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SAFETY OF PAROXETINE AND IMIPRAMINE IN THE TREATMENT OF ADOLESCENT DEPRESSION

Karen Dineen Wagner, M.D., Ph.D.[1], Boris Birmaher, M.D.[2], Gabrielle Carlson, M.D.[3],Greg Clarke, Ph.D.[4], Graham Emslie, M.D.[5], Barbara Geller, M.D.[6], Martin B. Keller, M.D.[7], Rachel Klein, Ph.D.,[8] Stanley Kutcher, M.D.[9], George Papatheodorou, M.D.[10], Neal Ryan, M.D.[11], Michael Strober, Ph.D.[12], Elizabeth Weller, M.D.[13]

Background: There is little controlled data available about the relative safety of paroxetine and imipramine in the treatment of adolescent depression.

Method: Two hundred seventy five adolescent outpatients between the ages of 12 and 19 years who met DSM-IV criteria for major depression participated in a multicenter double-blind placebo controlled trial of paroxetine and imipramine treatment. Patients were treated for 8 weeks with paroxetine, imipramine, or placebo. Patients who were non-responders were allowed to have doses titrated up to paroxetine 40 mg or imipramine 300 mg at week 6. Cardiovascular functioning (EKG, heart rate, blood pressure), clinical laboratory studies, and adverse events were monitored during the course of treatment.

Results: The mean dose of medication for the paroxetine group (n = 93) was 28.0 mg, sd = 8.5, and the imipramine group (n = 95) was 205.8 mg, sd = 63.9. The most frequently reported adverse experiences were headache in the paroxetine (33%) and placebo (39%) groups and dizziness in the imipramine group (47%). Other common symptoms were dry mouth reported by 26% patients overall and nausea reported by 22% patients overall. Insomnia and somnolence were reported by 14% and 15% of paroxetine and imipramine groups respectively. Thirty two percent of the imipramine patients withdrew for an adverse event which was significantly higher (p< .05) than the 10% paroxetine and 7% placebo adverse event withdrawals. The imipramine patients had significantly (p<. 05) more cardiovascular adverse events (43%) such as tachycardia, postural hypotension, EKG abnormalities including QT prolongation, than either the paroxetine (7%) or placebo (12%) groups.

Conclusion: The results of this study demonstrate the safety of paroxetine in the treatment of adolescent depression. Side effects were modest with paroxetine. Given the high rate of adverse cardiac events with imipramine, clinicians should carefully monitor cardiovascular functioning when treating depressed adolescents with imipramine.

[1]Karen Dineen Wagner, M.D., Ph.D., Univ. of Texas Med. Branch, 301 Univ.,Galveston,TX 77555-0425, [2] Boris Birmaher, M.D.,U.of Pittsburgh Sch. of Med., Pittsburgh, PA, [3]Gabrielle Carlson, M.D., State U.of NY at Stony Brook, Stony Brook,NY, [4]Greg Clarke, Ph.D., Oregon Health Sci. Univ., Portland,OR, [5]Graham Emslie, M.D.,UT Southwestern at Dallas, Dallas, TX, [6]Barbara Geller, M.D., Wash. U. Sch. of Med., St. Louis, MO, [7]Martin B. Keller, M.D., Brown U.Sch. of Med., Providence,RI, [8]Rachel Klein, Ph.D., NY State Psy. Institute, New York, NY, [9]Stanley Kutcher, M.D., Children's Hospital, Halifax, Scotia, Canada, [10]George Papatheodorou, M.D., Sunnybrook Health Sci. Ctr., Toronto, Ont., Canada, [11]Neal Ryan, M.D., U. of Pittsburgh, Pittsburgh, PA, [12]Michael Strober, Ph.D., U.of CA, LA Med.Ctr., Los Angeles,CA, [13]Elizabeth Weller, M.D., Ohio State U. Med., Ctr., Columbus, OH.

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