure period, dosage and base case probabilities for major bleeds and hepatotoxicity were based on the warfarin raw data from the Sportif III and V trials. The benefits associated with using warfarin therapy versus a proxy future drug in patients with AF were quantified using the quality-adjusted life year (QALY) framework. Univariate and multivariate probabilistic sensitivity analyses using Bayesian second-order Monte Carlo simulation were conducted. Hepatoxicity-related risks were estimated pursuant to FDA’s usage of Hy’s Law. RESULTS: The results of the base-case analysis demonstrate that treatment with warfarin results in an expected cost $307 less than treatment with a proxy future anticoagulant drug ($882.70 compared with $1189.90, respectively). The proxy drug profile is not cost effective (incremental cost-effectiveness ratio of $960,000 per QALY) compared to warfarin. Warfarin dominates treatment vs. the proxy drug with 84% probability. CONCLUSIONS: Recent new anticoagulant candidate drugs have not been shown to be cost-effective compared to warfarin. To achieve market acceptance, future anticoagulant drugs must be able to demonstrate competitive cost, non-inferiority of stroke/major bleed prevention and a superior safety profile including reduction of hepatotoxicity risk.

THE EVALUATION OF HEALTH RELATED UTILITY (EQ5DINDEX) AND RESOURCE USE IN PATIENTS WITH STROKE COMPLICATED BY UPPER AND LOWER LIMB SPASTICITY
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OBJECTIVES: To assess the cost-effectiveness of 18-month treatment with clopidogrel versus aspirin in high-risk patients with a recent history of Ischemic Stroke (IS) or Transient Ischemic Attack (TIA) in four European countries: Belgium, France, Switzerland, and UK. METHODS: We developed a Markov model based on patients with IS or TIA in the previous 90 days (median 15 days) who were treated with clopidogrel in the MATCH trial and followed prospectively for the occurrence of recurrent IS or TIA, myocardial infarction (MI), other cardiovascular death, life threatening bleeding, or major bleeding. The event rates for IS and TIA patients treated with aspirin were derived from a Cochrane review comparing clopidogrel and aspirin by using a relative risk increase (RRI) of 1.11 for serious vascular events (all strokes, MI, cardiovascular deaths). For major bleedings with aspirin vs. clopidogrel, we used a RRI of 1.12 (CAPRIE trial). Death rates for other causes were country specific and adjusted for this population. Lifetime perspective was chosen and discount rates were applied according to the local guidelines. RESULTS: Eighteen-month treatment with clopidogrel compared to aspirin was associated with a gain in quality adjusted life years (QALY) ranging from 31 years/1000 patients in the UK to 36 years/1000 patients in Belgium. The incremental cost per patient varied from 487€ in UK to 724€ in Belgium and the cost per QALY was 20,111€ in Belgium, 18,882€ in France, 15,620€ in Switzerland, and 15,713€ in UK. Sensitivity analyses showed that all results were robust under various assumptions. CONCLUSION: Consistent results are found across the four countries with incremental cost-effectiveness ratio below the acceptable thresholds, demonstrating that clopidogrel compared to aspirin is always cost-effective in the studied population.