Approcci Innovativi Integrati per la Riduzione del Rischio Trasfusionale

Roma 16 Marzo 2011

Nuove metodologie per la prevenzione delle infezioni trasmissibili con emocomponenti

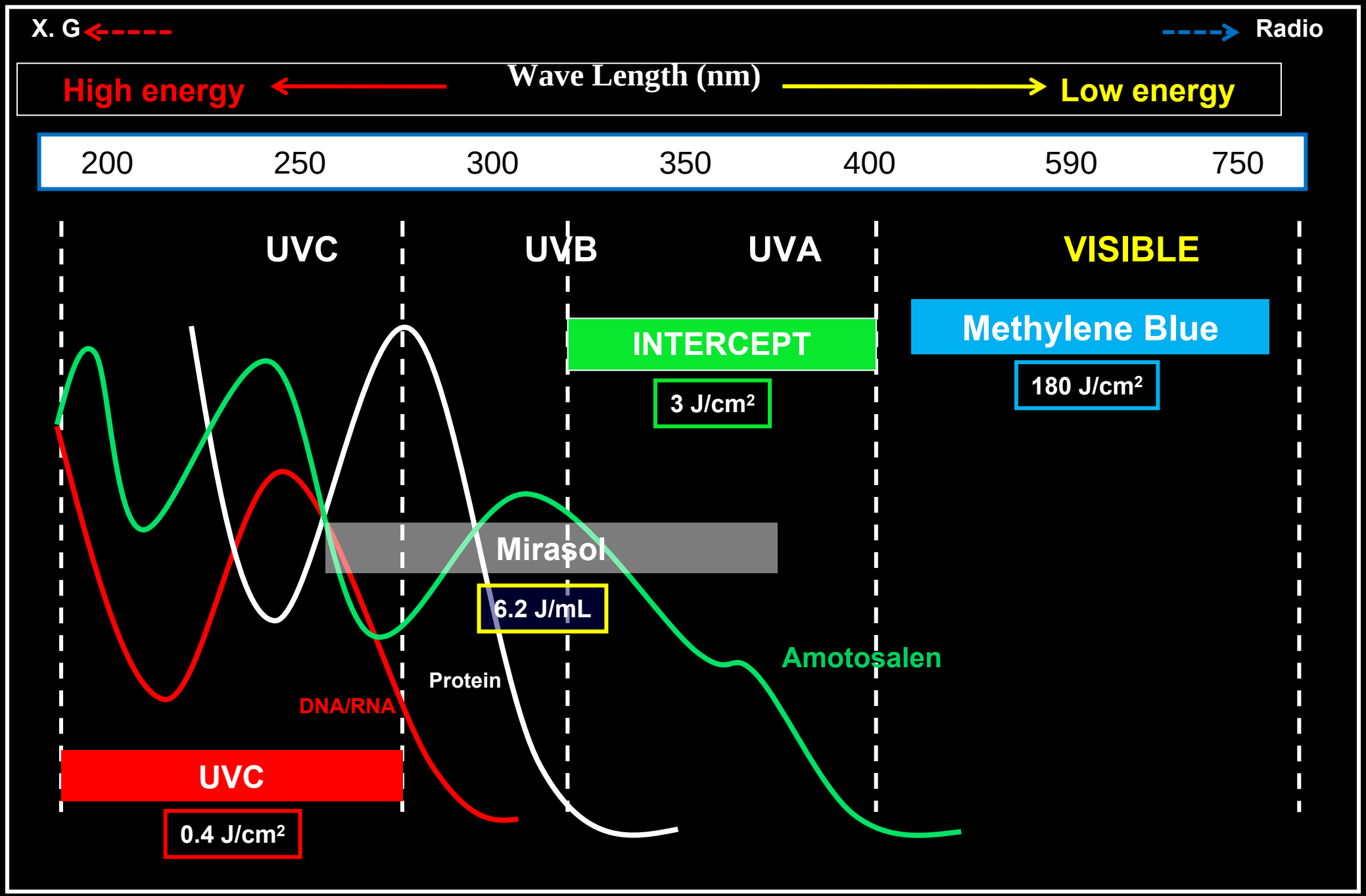
Dr. Anna Maria Quaglietta

Dipartimento di Medicina Trasfusionale

A.S.L. PESCARA

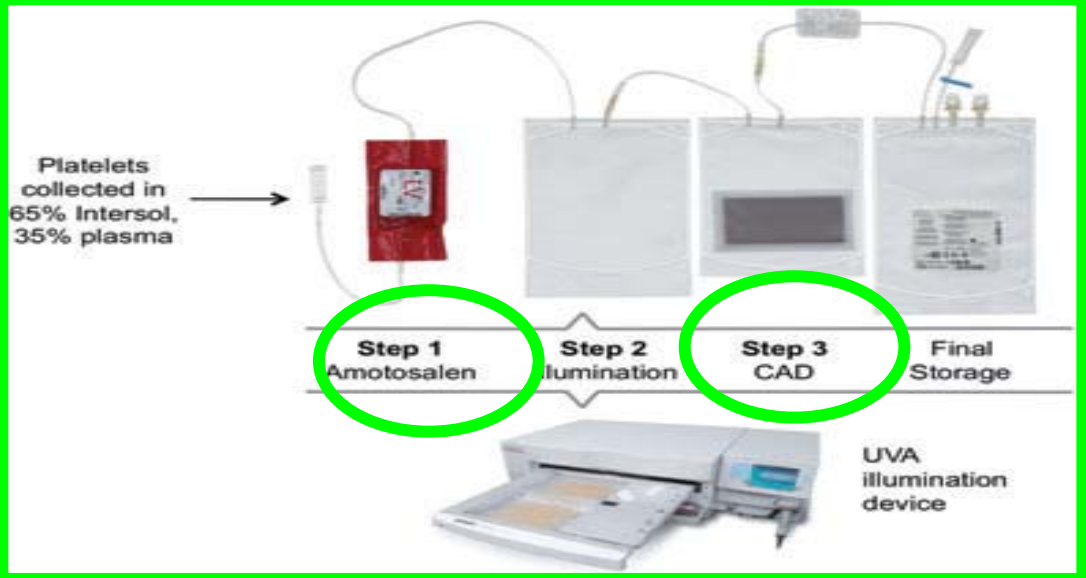
Sistemi per la riduzione /inattivazione dei patogeni negli emocomponenti

		Produttore	Tecnica	Stato
PLASMA	VIRUS BATTERI PARASSITI	Cerus	Amotosalen + UV	Marchio CE
		Caridian BCT	Riboflavin + UV	Marchio CE
		MacoPharma	Methylen blue	Marchio CE
		Octapharma	Solvent and detergent	Marchio CE
PIASTRINE	VIRUS BATTERI PARASSITI	Cerus	Amotosalen + UV	Marchio CE 2002
		Caridian BCT	Riboflavin + UV	Marchio CE 2007
		Macopharma	UVC	Phase III
GLOBULI ROSSI	VIRUS BATTERI PARASSITI	Cerus	S 303	Phase II
		Caridian BCT	Riboflavin + light	Phase III
	PRIONI	Macopharma	Specific ligands	Marchio CE
		Pall	Specific ligands	Marchio CE
	Sistemi in uso in Italia			

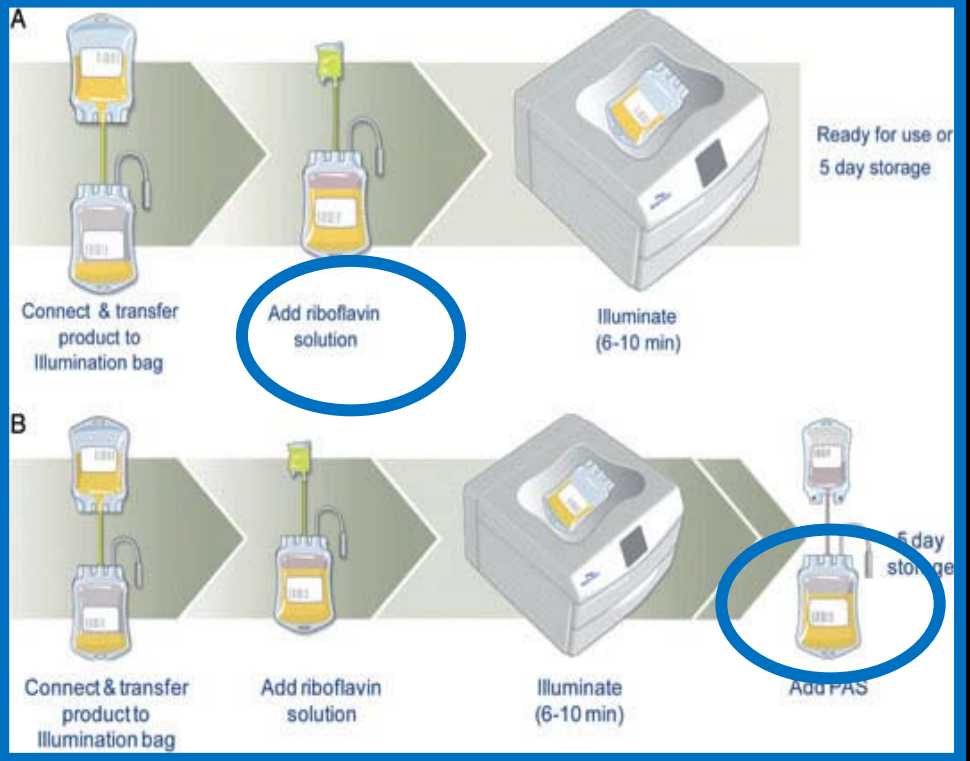

X. G
Radio
High energy
Wave Length (nm)
Low energy
200
250
300
350
400
590
750
UVC
UVB
UVA
VISIBLE
INTERCEPT
3 J/cm²
Methylene Blue
180 J/cm²
Mirasol
6.2 J/mL
Amotosalen
Protein
DNA/RNA
UVC
0.4 J/cm²

Sistemi di Inattivazione - Riduzione dei patogeni dei Concentrati Piastrinici

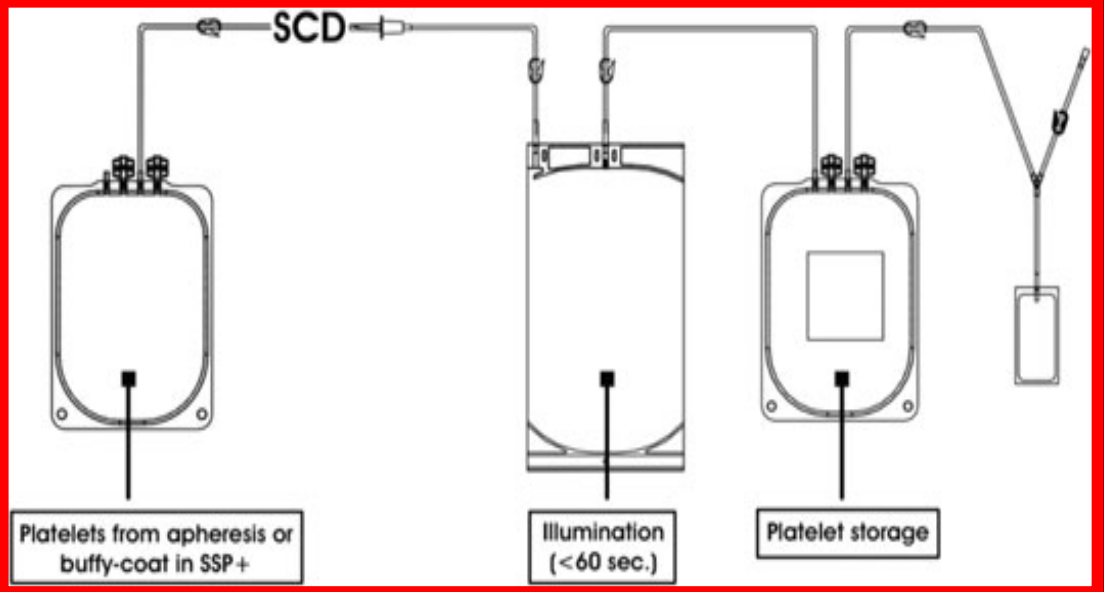
CERUS Corp. INTERCEPT Blood System



CARIDIAN BCT MIRASOL PRT



Maco Pharma's UV Theraflex



Virus : Log $_{10}$ di riduzione dei virus conosciuti transfusion-trasmitted nelle piastrine

Enveloped	Amotosalen	Riboflavin
HIV		
• Cell free	>6.2	5.9 (includes cell-associated)
• Cell associated	>6.1	See above
• Proviral	To limit of detection	4.5
HBV	> 5.5 CID50°	>4.0
HCV	➢4.5 CID 50	>3<6
HTLV-I cell associated	4.7	
HTLV-IIcell associated	5.1	
CMV cell associated	>5.9	
WNV	>6.0	5.2
Non enveloped	**Amotosalen**	**Riboflavin**
B19	4-5.5	
HAV	0*	>2.0

° Chimp infectioous Dose where 50% of the animals become infected

* No reduction was observed

Stramer et al Transfusion 2009;49:Supplement

Virus :Log 10 di riduzione su modelli di virus nelle piastrine		
Enveloped	Amotosalen	Riboflavin
Vesicular stomatitis	>5.8	>6.3
Influenza A (H5N1)	>5.9	
Duck HBV	>6.2	
Bovine viral diarrhea	>6.0	
SARS	> 6.2	
Vaccinia	➢5.2	
Non enveloped	Amotosalen	Riboflavin
Bluetongue	6.1-6.4	
Calicivirus	1.7-2.4	
Simian adenovirus 15	0.7-2.3	
Human adenovirus 15	>5.7	
Porcine parvovirus	0	>5.0
Protozoa/rickettsia: Log 10 di riduzione di protozoi e rickettsie nelle piastrine		
Plasmodium falciparum	>6.0	
Trypanosoma cruzi	>5.	6.0
Leismania mexicana	>5.0	
Leishmania major ,strain Jish	>4.3	>5.0
Babesia microti	>5.3	
Orientia tsutsugamushi		>5.0

Stramer et al Transfusion 2009;49:Supplement

Batteri e spirochete:Log 10 di riduzione nelle piastrine

Batteri Gram Negative	Amotosalen	Riboflavin	Theraflex UV
Escherichia coli	>6.2	>4.4	>4.0
Serratia marcescens	>6.7	4.0	>5.0
Klebsiella pneumonie	>5.6		4.8
Pseudomonas aeruginosa	4.5	>4.5.>4.7	>4.9
Salmonella cholerasius	>6.2		
Yersinia enterocolitica	5.9		
Enterobacter cloacae	5.9		>4.3
Batteri Gram Positive	**Amotosalen**	**Riboflavin**	**Theraflex UV**
Staphilococcus epidermidis	>6.6	4.2	4.8
S. Aureus	6.6	3.6	>4.8
S.Aureus MRSA Strain		4.8	
Streptococcus pyogenes	>6.8		
Listeria monocytogenes	>6.3		
Corynebacterium minutissimum	>6.3		
Bacillus cereus (includes spores)	3.6		
B.Cereus vegetative	>5.5	1.9	4.3
B. Cereus (isolated from donated blood)		2.7	
Bifidobacterium adolescentis	>6.0		
Propionibacterium acnes	>6.2		4.5
Lactobacillus species	>6.4		
Clostriuium perfrigens (vegetatiive form)	>6.5		>4.7
Spirochetes	**Amotosalen**	**Riboflavin**	**Theraflex UV**
Treponema pallidum	>6.8 to <7.0		
Borrella burgdorferi	>6.8		

Stramer et al Transfusion 2009;49:Supplement

Effetto sui leucocti nelle piastrine e plasma

	Amotosalen	
	Platelets	**Plasma**
T-cell Log Reduction (LDA)	**> 5.4**	**≥ 6.1**
DNA Adducts / Base Pairs*	**1 / 83**	**1 / 89**
Cytokine Synthesis	**Inhibited**	
Murine Model for TA-GVHD	**Prevented**	

Corash and Lin: Bone Marrow Transplantation 2004;33:1-7

The *euroSPRITE* trial: Results				The *SPRINT* trial: Results		
	PCT	CONTROL	p	PCT	CONTROL	p
Platelet transfusion	311	256		2678	2041	
N°transf/patients.	7.5	5.6	0.09	8.4	6.2	0.001
Platelet dose x10^{11}	3.9	4.3	<0.001	3.7	4.0	0.001
Storage day	3.5	3.4	0.28	3.4	3.6	0.05
1h C. Increment 10^9/L	27.5	35.8	0.03	21.4	34.1	0.001
1h C.C. Increment 10^9/L	13.1	14.9	0.11	11.1	16.0	0.001
24h C. Increment 10^9/L	16.9	24.7	0.004	13.2	21.5	0.001
24h C.C. Increment 10^9/L	7.4	10.6	0.021	6.7	10.1	0.001
Transfusion interval	3.0	3.4	0.13	1.9	2.4	<0.001

Blood. 2003;101:2426–33.

Blood. 2004;104:1534-41.

INTERCEPT BLOOD SYSTEM: studi di efficacia e sicurezza

The *euroSPRITE* trial: Results

	PCT	CONTROL	p
Patients	52	51	
Any emor-ragic event	41 (79%)	38 (79%)	NS
Severe Emorragic event	3 (6%)	3 (6. %)	NS
Trasfusions with acute reactions	**6%**	**5%**	**0.61**
Serious Advers event	**27%**	**25%**	**0.53**
Death	**7.7%**	**9.8%**	**0.34**

Blood. 2003;101:2426–33.

The *SPRINT* trial: Results

	PCT	CONTROL	p
Patients	318	327	
Grade 2 bleeding	186 (58.5%)	188 (57.5%)	<0.01 ns
Grade 3-4 bleeding	13 (4.1%)	20 (6.1%)	<0.01 ns
Any Advers event	**99.7%**	**98.2%**	**0.12**
Grade III -IV Advers event	**78.9%**	**78.6%**	**0.92**
Serius Advers savent	**27%**	**24.8%**	**0.53**
Treated Advers event	**3.4%**	**3.6%**	**0.43**
Death	**3.5%**	**5.2%**	**0.34**

Blood. 2004;104:1534-41.

INTERCEPT BLOOD SYSTEM
emovigilanza ed impatto dell'uso in routine

- A prospective observational cohhort safety study of **5106 platelet transfusions** with components prepared with phochemical pathogen inactivation treatment

  J.C.Osselaer. P. Accorsi et al Transfusion 2008 ;48:1061–1071

- An active haemovigilance progamme characterizing the safety profile of 7437 platelet transfusions prepared with amotosalen photochemical treatment

  J.C.Osselaer Vox sanguinis 2008;94:315–323

- **An active haemovigilance progamme characterizing the safety profile of 7483 transfusions with plasma components prepared with amotosalen UVA photochemical treatment**

  J.C.Osselaer Transfusion 2010 ;501:1210–1219

- **Use of additive solutions and Pathogen inactivation treatment of platelet components in a regional blood center : impact on patient outcomes and component utilization during a 3 –year period**

  J P Cazenave Transfusion 2011 51 623-629

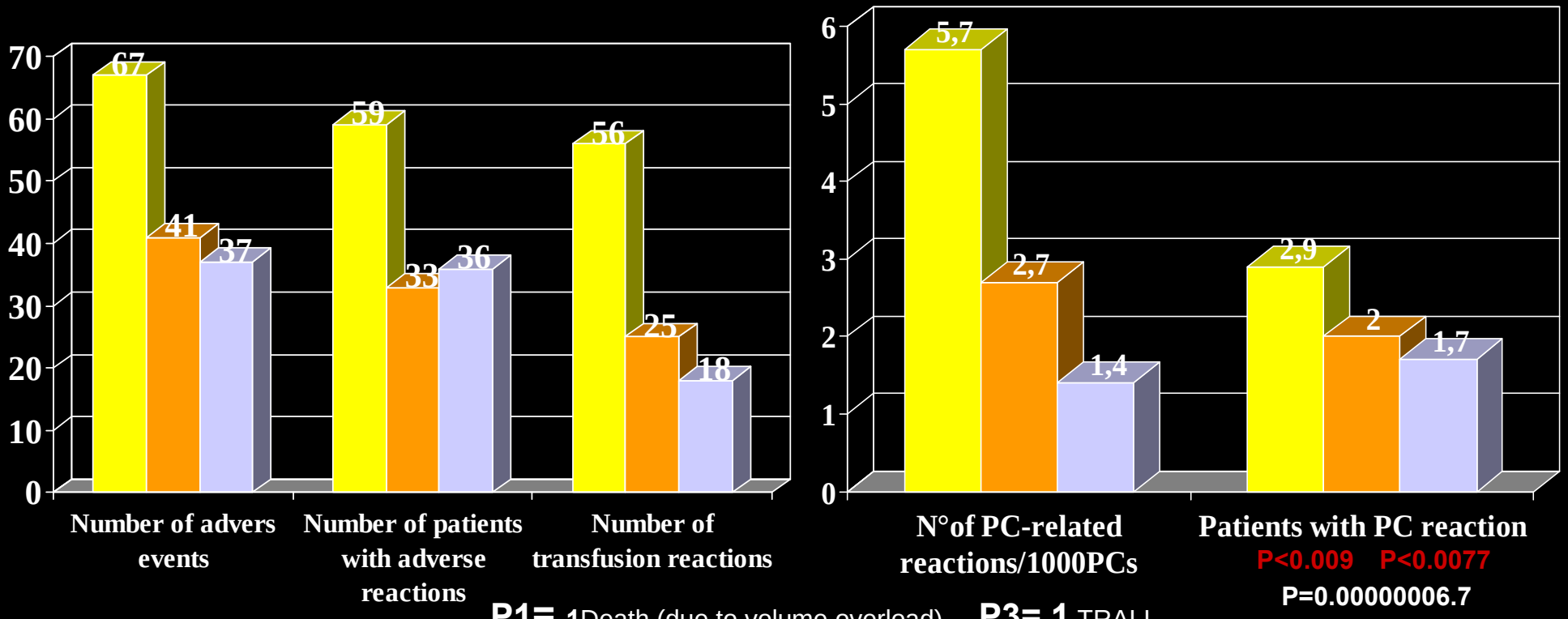
INTERCEPT BLOOD SYSTEM
Emovigilanza ed impatto dell'uso in routine Studi Europei

Transfusions	5106 plt	7437plt	7483 plasma
Patients	651	1400	3232
Transfusions with no reaction	98.9%	99.1%	99.9%
Transfusions with reported reactions	1.1%	0.7%	0.11%
Not attributed to transfusion	0.3%	/	
Possibly. probably. or related to platelet transfusion	0.8%	0.7%	0.11%
Transfusion reactions	42 (32 pz)	55 (39 pz)	8 (8 pz)
Serious adverse event Grade >2	1 possibly related 2 unrelated	1 possibly related 4 Unrelated	3 Probably related
TRALI Episodes	NO	NO	NO
Dead	NO	NO	NO

J.C.Osselaer

INTERCEPT BLOOD SYSTEM
Emovigilanza ed impatto dell'uso in routine Studi Europei

Number of components transfused **EFS ALSACE**	10629 PCs-PLASMA P1:2003/2004	9151 PCs PAS P2:2005/2006	13241 PCs INACTIVATION P3: 2006/2007
Number of patients transfused	**2050**	**1678**	**2069**



P1= 1Death (due to volume overload) **P3= 1** TRALI

P1=P2=P3 Numbers trasfusion episode. total dose of PCS. **P3vs P1**= incresed PCS trasfused

J P Cazenave Transfusion 2011 51 623-629

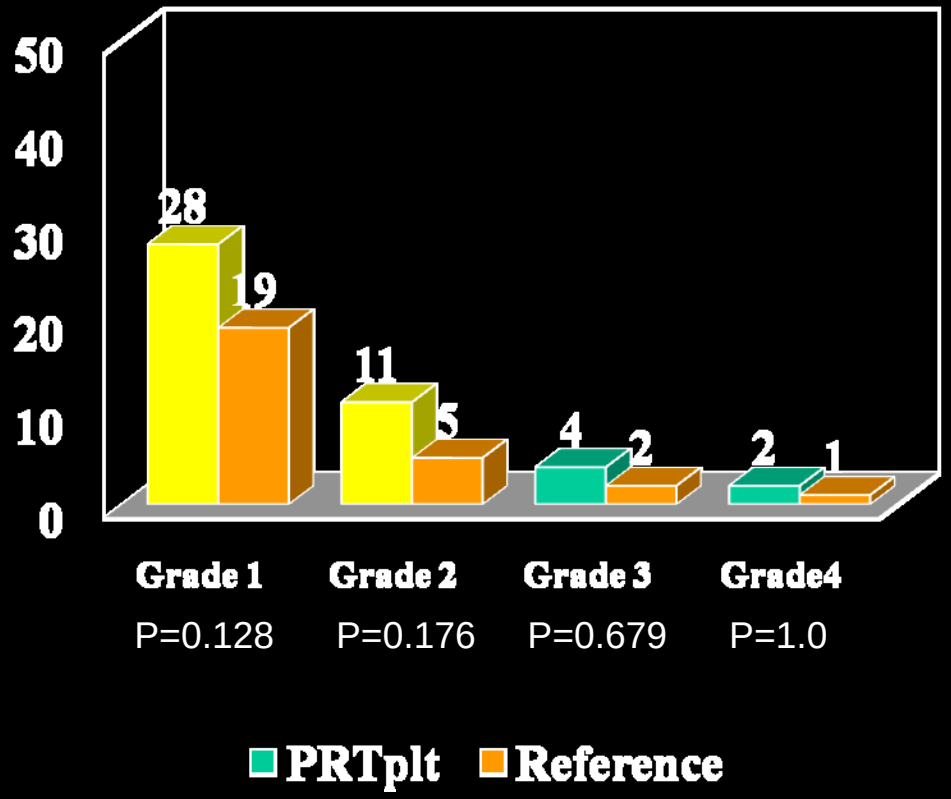
MIRASOL clinical evaluation TRIAL : Results

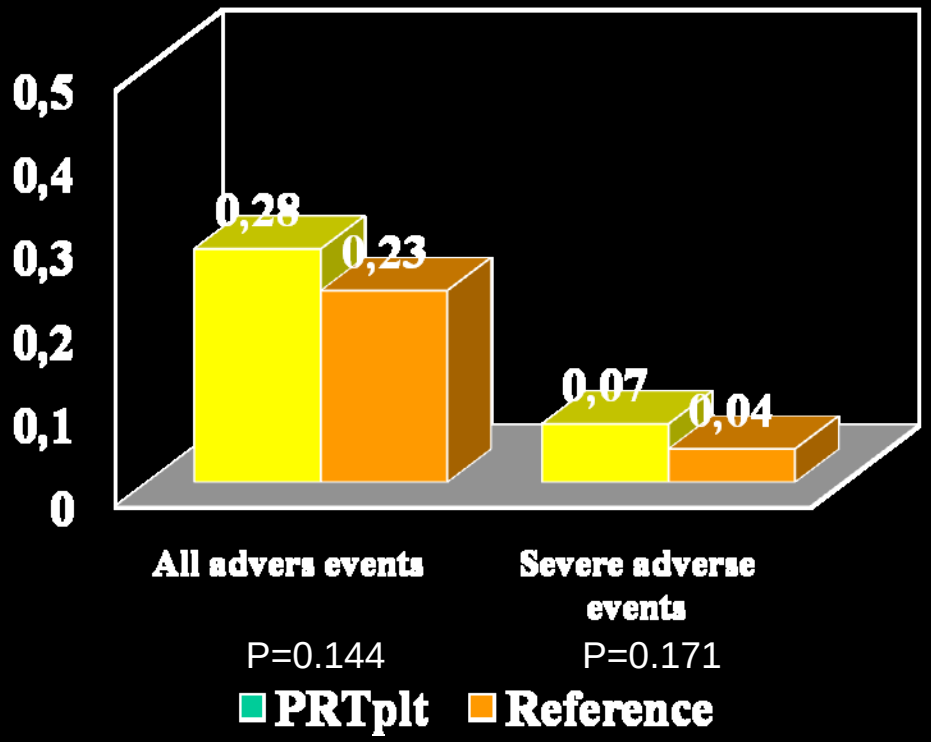
	PCT	CONTROL	p	PCT	CONTROL	p
	First eight transfusions within the 28 day			within the 28 day		
Platelet transfusion	258	209		303	238	
N°transf/patients.	4.0	3.0	0.09	4.5	3.0	0.001
Platelet dose $x10^{11}$	5.37	5.38	0.96	5.23	5.22	0.98
Storage day	2.8	2.6	0.08	2.7	2.6	0.22
1h C.C. Increment 10^9/L	11.7	16.9	0.0001	11.0	16.6	0.001
24h C.C. Increment 10^9/L	6.6	9.8	0.0014	7.1	10.07	0.001
Transfusion interval	2.32	2.72	0.0107	2.16	2.3	0.290

Transfusion 2010; 50:2362–2373

MIRASOL clinical evaluation TRIAL: Results

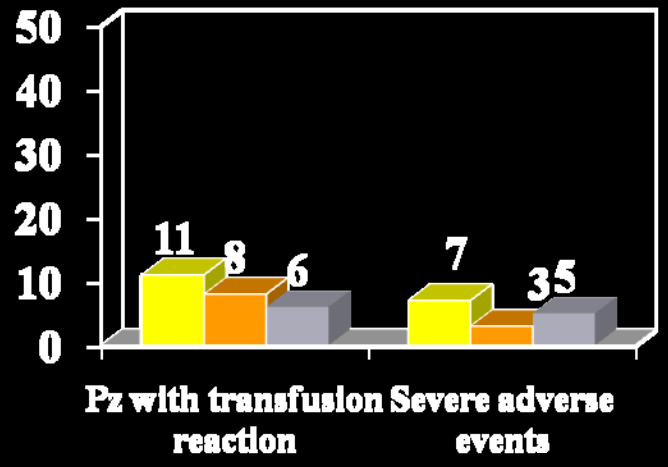
Bleeding by WHO Grade and adverse events

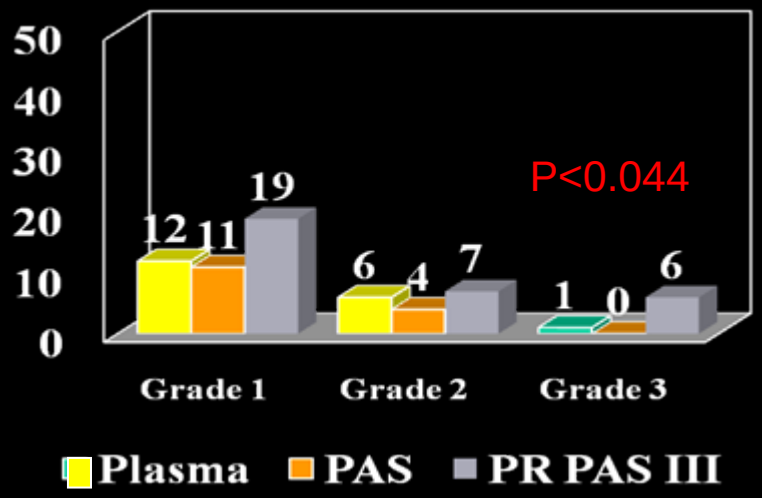




Clinical effectiveness of leucoreduced, pooled donor platelet concentrates, stored in plasma or additive solution with and without pathogen reduction

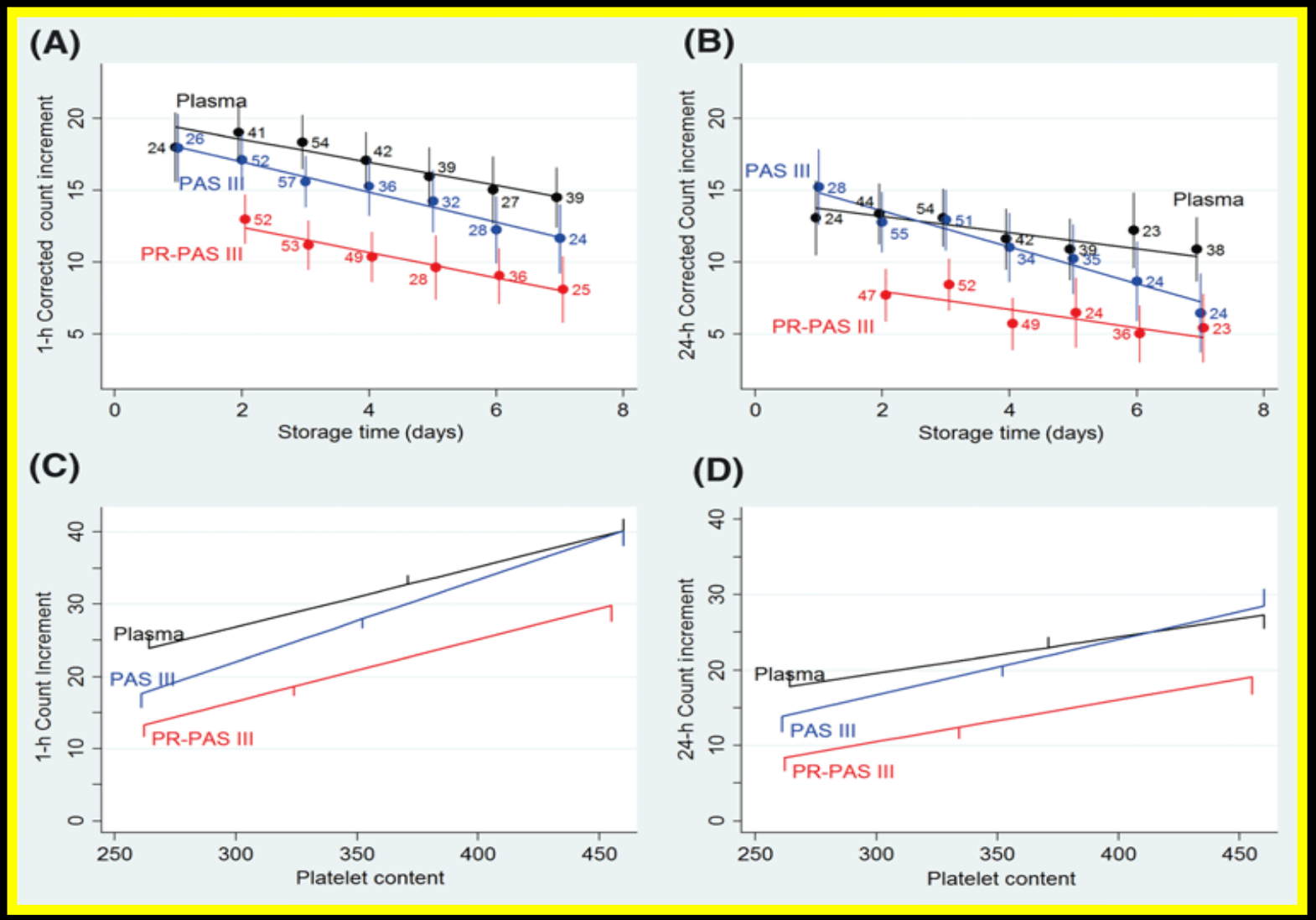
	PLASMA	PAS III	PR PASIII	p
Platelet transfusion	357	381	391	
Platelet dose $x10^{11}$	3.9	3.6	3.4	<0.001
Storage day	4.0	3.8	4.0	
1h C.C. Increment 10^9/L	17.1	15.3	11.4	<0.0001
24h C.C. Increment 10^9/L	12.8	11.6	7.9	0.0001
Transfusion interval (h)	81	77	61	<0.001





H. Kerkhoffs BJH 2010;150:209–217

Clinical effectiveness of leucoreduced, pooled donor platelet concentrates, stored in plasma or additive solution with and without pathogen reduction



Aumentando la dose di $2x10^{11}$ (3 buffy-coat) ,si dovrebbe bilanciare l'effetto sull'efficacia

H. Kerkhoffs BJH 2010;150:209–217

Impatto della Dose sull'incremento post trasfusionale, grado "di sanguinamento ed intervallo trasfusionale

Trial	N°	Dose x10e11	Incremento 1h	Intervallo gg	Grado >2 sanguinamento
Plado *	417	2.0	10000	1.1	58%
Plado *	423	4.0	19000	1.9	59%
Plado *	432	8.0	38000	2.9	60%
SPRINT Test	318	3.7	21000	1.9	59%
SPRINT Ref	327	4.0	34000	2.4	58%
EU:SPRITE -Test	52	3.9	28000	3.0	54%
EU:SPRITE - Ref	51	4.3	36000	3.4	49%
Hovon test	87	3.4	20000	2.5	13%
Hovon PAS III	94	3.6 P<0.001	29000	3.2	4% P<0.044
Hovon Plasma	99	3.9	34000	3.4	7%
Mirasol Test	258	5.37	12000	2.3	19%
Mirasol Ref	209	5.38	17000	2.7	13%

**J. Slichter N. Engl J Med 2010 362 600-613*

Meta-analysis of the randomized controlled trials of the hemostatic efficacy and capacity of pathogen-reduced platelets

TABLE 3. Effects of PR on the hemostatic efficacy of transfused PLTs

	Meta-analysis of four RCTs[15-17,44]					
	Q test for homogeneity:	Summary mean difference*			SPRINT trial[1]	
Effect of PR	p value	Mean†	95% CI‡	p value	Mean difference	p value
Reduction in 1-hr CCI	>0.10	3260	2450-4791	<0.05	4900	<0.001
Reduction in 24-hr CCI	>0.75§	3315	2027-4603	<0.05	3500	<0.001
Increase in total PLT transfusions	>0.25‖	0.93	0.[illegible]-1.70	<0.05	2.2	<0.001
Reduction in the interval between PLT transfusions (number of days)	>0.50	0.41	0.13-0.67	<0.05	0.5	<0.001

* The direction of the difference is indicated in the first column (under "effect of PR").
† The results integrated from the Mirasol study[15] pertain to all "on-protocol" transfusions given within the 28-day study period. Substitution of the (selected) results pertaining to the first eight "on-protocol" transfusions for which a 1-hr CCI had been obtained within 30 to 90 min did not alter the results of the meta-analysis.
‡ When the 95% CI does not include the null value of 0, the corresponding summary mean difference is statistically significant ($p < 0.05$).
§ Across three[15-17] RCTs. Janetzko and colleagues[44] did not report 24-hr CCIs.
‖ Across three[16,17,44] RCTs. The Mirasol study[15] did not report this outcome.

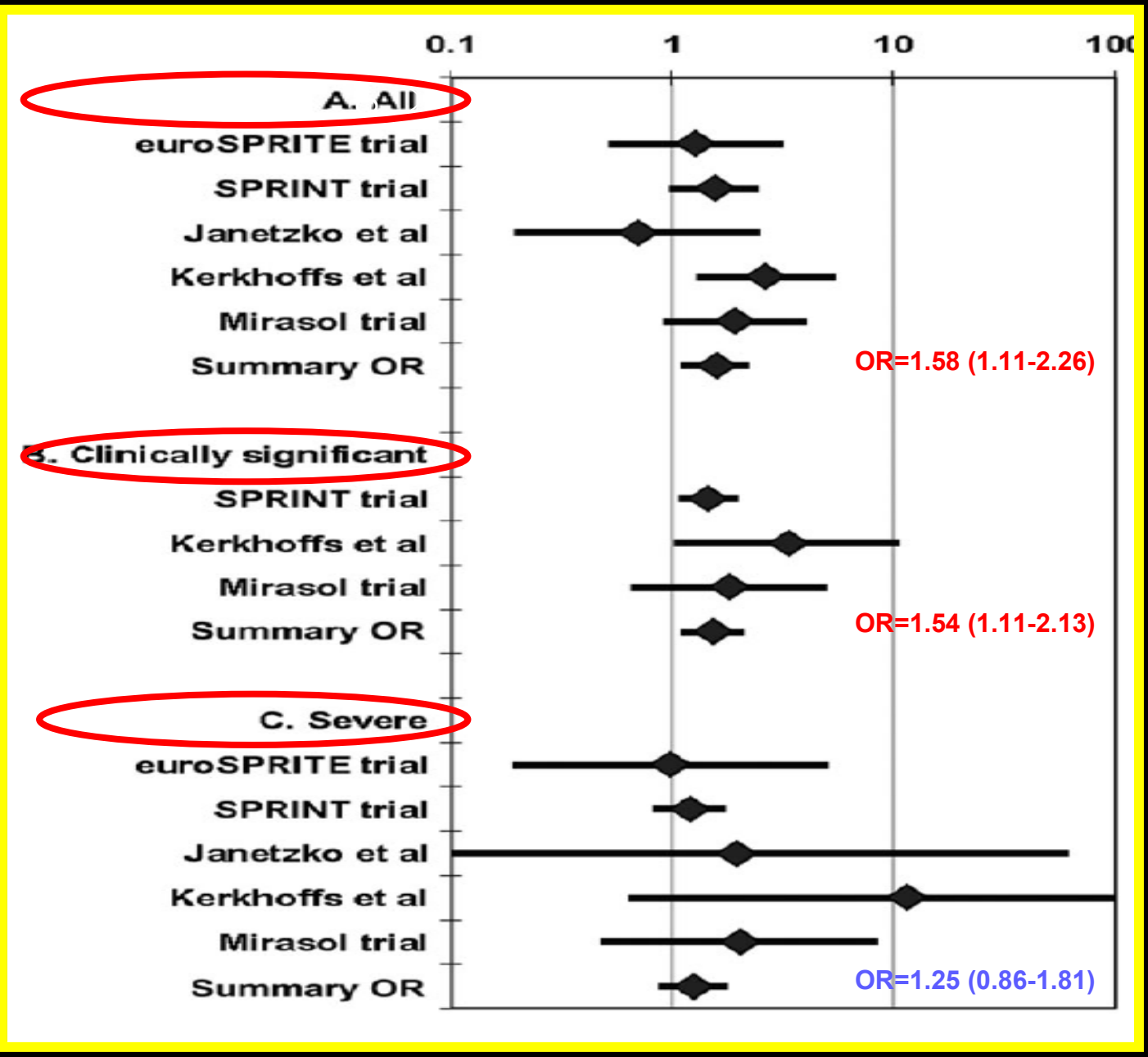
TABLE 4. Effects of PR on the hemostatic efficacy of transfused PLTs stratified by PR technology

	Amotosalen-HCl/UVA light technology				Riboflavin/UVA light technology	
	Meta-analysis of three RCTs[16,17,44]					
	Q test for homogeneity	Summary mean difference*			Mirasol trial[15]	
Effect of PR	p value	Mean	95% CI†	p value	Mean difference‡	p value
Reduction in 1-hr CCI	>0.25	3156	1856-4457	<0.05	5214	<0.0001
Reduction in 24-hr CCI	>0.50§	3512	2006-5018	<0.05	3210	0.001
Increase in total PLT transfusions	>0.25	0.93	0.16-1.70	<0.05	NS‖	NS‖
Reduction in the interval between PLT transfusions (number of days)	>0.50	0.48	0.17-0.79	<0.05	0.4	0.01

* The direction of the difference is indicated in the first column (under "effect of PR").
† When the 95% CI does not include the null value of 0, the corresponding summary mean difference is statistically significant ($p < 0.05$).
‡ Pertaining to the first eight "on-protocol" transfusions for which a 1-hr CCI had been obtained within 30 to 90 min (see text).
§ Across two[16,17] RCTs. Janetzko and colleagues[44] did not report 24-hr CCIs.
‖ NS = not significant. The mean ± SD per patient-day (as opposed to mean ± SD for the entire study period) was reported (see Table 1).

E:C Vanvakas Transfusion 2010

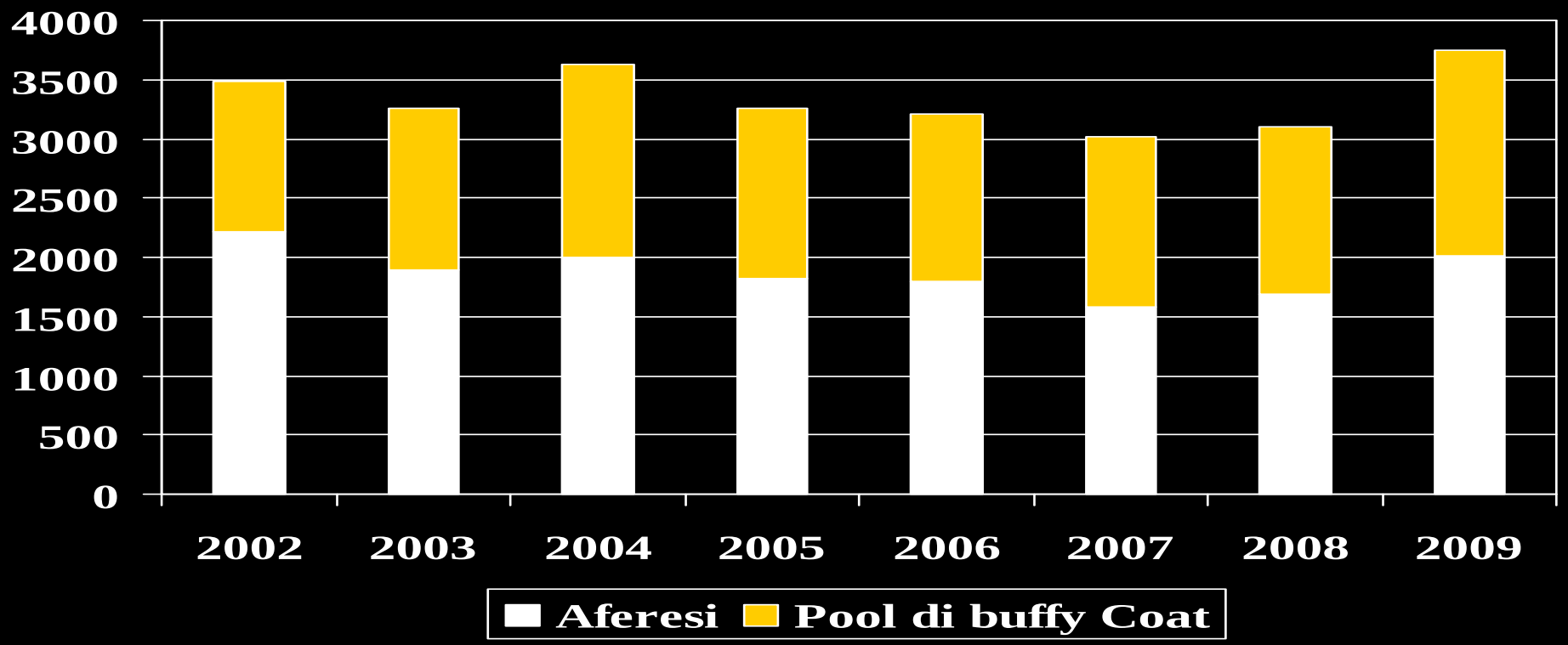
Results: Hemostatic Capacitjy



E:C Vanvakas Transfusion 2010

DMT PESCARA:
Trasfusioni di CP - aa 2002-2009

Paz/anno	381	359	367	381	368	302	375	441



Data base SPSS: 27650 tx - 2453 paz - 21 parametri /tx

DMT - Pescara
Strategie per diminuire il rischio di TTI e TAS

Riduzione contaminazione dei prodotti

- Screening del donatore
- Disinfezione del sito di prelievo
- Diversione della prima aliquota donata

Riduzione esposizione del ricevente

- Ottimizzare indicazioni trasfusionali
- Ridurre trigger trasfusionali
- impiego prodotti da aferesi

Ottimizzazione processi di manipolazione e stoccaggio

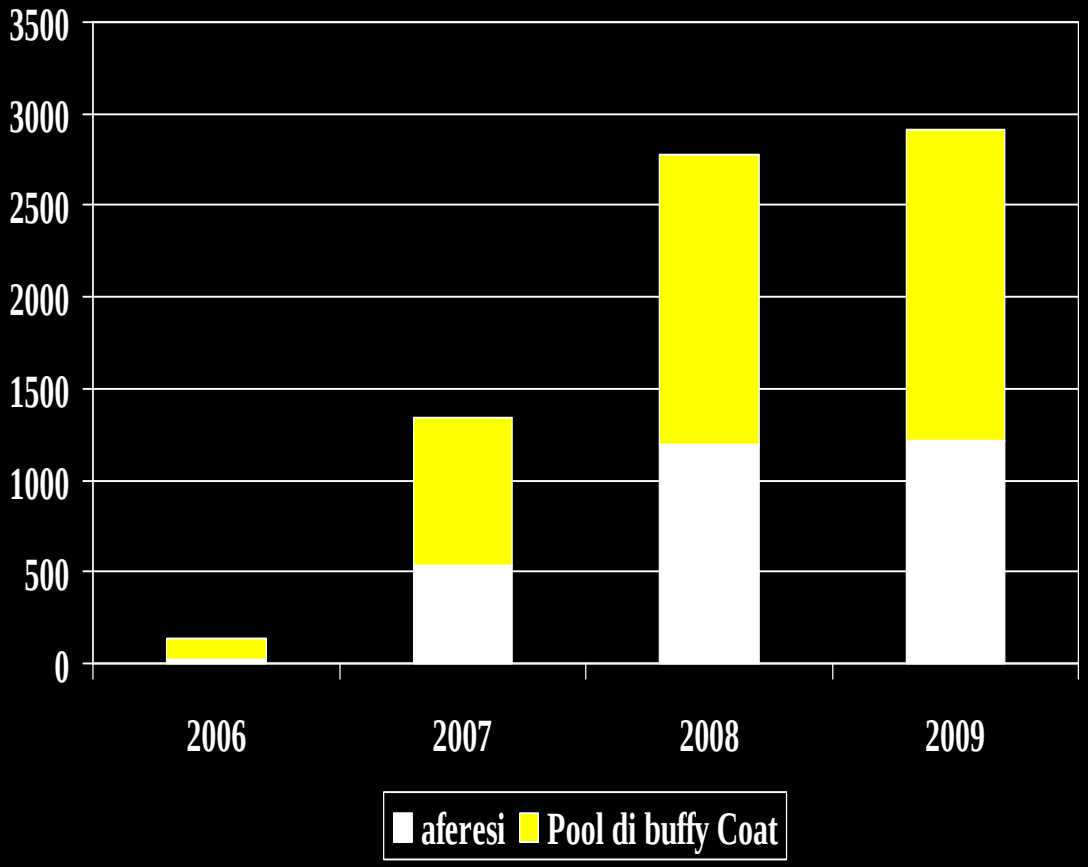
- Temperatura di stoccaggio
- Tempo di stoccaggio
- Leucodeplezione

Valutazione batterica pretrasfusione

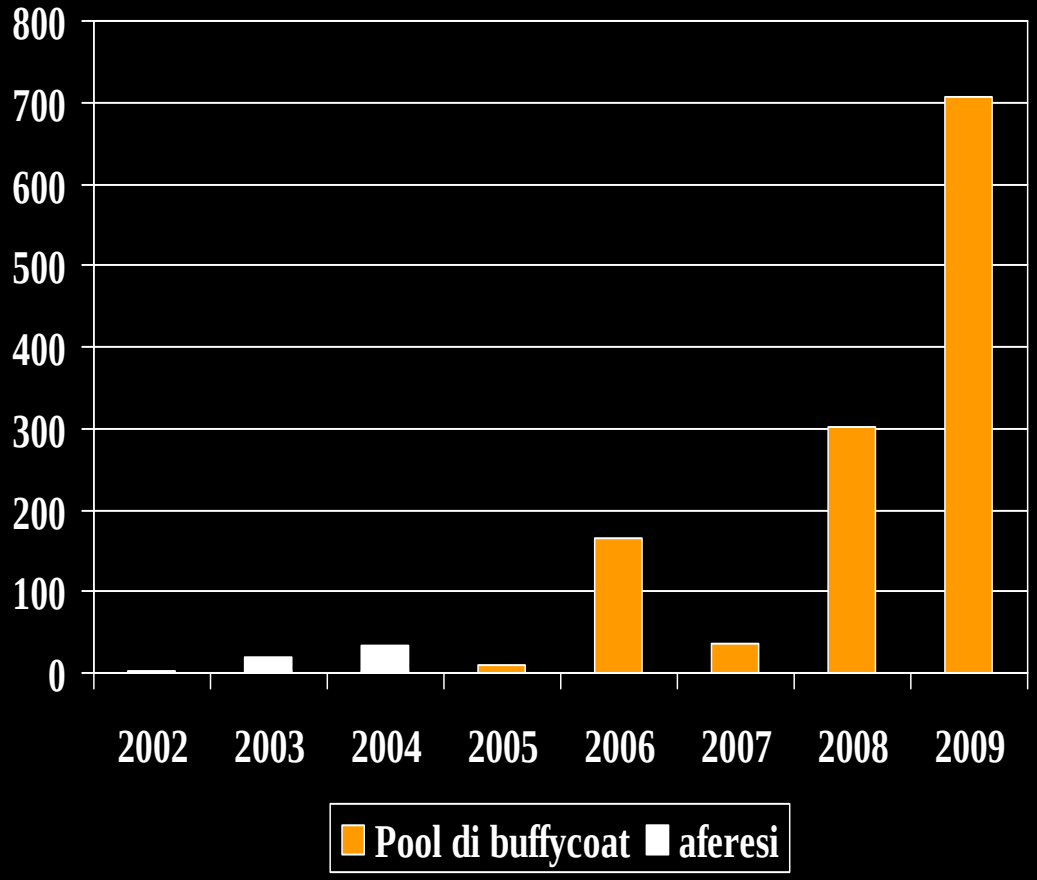
- Controllo batteriologico dei concentrati piastrinici con BacT/Alert
- Ispezione del prodotto pre-trasfusione

Implementare la procedura di Inattivazione dei patogeni

DMT - Pescara
Implementazione delle strategie di riduzione del rischio settico



Controllo batteriologico con Bactec/Alert



Inattivazione con Intercept

Requisiti dei sistemi di inattivazione

INTERCEPT Blood System

PRODOTTO

- Conservazione delle proprietà funzionali
- Efficace per ampio spettro di patogeni (virus. batteri. parassiti. “leucociti”)

PAZIENTE

- Efficacia clinica
- Sicuro (no tossico / no mutageno)
- No immunogenico

STRUTTURA

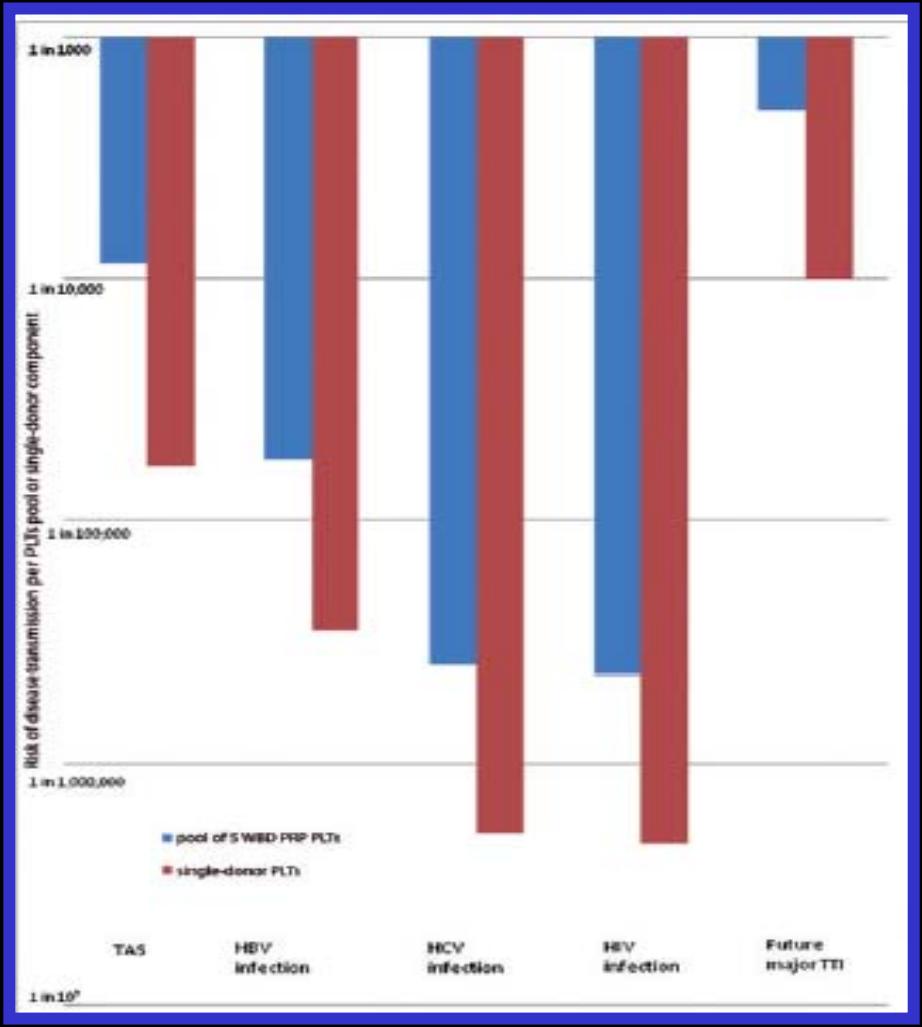
- Applicabile in routine
- Pratico

- Piattaforma unica per
  - Piastrine
  - Plasma
- Sistema adatto all’ impiego *“home-made”*
- Facilità d’uso
- Marchio CE
- Evidenza di efficacia e di non tossicità

DMT di Pescara - Razionale inattivazione

- Concentrati piastrinici da Pool di buffy-Coat
- Impiego “split” Concentrati Piastrinici da aferesi nello stesso ricevente
- Concentrati Piastrinici con storage > 3gg (~ 8%)
- HPC-trapianti CMV+/CMV-
- Irradiazione con Ce 136 in tutti i CP
- n° 5 pz./anno con TTP
- ⇧n° pazienti profondamenti immunodepressi

Razionale dell'inattivazione dei concentrati piastrinici da sangue intero



Rischio TTI
stimato > 4-5 volte

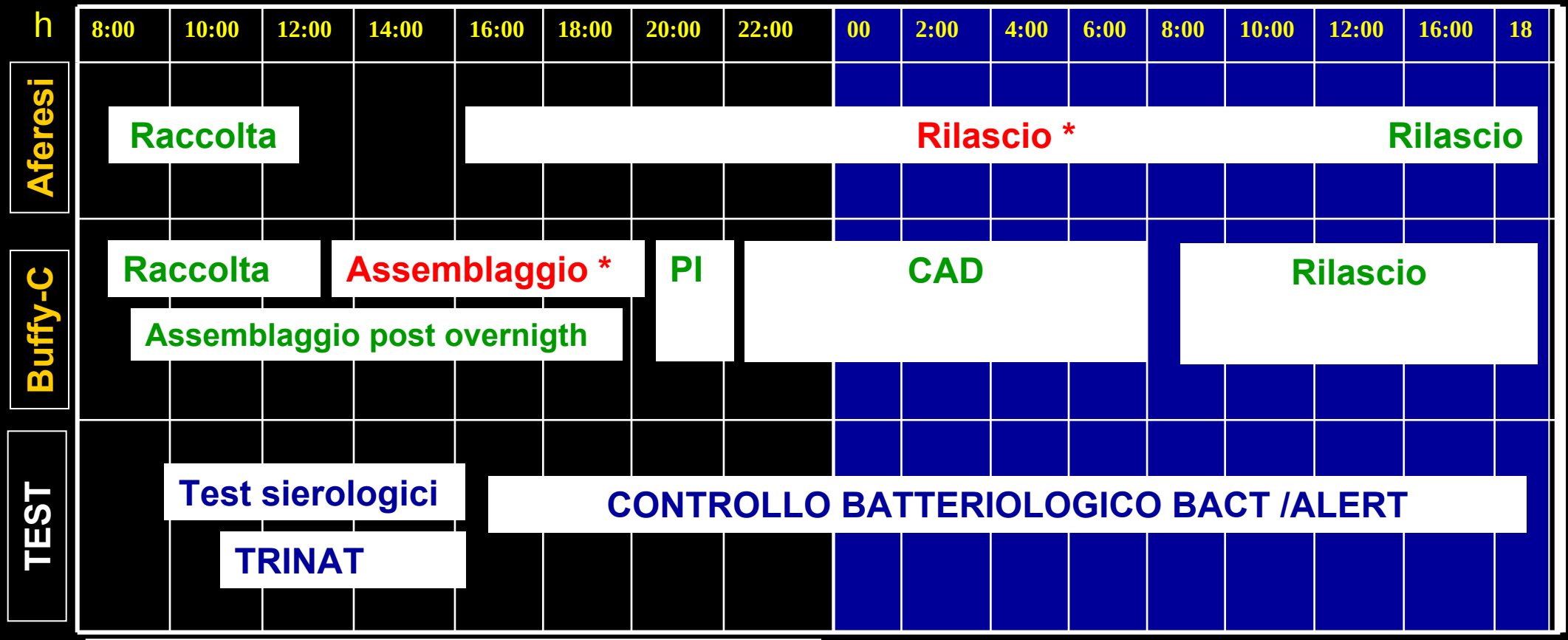
a) Numero di unità di plt da sangue intero
b) Numero di unità da aferesi splittate
c) Intervallo di donazione

Rischio TAS
5 volte maggiore PRP verso Aferesi
Equivalente per i Buffy-coat

Concentrati da aferesi
Concentrati da sangue intero

E:C Vanvakas Transfusion 2009 49.

DMT di Pescara:
flusso di lavorazione e rilascio dei concentrati piastrinici



* Grave carenza di concentrati piastrinici

POST TRANSFUSION ABSOLUTE INCREMENT A COMPARISON BETWEEN STANDARD AND INACTIVATED PLATELET CONCENTRATES

A Quaglietta ISBT - BERLIN JUNE 26- JULE 1 .2010

Patients n°	146
Age y.	64(21-29)
Gender (M/F)	*93/53*
Diagnosis	
AML/ALL	54/16
Lymphoma	27
Chronic Leukemia	10
Multiple Myeloma	41
MDS	19
Other diagnoses	13

PLATELETS	INACTIVATED	UNTRATED	p
Transfusion N°	314	314	
Storage (d)	3.3 ±1.2	3.4 ± 1.5	ns
Plt Infused x 10^{11}	3.4 ± 0.6	3.5 ±0.6	ns
ABO Identical	68.4%	61.1%	0.01
ABO matched	13.4%	10.8%	
ABO mis-matched	18.2%	28&	
Split %	8.3	8	ns

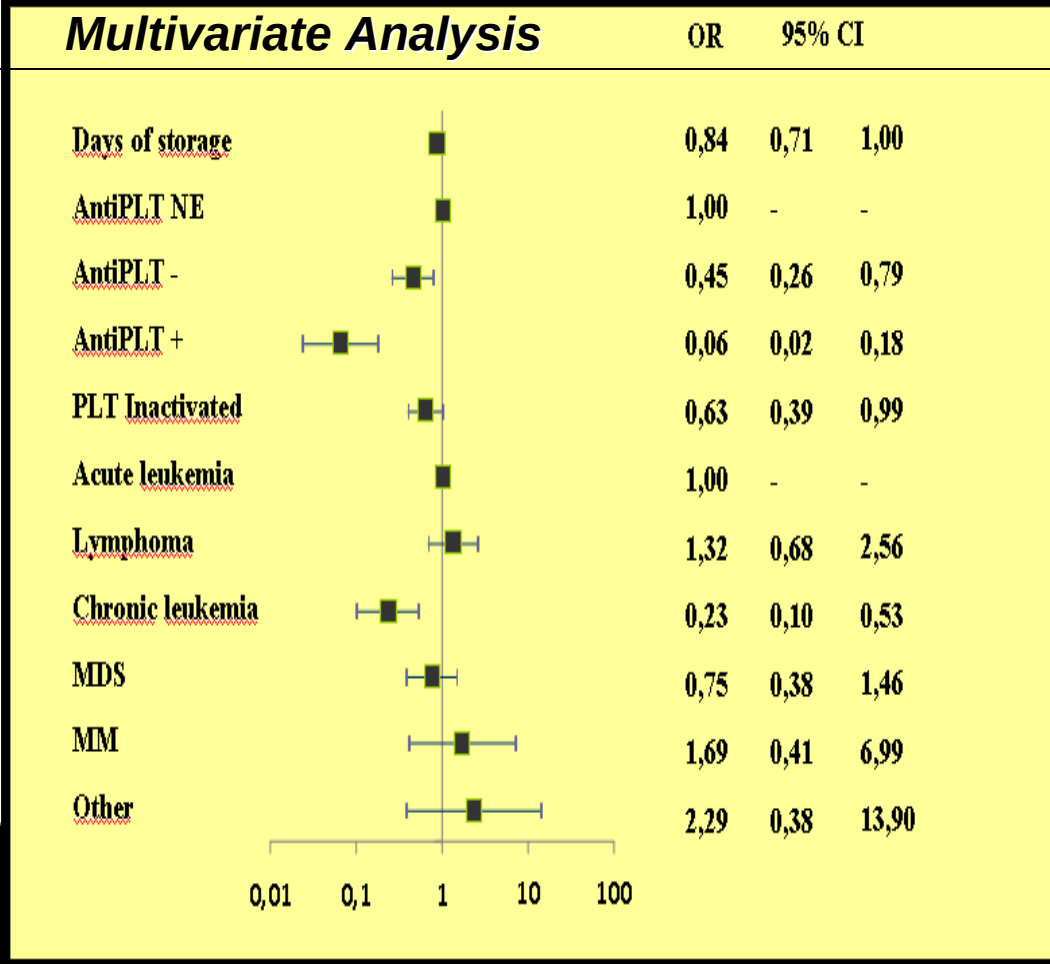
Man-Whitney U ** Chi Square tests

POST TRANSFUSION ABSOLUTE INCREMENT. A COMPARISON BETWEEN STANDARD AND INACTIVATED PLATELET CONCENTRATES

A Quaglietta ISBT - BERLIN JUNE 26- JULE 1 .2010

	INACTIVATED	UNTREATED	P*
Plt-pre 10^9/L	11812 ± 8045	12400 ± 8102	ns
Plt-post 10^9/L	21024 ± 16315	23716 ± 16534	0.04
IA 18-24h 10^9/L	9090 ± 14082	10893 ± 15088	0.06
Transfusion interval	2.0 ±1.6	2.3 ±1.8	0.2

NO advers events



STUDIO MULTICENTRICO

DMT Pescara. DMT Roma Ovest. SIT Tricase

DMT PESCARA e ROMA OVEST

PLT da Aferesi (AMICUS BCS) + INTERSOL

N° PROCEDURE / ANNO 1000 per centro

riceventi CMV negativi

INATTIVAZIONE:

PLT > 3 g di storage (alte rese. stesso paziente)

PLT da pool di BC (5-6unità) + INTERSOL

N° BC/ ANNO 500 per centro

INATTIVAZIONE: quando possibile

S.I.T. TRICASE

PLT da Aferesi (AMICUS BCS) + INTERSOL

N° PROCEDURE / ANNO 600 per centro

INATTIVAZIONE: Tutti

PLT da pool di BC (5-6unitò) + INTERSOL

N° BC/ ANNO 500 per centro

INATTIVAZIONE: Tutti

Dati demografici dei 548 riceventi trasfusi alternativamente con CP inattivati e non

PAZIENTI	**548**
Età	**56.12 ± 20.8**
Sesso (M/F)	***313 / 235***
DIAGNOSI	
LAM/LAL	**141 / 46**
Aplasia Midollare	**10**
Linfomi	**124**
Leucemie croniche	**27**
Mieloma Multiplo	**61**
Sindromi Mielodisplastiche	**59**
Tumori solidi	**80**

PLT inattivate e non inattivate: Confronto in 548 riceventi

	TOTALE	INATTIVATE	NON INATTIVATE	P
N° trasfusioni	5894	1770	4124	
Giorni storage	3.42±1.45	3.37 ±1.65	3.44 ± 1.35	<0.007
Plt infuse x10e11	3.56±0.99	3.48 ± 0.77	3.61 ±1.07	<0.20
% ABO Ident.	70.3	77.2	67.4	<0.0001 *
% ABO Comp	14.0	13.2	14.4	
% ABO Incompat	15.7	9.7	18.2	
% Split	21.9	11.6	26.4	<0.0001 *

Man-Whitney U per variabili continue
* Chi Square tests per variabili categoriche

PLT inattivate e non inattivate: Confronto in 548 riceventi

	TOTALE	INATTIVATE	NON INATTIVATE	p*
N° trasfusioni	5894	1770	4124	
Plt-pre C	14379 ±13955	11949 ± 10894	15698 ± 15220	<0.0001
Plt-post 10^9/L	27408 ±20656	21793 ± 18435	30610± 21169	<0.0001
IA 18-24h 10^9/L	12969 ± 16714	9600 ± 15229	15041 ± 17245	<0.0001
Intervallo trasfusionale	2.32 ±1.64	2.22 ± 1.59	2.37 ± 1.66	<0.67

Man-Whitney U

Fattori influenzanti l'efficacia trasfusionale: Analisi Logistica

Variabile	OR (IC 95%)	P
Età	0.992 (0.988-0.995)	<0.0001
Sesso		
Femmine	1.74 (1.49-2.04)	<0.0001
Maschi	1.0 (cr)	
Dose infusa	1.30 (1.19-1.41)	<0.0001
Giorni storage	0.90 (0.85-0.95)	<0.0001
No Split unità	1.62 (1.33-1.97)	<0.0001
Inattivazione	0.44 (0.37-0.52)	<0.0001
Compatibilità AB0		
Plts AB0 compatibili	1.24 (0.93-1.66)	0.13
Plts AB0 identiche	1.54 (1.23-1.93)	<0.0001
Plts AB0 incompatibile	1.0 (c.r.)-	

EMOVIGILANZA

	PLT INATTIVATE	PLT NON INATTIVATE
PAZIENTI	548	
REAZIONI TRASFUSIONALI	3	3
PESCARA DMT	1	3
ROMA OVEST DMT	0	0
TRICASE SIT	2	NE
EVENTI AVVERSI GRAVI	0	0

CONTAMINAZIONE BATTERICA	PLT AFERESI	PLT POOL BUFFY-COAT
ROMA OVEST DMT	0	0.58%
TRICASE UO	NE	NE
PESCARA DMT	O.49%	0.23%

N unità	Germe	Inattiv.	Trasf	Reaz	Sepsi
1583	Dermacoccus Nishinomiyaensis	No	Si	No	No
2729	S.Epidermidis	No	No	/	/
3335	E.Coli	No	Si	No	No
4839	S.Epidermidis	No	Si	No	No
800643	Str.Salivarius	Si	Si	No	No
802011	Klebsiella Pneumoniae	No	Si	No	No
802013	Klebsiella Pneumoniae	No	Si	No	No
802292	Dermacoccus spp. Kocuria spp	Si	Si	No	No
12632	S.Epidermidis	No	No	/	/
12655	Dermacoccus spp. Kocuria spp	No	No	/	/

CONCLUSIONI

L'inattivazione degli emocomponenti è una metodica ormai utilizzata da numerosi centri e consente non solo una riduzione del rischio delle infezioni trasmissibili, ma anche una diminuzione delle reazioni avverse , una alternativa all'irradiazione degli emocomponenti e allo screening della contaminazione batterica ed un aumento dei tempi di storage.

I dati europei relativi all'emovigilanza su di un largo numero di pazienti. hanno dimostrato un'ottima tollerabilità dei concentrati piastrinici inattivati con Intercept . con un'evidenza di riduzione delle reazione trasfusionali acute.

CONCLUSIONI

I dati relativi alla Meta-Analisi sulla efficacia e capacità emostatica delle Piastrine inattivate mostrano una diminuzione degli incrementi post trasfusionali ed un aumento delle complicanze emorragiche di lievi e medie grado .

Nella nostra esperienza questi risultati trovano riscontro in una bassa incidenza di reazioni lievi. Si conferma l'effetto sull'efficacia trasfusionale valutata come Incremento Assoluto. a fronte di un intervallo trasfusionale invariato.

CONCLUSIONI

L’impiego in routine potrebbe giovarsi di possibili strategie quali l’aumento delle dose o il miglioramento di altri parametri di sicuro impatto sull’efficacia , in attesa di chiarire i reali fattori influenzati le capacità emostatiche delle piastrine inattivate.