

Literature Review on Whole Blood Automation Using Automated Blood Processing System (ABPS)

Literature Review on Whole Blood Automation Using Automated Blood Processing System (ABPS)
Nil S. Comasòlivas, MSc, MD; Anna Costansa, MBA; Koenraad Dierick, MSc, MBA
Terumo BCT Europe NV, Zaventem, VBR, Belgium

Introduction
There is a growing demand for automated blood processing systems to increase efficiency and reduce the risk of human error. The aim of this study was to review the literature on automated blood processing systems and to identify the key factors that influence their performance.

Objectives and Methods
The aim of this study was to review the literature on automated blood processing systems and to identify the key factors that influence their performance. The search strategy was based on the following keywords: 'automated blood processing system', 'whole blood automation', and 'blood processing system'.

Results
From the 23 articles that were included in the review, the following parameters were found to be most important for ABPS performance: (1) the quality of the input blood, (2) the quality of the reagents, (3) the quality of the sensors, and (4) the quality of the software. The most important parameter was the quality of the input blood, which was found to be the most critical factor for ABPS performance.

Conclusions
The results of this study show that the quality of the input blood is the most important factor for ABPS performance. The quality of the reagents, the quality of the sensors, and the quality of the software are also important factors, but they are less critical than the quality of the input blood.

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ABSTRACT CONTACT AUTHOR GET POSTED

Nil S. Comasòlivas, MSc, MD; Anna Costansa, MBA; Koenraad Dierick, MSc, MBA
Terumo BCT Europe NV, Zaventem, VBR, Belgium



PRESENTED AT:

INTRODUCTION

There is a global trend to automatize medical procedures to increase efficiency and deliver the highest quality standards. In Blood component preparation laboratories, automation might ease the multiple and repetitive steps performed manually or semi-automatically and can increase the blood bank operational and production efficiency and consistency of the components. [1] [2]

The implementation in Blood Bank centers of automated Whole Blood procedures compared with manual and/or semi-automated ones has been reported to provide space, time and cost savings as well as achieving suitable product quality in line with international standards. [2] [3] [4] [5] [6] [7]

The Automated Blood Processing System (ABPS) can process up to four Whole Blood (WB) units simultaneously into red blood cell concentrates (RBCCs), a plasma concentrate, an interim platelet unit (IPU), and with a residual leucocyte unit. The IPU is a highly concentrated platelet product in 30ml of plasma, which can be pooled with Platelet Additive Solution (PAS) to create a platelet concentrate (PC) as well. [8] [9]

The only current medical device that can perform the ABPS is the Reveos® system, developed by the global manufacturer Terumo Blood and Cell Technologies®. It provides an alternative solution to the semi-automatic or manual WB processing methods. [6]

OBJECTIVES AND METHODS

The aim of this study is to review and summarize the existing literature related to the ABPS to understand the available data and the current positioning compared with semi-automated Blood Processing System (SBPS) and manual Blood Processing Systems (MBPS).

Methods:

We have performed a Literature Review through the PubMed Database, the ISPOR Publication Database, the International Society of Blood Transfusion Database, the Transfusion Database and using the Embase® search engine.

The first search yielded a total of 78 results (excluding duplicates). After the abstract and title screening, 39 publications were eligible. After the full-text assessment for eligibility, 10 publications were excluded, and 29 publications were included in the literature review.

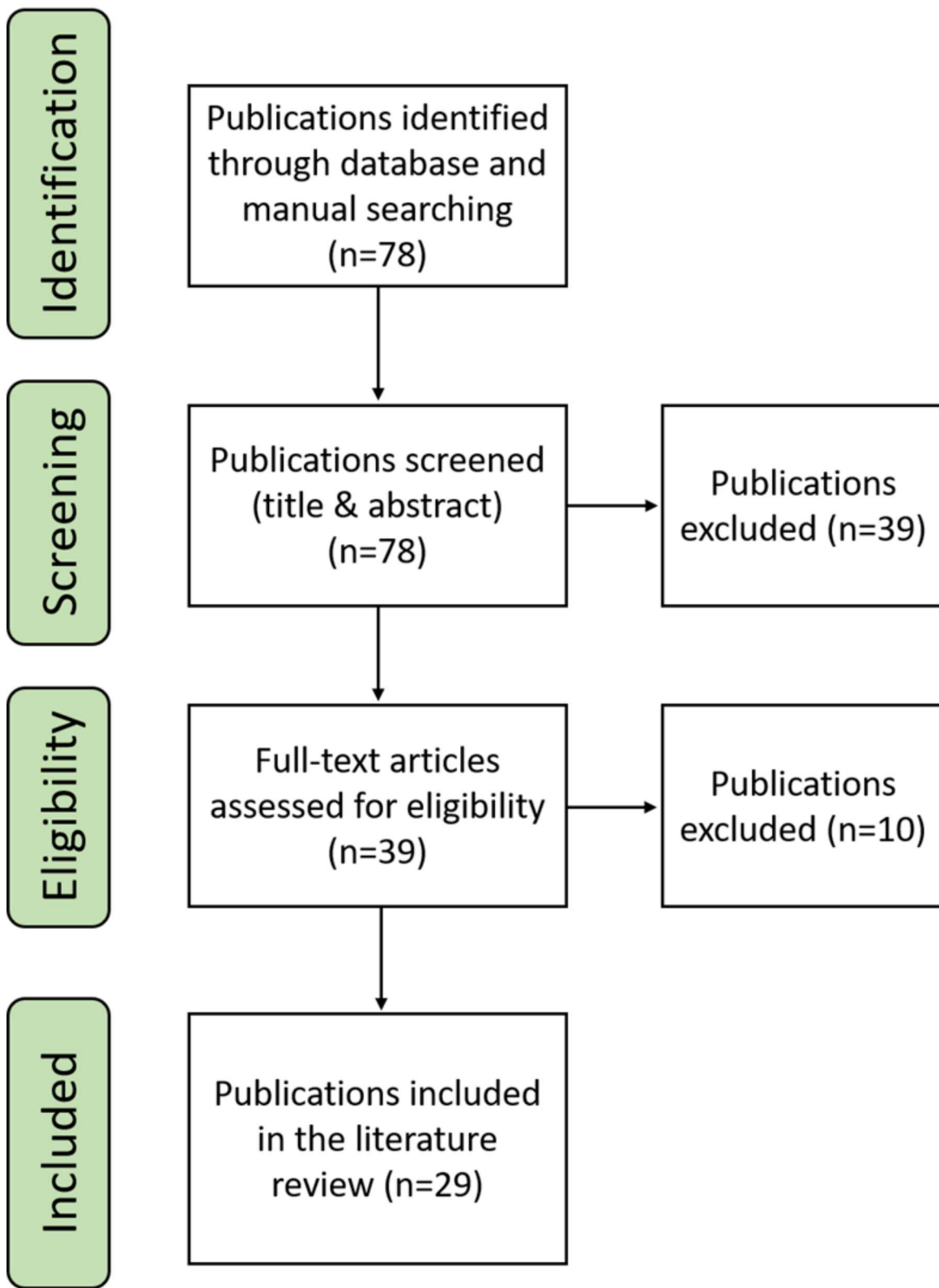


Figure 1. Literature Review Methodology

RESULTS

From the 29 scientific publications that were assessed, 5 key differentiator parameters were found related to ABPS:

Blood Bank and procedure operational efficiency and productivity, traceability and synergies.

ABPS can increase the efficiency and productivity of routine Blood Bank operations, [10] [11] [7] can shorten the production time of blood products [12] [2] [13] and requires less physical space due to the combined functions (centrifuge and fractionator) and the centralization of all the WB processes in only one device (Reveos®), [14] as well as reducing the number of operational steps and variations due to manual operations and the training time of the operators. [15] [16]

ABPS permits complete process traceability. [15]

Conversion from SBPS to ABPS has allowed an escalation of 10% in collections. [11]

Furthermore, the ABPS' (Reveos®) software that provides data on the quantity of several blood parameters can contribute for better planning for further processing of products such as pooled PC. [17]

ABPS enables synergies with other medical technologies such as Mirasol PRT®, eliminating the need for additional safety measures related to gamma-radiation and bacterial screening. [18]

Product and procedure quality, standardization and compliance with legislations, regulations and standards.

ABPS meet all the local and international legislations, such as the European Union regulatory standards [19] [20] [12] [21] [22] and the Canadian CSA standards [10] [23] [24] as well as international guidelines such as the ones from the American Association of Blood Banks (AABB). [25] It improves the standardization [26] and achieves all the quality control parameters [17] [27] and quality requirements, [9] [28] with higher-quality, safer blood products, [29] [30] [31] irrespective of operator influence. [32]

Processes' flexibility, customization, display, ease of use and better ergonomomy.

ABPS' operators have reported that the system is operator-friendly, demanding minimal staff training time, [14] very easy to use [30] [11] and with a better device ergonomomy. [16]

The platelet Yield Index (PYI), displayed in the device screen after the end of the separation phase, is a useful tool to optimize selection of IPU for tools to produce leuco-reduced platelet concentrate (LPC), [31] and allows for optimal pooling into therapeutic doses. [14]

The different options that ABPS has to process WB, such as the fresh (2-8h) WB or the overnight-held WB, achieve the same quality of the components without any significant differences. [26]

High hemoglobin (Hb) yield in RBCCs.

ABPS produce RBCCs with higher volume and Hb levels compared to the "Top-bottom-system" (BAT). It can reach up to 34ml additional volume per RBC unit. Each RBC contains more than 40g of Hb, [28] and the Hb yield is increased by up to 6g/RBC unit. [33] On the other side, the mean Hb per RBC trended higher in the RBCCs processed through the "Top-to-top-system" (TAT) compared with ABPS or BAT. [34]

High, in-vitro, functional granulocytes concentrates (GC).

In-vitro, functional Granulocyte concentrate (GC) can be pooled from residual leukocyte units produced by ABPS. Although it has a suboptimal therapeutic dose, this type of GC, due to its availability, could be considered an option in acute situations until regular GC from donors stimulated with G-CSF are available. [35]

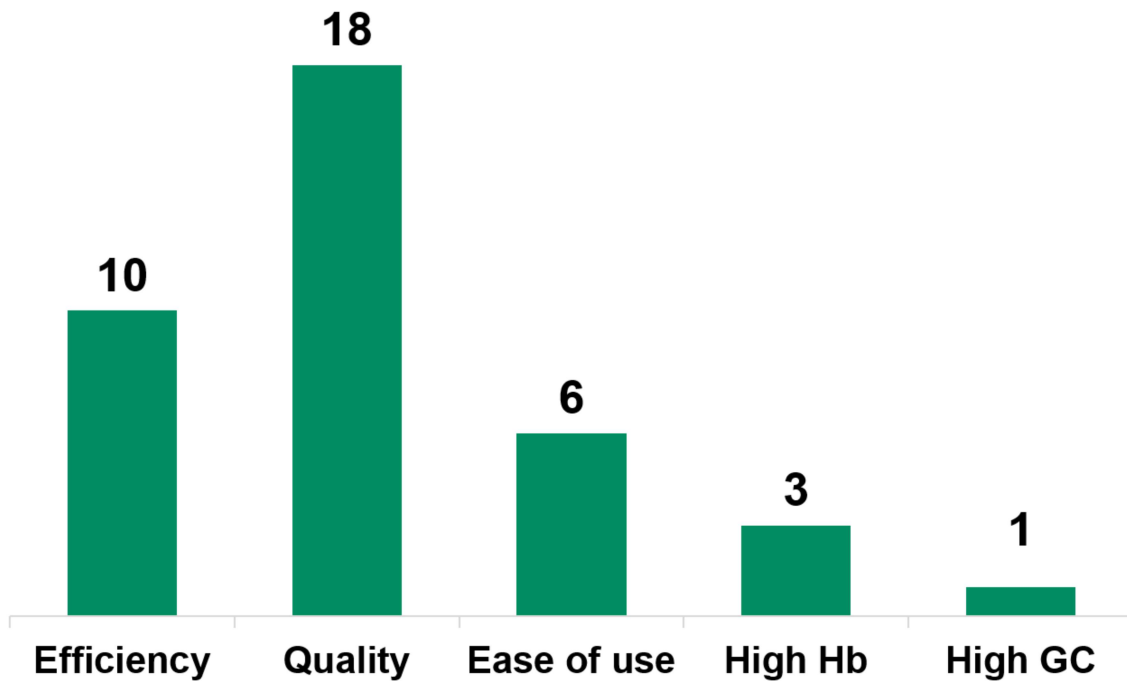


Figure 2. Quantity of publications that have a connection with each one of the 5 key differentiator parameters.

CONCLUSIONS

Although ABPS have been on the market for several years, there are still limited scientific publications based on them. The common topics found are based on the operational efficiencies in the blood bank center that ABPS provides as well as the intuitive, easy-to-use platform that allow operators to monitor the process easier and better. Furthermore, the system has all the quality standards from international guidelines and regulatory entities required for any center.

Two scientific publications concluded that higher Hb content can be obtained using ABPS compared to Top-to-Bottom methods. However, due to the limited evidence on this hematological aspect, we encourage healthcare and blood bank centers to further investigate it.

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AUTHOR INFORMATION

Nil S. Comasòlivas, MSc, MD. Market Access and Health Economics Manager

Anna Costansa, MBA. Marketing Manager

Koenraad Dierick, MSc, MBA. Market Access and Health Economics Director

ABSTRACT

INTRODUCTION

The Automated Blood Processing System (ABPS) can process up to four Whole Blood (WB) units simultaneously into red blood cell concentrates (RBCCs), a plasma concentrate, an interim platelet unit (IPU), and with a residual leucocyte unit. It provides an alternative solution to the semi-automatic or manual WB processing methods.

OBJECTIVES

The aim of this study is to review and summarize the existing literature related to the ABPS to understand the available data and the current positioning compared with semi-automated Blood Processing System (SBPS) and manual Blood Processing Systems (MBPS).

METHODS

We have performed a Literature Review through the PubMed Database, the ISPOR Publication Database, the International Society of Blood Transfusion Database, the Transfusion Database and using the Embase® search engine.

The first search yielded a total of 78 results (excluding duplicates). After abstract screening and criteria assessment, 49 publications were excluded from the final review.

RESULTS

From the 29 scientific publications gathered in the literature review, 18 (47%) reported that the ABPS achieves all the quality control requirements and is compliant with diverse international standards of Blood quality and safety; 10 (26%) reported that the implementation of ABPS increases the efficiency of WB processing, blood bank operations and productivity; 6 (16%) reported that ABPS is operator-friendly, easy to use, with different options to process WB, and with a platelet yield index display that optimizes the selection of interim platelet units; 3 (8%) reported that ABPS produce Red Blood Cell Concentrates with higher volume and hemoglobin levels compared to other systems; 1 (3%) reported that in-vitro, functional granulocyte concentrates can be pooled from residual leukocytes units produced by ABPS.

CONCLUSIONS

Although ABPS have been on the market for several years, there are still limited scientific publications based on them. The common topics found are based on the operational efficiencies in the blood bank center that ABPS provides as well as the intuitive, easy-to-use platform that allow operators to monitor the process easier and better. Furthermore, the system has all the quality standards from international guidelines and regulatory entities required for any center.