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Therapeutic drug monitoring of busulfan by UPLC-tandem mass spectrometry

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Background: Busulfan (Bu) is an alkylating agent commonly used in preparative regimens for patients undergoing hematopoietic stem cell transplantation (HSCT) for various types of malignancies. A rapid, selective, reliable, precise, accurate, and reproducible method for quantification of Bu in human plasma using Acquity UPLC system coupled to triple quadrupole tandem mass detector (TQD) has been developed and validated to be used routinely for TDM of Bu employing Busulfan-d8 as an internal standard (IS).

Methods: The drug and IS were extracted by ether and analyzed on Acquity UPLC BEH C18 column (2.1x50 mm, 1.7 μ m). Quantitation was achieved using positive electrospray ion source (ESI+) interface employing MRM mode.

Results: The method was validated over the concentration range of 25–2000 ng/ml (r>0.99). Intra- and inter-run precision of Bu assay at four concentrations (50, 500, 1250 and 1750 ng/ml) ranged from 1.2 to 6.5% with accuracy (bias) varied from -10.7 to -0.2% indicating good precision and accuracy. Stability of Bu in human plasma samples at different conditions showed that the drug was stable under the studied conditions.

Conclusion: The suitability of the developed method for routine TDM was demonstrated by measuring Bu in human plasma samples of patients under preparative and conditioning regimens who will undergo hematopoietic cell transplantation (HCT) for various malignancies including acute myeloid leukemia (AML) and myelodysplastic syndrome (MDS) as well as non-malignancy conditions such as thalassemias.

Biography

Kamal Matar is an Associate Professor and Chairman of the Department of Pharmacology & Therapeutics at Kuwait University. He is also a Director of Therapeutic Drug Monitoring & Clinical Toxicology (TDM&CT) Unit, Faculty of Medicine, Kuwait University. He is involved in training Graduate students as well as Resident Physicians in the utilization of a wide variety of analytical techniques used for TDM. He completed his PhD at Cardiff University, UK, in 2000. He has published over 40 peer-reviewed articles and over 30 abstracts in international conferences. He is serving as a Reviewer for some international journals such as: *Journal of Chromatography B, Journal of Pharmaceutical & Biomedical Analysis, Medical Principles & Practice, Chemotherapy, Drugs, Analytical Chemistry Insights and Journal of Antimicrobial Chemotherapy*. He is a member of International Association of Therapeutic Drug Monitoring & Clinical Toxicology (IATDMCT).

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