A pilot study evaluating the efficacy of Mirasol pathogen reduction technique for platelet concentrates.

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Introduction

- Primary function of BTS is to ensure safety of blood supply.
- Multi-layered strategies need to be incorporated into processing of blood components, to minimize untoward transfusion events.

Tiers of blood safety

- ✓First major level: careful blood donor screening
- ✓Second level: optimization of processing and storage.
- ✓Third level: pathogen detection.
- ✓Fourth level: pathogen reduction.

Bacterial contamination

- Platelet concentrates contaminated with bacteria may cause acute septic reactions that are sometimes fatal.
- Despite
  - Improved disinfection of venipuncture site,
  - Use of blood diversion pouches.
  - Use of bacterial detection (BacT/ALERT).

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  - Presence of asymptomatic bacteremia in donors.
- Risk of bacterial contamination is not completely eliminated.

Mirasol PRT

- In 2007, use of riboflavin and UV-light treatment of platelets and plasma (Mirasol PRT, Terumo BCT) was approved for commercial use in Europe.
- Based on ability of Riboflavin (Vitamin B2) to function as a photosensitizer and selectively damage the nucleic acids of microbes upon exposure to UV light.
- Riboflavin, a natural component found in food is classified as “Generally-Recognized-As-Safe” compound by US-FDA.

Objective

In vitro assessment of the ability and efficacy of Mirasol PRT.

Aimed at preventing bacterial regrowth by spiking buffy coat pooled platelets (BCPP) when challenged with clinically relevant load of *Staphylococous epidermidis.*

Material and methods

- Prospective single-blinded randomized pilot project.
- Time period: From June 2014 to July 2014
- Ethical clearance from the IEC, AIIMS, New Delhi

Platelet concentrate preparation

- 4 ABO and Rh (D) type matched WB-derived buffy coat bags, prepared from 450 ml quadruple top and bottom bags .
- Pooled using Teruflex BP-kit with Imugard III-S-PL, Terumo BCT, Tokyo, Japan).

Bacteria propagation and storage

- **Working culture of S. epidermidis, ATCC #12228, (American Type Culture Collection, Manassas, VA, USA) at 30 CFU/ml conc. for inoculation of BCPPs.**

Steps for preparation of working culture

Strain grown in tryptic soya broth for 1-2 days

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Cultures concentrated and suspended in peptone water

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Preparation of desired concentrations
(10-fold end point dilution scheme)

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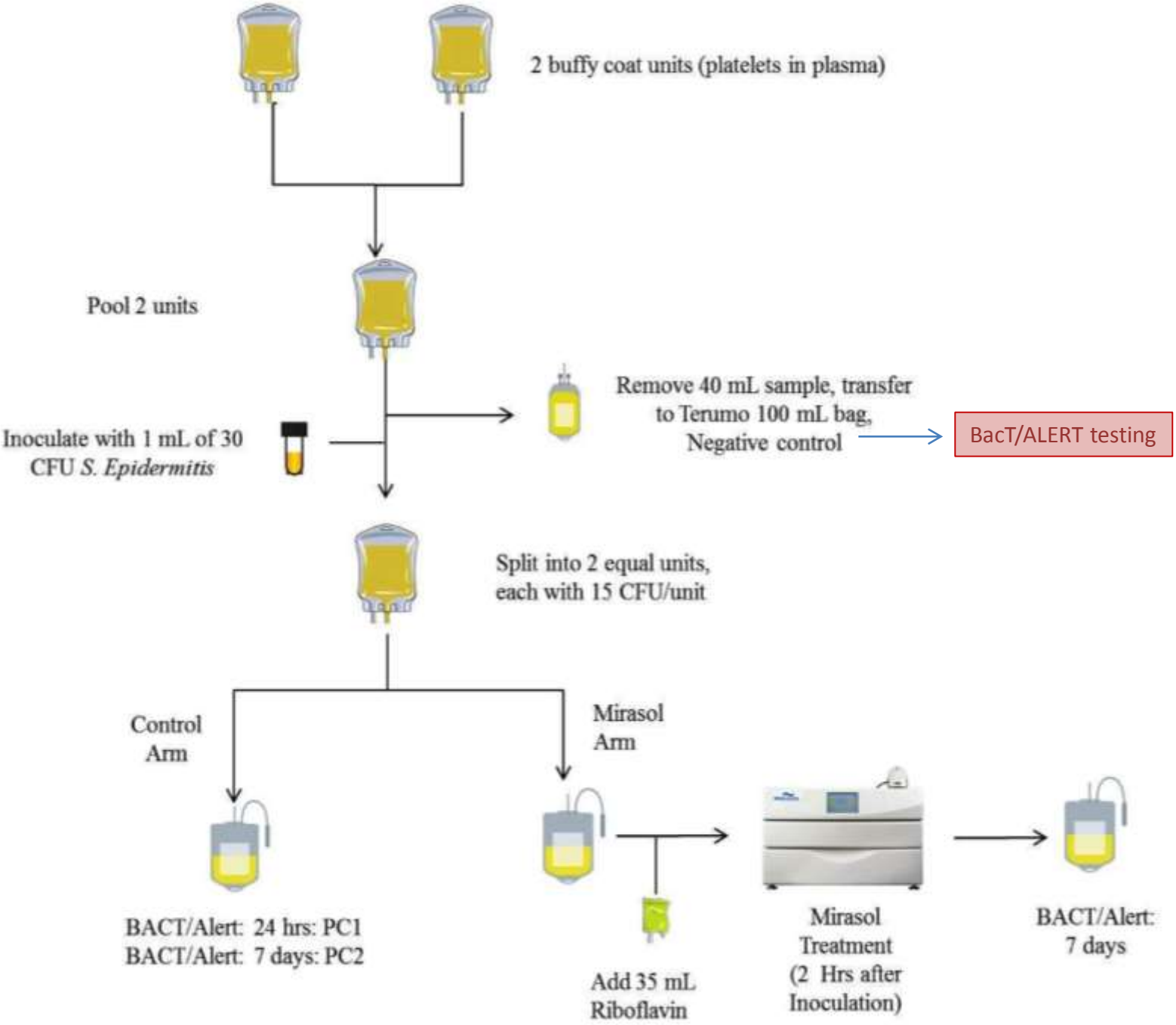
Storage at 4°C for up to 2 weeks

General study design



Results

- A total of 32 treatment cycles were performed
- Mean parameters of BCPP units included in the study

Volume (ml)	Plt yield ($\times 10^{11}$)	pH	Plt conc.
241.8 ± 29.8	2.27 ± 0.37	7.0 ± 0.11	9.44 ± 1.57 ($\times 10^{9}$)/L

Results:

	Negative Control (NC)	Positive Control (PC_1)	Positive Control (PC_2)	Mirasol treated units
Valid	30	12	30	27
Invalid	2	20	2	4* *- 2 NC and 2 PC_2 samples were invalid.
Failed	0	0	0	1
Total	32	32	32	32

Results

- Mirasol treatment arm of the BCPPs (T) demonstrated 96.7% success rate at preventing bacterial growth in contaminated platelet units (1 of 28 BCPP units showed growth).
- Sensitivity of bacterial screening of PCs by BacT/ALERT
  - After 24 hrs. incubation was only 28.6%,
  - After 7 days of incubation was 100%.

Conclusions

- Mirasol system was effective in inactivating ***S. epidermidis*** when it was deliberately inoculated into BCPP at clinically relevant concentrations.
- Such systems may significantly improve blood safety by inactivating traditional and emerging transfusion-transmitted pathogens

Limitations

1. Assumption that any growth seen in PC was due to the spiked S. epidermidis only.
2. Quantitative reduction of bacterial load in terms of “log reduction.”
3. Quality parameters and function of the treated platelets were not tested.

Future prospect…

- This is a **1st prospective *in-vitro* pilot study from India** regarding pathogen inactivation in blood components.
- Considering high morbidity and mortality associated with bacterial infections and the high cost of treatment, more Indian studies (both *in vitro* and *in vivo*) are required,
  - **To evaluate other viral and bacterial strains;**
  - **To check the cost-effectiveness of bacterial inactivation in developing countries.**

Acknowledgement

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Thank you