

Comparing two treatment protocols for gestational trophoblastic disease: weekly single-dose intramuscular and 8-day intravenous injections of methotrexate

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Abstract

Introduction: The essentials of gestational trophoblastic disease (GTD) treatment are evacuation of the uterus followed by chemotherapy. Methotrexate, an antagonist of folinic acid and an antimetabolite agent, has an important role in the treatment of patients with gestational trophoblastic disease. The efficacy of single agent chemotherapy with methotrexate in low and medium risk GTD is well-established and numerous studies for lowering its toxicity and fewer numbers of expected visits and consequently lower time and money expenditures are on rise. This medication has produced excellent remission rates with acceptable toxicity, cost-effectiveness and better compliance by patients. The aim of this study was to compare two methods of weekly single-dose intramuscular and 8-day intravenous injections of methotrexate, in low and medium risk GTD patients who required single agent chemotherapy.

Materials & Methods: This was a clinical trial study conducted for three years (2002-5) in the Gynecology Oncology Department of Ghaem Hospital in Mashad. All patients with low and medium risk GTD who required single agent chemotherapy were assigned into two groups. The first group consisted of 33 patients who received IV injections of methotrexate 1 mg/m^2 of body surface area and folinic acid 0.1 mg/m^2 every other day for a total of 8 days. The second group consisted of 14 patients that received weekly single-dose IM injections of methotrexate 50 mg/m^2 . These two groups were matched for age, number of pregnancies, blood groups, histological characteristics and the interval between end of the antecedent pregnancy and start of chemotherapy. The results were analyzed by SPSS software. For statistical calculations t-test and χ^2 were used and a confidence interval of 95% and a p-value of ≤ 0.05 , as the significant value, were regarded for the study.

Results: The mean age of the first group was 25.38 ± 7.33 years and 25.7 ± 7.52 for the second group. Response rates fewer than four courses of chemotherapy in the first group was 45.5% and in the second group was 28.5% ($p=0.018$). The results showed that 9.9% of the patients in the first group and 42.1% of those in the second group needed nearly a 1.5-time increase in the dose of the medication ($p=0.001$). Requiring a change to the second line of therapy from methotrexate to actinomycin D was 6.6% in the first and 7.1% in the second group ($p=0.715$). Combination chemotherapy with EMA/CO (Etoposide, methotrexate, actinomycin D, cyclophosphamide and vincristine) regimen were needed by 9.9% of the patients in the first and 14.2% in the second group ($p=0.656$). Eventually, both groups achieved complete remission with no recurrence of the disease during the follow-up period.

Conclusion: The weekly single-dose intramuscular injection of methotrexate is an effective, low toxic, inexpensive and accessible method that can be performed in every center for low and medium risk GTD patients that need single agent chemotherapy as compared with 8-day intravenous injections.

Key Words: Gestational trophoblastic disease, Methotrexate, Actinomycin D, EMA/CO, Chemotherapy, hCG, Metastatic gestational trophoblastic disease, Hydatid mole.

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