A CLINICAL TRIAL

UNCONDITIONAL POWER FOR SECONDARY OBJECTIVES IN VOI for individual model parameters. Very efficient and timesaving approach for the calculation of the conﬁdence in achieving study results. We will present further conﬁrmation that for cost-effectiveness models that meet the linear-based metamodel provided reliable estimates of the EVPPI. We conclude that for cost-effectiveness models that meet the linear criterion, regression based metamodeling promises to be a very efﬁcient and timesaving approach for the calculation of the VOI for individual model parameters.

MC4

UNCONDITIONAL POWER FOR SECONDARY OBJECTIVES IN A CLINICAL TRIAL
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OBJECTIVES: Sample size estimation in controlled clinical trials is determined to insure that the primary objective can be achieved with certain probability (i.e., power) based on the available information and study assumptions. Power to achieve secondary objectives is usually based on the sample size calculated for the primary objective. If the secondary objectives are evaluated on a sub-sample of the study population, then the sample size becomes a random variable and power is calculated conditioned on the average of sample sizes (i.e., conditional power). This may prove problematic when the sample size for the secondary objectives is different from its mean. We present a method to calculate unconditional power (i.e., power taking into consideration sample size variability) in the situation where secondary objectives are evaluated on a sub-sample of the study population.

METHODS: The joint distribution of the test statistics and the sample size for the secondary objectives was considered. Based on the joint distribution, unconditional power of the statistical tests for the secondary objectives was deﬁned. The relationship between unconditional power and traditional power condition on the expectation of the sample size was then explored. RESULTS: By analytical reasoning, we found that conditional power is higher than unconditional power when z-test is used to test the equivalence of two population means with known standard deviation at signiﬁcant level 0.05. Results can be generalized to other types of statistical tests where the type I error rate is 0.05. CONCLUSIONS: Under the design speciﬁcations studied, conditional power was consistently greater than the true power. This may give the researcher an overly optimistic conﬁdence in achieving study results. We will present further results under different design speciﬁcations and will highlight situations where conditional power can be used with application to pharmacoeconomic outcomes.

Cost Evaluation Studies in Cardiovascular Diseases

CV1

ATRIAL BASED PACING DECREASES ATRIAL FIBRILLATION RELATED HOSPITALIZATIONS AND COSTS IN BRADY-TACHY SYNDROME
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Atrial Fibrillation (AF) presents gross economic problem for health care payers. Atrial based pacing is an accepted method of treatment of bradycardia-tachycardia syndrome (BRTS).

OBJECTIVES: to compare resource utilization and costs of care in BRTS before and after atrial based pacemaker implantation.

METHODS: Observational, retrospective, uncenter study included 143 pts (84F; 61M; mean age 68,5) with BRTS, paroxysmal AF and atrial based pacing system (AAI 64,8%; DDD 35,2%) implanted during one year. The data on utilized resources were collected in time window: from 1 year before implantation to 3 years after implantation. The costs were calculated from the public health care payer perspective.

RESULTS: During the 3 years after implantation 20 patients died (13.8%) and the cost analysis was performed among survivors. At least one AF episode was reported in 103 pts (82.4%) and 19 (15.2%) had chronic AF at the end of study period. There were 338 AF related hospitalizations before implantation (mean 2.7 per year, per patient) compared to 423 (during 3 years; mean 1.13 per year, per patient; Wilcoxon test p < 0.001). The distribution of costs before implantation was: hospitalizations 82.0%, drugs 10.7%, consultations 4.1%, AF complications (mainly stroke) 3.2% and after implantation: hospitalizations 38.3%, followed by drugs 24.4%, pacing complications costs 21.1%, consultations 6.1%, pacemaker follow-up 4.2% and AF complications 5.9%. The mean annual cost of care of AF decreased after implantation from 3138 PLN (~1569 Euro PPP) to 1923 PLN (~961 Euro PPP) (p < 0.001) and the savings were mainly associated with lower hospitalization rate which was not only economic but also clinical proﬁt.

CONCLUSIONS: Atrial based pacing decreases number of hospitalizations and overall costs of therapy in bradycardia-tachycardia syndrome. Hospitalizations due to AF represent the major cost driver in group of patients with brady-tachy syndrome.

CV2

COSTS OF CARDIOVASCULAR DISEASE: A CASE-CONTROL STUDY
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OBJECTIVES: The term cerebrovascular disease designates any abnormality of the brain resulting from a pathologic process of the blood vessels. Medical and neurological complications after stroke or transient ischemic attack have a high economic impact. The objectives of the study were to assess the social costs of subjects with cerebrovascular disease, almost one transient ischemic attack or stroke (case) and to compare the costs of these subjects with the costs attributable to subjects without cerebrovascular disease (control).

METHODS: Data were collected from a population based naturalistic prospective survey (a representative sample of the Italian general population aged from 40 to 79 years). Subjects with cerebrovascular disease going to general practitioners (GP) were enrolled. We matched each of them by age and sex with controls. We conducted a Cost of Illness (COI)