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—【Original】——原　著—

Safety of 400-ml whole-blood collection in 17-year-old Japanese male donors

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Background: To overcome the shortage of blood and blood products, it is necessary to increase the total volume of blood collected from donors. This requires modifying the current standard of 200-m*l* whole-blood collection for young people (16-17 year-old), which is specified by the Departmental Regulation No.22 (Kouseishou-rei dai-22 gou). The objectives of this study were to evaluate the safety of 400-m*l* whole-blood collection in 17-year-old males.

Methods: A total of 322 male volunteers aged 17 years and 363 aged 18 or 19 years were recruited for blood collection through advertisements at schools and blood center donation sites. Blood collected from the 17-year-old males was not used for transfusion, whereas that collected from the 18-19 year-olds was used for transfusion as normal. To evaluate the safety of 400-m*l* whole-blood collection in the 17-year-old males, Fisher's exact test was used to compare vasovagal reaction (VVR) occurrence rates between the two groups by using a two-by-two contingency table. Significance was defined as $P<0.05$.

Results: Among the 17-year-old males, six side effects (1.86%)—five cases of VVR and one of subcutaneous hemorrhage—were observed at the blood collection site. Among the 18-19 year-olds, eight cases of VVR (2.22%) were reported. As for late-onset donor reaction, 56 (17.7%) were reported in the 17-year-old males and 35 (10.0%) in the 18-19 year-olds as assessed by post donation questionnaire. No difference was observed in the recovery rate of biochemical data (plasma components) between the two groups.

Conclusion: In terms of the VVR occurrence rate, there was no significant difference between the two groups ($P=0.7935$; $P>0.05$). The recovery rate of cell counts and plasma components to the original level was similar between the two groups. We conclude that 400-m*l* whole-blood collection can be performed safely in 17-year-old males in Japan.

Keywords: 17-year-old male donors, VVR, late-onset donor reaction, 400-m*l* whole-blood collection, plasma components

INTRODUCTION

The number of blood donors in Japan decreased to 4.99 million in 2006 from the recent maximum of 6.30 million in 1995 due to a change in the population structure, and a further acceleration of this trend is expected[1)2)].

The total volume of donated blood was 1.84 million *l*, which is a decrease of 0.6% from the previous year[1)2)].

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The insufficiency in the supply of blood and blood products is a cause for concern, particularly in a society with a low birthrate coupled with increasing longevity, since many blood products will be required to meet the demands of an aging population and the diseases associated with it[3)4)]. It is therefore proposed that 400-m*l* whole-blood collection in young people (aged 16-17 years) should be adopted in place of the 200-m*l* whole-blood collection currently set as the standard volume of blood collected from donors as regulated by a ministerial decree (Kouseishou-rei dai-22 gou) of the Ministry of Health, Labour and Welfare (MHLW). However, the safety of 400-m*l* whole-blood collection in young blood donors in Japan has not been evaluated yet. Fainting at the blood donation site may cause serious injury to blood donors[5)]. This fainting is often associated with vasovagal reaction (VVR), which is caused by blood vessel dilation due to an increase in vagal tone. The central autonomic pathways, precipitated by emotional factors and hyperventilation, play a critical role. Hypo perfusion of the reticular activating system and cerebral cortex is the final common pathway for the majority of episodes[6)]. As for the definition of VVR in this study, we used the diagnostic criteria described in the MHLW guideline[7)] concerning compensation damage to the health of blood. Diagnosis is performed based on observation at the time of occurrence at the blood collection site. VVRs that occur late after donation on the same day are in principle defined as delayed VVR. Further, we define other symptoms, such as fatigue, sweating and vomiting, occurring within several days as late-onset donor reactions in this paper.

We examined the safety of 400-m*l* whole-blood collection in 17-year-old males in this study. In a previous study on the safety of blood donation in young people, it was reported that giddiness and fainting were mainly caused by side effects such as VVR at the time of blood withdrawal. The study reported that factors associated with a high incidence rate of side effects included low body weight, young age, or first-time donation[8)~10)]. The rate of VVR occurrence in normal blood donors has been reported as approximately 1% [8)~10)]. The occurrence rate of VVR in Japan is also approximately 1% [11)].

METHODS

Before the trial, we informed the voluntary participants (17-year-old males) and their parents of the contents of this study and obtained the written consent of both child and a parent. 400-m*l* whole-blood collection was then carried out after a medical check. Similar informed consent was obtained prior to 400-m*l* whole-blood collection from another group consisting of 18-19-year-old male. All participants were recruited through advertisements at high schools and blood centers. The number of 17-year-old and 18-19-year-old males who participated in the trial was 322 and 363, respectively. Data were collected at nine institutions in seven regions across the country (Japanese Red Cross Blood Centers in Hokkaido, Miyagi, Tokyo, Aichi, Osaka, Okayama, and Fukuoka). The study period was from April 1, 2005 to September 30, 2005. Three months later, a follow-up survey was conducted on the same donors. This follow-up survey was conducted from July 1, 2005 to December 30, 2005. Further, a pre-donation interview recorded the following information: age, number of times of blood donation (donor status), total amount of donated blood annually, amount of collected blood, height, body weight, circulatory blood volume (CBV) and blood withdrawal time. CBV was estimated by the following equation proposed by Ogawa et al[12)], which has been shown to be the most suitable for Japanese people.

$CBV = 0.168H^3 + 0.050W + 0.444$ *H: height (m), W: body weight (kg)

The ratio of the amount of blood collected to the total CBV was also computed. Further, changes in hematological, biochemical and other laboratory data (blood cell counts, plasma components and so on) before and after the 400-m*l* whole-blood collection were compared. The following data were recorded in the follow-up survey (three months after collection): systolic BP (mmHg), diastolic BP (mmHg), pulse rate, erythrocyte count, leukocyte count, platelet count, hematocrit (Ht), hemoglobin concentration (Hb), mean corpuscular volume (MCV), mean corpuscular hemoglobin (MCH), mean corpuscular hemoglobin concentration (MCHC), serum iron, total iron-binding capacity (TIBC), ferritin, and alkaline phosphatase (ALP). Table 1 shows the background characteristics of participants in the two groups. The number of subjects, average value, and standard deviation were calculated for every item, and a two-sample *t*-test was carried out.

To evaluate the safety of 400-m*l* whole-blood collection in the 17-year-old male group, Fisher's exact test was used to examine two-by-two contingency tables of

Table 1　Background subject characteristics of 17 year-old and 18-19-year-old males

Background category	17-year-old males		18-19-year-old males		P
	N	Average ± SD	N	Average ± SD	
Age	322	17.6 ± 0.3	363	19 ± 0.5	—
Number of donations	322	1.8 ± 1.6	362	1.8 ± 2.8	0.896
Donation times (/year)	322	1.5 ± 1	362	0.9 ± 1.6	—
Height (cm)	322	171.1 ± 5.4	363	171.7 ± 5.6	0.146
Body weight (Kg)	322	64.8 ± 10.2	363	64.6 ± 8.7	0.9156
CBV (m*l*)	322	4,526 ± 549.0	363	4,529.4 ± 466.9	0.8909
Collected volume (m*l*)	322	398.7 ± 19.2	363	399.2 ± 13.9	0.7074
Collection time (min)	154	7.8 ± 2.9	172	7.3 ± 2.5	0.1126
Collected volume/CBV (%)	322	8.9 ± 1.0	363	8.9 ± 0.9	0.7423
systolic BP (mmHg)	322	120.5 ± 12.1	363	121.6 ± 12.4	0.105
diastolic BP (mmHg)	322	65.1 ± 8.8	363	64 ± 8.6	0.4889
pulse PRD (min)	321	72.6 ± 12.1	363	72.4 ± 11.6	0.0951
erythrocyte count ($\times 10^4/mm^3$)	303	503 ± 32.1	318	504.8 ± 30.2	0.4803
leukocyte count ($\times 10^2/mm^3$)	303	59.6 ± 13.3	318	60.2 ± 14.5	0.5652
platelet count ($\times 10^4/mm^3$)	303	24.5 ± 4.7	318	24.1 ± 4.6	0.3157
Ht (%)	303	44.9 ± 2.5	318	45.3 ± 2.3	0.0318
Hb (g/d*l*)	303	15.2 ± 0.9	318	15.4 ± 0.8	0.0011
MCV (f*l*)	303	89.3 ± 3.2	318	89.8 ± 3.6	0.0618
MCH (pg)	303	30.1 ± 1.2	318	30.5 ± 1.4	0.0005
MCHC (%)	303	33.7 ± 0.7	318	33.9 ± 0.8	0.0004
serum iron (μg/d*l*)	303	106.9 ± 37.8	318	110.4 ± 38.9	0.2178
TIBC (μg/d*l*)	303	323.3 ± 37.9	318	314.4 ± 37.2	0.003
ferritin (ng/m*l*)	303	39.7 ± 20.5	318	58.6 ± 35.8	< .0001
ALP (u)	303	348.4 ± 103.6	318	283 ± 97.9	< .0001

SD: standard deviation

Table 2　VVR occurrence and donor age after 400-m*l* whole-blood collection

Age Group	Response		Total
	Non AEs	AEs	
17-year-old males	316 (98.1%)	6 (1.9%)	322
18-19-year-old males	354 (97.8%)	8 (2.2%)	362
Total	670	14	684

AE s: adverse events　　P = 0.7935

"age versus side effects" and "age versus late-onset donor reaction" in the post donation (one week after blood collection) questionnaire.

For the 17-year-old male group, a logistic linear regression analysis was used to evaluate relationships between side effects and sleep duration, and between side effects and the period of the last meal and needle placement. Fisher's exact test was also used to compare continuous variables. Significance was defined as $P<0.05$. SAS 9.1.3 for Windows and SPSS 12.0J for Windows were used for statistical analysis.

Ethics

This survey was approved by the Ethics Committee of Tokyo Medical and Dental University.

RESULTS

Table 1 shows background characteristics of the trial participants. Statistically significant differences were observed between groups before blood collection with regard to variables such as Ht, MCHC, ferritin, and ALP level. Baseline ferritin values were originally lower in the 17-year-old than 18-19-year-old male group.

① Safety of 400-m*l* whole-blood collection in 17-year-old males

The number of VVR episodes was five (1.51%) in 17-year-old and eight (2.22%) in the 18-19-year-old male groups. One subcutaneous hemorrhage (0.3%) was observed in the 17-year-old male group. Table 2 is the two-by-two contingency table showing the relationship between age and side effects; no statistical significance was observed using Fisher's exact test($P=0.793$; $P>0.05$). In fact, more episodes of VVR were observed in the 18-19-year-old male group, mainly among first-time donors. Six of eight donors who experienced VVR at site were first-time donors. Among first-time donors, the number of VVR episodes was 1 of 14 (7.14%) in the 17-year-old male group, and 4 of 122 (3.28%) in the 18-19-year-old male group. Among the repeated donors, however, the number of VVR episodes was 4 of 308 (1.25%) in the former and 2 of 241 (0.83%) in the latter. It thus

appears that repeated donors have a lower tendency to VVR symptoms than inexperienced donors.

Table 3 shows the relationship between age and late onset donor reaction. The post donation questionnaire was completed one week after collection. A greater number of instances of late-onset donor reaction was observed among volunteers in the 17-year-old male group than in the 18-19-year-old male group and a significant statistical difference was observed between the two groups with Fisher's exact test (P=0.0047; P< 0.05). The reported number of cases of late-onset donor reaction in the 17-year-old male group was 2.23 times greater than that in the 18-19-year-old male group.

②Recovery of hematological and biochemical markers

The follow-up survey was conducted three months after collection. Overall, no significant difference was observed between the 17-year-old and 18-19-year-old groups. Table 4 shows the recovery rate of hematological and biochemical markers. The figures before collection were defined as 100%. The recovery rates of erythrocyte coun; Hb and Ht in the 17-year-old males were 102.3%, 100.8% and 101.4% respectively in three months, which exceeded their original levels. Further, other hematological values recovered to the original or near-original level. The recovery rate of ferritin in the 17-year-old males was 77.1% and 69.0% in 18-19-year-old group.

③ Other analysis

To further analyze the safety of 400-m*l* whole-blood collection, factors such as sleeping time, interval between a meal and needle placement, side effects, and late-onset donor reaction in the 17-year-old male group were analyzed. The first logistic linear regression analysis was conducted using sleeping duration (odds ratio: 1.36) and the interval of time between a meal and needle placement (odds ratio: 1.00) as the explanatory variables. However, results showed no significant correlation between these factors. Although it is generally believed that VVRs are associated with the interval of time from the last meal to needle placement and sleeping duration[13], no significant correlations were observed in this study.

Table 3 Late-onset donor reaction within one week after and donor age after 400-m*l* whole-blood collection

Age Group	Post donation questionnaire		Total
	Non-LDR	LDR	
17-year-old males	261 (82.3%)	56 (17.7%)	317
18-19-year-old males	314 (90.0%)	35 (10.0%)	349
Total	575	91	666

LDR: Late-onset donor reaction P = 0.0047

DISCUSSION

The VVR occurrence rate was not significantly different between the 17-year-old and 18-19-year-old male groups. The incidence of VVR in the 17-years-old males was low, with one exception of brief unconsciousness. Other donors with VVR (n=4) recovered within 1h with supine rest, and no special treatment was required. As to VVR, the safety of 400-m*l* whole-blood collection in the 17-year-old male donors was not different to that in the 18-19-year-old male donors, therefore, confirming the safety of this procedure in these donors. Since first-

Table 4 Recovery rate of blood count and plasma components in the two groups

Blood count and plasma components	17-year-old male group Recovery rate (%)		18-19-year-old male group Recovery rate (%)	
	308		318	
leukocyte count	103.6 ± 23.0	NS	103.5 ± 30.8	NS
erythrocyte count	102.3 ± 17.3	P < 0.01	100.8 ± 4.3	P < 0.05
Hb	100.8 ± 5.0	P < 0.05	100.2 ± 4.5	NS
Ht	101.4 ± 5.6	P < 0.01	99.8 ± 4.6	NS
MCV	99.2 ± 2.0	P < 0.01	99.0 ± 1.7	P < 0.01
MCH	98.6 ± 2.3	P < 0.01	99.4 ± 2.1	P < 0.01
MCHC	99.5 ± 2.2	P < 0.01	100.4 ± 2.4	P < 0.05
platelet count	102.6 ± 13.8	P < 0.01	104.0 ± 3.7	P < 0.01
serum iron	108.1 ± 52.0	NS	104.9 ± 50.8	NS
TIBC	108.0 ± 9.2	P < 0.01	109.2 ± 7.5	P < 0.01
ferritin	77.1 ± 40.7	P < 0.01	69.0 ± 42.2	P < 0.01
ALP	105.3 ± 24.1	P < 0.05	99.4 ± 13.7	NS

Table 5　Relationship between CBV ratio and adverse effects

	17-year-old males		18-19-year-old males	
CBV ratio (%)	number of donors	adverse effects (ill health) (%)	number of donors	adverse effects (ill health) (%)
less than 8	45	5 (11.1)	42	6 (14.3)
8.0-8.9	100	15 (15.0)	127	12 (9.4)
9.0-9.9	118	25 (21.2)	143	12 (8.4)
more than 10	53	11 (20.8)	37	5 (13.5)
total	316	56 (17.7)	349	35 (10.0)

time donors were more prone to adverse events, the mental aspects of donors, rather than the blood volume collected, appear more related to the adverse events. Close attention should be paid to the psychological aspects of donors, such as pain control for young donors, on the basis of a report that younger first-time donors with low body weight are generally at high risk[14]. It is also reported that the interpersonal skill of the phlebotomist also affects the occurrence rate of donor reactions among donors[15]. For young blood donors, operational consideration, such as an education program to the phlebotomists to reduce the biased barrier of pain, and the provision of sufficient space to rest after collection, should be implemented at all blood collection centers.

Instances of late-onset donor reaction, such as dizziness, sweats, sudden weakness, or unconsciousness were reported quite often in the 17-year-old male group in the post donation questionnaire (within a week after blood collection). Generally, most symptoms were for unspecific complaints, such as oppression and lightheadedness. It is reported that minor sickness after blood collection is observed in about 10% of donors in general[16] and that the volume of blood collection is irrelevant. Such late-onset donor reactions are not specific to 17-year-old males in this regard. Although no associated factors could be identified there is a general tendency toward severe delayed VVR symptoms after 400-m*l* whole-blood collection regardless of age[17)18)]. It is suggested that restriction of physical activity and adequate rest immediately after blood withdrawal is essential to avoiding delayed VVR or late-onset donor reaction. Donors should act on their own judgment immediately after blood donation. In addition, it is also recommended that sufficient space for donors to rest after collection is required at a fixed site, especially for high risk groups, such as young blood donors.

The relation between the CBV ratio (percentage of collected blood volume to total CBV)and signs of ill health after blood collection is shown in Table 5. In 17-year-old males, ill health ratio was 11.1% if CBV ratio was less than 8.0%, while in the 18-19-year-old group the ill-health ratio was 20.8% if CBV ratio was more than 10.0%. The ill health occurring after blood collection appeared to be associated with CBV ratio in the 17-year-old male group. Donor body weight is the only screening criterion in the present blood-collecting standard, and this variable surely also reflects the amount of CBV. It is desirable to consider additional criteria in estimating CBV for decision-making on blood collection volume. A shorter donor will have a lower CBV than a taller person who has the same body weight.

The recovery rates of biochemical markers were satisfactorily close to the original levels. However, ferritin value in the 17-year-old males was slightly lower compared with that in the 18-19-year-old males before blood collection. A recovery delay in other plasma components, such as ALP, was observed in the 18-19-year-old male group but was not significant. These data indicate that male teenagers, namely puberty is usually considered around 11-15 years boys, are still in the middle of bone growth[19)~21)].

With regard to blood donation age in other countries, the U.S universal standard of donor age is shown in the "AABB Standards for Blood Bank and Transfusion Services 24th edition; BBTS"[22], in which the standard age of blood donation is set at the age of 16 or the age established under applicable state law. Further, most states allow 450/500-m*l* whole-blood collection from 16-year-olds. Further, in Australia, 470-m*l* whole-blood collection is performed in 16-year-olds. Currently, 470-m*l* whole-blood collection is similarly carried out from 17-year-olds in Britain, and 450-m*l* whole-blood collection is conducted in Canada[23]. Thus, blood donation age may tend to be lower in other developed countries in the future.

According to blood donation data in the 2006 fiscal year of the Japanese Red Cross Society, the total num-

ber of the 17-year-old male blood donors (200-m*l* whole blood collection) was 34,816, and the total number besides deferred donors was 24,629. On trial calculation, the amount of blood donation by 17-year-old males at 400-m*l* whole-blood, is estimated to increase to 4,925 *l*, which would provide 0.55% of overall donation. Moreover, if similarly carried out in the 17-year-old girls, the total number besides the deferred donors is 14,490 and the increase in the amount of blood donation is estimated as 2,898 *l* (0.79%). Overall, the total volume of blood donation will increase to 7,823 *l*. This means a total increase in 0.61% of 400-m*l* whole-blood donation. However, with regards to blood donation by young females, the FDA report also highlights the problem of iron deficiency anemia[24]. It is therefore necessary to carefully examine the annual amount of total collection and the annual number of times of blood donation.

Further, one report stated that more blood donation experience at the time of youth contributes to a greater subsequent promotion of blood donation thereafter[25], while other showed evidence that 400-m*l* whole-blood first-time donors would have fewer side effects at second blood collection than 200-m*l* whole-blood first-time donors[26]. These findings suggest that carrying out 400-m*l* whole-blood collection in 17 year-olds can be considered as future contributing to a subsequent increase in the amount of blood donation.

CONCLUSION

This study found no significant difference between 17- and 18-19-year-old males with regard to side effects at the time of 400-m*l* whole-blood collection. However, young blood donors are still a high risk population group compared to general blood donors. Implementation of 400-m*l* whole-blood collection in 17-year-old males will therefore require sufficient consideration and observation of the donors, even with regard to post donation status, especially in terms of controlling water hydration and physical activity after blood donation to avoid late-onset donor reaction. The results of this study suggest the possibility that a low CBV was related to the incidence of late-onset donor reaction. Therefore, hydration by infusion or oral ingestion is critical when the ratio of collected blood volume to an amount of CBV is high.

As VVR incidence in a previous study tended to be higher with smaller CBV, especially in female donors[27], CBV should be considered in addition to body weight for use as a new screening criterion in the donor selection process.

With regard to further study, the safety of 400-m*l* whole-blood collection in young females (16 and 17 year-old) should be examined to ensure a stable supply of blood products in the future. The upper limit of age was assessed in a previous study, which showed relatively few donor reactions among aged people[23]. The upper limit of donor age for blood donation in Japanese should also be examined to ensure a stable supply of donated blood and blood products for the future blood program.

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17 歳男性の 400m*l* 全血採血の安全性に関する研究

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要旨：

【目的】今後懸念される献血量の減少や血液製剤確保の観点から，現行の省令で定める採血基準で行われている若年者（16 歳，17 歳）の 200m*l* 全血採血について見直しを行う必要性がある．本研究では 17 歳男性（検討群）に 400m*l* 全血採血を行い，同時に現在の基準で行われている 18 歳及び 19 歳男性（対照群）にも 400m*l* 全血採血を行い，両群の比較検討をした上で，17 歳男性の 400m*l* 献血の安全性について検討をした．

【方法】採血は全国 7 地域 9 施設で行われた．各血液センターより集計された 17 歳男性ボランティアは 322 名，18 歳及び 19 歳男性ボランティアは 363 名であった．採血前には問診を行い，採血時に観察行い VVR 等の副作用の有無を調べ，採血後にその後の体調の不良などを質問票で調査した．また採決前と採血後の血液学的生理検査データの変化を 3 カ月後の追跡調査で行った．400m*l* 全血献血の安全性と年齢の関係では，副作用の発生と質問票の結果を基に，それぞれの群でのクロス表を作成し，Fisher の正確検定を行った．（$P<0.05$）

【結果】採血時の副作用発生状況は 17 歳男性の場合では 6 例（1.81%）で，5 例は VVR（血管迷走神経反射）であり，1 例は皮下出血であった．18 歳及び 19 歳男性の場合は，VVR が 8 例（2.22%）見られた．また問診票による追跡調査の結果では，17 歳男性では 56 例（17.70%），18 歳及び 19 歳男性では 35 例（10.00%）に，吐き気やだるさ等の何らかの体調不良を訴えると言った結果が見られた．さらに血液学的生理検査の結果では，採血の前後で両群間に大きな差は見られなかった．

【結語】献血による採血に伴う VVR の発生に関して，17 歳男性群と 18 歳及び 19 歳男性群との間では，副作用の発生状況に何ら差は見られなかった．また追跡調査の結果では血液学的生理データの回復も，両群においてほぼ全快していることがわかった．よって本研究では，将来の輸血用生物由来血液製剤の安定供給を確保するために，現行の採血基準を見直し，17 歳男性に全血 400m*l* 採血を行うことは，安全であり医学的にも問題ないことがわかった．

キーワード：

17 歳男性献血者，VVR（血管迷走神経反応），遅発性副作用，400m*l* 全血採血，血漿成分

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