BACKGROUND: Gemcitabine has mild renal toxicity, but cases of gemcitabine-associated hemolytic-uremic syndrome (HUS) have been reported. METHODS: A case is presented of a 45-year-old woman on prolonged gemcitabine treatment for ovarian cancer who developed HUS and recovered after drug discontinuation. A mini-review of the literature based on a MEDLINE search follows. RESULTS: Including our own patient, a total of 26 cases of gemcitabine-associated HUS were identified. Median patient age was 52 years. Treatment was for various tumors at advanced stages, and in some patients, other anticancer drugs previously had been administered. Mean time between initiation of gemcitabine therapy and onset of HUS was 7.4 +/- 3.5 months, or 21.9 +/- 10.9 doses of gemcitabine. The calculated median cumulative dose of gemcitabine was 20,000 mg/m\(^2\) (range, 2,450 to 48,000 mg/m\(^2\), or a total of 70,000 mg). The onset of disease was noted up to 2 months after the last gemcitabine infusion. Diagnosis of HUS was confirmed histologically in 13 patients and based on clinical findings in the other 15. Treatment included drug discontinuation, steroids, fresh frozen plasma, hemodialysis, absorption chromatography, plasmapheresis, and various combinations thereof. Of 23 patients with reported outcome, 11 died within a few weeks. In two cases, death was believed to be a direct consequence of HUS. Reexposure to the drug was reported in three patients but was uncomplicated in only one. CONCLUSION: There are only a few confirmed cases of gemcitabine-associated HUS despite the widespread use of the drug. This potentially fatal complication is difficult to treat and should be widely known.