Topical aminolevulinic acid HCI photodynamic therapy.

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Photodynamic therapy (PDT) is the treatment of tumors or dysplasic tissue with drugs that produce cytotoxic metabolites when exposed to light. Aminolevulinic acid HCI (5-aminolevulinic acid HCI; ALA) is a prodrug that is metabolized intracellularly to form the photosensitizing molecule protoporphyrin (PpIX). When PpIX is activated by light, cytotoxic reactive oxygen species and free radicals are generated. ALA can diffuse through skin and preferentially localizes in tumors and dysplasic tissue; subsequent exposure of PpIX-loaded tumor cells to light can destroy the tumor. After application of a 20% solution of ALA to actinic keratosis lesions of the head, PpIX (as measured by skin fluorescence) peaked 11 hours after treatment and the mean clearance half-life was 30 hours. In phase II trials 10 J/cm2 of blue light (wavelength = 417 nm) delivered at 10 mW/cm2 for 1000 seconds was found to provide maximal therapeutic effect on lesions of the head after treatment with 20% ALA. In phase III trials of ALA PDT in 241 patients with lesions of the head 72% of patients had a complete response to treatment at 12 weeks versus 20% of those treated with vehicle and light alone. Some of these patients had been retreated at 8 weeks. In these trials 12% of ALA-treated patients and 37.5% of those receiving vehicle whose lesions had cleared at 8 weeks had relapsed at 12 weeks. When the total number of lesions were considered the recurrence rate was 5 and 27.9% for ALA- and vehicle-treated lesions, respectively. All patients reported some degree of burning or stinging during PDT but this usually subsided after irradiation was completed and was rarely treatment-limiting. Localized erythema and edema were also common. No other significant adverse effects were noted and treatment was generally well tolerated. A well designed dermal applicator ensured perilesional skin was spared collateral damage.