OBJECTIVES: To identify response shift using two structural equation modeling (SEM) techniques with the SF-36 Health Survey. METHODS: Hypertensive patients with coronary artery disease (CAD) who completed both baseline and one year follow-up of the SF-36 were included (n = 909). An occurrence of response shift using SEM techniques with the SF-36 was identified. OortSEM was used to conduct SEM procedures. A variety of fit indices were used to determine model fit. For both SEM approaches, response shift is defined based on changes in various parameters in the measurement model. Effect size indices were calculated for the contribution of response shift on the change of SF-36 domain scores. We hypothesized the divergence in defining type of response shift linked to changes in various parameters will lead to different findings. RESULTS: Only the SF-36 physical functioning (PF) scale was identified with recalibration response shift using both Oort and Schmitt SEM approaches. With Oort approach, recalibration was identified by the change in intercepts, whereas Schmitt approach defines recalibration as the change in factor variances or factor loadings over time. Effect size of the recalibration response shift on the change of PF domain score was marginal – 0.118. CONCLUSIONS: This is the first study to identify response shift in hypertensive CAD patients using SEM approach. Recalibration response shift was identified using both Oort and Schmitt SEM approaches. Different interpretation of specific PF items by hypertensive CAD patients before and after treatment may contribute to the recalibration response shift. By looking more closely at the SF-36 PF domain scores among hypertensive CAD patients will enable us to provide nuanced attention and direct treatment for the most impaired aspects of quality of life.

PCV112 EXTENSION OF META-ANALYSIS IN COMPARING OF FIMASARTAN WITH LOSARTAN IN BLOOD PRESSURE LOWERING EFFECT
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OBJECTIVES: A new drug fimasartan has been developed and currently approved in Korea. The clinical hypertension treatment is to identify whether the main results of direct comparative study maintains consistency with those of extension of meta-analysis in the blood pressure lowering effect of fimasartan with losartan. METHODS: Systematic reviews of literatures of clinical trials including fimasartan or losartan were conducted. The blood pressure change from baseline was used as an effectiveness measure and was pooled in RevMan 4.2. For direct comparison, the head-to-head randomized controlled trial (RCT) of fimasartan and losartan was used. For indirect comparison, it followed to method of adjusted indirect comparison (Bucher 1997) using common comparator and used ITC (Indirect Treatment Comparison) program (CADETH). In addition, Bayesian treatment comparison (BTC) was performed on which combines whole pairwise comparison studies together by Winbugs program. After that, the results were compared with that of a direct comparison. RESULTS: In regard to direct comparison, there is only the head-to-head trial (Phase III) report of comparing fimasartan with losartan, which had conducted locally. For indirect comparison, the search identified one report of the trial of comparing fimasartan with placebo (Phase Ib), and the 6 of articles of comparing losartan with placebo were selected and measured estimates were pooled. The change in reduction in diastolic blood pressure of losartan and fimasartan versus placebo was –2.7 mmHg as direct estimate retrieved from RCT, and –3.315 mmHg as combined estimate through MTC analysis, respectively. In SBP reduction, it was –4.3 mmHg and –3.995 mmHg respectively. CONCLUSIONS: This study found that estimates obtained from indirect comparison were available for better comprehension of direct. The results from the two comparisons methods both indicated consistently that the antihypertensive effect of fimasartan is better than losartan.

Sensory Systems Disorders – Clinical Outcomes Studies

PSS1 STEVENS-JOHNSON AND RED MAN SYNDROME: A CASE REPORT ON ADVERSE DRUG REACTIONS OF SIMULATIVE USE OF PHENYTOIN AND VANCOMYCIN
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OBJECTIVES: Adverse drug reactions (ADRs) are a common cause of injury to hospitalised patients and are likely preventable. Monitoring spontaneous adverse drug reactions is one of the epidemiological methods for assessing the safety of drugs in a hospital setting. Many studies reported that spontaneous reactions and gastrointestinal disturbances are the top most reported ADRs. METHODS: The author reports a case of 22-year-old girl who developed Stevens-Johnson syndrome and Red Man syndrome after receiving phenytoin and vancomycin simmultaneously. RESULTS: This was 22 year old girl presented with chief complaints of headache, nausea, vomiting and sweating. Diagnosed as a case of post fossa tumor and operated on 3rd day after admission. She was treated with different medications along with vancomycin 1gm 12hourly, phenytoin 100mg 8 hourly and dexamethasone 2gm 8 hourly. On the day 15 of vancomycin and phenytoin treatment, the patient developed severe cutaneous reaction and was diagnosed with Stevens-Johnson syndrome. She was on phenytoin for 3 years and stopped phenytoin and phenobarbitone respectively. The reaction persisted for approximately 55 days with progressive improvement and the patient was treated with hydroxycryl 30mg, 6 hourly, hydrocortisone 100mg, 6 hourly with gradual tapering of the dose and topical treatment of the lesions. CONCLUSIONS: Although there are reports on the adverse drug reaction with monotherapy of phenytoin and vancomycin or in involvement with other medications. However, there are no reports on the development of Stevens-Johnson and Red man syndrome when phenytoin and vancomycin were used simultaneously with other drug treatment. It also confirms the possible increased risk of developing Stevens-Johnson syndrome when phenytoin is associated to corticosteroids.

PSS2 DIAGNOSED AND UNDIAGNOSED DRY EYE, SYMPTOM SEVERITY, AND ASSOCIATED FACTORS AMONG MEN AND WOMEN IN THE UNITED STATES
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OBJECTIVES: To examine factors associated with dry eye disease (DED) in the US. METHODS: We conducted a cross-sectional survey of 4000 participants in the Women’s Health Study and Physicians’ Health Study with diagnosed DED or severe symptoms. We assessed the current level of symptoms by the Ocular Surface Disease Index (OSDI) and the frequency of eye assessment (Ocular Assessment Questionnaires, diagnosis, co-morbidities, treatments, and patient satisfaction. RESULTS: 3590 (84.8%) subjects returned questionnaires. 2099 participants reported a diagnosis of DED, and 1291 denied DED diagnosis (73.9% of these had reported DED diagnosis previously). Among 451 subjects selected based on severe symptoms alone, 114 (25.3%) reported a new diagnosis of DED, which was more strongly associated with severe symptoms by SANDE-40 (OR = 2.24, p = 0.001), than by OSDI 33-100 (OR = 1.38, p = 0.25). Blepharitis (OR = 2.03, p = 0.05) was also associated with new DED diagnoses. Among those who currently denied DED diagnosis, 15.9% had severe (SANDE-40) and 40.4% had moderate-mild symptoms (SANDE 15-40). Adjusting for age and sex, participants with symptoms only were less likely than diagnosed patients to have an eye exam ≥1/year (OR = 0.71, p = 0.02), use antidepresants (OR = 0.76, p = 0.04), or use topical tear (OR = 0.67, p = 0.005). CONCLUSIONS: Recalibration response shift by using both Oort and Schmitt SEM approaches. With Oort approach, recalibration was identified by the change in intercepts, whereas Schmitt approach defines recalibration as the change in factor variances or factor loadings over time. Effect size of the recalibration response shift on the change of PF domain score was marginal – 0.118. This is the first study to identify response shift in hypertensive CAD patients using SEM approach. Recalibration response shift was identified using both Oort and Schmitt SEM approaches. Different interpretation of specific PF items by hypertensive CAD patients before and after treatment may contribute to the recalibration response shift. By looking more closely at the SF-36 PF domain scores among hypertensive CAD patients will enable us to provide nuanced attention and direct treatment for the most impaired aspects of quality of life.

PCV112 EXTENSION OF META-ANALYSIS IN COMPARING OF FIMASARTAN WITH LOSARTAN IN BLOOD PRESSURE LOWERING EFFECT

H11002

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