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Integrative Review

Intraoperative patient safety during liver transplantation: integrative review

Segurança do paciente no intraoperatório do transplante hepático: revisão integrativa

Seguridad del paciente en el intraoperatorio del trasplante de hígado: revisión integradora

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Descriptores
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Abstract

Objective: To analyze the scientific evidence that supports safe intraoperative liver transplantation practices.

Methods: Integrative literature review within six databases. The review followed six steps: development of the research question; definition of criteria for searching the literature; data collection; critical analysis of the material obtained; evaluation and interpretation of information; and, presentation of the results obtained.

Results: A total of 511 publications were identified, 16 of which were included for analysis, considering the inclusion and exclusion criteria. Evidence supporting safe liver transplantation practices was presented in the following categories: Hypothermia-related care, Recommendations for early extubation, Blood component transfusion, and, Anesthesia protocol.

Conclusion: The evidence found in the integrative review provides support for development of a safe surgery checklist related to liver transplantation.

Resumo

Objetivo: Analisar evidências científicas que subsidiem práticas seguras no intraoperatório do transplante hepático.

Métodos: Revisão integrativa da literatura, a partir de seis bases de dados. A revisão seguiu seis etapas: elaboração da questão de pesquisa; definição dos critérios para a busca na literatura; coleta dos dados; análise crítica do material obtido; avaliação e interpretação criteriosa das informações; e apresentação dos resultados obtidos.

Resultados: Foram identificadas 511 publicações, sendo 16 incluídas para análise, considerando-se os critérios de inclusão e exclusão. As evidências que subsidiam as práticas seguras em transplante hepático foram apresentadas nas seguintes categorias: Cuidados relacionados à hipotermia, Recomendações para extubação precoce, Transfusão de hemocomponentes e Protocolo anestésico.

Conclusão: As evidências apontadas na revisão integrativa apresentam subsídios para a elaboração de um *checklist* de cirurgia segura direcionado ao transplante hepático.

Resumen

Objetivo: Analizar las evidencias científicas que proporcionan prácticas seguras en el intraoperatorio del trasplante de hígado.

Métodos: Revisión integradora de la literatura a partir de seis bases de datos. La revisión se realizó en seis etapas: elaboración de la pregunta de investigación, definición de los criterios para la búsqueda de literatura,

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recolección de datos, análisis crítico del material obtenido, evaluación e interpretación criteriosa de la información y presentación de los resultados obtenidos.

Resultados: Se identificaron 511 publicaciones, de las cuales 16 se incluyeron para el análisis, considerando los criterios de inclusión y exclusión. Las evidencias que proporcionan las prácticas seguras en el trasplante de hígado fueron presentadas en las siguientes categorías: Cuidados relacionados con la hipotermia, Recomendaciones para la extubación precoz, Transfusión de hemocomponentes y Protocolo anestésico.

Conclusión: Las evidencias señaladas en la revisión integradora presentan datos para la elaboración de un *checklist* de cirugía segura orientada al trasplante de hígado.

Introduction

Major advances have been seen in health and patient safety in recent years. The initiatives promoted by the World Health Organization (WHO) in the surgical setting, especially the 2009 global challenge, "Safe Surgeries Save Lives", and the publication of the safe surgery checklist guideline and are the most important [1,2]

The National Health Surveillance Agency (ANVISA), in Brazil, launched the National Patient Safety Program in 2013, including a suggestion of a surgical safety protocol and safe surgery checklist, which are fundamental for quality in perioperative care.[1,2]

Operating rooms are complex units with intense circulation of professionals and patients, where procedures of different complexities occur; these are factors that contribute to the occurrence of adverse events (AEs). The safe surgery checklist is recommended for all surgical procedures, which can minimize the risk of AEs.[1-3]

Studies have shown that adherence to the safe surgery checklist can reduce postoperative complications by up to 60%, and the mortality rate by up to 50%. [2,4-6] The checklist, when adapted to the institution, as well as the surgical procedure, constitutes an essential element for the promotion of safety, especially in major surgeries.[7,8]

In this scenario, liver transplantation (LT) is a surgery of great complexity, considering the surgical time, presence of the anhepatic phase, and the factors related to the graft. This procedure presents considerable risks, as the liver is a vital organ responsible for maintaining hemodynamic stability, especially regarding blood coagulation and albumin secretion. Liver transplantation consists of the total removal of the diseased liver and replacement with a healthy one, and with hepatic vascular and biliary tract anatomic reconstruction as close to the physiological pattern as possible.[9,10]

During transplantation, in addition to prolonged intraoperative time (six to ten hours), hemodynamic changes can occur, especially in the anhepatic phase. At the time the liver is removed to enhable its replacement with a healthy organ, there is frequently an increased risk of bleeding due to coagulation factors, related hydroelectrolytic disorders, and acid-base balance, which makes these patients more vulnerable to complications.[10,11]

Thus, constant perioperative management is necessary, enabling safety and effectiveness regarding the peculiarities of transplantation, considering that surgical safety is directly related to the complexity of the patient and the procedure. Moreover, the surgical health teams are still poorly oriented, or even structured, to promote teamwork in order to minimize risks and promote safe surgeries.[1,2] The National Surveillance Agency (ANVISA) proposes monitoring throughout donor selection, extraction, preparation, conservation, control, distribution, and implantation of the organs, by means of biovigilance.[12]

Still, despite progress in treatments, techniques, and surgical safety, about 50% of preventable AEs continue to occur. Consider the world reality in which the perioperative AE rate is 3%, and the mortality rate is 0.5%; about 7 million patients experience significant complications per year, and one million people die during or immediately after the surgery.[1,2]

A search for evidence in the national and international literature can support the development of a safe surgery checklist, focused on liver transplantation, ensuring higher safety from the health team in the conduct of the procedure, better quality of care, and a lower chance of AEs. Thus, this study proposes to analyze scientific evidence that supports safe intraoperative liver transplantation practices.

It should be considered that the WHO checklist establishes three moments involving safety in the surgical environment: the first is called "Sign in", which occurs before induction of anesthesia, followed by "Time out", performed immediately before the surgical incision, and finally, a "Sign out" before the patient leaves the room.[1,2]

It is believed that such evidence identified in the literature can support the adaptation of the LT checklist for the three steps proposed by the WHO, considering that in several situations, due to the severity of the patient and the logistics, many patients were not evaluated by the team that is inducing anesthesia and, also because they frequently present hemodynamic changes due to liver injury. At this stage, there is also the team's investigation regarding receipt of the graft, identification, preparation of the *backtable,* and the need to verify donor and recipient data. In addition, at the end of the surgical procedure, which involves the participation of several professionals, it is necessary to check surgical issues, intravenous access, infusions and drains, among other issues, before transporting the patient to the intensive care unit.

Methods

This was an integrative literature review, conducted from January to March of 2019, at the Federal University of Santa Catarina. The review protocol followed six steps: development of the research question; definition of search criteria for literature review; data collection; critical analysis of the material obtained; evaluation and careful interpretation of the information obtained; and, presentation of results obtained.[13]

In the first step, we sought to define clearly the theme to be investigated, to analyze the largest possible number of publications related to surgical safety in liver transplantation. Thus, the guiding question defined was: "What evidence in the scientific literature supports safe practices during intraoperative liver transplantation?"

The databases searched were: the Latin American and Caribbean Health Sciences Literature (LILACS), Biomedical Literature Citations and Abstracts (PUBMED), Scopus, Web of Science, the Cumulative Index to Nursing and Allied Health Literature (CINAHL), and the Scientific Electronic Library Online (SciELO).

Publications were searched using a combination of descriptors: "intraoperative period", "operating rooms", "liver transplantation", "safety management", "safety", "patient safety" and "checklist", in Portuguese, English and Spanish, without restricting publication years. For each database, the association between the Boolean operators OR and AND was used, developed with the support of a librarian for all databases, considering Scopus as an example: "intraoperative period" OR "Intraoperative" OR "Transoperative" OR "surgicenters" OR "Surgicenters" OR "Surgicenter" OR "Surgical Center" OR "Surgical Centers" OR "Surgery Center" OR "Surgery Centers" AND "liver transplantation" OR "Liver Transplantation" OR "Liver Transplantations" OR "Hepatic Transplantation" OR "Hepatic Transplantations" OR "Liver Grafting" OR "liver transplant" OR "liver transplants" OR "hepatic transplant" OR "hepatic transplants" AND "patient safety" OR "safety" OR "safety management" OR checklist*.

The inclusion criteria for the studies were: primary studies, experience reports, protocols, and guidelines available in online databases; all publication dates; Portuguese, English, and Spanish languages; addressing liver transplantation with a deceased donor. The exclusion criteria were: letters, editorials, books, abstract of event annals, theses, and dissertations.

The database search was performed in January of 2019, after which the material obtained was submitted to the bibliographic management tool, Mendeley®, and duplicate articles were excluded. Subsequently, two researchers, separately read the title and abstract, excluding articles that were not related to the proposed theme, considering the guiding question, objective, inclusion and exclusion criteria. Then, the articles were read in their entirety, seeking to identify information that could support the adaptation of the checklist for the LT surgical procedure.

After reading all the articles, those that would be part of the sample was defined using consensus between the researchers, and the information was synthesized with the help of a script. In both stages, the inclusion and exclusion criteria, guiding question, and objective of the study were used. The information required for the study was organized in an electronic spreadsheet, with the aid of Excel version 2013 software, in which the following data were recorded: title, year of publication, authors, journal, database, objectives, type of study, level of evidence, results, and recommendations.[13]

During the critical analysis stage, a meeting with the researchers sought to evaluate the information obtained from the included publications, as well as the classification of the evidence level of the studies[14], the possible biases, and the main findings of the studies.

The evaluation and careful interpretation of the information obtained was performed with the researchers and two professionals with expertise in the subject, which were defined by the time of working in LT in a surgical environment (over ten years), and the most important recommendations were identified, as well as the higher level of evidence that can support changes in practice. The flowchart for the database search process is presented below (Figure 1).

A total of 511 publications were identified. After reading the title and article abstracts, 278 were excluded, 252 were related to studies that only addressed the reason for transplantation, main results related to transplantation, graft survival, and quality of life; and the other 26 manuscripts were discussion articles, experience reports, and editorials. Next, 27 manuscripts were read in their entirety, and 11 articles were excluded because they were not related to the intraoperative theme. Finally, 16 articles were selected for review.

The recommendations for intraoperative surgical safety during liver transplantation, which could support changes in practice, were organized into

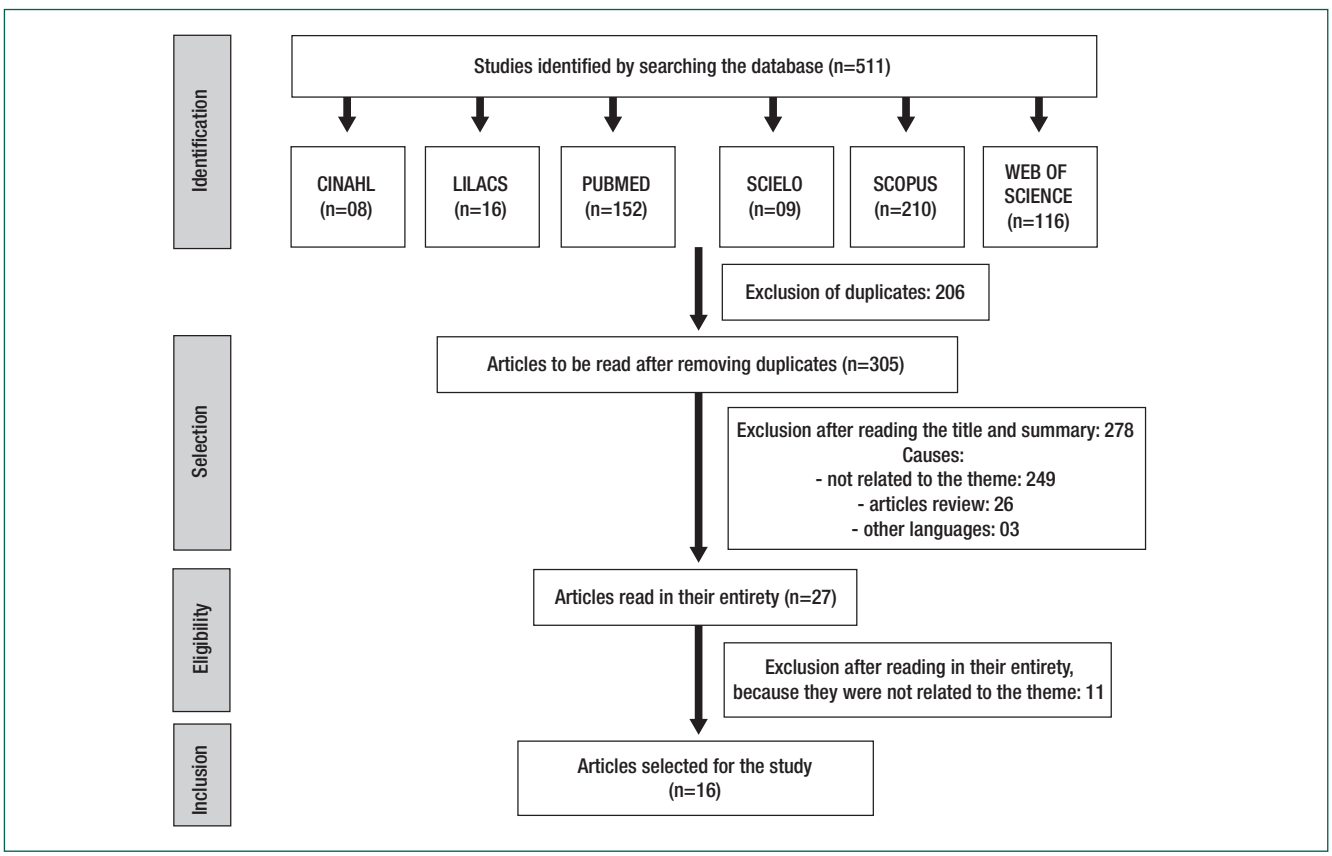

Figure 1. Flowchart of selection process of the study

four categories, considering the most relevant findings: hypothermia-related care; recommendations for early extubation; blood component transfusion; and, anesthesia protocol.

Results

The publications included in the review were mostly published in the Scopus database (11; 68.75%), followed by Web of Science (3; 18.75%). The studies were published between 1996 and 2018; however, most were concentrated in 2010. Regarding the level of evidence, studies were concentrated at evidence level 4 (11; 68.75%), with only one classified as level 2 (6.25%). The results are presented below, containing the reference, method, level of evidence, and objectives (Table 1).

Next, the recommendations for surgical safety during intraoperative liver transplantation are presented, structured using the four categories noted previously.

Category 1 - Hypothermia related-care

This category presents evidence for the prevention of intraoperative hypothermia. The information obtained indicates the need to maintain the patient's temperature as close to 36ºC as possible, as this condition can affect coagulation, cardiac function, contribute to the emergence of cardiac arrhythmias and postoperative infections, in addition to the risk of cardiorespiratory arrest.[22,28,30]

The evidence found in the studies analyzed indicates that in the intraoperative period, body temperature should be continuously monitored, using devices that verify core temperature by means of a pulmonary artery catheter, esophageal tube, or urinary catheter.[22,28,30]

Category 2 - Recommendations for early extubation

In this category, the evidence for early extubation is mentioned, showing that mechanical ventilation after liver transplantation is no longer justified, and early extubation in the operat-

Table 1. Summary of articles included in the study

Reference	Method/Level of Evidence	Objectives	Category of the study
Houben et al. (2018)[15]	Randomized study protocol / 7	Present a randomized study protocol using a sealing device (LigaSure™) and ultrasound dissector (HARMONIC ACE® + 7) during the intraoperative period.	Category 3
Nascimento et al. (2018)[16]	Case report / 7	To describe the case of a cirrhotic patient on warfarin, whose coagulation management during liver transplantation was guided by thromboelastometry.	Category 3
Akbulut et al. (2013)[17]	Cohort study, case control / 4	To investigate the therapeutic efficacy and safety of the continuous auto-transfusion system during liver transplantation in patients with hepatocellular carcinoma.	Category 3
Schumann, Mandell, & Marcaldo (2013)[18]	Quantitative, descriptive study / 4	To describe intraoperative care and the role of anesthesiologists in intraoperative management of liver transplantation.	Category 4
Biancofiore, & Rocca (2012)[19]	Quantitative, descriptive study / 4	To investigate how the intraoperative and postoperative approach are developed for patients undergoing orthotopic liver transplantation.	Categories 2 & 4
Feng et al. (2010)[20]	Randomized clinical trial / 2	To evaluate the use of the low central venous pressure technique, aiming at greater safety in liver transplantation.	Categories 3 & 4
Skurzak et al. (2010)[21]	Quantitative cohort study / 4	Provide a simple extubation rule for accelerated weaning in the operating room, through safe operational simple scoring after liver transplantation.	Category 2
Rocca et al. (2010)[22]	Experience report study / 5	To present a prevention policy to detect early errors in liver transplantation.	Categories 1, 3 & 4
Glanemann et al. (2007)[23]	Quantitative, retrospective study / 4	To identify whether early extubation in the operating room increases patient survival and safety.	Categories 2 & 3
Massicotte et al. (2008)[24]	Prospective, non-experimental comparative study / 4	To evaluate whether anesthesiologists could reduce intraoperative red blood cell transfusion requirements during liver transplantation by eliminating plasma transfusion.	Category 3
Mandell et al. (2002)[25]	Cohort study / 4	To evaluate which characteristics of unselected liver transplant recipients would result in success or failure of immediate postoperative extubation.	Category 2
Schroeder et al. (2004)[26]	Quantitative, retrospective study / 4	To evaluate the clinical safety of low central venous pressure fluid management strategy in patients undergoing liver transplantation.	Category 3
Viana et al. (1999)[27]	Quasi-experimental study / 3	To evaluate the experience of the Liver Transplant Unit of the University Hospital of Coimbra, regarding the intraoperative circulatory aspects performed in patients with familial amyloid polyneuropathy.	Categories 2 & 4
Neelakanta et al. (1998)[28]	Quantitative, retrospective study / 4	To review the experience with heat exchangers during orthotopic liver transplantation, and investigate the effects of normothermia on blood loss, during the neohepatic period, and on cardiac stability during reperfusion of the donated liver.	Category 1
Neelakanta et al. (1997)[29]	Quantitative, retrospective study / 4	To evaluate the value and safety of tracheal extubation in the operating room at the end of liver transplantation.	Category 2
Russell, & Freeman (1996)[30]	Quantitative, prospective study / 4	To compare bladder, esophageal and pulmonary artery temperatures in a group of patients undergoing liver transplantation.	Category 1

ing room is feasible, safe, and well tolerated by most patients. [21-23,25,27]

Early extubation followed by spontaneous breathing improves venous drainage and donor graft circulation, contributing to early liver graft recovery, as it avoids any potential decrease in hepatic blood flow, provides greater patient comfort, and facilitates early mobilization. Most patients do not require ICU tracheal reintubation.[23,29]

Category 3 - Blood component transfusion

This category presents evidence to minimize the use of blood components, as blood products increase the chance of morbidity or mortality, as well as the chance of developing antibodies, which increases the risk of rejection.[24]

The factors to minimize component use involve frequent testing, blood gas analysis, biochemistry, red blood cell count, thromboelastogram, rigorous coagulation monitoring, and autologous red blood cell transfusion, using systems such as continuous auto transfusion or a cell saver. Coagulation can be monitored by time evaluation of active partial thromboplastin and platelets. Transesophageal echocardiography can also be used. Additionally, in terms of intraoperative bleeding improvement, the use of warfarin was effective, as patients did not receive blood transfusions until the end of the transplant. A research protocol in which a sealing device (LigaSure ™) and ultrasound dissector (HARMONIC ACE® + 7) will be used intraoperatively; evidence suggests that an 80% reduction, approximately, in intraoperative bleeding will be achieved.[15-17,22-24]

With regard to the manner of performing auto-transfusion, anesthetists can use techniques such as low central venous pressure during transplantation, although this is not recommended for patients with terminal liver disease and potentially compromised hypovolemic function.[20,26]

Category 4 - Anesthesia Protocol

The evidence points to the need to use anesthesia protocols, which aim to minimize and prevent AEs, and properly manages them during liver transplantation. The findings indicate the need for adoption of anesthesia standards with institutional protocols to increase patient safety.[18,20,22] Anesthesia management in liver transplantation should be based on an adequate vital sign monitoring system and medication administration, due to systemic effects in patients, and should be well known in anesthesia practice, in addition to anesthesia risk management.[22,27]

Discussion

The review identified only one study with a high level of evidence (Level 2). It is noteworthy that the publication of scientific knowledge is the basis for changes in practice, as well as indispensable in care, enabling autonomous professionals, and forming the basis of clinical practice and safety in the work process.[31,32]

The number of studies focused on patient safety in the operating room remains minimal. The need to conduct strong studies with evidence-based research designs (Randomized Controlled Trials and Cohort Studies) is stressed.[11] In the identified studies, no evidence was identified to support the LT checklist adaptation in the three steps proposed by the WHO, as no information was found that could guide staff to track data related to aortic clamping, ischemia time, organ perfusion conditions, operating room graft receipt, backtable identification and preparation, warm ischemia time, or organ reperfusion. There was no information to support the professional team in donor and recipient data conferencing. Such information is fundamental and essential to prevent adverse events, and to promote quality and safety in the care provided to patients undergoing LT.

In order to perpetuate transplant safety, the ANVISA in Brazil recommends monitoring strategies during donor selection, extraction, preparation, conservation, control and distribution of the organ, tissue or cells to their use by the recipient. The purpose of this institution is to track and map, in addition to identifying data related to possible adverse events, proposing that professionals involved in the donation and transplantation process identify which situations can compromise the

process.[12] Thus, despite the majority of the studies presenting only a level of evidence of IV, it was possible to identify relevant information regarding the prevention of complications and adverse events in the safe development of liver transplantation surgery. Such findings can support significant changes to intraoperative patient safety.

Evidence related to the prevention of intraoperative hypothermia, as well as to major surgeries, was highlighted in the studies, which emphasized the importance of maintaining body temperature above 36°C, preventing risks to the patient which can progress to arrhythmias and even death.[22,28,30] The evidence indicates actions achievable by the team for promoting preventive, passive, and active procedures to warm the patient, contributing to the prevention of complications.[33]

Other evidence related to safe surgery involves early extubation. Studies show the importance of this practice in minimizing the risk of infections, due to the low immunity manifested by the liver transplant recipient.[23,25,34] They also indicate the low adherence of the anesthesia team, as no protocols or institutional guidelines are available. The importance of safety based on effective actions that support the team in all of its activities is reinforced, to protect patients undergoing invasive and complex procedures.[31,35]

Regarding the intraoperative period, the evidence indicates the importance of reducing the use of blood components. Studies iterate the need for careful evaluation for blood products.[18,22,24] Blood transfusion can result in serious risks to the patient, such as infections, nonhemolytic febrile reaction, lung injury, hypocalcemia, non-immune hemolysis, allergic reaction, hemolysis, hypothermia, among others. Therefore, strategies that minimize the risk of bleeding should be used, as well as up-to-date protocols that could standardize actions and minimize AEs.[36,37] Evidence shows the importance of targeted care to minimize the risk of bleeding, such as medication use, equipment, instruments, and support tools for intraoperative care.[15,16]

The development of anesthesia during liver transplantation using good practice guides was demonstrated in the studies.[18,19,22,27] Its use leads to greater safety of the professional team and patients, and consequently, higher quality anesthesia induction for the surgical procedure. Its use can reduce the risks to patients, helping the decision-making related to the demand presented by the patient.[35,38]

In this sense, the information identified in this study can support the construction of a checklist adapted to intraoperative liver transplantation. The nurse is the professional who manages and coordinates the surgical environment, from the time of the patient's arrival in the room, anesthetic induction, organ reception, backtable follow-up, recipient and donor data checking, among others, through to patient transfer to the intensive care unit.[39]

In view of the evidence obtained, the operating room nurse can integrate into his daily routine: the control and monitoring actions of hypothermia, anesthesia, and blood products, recording unwanted or unexpected effects that can appear during the intraoperative period. At the same time, nurses can introduce nursing interventions related to the evidence presented, minimizing risks associated with such situations, and enhancing intraoperative safety during LT. Safety in major surgeries emerges as an ethical, moral and quality responsibility, a commitment of the surgical team, as many patients arrive in the operating room with serious health conditions, especially in LT. [1,10,25]

Lack of information that can provide actions directed to intraoperative monitoring of LT is a limitation. From a methodological point of view, limitations of the search strategy and the selected databases may have contributed to the reduced number of publications on this subject, and the absence of studies with strong levels of evidence (double blind randomized, pre- and post-test, cross-sectional studies, among others).

Conclusion

The evidence identified to support future development of a safe surgery checklist related to this procedure, are: prevention of hypothermia; importance of early extubation planning; definition of criteria for the use of blood components; and

the importance of developing and adopting protocols and guidelines for the anesthesia intervention. Considering the findings of this study, further studies on this subject are recommended. In addition, there is a need for additional studies investigating the prevention of intraoperative AEs related to maintaining body temperature, surgical positioning, blood product transfusion, organ reperfusion, among other themes that promote safe practice in this type of surgery.

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