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Evaluation of TACSI System for Automated Production of GMP-Compliant Human Platelet Lysate for Clinical-Scale Expansion of Mesenchymal Stem Cells

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Background/Case Studies: Mesenchymal Stem Cells (MSCs) are ideal candidates in regenerative and immunomodulatory therapies. For clinical-grade MSC isolation and expansion, the use of GMP-compliant growth media, without xenogenic protein contamination, it is a mandatory prerequisite. Human Platelet Lysate (HPL) has been efficiently implemented into clinical scale manufacturing of MSCs as animal serum substitute. HPL can be prepared according to blood bank procedures where a high standardization is strongly recommended. We routinely use the Terumo TACSI system for automated preparation of Leukoreduced Buffy-Coats pooled Platelet Concentrates (LBC-PCs). This device, reducing variability due to manual operation, standardizes LBC-PCs quality at a high level. Aim: to evaluate the TACSI system to obtain LBC-PCs suitable for preparing HPL for clinical MSCs propagation. **Study Design/Methods:** Ten LBC-PCs were prepared using TACSI device. For each LBC-PC unit, four 0-group BC and one AB-group plasma were pooled together, processed by TACSI and frozen at –35°C. Samples for quality controls were taken from each unit. To improve standardization and reduce individual donor variations, the LBC-PCs were thawed at 37°C and pooled in a single HPL unit, resulting in a batch of 50 different donors. The HPL was finally divided into aliquots of 100-150 ml each and frozen again at –35°C until use. For the use in cell culture HPL bag was thawed at 37° C and the content was transferred into 50 ml tubes and centrifuged at 4000 g for 15 min. The supernatant was added at 10% of concentration in alpha MEM + 2 mM Glutamine + antibiotics + 2 U/ml of heparin. **Results/Findings:** A HPL batch of 50 donors was produced from 10 LBC-PCs. Plts concentration in BC-PCs was (1030 ± 115) × 10^3/ll, volume (322 ± 12) ml, plts content (3.3 ± 0.3) × 10^{11}/unit and residual WBC (0.05 ± 0.07) × 10^{11}/unit. Preliminary data showed that MSC isolation using HPL is more advantageous in term of cellular growth in comparison with commercial Medium (Lonza, Stem Cell, LiStar) for MSC isolation and expansion containing foetal bovine serum. No differences were observed in term of immunophenotype and multipotent capacity. **Conclusion:** HPL represents a GMP-compliant alternative for the clinical production of MSCs, resulting also more advantageous in term of cellular growth. The TACSI system improves standardization of HPL products, limiting manual operations and allowing preparation of high quality BC-PCs in a short period time.

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Retrospective Evaluation of Testing Plasma Samples from Cadaveric Donors with the Roche Cobas® TaqScreen MPX Test

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Background/Case Studies: Screening of cadaveric donors is generally more difficult than screening of living donors due to the sample quality. Retrospective NAT testing results were analyzed to determine NAT test performance with cadaveric donor samples. **Study Design/Methods:** Plasma samples were collected from cadaveric donors within 24 hours of death and tested within 64 hours of collection. Plasma samples from cadaveric donors were tested as outlined in the Roche cobas® TaqScreen MPX Test package insert. All serology tests were performed with the Abbott PRISM platform. The tests were anti-HCV, anti-HIV-1/2 and anti-HBc. The confirmatory tests used were the RIBA test for anti-HCV (Chiron), Western Blot for anti-HIV (BioRad), and Total Core Confirmatory Test for anti-HBc (Siemens). **Results/Findings:** 316 plasma samples from cadaveric donors were tested with the cobas TaqScreen MPX Test and all sample test results were non-reactive. The serology results are summarized in Table 1. Of the serology positive samples, 20 were positive for anti-HIV-1/2, 1 for both HCV & anti-HBc, 4 for anti-HBc. The anti-HCV positive sample was confirmed positive as were 3 of the anti-HBc positive samples. One anti-HBc positive sample was confirmed negative and the remaining sample had insufficient volume for confirmatory testing. Twelve of the anti-HIV-1/2 positive samples were confirmed negative, one sample had an indeterminate result and 7 samples had insufficient volume for confirmatory testing. **Conclusion:** The one HCV serology positive NAT negative sample is most likely an infected carrier with a low viral load below the limit of detection of the NAT test. In addition, there were three confirmed anti-HBc samples that were HBV NAT non-reactive and these probably represent samples from donors with an occult HBV infection. In this study, there were no false reactive NAT results nor any tests that were inhibited (no IC drop-outs) demonstrating that the cobas® TaqScreen MPX Test is a highly specific test even when using cadaveric plasma samples which are known to be less than optimal.

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TABLE 1. Abbott PRISM serology results

	Anti-HIV	HBsAg	Anti-HBc	Anti-HCV
Incomplete/ Invalid *	2	0	0	1
Initiallyreactive**	3	2	0	0
Positive***	20	0	5	1
Non-reactive	280	302	299	302
Not tested	11	12	11	12
Quantity not sufficient	0	0	1	0

* Incomplete/invalid: PRISM test results were not obtained due to viscosity of the sample; ** Initially reactive: reported when the sample is tested one time and yields a reactive result but insufficient sample was available for the duplicate retest required by FDA regulations; *** Positive: samples were tested 3 times in total, at least two of which gave reactive results, before being reported as positive

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CD26 Deficient Recipient Mice Exhibit Improved Transplant Efficiency Primarily Through Enhanced Long-Term Engraftment

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Background/Case Studies: A firm understanding of the biology of hematopoietic stem and progenitor cell (HSC/HPC) trafficking is critical for the development of methods to improve transplant efficiency and subsequent immune reconstitution during hematopoietic stem cell transplantation (HSCT) in the clinical setting. Our earlier findings suggested that suppression of CD26/DPPIV enzymatic activity in the donor cell population can be utilized as a method for increasing transplant efficiency. However, transplant recipient factors should not to be overlooked, given the potential for the bone marrow (BM) microenvironment to regulate the transplantation process. We investigated whether inhibition or loss of CD26 activity in recipient mice alters transplant efficiency. **Study Design/Methods:** Histological analysis was done on formalin-fixed paraffin-embedded tissues from CD26–/– and C57BL/6 mice using a polyclonal biotinylated anti-mouse CD26 antibody. Homing and engraftment experiments were used to ascertain the transplant efficiency of BoyJ (CD45.1+) donor mouse BM cells into lethally irradiated C57BL/6 or CD26–/– (CD45.2+) congenic recipient mice. For homing, donor cells were monitored by flow cytometric analysis by calculating the % of CD45.1+ and CD45.2+ Sca+lin- cells in the BM of recipient mice 24 h post transplantation of 20 × 10^6 BM MNCs. Engraftment of donor cells was evaluated by the contribution of CD45.1+ donor cells to hematopoiesis in the context of CD45.2+ recipient cells in the peripheral blood (PB) 6 mos post transplantation of 1 × 10^5 donor MNCs. **Results/Findings:** CD26 expression was present in the spleen, BM and liver. We observed a 14.74% ± 0.96%, 17.81 ± 1.68%, and 20.74 ± 2.22% homing efficiency of Sca+lin- cells into the BM of C57BL/6, Diprotin A treated C57BL/6, and CD26–/– recipient mice, respectively. When the effect of donor cell manipulation is compared to recipient manipulation there is a statistically greater level of