Disclosure of Grants Conflict of Interest

A. Brand: Nothing to disclose; P. C. Huijgens: Nothing to disclose; J. H. Kerkhoffs: Nothing to disclose; V. M. Novotny: Nothing to disclose; M. R. Schipperus: Nothing to disclose; P. A. Te Boekhorst: Nothing to disclose; L. van Pampus: Nothing to disclose; W. L. van Putten: Nothing to disclose; D. J. van Rhenen: Nothing to disclose; J. J. Zwaginga: Nothing to disclose

P6-020A

Do Multiple Interventions to Reduce Adverse Reactions in Young Female Donors Lower Rates of Reaction? A Preliminary Analysis

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Background: Donor hemovigilance studies have identified donor estimated blood volume (EBV) as one of several risk factors for vasovagal reactions. Pre-donation hydration and practice of applied muscle tension (AMT) exercises have been shown to mitigate the risk of reaction. With the goal of reducing adverse reactions, these interventions were adopted at our blood centers. **Methods:** We report on the rates of mild, pre-faint and loss of consciousness (LOC) reactions in female allogeneic whole blood donors, age 17-22 years, in the same 6-month period in two successive years before and after implementation of interventions consisting of (1) deferring donors younger than 23 years with EBV < 3500 mL, (2) promoting drinking 16 oz of water within 30 minutes before donation, and (3) familiarizing donors with the value of AMT in preventing or limiting reactions. **Results:** In female donors under 23 years of age, there was a 22% decrease in mild reactions ($p < 0.0001$), 17% decrease in pre-faint reactions ($p = 0.054$) and 18% decrease in LOC reactions ($p = 0.021$)—see table. Comparing the rate of mild reactions before and after the adoption of the interventions, we saw a significant decrease even after restricting the analysis to donors with EBV ≥3500 mL, indicating that hydration and AMT may have had an impact. A small number (246) of donors with EBV < 3500 mL donated after the adoption of the interventions. While the change in the reaction rates pre- and post-intervention for donors with EBV < 3500 mL was large, with only 8 of these donors having reactions the number of events pre and post-intervention were not statistically significantly different. **Conclusions:** Hydration, education about AMT and exclusive recruitment of donors with ≥3500 mL of blood appear to have resulted in the desired effect of reducing over all reaction rates, specifically mild and LOC reactions. Among donors with EBV ≥3500 mL there was significant reduction in mild reactions.

Disclosure of Commercial Conflict of Interest

M. Bravo: Nothing to disclose; B. Custer: Nothing to disclose; H. Kamel: Nothing to disclose; P. Tomasulo: Nothing to disclose

Disclosure of Grants Conflict of Interest

M. Bravo: Nothing to disclose; B. Custer: Nothing to disclose; H. Kamel: Nothing to disclose; P. Tomasulo: Nothing to disclose

Transfusion-Transmitted Diseases: Retroviruses

S1-010A

Prevalence and Incidence of HIV and HCV Infections Among Allogeneic Donations Since the Introduction of Nucleic Acid Testing in the United States

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Background: Nucleic acid testing (NAT) for HIV and HCV was introduced for screening of blood donations in the US in 1999. This study analyzed temporal trends in prevalence and incidence of these two infections since the introduction of NAT. **Methods:** Data on allogeneic donations between 1999 and 2008 were analyzed. All donations were tested for antibodies and viral RNA for HIV (anti-HIV and HIV RNA) and HCV (anti-HCV and HCV RNA) as well as other markers. Serologic and NAT reactivity were confirmed using additional tests. A confirmed serologic or NAT yield donation was a confirmed infection. Prevalence is the number of confirmed infections over total number of donations tested while incidence is the number of new infections (cases) among repeat donors (RP) over total number of person-years (py) observed. Incidence for first-time donors (FT) was derived by multiplying that among RP by the overall risk ratio of NAT yield rates between FT and RP donors (2.51 for HIV and 3.47 for HCV). Incidence for all donors was the weighted average based on percent of donations from FT and RP donors. Residual risk (RR) was determined using the window period model. **Results:** Prevalence rates (/105), incidence rates (/105 py) and RR (/106 donations) of HIV (anti-HIV or HIV RNA) and HCV (anti-HCV or HCV RNA) are listed in the Table. There was a decrease in prevalence by 22% for HIV and 55% for HCV between 1999 and 2008 (in bold). The incidence of HIV and HCV among repeat donors increased in 2007-2008 compared to 1999-2000 (in bold) although the overall levels remained low at 2.73 or 4.28/105 py respectively in 2007-2008 (in bold), with a RR estimate of 0.68/106 (1:1,467,000) or 0.87/106 (1:1,152,000) (in bold) by assuming an infectious window period of 9.1 or 7.4 days, respectively. **Conclusion:** The prevalence of HCV infections among allogeneic donations decreased significantly since the introduction of NAT. The identified increase in HIV and HCV incidence in 2007-2008 warrants continuous monitoring and investigation.

Disclosure of Commercial Conflict of Interest

R. Y. Dodd: Nothing to disclose; K. Dorsey: Nothing to disclose; F. Musavi: Nothing to disclose; E. P. Notari: Nothing to disclose; S. L. Stramer: Nothing to disclose; S. Zou: Nothing to disclose

Disclosure of Grants Conflict of Interest

R. Y. Dodd: Nothing to disclose; K. Dorsey: Nothing to disclose; F. Musavi: Nothing to disclose; E. P. Notari: Nothing to disclose; S. L. Stramer: Nothing to disclose; S. Zou: Nothing to disclose

	Pre-intervention	Post-intervention	Relative reduction in rate	p Value
Donations from Female donors < 23 years old (N)	33509	32196		
Mild reactions - Rate/1000 donations	22.9	18.0	22%	<0.001
Pre-faint - Rate/1000 donations	7.5	6.3	17%	0.054
Loss of consciousness - Rate/1000 donations	9.2	7.5	18%	0.021
Donations from female donors < 23 years old with EBV <3500mL (n)	5572	246		
Mild reactions - Rate/1000 donations	32.1	20.3	37%	0.3
Pre-faint - Rate/1000 donations	12.6	0.0	100%	0.077
Loss of consciousness - Rate/1000 donations	13.8	12.2	12%	0.83
Donations from female donors < 23 years old with EBV =/>3500mL (n)	27937	31950		
Mild reactions - Rate/1000 donations	21.1	18.0	15%	0.006
Pre-faint - Rate/1000 donations	6.5	6.3	3%	0.77
Loss of consciousness - Rate/1000 donations	8.3	7.5	9%	0.3

仮訳

血漿または血小板用添加液（病原体不活化処理および未処理）中で 7 日間保管した、ランダム供血者由来白血球除去プール血小板濃厚液の血液腫瘍疾患患者における臨床的有効性および安全性

緒言：血小板製剤の安全性を維持し、あるいは向上させた上で、保存期間を延長することが新規血小板製剤開発の主な目的である。多施設共同ランダム化比較試験において、血液腫瘍患者を対象として、3 種類のバフィーコート由来血小板製剤［血漿保存血小板（血漿 PC）、PAS III 保存血小板（Intersol、PAS III-PC）、ソラレン病原体不活化処理済み PASII 保存血小板（Intercept、PR PAS III-PC）］の輸血の有効性を検討した。血小板は最大 7 日間保管した。本稿では、血漿 PC と PR PAS III-PC との比較を行った中間解析データについて報告する。

方法：血漿 PC、PAS III-PC、PR PAS III-PC のいずれかの血小板を最大 5 回まで輸血する試験に、患者をランダムに割り付けた。選択基準は以下のとおり：年齢 18 歳以上、血液腫瘍疾患、予想 PC 輸血回数 2 回以上、同意取得。除外基準は以下のとおり：抗 HLA/HPA 抗体陽性の確定もしくは疑い、妊婦、臨床的に重大な自己免疫性血小板減少症。本試験の主要エンドポイントは、輸血後 1 時間の補正血小板増加数（1-hr CCI）とした。二次エンドポイントは、輸血後 24 時間の CCI、CTC グレード 2 の出血、赤血球・PC 輸血の必要量、PC 輸血間隔、輸血副作用とした。本試験は非劣性試験としてデザインし、1-hr CCI 平均値の 20%を超える減少を劣性と定義した。

結果：2007 年 3 月に試験を開始し、2008 年 12 月の中間解析時において評価可能な患者は 199 例であった（血漿 PC n=68、PAS III-PC n=64、PR PAS III-PC n=67）。中間解析データに基づき、血漿 PC 群、PR PAS III-PC 群に割り当てられた最初の 135 例の患者の PC 輸血データおよび出血性合併症に関して報告する。PR PAS III-PC の輸血（n＝252）後の 1-hr CCI 平均値は 11 .4±5.4 であり、血漿 PC（n＝212）の 17.5±7.1 と比較して、平均値の差は 34.2%（P ＜ 0.0001）であった。24-hr CCI は、それぞれ 8.0±5.6、13.0±7.9 であり、平均値の差は 33.5%（P＜0.0001）との結果であった。PR PAS III-PC 群の 24 例が出血事象を発現したが、血漿 PC 群では 14 例であった（P＝0.045）。以上のデータの検討後、独立した Data Safety Monitoring 委員会は、PR PAS III-PC 群への登録中止を勧告した。

結論：本試験の最終解析は完了していないが、2 回目の中間解析データにより、病原体低減化処理 PASIII 保存血小板の劣性が強く示された。本試験は患者の登録が終了したばかりであり、2009 年 9 月までには登録患者全員の解析が終了する予定である。

※HOVON：1985 年に設立されたオランダを中心とする血液がん研究グループ。このグループの主導で、これまでに 100 以上の臨床試験が実施されている。