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Evaluation of Trabectedin Safety and Effectiveness at a Tertiary Cancer Center at Qatar: A Retrospective Analysis

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Abstract : Purpose: Trabecatine is a is a potent marine-derived antineoplastic drug which binds to the minor groove of the DNA, bending DNA towards the major groove resulting in a changed conformation that interferes with several DNA transcription factors, repair pathways and cell proliferation. Trabectedin was approved by the European Medicines Agency (EMA; London, UK) for the treatment of adult patients with advanced stage soft tissue sarcomas in whom treatment with anthracyclines and ifosfamide has failed, or for those who are not candidates for these therapies. The recommended dosing regimen is 1.5 mg/m2 IV over 24 hours every 3 weeks. The purpose of this study was to comprehensively review available data on the safety and efficacy of trabectedin used as indicated for patients at a Tertiary Cancer Center at Qatar. Methods: A medication administration report generated in the electronic health record identified all patients who received trabectedin between November 1, 2015 and November 1, 2017. This retrospective chart review evaluated the indication of trabectedin use, compliance to administration protocol and the recommended monitoring parameters, number of patients improved on the drug and continued treatment, number of patients discontinued treatment due to side-effects and the reported side effects. Progress and discharged notes were utilized to report experienced side effects during trabectedin therapy. A total of 3 patients were reviewed. Results: Total of 2 out of 3 patients who received trabectedin were receiving it for non-FDA and non-EMA, approved indications; metastatic rhabdomyosarcoma and ovarian cancer stage IV with poor prognosis. And only one patient received it as indicated for leiomyosarcoma of left ureter with metastases to liver, lungs and bone. None of the patients has continued the therapy due to development of serious side effects. One patient had stopped the medication after one cycle due to disease progression and transient hepatic toxicity, the other one had disease progression and developed 12 % reduction in LVEF after 12 cycles of trabectedin, and the third patient deceased, had disease progression on trabectedin after the 10th cycle that was received through peripheral line which resulted in developing extravasation and left arm cellulitis requiring debridement. Regarding monitoring parameters, at baseline the three patients had ECHO, and Creatine Phosphokinase (CPK) but it was not monitored during treatment as recommended. Conclusion: Utilizing this medication as indicated with performing the appropriate monitoring parameters as recommended can benefit patients who are receiving it. It is important to reinforce the intravenous administration via central intravenous line, the re-assessment of left ventricular ejection fraction (LVEF) by echocardiogram or multigated acquisition (MUGA) scan at 2- to 3-month intervals thereafter until therapy is discontinued, and CPK and LFTs levels prior to each administration of trabectedin.

Keywords : trabectedin, drug-use evaluation, safety, effectiveness, adverse drug reaction, monitoring
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