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## ACCEPTED MANUSCRIPT

#### Ifosfamide and Doxorubicin in the Treatment of Advanced Leiomyosarcoma

Serkan Akin<sup>1</sup>, Omer Dizdar<sup>2</sup>, Yusuf Karakas<sup>1</sup>, Alev Turker<sup>1</sup>, Ayse Kars<sup>1</sup>

<sup>1</sup>Hacettepe University Cancer Institute, Department of Medical Oncology, Ankara, Turkey

<sup>2</sup>Hacettepe University Cancer Institute, Department of Preventive Oncology, Ankara, Turkey

#### **Correspondence:**

Dr. Serkan AKIN, MD, Hacettepe University Cancer Institute, Department of Medical Oncology, Ankara/ Turkey

06100, Tel: +90 5322276104, fax: +903123052935, e-mail: drserkanakin@gmail.com

#### Abstract

**Purpose:** Leiomyosarcomas (LMS) are rare tumors with poor prognosis due to the high rate of recurrent and metastatic disease. The combination of doxorubicin (Adriamycin) and ifosfamide (AIM) results in moderate response rates of 10 to 30%. The aim of this study was to assess the efficacy of the AIM regimen along with multimodality treatment including surgery and radiotherapy in patients with LMS.

**Methods:** The clinicopathologic characteristics and outcomes of 51 patients with recurrent or metastatic LMS diagnosed between 2000-2014 who received the AIM regimen were analyzed retrospectively. Treatment consisted of ifosfamide 2500 mg/m<sup>2</sup> on days 1-3 (with mesna 2500 mg/m<sup>2</sup> days 1-3, 4-hour i.v. infusion), and doxorubicin 60 mg/m<sup>2</sup> on day 1 (2-hour i.v. infusion), which was repeated every 21 days.

**Results:** The mean age of the patients at diagnosis was  $48.9\pm11.2$  years. Forty-two patients were female (82.4%). The primary tumor site was the uterus in 30 (58.8%) patients. The most common metastatic sites were lung and liver. The median follow-up was 27.9 months (min: 4.3 max: 164.8). The median progression-free survival (PFS) was 6.7 months (95% CI: 4.1-9.2). The median overall survival (OS) was 24.6 months (95% CI: 16.2-33.0). The overall response rate was 12% (6/51 pts). Response rates were higher in patients with uterine LMS (17%) compared with those with non-uterine LMS (5%); however, the OS times were similar. Surgical intervention for local or distant recurrence was associated with improved median OS (41 vs. 16.6 months, p<0.001). Myelosuppression was the major toxicity of this combination.

**Conclusions:** In our study, the AIM regimen was effective in patients with LMS. Resection of local/distant recurrence was found to improve survival in our study.

Key Words: Leiomyosarcoma; ifosfamide; doxorubicin; AIM.

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