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RESEARCH ARTICLE

Evaluation Of the Quality of Packed Red Cell (PRC) In the Blood Donation Unit (BDU) Of the Indonesian Red Cross (IRC) Of Banda Aceh City: Haemolysis Rate as An Indicator of a Good Quality Control Process

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Abstract: PRC is the most commonly used component of blood. This blood component comes from whole blood which then goes through a centrifugation process to separate into PRC blood components. In this separation process, it is not uncommon to cause haemolysis, which in the end PRC blood products do not provide a therapeutic effect for recipients. This study will look at the percentage of haemolysis that occurs during separation and whether it is still up to standard. This study aims to determine the risk of haemolysis in the processing of PRC blood products stored for 30 days at BDU of IRC of Banda Aceh City. Research benefits are knowing the risk of haemolysis in the processing of PRC blood products stored for 30 days at BDU of IRC of Banda Aceh City. This study used the cross-sectional method. The samples in this study amounted to 95 donor blood samples taken from blood bags with a shelf life of 30 days. Techniques sample sampling using a total sampling technique. Samples will be examined quantitatively with a value of the percentage of haemolysis of the blood sample. The samples test will be seen whether haemolysis occurs (<0.8%) or not/non-haemolysis (>0.8%) automatically using the HemoCue Plasma/Low tool. Of the 95 samples tested, 7.3% (7) of the samples were haemolyzed and 92.8% (88) samples did not have haemolysis. This study showed that the majority of samples did not have haemolysis with a percentage of 92.8% and those with haemolysis were only 7.3%. This shows that the quality of blood services at BDU of IRC of Banda Aceh City is still by Peraturan Menteri Kesehatan (PMK) or regulation of the minister of health standard No. 91 yr. 2015 with the percentage of samples that do not undergo haemolysis above 75%.

Keywords: haemolysis, PRC, RBC, whole blood

INTRODUCTION

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Blood is a gigantic organ circulating in a cardiovascular system, consisting of corpuscular/cellular blood components and non-corpuscular/liquid blood components. Components of corpuscular blood are a living biological material (*viable*) consisting of erythrocytes or red blood cells (RBC), leukocytes (white blood cells) and *platelets (platelets*).[1] The main role of blood is to circulate oxygen to all body tissues played by haemoglobin contained in RBC.

The blood has blood components, blood components are parts of the blood that are separated by physical/mechanical means (centrifugation, filtration and clotting) in an aseptic way, with pyrogen-free tools. The blood component is any therapeutic substance made from human blood. The processing of blood components is the act of separating the blood components of the donor with a certain procedure into ready-made blood components. In the process, quality and safety aspects must be guaranteed to obtain the expected final blood component.[2]

Blood processing is a way of separating complete blood / WB (WB = Whole Blood) into cellular blood components such as concentrated red blood cells / PRC (PRC = Packed Red Cell), Buffy coat, Concentrated platelets / TC (TC = Thrombocyte Concentrate), and non-cellular blood components, namely: Liquid plasma / LP (LP = Liquid Plasma) and frozen fresh plasma / FFP (FFP = Fresh Frozen Plasma).[3]

PRC comes from WB separated from its plasma. The separation process can be done through centrifugation and manual methods (not recommended).[4] Separation using the centrifugation method lasts about 3 minutes and 30 seconds. The process of processing PRC blood products has the risk of haemolysis.[5]

Red blood cell (RBC) haemolysis has been reported in the Blood Donor Unit (BDU). This suggests significant clinical implications for transfused patients because free haemoglobin breaks away into dimers that must be restricted to haptoglobin to be released by the reticuloendothelial system. Once the binding capacity of haptoglobin has passed, then hemoglobinemia occurs. Haemolysis is caused by damage from RBC, which causes the release of haemoglobin and produces plasma discolouration. Abnormal haemolysis in one RBC unit may be caused by several factors including improper handling during blood processing, improper storage conditions, bacterial haemolysis, antibodies that cause complement lysis, damage to the RBC membrane, or abnormalities in the donor's blood. The degree of haemolysis is described as the per cent of free haemoglobin associated with total haemoglobin with proper correction for haematocrit. Acceptable haemolysis levels have not yet been established in North America, but the value of 1% is currently used to assess the biocompatibility of stored blood material, given that the *Council of Europe* has set the standard at 0.8%.[4] This emphasizes the need for adequate control of the varied processes involved in the preparation of RBC from *whole blood* to minimize the occurrence of

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haemolysis.[6] A careful evaluation of the production process will minimize RBC wasted due to haemolysis. In this study, the percentage of haemolysis will be seen when the processing of PRC blood products is carried out

METHODS

This study uses a *cross-sectional*/cross-sectional method. The samples in this study amounted to 95 donor blood samples taken from blood bags with a shelf life of 30 days for the period June-August 2022. The sampling technique uses a total sampling technique. Samples will be examined quantitatively with the value of the percentage of haemolysis of the blood sample. The samples test will be seen whether haemolysis occurs (<0.8%) or not/non-haemolysis (>0.8%) automatically using the HemoCue Plasma/Low tool.
Calculate the percentage of haemolysis by using the formula:

$$\% \text{ Haemolysis} = \frac{(100 - HT) \times \text{HemoCue Plasma Level/Low Hb (g/dL)}}{\text{Haemoglobin Sysmex level XT-1800}i \text{ (g/dL)}}$$

This research has passed an ethical review from the Health Research Ethics Commission with **No.770/KEPK/FKUMSU/2022**.

RESULTS

Donor blood samples taken through a blood bag with a shelf life of 30 days, were tested on a quantitative basis by looking at the percentage of haemolysis of the blood sample. The samples test will be seen whether haemolysis occurs (<0.8%) or not / non-haemolysis (>0.8%) automatically using the HemoCue Plasma / Low tool. The examination is carried out at one time using a blood bag two days before the expiration date.

Table 1 Overview of the risk of h haemolysis in the processing of PRC blood products in BDU of IRC of Banda Aceh City

Blood components	Percentage (%)	
	Haemolysis (%)	Non Haemolysis(%)
PRC	7,3 (7)	92,8 (88)

Table 1 shows an overview of the risk of haemolysis in the processing of PRC blood products in BDU of IRC of Banda Aceh City. Of the 95 samples tested, 7.3% of the samples had haemolysis and 92.8% did not have haemolysis.

DISCUSSION

PRC quality control should be carried out to ensure that the processing and storage processes are carried out consistently to minimize the risk of transfusion reactions and provide an optimal healing effect. PRC quality standard indicators include volume, haemoglobin or haematocrit, haemolysis at the end of storage, and bacterial contamination. Haemolysis during blood storage is the most severe manifestation of erythrocyte storage and is an important parameter for assessing the quality of stored PRC and is associated with bacterial contamination[7-8]. Table 1 shows an overview of the risk of haemolysis in the

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processing of PRC blood products in BDU of IRC of Banda Aceh City. From the test, 7.3% of samples had haemolysis and 92.8% did not have haemolysis. The results of the haemolysis test at BDU of IRC of Banda Aceh City show that the haemolysis incidence rate is still acceptable because the percentage of non-haemolysis events is above 75% which shows that the value of haemolysis events can still be tolerated according to Regulation of the Minister of Health/ Peraturan Mentri Kesehatan (PMK) No 91 yr 2015 non-haemolysis values above 75% of the number of samples with acceptance criteria of > 0.8%.[7]

Haemolysis describes damage or impaired integrity of the membrane of red blood cells that causes the release of haemoglobin haemolysis describes damage or impaired integrity of the membrane of red blood cells that causes the release of haemoglobin. Haemolysis of the blood components of the blood is usually manifested by the presence of free haemoglobin in the suspended red blood cell medium. Some diseases such as haemolytic anaemia or some processes such as blood centrifugation can cause premature damage to red blood cells.[8] From this study, researchers want to convey several factors that cause haemolysis, including; collecting and processing complete blood (WB) into blood components of the blood can cause damage to red blood cells, so the release of haemoglobin into the plasma of the supernatant is inevitable. Examples include delays between collection and separation, stirring of anticoagulants with blood, large variations in centrifugation velocity, rapid resuspension of RBC in additive solutions, and variations in the configuration or composition of blood storage bags. In addition, concentrated red blood cells (PRC) are also sometimes washed in saline before transfusion. Additional manipulations to these cells may also contribute to red blood cell damage resulting in the loss of protection of the plasma protein membrane covering the cell by washing. Therefore there are many concerns from experts in this case doctors about the use of this manipulated blood component of the blood.[9] 2) Stress Shear and Mechanical Haemolysis; Haemolysis is sometimes caused by stress shear turbulence (Reynolds stress), which can occur under the following circumstances: on the crumpled edges of the tube, the partial closure of the transfer tube, and in the place of entry into the blood collection bag during the stripping of red blood cells on the segment of the sample tube into a partially opened blood collection bag. The shear that triggers red blood cell damage may occur during the resuspension of hard-packed RBC. Shaking of the blood bag during stirring before filtration may also cause red blood cells to break more easily, resulting in lysis.[9,10,11,12,13] 3) Bacterial contamination; Abnormal haemolysis in a unit of concentrated red blood cells (RBC) may also be caused by bacteria contamination. The suspicion that the blood unit has been contaminated with contamination can be characterized by the discovery of clots, discolouration (if cells or plasma change colour to brownish or

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purplish), abnormal masses in the blood fluid, turbid or opaque plasma, the presence of strange gases or odours in the blood components of the blood.[9,14,15] 4) Temperature; Blood temperature and blood components during storage, filtration, or processing are very important factors in haemolysis. Temperature greatly affects the ability of the membrane to deform, therefore, the stability of the membrane during processing must be maintained. Red blood cells can be lysed by unexpected clots, for example, blood is stored in a refrigerator where the temperature is not properly controlled or placed in a freezer without cryoprotective agents. The blood components must be transported in a way that will guarantee the maintenance of temperatures from 1-10 Celsius degrees. Therefore, the presence of abnormal levels of free haemoglobin in the plasma from the blood of the donor may occur as a result of damage by the wrong temperature during the wrong transportation, storage, or handling at the time of blood donation.[9,16,17] 5) Osmotic Changes (Hypotonic and Hypertonic) and pH; The extreme exposure of RBC to hypotonic or hypertonic solutions, to extreme pH changes, to anticoagulants, and solution additives in blood storage bags may cause damage or lysis in the easily broken RBC population. [10,18,19] 6) Blood Age and Storage Duration; Blood donation for transfusion is routinely stored for 35 to 42 days, depending on the composition of the anticoagulants and preservatives contained in the blood bag. Previous studies on the effects of blood storage have shown significant changes in the integrity of the RBC membrane and this affects the process of haemolysis. [10,20,21] 7) the presence of leukocytes; The presence of leukocytes in the unfiltered unit of concentrated red blood cells (PRC) plays a role in increasing haemolysis during storage. During storage, the damaged leukocytes will release several chemical substances and enzymes such as hydrogen peroxide and protease. Proteases released by leukocytes during storage have been reported to cause lysis in concentrated red blood cells (PRC) during storage and may interfere with their metabolism and survival. The disruptive effects of these leukocytes can be reduced or eliminated using leukocyte removal and by leukocyte filter.[14] In another study conducted by Teuku Ilhami Surya Akbar at BDU of IRC Daerah Khusus Ibukota (DKI) Jakarta in 2014, it showed no relationship between the incidence of haemolysis in the process of processing PRC blood components in BDU IRC DKI Jakarta which was shown by the absence of haemolysis incidence in the blood processing process.[11]

Transfusions of red blood cells that have undergone haemolysis to patients result in free haemoglobin toxicity which can cause adverse effects, such as kidney damage and some extreme cases can even lead to death.[12] Quality assurance of blood transfusion services are fulfilled to ensure the safety of blood when given to patients.

CONCLUSIONS

This study showed that the majority of samples did not experience haemolysis with a percentage of 92.8% and those with

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haemolysis were only 7.3%. This shows that the quality of blood services at BDU of IRC of Banda Aceh City is still by PMK standard No. 91 yr 2015 with the percentage of samples that do not undergo haemolysis above 75%.

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