

Cost-effectiveness of infusion pumps to reduce errors in a Pediatric ICU

Custo-efetividade de bombas de infusão para a redução de erros em uma UTI Pediátrica
El costo-efectividad de bombas de infusión para la reducción de errores en una UTI Pediátrica

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ABSTRACT

Objective: To analyze cost-effectiveness and to calculate incremental cost-effectiveness ratio of the use of infusion pumps with drug library to reduce errors in intravenous drug administration in pediatric and neonatal patients in Intensive Care Units. **Methods:** Mathematical modeling for economic analysis of the decision tree type. The base case was composed of reference and alternative settings. The target population was neonates and pediatric patients hospitalized in Pediatric and Neonatal Intensive Care Units, comprising a cohort of 15,034 patients. The cost estimate was based on the bottom-up and top-down approaches. **Results:** The decision tree, after RollBack, showed that the infusion pump with drug library may be the best strategy to avoid errors in intravenous drugs administration. **Conclusion:** The analysis revealed that the conventional pump, although it has the lowest cost, also has lower effectiveness. **Descriptors:** Nursing; Technology Assessment, Biomedical; Cost-Benefit Analysis; Pharmaceutical Preparations; Drug-Related Side Effects and Adverse Reactions.

RESUMO

Objetivo: Analisar o custo-efetividade e calcular a razão de custo-efetividade incremental do uso de bombas de infusão com biblioteca de fármacos para reduzir erros na administração de medicamento pela via intravenosa, em pacientes pediátricos e neonatais em Unidades de Terapia Intensiva. **Método:** Modelagem matemática para análise econômica, do tipo árvore de decisão. O caso-base foi composto pelos cenários de referência e alternativo. A população alvo foram pacientes neonatos e pediátricos internados em Unidades de Terapia Intensiva pediátrica e neonatal, compondo uma coorte de 15.034 pacientes. A estimativa de custos foi baseada nas abordagens *bottom-up* e *top-down*. **Resultados:** A árvore de decisão, após *RollBack*, mostrou que a bomba de infusão com biblioteca de fármacos pode ser a melhor estratégia para evitar erros na administração de medicamentos intravenosos. **Conclusão:** A análise revelou que a bomba convencional, embora tenha o menor custo, tem também menor efetividade.

Descritores: Enfermagem; Avaliação da Tecnologia Biomédica; Análise Custo-Benefício; Preparações Farmacêuticas; Efeitos Colaterais e Reações Adversas Relacionados a Medicamentos.

RESUMEN

Objetivo: Analizar el costo-efectividad y calcular la razón de costo-efectividad incremental del uso de bombas de infusión con una biblioteca de fármacos para reducir errores en la administración de medicamentos por vía intravenosa, en pacientes pediátricos y neonatales en unidades de terapia intensiva. **Método:** Modelaje matemático para el análisis económico, del tipo árbol de decisión. El caso base se compone de escenarios de referencia y alternativo. La población objetivo fueron pacientes neonatos y pediátricos internados en unidades de terapia intensiva pediátrica y neonatal, componiendo una cohorte de 15.034 pacientes. La estimación de costos se basó en los enfoques *bottom-up* y *top-down*. **Resultados:** El árbol de decisión, después de *Roll Back*, mostró que la bomba de infusión con biblioteca de fármacos puede ser la mejor estrategia para evitar errores en la administración de medicamentos intravenosos. **Conclusión:** El análisis reveló que la bomba convencional, aunque tiene el menor costo, tiene también menor efectividad.

Descriptorios: Enfermería; Evaluación de la Tecnología Biomédica; Análisis Costo-Beneficio; Preparaciones Farmacéuticas; Efectos Colaterales y Reacciones Adversas Relacionadas con los Medicamentos.

INTRODUCTION

Drug administration is one of the most common interventions used in clinical practice. Drugs are routinely used in the hospital context, considering their diverse indications. However, its use offers several risks, especially when not used properly⁽¹⁾.

It should be noted that the medication process is interdisciplinary. Nursing participates in the phases of preparation, administration and monitoring of patients and, for this reason, it is pointed out as the category that has the ability to intercept errors⁽²⁾.

Injectable drugs administration is one of the most important and one of the most critical activities in a Pediatric Intensive Care Unit (PICU). This unit has clients in the age range of 29 days to 18 years of life, which is why the volume administered as well as the rate of infusion varies greatly according to the age and weight of patients.

Likewise, the type of pump used for infusion can also vary. Not infrequently, for injectable drugs with volumes up to 60 ml, syringe infusion pumps are chosen and, for those over 60 ml, the best option is the use of linear peristaltic finger-type infusion pump.

For this reason, injectable drugs administration in these units requires the direct involvement of the nurse and the use of high precision infusion pumps, which can increase the accuracy of the infusion.

Errors in venous infusions administered by infusion pumps are reported by nursing professionals; so much so that, in a study about lapses, slips and mistakes in the use of equipment in Intensive Care Units, a set of situations occurred in which there were errors that compromised patient safety. Among these, those involving infusion pumps (IP) were highlighted in the statements, due to the frequency of occurrence⁽³⁾.

Any error in the drug administration process can lead to what is conventionally called medication error. In general, the incidence of preventable adverse events, such as those related to medication errors, is high and its severity is higher than in non-preventable adverse events⁽⁴⁾.

Patients in Pediatric or Neonatal Intensive Care Units are among the most vulnerable ones. Prematurity, disease severity, limited compensatory mechanisms and prolonged hospitalization increase the risk of death, ranging from 6.94% to 17.6%. There is exposure to medication errors, especially in administration⁽⁵⁾.

Pediatric and neonatal patients can receive 15 to 20 intravenous medications per day in the PICU by means of infusion pumps. Severity could even be considered a justification for prescribing and using off-label medications, invoking the risk/benefit ratio. Therefore, this reinforces the need to evaluate this condition, taking into account the potential risk of sequel associated with the administration of these drugs, whose prevalence can reach 40%⁽⁶⁾.

Errors that occur in the administration are the most difficult to intercept and their impact depends on the route of administration, the type of drug and the characteristics of the patient⁽⁷⁾.

Therefore, ensuring greater safety in the handling of injectable drugs with a narrow therapeutic window administered intravenously to critically ill pediatric patients should be a priority.

In the past five years, the Emergency Care Research Institute (ECRI) has been pointing out errors in drug administration

involving the use of infusion pumps in its TOP 10 list of health technology hazards. For 2017, ECRI warns, at the top of its list, that infusion errors can be fatal if simple safety steps are ignored, despite the fact that infusion pumps⁽⁸⁾.

Studies reveal alarming data on the problems related to drug administration in PICUs. It is estimated that 74% of the patients hospitalized in these units suffered some type of incident; 84% suffered adverse events (AE); and 66% of the errors occurred were related to drugs, of which 38% were due to dosing errors, followed by omission and administration errors⁽⁹⁾.

Mortality associated with ADE is not yet well documented in the literature. There are no national data on this regard. It is estimated that the probability of permanent sequels and deaths of patients in the Neonatal Intensive Care Unit (NICU), caused by adverse events, is 0.6%. NICU can be characterized as a unit that receives patients less than 29 days old⁽¹⁰⁾.

Regarding the financial magnitude and length of stay related to adverse events, another study identified that the amount spent on hospital admissions is 200.5% higher in the occurrence of events than in hospitalizations without events. In addition, hospitalization time is, on mean, 28.3 days longer⁽¹¹⁾.

For these reasons, a number of actions have been proposed to reduce errors in drugs venous administration and costs of associated adverse events over the last decade. Equipment is being standardized as has been done with drug concentrations⁽¹²⁾.

In Brazil, smart pumps, with dose-reduction software (drug library), are being made available on the market and are recommended as an alternative to reduce errors in injectable drugs administration in Intensive Care Units.

However, the incorporation of this technology in the infusion of injectable drugs in health services may still be impaired in recent years, with the consequent reduction of dose errors during infusions; and the cost of their inputs.

Based on the above, the structured question of research is: does the infusion pump with drug library compared to the conventional infusion pump have a good cost effective to reduce rates of adverse drug events (ADE) during intravenous drug administration in pediatric patients and neonates in Intensive Care Units?

OBJECTIVE

This study aims to analyze cost-effectiveness and calculate the incremental cost-effectiveness ratio (ICER) of infusion pumps with drug library to reduce ADE during intravenous drug administration in pediatric and neonatal patients in Intensive Care Units.

METHODS

Ethical aspects

This is a study of Health Technology Assessment (HTA), which can be understood as a comprehensive way to investigate the technical (often clinical), economic and social consequences of the use of health technologies in the short and long term, as well as its direct and indirect effects, both desirable and undesirable⁽¹³⁾.

It was delineated as a mathematical model for economic analysis, of the decision tree type, and followed the recommendations of the *Diretriz Metodológica de Avaliação Econômica* (freely translated as Methodological Guideline for Economic Assessment)⁽¹⁴⁾ of the Ministry of Health of Brazil. Thus, it should be emphasized that the manuscript does not need presentation of the Opinion of the Research Ethics Committee.

Design, place of study and period

Considering that mathematical modeling settings were used, the base case was composed of two settings: a reference one, using conventional infusion pumps, without drug library; and an alternative, using infusion pumps with drug libraries. The model suggests that the problem of the study begins with the possibility of avoiding ADE during intravenous injections administration with volumes greater than 60 ml, using peristaltic volumetric infusion pumps.

In the reference setting, the volumetric peristaltic type infusion pump was used. In the alternative setting, infusion pumps were used with drug libraries, replacing conventional infusion pumps.

It was considered, in the modeling, that the infusion pump used in the reference setting is a single channel, whose infusion sets are replaced every 72 hours of use. In the alternative setting, the infusion pump with drug library, single channel, has infusion equipment that is replaced every 96 hours of use, according to the manufacturer's recommendation.

In both settings, different probabilities of intercepting errors and avoiding ADE are expected. When these errors are not intercepted and ADE occur, they may result depending on their severity, length of stay or death of the patient.

Population or sample; inclusion and exclusion criteria

The target population was neonates and pediatric patients admitted to Pediatric and Neonatal Intensive Care Units. Population was estimated by the epidemiological method, considering the number of patients hospitalized in public health network hospitals, linked to the State Health Department (SHD) of the state of Rio de Janeiro, in 2015, comprising a cohort of 15,034 patients. Considering the method used, inclusion and exclusion criteria are not used.

Study protocol

The following assumptions were assumed and incorporated into the model:

1. The mean length of stay in the Intensive Care Unit is 19.61 days, ranging from 18.88 to 20.92 days of hospitalization (SHD-RJ);
2. Equipment for infusions using conventional pumps are changed every 72 hours; and using drug library pumps, every 96 hours (pump manufacturer's recommendation);
3. The mean number of infusion pumps needed to meet the demand for injectable drugs in the unit is 3 pumps per patient/day (arbitrary);
4. Willingness to Pay (WTP) was estimated at 1 GDP Per capita R\$ 28,105.41 (Brazilian currency, *reais*), considering the year 2016

(Per Capita GDP of USD 8,649.95) and the US dollar quotation on 12/29/2016 that was R\$ 3.2492;

5. From 14% to 38% of patients admitted to an ICU will experience adverse events related to drug dose errors, resulting in prolonged hospitalization time⁽⁹⁾;
6. The mean rate of serious ADE is 0.023, ranging from 0.022 to 0.024⁽¹⁵⁾;
7. In the event of serious ADE, admission to the unit may last from 17 to 28.3 days⁽¹¹⁾;
8. The probability of death of patients in the Intensive Care Unit caused by ADE is 0.6%⁽¹⁰⁾;
9. The use of conventional infusion pump can prevent ADE related to the dose error of 62% to 86% of infusions of intravenous injectable drugs in Intensive Care Unit, and drug library infusion pumps of 79% to 90%^(9,15).

Analysis of results, and statistics

The analysis was based on the *Sistema Único de Saúde* (Brazilian Unified Health System). The mean time of 19.61 days of these patients in the Intensive Care Unit was considered, which is the time horizon of the study. The method used for cost estimation was based on bottom-up and top-down approaches. No discount or inflation rates were applied, considering the short time horizon.

The uncertainties of the model were treated by probabilistic sensitivity analysis, based on the Monte Carlo simulation, considering cost variables. They were assigned Gamma distributions and probability variables. These variables included effectiveness, and probability variables. These variables included effectiveness, for which were assigned Beta distributions. α (alpha) and β (beta) distributions of Beta distributions, and α and λ lambda of Gamma distributions were estimated from means and standard deviations of the variables used in the analyzes.

The TreeAge® Software was used to construct the Decision Tree Model for cost-effectiveness analysis, according to Figure 1. The decision tree was chosen considering the short time horizon of the analysis (19.61 days); it was envisaged that the model will work adequately with the study population group (Pediatric and Neonatal Intensive Care Unit) patients exposed to errors and ADE during intravenous infusion pump administration and the time available for analysis and conclusion of the study.

Annual costs by settings were estimated from a literature review. Only direct medical costs were considered, referring to the "therapeutic package", consisting of costs with hospitalization in the bed of intensive therapy (top-down); costs related to the equipment required for each of the infusion pumps (bottom-up); costs of adverse events resulting from errors with intravenous drug administration (top-down); and extra daily costs resulting from the adverse events that caused postponement of the discharge from the unit (top-down).

Hospitalization costs in the reference setting were estimated between R\$ 3,002.4 and R\$ 8,893.37, with a mean of R\$ 5,947,885, for approximately 20 days of stay (hospitalization). The mean value for admission to the Infant ICU I, Infant ICU II, Infant ICU III, Neonatal ICU I, Neonatal ICU II, Neonatal ICU III in hospital admissions (approved) performed in the state of Rio de Janeiro in 2016. In the therapeutic package were added a further R\$ 434.00, referring to the cost with 20 equipment of conventional infusion

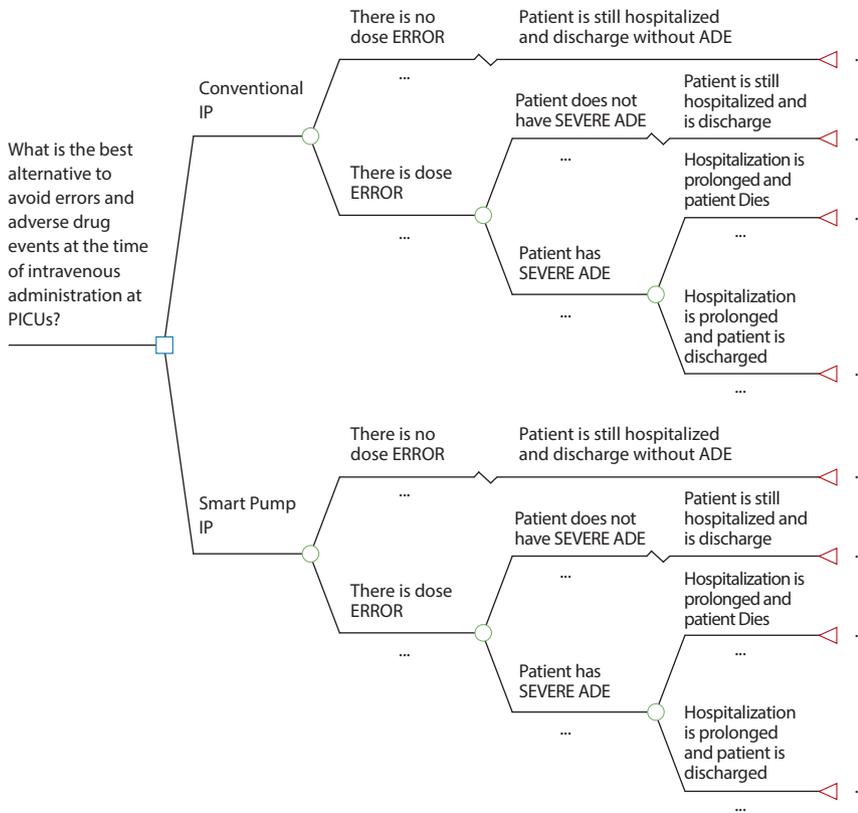


Figure 1 –Decision Tree Model's structure. Jan. 2017

pumps, necessary to meet the demand for infusions during hospitalization.

In the alternative setting, using infusion pumps with drug libraries, hospitalization costs increased by a further R\$ 1,238.40, related to the cost of 15 infusion pumps with a drug library, necessary to meet the demand for infusions during hospitalization.

Equipment's mean cost was estimated at R\$ 82.56, ranging from R\$ 76.80 to R\$ 88.32 for the smart pump equipment. For the conventional pump equipment, the mean cost was estimated at R\$ 21.70, which can range between R\$ 18.80 and R\$ 24.60. These are values used for sale, directly by the company B. Braun, referring to pumps equipment of Infusomat Space® and Infusomat Compact®, respectively.

Preventable adverse events costs were estimated at R\$ 3,200.00 per day of hospitalization. For purposes of estimating avoided costs, only those resulting from errors related to infusion of intravenous drugs with potential for serious adverse events were considered, having as sources of information the scientific literature⁽¹⁶⁾. Distributions for probabilistic sensitivity analysis are shown in Figure 2.

Figure 2 - Distributions and their respective parameters imputed in the model. Text Report of distributions imputed in the Model and created by the author using the Treeage® software. January 2017.

Type	Name (distribution)	Description	Alpha	Lambda Beta
gamma	dist cost hosp sp	distribution of hospitalization costs with smart pump	(7186.28^2) (4165.544^2)	$7186.28/(4165.544^2)$
beta	dist_efe_sp	distribution of discharge effectiveness with cp without ade	$((0.9064^2)$ $* (1-0.9064)/(0.04044^2))$	$(0.9064*(1-0.9064)/$ $(0.04044^2))-((0.9064^2)*(1-$ $0.9064)/(0.04044^2))$
beta	dist_efe_cp	distribution of effectiveness of cp	$((0.74^2)$ $* (1-0.74)/(0.1697^2))$	$(0.74*(1-0.74)/(0.1697^2))-$ $((0.74^2)*(1-0.74)/(0.1697^2))$
gamma	dist hosp cost cp	distribution hospitalization costs using conventional pump	$(6381.88^2)/(4165.544^2)$	$6381.88/(4165.544^2)$
gamma	dis_costs_ade	distribution of costs with ade	$(72480.00^2)/(25568.981^2)$	$72480.00/(25568.981^2)$
beta	dist dose erro prob	distribution of the dose error probability	$((0.26^2)*(1-0.26)/(0.1697^2))$	$(0.26*(1-0.26)/(0.1697^2))-$ $((0.26^2)*(1-0.26)/(0.1697^2))$
beta	dist sev ade prob	distribution of occurrence of severe ade probability	$((0.023^2)*(1-0.023)/(0.001414^2))$	$(0.023*(1-0.023)/(0.001414^2))-$ $((0.023^2)*(1-0.023)/$ $(0.001414^2))$
beta	dist_death prob_sev ade	distribution of death probability by severe ade	$((0.03^2)*(1-0.03)/(0.04242^2))$	$(0.03*(1-0.03)/(0.04242^2))-$ $((0.03^2)*(1-0.03)/(0.04242^2))$

RESULTS

The decision tree, after RollBack, showed that the infusion pump with drug library may be the best strategy to avoid ADE during intravenous drugs administration.

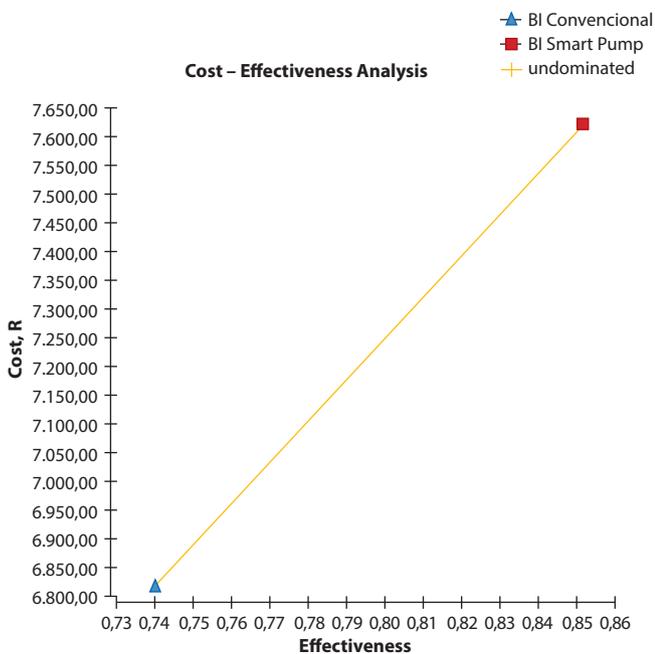


Figure 3 - Cost-Effectiveness Acceptance Curve Chart. Cost-Effectiveness Analysis of the Decision Tree Model proposed by the author and created using Treeage[®] software. Rio de Janeiro, RJ, Brazil, 2017

It is possible, in the base case, to achieve a mean effectiveness of up to 0.86, which corresponds to avoiding dose-related ADE in 86% of intravenous drug infusions using drug library infusion pumps, at a cost that can vary from R\$ 7,600.00 to R\$ 7,650.00. An effectiveness of up to 0.74 can be achieved by using conventional infusion pumps at a cost that can vary from R\$ 6,800.00 to R\$ 6,850.00 (Figure 3).

The cost-effectiveness analysis revealed an incremental cost-effectiveness ratio (ICER) of R\$ 4,834.13, within the willingness to pay threshold defined in the base case.

This ICER means that in order to obtain an additional unit of effectiveness. In other words, to avoid a ADE due to a dose error in the base case, using an intelligent infusion pump, it is necessary to pay an additional R\$ 4,834.13.

The acceptability curve, according to Figure 3, has shown that the probability that the drug library infusion pump is more cost-effective than the conventional infusion pump becomes larger, from a willingness to pay threshold of just over R\$ 6,000.00. Considering the willingness to pay threshold of R\$ 28,105.41, the probability that the infusion pump with a drug library is cost-effective is 75%.

CE Acceptability Curve
 ■ BI Convencional
 ▲ BI Smart Pump

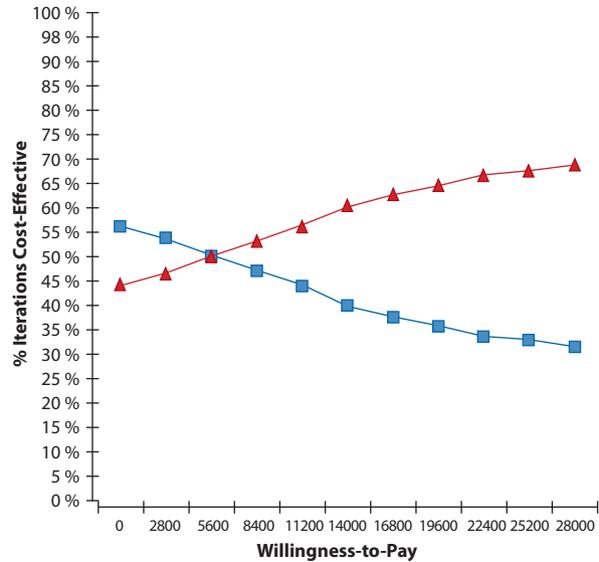


Figure 4 - Cost-Effectiveness Acceptance Curve Chart. Cost-Effectiveness Analysis of the Decision Tree Model proposed by the author and created using Treeage[®] software. Rio de Janeiro, RJ, Brazil, 2017

In the probabilistic analysis, 10,000 second-order Monte Carlo simulations were performed to deal with the uncertainties related to the variability of the imputed parameters in the model. Scatter plots of cost-effectiveness were generated according to Figure 5.

The effectiveness of the infusion pump with drug library varied between 75% and 99% (red triangle in the graph), with little scatter. With regard to costs, scatter was slightly higher, with a higher concentration of simulations between the ranges of R\$ 2,000.00 and R\$ 10,000.00.

Cost - Effectiveness Scatterplot

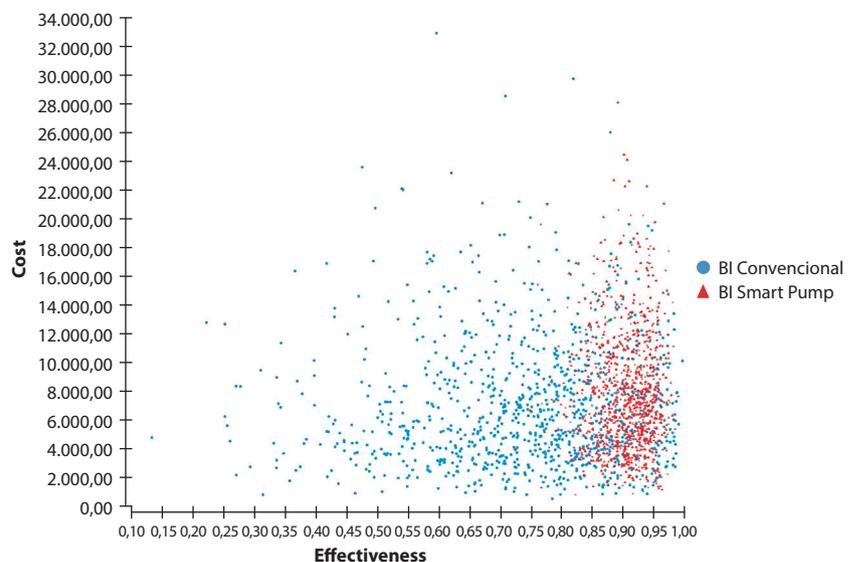


Figure 5 - Scatter Plot of Cost-Effectiveness Source. Probabilistic sensitivity analysis (Monte Carlo) of the Decision Tree Model proposed by the author and created using Treeage[®] software. Rio de Janeiro, RJ, Brazil, 2017

Scatter plot also shows a great scatter in relation to the effectiveness of the conventional infusion pump (blue circle), varying between 15% and 99%, with a higher concentration of the simulations in the range of 70% to 90%. In terms of costs, scatter was very similar to that observed in the drug library infusion pump, but with a slightly higher variability.

DISCUSSION

The study presented a brief review of the literature on effectiveness of the use of conventional infusion pumps and drug libraries, using the information derived from this review to support the assumptions assumed and imputed in the presented Decision Tree Model. The predominance of observational studies was noticed as characteristic of the researched literature.

Economic analysis results estimated the cost-effectiveness ratio of the use of infusion pumps with drug libraries for reduction of dose-related adverse events in intravenous injectable drugs administration in Pediatric and Neonatal Intensive Care Units. As there was no dominant strategy, any of the strategies may be cost-effective, depending on the willingness to pay for them.

The analysis revealed that the conventional pump, although it has the lowest cost, also has lower effectiveness. Differently, the drug library infusion pump presented higher cost and greater effectiveness.

Some studies have been inconclusive regarding the effectiveness of smart pumps in the reduction of ADE, demonstrating that there is no risk reduction associated with the implantation of smart pumps⁽¹⁷⁾, although others conclude that this technology can prevent dosing errors, thus increasing the patient safety⁽¹⁸⁾.

Considering the deterministic analysis and the willingness to pay (WTP), which in the base case is R\$ 28,105, 41, the best strategy for avoiding dose-related ADE during infusion of intravenous drugs is the infusion pump with drug library.

Reduction of ADE due to dose error when using infusion pumps can represent a significant saving of resources and an increase of saved lives, in view of the potential death related to these events.

In the base case, with a disbursement of R\$ 28,000.00, there is a 75% probability that the infusion pump with a drug library will be cost-effective if it is used to reduce the dose-related ADE rate in venous infusions of drugs in Intensive Care Unit. The highest probability that the conventional pump is cost-effective is 55% and this probability percentage can be reached if the willingness to pay threshold is R\$ 6,000.00.

In all 10 thousand simulations, only 4 exceeded the willingness to pay threshold of just over R\$ 28,000.00, which reduces the uncertainty of the model regarding the option of incorporating the infusion pump with a drug library, considering this willingness to pay.

Probabilistic analysis has shown that the infusion pump with drug library is actually more cost-effective than conventional, confirming what has already been revealed by the acceptability curve. This curve demonstrated that the infusion pump with drug library is more likely to be cost-effective compared to the conventional infusion pump, from a threshold of approximately R\$ 6,000.00.

Study limitations

Due to the short time available for this study, it was not possible to implement the budget impact analysis of the adoption of the strategy with the best cost-effective for the target population. Thus, it is suggested that the complementary economic analysis be studied.

Contributions to the fields of Nursing, Health or Public Policy

The measure of effectiveness of interest in this study is the avoided ADE rate related to dose errors during infusion of drugs using infusion pumps.

Thus, by avoiding ADE, gains of benefits for the studied population is provided, which are so greater the greater the effectiveness of the strategy used. The study demonstrated that using infusion pumps with drug libraries is more cost-effective than using conventional infusion pumps.

CONCLUSION

The results of this economic analysis may represent a new perspective to address the problem of ADE related to dose errors in infusions of drugs in the PICU and NICU, almost always addressed in the scientific literature, from two approaches not rarely dissociated from one another.

The first approach is based on the concern with the increase of ADE rates in these units, which has contributed to the advancement of the scientific knowledge about the best strategy to reduce them. The second is related to the increase in hospital costs associated with the incorporation of technologies and the adverse event itself. The same is made explicit in the growing number of published studies on the subject, although their results do not have robustness and strength of recommendation to offer solid support to the conducts on this situation.

The new perspective pointed out by the results of cost-effectiveness analysis expands the discussion beyond horizons of isolated analyzes of effectiveness and costs of strategies for the reduction of ADE in PICUs and NICUs. In the same study, it considers costs and benefits of adopting one or another strategy, drawing attention to the effectiveness achieved with the strategy in terms of avoided ADE related to drug dose error.

Therefore, since using infusion pumps with drug libraries is more cost-effective, the possible constraint to adopting this strategy could be only of budget.

Considering a scale of evaluation of the reliability of the scientific evidences, its contribution can be very useful to understand the problematic of this study, although the value of observational studies can be reduced in the absence of more consistent data, and for effectiveness evaluation purposes.

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