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Effectiveness of Refrigerated Centrifuge Calibration on Product Quality of Thrombocyte Concentrate Blood Components at Tangerang City Red Cross

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ABSTRACT

Introduction: The processing of blood components in each bag must go through a standardized process, documented with clear processes and procedures. The blood components produced must be tested for product quality so that it can be known to what extent the performance capabilities of officers and equipment in producing a product are. This study aims to determine the effectiveness of Refrigerated Centrifuge calibration on the product quality of Thrombocyte concentration blood components at Tangerang City Red Cross.

Methods: This experimental study was conducted at the Tangerang City Red Cross. The quality of the Thrombocyte Concentrate blood component products was measured using the Hematology Analyzer tool. Data collection was carried out in January - May 2022. The number of samples in this study was 50 samples.

Result: The product quality of the blood component Thrombocyte Concentrate measured before the calibration of the Refrigerated Centrifuge device was 29 blood bags (58%) met the standard, and 21 blood bags (42%) were less than the standard. While the product quality of the blood component of the Thrombocyte Concentrate after the calibration of the Refrigerated Centrifuge was carried out, there was product quality that met the standards, namely 42 blood bags (84%) and 8 blood bags (16%) less than the standard, for the Thrombocyte Concentrate product standard according to PMK 91 years 2015, i.e., $> 60 \times 10^9$ cells/ μ L.

Conclusion: Refrigerated Centrifuge calibration is effective for Thrombocyte concentration blood component products at Tangerang City Red Cross.

Keywords: Calibration, refrigerated centrifuge, quality, thrombocyte concentrate, Tangerang City Red Cross.

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INTRODUCTION

The processing of blood components in each blood bag must go through a standardized process, documented with clear processes and procedures. The blood components produced must be tested for product quality so that it can be known to what extent the performance capabilities of officers and equipment in producing a product are. All processes carried out must be validated and traced to the history of these blood component products if errors occur at a later date. In Permenkes 91 of 2015, it is stated that quality tests can be carried out on 1% of the total product produced, or it can follow the policies of each blood center.¹ In the era of development, blood transfusions no longer provide all blood components but only the

necessary ones; for example, platelets are given only platelets. Platelet transfusion therapy is indicated for prevention and treatment. For example, bone marrow suppression causes thrombocytopenia.²

High standards of quality and safety of blood components must be guaranteed. High standards can only be achieved by applying GMP principles during collection, preparation, storage, delivery, quality control, and quality assurance³. However, there is data on blood products whose quality is not up to standard at the Blood Transfusion Unit in Tangerang City, namely TC (Thrombocyte Concentrate) blood components. In 2020, there will be 55 bags, and in 2021, there will be 46 bags of TC blood component products whose quality is not up to standard. Permenkes

namely $> 60 \times 10^9$ cells/ μ L.

Good TC quality is the total thrombocyte content $> 60 \times 10^9$ cells/ μ L, with no red blood cells.¹ To meet product quality, medical equipment must make good and calibrated TC blood component products to find out the causes of increased TC blood products that are damaged or of poor quality. Therefore, to ensure the availability of medical devices according to service standards, requirements quality, security, benefits, safety and usability, it is necessary to carry out testing and calibration.¹

Furthermore, the quality of the equipment as a support for the fulfillment of quality in blood transfusion services needs to be considered and programmed gradually and continuously to ensure the

maintenance of each blood component product's quality. Therefore, this study aims to determine the effectiveness of Refrigerated Centrifuge calibration on the product quality of Thrombocyte concentrate blood components at Tangerang City Red Cross.

METHODS

This type of research used quantitative design, an experiment that aims to determine the effectiveness of Refrigerated Centrifuge Calibration on the quality of Thrombocyte Concentrate Blood Components at Tangerang City Red Cross. This study used a pre-experimental research design with pre- and control (self-control), which means that the researcher only intervened in a group of TC blood products without comparison. The effectiveness of the treatment was assessed by comparing pre-test scores with post-test pre-experimental and post-test without control designs. The sample was TC blood component products in January - May 2022. The sample collection method used was total sampling. According to Sugiyono (2011), total sampling is a sampling technique when all population members are used as a sample of 50 TC blood bags at the Tangerang City Red Cross⁴. This research was conducted at Tangerang City Red Cross on Steet Major General Sutoyo no. 15, Sukarasa, Tangerang, Tangerang City, Banten, from 01 January 2022 to 31 May 2022.

RESULT

Sample characteristics

Thrombocyte Concentrate blood component product samples were tested on the Hematology Analyzer before being calibrated on the Refrigerated Centrifuge.

Based on Table 1, it can be seen that 50 blood bag samples were taken. Most of the samples were 45 (90%) male, and a small portion of the female were 5 (10%) samples. It also can be seen that 50 blood bag samples were taken, most of which consisted of 20 (40%) blood group A samples, 20 (40%) O samples, and a small portion consisted of 10 (10) B blood group samples. 20% sample and AB as much as 0 (0%) sample.

Table 1. Thrombocyte Concentrate blood component product samples for Jan - May 2022

Donor characteristics	Frequency (n)	Percentage (%)
Gender		
Man	45	90
Woman	5	10
Blood type		
A	20	40
B	10	20
O	20	40
AB	0	0
Total	50	100

Table 2. Blood component product samples Thrombocyte Concentrate before calibrating the Refrigerated Centrifuge at Tangerang City Red Cross

TC Blood Component Product Quality	Frequency (n)	Percentage (%)
Good	29	58
Not up to standard	21	42
Total	50	100

Table 3. Thrombocyte Concentrate blood component product samples after calibration of the Refrigerated Centrifuge at Tangerang City Red Cross

TC Blood Component Product Quality	Frequency	Percentage (%)
Good	42	84
Not up to standard	8	16
Total	50	100

Table 4. Comparison of Thrombocyte Concentrate blood component product samples before and after calibration of the Refrigerated Centrifuge at Tangerang City Red Cross

	Before Calibration	After Calibration
Standard compliant TC	29 (58%)	42 (84%)
TC that is not up to standard	21 (42%)	8 (16%)

Bivariate Analysis

Quality of blood component products *Thrombocyte Concentrate* before calibrating the Refrigerated Centrifuge tool at Tangerang City Red Cross are described in Table 2.

Based on Table 2, it can be seen that the product quality of the Thrombocyte Concentrate blood component before the calibration of the Refrigerated Centrifuge device at Tangerang City Red Cross had product quality that complied with standards, namely 29 blood bags (58%) and 21 blood bags (42%) that did not meet the standard with an average value of 55×10^9 cells/ μ L.

The quality of thrombocyte concentrates blood component products after calibrating the Refrigerated Centrifuge tool at Tangerang City Red Cross is described in Table 3.

Based on Table 3, it can be seen that the product quality of the Thrombocyte Concentrate blood component after the calibration of the Refrigerated Centrifuge device at the Tangerang City Red Cross there was product quality that complied with the standard, namely 42 blood bags (84%) and 8 blood bags that did not meet the standard (16%).) with an average value of 72×10^9 cells/ μ L. Based on comparative bivariate analysis, there was a significant difference in quality between the groups before calibration and after calibration ($p < 0.05$). Moreover, there were differences in TC quality after calibration, described in Table 4.

DISCUSSION

Based on the results of the study, it was found that the quality of the Thrombocyte

Concentrate blood component product before the Refrigerated Centrifuge calibration was carried out, there were 21 blood bags (42%) that were not of the standard quality obtained from the study. Experiencing quality that is not up to standard, namely, the type of blood component product Thrombocyte Concentrate whose value is far from ideal, namely $> 60 \times 10^9$ cells/ μ L pocket.¹ Based on the opinion, the Refrigerated Centrifuge has not been calibrated yet.

Based on the results of the Refrigerated Centrifuge calibration for Thrombocyte Concentrate blood component products, there was an increase in quality according to standards in the Thrombocyte Concentrate blood component products of 42 blood bags (84%), and there were TCs that did not meet the standards of 8 blood bags (16%). Intervened by calibrating the Refrigerated Centrifuge so that Refrigerated Centrifuge was following its proper value, so a study was carried out on the manufacture of 50 blood bags of Thrombocyte Concentrate blood component products in January for 5 months by managing blood components from whole blood to obtain Thrombocyte Concentrate blood components and then carried out checking the quality of the value by using the tool *Hematology Analyzer*. After calibration, *Refrigerated Centrifuge* was carried out by a 3rd party PT. Abhimata Manunggal in May until the tool is declared proper and calibrated according to standards. Apart from that,

the use of calibration accompanied by other quality control applications such as pre-filtration can also improve the quality of thrombocyte concentrate products.⁵

CONCLUSION

The quality of blood component products before the Refrigerated Centrifuge calibration was carried out; there were quality blood component products that were not up to standard, namely as many as 50 blood bags. After the Refrigerated Centrifuge calibration, the quality of blood component products changed results; most blood bags were according to standard quality. Moreover, Refrigerated Centrifuge calibration is effective for Thrombocyte Concentrate blood component products at Tangerang City Red Cross in 2022.

We also suggest that blood center officers always manufacture blood components per standard operational procedures to maintain the quality of blood component products, carry out Refrigerated Centrifuge maintenance in stages, and routinely clean every day before and after performing services.

DISCLOSURES

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This research did not receive external funding.

Conflict of Interest

There are no conflicts of interest in this study.

Author Contribution

All authors contributed equally to this manuscript.

Ethical Considerations

Research publication ethics for this study complies with ICMJE and COPE protocols.

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