CARDIOVASCULAR DISORDERS—Conceptual Papers & Research on Methods

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MODELING THE EFFECT OF DIFFERENTIAL COMPLIANCE WITH ANTIHYPERTENSIVE DRUGS ON CLINICAL ENDPOINTS
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OBJECTIVES: Compliance with antihypertensives is influenced by various factors, and influences blood pressure (BP) control and cardiovascular outcomes. Differences in compliance, e.g., the improvement associated with fixed-dose combinations (FDCs), are acknowledged, but have not been incorporated into cost-effectiveness modeling because the chain of causality between compliance and outcomes is complex. We developed a method to quantify this chain of effects which can use simple compliance parameters such as medication possession ratios, or more sophisticated inputs; it can also be tailored to specific decision problems.

METHODS: First the effect of variation in compliance on simulated dosing histories is modeled. Second, the rate of fall/rise in BP on initiating/withdrawing treatment, and the full-compliance BP reduction, are used to estimate corresponding BP trajectories. Finally clinical endpoints are modeled from these BP trajectories, based on existing evidence. In an illustrative example, the effect of choosing an FDC over the corresponding component-based regimen was modeled. The FDC effect was modeled as an 11% reduction in missed doses [reference], distributed evenly across interruptions of different lengths. Systolic blood pressure (SBP) trajectories were estimated assuming bio-equivalence between FDC and component-based regimes, and the mean SBP calculated. The Framingham risk equation was used to predict the number of strokes which would be expected on the component-based regimen, and the expected number which FDC use would avoid were calculated. RESULTS: This approach allows quantification of compliance-mediated health effects with great flexibility. CONCLUSIONS: More detailed data on the effects of FDC use on compliance can be incorporated, and different treatment efficacies and/or different durations of action can be substituted, as can different BP summary statistics, different clinical endpoints, and different sources for the relationships between them. Reference: Taylor A et al. Adherence to antihypertensive therapy with fixed-dose amlopidine besylate/benazepril versus comparable component-based therapy. Congestive Heart Failure 2003;9:324–32.

PCV123

THE CARDIOVASCULAR PREVENTION MODEL (CPM), A GENERICALLY APPLICABLE MODEL FOR UNDERTAKING COST-EFFECTIVENESS ANALYSES OF PREVENTIVE INTERVENTIONS
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OBJECTIVES: To develop an epidemiological and economic model of cardiovascular disease (CVD, comprising coronary heart disease and stroke) that can be used to predict the future incidence of CVD in a given population (with representative cross-sectional data on cardiovascular risk factors) and undertake cost-effectiveness analyses of primary preventive strategies.

METHODS: The CPM is a Markov model comprising four health states: ‘Alive without CVD’, ‘Alive with CVD’, ‘Dead from CVD’ and ‘Dead from non-CVD causes’. Individual subjects’ risks of CVD are derived from Framingham and UKPDS risk equations for non-diabetic and diabetic individuals, respectively. The risks of non-CVD death are drawn from local mortality data. To illustrate the function of the CPM, it was populated with 1335 Australian subjects from the nationally-representative 1999–2000 Australian Diabetes, Obesity and Lifestyle study who were: aged 35–74 years; free of CVD; and met current criteria for reimbursed access to statin treatment. Follow-up was simulated until death or age 75 years. The cost-effectiveness of atorvastatin for the primary prevention of CVD was modelled via decision analysis, using efficacy data from a recent meta-analysis of randomized trials and Australian cost and utility data. A 5% annual discount rate was applied.

RESULTS: The CPM predicted that of Australians currently aged 35–74 years who were CVD-free but met criteria for lipid-lowering treatment, 23.3% would develop CVD and 24.3% would be dead by age 75 years without statin treatment. Atorvastatin would reduce these figures to 16.5% and 22.2%, representing numbers needed to treat of 14.7 and 46.2 to prevent CVD and death, respectively. The estimated ICERs were AUD$54,100/Year and AUD$35,600/Quality Adjusted Life Year (QALY).

CONCLUSIONS: The CPM allows for the prediction of future incidences of CVD in a population where representative cross-sectional data on cardiovascular risk factors are available. It can also be applied to cost-effectiveness analyses of primary preventive interventions for that population.

INDIVIDUAL’S HEALTH—Clinical Outcomes Studies

PIHI

CHANGES IN PELVIC FLOOR MUSCLE STRENGTH, ITS DURATION AND ITS RELAXATION ABILITY DURING PREGNANCY
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OBJECTIVES: To assess the strength and duration of pelvic floor muscle contraction and the ability of muscle relaxation before and during pregnancy.

METHODS: Our study focused on examining the strength of duration and ability of relaxation of pelvic floor muscle in cases of nulliparous young women and pregnant women in the second and third trimesters. The measurement of parameters characterizing the functional abilities of the muscle was performed by vaginal pressure measurement equipment. The statistical data were calculated according to mean, standard deviation, Fisher’s exact test, T-test methods and the results were considered to be relevant at p < 0.05.

RESULTS: Out of 119 measurements the data of 93 women were processed. The maximum muscle strength (103.13 ± 54.12) of nulliparous women (n = 36) was significantly higher (p = 0.00348) than that of pregnant women (n = 57); (68.3 ± 47.23). The duration of maximum contraction in case of nulliparous women (6.4 sec ± 4.9) proved to be markedly longer (p = 0.011067) than during pregnancy (3.98 sec ± 4.011). Although the maximum muscle strength is higher in the second trimester than in the third trimester the difference is not significant. Regarding the duration of maximum contraction no marked difference was found. A total ability of relaxation could only be observed in one third of the sample but no significant difference was detected between