Comparison of Improvacuter EDTA Tube with BD Vacutainer EDTA Tube for Routine Hematological Analysis: Clinical Significance of Differences, Stability Study, and Effects of K₂ and K₃ EDTA

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Background: The type of blood collection tubes is an important pre-analytical factor that may affect test results. We compared the test results of the Improvacuter EDTA tube (Improve Medical, China) with those of the currently used BD Vacutainer EDTA tube (Becton Dickinson, USA) and investigated the effects of K₂ and K₃ EDTA additives.

Methods: Peripheral blood samples from 100 outpatients were collected into the aforementioned tubes. The samples were evaluated for 17 hematological analytes, hemoglobin A1c, and erythrocyte sedimentation rate (ESR). The results were analysed using the paired *t*-test for comparison. Bland-Altman plots and Passing-Bablok regressions were used for analytes with statistically significant differences in the comparison. If the differences were not within total allowable error, they were defined as clinically significant. For stability testing, the initial results were compared against those from samples preserved for 72 hours. White blood cell count, red blood cell count, platelet count, and mean corpuscular volume from both tubes were compared to ascertain the differences between K₂ and K₃ EDTA additives.

Results: Hematocrit, mean corpuscular volume, mean corpuscular haemoglobin concentration, and ESR showed statistically significant differences ($P<0.05$) between two tubes. However, these differences were not considered clinically significant. Most of the analytes presented statistically significant differences in stability test; however, they were not clinically significant either. Additionally, the differences in the hematological parameters shown in the outcome were not clinically significant, depending on the type of the EDTA additives.

Conclusions: The results indicate that Improvacuter EDTA tubes showed satisfactory performance. We conclude that the tubes are suitable for common clinical hematological use. (*J Lab Med Qual Assur* 2016;38:77-86)

Key Words: BD Vacutainer, Improvacuter, Comparison, Stability, K₂ and K₃ EDTA

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INTRODUCTION

For many modern clinical laboratories with automated analyzing systems, pre-analytical quality control has become very important, as pre-analytical error is the most

common error in practice [1]. One of the pre-analytical variables is specimen collection process. A considerable number of tests are performed in clinical laboratories handling blood as samples. The quality of blood specimen is influenced by several factors. One of the important

factors is the performance of blood tubes.

There are numerous kinds of blood tubes, and some of them are evacuated tubes. All the evacuated tubes contain some types of additives except plain tubes. For hematologic analysis, di- and tri-potassium (K_2 and K_3) salt of ethylenediaminetetraacetic acid (EDTA) are the standard anticoagulant additives nowadays. There have been several reports about the effects on the results of analytes due to the K_2 and K_3 EDTA additives [2-5]. It has been mostly referred to the red cell shrinkage effect due to hyperosmolar EDTA K_3 and dilution effect from the liquid form K_3 EDTA [3], however, there is no definite consensus about appropriate kind of EDTA for routine hematologic analysis. Therefore, it is important to ascertain that the exposure of blood specimens to the blood tube additives does not influence on targeted laboratory analytic result.

Currently in Korea, BD Vacutainer tube (Becton Dickinson, Franklin Lakes, NJ, USA) and Greiner Vacuette tube (Greiner Bio-One GmbH, Frickenhausen, Germany) are commonly used in clinical laboratories. While lately Improvacuter tube (Improve Medical, Guangzhou, China) has been introduced, Improvacuter EDTA tube has been evaluated earlier for hematologic analysis. However, the study was only for normal healthy people [6], and there has not been any evaluation for patients under routine clinical hematologic laboratory tests until now.

Therefore, the aim of this study was to evaluate that whether the currently using BD Vacutainer EDTA tube and newly introduced Improvacuter EDTA tube are comparable to each other, for common laboratory use in analyzing several hematologic parameters and some additional analytes. For that purpose, we conducted comparison study between the above-mentioned two kinds of tubes and stability test for each tube. In addition, effects of K_2 and K_3 EDTA anticoagulants on the hematologic analytes were studied for the reason that different kinds of anticoagulants were added to the study tubes: spray-dried K_2 EDTA was applied to BD Vacutainer EDTA tube and liquid K_3 EDTA was used as additive in Improvacuter tube.

MATERIALS AND METHODS

1. Subjects and Study Design

The study was conducted in August 2015 at Gangnam Severance Hospital in Seoul, Republic of Korea. This study was approved by institutional review board (2015-0138-001) and informed consents were obtained from all the participants.

Based on Clinical and Laboratory Standards Institute guideline EP09-A3, at least 40 samples should be analyzed. Most of pre-existing studies about comparison of blood tubes included around 40 healthy adults. In this study, however, total 100 patients participated to evaluate the tubes at wider and various reportable range. All participants were outpatient-clinic visitors who were scheduled to have blood sampling for their own examinations. All of them were adults (≥ 18 years old), with a mix of males and females.

Venous blood was collected by the phlebotomists of the specimen collection room in the hospital. The scheduled blood sampling for currently using BD Vacutainer EDTA tube and additional 3 mL blood sampling for Improvacuter EDTA tube were performed. Blood samples were collected in a randomized drawing order using needles of BD product, and the tubes were filled to capacity. Both tubes were gently inverted about ten times immediately after collection in order to mix the EDTA anticoagulant evenly with blood and were sent to the laboratory through automated transport system for analysis without delay.

2. Laboratory Analyses

The following 17 hematologic analytes were measured in both tubes from 100 subjects at initial time using XN-9000 (Sysmex, Kobe, Japan) for comparison study: white blood cell count (WBC), neutrophil (%), lymphocyte (%), monocyte (%), eosinophil (%), basophil (%), red blood cell count (RBC), hemoglobin (Hb), hematocrit (Hct), mean corpuscular volume (MCV), mean corpuscular hemoglobin concentration (MCHC), mean corpuscular hemoglobin (MCH), red cell distribution width (RDW), platelet count (PLT), platelet distribution width (PDW), mean platelet volume (MPV), and reticulocyte count. Hemoglobin A1c

(HbA1c) and erythrocyte sedimentation rate (ESR) were additionally analyzed using Tosho G8 HPLC analyzer (Tosoh Bioscience Inc., San Francisco, CA, USA) and Alifax Test 1 (Alifax, Polverara, Italy), respectively.

For the stability test, all the samples were stored at 4°C for 72 hours after the first measurement according to standard laboratory practice. After storage period, they were re-analyzed for all the analytes measured at the first time except for ESR, because ESR varies significantly according to the time delay, and for that reason, stability of ESR is insignificant in clinical context. All analyses were carried out in the same reagent and calibrator lots for each 0 hour and 72 hour study, respectively.

3. Statistical Analysis and Clinical Significance

The normality of distribution of all the analytes data was confirmed by normal probability plot. Data was described as the mean $\pm$ SD. The paired *t*-test was used for both comparison and stability study to figure out whether there were statistical differences between the BD Vacutainer EDTA tube and Improvacuter EDTA tube for all the analytes. Level of significance for all statistical comparisons was set as $P < 0.05$. Bland-Altman plots and Passing-Bablok regressions were used for the analytes which showed statistically significant differences in the comparison study. Additionally the differences between tubes were calculated according to the formula: Difference (%) = [(Improvacuter EDTA tube mean - BD Vacutainer EDTA tube mean) / BD Vacutainer EDTA tube mean] $\times$ 100]. The calculated differences of all parameters were compared with the current total allowable error based on biological variation [7,8], except for ESR and PDW because total allowable errors for them were not available. Instead, the criteria $\pm 10\%$, which was provided from the manufacturer of Alifax Test 1, was applied to ESR. If the calculated differences were not within the total allowable error, they were considered as clinically significant. All the statistical analyses were performed using Analyze-it Method Validation ver. 4.20 (Analyze-it Software, Leeds, UK) and IBM SPSS ver. 20.0 (IBM Co., Armonk, NY, USA).

4. Effects of K₂ and K₃ EDTA Anticoagulant on the Results of Specific Analytes

Since BD Vacutainer EDTA tube uses spray-dried K₂ EDTA and Improvacuter EDTA tube uses liquid K₃ EDTA as anticoagulant additives respectively, we schemed to evaluate the effect of these different anticoagulants on some specific hematologic parameters.

For red cell shrinkage effect assessment we have chosen Hct and MCV as indicators. Particularly for MCV, which was analyzed directly from the automated blood analysis system, we figured out whether there were any cases that the type of red cell volume is classified differently due to the different result values from each K₂ EDTA tube and K₃ EDTA tube. In detail, the reference interval for MCV was set between 80 and 98 fL in this study, same for male and female, which was provided from the manufacturer of XN-9000 and validated in our laboratory. If the value of MCV was within the reference interval, the result was classified as normocytic. When the MCV value was less than 80 fL, the result was categorized as microcytic. In contrast, if the MCV value was over than 98 fL, the result was categorized as macrocytic.

For evaluation of dilution effect due to liquid form K₃ EDTA, we compared WBC count, RBC count, and PLT count of each two tubes using previously performed comparison study data and assessed whether cell counts were declined in Improvacuter K₃ EDTA tube compared to the BD Vacutainer K₂ EDTA tube.

RESULTS

1. Comparison Study between BD Vacutainer EDTA Tube and Improvacuter EDTA Tube

The statistic results of comparison study between BD Vacutainer EDTA tube and Improvacuter EDTA tube performed at initial time are summarized in Table 1. For four analytes, there was a statistically significant difference between the two tubes: Hct, MCV, MCHC, and ESR. For these parameters, Bland-Altman difference plots were figured. The plots showed that most of the differences between the BD Vacutainer EDTA tube and Improvacuter EDTA tube results were within the 95%

Table 1. Comparison of hematological parameters of BD Vacutainer tubes and Improvacuter tubes

Variable	BD (0 hr)	Improve (0 hr)	Difference (%)	Total allowable error	P-value
White blood cell count ($\times 10^3/\mu\text{L}$)	6.62 $\pm$ 2.45	6.61 $\pm$ 2.47	-0.09	$\pm 15\%$	0.645
Neutrophil (%)	56.39 $\pm$ 13.76	56.78 $\pm$ 15.04	3.56	Target $\pm 3\text{SD}$	0.670
Lymphocyte (%)	31.53 $\pm$ 11.26	31.11 $\pm$ 11.63	2.82	Target $\pm 3\text{SD}$	0.210
Monocyte (%)	7.79 $\pm$ 2.93	7.72 $\pm$ 2.96	3.12	Target $\pm 3\text{SD}$	0.470
Eosinophil (%)	2.09 $\pm$ 1.79	2.06 $\pm$ 1.80	-1.98	Target $\pm 3\text{SD}$	0.273
Basophil (%)	0.48 $\pm$ 0.25	0.48 $\pm$ 0.27	11.99	Target $\pm 3\text{SD}$	0.774
Red blood cell count ($\times 10^6/\mu\text{L}$)	4.44 $\pm$ 0.60	4.43 $\pm$ 0.60	-0.01	$\pm 6\%$	0.864
Hemoglobin (g/dL)	13.51 $\pm$ 1.87	13.50 $\pm$ 1.86	-0.06	$\pm 7\%$	0.360
Hematocrit (%)	40.11 $\pm$ 5.05	40.45 $\pm$ 5.04	0.86	$\pm 6\%$	<0.0001
Mean corpuscular volume (fL)	90.70 $\pm$ 5.23	91.50 $\pm$ 5.28	0.88	$\pm 2.42\%$	<0.0001
Mean corpuscular haemoglobin concentration (g/dL)	33.65 $\pm$ 1.17	33.34 $\pm$ 1.16	-0.91	$\pm 1.27\%$	<0.0001
Mean corpuscular haemoglobin (pg)	30.54 $\pm$ 2.21	30.52 $\pm$ 2.22	-0.04	$\pm 2.5\%$	0.630
Red cell distribution width (%)	13.08 $\pm$ 1.54	13.10 $\pm$ 1.54	0.11	$\pm 4.6\%$	0.175
Platelet count ($\times 10^3/\mu\text{L}$)	255.32 $\pm$ 78.95	254.84 $\pm$ 79.08	-0.17	$\pm 25\%$	0.305
Platelet distribution width (fL)	12.02 $\pm$ 2.00	12.02 $\pm$ 1.99	0.14	-	0.965
Mean platelet volume (fL)	10.50 $\pm$ 0.95	10.50 $\pm$ 0.94	-0.01	$\pm 5.84\%$	0.838
Reticulocyte ($\times 10^3/\mu\text{L}$)	74.43 $\pm$ 25.50	74.15 $\pm$ 24.83	0.03	$\pm 16.8\%$	0.525
Hemoglobin A1c (%)	5.50 $\pm$ 0.66	5.49 $\pm$ 0.66	-0.14	$\pm 3\%$	0.090
Erythrocyte sedimentation rate (mm/hr)	16.96 $\pm$ 17.47	16.15 $\pm$ 16.58	-4.44	$\pm 10\%$	0.004

Values are presented as mean $\pm$ SD. Level of significance (*P*-value) was tested using the paired *t*-test.

limits of agreement, and the number of outliers was limited (Fig. 1). Passing-Bablok regression analysis revealed that there is definite linearity between two kinds of tubes and the values of R^2 were near 1 for all cases (Fig. 2). Also 95% confidence interval (CI) for intercept of the regression included value zero and 95% CI of slope included value one for the four analytes (data not shown in the figure), which means there are no constant or proportional differences between the results from two kinds of tubes. For the calculated difference (%) of these four analytes, they were all within the total allowable error range defined in prior to the analysis. All the other comparison results except for these four analytes showed no statistically significant differences.

2. Stability Test for BD Vacutainer EDTA Tube and Improvacuter EDTA Tube

The statistic results of stability study for each BD Vacutainer EDTA tube and Improvacuter EDTA tube

are summarized in Table 2. The stability test revealed that many of the analytes results re-measured at 72 hour after sampling showed statistically significant differences when compared to the results at 0 hour. However, most of the calculated differences according to the above-mentioned formula were located within the total allowable error defined in prior to the analysis. There were two parameters which exceeded the total allowable error: MCHC and MPV: -1.71% and -1.84% in MCHC, and 8.06% and 8.24% in MPV, for BD Vacutainer EDTA tube and Improvacuter EDTA tube, respectively.

3. Differences between K_2 EDTA and K_3 EDTA in Analysis of Hematologic Parameters

As for the red blood cell shrinkage effect, Hct from Improvacuter K_3 EDTA tube was 0.86% higher than from BD Vacutainer K_2 EDTA tube with statistical significance ($P < 0.0001$), in contrary to the previously reported studies [3] (Table 1). However, as mentioned

Fig. 1. Bland-Altman difference plot between BD Vacutainer and Improvacuter tubes for 4 analytes that showed statistical significance ($P < 0.05$) when compared using the paired t -test. (A) Hematocrit. (B) Mean corpuscular volume. (C) Mean corpuscular hemoglobin concentration. (D) Erythrocyte sedimentation rate.

before, the difference was within the total allowable error and clinically insignificant. The estimated MCV from both tubes also did not show clinically significant difference (Table 1). When applying the above-mentioned reference range of MCV, only two cases out of total 100 subjects (2%) were differently categorized due to the inconsistent MCV results of two tubes: one case was microcytic in BD Vacutainer tube but normocytic in Improvacuter tube, the other case was normocytic in BD Vacutainer tube but classified as macrocytic in Improvacuter tube (data not shown).

For dilution effect, all the results of WBC count, RBC count, and PLT count did not show statistically significant

differences between BD Vacutainer spray-dried K_2 EDTA tube and Improvacuter liquid K_3 EDTA tube ($P > 0.05$) (Table 1), which means there was no dilution effect due to the liquid form K_3 EDTA anticoagulant.

DISCUSSION

A large number of articles have been published evaluating many kinds of blood tubes for different analyzing purpose. Particularly in Korea, many laboratories and hospitals have routinely used BD blood tubes. However, a variety of other brands of blood tubes have been introduced recently and related comparison and stability studies have been

Fig. 2. Passing-Bablok regression analysis: Comparison between BD Vacutainer and Improvacuter tubes for 4 analytes that showed statistical significance ($P < 0.05$) when compared using the paired t -test. (A) Hematocrit. (B) Mean corpuscular volume. (C) Mean corpuscular hemoglobin concentration. (D) Erythrocyte sedimentation rate. Abbreviation: CI, confidence interval.

performed for implementation of new kinds of blood tubes [6,9,10].

This research performed the comparison study for the BD Vacutainer EDTA tube and Improvacuter EDTA tube for 17 routine hematologic analytes and additional two analytes, HbA1c and ESR. The stability test for each tube and evaluation of the effect of different anticoagulants, K_2 EDTA and K_3 EDTA, were also conducted.

The result of comparison study between the BD Vacutainer EDTA tube and Improvacuter EDTA tube suggested that there are no clinically significant differences for all the hematologic analytes mentioned before and also for two additional analytes, HbA1c and ESR. Although

the paired t -test showed statistically significant differences for some analytes, all the differences were within the total allowable error. Also Bland-Altman difference plots demonstrated in most of the results were within the total allowable error, and Passing-Bablok regression analysis revealed that the 95% CI of slope included value one and intercept included value zero, which suggests the two tubes are interchangeable in use.

The stability test for 72 hour at 4°C also suggested favorable outcome for both tubes. Although the differences from most of the analytes between the 0 hour result and 72 hour were statistically significant, they were within the total allowable error and therefore not likely to be of

Table 2. Stability of hematological analytes in BD Vacutainer tubes and Improvacuter tubes after 72-hour storage at 4°C

Variable	BD Vacutainer				Improvacuter				Total allowable error
	BD (0 hr)	BD (72 hr)	P-value	Difference (%)	Improve (0 hr)	Improve (72 hr)	P-value	Difference (%)	
White blood cell count ($\times 10^3/\mu\text{L}$)	6.62 $\pm$ 2.45	6.43 $\pm$ 2.23	0.001	-2.22	6.61 $\pm$ 2.47	6.35 $\pm$ 2.12	0.001	-2.90	$\pm 15\%$
Neutrophil (%)	56.39 $\pm$ 13.76	56.44 $\pm$ 14.89	0.952	4.10	56.78 $\pm$ 15.04	56.24 $\pm$ 14.84	0.01	-0.25	Target $\pm 3\text{SD}$
Lymphocyte (%)	31.53 $\pm$ 11.26	30.87 $\pm$ 11.49	0.073	2.92	31.11 $\pm$ 11.63	30.96 $\pm$ 11.42	0.398	0.24	Target $\pm 3\text{SD}$
Monocyte (%)	7.79 $\pm$ 2.93	8.07 $\pm$ 2.95	0.02	8.60	7.72 $\pm$ 2.96	8.21 $\pm$ 3.16	<0.0001	7.21	Target $\pm 3\text{SD}$
Eosinophil (%)	2.09 $\pm$ 1.79	2.22 $\pm$ 1.84	<0.0001	8.72	2.06 $\pm$ 1.80	2.18 $\pm$ 1.91	0.00	9.80	Target $\pm 3\text{SD}$
Basophil (%)	0.48 $\pm$ 0.25	0.54 $\pm$ 0.27	0.01	27.19	0.48 $\pm$ 0.27	0.55 $\pm$ 0.26	<0.0001	26.88	Target $\pm 3\text{SD}$
Red blood cell count ($\times 10^6/\mu\text{L}$)	4.44 $\pm$ 0.60	4.42 $\pm$ 0.59	0.004	-0.29	4.43 $\pm$ 0.60	4.42 $\pm$ 0.60	<0.0001	-0.37	$\pm 6\%$
Hemoglobin (g/dL)	13.51 $\pm$ 1.87	13.51 $\pm$ 1.87	1.000	0.00	13.50 $\pm$ 1.86	13.47 $\pm$ 1.86	0.003	-0.26	$\pm 7\%$
Hematocrit (%)	40.11 $\pm$ 5.05	40.82 $\pm$ 5.17	<0.0001	1.75	40.45 $\pm$ 5.04	41.11 $\pm$ 5.18	<0.0001	1.61	$\pm 6\%$
Mean corpuscular volume (fL)	90.70 $\pm$ 5.23	92.57 $\pm$ 5.65	<0.0001	2.05	91.50 $\pm$ 5.28	93.34 $\pm$ 5.73	<0.0001	1.99	$\pm 2.42\%$
Mean corpuscular haemoglobin concentration (g/dL)	33.65 $\pm$ 1.17	33.07 $\pm$ 1.13	<0.0001	-1.71	33.34 $\pm$ 1.16	32.73 $\pm$ 1.12	<0.0001	-1.84	$\pm 1.27\%$
Mean corpuscular haemoglobin (pg)	30.54 $\pm$ 2.21	30.62 $\pm$ 2.16	0.022	0.30	30.52 $\pm$ 2.22	30.57 $\pm$ 2.19	0.166	0.13	$\pm 2.5\%$
Red cell distribution width (%)	13.08 $\pm$ 1.54	12.98 $\pm$ 1.54	<0.0001	-0.80	13.10 $\pm$ 1.54	13.09 $\pm$ 1.60	0.560	-0.12	$\pm 4.6\%$
Platelet count ($\times 10^3/\mu\text{L}$)	255.32 $\pm$ 78.95	244.70 $\pm$ 76.08	<0.0001	-4.20	254.84 $\pm$ 79.08	246.90 $\pm$ 77.38	<0.0001	-3.25	$\pm 25\%$
Platelet distribution width (fL)	12.02 $\pm$ 2.00	13.98 $\pm$ 2.32	<0.0001	15.06	12.02 $\pm$ 1.99	14.09 $\pm$ 2.31	<0.0001	15.82	-
Mean platelet volume (fL)	10.50 $\pm$ 0.95	11.53 $\pm$ 0.96	<0.0001	8.06	10.50 $\pm$ 0.94	11.54 $\pm$ 0.94	<0.0001	8.24	$\pm 5.84\%$
Reticulocyte ($\times 10^3/\mu\text{L}$)	74.43 $\pm$ 25.50	72.50 $\pm$ 23.53	0.001	-1.61	74.15 $\pm$ 24.83	72.57 $\pm$ 23.07	0.001	-1.34	$\pm 16.8\%$
Hemoglobin A1c (%)	5.50 $\pm$ 0.66	5.52 $\pm$ 0.66	0.001	0.34	5.49 $\pm$ 0.66	5.51 $\pm$ 0.67	<0.0001	0.39	$\pm 3\%$

Values are presented as mean $\pm$ SD. Level of significance (P-value) was tested using the paired t-test.

clinical relevance except for MCHC and MPV. However, these amounts of differences would be irrelevant for clinical practice. These results are more favorable than those reported before in that the both tubes used in this study showed more stable results. Some prior studies reported that WBC, MCV, MCHC, and basophil were the analytes that mostly showed larger differences than the total allowable error [6,11]. In conclusion, both tube evaluated in this study showed satisfactory results in stability test.

If we discuss the effect of EDTA with different salts, in fact, all salts of EDTA are hyperosmolar, which causes water to leave from inside of the cells and eventually results in cell shrinkage in high EDTA level. The higher the concentration of EDTA, the greater the osmotic withdrawal of water from cells. Therefore it is important to ensure that the blood tubes are completely filled to the suggested volume so that the concentration of anticoagulant in the blood sample would be appropriate. However, some studies reported that even with the sufficiently collected blood volume, red cell volume shrank and cell count also decreased [3]. In contrary to those reports, the comparison of K₂ EDTA tube and K₃ EDTA tube in this study suggests that the differences between results obtained from each tube are minimal and unlikely of any clinical significance, both for red cell shrinkage effect and dilution effect.

Our study had some limitations. First, the evaluation about K₂ and K₃ EDTA were not based on the tubes of the same company; the K₂ EDTA tube was the product of BD and the K₃ EDTA tube was from Improve Medical. It could have affected the results although both tube were made from plastic. Second, all the blood samples used for evaluation had sufficient volume for routine hematological analysis. Therefore, the dilution effect of liquid K₃ EDTA with insufficient blood volume could not be assessed.

Up to date, several studies, which evaluated commercial blood tube products for routine laboratory use, have been reported. What makes this study different from previous one is that we included sufficient number of 100 patient-subjects, which enables it to have strong statistical power and to be evaluated within wider reportable range.

In addition, we have observed that the two different anticoagulants, K₂ and K₃ EDTA, did not make any difference in hematologic analytes. The results of our study are probably useful information for those planning to implement Improvacuter EDTA tubes to the clinical laboratory instead of currently used BD Vacutainer EDTA tubes for hematologic analysis, or vice versa.

Preferably further studies should progress to include the analysis on insufficient blood volume effect associated with K₂ and K₃ EDTA anticoagulant additives, which are not infrequent circumstances for the blood samples from the emergency room or pediatric wards. Also further studies about other factors besides of mentioned ones here, such as vacuum function of the blood tube, will be needed because that is directly related to the appropriate blood sampling volume and the malfunction of vacuum causes inconvenience for both patient and phlebotomist. However, this factor is considered to be beyond the scope of this article.

In conclusion, we have conducted comparability test and demonstrated that Improvacuter EDTA tubes performed equivalently to the currently used BD Vacutainer EDTA tube for routine hematologic analytes. Therefore, these tubes are interchangeable for routine laboratory hematologic analysis. For the stability test, most of the results from both tubes did not show any clinically significant differences when comparing the results of 0 hour to those of 72 hour. These results indicate that stability of both tubes is suitable for routine laboratory use. Also we were not able to find any clinically meaningful differences about the parameters related to red cell shrinkage effect or dilution effect between the use of K₂ and K₃ EDTA coagulants, at least in optimal conditions such as in this study; when applied to the sufficient blood sampling volume and analyzed without time delay.

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일반혈액검사(Complete Blood Cell Count)/적혈구침강속도/당화혈색소 검사종목을 대상으로 한 EDTA 플라스틱 진공채혈관 Improve IMPROVACUTER과 BD Vacutainer 진공채혈관의 성능 비교 평가

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배경: 검사에 사용하는 진공채혈관의 종류는 검사결과에 영향을 미칠 수 있는 중요한 분석 전 요인 중 하나이다. 본 연구에서는 Guangzhou Improve Medical Instruments사의 Improvacuter EDTA 진공채혈관(Guangzhou Improve Medical Instruments Co. Ltd., China)과 현재 도입되어 사용 중인 Becton Dickson사의 Vacutainer 진공채혈관(BD, USA)을 이용한 측정값을 비교하고, K₂ EDTA와 K₃ EDTA 첨가제의 영향을 분석하였다.

방법: 총 100명의 외래 환자를 대상으로 두 회사의 EDTA 진공채혈관에 말초혈액을 채혈하였다. 평가 검사종목은 검사실에서 가장 빈번하게 시행하고 있는 17개의 혈액학적 항목 및 다른 2가지 항목이었다. 각 진공채혈관의 측정값은 paired t-test를 이용하여 비교분석하였다. 비교분석에서 통계적으로 유의한 차이를 보이는 항목에 대해서는 Bland-Altman plot과 Passing-Bablok regression을 이용하여 추가적으로 분석하였다. 만약 그 차이가 총 허용오차(total allowable error)를 벗어난 경우 임상적으로 유의하다고 판단하였다. 안정성 검사를 위해서는 채혈 당일의 측정값을 기준으로 하여 냉장보관 3일 후의 측정값과 비교하였다. 또한 K₂, K₃ EDTA 첨가제의 차이를 분석하기 위해 각 채혈관의 백혈구, 적혈구, 혈소판 수치 및 평균 적혈구용적을 비교하였다.

결과: 비교평가에서는 적혈구용적률(hematocrit), 평균 적혈구용적(mean corpuscular volume), 평균 적혈구혈색소농도(mean corpuscular hemoglobin concentration), 적혈구침강속도(erythrocyte sedimentation rate)에서 두 진공채혈관 측정값 사이에 통계적으로 서로 유의한 차이가 있었으나($P < 0.05$) 임상적으로는 유의하지 않은 차이였다. 안정성 검사에서는 대부분의 검사종목들이 통계적으로 유의한 차이를 보였지만, 이들 차이도 임상적으로 유의하지 않았다. 또한 K₂ EDTA와 K₃ EDTA 첨가제 종류에 따른 혈액학적 분석결과와 차이는 임상적으로 유의하지 않았다.

결론: Improvacuter EDTA 진공채혈관은 비교평가와 안정성 검사에서 만족스러운 결과를 보였으며, 따라서 임상검사실에서의 일반혈액검사에 적합할 것으로 생각된다.

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