

THE NEW ANTIDEPRESSANT DULOXETINE: CARDIOVASCULAR EFFECTS

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Introduction: Duloxetine is a potent and balanced blocker of the recapturing of both serotonin and norepinephrine. This analysis aims at evaluating the cardiovascular safety of duloxetine in terms of its effects on the heart rate, arterial pressure and electrocardiographic tracing.

Methods: The data was analysed from 8 randomised, double-blind, controlled vs. placebo and/or vs. active comparator studies, which involved a total of 777 patients. The patients in therapy with duloxetine were administered a dose varying between 40 and 120 mg/die (n=1139), and those taking fluoxetine (n=70) or paroxetine (n=359) were administered a dose of 20 mg/die. The duration of the studies was either 8 or 9 weeks.

Results: The patients in therapy with Duloxetine showed a statistically significant variation in the heart rate vs. the placebo (1.6 vs. -0.6 beats/minute) and in the systolic pressure (1,0 vs. -1.2 mm Hg). No statistically significant differences were observed in the diastolic pressure vs. placebo (duloxetine 1.1 vs. placebo 0.3 mm Hg) or in the incidence of pressure increases (systolic, diastolic, totals) for at least three consecutive visits. Moreover, no statistically significant differences were observed in the pressure (diastolic and systolic) vs. fluoxetine or paroxetine. The differences observed between the drug and the placebo in the mean variations of the electrocardiogram (QT, PR and QRS intervals) were neither statistically nor clinically significant, with the exception of a significant diminishing of the PR and QRS intervals in patients in therapy with duloxetine 120 mg/die vs. placebo.

Conclusions: These results demonstrate how duloxetine has modest effects only on the heart rate and pressure, nor does it have any clinically relevant effects on the electrocardiograph profile in the cohort of patients included in the clinical trials. The effects of duloxetine at a cardiovascular level are comparable with those of the other drugs which have been considered up to date as the first choice in the therapy of depression.