FIRST VALIDATION AND IMPLEMENTATION OF THE ORBISAC SYSTEM IN A SWISS BLOOD-CENTER WITHIN THE SCOPE OF INTRODUCING THE PATHOGEN INACTIVATION SYSTEM INTERCEPT

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Background: Due to rising demands of platelets (plts), the capacity to produce platelet concentrates (PC) from Buffy-Coats (BC) needed to be increased at our facility. In addition, the decision to treat 100% of PC with the pathogen-inactivation system INTERCEPT^{TM} extended the production time significantly. These facts made it necessary to optimize the efficiency of PCBC production. Two systems for semi-automation of PCBC production were tested and we decided on the OrbiSac System from CaridianBCT® since it allows among other things automated pooling of BCs. Two machines were in place for this validation.

Aims: One goal was to produce more PCBC in a shorter period of time with the same staff. Furthermore, the PCBC had to meet the process entry requirements for INTERCEPT, called guard bands (volume 255-420mL, 2.5-6.0x10^{11} plts/unit, <1x10^{6} WBC /unit, <4x10^{6} RBC/mL, 32-47% plasma).

Finally after INTERCEPT the products had to meet Swiss specifications (≥ 2.4x10^{11}plts/unit, <5x10^{9} RBC/unit, <1x10^{6} WBC/unit, pH≥ 6.4 after 5d). Focus was here on pH since we validated INTERCEPT extensively before and were now mainly interested to see if PC from OrbiSac have an acceptable pH after 5d.

Methods: Efficiency:

The manufacturing process with the OrbiSac System was compared to the efficiency of the current process (manual pooling of BCs followed by soft spin centrifugation and a 2nd expression with a MacoPress including in-line leukoreduction).

INTERCEPT- compatibility:

BCs were produced from whole blood (450mL) using MacoPress Classic separators. To get 1 leukoreduced PCBC, 5 ABO/Rh-matched BCs and 250ml SSP^{+} as additive solution (PAS) were processed with the OrbiSac System. The products (n=18) were analyzed for guard band specifications and some of those products (n=6) were further treated with INTERCEPT after approx. 2h resting time. 3 additional PCBC were manufactured and processed with INTERCEPT without resting time to create a putative worst-case scenario concerning pH after 5d.

Results: The measured platelet content of PCBC (n=18) before INTERCEPT was 3.7x10^{11} (range 2.8-5.2) in 335mL (range 314-353) containing 37% plasma (range 34-42) in PAS. RBC were 1.2x10^{6}/mL (range 0.3-2.1) and WBC were 0.017-0.166x10^{6}/unit.

All 6 PCBC further processed with INTERCEPT after a resting time (n=6) met Swiss specifications including pH (range 7.0-7.1).

1 of the 3 runs without resting before INTERCEPT did not meet the specifications for plts/unit (2.3x10^{11} instead ≥2.4x10^{11}). All other Swiss specifications and the guard bands were met including pH (range 7.0-7.1). Investigations on the failed run showed that the platelet content of the initial BC-pool was already poor.

The two OrbiSac devices increased production capacity after implementation from 20 to 30 PCBC/day while manufacturing time was reduced from 13h to 9h and staff involved was reduced from 4 to 2 operators.

Summary/Conclusions: The OrbiSac System is well suited to efficiently produce PCBC for the INTERCEPT System. All PCBC met the INTERCEPT process entry criteria. After INTERCEPT, one PCBC did not meet Swiss specifications for platelet content which was very likely due to a poor BC-pool and not related to separation by OrbiSac or the INTERCEPT Process.