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#### Research Article

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# Evaluation of BD Vacutainer Eclipse and BD Vacutainer Ultra-Touch butterfly blood collecting sets in laboratory testing

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## Introduction

phlebotomy.

#### **Abstract**

**Objectives:** Choosing the right device for blood collection is an issue that is frequently encountered in laboratory medicine. The purpose of this study was to compare the quality of the samples collected in terms of hemolysis index, pain intensity and tube filling rates of the samples drawn with BD Vacutainer<sup>®</sup> EclipseNeedle and BD Vacutainer Ultra-Touch<sup>TM</sup> Butterfly Blood Collection Set, which is currently used in laboratories.

**Methods:** Blood samples were drawn from the 44 apparently healthy adult individuals from different arm sites by routine phlebotomy into Citrate, SST and EDTA tubes in Karapınar State Hospital. K, P, AST, LDH tests and hemolysis index were analyzed by Mindray BS-800 chemistry analyzer. Complete blood count (CBC) was determined by Mindray BC 6000.

**Results:** There was no significant difference in K, P, AST, LDH and CBC values between the devices for hemolysis (p>0.05). No significant difference was found out with respect to visual hemolysis and hemolysis index, tube filling speed and pain intensity between the devices.

**Conclusions:** Our findings demonstrate that two sets may used for venipuncture blood collection without creating additional hemolysis risk.

Most laboratory specialists can ignore the possibility of factors other than laboratory conditions contributing in test results particularly with abnormal values. An important part of clinical and laboratory evidence suggests that most of the laboratory errors occur at the preanalytical phase (70%), emphasizing the need to acquire or apply more accurate methods to solve and classify possible traps in this basic stage of laboratory work [1].

**Keywords:** blood collection set; clot; hemolysis; pain;

Most of the problems in preanalytical phase is related to the factors (especially hemolysis) are associated with collecting samples immediately. Causes of pre-analytical hemolysis are associated with sample collection, inappropriate transportation methods, extreme temperature, sample handling, delayed processing, and prolonged storage [2–4].

Hemolysis can notably effect the reliability of test results – especially potassium (K), aspartate aminotransferase (AST), lactate dehydrogenase (LDH), phosphorus (P) and bilirubin etc. – and requires to repeat the tests. Repeating the test can increase patient discomfort, hospital costs, and working hours.

In hemolyzed samples, biochemistry test results may not reflect the patient's clinical condition, either due to spilling of red blood cell contents into the serum or plasma (in fact changing the plasma concentration of the analytes) or due to red blood cell contents interfering with the testing methodology (i.e., hemoglobin could discolor a solution and effect spectrophotometric absorbance measurements at certain wavelengths). Overall, the analytes which are frequently affected by this primary interference mechanism are K, LDH, and AST with increased concentrations. Many of other analytes can increase or decrease based on the testing methodology; most laboratories examine the degree of hemolysis in the sample and have protocols in compliance with the laboratory manager's instructions

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(for example: the hemoglobin (H), icterus (I) and lipaemia (L)/(HIL) index, in turn, corresponds to the approximate concentration of hemoglobin, bilirubin, or lipid present in the sample) to address resulting hemolyzed samples. Hemolyzed samples can significantly affect the delivery and quality of health care [5–7].

Improper design or use of blood collection devices can adversely affect the accuracy of laboratory test results. Vascular access devices such as catheters and needles may lead to cell lysis by exerting shear forces across the blood stream. Components from blood collection tubes such as stoppers, lubricants, surfactants and separating gels can leak into samples and/or adsorb analytes from the sample; special tube additives can also change analyte stability. Due to these interactions with blood samples, blood collection sets are a potential source of pre-analytical errors in laboratory tests. Therefore, selection of device for blood collection becomes the most important consideration in optimizing the preanalytical phase and achieving consistent results [8]. While the main determinants have preanalytical interchangeability, the blood collection technique has a significant impact on the reliability of laboratory test results. The butterfly collection set, which is a small needle attached to the elastic plastic wings and connected with an extension flexible tube, can be considered a reliable alternative to the classic straight needle for collecting blood in selected patient groups. In fact, an adapter can simply be attached so that it can fit into a vacuum needle holder and a vacuum system. Blood collection with the butterfly blood collection set can be extremely difficult or easier and less painful to relieve the supportive hand (venipuncture in the hand, leg, heel or skull) in newborns, children, small animals and patients with small, hard and atypical venous access. Moreover, the use of a butterfly collection set which is less frightening due to the reduced size of the needle, may make sense in some other situations, especially when approaching nervous or anxious patients. Ease of use for unprofessional or inexperienced laboratory technicians and nurses is an extra advantage of this system because the needle does not need to be held once when in the vein. The disadvantages of the butterfly collection sets are high cost, increased chance of needle damage, and there is a small chance of blood spillage as the needle is retracted.

There are very few studies on optimal methods for collecting blood samples from catheters [9]. In the study performed by Lippi et al. [10], the degree of hemolysis assessed by measurement of free plasma hemoglobin, LDH and AST did not appear to be higher between a conventional straight needle and butterfly set.

In this study, we evaluated the quality of samples collected using the BD Vacutainer® Eclipse<sup>TM</sup> Blood Collection Needle compared to the samples collected using the BD Vacutainer® Ultra-Touch<sup>TM</sup> Butterfly Blood Collection Set for selected serum chemistry analyte performance, and complete blood count parameters (CBC). In addition, an assessment was made for the potential of hemolysis as measured by comparisons of changes in potassium, aspartate transaminase and lactate dehydrogenase concentration as well as the hemolysis index, pain scale and by visual inspectation.

#### Materials and methods

The blood samples were collected from the 44 apparently healthy adult subjects by routine phlebotomy into BD Vacutainer® Citrate (Ref. No: 363803, Lot No: 914612, 2.7 mL/13  $\times$  75 mm), BD Vacutainer® SSTTM (Ref. No: 367955, Lot No: 9127605, 5.0 mL/13  $\times$  100 mm) and BD Vacutainer® EDTA (Ref. No: 368841, Lot No: 9043866, 2.0 mL/13  $\times$  75 mm) tubes in Karapınar State Hospital. A total of six tubes of blood were collected from each subject as; three tubes using the BD Vacutainer® EclipseTM Blood Collection Needle (Ref. No: 3290672, Lot No: 9080926, 21Gx1-1/4") and three tubes using the BD Vacutainer® Ultra-TouchTM Butterfly Blood Collection Set (Ref. No: 367393, Lot No: 8332922, 21Gx3/4"  $\times$  7").

Venipunctures were performed according to a randomization schedule which accounted for randomization of device and arm. All blood samples were drawn by the same phlebotomist and blood collection was performed from two arms at the same time with needle and butterfly set 10 s between them consecutively. The study tubes were collected in the recommended order of draw BD Citrate (3–4 Tube inversions, 1,500 relative centrifugal force [RCF], 15 min), BD SST<sup>TM</sup> (5 Tube inversions, 1,300 RCF, 10 min), BD EDTA (8–10 Tube inversions) [11] and handled and processed according to the test plan.

BD SST<sup>TM</sup> tubes were inverted 5 times immediately after collection and clotted for 30 min in an upright position. Following centrifugation at 1,300 RCF for 10 min, the tubes were evaluated for visual hemolysis. The hemolysis index was also measured on the Mindray BS-800 (Mindray Bio-Medical Electronics Co., Ltd, Shenzhen, China). Serum was tested for 4 selected routine chemistry analytes on the Mindray BS-800 (within 8 h after centrifugation) (Table 1).

BD EDTA tubes were inverted 8–10 times immediately after collection and visually inspected for clot formation. Specimens were analyzed for platelets (PLT) on the Mindray BC-6000 (Mindray Bio-Medical Electronics Co., Ltd, Shenzhen, China) within the same day as that of collection and evaluated for visual hemolysis.

The presence of hemolysis was detected in serum by K, AST, P and LDH results, which have been shown to be widely accepted indicators of hemolysis [12, 13]. In addition, visual hemolysis was assessed for each tube in the study. In addition, the Universal Pain Assessment Tool (UPAT) [14] was also used to evaluate the level of pain by looking at changes in individuals' faces, and to assess the level of pain to harmonize them with UPAT. Tube filling rate is assessed for 5 mL SST tubes for each blood collection device by the help of a chronomometer.

Table 1: Summary statistics.

Mindray BS-800								
Analyte/unit	Device type	n	Mean	SD	Bias, %	Range obtained [min-max]		
AST, U/L	BD Eclipse	44	19.7	4.5	-0.8	10.5–28.9		
	BD UTBCS	44	19.5	4.4		10.6-28.5		
K, mmol/L	BD Eclipse	44	4.2	0.2	-0.9	3.7-4.8		
	BD UTBCS	44	4.2	0.2		3.7-4.7		
LDH, U/L	BD Eclipse	44	201.5	41.8	3.8	117.9-285.1		
	BD UTBCS	44	205.3	39.2		126.91-283.8		
P, mmol/L	BD Eclipse	44	3.0	0.4	0	2.1-3.9		
	BD UTBCS	44	3.0	0.4		2.0-4.0		

BD UTBCS, BD Vacutainer®-Ultra-Touch™ Butterfly Blood Collection Set; BD Eclipse, BD Eclipse: Blood Collection Needle with Pre-attached Holder; PLT, Platelet; n, number of samples; SD, standard deviation; K, potassium; AST, aspartate aminotransferase; P, phosphor; LDH, lactate dehydrogenase.

The study protocol was approved by the local ethics committee of Scientific Research Committee of Konya Provincial Health Directorate (Approval number: 86737044-806.01.03).

#### Statistical analysis

For discrete and continuous variables, descriptive statistics (mean, standard deviation, median, minimum value, maximum value, and percentile) were given. In addition, the homogeneity of the variances, which is one of the prerequisites of parametric tests, was checked through Levene's test. The assumption of normality was tested via the Shapiro-Wilk test. To compare the differences between the two groups, the Student's t test was used when the parametric test prerequisites were fulfilled, and the Mann-Whitney U test was used when such prerequisites were not fulfilled. If the differences between the two dependent groups meet the pre-conditions of the parametric test, Paired t test; if not, it was evaluated with the Wilcoxon test. The relations among the parametric tests were evaluated by Spearman correlation coefficient. Statistical compliance between measurements was given by two-way random class correlation coefficient and concordance coefficient. The compatibility and bias of the devices were examined with Youden and Bland Altman graphics. p value <0.05 was considered to be statistically significant for every analysis. Statistical package program Syntax Function SPPS 20 (IBM Corp. Released 2011. IBM SPSS Statistics for Windows, Version 20.0, Armonk, NY: IBM Corp.) was used to evaluate the data.

#### Results

Mean biases are found respectively for platelet count (-0.9%), platelet cluster (-1.6%), AST (-0.8%), K (-0.9), LDH (1.9%), P (0.0%), hemolysis (-4.5%), lipemia (11.8%), icterus (-2.8%). Also these parameters have values as platelet count (10%), AST (10%), K (0.3 mmol/L), LDH (20%), P (0.4 mmol/L) with a predetermined clinical acceptance limit (CAL) [15], which represents an estimate of the maximum allowable difference or change in test results on average. The summary statistics for each tube type and each device type are shown in Tables 1 and 2. The mean and SD are listed to one more decimal place than that reported by the analyzer. We found agreement in all parameter measurements between BD UTBCS and BD Eclipse™ as shown in Table 3 (p<0.05). Bland-Altman plots have showed the 95% agreement interval in the set of differences between samples was always within the current analytical quality specifications for desirable bias derived from biological variation (Figure 1).

#### Discussion

Laboratory testing is an integral part of medical decision and an appropriate phlebotomy procedure is an important factor in collecting sufficient samples for analysis. This can be particularly challenging with the variable skill sets of blood-drawing medical staff, failure to follow appropriate procedures may result in poor sample quality, for

Table 2: Summary statistics for Mindray BC-6000.

Analyte	Device type	n	Mean	SD	Bias, %	Range obtained (min-max)
PLT (×10 <sup>3</sup> /μL)	BD Eclipse	44	255.4	65.1	-0.9	125-385.7
	BD UTBCS	44	253.0	60.4		132.1-373.8

BD UTBCS, BD Vacutainer<sup>®</sup>-Ultra-Touch™ Butterfly Blood Collection Set; BD Eclipse, BD Eclipse: Blood Collection Needle with Pre-attached Holder; PLT, Platelet; n, number of samples; SD, standard deviation.

Table 3: ICC values and confidence intervals (95%) of the hemogram parameters measured on both devices.

	ICC	95% Lower (ICC)	95% Upper (ICC)	p
BD Eclipse (Visual Hemolysis)	0.6484	0.3556	0.8081	0.001
BD UTBCS (Visual Hemolysis)				
X1-Y1				
BD Eclipse (Instrument Hemolysis Index)	0.8099	0.6517	0.8963	0.001
BD UTBCS (Instrument Hemolysis Index)				
X2-Y2				
BD Eclipse (Visual Lipemia)	0.7648	0.5689	0.8716	0.001
BD UTBCS (Visual Lipemia)				
X3-Y3				
BD Eclipse (Instrument Lipemia Index)	0.9722	0.9491	0.9848	0.001
BD UTBCS (Instrument Lipemia Index)				
X4-Y4				
BD Eclipse (Instrument Icterus Index)	0.9385	0.8873	0.9665	0.001
BD UTBCS (Instrument Icterus Index)				
X6-Y6				
BD Eclipse K (potassium)	0.7664	0.5719	0.8725	0.001
BD UTBCS K (potassium)				
X7-Y7				
BD Eclipse (LDH (Lactate dehydrogenase)	0.8818	0.7834	0.9355	0.001
BD UTBCS (LDH (Lactate dehydrogenase)				
X8-Y8				
BD Eclipse AST (Aspartate aminotransferase)	0.9757	0.9555	0.9867	0.001
BD UTBCS AST (Aspartate aminotransferase)				
X9-Y9	0.0007	0.0013	0.0044	0.004
BD Eclipse (P) Phosphor BD UTBCS (P) Phosphor	0.9897	0.9812	0.9944	0.001
X10-Y10				
BD Eclipse (Instrument platelet cluster)	0.6792	0.4121	0.825	0.001
BD UTBCS (Instrument platelet cluster)	0.0792	0.4121	0.823	0.001
X12–Y12				
BD Eclipse (PLT) platelets	0.9741	0.9521	0.986	0.001
BD UTBCS(PLT) platelets	0.7741	0.7321	0.700	0.001
X16-Y16				
BD Eclipse Tube filling speed	0.344	-0.2023	0.642	0.001
BD UTBCS Tube filling speed	0.5	0,2023	0.012	0.001
X17-Y17				
BD Eclipse Pain Asking Patient	0.1766	-0.5089	0.5507	0.001
BD UTBCS Pain Asking Patient				
X18-Y18				
BD Eclipse Universal Pain Assessment Tool	0.4427	-0.02136	0.6959	0.001
BD UTBCS Universal Pain Assessment Tool				
X19-Y19				

ICC, intraclass correlation coefficient; X, BD Eclipse; Y, BD UTBCS; BD Eclipse, Blood Collection Needle with Pre-attached Holder; BD UTBCS, UltraTouch™ Butterfly Blood Collection Set. Parameters with significant difference between two analyzer in the same samples with ICC<90.

example, *in vitro* hemolysis is the most common problem [8]. Inappropriate samples (hemolyzed, insufficient, activated or clotted) can account for more than 80% of errors occurring in the preanalytic phase due to blood draw problems from patients [1]. As these expensive phlebotomy systems are often used excessively to draw blood for routine laboratory tests, there is a common agreement on the problem of using intravenous catheters and butterfly collection sets. While a high risk of obtaining

inappropriate specimens is frequently associated with the material used for venipuncture small catheters [16], there are very few reliable researches in the literature investigating the power of butterfly collection sets on hematological, coagulation and clinical chemistry testing. Basically, laboratory measurements appear to be unaffected by where the sample was withdrawn, whether there was a tourniquet, or the time between blood sampling and analysis [17, 18].

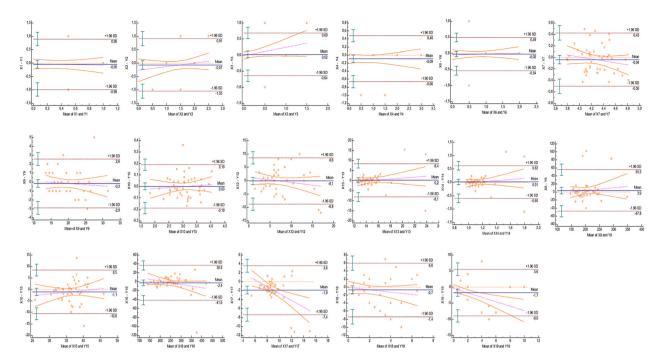


Figure 1: Blot-Altman graphics among all parameters.

On the other hand, studies suggest that blood sampling from intravenous catheters, using butterfly collection sets and other similar collection sets often leads to hemolysis resulting in higher test cancellation than using a conservative straight needle [16, 19-21]. This has influenced the development of relevant guidelines and recommendations for collecting specimens from indwelling catheters or cannulas by the International Federation of Clinical Chemistry and Laboratory Medicine (IFCC) [22, 23]. For example, sufficiently large shear stress and mechanical stress caused by the use of PVC, polyurethane and teflon catheters can affect membrane functions and integrity, causing changes in shape, cell activation, damage, and flow of intracellular components into the serum [20]. The potential alteration of cell integrity, especially during blood collection and hemolysis, can lead to unintended consequences requiring repeated blood collections, especially for hematological (PLT), enzymatic (AST, LDH, P) and electrolytic (K) assays [16]. Previous studies have found that blood sampling from peripheral catheters could be clinically permitted for hemoglobin and for most of the clinical chemistry analysis and clotting parameters [24-28]. Although PVC and other plastic materials are widely used for disposable medical devices, they can react negatively when they contact with body tissues and fluids (synovial, pleural fluids etc.). While the surface hydrophobicity of several artificial surfaces and the effect of blood cells on the tubing walls are possible causes of in vitro hemostatic activation, it may be considered that collecting the blood sample in butterfly collection sets may cause variations compared to blood collection directly to the vacuum tubes with straight needles. Although the risk of platelet activation and hemolysis increases in the long plastic tubes of butterfly collection sets, platelet counts, clotting parameters and potassium measurements are considered to be more vulnerable to changes caused by blood collection technique. A study performed by Sonntag et al. [29] declared that the concentrations of plasma K and LDH are considerably affected by hemoglobin concentrations 0.2 g/L. Another study has been conducted by Lippi and colleagues [30], in which they did not observe substantial differences in routine hematological and clinical chemistry testing for samples collected with the butterfly collection sets vs. straight needle. In the literature, published researches studying the association between BD Vacutainer® UltraTouch™ Push Button Blood Collection Set and the BD Vacutainer® Eclipse™ Blood Collection Needle are limited.

In our study, there are two different comparisons that can be relevant to clinical practice based on utilizing the new BD Vacutainer UltraTouch Push Button Blood Collection Set. We made up clinical equivalence for the selected hematology, clinical chemistry and coagulation parameters in each tube collected using the BD Vacutainer Eclipse Blood Collection Needle and BD Vacutainer UltraTouch Push Button Collection Set. There

was no significant difference in gauge comparison of the BD Vacutainer® UTBCs vs. current BD Vacutainer® Eclipse™ for hemolysis index. Furthermore, both blood collection sets have the acceptance limit of 20 hemolysis index units, which had been set for the mean and 95% confidence intervals. In addition, no significant difference in visual hemolysis or the hemolysis index was noted between the blood collection sets.

Activation of clotting cascade or clotting was assessed by measuring CBC (specifically platelet count/clumping) and by visual clot formation inspectations. All the CBC parameters demonstrated equivalence and no clots were detected in any BD Citrate or BD EDTA tubes collected with both device (Tables 1 and 2), no evidence of increased activation of clotting cascade or clotting was observed in anticoagulated specimens collected with both device.

The correlation between the two analytes is based on the intraclass correlation coefficient (ICC). In some publications, the correlation coefficient above 0.90 was interpreted as being very well [31], while others were found to be moderate compliance between 0.90 and 0.95 [32]. In the ICC analysis we conducted to examine the compatibility of the two blood collection sets in by dividing into two classes. One of them is visual and individual evaluation parameters. The other is coagulation parameters and K. In our study, visual hemolysis, instrument hemolysis index, visual lipemia, instrument lipemia index, instrument icterus index, LDH, AST, P, instrument platelet cluster, PLT, tube filling speed, Pain Asking Patient and Universal Pain Assessment tools are found the ICC=0.81, 0.90, 0.87, 0.98, 0.97, 0.94, 0.99, 0.99, 0.82, 0.99, 0.64, 0.55, 0.69, respectively. K is found to be ICC 0.87. Accordingly, instrument lipemia index, instrument hemolysis index, instrument icterus index, LDH, AST, P and PLT parameters compatibility between the two blood collection sets appears to be very well (ICC is above 0.90). However, for visual hemolysis, visual lipemia, K, instrument platelet cluster, tube filling speed, pain asking patient and universal pain assessment tool are found to be ICC values 0.81, 0.87, 0.87, 0.82, 0.64, 0,5 and 0.70, respectively. From these results, we supposed that compatibility between two blood collection sets are incompatible for these parameters according to ICC values (Table 3, Figure 1). However, although it has been reached to statistical significance, it should be pointed out that the overall discrepancy between the two blood collection devices was limited and mostly within the relative critical differences and current analytical quality specifications for desirable bias [33]. Based on these results, although statistically significant, the differences did not reach clinical relevance in any case for both blood collection devices. We suppose that these results could be attributed to the

differences in technologies between the two blood collection sets or depend on the different lab technicians's skills, working and knowledge. Phlebotomy equipment will keep advancing day by day; selecting the most appropriate blood collection system mainly depends on considerations of convenience, reliability, safety and cost [22].

In our study, the use of either sets for drawing blood, BD Vacutainer® UltraTouch™ Push Button Blood Collection Set or BD Vacutainer® Eclipse™ Blood Collection Needle did not affect the quality of the samples collected. So, using butterfly collection sets had little or no clinical effects. They may be a reliable alternative to the ordinary straight needle collection sets when indicated and within definite limitations for collecting samples for routine clinical chemistry laboratory testing.

The main limitation of the study is the number of participants (n=44). Another limitation is that blood was not drawn from the same arms for each healthy adult. From the literature, there are limited studies investigated the butterfly collection sets on hematological, coagulation and clinical chemistry testing. We also did not standardize the needle diameter (same gauge for both straight needle and butterfly collection sets). Pain scale measurements can change depending on the patients.

It is better to conduct further comparative studies. In addition, there may have been a bias in the selection of the subjects, as those who are severely needle phobic would not likely to agree about including in the study. In addition, the data obtained and the information in the study are limited to the questions posed concerning the 44 healthy adults in the Karapınar State Hospital and are not applicable to general population.

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Conflict of interest: The authors declare no conflict of interest and the authors have no competing interests.

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