Poster

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Chair: Wei-Chi Ku, Taiwan

Wed. Sep 27, 2017 12:30 PM - 1:30 PM Annex Hall (1F)

(Wed. Sep 27, 2017 12:30 PM - 1:30 PM Annex Hall)

[P27-7-6] Development and validation of an ICP-MS method to quantitatively determine cobalt in volumetric absorptive microsampling (VAMS) devices for the follow-up of metal-on-metal prosthesis patients

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Keywords: Volumetric absorptive microsampling, VAMS, Cobalt, ICP-MS Metal-on-metal hip prostheses

Background

Metal-on-metal (MoM) prostheses, i.e. prostheses in which the bearing surfaces are made of a metal alloy, may release excess amounts of cobalt and chromium upon wear and corrosion, potentially causing adverse local tissue reactions and systemic toxicity. As the systemic cobalt level increases with the degree of implant wear, this level is monitored as a means of assessing implant function, the risk of adverse effects and the need for implant revision. Since patients' cobalt levels are measured regularly, it is worthwhile evaluating whether this can be done in a home setting. Therefore, a method to determine cobalt in volumetric absorptive microsampling (VAMS) devices was developed.

Methods

In this method, the VAMS undergo an aqueous extraction, followed by protein precipitation. The resulting supernatant is further diluted with Milli-Q® water and analyzed using an Agilent 7900 ICP-MS. Special attention was paid to evaluating the impact of hematocrit on extraction recovery, as VAMS are known to be more vulnerable to this type of hematocrit effect. Furthermore, all employed materials were evaluated for their inherent cobalt contamination and replaced by better alternatives wherever necessary. The analytical validation was carried out based on FDA guidelines. In the near future, the method will be applied to VAMS samples of both patients and healthy volunteers. Importantly, the VAMS-based results will be compared with those obtained by routine analysis of the corresponding liquid blood samples to evaluate the validity of the VAMS-based method in a clinical setting.

Results

Cobalt levels between 3 and 300 g/L can be quantitatively determined (%bias and imprecision 15% (or 20% at LLOQ)), starting from VAMS samples containing approximately 10 L of spiked blood. This indicates that the method is sufficiently sensitive, since the suggested cut-off for acceptable cobalt levels in MoM-prosthesis patients is 4 g/L. No hematocrit effect could be observed. The recovery proved to be both high and hematocrit-independent. Samples were stable up to at least one week at room temperature. Furthermore, the analysis of a reference material gave acceptable results.

Conclusions

An ICP-MS method was set up to allow quantitation of cobalt in VAMS for the follow-up of MoM-prosthesis patients.