ORAL METHOXSALEN PHOTOCHEMOTHERAPY FOR THE TREATMENT OF PSORIASIS: A COOPERATIVE CLINICAL TRIAL

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Extensive psoriasis in 1,308 patients has been treated two or three times a week with oral 8-methoxypsoralen followed by high intensity, long-wave ultraviolet light (PUVA). Excluding 169 patients still under early treatment, psoriasis cleared in 88% and failed to clear in 3%. One percent dropped out due to complications of treatment, and 8% for other reasons. The twice-a-week schedule was superior for patients with lighter skin types. Once a remission was induced, there was no difference in its maintenance when patients were treated once a week, once every other week, or once every third week. Each of these schedules was superior to no maintenance treatment. Immediate side effects of the 45,000 treatments administered in the first 18 months of this study were uncommon, temporary, and generally mild. No clinically significant changes in laboratory screening or eye examinations attributable to PUVA have been uncovered.

In December, 1974, the first report was published on the use of oral 8-methoxypsoralen followed by high-intensity, long-wave ultraviolet light (UVA, 320 nm) for the treatment of psoriasis [1]. The treatment is known as PUVA (psoralen plus UVA). In July, 1975, a randomized cooperative clinical trial was initiated among 16 centers in the United States to investigate the safety and efficacy of various PUVA treatment schedules. This report is based on data obtained by the participating investigators on 45,000 treatments administered to 1,308 patients during the first 18 months of this ongoing study. (The participating investigators, the centers, and the number of patients from each center are listed in Appendix 1.)

PUVA is an experimental technique, not yet approved by the Food and Drug Administration, that has been used to induce and maintain a temporary remission of psoriasis. In the present study, each of the 16 centers was asked to enter 50 or more patients with at least 30% of their body affected by psoriasis at the time of the first treatment. After 50 such patients were entered, patients with less involvement could be included. Exclusions for entry were pregnancy, aphakia, use of systemic cytotoxic agents within a month of the first treatment, and use of topical medications other than emollients for areas other than the scalp, intertriginous regions, or soles of feet.

METHODS

8-Methoxypsoralen was provided in 10-mg capsules and administered according to the schedule in Appendix 2. Special UVA light box treatment systems developed and prepared by the GTE Sylvania Lighting Products Group, Danvers, Mass, were used [12]. UVA treatments were given 2 to 3 h after ingestion of 8-methoxypsoralen (Oxsalen, provided by the Paul B. Elder Company, Bryan, Ohio). Patients were completely disrobed and stood in the light box during UVA exposure. They wore goggles during treatment and were instructed to wear sunglasses for the remainder of the day. Treatments were administered by trained technicians and ranged from less than 1 min to more than 1 h.

The exposure (in joules/cm²) for the first treatment was based on skin type, a graded estimate of sun tolerance and facultative tanning determined from history and racial extraction (Appendix 3). Since therapeutic results on the extremities lagged behind those on the trunk, the protocol allowed for additional exposure to the extremities, beginning with the first treatment and increasing to 1 1/2 the total-body dose.