Risk management and safety in the use of patient-controlled analgesia pumps: a scoping review

Gestão de risco e segurança no uso de bomba de analgesia controlada pelo paciente: revisão de escopo

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DOI 10.5935/2595-0118.20230041-en

ABSTRACT

BACKGROUND AND OBJECTIVES: Patient-controlled analgesia (PCA) is effective in controlling pain, but has numerous associated risks, such as: hypotension, respiratory depression, seizures and excessive sedation. The promotion of patient safety aims to reduce the risk of unnecessary health injuries and, therefore, it is important to analyze the failures and risk factors present throughout the process proactively. Therefore, the aim of this study was to map the available evidence on the risks of adverse events associated with the PCA technique and patient safety actions.

CONTENTS: This is a scoping review conducted according to the JBI methodology, whose research question was based on the PCC strategy. The source of information is open and the search occurred in three stages. The databases used were: Medline/Pubmed; LILACS; CINAHL/ EBSCOhost; CENTRAL; Portal Capes; SCOPUS; Web of Science; Google academic; Brazilian Digital Library of Theses and Dissertations; Portal NICE; and Portal ISMP. The search strategy was divided into 3 stages: the first occurred in Medline and Cinahl to identify articles and index terms on the topic; the second used all keywords in all included databases; the third consisted of tracking searches in the reference lists of the included studies. The search resulted in 1,164 studies, of which 83 were selected based on the inclusion criteria: addressing the risks associated with the PCA pump or safety measures, hospital context, without restriction as to the type of study, language, and year. The studies are distributed in categories: previous diseases, profile of indications, types of opioids, types of pump and infusion, adverse effects, incidents without harm, stages of risk, and safety measures.

CONCLUSION: This study made it possible to identify the risks of adverse events associated with the use of PCA in different stages and safety actions, demonstrating that when performed with appropriate patients, trained staff, safe devices, and correct prescription it provides a statistically significant improvement in pain relief, safely with advantages that conventional analgesia does not have.

Keywords: Patient safety, Patient controlled analgesia, Risk management.

RESUMO

JUSTIFICATIVA E OBJETIVOS: A analgesia controlada pelo paciente (ACP) é eficaz no controle da dor, porém apresenta inúmeros riscos associados, tais como: hipotensão arterial, depressão respiratória, convulsões e sedação excessiva. A promoção da segurança do paciente visa reduzir o risco de lesões desnecessárias à saúde e, para tanto, é importante analisar as falhas e fatores de risco presentes em todo o processo de forma proativa. Portanto, o objetivo deste estudo foi mapear as evidências disponíveis sobre os riscos de eventos adversos associados à técnica de ACP e a ações de segurança do paciente.

CONTEÚDO: Trata-se de uma revisão de escopo realizada segundo a metodologia *Joanna Briggs Institute* para *Scoping Reviews*, cuja questão de pesquisa se baseou na estratégia PCC (P: população; C: conceito; C: contexto). As bases de dados utilizadas foram: Medline/Pubmed, LILACS, CINAHL/EBSCOhost, CENTRAL, Portal Capes, SCOPUS, *Web of Science*, Google acadêmico, Biblioteca Digital Brasileira de Teses e Dissertações, Portal NICE, Portal ISMP. A estratégia de busca foi dividida em 3 etapas: a primeira ocorreu na Medline e Cinahl para identificar artigos e termos de índice sobre o tema; a segunda utilizou todas as palavras-chaves em todas as bases de dados incluídas; a terceira consistiu no rastreamento de pesquisas nas listas de referências

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Presented on October 25, 2022.
Accepted for publication on July 20, 2023.
Conflict of interests: none – Sponsoring sources: none.

HIGHLIGHTS

- Risk management in pain management is of utmost importance.
- The use of the patient-controlled analgesia pump requires that proactive risk measures are implemented in order to ensure patient safety.
- Risk situations were identified that can assist the professional in the implementation of these preventive measures, such as: programming failures; defective pump; inappropriate patient selection; lack of education and training of professionals, patient and family; errors in prescription, dispensing, preparation and administration of drugs.

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dos estudos incluídos. A busca resultou em 1.164 estudos, dos quais 83 foram selecionados com base nos seguintes critérios de inclusão: abordagem dos riscos associados à bomba de ACP ou a medidas de segurança, contexto hospitalar, sem restrição quanto ao tipo de estudo, idioma e ano. Os achados sintetizados estão distribuídos em categorias: doenças prévias, perfil das indicações, tipos de opioides, tipos de bomba e de infusão, efeitos adversos, incidentes sem lesões, estágios de risco e medidas de segurança.
CONCLUSÃO: Este estudo possibilitou identificar os riscos de eventos adversos associados ao uso da ACP em diferentes estágios e ações de segurança, demonstrando que quando realizada com pacientes adequados, com equipe treinada, dispositivos seguros e prescrição correta, fornece uma melhora estatisticamente significativa no alívio da dor, de forma segura e com vantagens que a analgesia convencional não possui.
Descritores: Analgesia controlada pelo paciente, Gestão de riscos, Segurança do paciente.

INTRODUCTION

Pain is defined as "an unpleasant sensory and emotional experience associated with, or resembling that associated with, actual or potential tissue damage", and is the main reason why an individual seeks a hospital referral[1,2]. Patient-controlled analgesia (PCA) is a distinctive and advantageous method of analgesia delivery, as the patient is in control of the drug delivery system[3,4]. Therefore, it improves patient satisfaction and reduces opioid consumption[5]. PCA encompasses a whole process that includes patient, nurse, pharmacist and prescriber, so that if any of the components fails, safety is compromised[6]. Error is not individual, but a consequence of a poorly designed system. Therefore, safety must be combined with a systemic approach that promotes proactive risk management capable of identifying risk trends and mitigations necessary to prevent poor outcomes[7-9]. The scoping review, by presenting less restrictive inclusion criteria, allows a broad mapping of risks and safety measures so that services can plan their actions with a focus on safe and quality care. Thus, this review aimed to map the available evidence on the risks of adverse events associated with the PCA technique and patient safety actions.

CONTENTS

The scoping review was prepared according to the methodology proposed by the Joanna Briggs Institute for Scoping Reviews[10]. The protocol was registered in the Open Science Framework with registration "osf.io/gkmc8" and link for access <https://osf.io/xbctp>.

Research question and inclusion criteria

The research question "What is the evidence on the risks of adverse events and safety actions in the use of PCA in hospitalized adults?". It was guided by the PCC strategy (P: population, C: concept and C: context). "P" corresponds to adult patients using PCA pumps (population), "C" to risks of adverse events and safety actions (concept), and "C" to hospitals (context).

Sources

Quantitative, qualitative and mixed methods studies, reviews, experimental, quasi-experimental, observational, descriptive and analytical studies, as well as theses, editorials, clinical practice guidelines, experience reports, texts and opinion articles were considered. There were no language restrictions or limitations on the date of publication.

Search strategy

The first stage of the search consisted of an initial limited search in Medline via Pubmed and CINAHL via Ebsco to identify articles on the topic, using only the descriptor "Patient Controlled Analgesia". The text words contained in the relevant articles and the index terms used to describe them were used to define the full search descriptors: "Patient Controlled Analgesia", "Patient Safety" and "Risk Management".
In the second step, a full search was conducted, using all keywords identified in the initial search across all included databases: Medline/PubMed; Excerpta Medica dataBASE (EMBASE - Elsevier); CINAHL/EBSCOhost; The Cochrane Central Register of Controlled Trials (CENTRAL); LILACS; Portal Capes; SCOPUS; Web of Science; Google Scholar. The search for unpublished literature occurred in the Brazilian Digital Library of Theses and Dissertations (*Biblioteca Digital Brasileira de Teses e Dissertações*), in addition to the websites of organizations on patient safety, such as the National Institute for Health and Care Excellence (NICE) and The Institute for safe medication practices.
The third step was based on tracing additional documents in the reference lists of all publications included in the review.
In order to exemplify how the descriptors were combined with the Boolean operators to perform the search, below is the search model performed in Medline via Pubmed, equivalent to the strategy used in the other databases (Table 1).

Table 1. Model of search strategy carried out on Medline via Pubmed

Search	Question	Records retrieved
#1	"Analgesia, Patient-Controlled" [MESH] OR "Analgesia, Patient Controlled" [tw] OR "Patient-Controlled Analgesia" [tw] OR "Patient Controlled Analgesia" [tw]	6,751
#2	"Patient Safety" [MESH] OR "Safety, Patient" [tw] OR "Medical Errors" [MESH] OR "Safety" [MESH] OR "Medical Mistakes" [tw] OR "Mistake, Medical" [tw] OR "Mistakes, Medical" [tw] OR "Errors, Medical" [tw] OR "Error, Medical" [tw] OR "Medical Error" [tw] OR "Medical Mistake" [tw] OR "Never Event" [tw] OR "Event, Never" [tw] OR "Events, Never"	193,624
#3	"Risk Management" [MESH] OR "Management, Risk" [tw] OR "Management, Risks" [tw] OR "Risks Management" [tw]	323,334
#4	Search #1 AND (#2 OR #3)	231

Study selection

In the selection of studies, all identified citations were grouped and uploaded into EndNote® (Clarivate Analytics, Philadelphia, Pennsylvania, United States) and duplicates removed. After a pilot test, titles and abstracts were screened according to the inclusion criteria with the support of Rayyan®, a web application for systematic reviews[11].

The full texts of potentially relevant studies were retrieved and assessed in detail against the inclusion criteria. Disagreements between reviewers at each stage of the selection process were resolved through discussion or with the support of a third reviewer. There was no analysis of the methodological quality of the sources of evidence because this was a scoping review.

The search results are organized into Preferred Reporting Items for Systematic Reviews and Meta-analyses for Scoping Review Flow Diagram (PRISMA-SCR)[12].

Data extraction

A collection instrument was developed, after testing several versions, containing several categorized items to fill in the essential data extracted from the studies selected during the collection. The first category presents the components: responsible for the extraction, bibliographic data and study characteristics. The second corresponds to the population data and has: patient profile, type of pathology, drug and pump characteristics. The third refers to the concept and consists of: adverse events, incidents without harm, risk stages and safety actions. The fourth deals with the context, i.e. the hospital institution. Disagreements between reviewers were resolved through discussion, without the need to activate the third reviewer. Data were obtained by two independent reviewers.

Data analysis and presentation

The extracted data were presented in tabular form, accompanied by a narrative summary describing how they relate to the aim and question of this review.

RESULTS

The search resulted in 1,164 scientific productions distributed in the databases. Figure 1 shows the stages of the study and the results obtained, totaling 83 articles, classified according to author, type of study, subject and results in table 2. Studies that did not meet the inclusion criteria of this review after full reading were excluded.

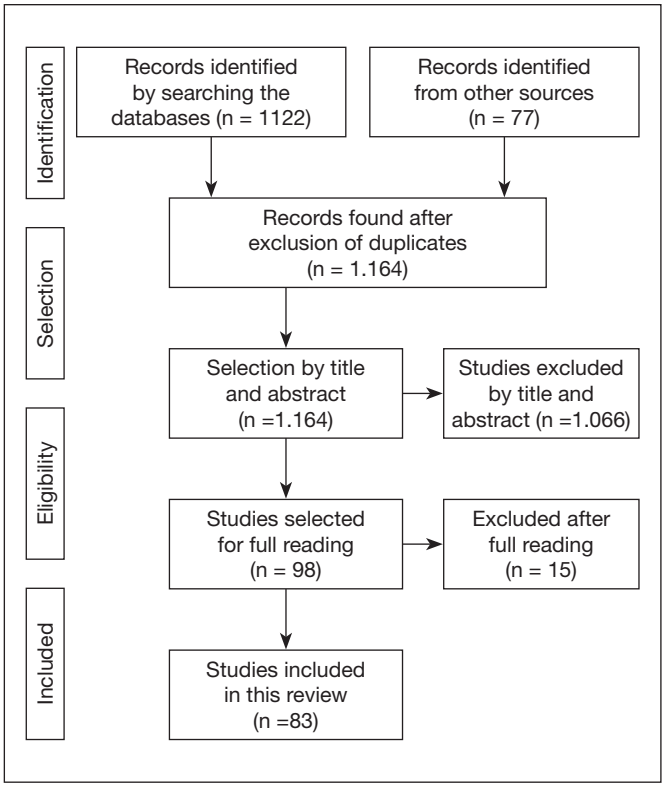

Figure 1. Flowchart of the selection of studies based on the Preferred Reporting Items for Systematic Reviews and Meta-Analyses Extension for Scoping Reviews (PRISMA-SCR)

Table 2. Description of studies included in the review

Authors	Type of study	Subject	Results
Vicente et al.[44]	Case report	Risk factors for adverse event associated with PCA pump and safety measures.	Programming error with inadequate dose adjustment has resulted in overdose and death. Anaesthesiologists, nurses, engineers and manufacturers can redesign pump interfaces and drug cassettes to minimize programming errors and improve their detection.
Reimer[53]	Letter to the editor	Risk factor for adverse event associated with PCA pump.	Failure to account for pump dead space volume and lockout interval can lead to opioid overdoses.
White[115]	Editor's letter	Importance of knowing the pump for PCA safety.	Pump features are important in the safety of PCA, but are not a substitute for professional supervision and monitoring.
Lederer, Benzer and Doyle[26]	Editor's letter	Risk factors associated with PCA.	The unpreparedness of the professional involved in PCA programming increases the risks of adverse events, so they should avoid: stress, alcohol or drugs, fatigue and emotional upset.
Prewitt et al.[97]	Cohort	Adverse events, risk factors and safety measures associated with PCA.	The following risk factors were identified: advanced age, renal failure, COPD, morbid obesity and sleep apnea. Incidents such as the wrong opioid and concentration selection and concomitant administration of benzodiazepines occurred. Smart pumps and monitoring are recommended.

Continue...

Table 2. Description of studies included in the review – continuation

Authors	Type of study	Subject	Results
Paul et al.[38]	Cohort longitudinal	Errors and safety measures associated with PCA.	The incidence of errors in PCA is low (less than 1%), but most occur in administration. Possible safety improvements are: well-designed pumps, printed medical orders, nursing education, independent double-checking, manuals, handover process and computerized order delivery system.
Paul et al.[94]	Prospective cohort	Adverse events and safety measures associated with PCA.	Following the introduction of the Root Cause Analysis process a reduction in the incidence of respiratory depression, severe hypotension and programming errors was noted.
Viscusi[111]	Controlled clinical trial	Risk factors associated with PCA.	PCA is subject to programming errors, tampering, unauthorized drug administration (proxy PCA) and malfunction.
Tran et al.[89]	Case study	Risks and safety measures associated with PCA pump.	PCA programming errors were identified. 159 potential errors were avoided within six months after implementing smart pumps with barcode verification of concentration and dosage limits.
Ahmad et al.[23]	Prospective observational study	Risk factors associated with critical incidents in PCA patient safety.	Three main categories of incidents were identified; programming errors, policy violations and patient selection. The largest contributing factor to PCA ICs was scheduling error. Strategies to minimize this problem include better education and vigilance.
Ohashi et al.[34]	Observational prevalence study	Risk factors associated with PCA pump.	Many errors related to correct identification of routes of administration, use of unauthorized drugs, inappropriate scheduling were highlighted. It is suggested to educate nurses, stressing the importance of labeling the routes, standardize the process of handling PCA, how and implement safety package.
Chumbley et al.[80]	Randomized controlled trial	Effectiveness of preoperative information related to PCA.	Patients in the leaflet group were better informed about PCA, became familiar with PCA use more quickly, and were less confused than the control group. However, there were no effects on pain relief, concerns about addiction and safety, and knowledge of adverse effects. There was no benefit from the preoperative interview.
and Salmon[81]	Randomized uncontrolled trial	Measures that make PCA effective and safe.	Information leaflet on adverse effects and instructions on the technique with clear language facilitated the use of PCA.
Akridge[45]	Clinical practice guide	PCA pump safety measures.	Smart pumps with built-in drug library and dose limits at various concentrations prevent medication errors.
Pasero[39]	Clinical practice guide	Risk factor for adverse event associated with PCA pump and safety measures.	Triggering PCA by family members is dangerous and therefore patient and family should be educated.
Cohen[19]	Clinical practice guide	Medication errors associated with PCA pumps.	The most frequently cited practice-related problems: incorrect PCA pump programming, a variety of programming steps, proper patient selection, family interference in analgesic administration.
Institute For Safe Medication Practices[17]	Clinical practice guide	Adverse events during PCA use.	PCA has great potential to improve pain management. However, it is necessary to know the factors that often contribute to the occurrence of adverse events during its use.
Institute For Safe Medication Practices[27]	Clinical practice guide	Strategies employed to reduce risks associated with PCA.	Practical strategies that reduce the risk of adverse events are described.
Cohen[29]	Clinical practice guide	Risk factors and safety measures associated with PCA.	Problems associated with PCA: proxy activation, improper patient selection, failure to monitor, failure to educate the patient, mixing medications, programming errors, device design failure, improper training, and prescribing errors. Some security measures cited were labeling and regular security rounds.
Pasero C and McCaffery M[93]	Clinical practice guide	Authorization for use of PCA pumps.	Conditions for use of other sedatives should be identified, provide adequate monitoring and rapid intervention in case of complications.
Weir[114]	Clinical practice guide	Evaluation of the PCA infusion system.	Need for changes to improve patient safety. Improvement for infusion monitoring. Integration of wireless connectivity decreases adverse events by 12%. For home use of PCA there is a need for improvement.

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Table 2. Description of studies included in the review – continuation

Authors	Type of study	Subject	Results
D'arcy[24]	Clinical practice guide	Use of oximetry or capnography in monitoring opioid respiratory depression via PCA pump.	Capnography is the most reliable indicator for monitoring respiratory depression due to opioid use during PCA. Professionals should associate the other safety measures during the use of PCA by the patient.
Cohen[54]	Clinical practice guide	Safety measures associated with PCA.	Recommendations to reduce programming errors: assess vulnerability to serious errors, limit concentrations, distinguish custom concentrations, clarify labels, employ independent double-checking, use barcode technology, use smart pumps and standardization of commands by pump suppliers.
D'arcy[25]	Clinical practice guide	Risk factors and safety measures associated with PCA.	Problems associated with PCA are inadequate patient selection, use of continuous infusion in opioid-naïve patients, proxy PCA and scheduling errors. Safety measures involve: use of smart pumps, training, independent verification, monitoring with capnography and pulse oximetry.
American Nurse Association[48]	Clinical practice guide	Safety measures associated with PCA.	It is important to obtain patient's health history, analyze risks, individualize dosage, monitor carefully, offer psychotherapeutic options in interdisciplinary team, maintain list of dangerous drugs and provide methods to decrease confusion between drugs.
Reg and David[104]	Clinical practice guide	Safety measures associated with the use of PCA in the postoperative period.	Spot checks of oxygenation with pulse oximetry and respiratory rate are not reliable to detect drug-induced respiratory depression. Continuous electronic monitoring of ventilation and oxygenation are preferable for any postoperative patient on opioids. Capnography should be used if that patient is on supplemental oxygen.
Stewart[51]	Clinical practice guide	Safety measures associated with PCA.	The study cites that there should be a rational framework for patient selection, analgesic agents, initial doses and subsequent dose adjustments.
Weininger et al.[113]	Clinical practice guide	Safety measures associated with PCA.	The application of platform-based solutions to PCA pump enables a safety lockdown that responds to respiratory depression.
Notcutt and Morgan[31]	Longitudinal retrospective	PCA in postoperative pain management.	The identification of specific hazards and management issues has led to improvements in the safety of the patient-controlled analgesia system.
Schug and Torrie[100]	Longitudinal retrospective	PCA in postoperative pain management..	PCA compared with other systemic opioid administration techniques did not result in a higher number of complications.
Sidebotham, Dijkhuizen and Schug[102]	Longitudinal retrospective	Risk factors for adverse event associated with PCA pump and safety measures.	The risk of serious complications associated with PCA is low, with the exception of hypoxemia and bradypnea. High-risk patients should be identified and prescribed with caution.
Teng et al.[109]	Longitudinal retrospective	Efficacy and adverse effects among PCA models.	Patients receiving epidural fentanyl-bupivacaine experienced better overall pain relief, whereas morphine via PCA, epidural or intravenous caused more adverse effects. The use of continuous epidural PCA with fentanyl-bupivacaine is considered safer in patients undergoing elective major surgery.
Hankin et al.[86]	Longitudinal retrospective	Adverse events involving intravenous administration of PCA.	Malfunctioning pumps were one of the main causes of adverse events reported. Operator errors were the most likely to be associated with more serious adverse outcomes. Incidences of major problems and vulnerabilities of PCA pumps should be identified and addressed.
Lee, Kim and Kim[91]	Longitudinal retrospective	Risk factors associated with postoperative PCA.	The main errors were: incorrect programming, device malfunction, prescription and patient error. Of the 222 operator errors, the most frequent type was failure to initiate drug administration, followed by programming errors by non-anaesthetic providers not authorized to program the device and wrong infusion rates set by authorized anaesthetists.
Hicks et al.[88]	Longitudinal retrospective	Risk factors and safety measures associated with PCA.	Causes of errors involve: human factors, equipment, communication, systems error, storage, labeling, packaging, documentation, contraindications, name confusion and incorrect order entry. Safety measures are: easy-to-set-up equipment, independent double-checking, standardized forms and staff training.
Moss [92]	Longitudinal retrospective	Implementation of Failure Modes and Effects Analysis (FMEA) as a strategy for identifying and correcting PCA failure modes.	In 2004, when most corrective actions were taken, there were 22 reported PCA errors. In October 2007, a new online occurrence reporting program was implemented, making reporting much easier. From October 2007 to September 2008, there were only 8 reported PCA errors, representing a 69% reduction from baseline. No serious adverse events were associated with any of these PCA errors.

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Table 2. Description of studies included in the review – continuation

Authors	Type of study	Subject	Results
Weber, Ghafoor and Phelps[56]	Longitudinal retrospective	PCA safety measures.	A standard order set was implemented, which decreased the number of cases of respiratory depression.
Peters, Mcguire and Ridling[95]	Longitudinal retrospective	Safety measure linked to PCA.	Failure Model and Effect Analysis (FMEA) applied by an interdisciplinary team was implemented to systematically identify risks associated with specific causes. In PCA FMEA identifies the failure; assigns severity, occurrence and classification; calculates the risk priority number (RPN); evaluates the results of interventions.
Pon and Huang[96]	Longitudinal retrospective	Risk factors and safety measures associated with PCA.	PCA may be related to adverse events due to very high bolus doses, particularly in opioid-naive patients. Invested in prescriber education and modification of the order form.
Ladak et al.[90]	Observational descriptive	Safety measures related to PCA.	A key strategy to improve patient safety is the development of an interdisciplinary team and smart pumps.
Tsui et al.[14]	Protocol	Adverse events and risk factors associated with PCA.	Episodes of bradypnea, hypercapnia and oxygen desaturation were identified, associated with female gender and systemic analgesia. Monitoring is recommended.
Chisakuta[77]	Case report	Risk factor for PCA-associated adverse event.	Confusing the PCA button with the nurse call button can lead to a dangerous overdose.
Heath[87]	Case report	Risk factor for adverse event associated with PCA pump.	Programming of the pump by anesthesiologists and resetting the parameters to zero at the end of each procedure increases the safety of PCA.
Berry[79]	Case report	Measures to make PCA effective and safe.	A root cause analysis system increases the effectiveness and safety of PCA.
Farbstein and Clough[83]	Case report	Adverse events and risk factors associated with PCA.	PCA-related incidents were: pump failure, ordering error, administration and dispensing. The team implemented the following actions: checklist; pump standardization; revised order forms; references for medication calculations; staff education and manual.
Elannaz et al.[16]	Case report	Adverse event related to PCA pump defect.	The incident was the result of multiple misuse: a disconnection of the tubing between the morphine bag and the patient, thus bypassing the anti-siphon valve, and an PCA cassette incorrectly stuck in an open position not detected by the pump. This indicates that vigilance must remain strict despite the widespread routine use of PCA.
Musshoff, Padosch and Madea[20]	Case report	Adverse event associated with the use of PCA.	Mortality from user programming errors in PCA was estimated as a low probability event. Experts recommend mechanisms to improve the safety of medical devices.
Dunwoody, Skledar and Freeman[55]	Case report	Safety issues with Meperidine use in PCA.	This provided a review of adverse events that were the basis for preventing unintended harm from PCA use. Drop in meperidine use to less than 10% of total opioid use. Adverse events decreased from 12 to less than 2 events per year.
Cohen and Smetzer[18]	Case report	Adverse event associated with PCA.	The use of PCA in cancer patients may be beneficial for initial opioid titration but has the potential to induce or exacerbate delirium.
Russell, Middleton and Hale[98]	Case report	Incident associated with PCA pump.	The pump was reset to default programming. With a different morphine dosage setting than administered caused an overdose, with no harm to the patient. This was recorded as device malfunction.
Hicks[78]	Case report	Risks, adverse events and safety measures associated with PCA.	The pump was improperly programmed, leading to morphine overdose and death. There were failures to double-check the device and to identify the adverse effects of opioids. Smart pumps, trained staff, electronic ordering, barcoded medications, capnography monitoring and continuous pulse oximetry are recommended.
Grissinger[41]	Case report	Risk factors, adverse events and safety measures associated with PCA.	One PCA-related death revealed numerous flaws. High-dose morphine was prescribed in an obese, opioid-naive patient, without continuous or frequent monitoring, with uninformed family who administered and also pressed the PCA button. Appropriate prescribing, patient and family education, and adequate monitoring are recommended.
Institute For Safe Medication Practices[43]	Case report	Risk factors, adverse events and safety measures related to proxy PCA.	A confused postoperative patient with delirium received high doses of analgesia by the activation of the pump by the companion, generating respiratory depression. There were failures in patient selection, family and staff education, signaling the prohibition of button use by others, and monitoring. Attention should be paid to patient, family and staff education, appropriate patient selection, visual reminders to avoid dose activation by anyone other than the patient and adequate monitoring.

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Table 2. Description of studies included in the review – continuation

Authors	Type of study	Subject	Results
Ferguson, Williams and Beard[84]	Experience report	Educational strategies employed to reduce errors associated with PCA.	The results of this investigation showed that there was a clinically significant difference in PCA pump errors, and this is also true statistically. Therefore, the educational intervention was effective in decreasing errors with the PCA pump.
Thomas and Rose[110]	Review	Measures to make PCA effective and safe.	The appropriate choice of opioid, settings for the demand dose and lockout interval influence the safety of PCA.
Institute for Safe Medication Practices[46]	Literature review	Safety actions in patient-controlled analgesia in teaching hospitals.	Effectiveness and safety of PCA can be achieved with patient selection, comprehensive education and equipment familiarization.
Langdale[4]	Literature review	Measures to make PCA effective and safe.	Patient and nurse education and protocols specifying prescribing, monitoring and treatment of adverse effects are key to PCA safety.
Etches[36]	Literature review	PCA in postoperative pain management.	PCA in appropriately selected patients has superior analgesia to traditional models.
Stone and Wheatley[105]	Literature review	Risk factors for adverse event associated with PCA pump and safety measures.	Risk factors for respiratory depression are: background infusion, morphine bolus >1mg, elderly, respiratory disease, proxy control, concomitant sedatives, operator error and equipment failure. Safety measures are: staff education, pump standardization, provision of clear instructions, human resources, monitoring and management plan.
Hicks et al.[32]	Literature review	Medication errors in PACUs.	Errors resulted in a higher than expected harm threshold (6.8%), with the majority of errors occurring during the administration phase (59%). Almost a quarter of the errors involved an inappropriate dose of a medication. Three-quarters of errors were influenced by distractions. More than 130 different products were present in the sample of cases analyzed. Problem areas identified involved epidural analgesia, patient-controlled analgesia and duplicate doses.
Cohen and Smetzer[28]	Literature review	Risk factors related to patient safety in PCA.	PCA by proxy, appropriate selection of patients for PCA, patient monitoring, patient education, medication mix-ups and prescription-related errors.
Tan and Schug[107]	Literature review	Use of PCA in patients being treated for acute pain.	PCA alone had a significantly lower rate of respiratory depression than PCA with background infusion or continuous morphine infusion. No serious complications resulting in morbidity or mortality occurred.
D'arcy[50]	Literature review	Safe use of PCA for pain relief.	The majority of patients who use PCA postoperatively do not experience problems. However, proper patient selection, constant monitoring during use, correct pump operation and programming, correctly applied policies and procedures, and adequate patient education on PCA use should be performed.
Eugene and Viscusi[11]	Literature review	Risks and benefits of PCA modalities.	PCINA has the potential to significantly improve postoperative pain due to the inherent simplicity and non-invasiveness of its administration. Fentanyl ITS has been shown to be safe and effective for postoperative pain management in several large randomized controlled trials, with efficacy equal to that of a standard IV morphine PCA regimen.
Alberta[35]	Literature review	Risk factors and safety measures associated with PCA.	The study addresses genetic and metabolic differences that cause variations in opioid response, increasing risk. It is important to be aware of drugs with similar names and programming errors such as selecting the wrong block or concentration. Safety measures: proper patient selection, use two independent nursing checks, identify lines, use prefilled bags or syringes and standardized orders.
Schein et al.[99]	Literature review	PCA pump-related errors and safety measures.	Most errors are related to poor pump programming and device malfunction. Smart pumps with barcode technology and other advances can make PCA safer.
Chumbley e Mountford[47]	Literature review	Risk factors and nursing care associated with PCA.	Programming errors are common, so nurses should be familiar with the parameters and settings.
Lattavo[30]	Literature review	Risk factors associated with PCA and nursing care to improve safety.	Some risks should be considered in patient selection such as: obstructive sleep apnea, use of central depressants and morbid obesity. Pump malfunction may be due to faulty motor, display board or software. Programming errors are due to improper medication, dosage and blockage. Patient errors were due to tampering or activation of the button by family members. The nurse should perform systematic evaluation of sedation.

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Table 2. Description of studies included in the review – continuation

Authors	Type of study	Subject	Results
Taylor[108]	Literature review	Risk factors associated with PCA.	Factors such as scheduling errors, improper dosing, inadequate patient selection and failure to monitor can be fatal.
Sardin et al.[40]	Literature review	Risk factors associated with PCA pump.	The maximum bolus number (Bmax) is an important parameter missing in some pumps. It prevents overdosing. Maximum cumulative dose (Dcmax) is more present, however it is more associated with problems as when reached it needs human intervention to reprogram.
Hicks, Hernandez and Wanzer[33]	Literature review	Risk factors, opioid pharmacology and nursing safety measures associated with PCA in the perioperative period.	Human errors occurred at every stage of opioid use, from prescribing (through transcription), dispensing, administration and monitoring. Opioids should be assessed for adverse effects and contraindications to avoid respiratory depression. Perioperative nurses can establish standardized processes.
D'Arcy[82]	Literature review	Risk factors and safety measures associated with PCA.	Proxy PCA is not recommended due to the high risk of complications. Proper patient selection, monitoring with continuous pulse oximetry and capnography, pain assessment, patient and family education and clear prescription should be performed.
Lisi[13]	Literature review	Adverse events, risk factors and safety measures associated with PCA.	Adverse events described are: respiratory depression, sedation, confusion, nausea, vomiting, pruritus and urinary retention. Risk factors for respiratory depression are: background infusion; PCA by proxy; advanced age; head injury; hypovolemia; use of hypnotics or sedatives; renal, hepatic, pulmonary or cardiac failure; sleep apnea and obesity. Stakeholders should be educated and safety measures implemented in pump purchase, prescription, dispensing and monitoring.
Surprise and Simpson[106]	Literature review	Safety measures associated with PCA.	Appropriately selected and educated patients can receive PCA. The provider should look at the individual needs of the patient in order to choose the appropriate settings for PCA thus allowing him/her control over the prescription.
Golembiewski, Dasta and Palmer[85]	Literature review	Risk factors associated with intravenous PCA.	Several disadvantages related to intravenous PCA have been described: programmer error, patient exposure to analgesic gaps, intravenous line permeability, dose stacking and catheter-related infection.
Shola and Neela Narayanan[101]	Literature review	Adverse events, risk factors and safety measures associated with PCA.	The most prevalent problems related to PCA are device safety events, operator error, opioid adverse reactions and patient-related. It focuses on improving the PCA pump with interoperable interface to improve safety.
Abrolat et al.[22]	Literature review	Safety measures associated with PCA.	The implementation of an acute pain service is desirable, but even without the institution, proper patient selection, patient and staff education should be considered. Regular visits and documentation of therapy, extended monitoring in patients with risk factors such as sleep apnea should also be performed.
Dening[15]	Case series	PCA in postoperative pain management.	The introduction of PCA in a planned and careful way, with training of staff and patients, makes the method effective and safe.
Etches[52]	Case series	Risk factors and incidence of respiratory depression during PCA.	Factors associated with higher risk of respiratory depression are: concomitant use of background infusion and sedatives, advanced age and sleep apnea. The risk in PCA is the same as in traditional intramuscular and spinal administration.
Syed et al.[21]	Case series	Adverse event propagation during PCA use.	Need for training and updates for professionals. Adverse events need to be reported and investigated to ensure learning and safe use of PCA in the perioperative period.
Sousa et al.[103]	Case series	Risks and adverse effects associated with PCA in cancer patients.	The most common adverse effects in cancer patients were sedation, constipation and nausea. Morphine had a higher risk than fentanyl for sedation.
Williams J[116]	Case series	Risk factors, adverse events and safety measures associated with PCA.	Failure to monitor culminated in 2 deaths related to respiratory depression during or after PCA use. One patient had no risk factor, the other had obstructive sleep apnea. The study addresses the need for continuous monitoring during PCA pump use, regardless of risk factors.
Wong, Mabuyi and Gonzalez[117]	Transversal	Safety measures associated with PCA.	It was noted that there may be more safety in hospitals that use only smart pumps, present educational materials, monitoring with pulse oximetry or capnography.

*PCA = Patient-controlled analgesia; PACU = Post-anesthesia care unit.

Table 3 summarizes the review findings in the following categories: previous diseases, indication profile, opioid types, pump and infusion types, adverse effects, non-injury incidents, risk stages and safety measures.

In the studies evaluated, adverse events were respiratory depression, related to overdose, and risk factors such as background infusion, advanced age, head injury, hypovolemia, use of hypnotics or sedatives, renal, hepatic or cardiac failure, sleep apnea and obesity[13]. Deaths were associated with overdose and signs and symptoms of overdose with extravasation of the analgesic. The presence of these reactions decreased analgesic efficacy because they were considered as distressing as pain[14].

Excessive sedation and seizures occurred due to overdosage and inadequate analgesia due to dose choice failures and incorrect setting of parameters such as the 4h limit and the lockout interval[15]. Respiratory and cardiorespiratory arrest and coma were associated with free infusion of all the opioid stored in the pump and drug confusion[16,17]. Delirium was recurrent in patients with cancer, chronic opioid use and polypharmacy[18]. Cardiac arrest, renal failure, gastrointestinal bleeding, hypoxic encephalopathy, anaphylaxis and hypotension were less common events also associated with overdose. There were a few incident cases, such as opioid overdose, which did not result in injury.

The errors and failures found in the studies were organized into risk stages. In programming, the errors were loss of a decimal point; misinterpretation of the prescription; failure to check settings; incorrect vial insertion; inactivated pump programming; confusion with mass and volume units, time and dosage; disconnection of the check valve; failure to perform individual programming; staff factors: inexperience, distraction by high workload, inadequate communication and turnover; difficult interface; reprogramming with criminal intent[16,17,19-26].

Failures related to the PCA device were due to miswiring; tubing not attached; pumps not requiring parameter review; dose standardized in milliliters; mechanical problems; insufficient batteries; unable to see syringe labels; activation button resembling a call bell; failure to provide visual or auditory feedback; cracked syringe or cassette allowing siphoning; defective motor, hardware, or software; defective *bolus* trigger and power cords[16,25-31].

Table 3. Summary of findings related to risks and safety measures in patient-controlled analgesia

Variables	n (%)	Variables	n (%)
Previous illnesses	7 (100%)	Over-sedation	4 (6%)
Obesity	3 (44%)	Seizures	4 (6%)
Sickle cell anemia	2 (28%)	Inadequate analgesia	4 (6%)
Sleep apnea	1 (14%)	Respiratory arrest	3 (5%)
Chronic renal failure	1 (14%)	Cardiorespiratory arrest	3 (5%)
Profile of referrals	27 (100%)	Coma	2 (3%)
Post-operative	22 (81%)	Delirium	2 (3%)
Oncological pain	4 (15%)	Cardiac arrest	1 (1%)
Acute pain	1 (4%)	Renal insufficiency	1 (1%)
Types of opioids	43 (100%)	Gastrointestinal bleeding	1 (1%)
Morphine	27 (63%)	Hypoxic encephalopathy	1 (1%)
Hydromorphone	7 (16%)	Anaphylaxis	1 (1%)
Meperidine	3 (7%)	Hypotension	1 (1%)
Fentanyl	3 (7%)	Incidents without injuries	5 (100%)
Oxycodone	2 (5%)	Overdosage	5 (100%)
Piritramide	1 (2%)	Risk stages	71 (100%)
Types of pumps	16 (100%)	Programming	19 (27%)
Abbott	7 (44%)	PCA device	15 (21%)
Graseby	6 (38%)	Administration	9 (13%)
Baxter	1 (6%)	Prescription	9 (13%)
Master	1 (6%)	Patient selection	8 (11%)
Carefusion	1 (6%)	Education	5 (7%)
Deltec	1 (6%)	Drug dispensing	3 (4%)
Types of infusion	43 (100%)	Preparation	3 (4%)
No basal infusion	30 (70%)	Safety measures	83 (100%)
With basal infusion	13 (30%	Education	16 (19%)
Adverse effects	66 (100%)	Safe pump	13 (16%)
Respiratory depression	26 (39%)	Proper patient selection	9 (11%)
Death	10 (14%)	Safe preparation and dispensing	8 (10%)
Nausea, constipation, vomiting or itching	5 (7%)	Appropriate PCA requests	7 (8%)

In the administration stage, the main failures were PCA by proxy; confusion of the demand button with the nursing request button; confusion of medications such as morphine and hydromorphone; incorrect patient identification; technique, rate, pharmaceutical form and route; lack of tube labels, unauthorized medication and failure to secure. Some factors contributed to such failures such as distractions, inexperienced staff, high workload and shift change[15,17,19,30,32-34].

In prescribing, errors occurred during the conversion from oral to intravenous drug; when calculating the dose for a morbidly obese, non-opioid-naive or elderly patient; basal infusion for patients with risks; prescription of non-steroidal anti-inflammatory drugs (NSAIDs) in the context of renal failure and active peptic ulcer; coadministration of incorrect opioids; inappropriate choice of protocol; choice of drug to which the patient is allergic; selection of meperidine for a patient with renal impairment; appropriate follow-up dose for an opioid other than the one prescribed; simultaneous requests for other opioids while PCA is in use; simultaneous administration of sedatives or hypnotics; inappropriate parameters; error of omission; incomplete, duplicate requests and inappropriate dose orders. Factors contributing to such failures were: communication failure, loss of information in transfers, use of non-standard dosages and insufficient patient data[23,27,28,32,33,35,36].

In the selection of patients, the risk profiles indicated were: individuals with advanced age, obesity, asthma, opioid tolerant, pre-existing respiratory impairment, renal impairment, obstructive sleep apnea, using drugs that potentiate opioids (benzodiazepines, muscle relaxants, antiemetics and barbiturates)[17,29,36,37]. In addition to infants, young children and confused elderly[28].

In the education stage, failures occurred in the inadequate education and training of professionals, lack of periodic evaluation and reassessment of proficiency and staff updates. Inadequate patient and family education was also recurrent[27,29,38].

In drug dispensing, failures occurred due to simultaneous requests for other opioids; confusion of concentration and dose; inadequate PCA refilling (improper syringe loading); illegibility and the use of ambiguous abbreviations in requests[30,33].

In the preparation, there was inadequate selection of drugs due to similar packaging such as morphine and meperidine and similar names such as morphine and hydromorphone[28,29].

Safety measures in the use of PCA have also been organized into stages. Educating the patient requires introducing them to the pump preoperatively; teaching them what constitutes "good" pain relief; warning of risks; addressing the importance of monitoring and reporting pain[15,17,19,22,36,40,41].

Educating family members means guiding them so that no one except the patient can press the button. Staff should be informed about the opioids used for PCA; the dangers of proxy PCA; the signs and symptoms of toxicity; errors; policy; adjustments if drugs are changed; and monitoring. Information guides can be made available at sites where PCA is used. It is important to promote: trainings; refresher sessions; annual pump recertification classes or assessments; simulations and acute pain rounds with pain consultants and specialists[22,23,27,28,39,42,43].

A safe pump is designed to be easier to program based on human factors engineering techniques; with drug library divided by areas; dose limits at multiple concentrations with alerts if exceeded; syringe pumping; non-numeric keypads; event reporting; flow confirmation alert; quick drug search; intuitive programming; built-in wireless system; respiratory monitoring module; bar coding; integration with medical and pharmacy records (interoperability); free-flow protection; fewer programming steps; visual and auditory feedback; milligram or microgram setting; differentiated appearance of activation button; patient guide for use; premarket testing; syringe or empty cassette alerts; tamper-resistant mechanism; long battery life; lightweight, robust frame; silent action; transparent overlays; anti-reflow valve[28,36,44-46]. General measures include: a single pump model; verification of default settings before dispensing; warning label "FOR PATIENT USE ONLY"; failure mode and effect analysis and surveillance[16,21,23,28].

Appropriate monitoring involves: pain assessment at 15-minute intervals in surgical recovery, on the ward hourly for the first 4 hours, and then every 4 hours with a standard scale; assessment of breathing by respiratory rate and quality; use of continuous pulse oximeter and capnograph (at least intermittent or for patients at risk); assessment of sedation; limit supplemental oxygen; monitoring more frequently in the immediate period after onset, during the first 24 hours and at night when hypoventilation and nocturnal hypoxia may occur; recording and checking settings, analgesic volume and intravenous access condition at each shift[15,17,27,28,41,44,47-50]; monitoring when patients are ready to stop PCA and using less potent analgesia[47].

Proper patient selection aimed at choosing appropriate patients by well-trained and informed professionals. The patient should be mentally alert and able to control their own pain and meet selection criteria such as adequate level of consciousness, cognitive ability and manual dexterity to activate the button[19,27]. Safety measures involved: obtaining health history and performing a physical examination to assess the patient's potential for opioid abuse; informed consent; analyzing the risks and benefits; individualizing the dosage; and assessing contraindications and comorbidities[36,43,48,51].

Appropriate prescribing is based on choice of compatible opioid (rapid onset, intermediate duration, minimal side effects and free of toxic metabolites); consideration of allergies, renal function and dosage; dose reduction when a patient is switched between opioids; *bolus* dose that provides significant analgesia and at 10% of daily dose; sufficient loading dose; opt for maximum cumulative dose parameter; lockout period that protects the patient from over-administration; background infusion for opioid tolerant patients or those with higher needs; functional assessment of pain relief; individual programmability; adding other drugs such as antiemetics; coanalgesics; prescription with modalities of administration; standard concentration for each opioid; and reassessing the adequacy of PCA at regular intervals[22,27,28,36,37,40,47,51-53].

Safe preparation and dispensing is related to clear labels with the total concentration of the drug; morphine in single concentration; ready-made preparations; warning labels on non-

-standard concentrations; set maximum dose limits; review dose adjustments; pack with naloxone its use guidelines; validate original order; confirm allergies; separate and clearly identifiable similar names in upper case; prescription forms; support information related to drug compatibility; supervise the pharmaceutical component of therapy; and preparation in a more controlled environment[17,28,33,46,54,55].

Appropriate PCA orders are standardized and electronic that follow the pump programming sequence, include monitoring and necessary precautions; highlighting allergies; doses in mg or mcg; uppercase letters for hydromorphone; standardized concentrations; blocking inappropriate concentrations; availability of morphine adjustment for patients with renal impairment; standardized conversion table for basal infusion rates; and limited verbal orders[17,23,56].

Safe administration includes allergy checking and signaling; warnings about restricted use to patient; label infusion lines; require patient to demonstrate how to activate pump; connect PCA close to patient; administer anxiolytics with caution; watch for concomitant opioids; make oxygen and naloxone readily available; double-check with physician before use; avoid proxy PCA; compare record with label; at the beginning of each shift document characteristics of therapy such as solution, method, parameters; double-check; and suggest to family members complementary measures to alleviate patient discomfort[28,39,48,54].

Safe programming involves independent double-checking; review of nursing policy on configuration and programming; review of pump settings during patient handover and at each shift change; quick reference leaflet for wards with programming tips and maximum dose warnings for each drug; barcode technology; simple to run program with few steps; easy to read menus; software protection against power outages and static interference; and personalized prescription for different delivery modes[21,23,44,46,54].

DISCUSSION

The morbidities identified in the studies draw attention to the different uses of PCA and the care to be taken in each case. Obesity is characterized by hemodynamic changes capable of altering drug kinetics and hepatic fatty infiltration that limits the metabolic activity of the liver. Therefore, the opioid dose should take into account the ideal body weight, the distribution of the drug in the excess body mass and the maintenance dose should be reduced[57].

Sickle cell anemia causes manageable pain crises with low doses titrated according to pain level and assessment of factors such as age, genotype, hydroxyurea use, fetal hemoglobin levels, and presence of acute chest[58].

In obstructive sleep apnea, the patient only resumes breathing when PaCo2 increases. However, morphine hinders this process, so the prescriber should contraindicate basal infusion and adjust the dose limit[59].

In renal failure, the challenge is to combine pain control with protection of renal function, so the prescriber should monitor renal function, select opioids with a safe pharmacological profile such as fentanyl and adjust the dose[60].

The literature indicates that post-surgical pain management with PCA produces physiological and functional outcomes associated with earlier discharge from hospital, faster ambulation and lower levels of pain and disability[61]. PCA is also shown to be effective in relieving acute and severe cancer pain with patients being able to titrate their analgesia without excessive sedation. In this case, the block interval chosen was longer than that used postoperatively. The main advantage highlighted was the shorter interval between the need for the analgesic and its administration, ideal for palliative care patients as well[62-64].

Morphine is considered the gold standard for PCA, but produces an active metabolite with renal elimination and can cause nausea, vomiting, pruritus, urinary retention, sedation and respiratory depression. It therefore requires caution in renal dysfunction, in the elderly and individual adjustment of dosage and parameters. Hydromorphone is indicated for patients with renal insufficiency and allergies. It is seriously confused with morphine, as the dosage of morphine is much higher. Meperidine is hepatically metabolized, renally excreted and has a central effect associated with risks of confusion, spasms and convulsions. Its safe use implies a daily dose of 10 mg/kg/day for up to three days, only in cases of allergy to morphine and hydromorphone. Fentanyl has a higher risk of programming errors because it is dosed in micrograms, and of adverse effects if associated with basal infusion, frequent and prolonged use, given that it has a short analgesic action and a long half-life. Oxycodone is similar to fentanyl in terms of adverse effects, but can be used on demand and associated with basal infusion. Piritramide is contraindicated in patients with porphyria and its safe use requires careful titration during long-term treatment to avoid accumulation[62,65].

Continuous background infusion does not improve the analgesic effect and increases the risk of adverse effects. However, it can be used in opioid-tolerant patients with cancer pain and pain crises if the *bolus* dose corresponds to 50-100% of the basal rate[66].

Respiratory depression is a consequence of an overdose of opioids or their interaction with sedatives. Its occurrence is associated with short intervals and blocks, repeated administrations and high doses. Risk factors are patients older than 70 years, using continuous basal infusion, with renal, hepatic, pulmonary, cardiac dysfunction, history of obstructive sleep apnea, use of central nervous system depressants, obesity, thoracic or upper abdominal surgery, boluses greater than 1 mg, hypovolemia and lack of understanding of the functioning of the PCA device. Its incidence is highest in the first 24 hours postoperatively and during the night.

The most reliable way of detecting hypoventilation is through capnography. There are other indicators such as changes in respiratory rate, quality of breathing and continuous pulse oximetry. This detects hypoxemia but may not be accurate without supplemental oxygen and low peripheral perfusion[67].

Respiratory and cardiac arrests and coma were consequences of respiratory depression. Reports of deaths associated with respiratory arrest were associated with staff delay in response and failure to recognize hypoventilation. Postoperative nausea and

vomiting are common adverse effects associated with opioid use, so concomitant use of antiemetics is recommended. Pruritus is less common and its treatment with antipruritic drugs may favor sedation, so it is recommended to choose another opioid. Sedation may be associated with accumulation of active metabolites, so fentanyl would be the safest option, or coadministration of NSAIDs[68]. Seizures have been reported in association with meperidine at high doses. Risk factors include: renal impairment and coadministration of liver enzyme-inducing drugs or phenothiazines[69]. Insufficient analgesia was due to inadequate adjustment of PCA parameters. *Delirium* is more common in elderly under-treated pain and oncology patients[68]. The remaining events were associated with opioid overdose.

Human failures during programming can be related to gaps in knowledge, lack of experience or high workload. Smart pumps enable the reduction of drug errors, but do not exempt staff from checking the device and connections and having the knowledge and clinical judgment to validate the accuracy of the information. Failures in surveillance can lead to irreversible harm if staff do not respond in a timely manner. Proper assessment of pain and sedation during the use of a high-risk medication makes therapy safer and more effective[70,71]. The PCA pump is for the exclusive use of the patient, as once sedated, he/she does not press the demand button[17].

It is the responsibility of the health professional to educate and assess the patient and family and to ensure the correct use that begins with the appropriate selection of the patient, who must have the cognitive, physical and psychological capacity to control their own pain. Knowing the patient and their history, choosing the most appropriate opioid and respecting the institution's standards are fundamental for safe prescribing. Care should be taken with preparation and dispensing, and access should be restricted, as these drugs are highly monitored[6,72-74].

The numerous risks brought together in this review enable organizations to assess their own risks more easily through their classification, description, relationship to other risks and their potential impact. Mitigation strategies can aim at risk avoidance, transfer to another co-responsible party or reduction. Risks should then be monitored and controlled through reassessment of current risks, identification of new ones and closure of non-threatening ones; audits documenting the effectiveness of response measures; variance analysis; measurement of technical achievements; reserve analysis and *status* meetings[75]. Safety measures also provide a large scope of useful actions for risk management.

Incident reporting is the cornerstone of any risk management process, but voluntary reporting is poorly performed due to factors such as: work overload; failure to recognize; disbelief in reporting; lack of feedback; fear of disciplinary or judicial action; lack of understanding of what types of incidents should be reported. Therefore, it is up to the institution to carry out educational activities and simulations on voluntary reporting combined with active search for incidents, as it is a quality management tool, not a disciplinary tool[76].

This research is limited by not carefully assessing the methodological quality of the selected studies. However, there are no systematically structured reviews on risk management in the use of PCA available in the literature; therefore, a scoping review is initially needed to recognize and gather the various types of evidence produced on the subject. In this way, with the risks mapped and the safety measures delimited, services can plan their actions to prevent incidents and adverse events through manuals, checklists, information leaflets and protocols based on these findings. The division into stages also makes it possible to create, at each stage of PCA, barriers capable of preventing the risk from affecting the patient.

Given the wealth of existing scientific production and the relevance of the topic for effective and safe pain control, it is worthwhile to conduct future systematic and effectiveness studies in this area, which also specifically address the different users and modalities of PCA cited in this review.

CONCLUSION

The idea of PCA provokes insecurities in health professionals, who historically assume the care of others. Long-standing studies and more recent ones show a variety of risks and adverse events during the use of the technique, which accentuates uncertainties and disbelief. However, the same literature reveals that with proper planning and management it is possible to obtain an effective method of pain control, safely with advantages that conventional analgesia does not have.

Opioids are not completely safe, so unintended and preventable harmful events can occur. Knowledge of the contributing factors, the diversity of adverse events, the stages of risk and the safety measures present in this review enables risk management and, consequently, the implementation of an analgesia system that balances efficacy and safety in favor of the patient.

AUTHORS' CONTRIBUTIONS

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Data Collection, Conceptualization, Resource Management, Project Management, Research, Methodology, Writing - Preparation of the Original, Writing - Review and Editing, Supervision, Visualization
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