PCV19

RANDOMISED, FLEXIBLE DOSE STUDY TO COMPARE THE EFFICACY AND SAFETY OF NIFEDIPINE SUSTAINED RELEASE WITH GINGKGO BILoba EXTRACT TO TREAT PATIENTS WITH PRIMARY RAYNAUD’S PHENOMENON IN KOREAN RAYNAUD’S PHENOMENON PATIENTS


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OBJECTIVES: To compare the efficacy and safety of a nifedipine sustained release (nifedipine SR), with ginkgo biloba extract as treatment for primary Raynaud’s phenomenon in Korean. METHODS: 6 Multi-centred, randomised, flexible dose and open study was conducted. Patients with primary Raynaud’s phenomenon were randomized to 3 centres and randomly assigned to either the Nifedipine SR group (Group N) or the Ginkgo biloba extract group (Group G) in the ratio of 2:1. After a run-in period of two weeks, participants received treatment for eight weeks. Primary efficacy evaluation was any percent change of the Raynaud attack rate between the reference value before treatment and after the 8-week treatment. A safety was also evaluated. RESULTS: Out of 134 patients with primary Raynaud’s phenomenon, 39 subjects dropped out of the program during the selection period. Ninety-three subjects (70.5% of the original pool) were randomly assigned, and 64 groups (Group N: 42; Group G: 22) among the 93 completed this clinical trial. There were 24 male subjects (23.81%) and 69 female subjects (74.19%), and the average age of the subjects was 39.20 (Group N: 37.67, Group G: 42.13). The percent change of the attack rate in Intention To Treat (ITT) group was 50.05% at 7 and 8 weeks after treatment in Group N, while it was just 31.02% in Group G (p-value = 0.03). The improvement was shown to be much higher in Group N than in Group G. No difference in QOL items was found between the two groups in this clinical trial. No significant adverse events occurred; severity of the adverse events incurred was mostly mild, and those adverse events were improved without any intervention. CONCLUSIONS: Nifedipine SR was more effective in treating Raynaud’s phenomenon than Ginkgo biloba for primary Raynaud’s phenomenon (Percent change of R : 50.1% vs. 31%). Both Nifedipine SR and Ginkgo biloba showed tolerability without serious adverse events.

PCV20

THE ASSOCIATION OF ASPRIN USE ON RISK OF HOSPITALIZATION IN CHF PATIENTS TAKING ACE INHIBITORS: A RETROSPECTIVE ANALYSIS OF A NATIONAL COHORT OF VETERANS

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OBJECTIVES: Aspirin may interact with ACE inhibitors to reduce their beneficial effects in patients with heart failure. The objective of this retrospective cohort study was to assess the risk of congestive heart failure (CHF) hospitalization in patients with heart failure (HF) taking ACE inhibitors in a large national cohort of veterans. METHODS: Exposure to aspirin was assessed between October 1, 2000 and September 30, 2001. Patients were characterized as prescribed: no aspirin, low-dose (<81 mg) aspirin, high-dose (>81 mg) aspirin. Time to HF hospitalization in these selected patients was assessed between October 1, 2000 and September 30, 2002. Chi-squared tests, Kaplan-Meier plots and log-rank tests were employed for testing bivariate associations. A multivariable Cox regression model was used to estimate the adjusted hazards ratio for the risk of CHF hospitalization after aspirin exposure after controlling for sociodemographic factors, comorbidities, comedinations, and years with HF. RESULTS: The final study cohort consisted of 157,088 HF patients with a mean age of 69.73 ± 10.19 years. The crude HF hospitalization rates differed significantly between the treatment groups (log-rank statistic for KM plot; p-value <0.005). In multivariate analysis of the association of aspirin use and hospitalization for CHF: the use of both high-dose aspirin (HR 1.26, 95% CI 1.19-1.34) and low-dose aspirin (HR 1.18, 95% CI 1.09-1.27) was associated with increased risk of CHF hospitalization with no aspirin use as the reference group. The results remained the same for high-dose aspirin in case of patients with both CHF and IHD, without IHD, age ≥ 65 years, and patients with Medication Possession Ratio (MPR) > 0.8. CONCLUSIONS: The theory of negative interaction between ACE inhibitors and aspirin may be true, but results must be interpreted with caution. Prospective studies would be needed to investigate this interaction further.

PCV21

CARDIOVASCULAR DISORDERS – Cost Studies

US BUDGET IMPACT OF INCREASING ASPRIN USAGE FOR PRIMARY AND SECONDARY PREVENTION OF CARDIOVASCULAR DISEASE

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OBJECTIVES: Cardiovascular disease (CVD) is a leading cause of death in the US, but regular use of preventive low-dose aspirin has proven to be an effective way to prevent CV events. The purpose of this study was to explore the potential economic impact in the US if aspirin usage were to be increased in line with current clinical guidelines for primary and secondary prevention of CV events. METHODS: The risk profile of the US population was modeled using NHANES data and the Framingham cardiovascular risk equations were applied to calculate risk for myocardial infarction, angina and stroke according to age and gender. Primary and secondary prevention patient populations were considered separately. Using publicly available unit costs, a budget impact model calculated the annual impact of increased preventive aspirin usage considering adverse events and diminishing aspirin adherence over a 10-year time horizon. RESULTS: In a base population of 1,000,000 patients, implementation of current clinical guidelines would prevent an additional 1273 myocardial infarctions, 2184 angina episodes and 565 strokes in primary prevention patients and an additional 578 myocardial infarctions, and 607 strokes in secondary prevention patients was not assessed in secondary prevention patient population. This represents a total savings to the Managed Care Organization (MCO) of $84.9 million for primary prevention and $32.7 million for secondary prevention and additional out of pocket expense to patients of $12.1 million for primary prevention and $2.9 million for secondary prevention for the cost of aspirin. CONCLUSIONS: This model suggests that there is a strong economic case, both for payers as well as for society, to encourage aspirin use for patients at appropriate risk and per clinical guidelines. It also provides an example of how minimizing costs does not necessarily have to imply rationing of care.