Comparative Efficacy of Bacterial Culture Versus Pathogen Inactivation to Reduce the Risk of Transfusion-associated Sepsis

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Presented at the
XXII Congrés de la Société Française de Transfusion Sanguine (SFTS)
Saint-Malo, France • June 27 & 28, 2005

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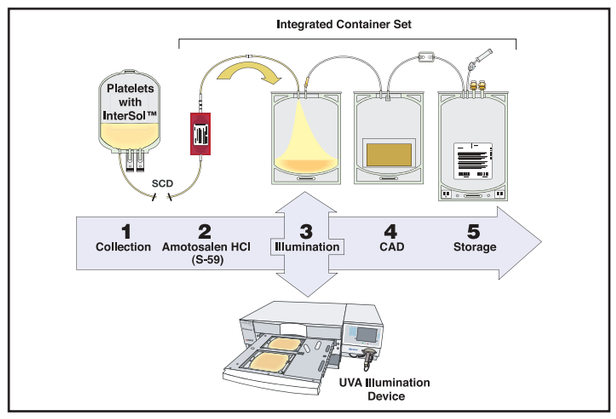
Objective

This study compared the efficacy of bacterial screening using a culture method (BacT/Alert System, Biomerieux) with pathogen inactivation (INTERCEPT Blood System, Baxter Healthcare) to prevent the transfusion of platelet components contaminated with bacteria.

Methods

Seven species of bacteria associated with transfusion-associated sepsis, including Gram-positive aerobes and anaerobes and Gram-negative aerobes were studied. Paired (Control and Test) platelet concentrates (PC) containing approximately $3x10^{11}$ platelets in 300 mL of 35% plasma and 65% InterSol® from double-dose apheresis collections were contaminated with each species of bacteria at approximately 10, 100, and 1,000 cfu per unit. After an overnight storage, the Test PC was treated with INTERCEPT (150 µM amotosalen and 3 J/cm^2 UVA, using steps 1 to 3 in Figure 1). The Control PC was not treated. Both units were assayed for aerobic and anaerobic bacteria using the BacT/Alert System on days 1, 2 and 5 of storage. A platelet sample was considered contaminated with bacteria if a positive signal was registered within 120 hrs of culture.

Figure 1: INTERCEPT System for Platelets



Results

Cultures failed to detect some low-dose inocula in Control PC (Table 1 and Figures 2 to 4). All Test PC treated with INTERCEPT remained negative by BacT/Alert cultures throughout the entire 5-day observation period regardless of the bacterial species and the contamination level (Table 1 and Figure 5).

Figure 2, Bacterial detection: results from untreated platelet concentrates (Day-1 samples)

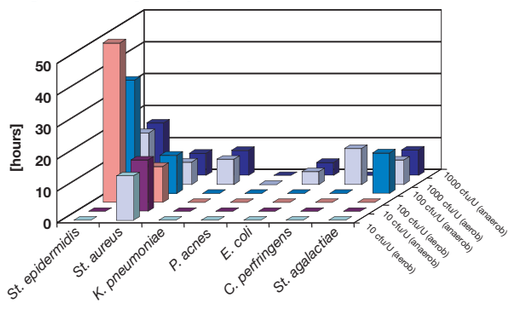


Figure 3, Bacterial detection: results from untreated platelet concentrates (Day-2 samples)

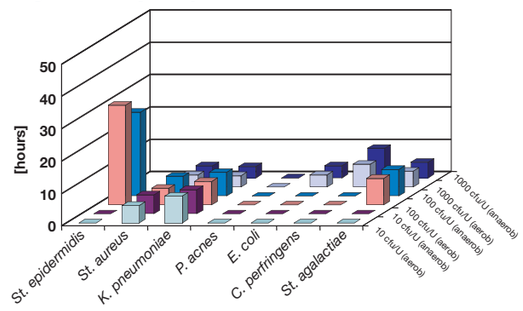


Figure 4, Bacterial detection: results from untreated platelet concentrates (Day-5 samples)

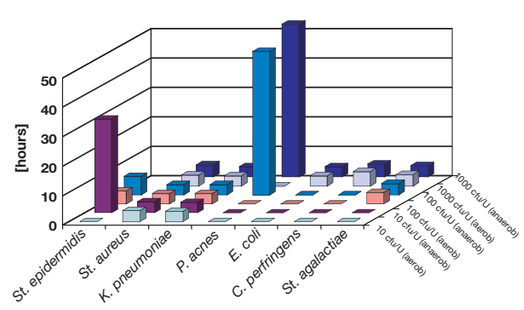


Figure 5: INTERCEPT treated platelet concentrates remained all negative

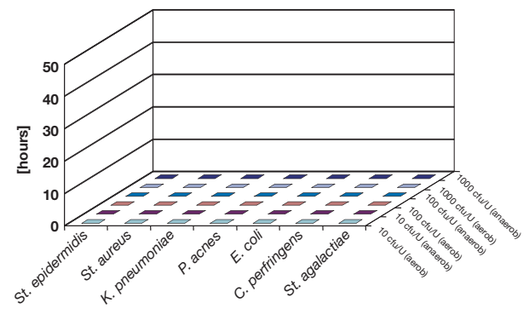


Table 1:

	Time (h=hours) to Positive Culture*					
	10 cfu/unit		100 cfu/unit		1,000 cfu/unit	
	aerobe	anaerobe	aerobe	anaerobe	aerobe	anaerobe
Inoculated Control PC (Untreated)						
Staphylococcus aureus	14 h	16 h	11 h	12 h	7 h	7 h
Staphylococcus epidermidis	Neg	D5 +30 h	50 h	35 h	16 h	16 h
Propionibacterium acnes	Neg	Neg	Neg	D5 +50 h	Neg	D5 +50h
Escherichia coli	Neg	Neg	Neg	Neg	4 h	4 h
Clostridium perfringens	Neg	Neg	Neg	Neg	11 h	D2 +10 h
Streptococcus agalactiae	Neg	Neg	D2 +8 h	13 h	8 h	8 h
Klebsiella pneumonia	D2 +8 h	D2 +8 h	D2 +7 h	D2 +7 h	8 h	8 h
Inoculated Test PC (treated with INTERCEPT)						
Staphylococcus aureus	**Neg**	**Neg**	**Neg**	**Neg**	**Neg**	**Neg**
Staphylococcus epidermidis	**Neg**	**Neg**	**Neg**	**Neg**	**Neg**	**Neg**
Propionibacterium acnes	**Neg**	**Neg**	**Neg**	**Neg**	**Neg**	**Neg**
Escherichia coli	**Neg**	**Neg**	**Neg**	**Neg**	**Neg**	**Neg**
Clostridium perfringens	**Neg**	**Neg**	**Neg**	**Neg**	**Neg**	**Neg**
Streptococcus agalactiae	**Neg**	**Neg**	**Neg**	**Neg**	**Neg**	**Neg**
Klebsiella pneumonia	**Neg**	**Neg**	**Neg**	**Neg**	**Neg**	**Neg**

* D = day sampled, where not indicated, samples were withdrawn on day 1.
Neg = No bacteria detected even when sampled on day 5 of platelet storage and after 120 h of culture.

Conclusions

- **Bacterial detection using cultures may fail to detect low levels of bacteria.**
- **Failure to detect bacteria will result in the release of contaminated platelet products with "test negative-to-date" status.**
- **Inactivation of bacteria using the INTERCEPT Blood System is capable of preventing release of contaminated platelet components.**

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