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Original Article

Validation of a safety assessment instrument for chronic renal patients on hemodialysis

Validação de instrumento de avaliação da segurança de pacientes renais em hemodiálise

Validación de instrumento de evaluación de la seguridad de pacientes renales en hemodiálisis

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Descritores
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Descriptores
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Abstract
Objective: To construct and validate a safety assessment instrument for chronic renal patients on hemodialysis.
Methods: Methodological study that comprised the instrument's construction and content validation by 14 experts, and evaluation of its understanding by nine nurses. Construction was based on the health legislation on hemodialysis and international patient safety standards. For analysis of the experts' agreement, intraclass correlation coefficient, content validity index, and binomial test were calculated.
Results: The items of the Likert-type scale were distributed into the six international patient safety goals, with 0.98 intraclass correlation coefficient. The final instrument had 57 items with a 0.96 content validity index, and binomial test ≥ 0.86.
Conclusion: The assessment instrument was considered understandable, relevant, and compatible with safety standards, showing content validity and compatibility to assess patient safety in hemodialysis treatment environments.

Resumo
Objetivo: Construir e validar um instrumento de avaliação da segurança de pacientes renais crônicos em hemodiálise.
Métodos: Estudo metodológico que abrangeu elaboração do instrumento e validação de conteúdo por 14 juízes; e avaliação da compreensão, por nove enfermeiros. A construção foi fundamentada na legislação sanitária sobre hemodiálise e padrões internacionais de segurança de pacientes. Para análise da concordância dos juízes, foi calculado o Coeficiente de Correlação Intraclasse, Índice de Validade de Conteúdo e teste binomial.
Resultados: Os itens do instrumento do tipo *Likert* foram distribuídos nas seis metas internacionais de segurança de pacientes, obtiveram Coeficiente de Correlação Intraclasse de 0,98. O instrumento final ficou com 57 itens com Índice de Validade de Conteúdo de 0,96 e teste binomial ≥0,86.
Conclusão: O instrumento foi considerado compreensível, relevante e condizente com os padrões de segurança, tendo demonstrado validade de conteúdo e compatibilidade para avaliar a segurança do paciente em ambientes de tratamento hemodialítico.

Resumen
Objetivo: Construir y validar un instrumento de evaluación de la seguridad de pacientes renales crónicos en hemodiálisis.
Métodos: Estudio metodológico incluyendo elaboración del instrumento y validación de contenido por 14 expertos; y evaluación de comprensión por nueve enfermeros. Construcción fundamentada en legislación sanitaria sobre hemodiálisis y en estándares internacionales de seguridad de pacientes. Concordancia de expertos calculada por Coeficiente de Correlación Intraclase, Índice de Validez de Contenido y test binomial.
Resultados: Los ítems del instrumento del tipo Likert fueron distribuidos en las seis metas internacionales de seguridad de pacientes, obtuvieron Coeficiente de Correlación Intraclase de 0,98. El instrumento final constó de 57 ítems con Índice de Validez de Contenido y test binomial ≥0,86.
Conclusión: El instrumento fue considerado comprensible, relevante y condicente con los estándares de seguridad, habiendo demostrado validez de contenido y compatibilidad para evaluar la seguridad del paciente en ámbitos de tratamiento hemodialítico.

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Introduction

Chronic renal patients on hemodialysis are vulnerable to a greater occurrence of adverse events (AE) due to the presence of comorbidities associated with kidney failure, recurrent use of invasive devices, and polypharmacy.[1]

In addition, some factors inherent to the hemodialysis unit may facilitate the occurrence of events: continuous infusion of high monitoring medications, long periods of routine and repetitive activities, continuous handling of patients by different professionals, infections, problems related to vascular accesses, and poor communication in urgent decisions associated with treatments.[1,2]

1. One study carried out in Scotland estimated that, of a total of 1551 deaths of patients on hemodialysis, 2.1% were due to complications such as hemorrhage by vascular accesses and falls, 9.6% due to infections associated with health care, and 9.3% due to failures or vascular access infections.[1] However, one study carried out in Brazil evaluated 117 medical records of patients on hemodialysis and showed a prevalence of 80.3% of AE.[3]
2. One strategy to improve patient safety culture in dialysis units is the development of specific and validated instruments able to identify the safety level in processes associated with the care provided in this setting, which may point out non-compliance gaps with safety standards.[4,5]

Therefore, the objective of the present study was to construct and validate a safety assessment tool for chronic renal patients on hemodialysis.

Methods

A methodological study based on Pasquali's psychometric theory[6] was carried out in three phases: instrument's construction, content validation, and evaluation of understanding by the target population, from January to December 2015.

The instrument's construction was carried out based on literature review in the portal of dissertations and theses of the CAPES, in the Scientific Electronic Library Online (SciELO), Medical Literature Analysis and Retrieval System Online (MEDLINE) via Pubmed (Public/Publish Medline), Scopus, and Literature in the Health Sciences in Latin American and the Caribbean (LILACS) databases and libraries.

Other theoretical foundations were considered, as follows: Accreditation standards of the Joint Commission International for certification of clinical care programs; resolutions no. 154/2004 and 11/2014 of the Brazilian National Health Surveillance Agency (ANVISA, as per its acronym in Portuguese); and Patient Safety National Program no. 529/2013.[7-10]

The construction's stage of the safety assessment instrument for chronic renal patients on hemodialysis (IASPRCH, as per its acronym in Portuguese) occurred from January to April 2015, and initially consisted of 62 items distributed into the six international patient safety goals.

In order to achieve the number of experts recommended by Pasquali[6] (six to 20), a higher number of experts were invited, considering that some could not respond or would refuse the invitation. They were selected through a search in resumes available in the Lattes Platform. The following inclusion criteria were considered: having experience in at least one of the thematic areas of the instrument (patient safety or hemodialysis) and validation of instruments.

After the search, 41 eligible experts were chosen. These received an invitation letter by email and had up to 20 days to return the instrument, in addition to an informed consent form (ICF) with instructions to carry out analysis and evaluation.

The instrument to be filled in for validation was constructed in Google Docs with initial information about the characteristics of the participants and items of the instrument with dichotomous questions about clarity, understanding, relevance, and if the item was associated with the safety of patients on hemodialysis. Each item had a space where experts could provide suggestions.

Of the 41 experts invited, 20 did not answer the email; two did not agree to participate in the study; and five did not answer within the estimated

time. In the end, 14 experts carried out the content validation.

After the expert validation, the IASPRCH went through analysis of the items' understanding, which consisted of the evaluation of intelligibility carried out with the target population.[5] Then, nephrologist nurses of three hemodialysis clinics in Fortaleza, capital city of the state of Ceará, were selected by convenience, totaling 12 professionals.

Nurses were approached in person in the abovementioned clinics, received an invitation letter, the ICF, and instruments for IASPRCH evaluation. The delivery time agreed was 20 days. The instrument contained questions regarding socio-professional characteristics, followed by dichotomous questions with regard to each item's understanding, with a space for suggestions.

For analysis of experts' agreement, in the content validation, the intraclass correlation coefficient (ICC) was calculated for each dimension of the instrument. The ICC is considered excellent when higher or equal to 0.75.[11]

For verification of nephrologist nurses' agreement, in the evaluation by the target population, the content validity index (CVI) was calculated, and the items with agreement equal or higher than 80% were considered valid.[6]

The binomial test was used to compare whether the proportion of nurses who agreed was statistically equal or higher than 0.80. It is worth mentioning that, for the tests carried out, a significance level of 5% and confidence interval of 95% were considered.

The present study was approved by the research ethics committee of the State University of Ceará, under protocol no. 984.409.

Results

The mean age of the experts who validated the instrument was 41±9 years, mean time of experience in hemodialysis was 10±8 years, and 13 (92.8%) were researchers in the patient safety or hemodialysis area. The overall ICC of the instrument was 0.98, with p <0.001, and the coefficient of each dimension is presented in table 1.

Table 1. Calculation of the ICC of the IASPRCH dimensions

Dimensions	*ICC	**95% CI
1- Patient identification	0.85	0.71 – 0.94
2- Effective communication	0.80	0.62 – 0.92
3- Administration of potentially dangerous medications	0.91	0.83 – 0.96
4- Proper procedure and intervention site	0.94	0.90 – 0.98
5- Risk of infections	0.94	0.89 – 0.97
6- Risk of injuries due to falls	0.95	0.90 – 0.98

*ICC – Intraclass correlation coefficient; ** CI – Confidence interval

The experts suggested an alteration in the dimension "correct identification", with the replacement of terms. However, in the dimension "effective communication", the item "receiving any type of prescription by verbal order" was modified, because experts affirmed that it would violate patient safety principles.

The designation of dimension 3 "administration of high monitoring medication" was replaced by "administration of potentially dangerous medications". In the dimension "proper procedures and intervention site", the term "surgical" was added to some items, specifying the type of procedure.

In the dimension "risk of infections", the need for Anti-HBs test "for nursing technicians" and specification of "positive serology for hepatitis C and human immunodeficiency virus (HIV)" were added. In the dimension "risk of falls", an item regarding the distance between armchairs/beds was modified.

At last, in the third stage of the study, which was the evaluation of the IASPRCH items' understanding by nine hemodialysis nurses, these presented a mean age of 39±11 years and mean length of professional experience in the area of 10±9 years, and most (88.9%) were specialists in nephrology nursing.

In the evaluation of understanding, the total CVI of the instrument with 62 items was 0.94. However, 18 items were evaluated as of difficult understanding. Of these, five items presented a CVI and binomial test lower than recommended, ranging from 0.66 (p=0.261) to 0.77 (p=0.563), thus being removed. After removal of the items, the instrument had 57 items, with a total CVI of 0.96 (Table 2).

The IASPRCH was completed with 57 items distributed into the following dimensions regarding the six national patient safety goals: patient iden-

Table 2. Binomial test for the items of the dimensions identification, effective communication, and potentially dangerous medications

Items	n(%)*	p-value**
1. Legible identification of the dialyzer and lines with patient name, serology, and first date of use.	9(100.0)	1.00
2. Identification of the hemodialysis session control sheet with: name, individuals taxpayers' register, date of birth, patient identification at the clinic, serologies, and HD session data.	9(100.0)	1.00
3. Supervision carried out by nurses together with nursing technicians before the beginning of each session, checking the correct identification of the hemodialysis control sheet, dialyzer, and lines. In addition to the undertaking of devices' pre- and post-test before each session for system's sterilization assurance.	9(100.0)	1.00
4. Identification of blood collection bottles with type of test, patient name, and other identification methods, such as individuals taxpayers' register and date of birth.	9(100.0)	1.00
5. Use of labels for record of medication dilution with dose, date, dilution time, name of the professional responsible for dilution, and patient name.	9(100.0)	1.00
6. Storage in washable compartments of the hemodialysis system with legible identification, patient full name, date of birth, differentiation by shifts, and serologies.	8(89.0)	0.86
7. Checking of any medication before administration applying the nine certainty technique: right patient, right medication, right dose, right time, right route of administration, right documentation, right action, right way, and right response.	8(89.0)	0.86
8. Full record with legible letter of test results received and signature of the professional who received information.	9(100.0)	1.00
9. Record in the patient's medical file with all information regarding clinical evolution and care provided. The same must contain the signing of each nursing professional and multidisciplinary team.	9(100.0)	1.00
10. Presence of a nursing station close to the hemodialysis room with easy access for professionals, which allows seeing all patients, with availability of the material required for hemodialysis.	8(89.0)	0.86
11. Availability of all measurement values of the internal volume of the dialyzer's fibers (prime) obtained during its processing. They must be recorded, dated, separated by shifts, and signed by the person who undertook the process for eventual consultation from patients and health authority, and kept in the patient's medical record.	9(100.0)	1.00
12. Availability of technical reports of analyses of the treatment and distribution system of water for hemodialysis, for technicians and health inspection, in accordance with the frequency required by the current legislation.	8(89.0)	0.86
13. Supervision of potentially dangerous medication administration carried out by nursing technicians and nurses (epinephrine, norepinephrine, propofol, dipyrone, propranolol, metoprolol, lidocaine, amiodarone, heparin, insulin, oral hypoglycemic agents, intravenous inotropic agents, neuromuscular blockers, intravenous moderate sedatives, acidic and basic solutions, injectable sterile water, injectable potassium phosphate, calcium gluconate, hypertonic glucose).	9(100.0)	1.00
14. Storage of potentially dangerous medications in exclusive and appropriate place.	9(100.0)	1.00
15. Visible and legible identification of the storage place for potentially dangerous medications.	9(100.0)	1.00
16. Use of devices that cause barriers in the occurrence of errors with the administration of potentially dangerous medications, such as bar codes.	8(89.0)	0.86
17. Publication of a list of all medications, especially of those potentially dangerous, used in the institution.	8(89.0)	0.86
18. Incorporation of security warning in computer systems of dispensation and prescription of potentially dangerous medications.	8(89.0)	0.86
19. Establishment and publication of maximum doses of potentially dangerous medications to be used in the unit.	9(100.0)	1.00
20. Standardization in the preparation and administration of potentially dangerous medications, thus preventing errors.	9(100.0)	1.00
21. Dispensation of potentially dangerous medications in containers for each patient and separated from other medications.	8(89.0)	0.86
22. Appropriate storage of acidic and basic solutions for hemodialysis out of direct sunlight, in good conditions of ventilation and environmental hygiene, according to manufacturer's recommendations and expiration date control.	9(100.0)	1.00

*n – Percentage agreement; ** p – Binomial test

Table 3. Binomial test for the items of the dimensions proper procedures and intervention site, risk of infections, and risk of injuries due to falls

Items	n(%)*	p-value**
23. Check of the correct puncture site and fremitus before puncturing the fistula.	9(100.0)	1.00
24. Check of the dressing's look, ostium, and catheter flow before connecting patients to the hemodialysis device.	9(100.0)	1.00
25. Check of all tests (TAP ‡, TTPA§, hemogram) required for the undertaking of the surgical procedure, carried out by nurses.	8(89.0)	0.86
26. Conducting of the time-out - All professionals of the team verbally confirm names and professions, patient identification, site or procedure to be carried out right before the beginning of the procedure.	9(100.0)	1.00
27. Antisepsis of the procedure's correct site.	9(100.0)	1.00
28. Patient guiding regarding critical steps of the procedure, its estimated duration, and possible complications.	9(100.0)	1.00
29. Patient questioning, before the procedure, regarding the presence of allergies and use of anticoagulants.	9(100.0)	1.00
30. Check of the informed consent form signed by the patient or accompanier before the beginning of the procedure.	9(100.0)	1.00
31. Prophylactic antibiotic administration after procedure.	8(89.0)	0.86
32. Hand hygiene of the nursing team before and after each procedure.	9(100.0)	1.00
33. Change of gloves at each new procedure (such as dressings, device handling, and hemodialysis system) by the nursing team.	9(100.0)	1.00
34. Undertaking of dressings with aseptic technique by nurses.	9(100.0)	1.00
35. Disinfection and cleaning of the device and surfaces that come into contact with patients at each session.	9(100.0)	1.00
36. Allocation of nursing technicians, with anti-HBs‖ reagent, exclusive for the care of patients with positive serology for hepatitis B, C, and HIV¶ during the whole hemodialysis session, thus preventing cross-infection.	9(100.0)	1.00
37. Exclusiveness of a nursing technician for new patients admitted to the institution with unknown serology.	8(89.0)	0.86
38. Processing of dialyzers with exhaust air system, specific benches for the cleaning stage, with a deep tank made of resistant material and suitable for cleaning and disinfection, supplied with treated water for hemodialysis with individualized depletion. In addition to specific benches for each sterilization stage of the dialyzer, also made of resistant material and suitable for cleaning and disinfection.	8(89.0)	0.86
39. Restriction on circulation and access of people to the dialyzer processing room.	9(100.0)	1.00
40. Monitoring and record of residual levels of sanitizing products used in the sterilization of dialyzers, before connecting patients.	9(100.0)	1.00
41. Use of disposable insulators in devices to measure blood and venous pressure.	9(100.0)	1.00
42. Continuous checking of the bacteriological quality of the water for hemodialysis and whenever pyrogenic manifestations, bacteremia, or suspicion of septicemia occur in patients.	9(100.0)	1.00
43. Biannual cleaning record of the drinking water reservoir.	9(100.0)	1.00

Continue...

Continuation.

Items	n(%)*	p-value**
44. Monthly bacteriological control record of the drinking water reservoir.	9(100.0)	1.00
45. Monthly cleaning and disinfection of the reservoir and water supply system for hemodialysis, with record of the professional in charge.	9(100.0)	1.00
46. Packaging of the dialyzers processed in individual lidded containers with patient identification.	9(100.0)	1.00
47. Check of each patient's clinical condition by nurses, associating with risk of falls at each hemodialysis session.	9(100.0)	1.00
48. Checking of the floor's cleaning and drying at each hemodialysis session or whenever necessary.	9(100.0)	1.00
49. Checking of the lifting of bed rails, whenever patients are making use of them.	9(100.0)	1.00
50. Supervision and assurance of devices for patient locomotion with assistance from family members or employees.	9(100.0)	1.00
51. Availability of equipment for checking anthropometric measures, appropriate for wheelchair users and individuals with special needs.	9(100.0)	1.00
52. Guidance for patients on asking help whenever necessary to enter and exit the hemodialysis room.	9(100.0)	1.00
53. Assurance of locomotion assistance for patients with special needs to use the bathroom.	8(89.0)	0.86
54. Maintenance of the wheels of armchairs and beds, which must be locked whenever in use by patients.	9(100.0)	1.00
55. Adequacy of furniture close to patients. They must be appropriately placed enabling circulation of professionals during the hemodialysis session, as well as the presence of accompaniers when required, preventing the risk of falls.	8(89.0)	0.86
56. Patient monitoring during the first walks after the undertaking of procedures (infusion of blood derivatives, fistula confection, catheter puncture).	9(100.0)	1.00
57. Daily emphasis on the guidance for the use of the device to assist in walking.	9(100.0)	1.00

*n – Percentage agreement; ** p – Binomial test; ‡ TAP – Prothrombin activation time; §TTPA – Thromboplastin partial activation time; ||Anti-HBs – Antibodies against the antigen of hepatitis B surface; ¶HIV – Human immunodeficiency virus

tification (seven items); correct communication, procedure, and intervention site (nine items); risk of infections associated with health care (15 items); and risk of injuries due to falls (11 items).

Discussion

The present study presented the limitation of not having evaluated time stability by test-retest, nor the construct validity of the instrument, in addition to the lack of studies considering the safety of patients on hemodialysis, thus restricting the comparison of the results.

The content of the IASPRCH items and its division according to international and national patient safety goals may contribute to the development of protocols and public policies with a focus on risks inherent to the care of chronic renal patients on hemodialysis, in addition to serving as a basis for promotion of patient safety nuclei in hemodialysis clinics required by the Brazilian legislation.[10]

The dimension "patient identification" was considered valid, with an emphasis on the use of at least two identification methods.[12] One study only showed patient name and, sometimes, the prescription was checked before the beginning of the procedure, with no use of identification wristbands during hemodialysis.[13]

However, one instrument with 17 items developed in Toronto, Canada, to standardize and strengthen safety culture in the hemodialysis unit, brought the importance of proper identification as an aspect to be dealt before connecting patients to hemodialysis devices.[4]

"Effective communication" was the dimension that presented the lowest ICC and was considered one of the most fragile variables in healthcare services. One study carried out in a hemodialysis unit showed no participation of nephrologist nurses and physicians during the visit to patients who were on dialysis in the unit's external areas, in addition to the lack of standardization when providing information regarding the general status and clinical condition of patients.[13]

Corroborating one study, ineffective communication is one of the three main causes of a sentinel event.[14] The negative repercussion of communication failure on the nursing team for the safety of patients on hemodialysis justifies the presence of this dimension in the instrument, so strategies are planned and carried out, in order to promote dealing with this issue.

The dimension "potentially dangerous medications" has ten items. Its presence in the instrument is justified by patients on dialysis requiring multi-drug complex regimes[2], especially for being high-surveillance drugs, such as heparin, which has a high incidence of hemorrhagic complications.[15]

Institutions should develop protocols so places where potentially dangerous medications are stored or handled may be provided with a list of all medications' names and correct doses, as well as containers easily identified and marked for an easy and safe access in clinical practice.

The dimension "proper procedures and intervention site" was considered valid, where its items approached the importance of time-out, which consists of a pause before the beginning of the procedure involving the whole team and allowing that all unanswered or confused questions are solved.[12]

The dimension "risk of infections" was the longest of the instrument (15 items) and all its items were considered valid and understandable. Risk of infection is among the main causes of death and hospitalization in patients on dialysis.[16] In one study based on the record of the total number of patients on dialysis in Scotland, infections associated with health contributed to 9.6% of deaths.[1] The following two areas were listed as of specific risk and deserve attention: hand hygiene and care with central venous catheters.[17]

The dimension "risk of injury due to falls" with 11 items presented the highest ICC, a fact justified by recommendations that the institution under study must establish a program to reduce the risk of falls, based on appropriate policies and procedures.[12] Accidental falls are common among the hemodialysis population, and this high rate is attributed to a combination of factors such as aging, renal disease morbidity, and risks associated with the treatment. In this respect, studies point out a 47% rate of episodes of falls.[18] These facts support its importance in the instrument, so each institution is able to record and identify its main causes of falls and, from then on, carry out interventions.

In general, the items of the instrument were considered compelling by researchers, with an index classified as excellent. Regarding the relevance criterion and association with patient safety, they were classified with an excellent index of agreement, which corroborates the results of one study that validated an instrument on patient culture and safety and that also had its items considered relevant.[19]

Conclusion

The safety assessment instrument for chronic renal patients on hemodialysis (IASPRCH) was constructed and validated regarding its content, and was considered excellent and compatible with patient safety standards by experts. In addition, it was evaluated as understandable by nephrologist nurses.

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Collaborations

Aguiar LL, Guedes MVCG, Almeida PC, and Oliveira RM collaborated in the stages of conception, analysis and interpretation of data, writing of the article, relevant critical review of the intellectual content, and final approval of the version to be published. Galindo Neto NM, Melo GAA, and Joselany Áfio Caetano contributed to the analysis and interpretation of data, writing of the article, relevant critical review of the intellectual content, and final approval of the version to be published.

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