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Construction and validation of a protocol for the use of intraoperative blood retrieval in liver transplantation

Construção e validação de protocolo para a utilização da Recuperação Intraoperatória de Sangue em transplante hepático

Construcción y validación de protocolo para uso de la extracción de sangre intraoperatoria en el trasplante de hígado

ABSTRACT

Objective: This study aimed to develop and validate the content of a Clinical Care Protocol (CCP) for the use of Intraoperative Blood Recovery (IBR) in Liver Transplantation (LT), focusing on standardizing the procedure, patient safety, and reducing the need for allogeneic blood transfusion and, consequently, adverse events. **Method:** The study followed a methodological model with three stages: 1) formulation of the guiding question on the evidence of IBR in LT; 2) elaboration of the protocol, with bibliographic survey and textual proposal; 3) validation of the content by expert judges from the areas of Nursing and Medicine, using the Content Validity Index (CVI), with an IVC ≥ 0.8 being accepted. **Results:** The risk and predictive factors of bleeding and need for blood transfusion in liver transplant patients were identified, in addition to the indications for IBR. During validation, the CVI reached 0.92, a satisfactory level of agreement. **Final remarks:** The validation demonstrated the feasibility, reliability and accuracy of the protocol, highlighting its importance for improving efficiency and safety in liver transplant services.
Descriptors: Liver transplantation; Blood transfusion, Autologous; Operative blood salvage; Clinical protocols.

RESUMO

Objetivo: Este estudo teve como objetivo desenvolver e validar o conteúdo de um Protocolo Clínico Assistencial (PCA) para a utilização da Recuperação Intraoperatória de Sangue (Rios) em transplante hepático (TH), com foco na padronização do procedimento, na segurança do paciente e na redução da necessidade de hemotransfusão alogênica e, consequentemente, de eventos adversos. **Método:** O estudo seguiu um modelo metodológico com três etapas: 1) formulação da questão norteadora sobre as evidências da Rios no TH; 2) elaboração do protocolo, com levantamento bibliográfico e proposição textual; 3) validação do conteúdo por juízes especialistas das áreas de Enfermagem e Medicina, utilizando o Índice de Validade do Conteúdo (IVC), sendo aceito um IVC ≥ 0,8. **Resultados:** Foram identificados os fatores de risco e preditivos de sangramento e necessidade de transfusão de sangue em pacientes transplantados hepáticos, além das indicações para a Rios. Durante a validação, o IVC alcançou 0,92, um nível satisfatório de concordância. **Considerações finais:** A validação demonstrou a viabilidade, confiabilidade e acurácia do protocolo, destacando sua importância para a melhoria da eficiência e segurança nos serviços de transplante hepático.
Descritores: Transplante hepático; Transfusão de sangue autóloga; Recuperação de sangue operatório; Protocolos clínicos.

RESUMEN

Objetivo: Este estudio tuvo como objetivo desarrollar y validar el contenido de un Protocolo de Atención Clínica (PCC) para el uso de la Recuperación Sanguínea Intraoperatoria (RII) en el Trasplante de Hígado (TH), centrándose en la estandarización del procedimiento, la seguridad del paciente y la reducción de la necesidad de transfusión sanguínea alogénica y, en consecuencia, los eventos adversos. **Método:** El estudio siguió modelo metodológico con tres etapas: 1) formulación de la pregunta orientadora sobre la evidencia de RIOS en HT; 2) elaboración del protocolo, con levantamiento bibliográfico y propuesta textual; 3) validación de contenido por jueces expertos en las áreas de Enfermería y Medicina, utilizándose del Índice de Validez de Contenido (IVC), aceptándose IVC ≥ 0,8. **Resultados:** Se identificaron factores de riesgo y predictivos de sangrado y necesidad de transfusión sanguínea en pacientes con trasplante hepático, además de las indicaciones de RIOS. Durante la validación, el IVC alcanzó 0,92, nivel de acuerdo satisfactorio. Consideraciones finales: La validación demostró la viabilidad, confiabilidad y precisión del protocolo, destacando importancia para mejorar la eficiencia y seguridad en los servicios de trasplante de hígado.
Descriptores: Trasplante de hígado; Transfusión de sangre autóloga; Recuperación de sangre operatoria; Protocolos de tratamiento.

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INTRODUCTION

Liver cirrhosis is a disease characterized by the replacement of normal liver tissue with nodules with an abnormal structure, surrounded by fibrosis, which can lead to portal hypertension and liver failure. The main causes include: viral hepatitis, metabolic and autoimmune liver diseases, alcoholism, and venous obstruction[1]. Initially, it may be asymptomatic, tending to progress to more severe conditions, such as gastrointestinal bleeding, ascites, hepatic encephalopathy, and renal failure[2]. In 2019, it was responsible for 2.4% of global deaths, ranking among the leading causes of morbidity and mortality in Brazil[3,4].

Liver transplantation (LT) is one of the main therapeutic approaches for terminal cases, with organ distribution based on the Model for End-Stage Liver Disease (MELD) score, which prioritizes the most critically ill patients[5]. Brazil is a world leader in transplants, ranking fourth among countries that performed the most liver transplants in 2022, with 90% of procedures financed by the Unified Health System (SUS)[6].

However, LT is a highly complex surgical procedure with a significant risk of intraoperative bleeding, leading to the need for blood transfusions, which may be associated with risks such as immunosuppression and infections[7]. To reduce the need for allogeneic blood transfusions, strategies such as Intraoperative Blood Recovery (IBR) are employed[8].

In IBR, blood lost in the surgical cavity is aspirated, added to an anticoagulant, filtered, centrifuged, and washed, and the recovered red blood cells are reinfused into the patient[9]. The method is indicated in surgeries with a risk of blood loss greater than 10% of the patient's blood volume, or when more than one unit of red blood cell concentrate is expected to be needed[7].

The advantages of IBR include: immediate availability of blood, cost reduction, reduced need for allogeneic transfusion, reduced surgical infection rate, and lower risk of disease transmission[10]. However, complications such as bacterial contamination, tumor cell implantation, risk of acute kidney injury secondary to hemolysis, and Disseminated Intravascular Coagulation (DIC) are possible. In addition, few studies have compared the efficiency and costs of Rios, raising questions about its cost-effectiveness[11].

After reviewing the literature on the subject, a gap in scientific knowledge was observed, with no consensus on the risk--benefit and cost-benefit ratios and the safety of IBR as a means of reducing allogeneic blood transfusions and complications in LT. Therefore, there is a need for more scientific evidence on the evaluation of this technology in healthcare and the creation of technical and scientific instruments—guidelines, checklists, or protocols—that standardize its implementation in LT, resulting in higher quality, safety, and efficiency, especially for its users.

Clinical Care Protocols (CCPs) are robust tools in clinical practice, developed with methodological rigor to ensure their credibility and legitimacy. They aim to facilitate decision-making, bringing greater safety to the patient, the team, and the service, in addition to promoting the rational use of resources and allowing the monitoring of process and outcome indicators[12].

Given the above, this study is believed to be relevant, as its objective is to

develop and validate the content of a CCP for the use of IBR in LT, to be applied in locoregional transplant centers, demonstrating the optimization of the efficiency of this technology and patient safety in terms of hemotherapy, reducing the need for allogeneic blood transfusions during organ transplants, particularly liver transplants, and, consequently, related adverse events, through evidence-based good practices established in scientific collections, as well as based on clinical care protocols.

METHOD

A methodological study was developed, whose main purpose was to construct a clinical care protocol for the use of intraoperative blood recovery in liver transplantation.

The protocol was developed and validated by following these steps: identifying and structuring questions about the evidence for protocols in LT using IBR; searching for answers in technical and scientific sources of information; identifying and synthesizing the best available evidence; developing the clinical care protocol itself; and validating the content by the judges.

To construct the protocol, an integrative review was conducted to search for evidence on the IBR procedure. The bibliographic search sought guidelines, checklists, and protocols published in the scientific literature using the expression "Intraoperative Blood Recovery in Liver Transplantation," based on the following steps: research question for the preparation of the review, literature search of primary and secondary studies, categorization of selected studies or data extraction, evaluation of studies included in the review, analysis and synthesis of results, and presentation of the review[14].

The protocol was developed based on the literature, which emphasized the indications, recommendations, and predictors required for the use of IBR in LT, and the content was subsequently validated by expert judges.

The period for data collection and presentation of the bibliographic research results was from July to December 2023, after approval by the Research Ethics Committee (REC) of the Hematology and Hemotherapy Center of Ceará (HEMOCE), under No. 6185346.

After the material was constructed, content validation was performed. To carry out this phase, professionals specializing in LT were consulted about the risk and cost-benefit of using IBR.

For the ideal selection of the number of specialists for the validation process, it was decided to follow the recommendations[15]: 13 specialists, to avoid a tie in opinions.

The selection of technical judges was based on proof of professional knowledge and assistance to the person undergoing liver transplantation, using the network or snowball sampling method. The first members of the sample were asked to indicate other people who could meet the established inclusion criteria; this was, therefore, a convenience sample. Once the names of the specialists were obtained, a search was conducted on the Lattes Platform to assess whether they met the inclusion criteria[16].

For the selection of technical judges, professionals were required to have proven knowledge in assisting individuals undergoing LT and IBR. The judges who participated in the study obtained a minimum score of five points and followed the

snowball sampling method, in which, upon identifying a subject who meets the criteria for participation in the study, they are asked to suggest other participants[16].

Those judges who met the inclusion criteria were invited to participate in the study by means of an invitation letter sent by email, containing: the presentation, objective, and methodology of the research, and explaining the role of the judge. An electronic form was created and applied on the Google platform, containing the evaluation of the instrument and the Free and Informed Consent Term (FICT), with a deadline of 15 days for evaluation and return of the questionnaire with suggestions. In the event of non-return, a new email and WhatsApp message were sent, encouraging participation.

The evaluation instrument involved four items: a) objective (interesting, relevant, and appropriate for the target audience); b) content (the information presented is relevant); c) language (material, mode, and comprehension); and d) inclusion of topics (appropriate, up-to-date, and in accordance with current recommendations)[17].

For content validation, the Content Validity Index (CVI) was used, employing a Likert scale to assess the agreement and representativeness of the items described; responses could include five options: a) strongly disagree; b) disagree; c) partially agree; c) agree; 5 strongly agree. For the protocol to be considered valid, a CVI greater than or equal to 0.8 was used as a reference [18].

The project was approved by the Research Ethics Committee (REC) of the Hematology and Hemotherapy Center of Ceará (HEMOCE), under No. 6185346.

RESULTS AND DISCUSSION

The stage of developing the protocol for the use of IBR in TH was based on an integrative review, to outline the profile of risk and predictive factors for bleeding and the need for allogeneic blood transfusion. Scientific evidence extracted from guidelines, checklists, and protocols on IBR was analyzed. The review was conducted using the PICO strategy, defining the following guiding question: What evidence is available in the literature, through guidelines, checklists, or protocols on the use of Intraoperative Blood Recovery (IBR) in Liver Transplantation (LT)?

The search was conducted in the following databases: Scopus, MEDLINE (PubMed), LILACS, EBSCO, Embase, Cochrane, CINHAL, Web of Science, Science Direct, and Capes Journal Portal, selecting articles published between 2013 and 2023. The initial search resulted in 3,362 articles, of which 470 were selected for preliminary reading and, after screening, 18 articles were included for detailed analysis.

Three main topics were identified to guide the construction of the protocol: indications for IBR in surgeries with potential bleeding, predictive factors for bleeding or the need for allogeneic transfusion in LT, and recommendations associated with the use of IBR in LT.

The resulting protocol, called "Protocol for the Use of IBR in Liver Transplantation," consists of an introduction, indications for IBR, predictors associated with the risk of high bleeding in LT, recommendations, IBR request, and references, totaling four pages (Figure 1). The objective is to provide an evidence-based tool to optimize the practice of IBR in LT, ensuring safety, quality, and efficiency in the care of patients undergoing this complex procedure.

Figure 1 - Protocol developed

PROTOCOL FOR THE USE OF INTRAOPERATIVE BLOOD RECOVERY (IBR) IN LIVER TRANSPLANTS

1 INTRODUCTION

Intraoperative Blood Recovery (IBR) is a valuable tool for blood conservation in the perioperative period. The method consists of aspirating blood from the surgical field, centrifuging it, washing it, and recovering only the red blood cells to be transfused to the patient. The main objective of IBR is to reduce or avoid allogeneic red blood cell transfusions and the associated risks and costs. Liver transplantation is considered a surgery with potential bleeding due to coagulopathy related to chronic liver disease and the surgical procedure. The use of IBR in liver transplantation is a method of great importance, as it reduces allogeneic blood transfusion and, consequently, immediate and late transfusion risks, along with other methods such as acute normovolemic hemodilution, hypervolemic hemodilution, permissive hypotension, and antifibrinolytics.

2 IBR RECOMMENDATIONS

- Surgery with anticipated blood loss ≥1000 ml (or 20% of total blood volume);
- When it is difficult to find cross-matched compatible blood;
- Patients with red blood cell alloantibodies;
- Patients who do not accept allogeneic blood.INR ≥ 2;

3 PREDICTORS ASSOCIATED WITH HIGH BLEEDING RISK IN LIVER TRANSPLANTATION

- INR ≥ 2;
- Platelet count ≤50 × 10^9/L;
- Hemoglobin level ≤8 g/dL;
- (MELD) ≥30;
- Serum albumin ≤2.5 gm/dl;
- Portal vein thrombosis;
- Retransplantation (transcapsular arterial neovascularization);
- Portal hypertension;
- Previous abdominal surgery.

4 RECOMMENDATIONS

Since 2018, HEMOCE has recommended the routine use of IBR in conjunction with Tranexamic Acid (TXA), based on the 2015 guidelines of the UK's National Institute for Health and Care Excellence (NICE) and in line with Patient Blood Management (PBM), which emphasizes, among the pillars of treatment for patients requiring transfusion, the use of antifibrinolytics as a strategy to reduce blood loss during surgery. The use of leukodepletion filters should be considered during the reinfusion of blood recovered in oncological surgery and when blood is recovered from an infected surgical field.

5 IBR REQUEST

- Requests from the SUS network must be sent by phone/WhatsApp to the IBR nursing coordination department.
- In cases of health insurance, the request must be made via the hospital, by email to solicita.rios@hemoce.ce.gov.br, attaching the medical request in the ADTS (Auxiliary Diagnostic and Therapy Service) tab of the health insurance plan.
- For individuals, the request must be made via the hospital, by email to solicita.rios@hemoce.ce.gov.br, attaching the medical request and the NAO SUS form (FORM.UA.0005) completed and signed by the hospital management.

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Of the 20 judges invited, only seven responded by evaluating the CCP proposal sent to them. The sample for this study was then composed of these specialists, 85.7% of whom were male. Of the professionals who validated the CCP content, one was a nurse and six were physicians; only 42.8% of the participants had a specialization title; all had more than five years of experience in transplantation; and, among them, only 28.6% had publications in the area of interest.

The CVI, an instrument with 12 items divided into four domains (objectives, language, content, and inclusion of topics), was used to validate the CCP content (Table 1).

Table 1 - Judge agreement and content validation, according to the CVI

1. Objectives of the protocol	PA	A	TA	I-CVI
1.1 Are the objectives consistent with the predictive factors proposed for the use of IBR in LT?	1	1	5	0,85
1.2 Are the objectives appropriate for implementation in the use of IBR in LT?	1	1	5	0,85
CVI – Total				**0,85**
2. Protocol language	**PA**	**A**	**TA**	**I-CVI**
2.1 Does the written language contain accurate, informative, and objective information about IBR at LT?	-	6	1	1
CVI – Total				**1**
3. Protocol content	**PA**	**A**	**TA**	**I-CVI**
3.1 Does the content facilitate the process of using IBR in LT?	-	2	5	1
3.2 Does the "introduction" content provide all the information necessary for a basic understanding of IBR and LT?	1	4	2	0,85
3.3 Does the content "Predictors associated with high bleeding risk in liver transplantation" incorporate all the information relevant to the requirements for using IBR in LT?	1	3	3	0,85
3.4 Does the "Recommendations" content incorporate all relevant information that contributes to the use of IBR in HT?	1	3	3	0,85
3.5 Does the "IBR Request" content provide all the information necessary to request the equipment?	-	2	5	1
CVI – Total				**0,91**
4. Inclusão de tópicos no protocolo	**PA**	**A**	**TA**	**I-CVI**
4.1 Description of the indication for IBR in LT?	1	3	3	0,85
4.2 Description of predictors associated with the risk of high bleeding in LT?	1	3	3	0,85
4.3 Description of recommendations that contribute to the use of IBR in LT?	-	3	4	1
4.4 Description of the request for IBR in LT?	-	2	5	1
CVI - Total				**0,92**
S - CVI				**0,92**

Caption: PA = partially agree; A = agree; TA = totally agree; I – CVI = individual content validity index of the item; CVI – total = total content validity index of the section; S – CVI = overall content validity index of the scale.
Source: Prepared by the authors.

Content evaluation is essential to ensure the overall quality of a technical-scientific product. Therefore, it was essential to adopt a systematic approach, based on evidence and best available practices[18], to develop the content of this CCP. To measure the agreement of the items by the experts, the CVI was chosen, in which scores 3 and 4 expressed the highest level. To calculate the CVI – total for each section, the values obtained for each item were added together, and the total was divided by the number of items in that section. To calculate the overall content validity index of the scale (S – CVI), the CVI – total for each section was added together, and the total was divided by the number of sections evaluated on the scale.

Regarding the results obtained, all domains – Objectives, Language, Inclusion of topics, and Content – and the CCP items achieved a CVI above 0.80 (minimum of 0.85 and maximum of 1.0; in the "Language" domain, the total CVI was 1.0). As the CVI calculation for the overall CCP scale was 0.92, above the required level, it is considered that the protocol achieved a satisfactory level of agreement. Similar scores were found in other studies, emphasizing that CVI values greater than 0.80 are considered to be an excellent level of agreement among experts[19].

In this study, it was not possible to evaluate the qualitative analysis or internal consistency due to the small number of judges who agreed to collaborate. However, the experts' opinions are reported in Table 1. The adaptation or inclusion of new elements suggested by the judges will be carried out later, during the CCP implementation process, when the usability and satisfaction with the CCP for the use of IBR in LT by the teams at the transplant centers will be evaluated.

Chart 1. Table of suggestions made by expert judges for improving the protocol for the use of IBR in LT

Judge	Recommendations
J1	Anemia (Hb of 8 mg/dL) may be a predictor of bleeding, but it is not a good indicator for the use of IBR; IAS positivity alone is not a strong indication for IBR; in the indications for IBR, write "patients with rare blood" instead of IAS positive.
J2	Indications for IBR in LT: blood loss greater than 500 ml, rare blood, refusal to take blood (regardless of whether or not the reasons are religious), and patients with anemia.
J3	I suggest researching other indications and increasing the bibliographic references, as well as further enriching the text presented.

Fonte: Elaborado pelos autores

It is worth noting the difficulty in obtaining responses from the members of the Expert Committee, even after sending the form containing the CCP proposal online, resulting in the content being evaluated only by professionals from liver transplant centers that use IBR, in Fortaleza. Therefore, the CCP for the use of IBR in LT may not sufficiently represent the different clinical scenarios and the diversity of practices and opinions on the subject, negatively interfering with the generalization of the results. Previous studies did not include consensus information on predictors of bleeding and the need for allogeneic transfusion in LT. This limitation restricted the depth of the discussion and the breadth of dialogue with other investigations.

The study by Lima[20] reports that the use of cell recovery devices is unnecessary in all liver transplants. The MELD score, the presence of portal vein thrombosis, creatinine level, INR, hemoglobin, and cold ischemia time were identified as significant risk factors for bleeding.

Another study cites the presence of portal vein thrombosis, previous abdominal surgery, inflammatory adhesions after surgery, and prolonged surgical time as risk factors for increased bleeding[21]. Liver transplantation is a procedure associated with a high risk of bleeding, which can result in serious complications and significantly increase mortality when massive transfusions are required. In this context, the creation of a predictive model to estimate transfusion needs is essential, as it contributes to reducing the indiscriminate use of blood components and improving patient clinical outcomes[22].

Given the findings of this study, it can be observed that the use of cell recovery in patients undergoing liver transplantation has demonstrated greater viability, especially in some specific clinical profiles. However, the effective implementation of this protocol in clinical practice requires careful analysis, considering aspects such as the availability of hospital infrastructure, the cost of equipment, the training of the multidisciplinary team, and the profile of the patients treated. In addition to representing a safe alternative by reducing the need for allogeneic blood components and, consequently, transfusion risks, the protocol with cell recovery stands out for offering autologous and compatible blood, promoting greater hemodynamic stability and, potentially, better postoperative outcomes.

This protocol stands out for its preventive and personalized nature, which is especially useful in scenarios of greater surgical complexity. Its selective adoption, based on well-defined clinical criteria, may represent a significant advance in the quality and safety of perioperative care in liver transplants.

The compiled and validated results of this research denote the viability of the technical and scientific knowledge of the time on the subject associated with the experience of using this technology by the transplant center team, but which needed this institutional arrangement to make IBR in LT more efficient for the SUS and safer for users, bringing about an improvement in services, as they formed a synthesis of topics related to the reality in which the researcher works, in addition to adding an instrument directed at the need.

FINAL CONSIDERATIONS

After a thorough process of content construction and validation by experts,

the CCP for the use of IBR in TH showed evidence of satisfactory validity, obtaining a CVI > 0.80 in all stages and 0.92 in its general version.

Despite the limitation of not being validated with the ideal number of judges and the endogeneity of this committee, the collaboration of the experts reinforced the relevance of the topic, providing valuable contributions. The protocol will be disseminated in coordination with the HEMOCE IBR service and transplant centers in Ceará that perform LT.

Finally, the creation of a Technical-Scientific Protocol, aimed at health professionals who work in liver transplantation and use Intraoperative Blood Recovery, has great potential to improve the quality of this service, a gap that has existed until now. The development of this material, with short texts and essential, concise information, can be an effective tool to facilitate the understanding of predictive factors and indications that reinforce and validate the operationalization of this technology in LT, guiding and optimizing its use to reduce allogeneic transfusion and, consequently, related adverse events.

It is hoped that this study will encourage new research and future evaluations on the effectiveness of implementing the "Protocol for the Use of IBR in Liver Transplantation" in real clinical settings and the satisfaction of professional users, allowing adjustments for its implementation in transplant centers other than locoregional ones.

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