Intra-operative Bone Marrow Processing for Bone Regeneration

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ABSTRACT

The study is the result of the multidisciplinary collaborative efforts of the Departments of Pathology, Apheresis, Orthopedic Surgery and the UC Davis Stem Cell Program. Background: Processing large amounts of bone marrow aspirate in order to obtain a stem cell concentrate to be used for cellular therapy applications may be performed using apheresis technology. However, a detailed protocol has not been published yet. Objective: The aim of our study was to develop a clinical protocol using the CobeSpectra apheresis device (CaridianBCT) to process stem cell products or bone marrow aspirate.

Materials and Methods: In vitro experiments: A total of ten in vitro experiments were performed to assess the feasibility of using CobeSpectra for semi-selective processing of mononuclear cells (MNC). In the three experiments whole blood was used for apheresis processing and the MNC recovery was determined. In another seven experiments, the whole blood admixed with stem cell products was processed; in this case the MNC and stem cell recovery were determined. In both types of experiments, pre- and post-processing samples were analyzed for sterility by standard culture methods.

Clinical protocol: The apheresis protocol was used to process bone marrow aspirate in one patient with avascular necrosis (AVN) of the femoral head. The concentrated stem cell product was implanted immediately after processing at the necrosis site and the patient was monitored for two years.

Results: In vitro experiments: The MNC recovery was 66-73% in the vitro experiments with whole blood only. Apheresis processing of whole blood admixed with stem cell products led to a stem cell recovery of 56%. All cultures on pre- and post-processing samples were negative. Clinical studies: The patient tolerated the procedure well and the cultures of the processed bone marrow were negative. The stem cell recovery was 93%. The patient had improved clinical and functional status with preserved joint space without evidence of bone collapse by imaging. Conclusions: Bone marrow aspirate may be successfully processed by apheresis within the intra-operative timeframe leading to adequate stem cell enrichment.

ACKNOWLEDGEMENTS

• Special thanks to the UCDMC Department of Pathology for the Clinical Research Award funds to continue this study.
• We acknowledge the contribution of A Jaworowski, to the protocol development and M. Defebe for preparation of the stem cell products.

REFERENCES

CONCLUSIONS

The advantages of apheresis technology are processing of larger volumes of the aspirate and semi-selective concentration of the MNC and stem cell compartment. Bone marrow processing using CobeSpectra apheresis technology can be used to appropriately process bone marrow within the intra-operative timeframe. More studies are needed to define the parameters of the bone marrow product used for implantation and their effect on targeted clinical outcome.

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