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POSTMARKETING SURVEILLANCE STUDY TO EVALUATE THE SAFETY AND EFFECTIVENESS OF DOXAZOSIN GITS WHEN ADDED TO HYPERTENSIVE PATIENTS NOT CONTROLLED WITH MONOTHERAPY

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Objective: to evaluate the effectiveness and safety of doxazosin GITS when added to hypertensive patients non responders to monotherapy.

Material and Methods: open label, non-comparative, multicentric, prospective study on hypertensive patients coming to the doctor’s office. Hypertensive patients not controlled (DBP ≥ 90 mmHg and/or SBP ≥ 140 mmHg) with one antihypertensive drug according to the VI revision of the Joint National Committee (JNC), were included in this study. Doxazosin GITS has been taken in addition to their antihypertensive medication. The initial dose of Doxazosin GITS was 4 mg/day and could be increased at 4 weeks interval to a maximum dose of 8 mg/day. During all the follow-up visits blood pressure and heart rate values have been determined. Adverse events occurrence and concomitant medication have been also recorded.

Results: 3631 patients with an average age 62.4±11.0 years, female gender 60% were included in the study and 3267 (90%) completed it. Effectiveness analysis was done in 3546 (97.7%) patient, 85 (2.3%) patients were excluded due to blood pressure values not recorded at basal or follow up visits. After 4 weeks treatment with Doxazosin GITS 39% patients achieved therapeutic goal based on the VI revision of the JNC. This percentage was increased to 61% after 16 weeks. The mean values of systolic blood pressure (SBP) and diastolic blood pressure (DBP) changed from 161.6±11.9 and 95.1±5.9 mmHg at baseline to 142.2±11.9 and 84.1±5.9 mmHg after 4 weeks (p<0.0001) and 136.8±11.9 and 80.6±5.9 mmHg after 16 weeks (p<0.0001). Patient distribution according to their entry antihypertensive showed that 42.5% were taking ACE inhibitors, 17.2% diuretics, 16.6% calcium blockers, 16.6% angiotensin II receptor blockers and 6.8% β-blockers. In all groups it was observed a significant increase in the percentage of controlled patients as well as significant reductions of PAS and PAD values when adding treatment with Doxazosin GITS. Safety analysis showed that 107 (2.9%) patient had an adverse event, 1.6% related to the drug. 16 (0.4%) patients reported serious adverse events, only one of them related to the drug.

Conclusions: 1. Doxazosin GITS is an effective added drug in patients not controlled in monotherapy. 2. Doxazosin GITS is an effective, safe drug used as add-on therapy with every antihypertensive treatment.

Key Words: Doxazosin GITS, Hypertension, Add-On Therapy

P-20

ANTIHYPERTENSIVE EFFECTS OF SPIRAPRIL IN PATIENTS WITH MILD TO MODERATE ARTERIAL HYPERTENSION


The aim was to evaluate the antihypertensive effects and safety of spirapril (S) in patients with mild to moderate arterial hypertension (AH). Thirty patients (mean office SBP/DBP - 159.7 ± 1.3/100.3 ± 2.7 mm Hg) after the wash-out period were included in 3 mths observation. The initial dose of S was 6 mg/daily on first mth. If therapy was ineffective, the S was uptitrated to 12 mg/daily on second mth and combined with hydrochlorothiazide (HCT) on third mth. All pts were performed office BP control, 24-hour ambulatory BP monitoring ("Meditech" Hungary), bicycle exercise test, EchoCG and serum potassium, creatinine, etc control.

The average decreasing of the office SBP and DBP was 27 and 13 mm Hg (p<0.0001); the 24-hour SBP and DBP -12 and 10 mm Hg (p<0.002). The heart rate diminished on 16 and 21 % according to measurement method. At 3-rd mth we noted the significant reducing of the left ventricular mass index (on 25%) and tendency to end-diastolic, end-systolic left ventricular volume decreasing. The pts showed much better exercise tolerance (the mean Δ =50 W) and significant reduction of SBP/DBP on all exercise steps (from 23/10 to 39/20 mm Hg). The target BP was achieved in 50% pts on monotherapy (dose 6 mg). The almost all pts, who took S in dose 12 mg, demanded the combined with HCT. The study was stopped in 5 (16.7%) pts due to adverse events. We did not observe the worsening of the biochemical patterns.

The treatment of mild to moderate AH pts by S is effective and well tolerated. If the monotherapy by 6 mg S is not enough for achieving of the target BP, it is not necessary to increase the dose of S. The more preferable is combination with diuretics.

Key Words: Spirapril, Hypertension, Effects

P-21

EFFECT OF PERINDOPRIL ERBUNIME, AN ANGIOTENSIN CONVERTING ENZYME INHIBITOR (ACE-I), IN THE TREATMENT OF 1022 AFRICAN-AMERICAN PATIENTS WITH MILD TO MODERATE HYPERTENSION: SUBGROUP ANALYSIS OF A 12 WEEK, OPEN-LABEL, ACEON® COMMUNITY TRIAL (ACT)

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There is an ongoing controversy regarding the efficacy of ACE-I in the African-American (AA) population. In this study, the efficacy and safety of perindopril erbumine on sitting blood pressure (BP) were analyzed in a subset of AA patients (n=1022), from a 12 Week, open-label, community study. All patients were treated with perindopril 4 mg QD for 6 weeks. Based on the BP response, dose was maintained on perindopril 4 mg or increased to perindopril 8 mg QD for an additional 6 weeks. BP was measured at Baseline (antihypertensives withdrawn), Week 6, and Week 12.

Treatment with perindopril (4 to 8 mg QD) for 12 weeks produced a clinically significant reduction in systolic (SBP) and diastolic (DBP) blood pressure. In AA patients with inadequate response at Week 6 (Group 2), increase in perindopril dose to 8 mg QD produced additional decrease in SBP and DBP, supporting the titration approach. At Week 12, BP control with perindopril defined as SBP/DBP <140/90 mmHg, SBP <140 mmHg or DBP <90 mmHg, SBP <140 mmHg, and DBP <90 mmHg was achieved in 38%, 69%, 48%, and 59%; respectively. Based on JNC VI classification (systolic/diastolic), an increase in shift of patients from Baseline to Week 12 in nonhypertensive BP categories was: Optimal 1%/3% to 6%/18%; Normal 3%/4% to 14%/24%; and High-Normal 6%/7% to 29%/18%. Additionally, treatment with perindopril controlled BP in a significant number of AA patients who were uncontrolled on previous ACE-I therapy. The antihypertensive effect of perindopril was well maintained throughout the 12 week period. Adverse events were reported in 19% of the patients, of which 1.3% were serious.
Cough and angioedema were reported in 5% and 0.9%, respectively.

Collectively, these results suggest that a large proportion of AA patients with hypertension can be successfully controlled with perindopril as monotherapy. As shown in Group 2, these data also lend credence for a titration approach in the control of BP in patients with an inadequate response at low dose of perindopril that is well tolerated in this population.

There is little data on the management of elderly hypertensive patients in the United States; Solvay Pharmaceuticals Inc, Marietta, GA, United States; Investigators. Orange County Heart Institute, Orange, CA, United States; Solvay Pharmaceuticals Inc, Marietta, Georgia; Solvay Pharmaceuticals Inc, Marietta, Georgia.

Key Words: African-American, Hypertension, ACE-Inhibitors

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EFFICACY AND SAFETY OF PERINDOPRIL ERBUMINE, AN ANGIOTENSIN CONVERTING ENZYME INHIBITOR (ACE-I), IN 2269 ELDERLY HYPTERTENSIVE PATIENTS: SUBGROUP ANALYSIS OF A 12-WEEK, OPEN-LABEL, ACEON® COMMUNITY TRIAL (ACT)

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There is little data on the management of elderly hypertensive patients in family practice. Furthermore, it has been well demonstrated that treatment of these patients decreases their risk of cardiovascular disease. The efficacy and safety of perindopril erbumine were analyzed in a subgroup of elderly (≥65 years) hypertensive patients (n=2269) who were included in a large, 12-Week, open-label, community study. All patients were treated with perindopril 4 mg QD for 6 weeks and could be uptitrated by the investigator to perindopril 8 mg QD for an additional 6 weeks depending on blood pressure (BP) response. Seated BPs were measured at Baseline (antihypertensives withdrawn), Week 6, and Week 12.

Following 12 Weeks of treatment, perindopril resulted in a significant reduction in systolic (SBP) (-18.2±0.3 mmHg, p<0.001) and diastolic (DBP) (-8.9±0.3 mmHg, p<0.001). The decrease in SBP resulted in a significant narrowing of pulse pressure (PP), an index of safety, in elderly patients with systolic hypertension. At Week 12, BP control with perindopril defined as SBP/DBP <140/90 mmHg, SBP <140 mmHg or DBP <90 mmHg, SBP <140 mmHg and DBP <90 mmHg was achieved in 40%, 85%, 43%, and 81%; respectively. Based on JNC VI classification (systolic/diastolic), an increase in shift of patients from Baseline to Week 12 in nonhypertensive BP categories was: Optimal 1%/6% to 6%/40%; Normal 3%/7% to 18%/28%; and High-Normal 6%/8% to 29%/17%. Additionally, perindopril treatment controlled BP in a significant number of patients who were uncontrolled on previous ACE-I therapy. The antihypertensive effect of perindopril was well maintained throughout the 12 week treatment period. There were 1.5% cardiovascular adverse events. Cough and postural hypotension was reported in 8% and 0.1%, respectively.

In conclusion, perindopril was effective and well tolerated in patients with mild to moderate hypertension. Furthermore, these data demonstrate the clinical benefit of titrating perindopril and provides encouragement for clinicians to adopt the titration approach for BP control.

The effect of perindopril, an ACE-I, on sitting blood pressure (BP) was investigated in a 12 week, open-label, multicenter, general practice setting in 8083 patients with mild to moderate hypertension. All patients were treated with perindopril at 4 mg QD for 6 weeks; based on the BP response, investigators were allowed to maintain the 4 mg dose or increase the dose to 8 mg for an additional 6 weeks. Men and women were equally represented and the majority of the patients were Caucasian. Seated BPs were measured at Baseline (antihypertensives withdrawn), Week 6, and Week 12.

Perindopril treatment (4 to 8 mg QD) for 12 weeks produced a clinically significant reduction in SBP and DBP. In patients with inadequate response at Week 6 (Group 2), increase in perindopril dose to 8 mg QD produced significant additional decrease in SBP and DBP, supporting the titration approach. At Week 12, BP control with perindopril defined as SBP/DBP <140/90 mmHg, SBP <140 mmHg or DBP <90 mmHg, SBP <140 mmHg and DBP <90 mmHg was achieved in 47%, 80%, 55%, and 72%; respectively. Based on JNC VI classification (systolic/diastolic), an increase in shift of patients from Baseline to Week 12 in nonhypertensive BP categories was: Optimal 1%/6% to 8%/26%; Normal 3%/7% to 18%/28%; and High-Normal 6%/8% to 29%/17%. Additionally, perindopril treatment controlled BP in a significant number of patients who were uncontrolled on previous ACE-I therapy. The antihypertensive effect of perindopril was well maintained throughout the 12 week treatment period. There were 1.5% cardiovascular adverse events. Cough and postural hypotension was reported in 8% and 0.1%, respectively.

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Key Words: Perindopril Erbumine, Elderly, ACE-Inhibitors

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EFFECT OF PERINDOPRIL ERBUMINE, AN ANGIOTENSIN CONVERTING ENZYME INHIBITOR (ACE-I), ON BLOOD PRESSURE IN PATIENTS WITH MILD TO MODERATE HYPERTENSION - A LARGE ACEON® COMMUNITY TRIAL (ACT) WITH 8083 PATIENTS

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Key Words: Perindopril Erbumine, Elderly, ACE-Inhibitors

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<td>−5.0 ± 0.2*</td>
<td>−5.9 ± 0.2*</td>
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<tr>
<td>≥65 (n = 2268)</td>
<td>72.4 ± 0.4</td>
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Values are expressed as Mean±SEM; *p<0.001

Key Words: Perindopril Erbumine, Elderly, ACE-Inhibitors

P-24

EFFECT OF PERINDOPRIL ERBUMINE, AN ANGIOTENSIN CONVERTING ENZYME INHIBITOR (ACE-I), ON SITTING BLOOD PRESSURE IN PATIENTS WITH MILD TO MODERATE HYPERTENSION - A LARGE ACEON® COMMUNITY TRIAL (ACT) WITH 8083 PATIENTS

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