Conclusion: This case illustrates the relevance of a sensitive antibody detection system to screen for HLA alloimmunization. A more accurate study of the frequency of alloimmunization will allow for evaluating its influence in the outcomes of platelet transfusion support and improving its effectiveness.

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Inactivated GMP-compliant human platelet lysate for clinical-scale expansion of mesenchymal stem cells

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Introduction: Mesenchymal Stem Cells (MSCs) are ideal candidates in regenerative and immunomodulatory therapies. The use of GMP-compliant growth media, without xenogenic protein contamination, is a mandatory prerequisite for clinical-grade MSC isolation and expansion. Pooled Human Platelet Lysate (HPL), obtained from 10 to 15 Buffy-Coats derived Platelet Concentrates (BC-PCs), has been efficiently implemented into clinical scale manufacturing of MSCs as animal serum substitute. To upgrade quality and safety we decided to prepare inactivated HPL with INTERCEPT Blood System (Cerus). Aim of this study: to compare quality of inactivated and not inactivated HPL in order to validate inactivation procedure for the use in clinical-scale expansion of MSCs.

Methods: We evaluated two batches of pHPL, inactivated (I-HPL) and not-inactivated (HPL). In particular, six pairs of BC-PCs were prepared. Each BC-PCs was made of four 0-group BC and one AB-group plasma. Each time a couple of BC-PCs was pooled and then split into two units; only one was inactivated. Samples for quality controls were taken from each unit. All the BC-PCs were frozen and thawed three times for platelet fragmentation. Finally all the inactivated BC-PCs were pooled in a single HPL unit, resulting in a batch of 60 different donors. The HPL was then divided into aliquots of 100–150 ml each and frozen again at −35°C until use. The same was made with the series of not inactivated BC-PCs. I-HPL and HPL were evaluated in BM-MSC culture through the analysis of cells morphology, growth kinetics, clonogenicity, immunophenotype, differentiation potential, karyotype, endotoxin levels and bacterial, fungal, mycoplasma contamination. Statistical analyses were performed with Wilcoxon signed Rank Test – paired samples.

Results: Plts content ($2.9 \pm 0.3 \times 10^{11}$/unit), volume ($318 \pm 5$ ml) and leukocyte contamination (0.18 ± 0.3 x10^6/unit) of BC-PCs resulted within the ranges defined as suitable for inactivation procedure. No statistical differences were observed in the efficiency of MSC expansion between I-HPL and HPL.

Conclusion: The use of HPL represents a promising tool for the development of cell therapeutics propagated in an animal serum-free system. I-HPL didn't report any statistical differences in comparison with not-inactivated HPL. Inactivation procedure improves HPL quality, resulting more advantageous in term of safety cellular growth.