Safety, Efficacy, and Cost-Effectiveness of Mononuclear Cell Collections for Autologous Immunotherapies: Experience from a European Private Collection Facility

Markus Dettke, Zahra Najafi, Bernhard Peball, Petra Krumm, Robert Schober
Cyto-Care.eu; Vienna, Austria

Background

Mononuclear cell (MNC) collection by leukapheresis (LA) constitutes a major component of the overall production costs of cellular therapies.

We report on the procedural and logistical challenges of LA at Cyto-Care, a privately operated cell collection and clinical apheresis center in Vienna, Austria.

Objectives

We retrospectively reviewed records from 1,620 LA procedures performed in 82 patients and 1,421 healthy donors. Data were analyzed across the following parameters:

- Collection efficiency
- Safety, patient satisfaction
- Logistics
- Cost structure and cost effectiveness

Patients & Methods

All patients participated in various industry-sponsored clinical phase I-III trials; the study sponsors were responsible for the manufacturing of the active cell compounds. All products were delivered as “fresh” products.

Diagnoses included primarily prostate cancer (79%) and ovarian cancer (16%). Depending on study protocol, LA was performed once (56%), twice (25%), or three times (19%), with a minimum interval of 2 weeks between repeated collections.

Healthy donor collections served R&D, CMC, and regulatory purposes.

MNC apheresis was performed using Terumo Optia devices with the cMNC protocol. In healthy donors, processed blood volume was 2.1 ± 0.5 × total blood volume (TBV).

Results

Product characteristics

	healthy donors	patients	p-value
WBC abs. (x10^{10})	1.6 (1.0 - 3.7)	1.3 (0.8-1.8)	0.02
MNC abs. (x10^{10})	1.52 (0.9-3.2)	1.12 (0.7-1.8)	0.001
Coll. efficiency (CE%)	68 (48-89)	58 (31-77)	0.001
Hematocrit (%)	< 3.0 (1.8-6.2)	3.9 (2.2-5.6)	0.02
Platelets (x10^{11})	1.7 (1.1-3.6)	1.4 (1.2-3.2)	0.03

Apheresis products from patients contained lower absolute WBC and MNC counts than those from healthy donors.

This was primarily attributable to marked differences in peripheral WBC counts between the two groups.

Short lead time, transport logistics

Fig. A

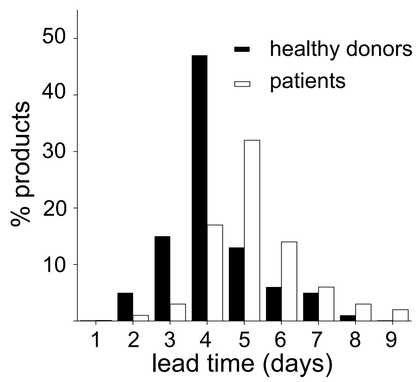


Fig. B

Median lead time from collection request to MNC harvest was 4 days for healthy donors and 6 days for patients (Fig. A).
Temperature monitored delivery was by direct courier - car or flight; maximum transport time within the EU was 24 hours (Fig. B).

Safety and patient satisfaction

Fig. A

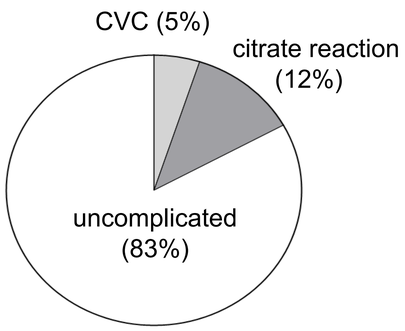
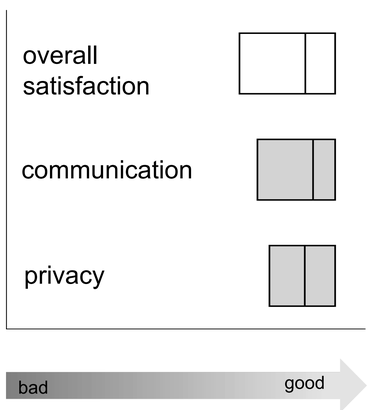
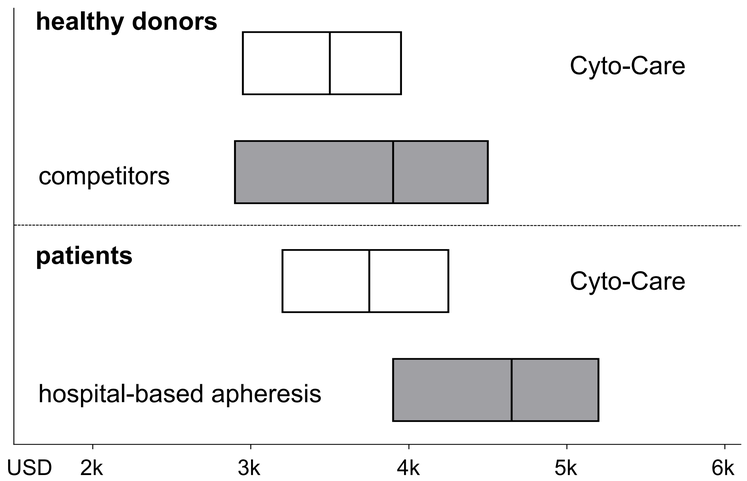


Fig. B



A CVC (femoral access) was required in 5% of patients; 12% experienced mild citrate-related side effects (Fig. A). NRS survey data indicated high overall patient satisfaction (Fig. B).

Cost effectiveness



Cost analysis revealed a 32% reduction in total patient-related apheresis costs compared to hospital-based centers.

Conclusion & Implications

Leukapheresis at this private, certified cell collection center is safe and effective, with low complication rates and high patient satisfaction. The service model is cost-competitive with hospital-based apheresis centers and contributes to reducing costs of goods for innovative cell and gene therapy products.

Contact: www.cyto-care.eu