



Handling errors in conventional and smart pump infusions: A systematic review with meta-analysis*

Erros de manuseio na bomba de infusão convencional e smart pump: revisão sistemática com metanálise

Errores de manejo en la bomba de infusión convencional y smart pump: revisión sistemática con metaanálisis

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-  Ana Paula Amorim Moreira¹
-  Márglory Fraga de Carvalho²
-  Roberto Carlos Lyra da Silva³
-  Cristiano Bertolossi Marta⁴
-  Eliana Rosa da Fonseca⁵
-  Maria Tereza Serrano Barbosa³

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¹ Universidade Federal do Estado do Rio de Janeiro, Programa de Pós-Graduação em Enfermagem e Biociências, Rio de Janeiro, RJ, Brazil.

² Corpo de Bombeiros Militar do Estado do Rio de Janeiro, Rio de Janeiro, RJ, Brazil.

³ Universidade Federal do Estado do Rio de Janeiro, Rio de Janeiro, RJ, Brazil.

⁴ Universidade do Estado do Rio de Janeiro, Rio de Janeiro, RJ, Brazil.

⁵ Universidade Federal do Rio de Janeiro, Rio de Janeiro, RJ, Brazil.

ABSTRACT

Objective: To identify the scientific evidence on the frequency of handling errors of conventional and smart pump infusions in intravenous insulin therapy in intensive care units. **Method:** A systematic review with meta-analysis conducted in the Virtual Health Library, MEDLINE via PubMed, Scopus and Web of Science databases. Articles were assessed regarding the level of evidence by applying the Oxford Center for Evidence-Based Medicine Evidence Scale. **Results:** Twelve (12) publications were selected which met the eligibility criteria. The programming error rate using the conventional infusion pump ranged from 10% to 40.1%, and the smart pump technology error rate ranged from 0.3 to 14%. The meta-analysis of two studies favored the smart pump in reducing the relative risk of programming errors by 51%. **Conclusion:** Based on selected articles, the smart pump reduces the risk of programming errors.

DESCRIPTORS

Infusion Pumps; Insulin; Medication Errors; Critical Care Nursing; Intensive Care Units; Review.

Corresponding author:

Ana Paula Amorim Moreira
Rua Vereador Duque Estrada,
109/408, Santa Rosa
CEP 24240-210 – Niterói, RJ, Brazil
moreira.ana78@gmail.com

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INTRODUCTION

The accelerated growth in incorporating new technologies in the health scenario is a reality, and this mainly impacts the care provided to patients within the Intensive Care Units (ICU) as it is a highly technological environment where health technologies are considered fundamental tools for achieving safe and efficient care.

One of the most used medical care devices (MCD) in ICUs are infusion pumps, which allow more rigorous control in the process of administering solutions/medications that are continuously infused⁽¹⁾. However, medication administration errors are of substantial significance, representing around 19.4% of all adverse events occurring in the hospital setting⁽²⁻³⁾.

Infusion pumps are generally designed to improve the accuracy of intravenous infusions, enabling healthcare professionals to program their flow, volume and timing. However, most Adverse Events (AE) associated with intravenous (IV) devices are the result of manual programming from incorrect settings on the infusion pump⁽²⁻³⁾. In this sense, although infusion pumps have revolutionized Intravenous Therapy (IVT) by providing more accurate intravenous infusions, healthcare professionals are still susceptible to causing AE when handling this equipment⁽⁴⁾.

Infusion pumps have become major infusion systems through great technological advancement, and with the advent of smart pumps which have customized software that contains the drug library, conventional infusion pumps have tended to be transformed into a computer capable of alerting the user if the programmed infusion has the medication out of the recommended parameters, such as dose, dosage unit (mcg/Kg/min, U/h, etc.), flow or concentration⁽⁵⁻⁶⁾.

However, even though practitioners have more technological resources available for their advantage in terms of their work and patient safety, an underutilization of these technologies in developing countries and medication mismanagement with the use of infusion pumps are still recurring problems all over the world.

In the last five years, the Emergency Care Research Institute (ECRI), a Pennsylvania-based non-profit organization specializing in medical devices, has presented medication administration errors involving the use of infusion pumps on its top 10 list of dangers in using health technologies⁽⁷⁾.

Thus, based on such alarming data related to medication administration errors with using an infusion pump, the US Institute for Safe Medication Practices (ISMP) recently released the 2016-2017⁽⁸⁾ list of best practices for improvement in the safety of using specific medications in the hospital environment, especially in the administration of Potentially Dangerous Medications (PDM), which have a narrow therapeutic safety margin and are associated with increased risk of injury or death to patients⁽⁹⁾. Insulin is a drug within the PDM group which is widely used for intensive care intravenous patients and requires the use of a programmable infusion pump with dosage error reduction software⁽⁸⁾. Hyperglycemia and hypoglycemia are associated with a higher risk of developing pressure injuries, falls,

surgical site infections, and venous catheter infections, which can all impact mortality, and therefore identifying cases and early implementation of venous insulin infusion for better glycemic control are necessary.

Monitoring and controlling the glycemic index of critically ill patients is a major challenge in care practice, as these require the proper management of smart technology to ensure safety in the dosage to be infused⁽¹⁰⁻¹²⁾. In addition, it is necessary to consider that smart pumps are not yet a widespread technology in Brazil, and that only a small portion of society has access to this technological resource.

The underuse of both conventional and smart infusion pumps can directly influence IVT and lead to negative outcomes for the patient, while the full use of these technologies can minimize waste with cost reduction, prevent (re)work and especially strengthen the quality and safety of care within the scope of IVT.

In this sense, this study aimed to: identify the scientific evidence on the frequency of programming errors of conventional and smart infusion pumps in intravenous insulin therapy in intensive care units.

METHOD

STUDY DESIGN

This is part of a research study that evaluated the cost-effectiveness of smart infusion pumps in which a systematic review was performed to synthesize the evidence. The review followed the steps listed in the Methodological Guidelines for the Development of Systematic Review proposed by the Brazilian Health Technology Network (*REBRATS – Rede Brasileira de Tecnologias em Saúde*)⁽¹³⁾, and the PICO strategy was structured as follows: Population/Patient (P): Adult patients admitted to the ICU on continuous use of insulin IV; Intervention (I): full use of infusion pump resources for control and monitoring IV insulin flow and infusion rate; Comparison (C): partial use of infusion pump features for control and monitoring IV insulin flow and infusion rate; and Outcomes (O): errors related to infusion pump handling in IV insulin administration.

Full use of infusion pump resources is considered for controlling and monitoring the insulin infusion rate and flow when the pump programmer uses the drug library feature, considering the database already recommended in the equipment software. A partial use of resources consists of using the infusion pump which has the drug library programming as a conventional infusion pump, disregarding the available resource.

The following question guided the research: “What is the frequency of errors resulting from the total and partial use of infusion pump resources to control and monitor the flow and rate of intravenous insulin infusion in ICU patients?”.

The search was performed in March 2016 based on the terms of the Descriptors in Health Sciences (DECS) and Medical Subject Headings (MESH) controlled vocabularies and corresponding synonyms in Portuguese and English: “Intensive Care Units”, “Infusion Pumps” and “Medication

Errors". The search involved the Regional Portal of the Virtual Health Library (VHL), covering the following scientific databases: Latin American and Caribbean Health Sciences Literature (LILACS), Spanish Bibliographic Index on Health Sciences (IBECs), Database of Nursing (*Base de dados de Enfermagem – BDEFN*) and the State Health Department of São Paulo (*SES-SP*). The Medical Literature Analysis and Retrieval System Online (MEDLINE) database was also consulted via PubMed, and the following multidisciplinary databases on the Capes Journals portal: Scopus (Elsevier), Web of Science (Thompson Reuters) and Cinahl (EBSCO).

One decided to evaluate the quality of the studies included in the meta-analysis using the Oxford Center for Evidence-Based Medicine Evidence Scale⁽¹⁴⁾ because this is a study which can guide decisions based on the meta-analysis results. The quality of the evidence set for the analyzed outcomes and the strength of the recommendation were assessed by the Grading of Recommendations Assessment, Development and Evaluation (GRADE).

The search strategy using the descriptors and synonyms can be seen in Chart 1.

Chart 1 – Search strategy used in MEDLINE Database via PubMed.

("smart infusion pumps"[All Fields] OR "Infusion System"[All Fields] OR "Drug Infusion System"[All Fields] OR "Perfusion Pump"[All Fields] OR ("infusion pumps"[MeSH Terms] OR ("infusion"[All Fields] AND "pumps"[All Fields]) OR "infusion pumps"[All Fields] OR "infusor"[All Fields]) OR "Infusion Pumps"[All Fields] OR "smart pumps"[All Fields] OR "intravenous medication administration"[All Fields] OR "intravenous pump"[All Fields]) AND ("Intensive Care Units"[All Fields] OR "Care Unit Intensive"[All Fields] OR ICU[All Fields]) AND ("potentially dangerous medications"[All Fields] OR ("insulin"[MeSH Terms] OR "insulin"[All Fields]) OR ("hypoglycaemia"[All Fields] OR "hypoglycemia"[MeSH Terms] OR "hypoglycemia"[All Fields]) OR ("hyperglycaemia"[All Fields] OR "hyperglycemia"[MeSH Terms] OR "hyperglycemia"[All Fields])) AND (errors[All Fields] OR "error frequency"[All Fields] OR ("epidemiology"[Subheading] OR "epidemiology"[All Fields] OR "frequency"[All Fields] OR "epidemiology"[MeSH Terms] OR "frequency"[All Fields]) OR "medication errors"[All Fields] OR "frequent errors"[All Fields]) AND (English[lang] OR Portuguese[lang] OR Spanish[lang])

SELECTION CRITERIA

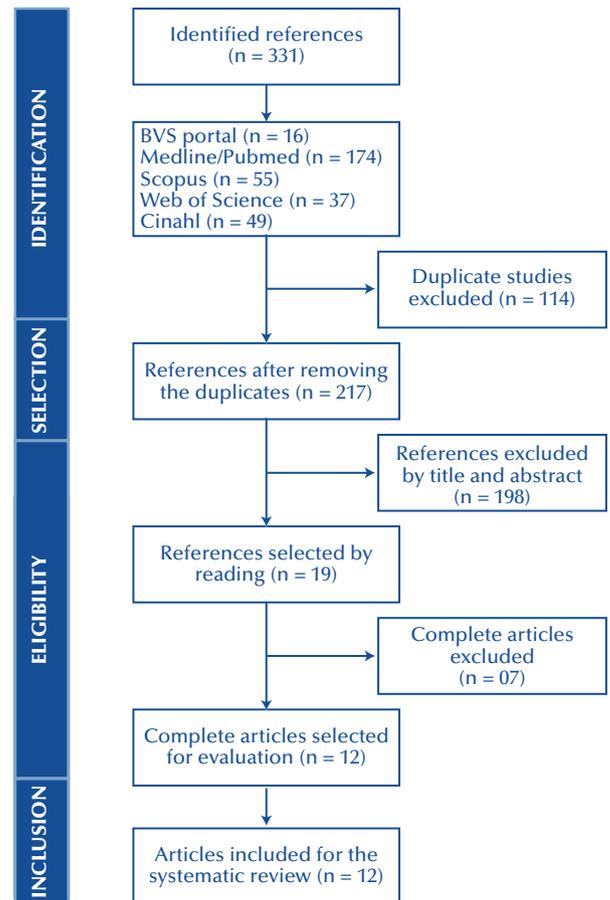
Inclusion criteria were: error-focused studies over the past 20 years involving infusion pump intravenous insulin use in adult ICU patients, published in English and Spanish, full text and available online.

Exclusion criteria were studies performed in the laboratory or in scenarios other than intensive care; those involving pediatric and neonatal patients; studies focusing on post-implementation acceptability of smart pumps; studies that addressed other perspectives (user training; interoperability with other technological resources) of using smart pumps; studies with subcutaneous insulin; and those presented in other formats (reviews, editorials, notes, abstract without annals, articles without abstracts or those without access to the full text).

In the eligibility phase, a pair of reviewers read the documents independently and deciding by consensus in three moments: by title, title and abstract and full text. Documents

were excluded in each reading step as described in the Prisma Flow⁽¹⁵⁾ shown in Figure 1.

While reading the title, 114 of the 331 retrieved documents and organized in EndNote Web reference manager software were deleted because they were duplicates. Next, 198 of the 217 documents remaining during the abstract reading were excluded because they were out of the scope of the research. Finally, seven of the 19 evaluated documents were excluded when reading the full text because they did not meet the inclusion criteria. Thus, the judges decided to include 12 documents.



Source: Adapted from Moher et al.⁽¹⁵⁾.

Figure 1 – Flowchart of article selection in the systematic review.

DATA ANALYSIS AND PROCESSING

Considering that the articles had different ways to mention and exemplify infusion pump programming errors, the authors of this review considered and standardized the nomenclature according to what is described in Chart 2.

Data from the selected studies were organized in a Microsoft Excel 2010 spreadsheet for the organization and summarization of the main information: title, journal, year of publication, authors, design and results.

The meta-analysis was performed by random effect model, using RevMan 5.3 software, considering a 95% confidence interval for estimating relative risk (RR).

Chart 2 – Standardization of types and actions related to infusion pump programming errors.

Programming errors	
Conventional pump	Total volume and infusion rate values in milliliters/hour (ml/h) programmed differently from those recommended by the institutional insulin protocol.
Smart pump	Programmed values below the relative limit (drug sub-dose offer), values above the absolute limit (“over” dose of the drug) and errors related to dose calculation based on the patient’s weight out of the previously established (IU/kg/h; Mcg/kg/min) in the library.
Actions related to programming errors	
Error correction	Cases in which the values were reprogrammed before the beginning of the infusion and/or when the complete infusion cancellation occurred.
Error evolution	In cases where the programmed doses overlapped, meaning that the user is aware that the values are out of the ideal parameters, either by the values contained in the drug library, or by the insulin protocol values and still maintains the original dose/flow rate and starts the infusion.

ETHICAL ASPECTS

This review was part of a secondary study using economic modeling, approved by the Research Ethics Committee of the Universidade Federal do Estado do Rio de Janeiro under No. 1.596.339/2016. It was conducted according to the recommendations of the Good Clinical Practices and National Health Council Resolution No. 466 of 2012. The Informed Consent Form was waived.

RESULTS

There was a predominance of US publications (66.66%; n = 8), higher production of manuscripts from 2010 to 2016

(66.66%; n = 8) and with observational design (75%, n = 9). It was observed that the handling error rate using the conventional infusion pump ranged from 10% to 40.1%, and using smart technology ranged from 0.3% to 14%.

The 12 manuscripts included in the review presented information on the percentage of programming errors, correction and evolution, according to the handling of infusion pumps and the level of scientific evidence attributed to the quality of the included studies, in agreement with the Oxford Center for Evidence-Based Medicine Evidence Scale⁽¹⁴⁾. The selected articles are shown in Chart 3 below.

Chart 3 – Distribution of articles about programming errors of infusion pumps in intravenous insulin therapy in intensive care units from 2001 to 2016.

AUTHORS	YEAR/COUNTRY	TITLE	DESIGN	RESULTS	Oxford Centre for Evidence-Based Medicine evidence scale
Schnock K O et al. ⁽¹⁶⁾	2017/ United States	The frequency of intravenous medication administration errors related to smart infusion pumps: a multihospital observational study	Observational, multicenter Cross-sectional	SP programming errors: 5.1% CP programming errors: 10.3%	4C
Goulding C; Bedard M. ⁽¹⁷⁾	2015/ Canada	Safety implications of the dose change alert function in smart infusion pumps on the administration of high-alert medications	Observational, cross-sectional	SP error correction: 2% Evolution of SP errors: 58%	4C
Mansfield, J; Jarrett, S. ⁽¹⁸⁾	2013/ United States	Using Smart Pumps to Understand and Evaluate Clinician Practice Patterns to Ensure Patient Safety	Case report	SP programming errors: 7.5% SP error correction: 16% Evolution of errors in SP: 84%	4C
Cousins D; Cartwright E. ⁽¹⁹⁾	2013/ England	Implementing and evaluating the patient safety benefits of dose error reduction software in electronic infusion devices in an NHS Hospital Trust	Observational, cross-sectional	SP programming errors: 1.4% SP error correction: 21.5% Evolution of errors in SP: 66.3%	4C
Kastrup M et al. ⁽²⁰⁾	2012/ Germany	Analysis of Event Logs from Syringe Pumps	Observational, Retrospective, Cross-sectional	SP programming errors: 0.85% SP error correction: 6.5% Evolution of errors in SP: 87.6%	4C
Cayot – Constantin et al. ⁽²¹⁾	2010/ France	Assessment of the usefulness to use a software supervising continuous infusion rates of drugs administered with pumps in ICU and estimation of the frequency of rate of administration errors	Observational, cross-sectional	SP ¹ programming errors: 11%	4C
Evans R S. et al. ⁽²²⁾	2010/ United States	Enhanced Notification of Infusion Pump Programming Errors	Observational, cross-sectional	SP programming errors: 14% CP ² programming errors: 10.7% CP error correction: 3.8%	4C
Hennings S et al. ⁽²³⁾	2010/ United States	A Comparison of Automated Infusion Device Technology to Prevent Medication Errors in Pediatric and Adult Intensive Care Unit Patients	Observational, Retrospective, Cohort	SP programming errors: 0.3% SP error correction: 0.4%	2B
Nuckols TK. et al. ⁽²⁴⁾	2007/ United States	Programmable Infusion Pumps in ICUs: An Analysis of Corresponding Adverse Drug Events	Observational, Retrospective, Cohort	SP programming errors: 33%	2B
Husch M et al. ⁽²⁵⁾	2005/ United States	Insights from the sharp end of intravenous medication errors: implications for infusion pump technology	Observational, cross-sectional	SP programming errors: 10.5% SP error correction: 0.3%	4C
Rothschild JM et al. ⁽²⁶⁾	2005/ United States	A controlled trial of smart infusion pumps to improve medication safety in critically ill patients	Randomized clinical trial	SP programming errors: 5% Evolution of errors in SP: 2.1% CP programming errors: 10% Evolution of errors in CP: 1.7%	1B
Calabrese A et al. ⁽²⁷⁾	2001/ United States	Medications administrations errors in adult patients in the ICU	Observational, cross-sectional study	CP programming errors: 40.1%	4C

¹ Smart Pump; ² Conventional Pump.

The meta-analysis results revealed no heterogeneity between the two studies included in the meta-analysis.

Heterogeneity was estimated from the Tau², I² and Chi² tests, as shown in Figure 2.

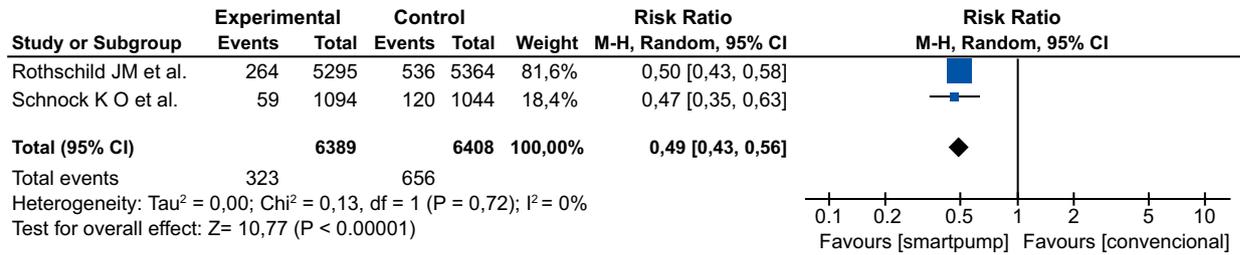


Figure 2 – Meta-analysis Forest Plot for the outcome of infusion pump handling errors in intravenous insulin administration.

The Forest Plot Graph of the meta-analysis (Figure 2) shows that the combined measurement of the estimated effects in the two studies suggests that using a drug library may be a protective factor (RR<1), thus being in favor of this technology.

The studies included in the meta-analysis do not differ regarding the characteristics of the analyzed populations (I² = 0%), however their designs are observational and therefore are considered fragile when compared to randomized clinical trials. Thus, they are lowered as to the level of evidence.

It is noteworthy that effectiveness studies are those which consider real aspects so that the outcome measure reflects the adversities experienced and not those attributed to chance, and therefore non-randomized studies are more appropriate to evaluate the effectiveness than the randomized studies.

However, the meta-analysis result showed that using the smart pump drug library compared to the conventional infusion pump can reduce the relative risk of programming errors by 51% (RRR = 1 – RR x 100) and with significant accuracy within a 95% confidence interval, ranging from 0.43 to 0.56. Therefore, this relative risk reduction may reach 57% in the best case scenario and 44% in the worst case scenario, which suggests a statistical significance at the p-value (0.05).

The risk evaluation for publication bias using a Funnel Plot with RevMan 5.3 software was impaired given the small number of articles included in the meta-analysis.

DISCUSSION

The quality of the evidence set and the recommendation strength considering the methodological weaknesses and the internal validity of the studies included in the meta-analysis were considered very low (GRADE).

Most studies were found in the United States and Europe, and no Brazilian studies were found. This enables us to assume that smart infusion pumps are not yet a reality in hospital practice or in Brazilian studies on the safety of patients with controlled intravenous insulin infusion.

Most authors^(16,18-26) highlighted how much programming errors are still present, even after implementation of smart infusion pumps in institutions. Also, considering a gap of at least 10 years late in the use of this smart technology in Brazil compared to the reality in Europe and the USA allows to reflect on how these infusion pumps are being incorporated into institutions, how they are handled, and above all, what can be done so that health professionals can

take full advantage of this technological resource to offer increasingly safe care.

Usability is a determining factor for the effective use of technology, and draws attention when the user underutilizes or ignores the configuration and/or safety alert which is essential to the patient’s drug safety. This can be attributed to the importance that the user attaches to available technology when its interface is not intuitive or easy to handle, or when faced with numerous long steps, or when protocols which are inaccessible are used to achieve the intended goal.

One study⁽²²⁾ pointed out that there was no significant difference between the percentage of programming errors occurred in using conventional pumps (10.7%) when compared to the errors occurred in handling smart pumps (14%)⁽²²⁾. In addition to the difference not being significant, this result showed that the percentage of errors in the smart pump was higher due to the fact that users of conventional pumps, were sensitized by identifying errors in the programming and corrected them (3.8%) before commencing infusion.

On the other hand, more recent studies⁽¹⁷⁻²⁰⁾ showed that there is still a high percentage of “error evolution” even after incorporating drug library infusion pumps, consisting of errors which occurred even when the health professional was warned about it. In these cases, the user ignored the infusion pump signaling about the programming error and started infusion under this condition.

The high rate in the error evolution percentage presented in the publications reveals a lack of awareness of those who handle infusion pumps about the harm they can cause the seriously ill patient. Technology is able to prevent further harm to patients, but it is not enough to prevent it from occurring given the imprudence of human intervention.

The most used tool for patient safety risk assessment from the nurse’s perspective is clinical auditing⁽²⁸⁾. A study⁽²⁸⁾ performed a survey of errors from reports issued by technology and spontaneous notification by the nursing staff. Although the fear of punishment is still a limiting factor, a discussion on errors can promote changes in important behaviors throughout the healthcare team, and this may impact the rate of errors observed in units as process failures are recognized. It was not the objective of the study in question, but the small difference in the error rates found in the two infusion pumps models can be considered, the repercussions that a medication error can generate in the critical care environment and the professional’s greater attention in identifying and quickly correcting their error regarding the

patient's severity or how this patient may get worse if there is any change in the insulin infusion dose.

Thus, the user does not seem to see the infusion pump as a technological barrier to error, but they view greater work attributed to its core activity so therefore they do not value it and do not use it to its full capacity. Studies which measure some of these usability issues linked to the health technology development industry are still scarce, and valuing the user experience and measuring its effects can help to understand the occurrence of errors related to performing tasks, especially because it involves light technology.

Of the 12 articles selected, only one⁽²²⁾ mentioned error correction in conventional infusion pumps, while another six^(17-20,23,25) addressed the possibility of correcting programming errors during infusion pump handling with the drug library. However, it is not reliable to state that adverse events were avoided because no harm to patients was reported.

Another point to be highlighted is the experience and usability level attributed to the professional who handles the drug library and who administers insulin to the patient. This variable (usability) related to the infusion pump user was not the object of this study, but was associated with sociodemographic characteristics, education level, digital inclusion/immigrant, English language proficiency, frequency and continuity of ICU training, among other facts which can influence the outcome, and this can be controlled by observing the equipment in use by populations (nurses) with the same characteristics and performance profile.

The literature also points out that the greater the number of associated technologies, the greater the chances of error interception and therefore the lower the incidence of

medication errors (in this case programming errors). This variable may have also interfered in interpreting the results, underestimating the listed rates and consequently compromising the internal validity of the study and limiting the extrapolation power of the results.

CONCLUSION

It is concluded that the smart pump can reduce the risk of programming errors; however, the scientific evidence indicates that even though health professionals nowadays have more access to increasingly complex technologies which enable safer care, such as the case with smart infusion pumps, programming errors related to handling this technology are closely related to professional awareness and human intervention, i.e. the human factor.

Thus, one should be aware of the usability of medical equipment and its close relationship with patient safety. One hopes that the research results may support adopting preventive measures in the occurrence of adverse events related to misusing infusion pumps, and especially emphasize the need for continuous training with the health team in order to qualify them to act as the first safeguard barrier to avoid errors.

In this sense, it was identified that smart infusion pumps are still a technology which is only available in a few institutions in Brazil, and for this reason it is suggested to develop institutional documents such as standards, routines, and protocols, in addition to further stimulating studies on safety measures which should be implemented to minimize and/or eliminate infusion pump programming errors.

Finally, further studies on effectiveness and usability are also suggested in order to reduce uncertainties before incorporating this technology, considering the limitations for extrapolating the results found.

RESUMO

Objetivo: Identificar as evidências científicas acerca da frequência de erros no manuseio das bombas de infusão convencional e *smart pump* na terapia insulínica intravenosa em unidades de cuidados intensivos. **Método:** Revisão sistemática com metanálise realizada nas bases de dados Biblioteca Virtual de Saúde, MEDLINE via PubMed, Scopus e Web of Science. Os artigos foram avaliados quanto ao nível de evidência pela aplicação da Escala de Evidência do *Oxford Centre for Evidence-Based Medicine*. **Resultados:** Foram selecionadas 12 publicações que atenderam aos critérios de elegibilidade. A taxa de erros de programação usando a bomba de infusão convencional variou de 10% a 40,1% e na tecnologia *smart pump* variou de 0,3 a 14%. A metanálise de dois estudos foi favorável a *smart pump* na redução do risco relativo de erros de programação em 51%. **Conclusão:** Considerando como base os artigos selecionados, a *smart pump* reduz o risco de erros de programação.

DESCRITORES

Bombas de Infusão; Insulina; Erros de Medicação; Enfermagem de Cuidados Críticos; Unidades de Terapia Intensiva; Revisão.

RESUMEN

Objetivo: Identificar las evidencias acerca de la frecuencia de errores en el manejo de las bombas de infusión convencional y *smart pump* en la terapia insulínica intravenosa en unidades de cuidados intensivos. **Método:** Revisión sistemática con metaanálisis llevada a cabo en las bases de datos *Biblioteca Virtual de Saúde*, MEDLINE por vía PubMed, Scopus y Web of Science. Los artículos fueron evaluados en cuanto al nivel de evidencia por la aplicación de la Escala de Evidencia del *Oxford Centre for Evidence-Based Medicine*. **Resultados:** Se seleccionaron 12 publicaciones que atendieron los criterios de elegibilidad. El índice de errores de programación utilizando la bomba de infusión convencional varió del 10% al 40,1% y en la tecnología *smart pump* varió del 0,3% al 14%. El metaanálisis de dos estudios fue favorable a la *smart pump* en la reducción del riesgo relativo de errores de programación en el 51%. **Conclusión:** Considerando como base los artículos seleccionados, la *smart pump* reduce el riesgo de errores de programación.

DESCRIPTORES

Bombas de Infusion; Insulin; Errores de Medicación; Enfermería de Cuidados Críticos; Unidades de Cuidados Intensivos; Revisión.

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