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ORIGINAL

Content validity for the identification of occupational and ergonomic risks in the management of Endoscopic Retrograde Cholangiopancreatography

Validez de contenido para la identificación de riesgos laborales y ergonómicos en el manejo de la Colangiopancreatografía Retrógrada Endoscópica

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ABSTRAC

Introduction: the team of professionals involved in the management of endoscopic retrograde cholangiopancreatography experiences occupational and ergonomic risks, for which validation instruments are required to facilitate the identification of these risks, in order to prevent occupational diseases.
Objective: to validate the instruments for identifying occupational and ergonomic risks in the management of endoscopic retrograde cholangiopancreatography, using statistical methods of competence coefficient, Aiken's V and calculation of confidence intervals.
Method: content validity was assessed using expert criteria based on Aiken's V. The study was conducted from February to April 2025. The experts' competency coefficient was taken into account. Content validation was performed using Aiken's V and its confidence intervals.
Results: The instrument was comprehensively validated, with a score of 0,98 for occupational hazards (98,21 %), while the ergonomic hazards instrument validation yielded an overall score of 0,99 for 98,93 %, which is considered good, above 75 %. The confidence intervals confirm the study's validity.
Conclusions: content validation was performed, which favors reliable research results. Specialist suggestions were taken into account based on the clarity and comprehension of the occupational risk instrument.

Keywords: Content Validity; Statistical Methods; Ergonomic Risks; Occupational Risks.

RESUMEN

Introducción: el equipo de profesionales que interviene en el manejo de la colangiopancreatografía retrógrada endoscópica experimenta riesgos laborales y ergonómicos, para los cuales se requiere de instrumentos de validación que favorezcan la identificación de estos riesgos, en aras de prevenir enfermedades ocupacionales.
Objetivo: validar los instrumentos de identificación de riesgos laborales y ergonómicos en el manejo de la Colangiopancreatografía Retrógrada Endoscópica, por métodos estadísticos de coeficiente de competencia,

V de Aiken y cálculo de intervalos de confianza.
Método: la validez de contenido se realizó a través de criterios de expertos basado en V de Aiken. El estudio se realizó en el periodo comprendido de febrero a abril del año 2025. Se tuvo en cuenta el coeficiente de competencia de los expertos. Se realizó la validación de contenido a través de V de Aiken y sus intervalos de confianza.
Resultados: la validación del instrumento se realizó de forma integral, atendiendo a los riesgos laborales un 0,98 para un 98,21 %, mientras que la validación del instrumento de riesgos ergonómicos aportó un valor general de 0,99 para un 98,93 %, que los coloca en el rango de bueno, por encima del 75 %. Los intervalos de confianza comprueban la validez del estudio.
Conclusiones: se realizó la validación de contenido, lo que favorece los resultados fiables de la investigación. Se tuvo en cuenta la sugerencia de los especialistas en función de la claridad y comprensión del instrumento de riesgos laborales.

Palabras clave: Validez de Contenido; Métodos Estadísticos; Riesgos Ergonómicos; Riesgos Laborales.

INTRODUCTION

Endoscopic Retrograde Cholangiopancreatography (ERCP) is an advanced endoscopic method that allows the study and treatment of the biliary and pancreatic duct. This study dates back to 1968 and has been put into practice by specialists worldwide, where the first reports of cannulation were reported by the United States, in the detection of bibliopancreatic diseases.[1]

It is considered that ERCP, seen with an ergonomic approach, facilitates the execution of processes, work performance, improvements in productivity and quality of services, besides incorporating preventive measures for the health of the specialists involved. Occupational risks cannot be seen in isolation when it comes to the management of an endoscopic procedure. All occupational and ergonomic risks must be taken into account in order to achieve the therapeutic approach presented.

The authors affirm that health institutions in their transition towards excellence should contemplate the ergonomic vision in the search for the perception of the worker's health. The latter has an impact on the productivity and quality of the services provided and should be of interest to health institutions.

The authors consider that social responsibility and the perception of occupational and ergonomic risks should be raised. Scientific development, therapeutic benefits, integration of the multidisciplinary team, communication in the work environment, social responsibility in the adequate management of diseases and the perception of risk in all its amplitude, contribute to the increase of productivity, efficiency and quality.

The components of occupational risks in ERCP and the complex activities arising from the technique itself are related to the different specialties involved. The technological development, the integration and coordination of the multidisciplinary team, the valuation of the work environment centered on ergonomics as an inseparable science, condition improvements in the quality of the services and constitute a step forward towards excellence.[2]

In this sense, scientific research is required in order to minimize the effects of exposure to occupational and ergonomic risks, as well as proposals for improvements to be complied with and controlled by health institutions. The identification of these risks requires the use of specific instruments directed to the professionals involved in the management of ERCP.[3,4]

Research instruments are essential tools in the process of data collection within a scientific research. They can be used in the evaluation of certain concepts and variables. In addition, they can be used in the comparison of results of different investigations.[5]

Medina M et al. assume in their book Research Methodology: Research Techniques and Instruments that a research instrument must be specific to collect and analyze information in the research process. They provide accurate and reliable information on the subject of the study.[6]

The authors agree with Medina M et al. regarding the need to choose the appropriate instrument to ensure the best research results. Among the different types of instruments are surveys, questionnaires, measurement scales, structured interviews, standardized tests, among others.

Validation of instruments is recommended in determining the reliability and precision of an instrument within an investigation. Validation is provided by empirical tests, expert review and statistical analysis. There are different types of content, criterion, concurrent and predictive validity. Hence the possibility for researchers to choose the type of validity to be carried out according to the research need.[7]

In this sense, the statistical method V of Aiken (1980) is applied. Since it allows the validation of the contents of an evaluative material. The coefficient assumes values from 0 to 1, with the value 1 being the maximum possible magnitude, indicating perfect agreement among the managers or experts. This coefficient

combines ease of calculation and statistical evaluation of the results.[8]

It is important to use more than one test to perform the validity of an instrument, as they can provide complementary information and security for its subsequent application, although not all research instruments require validation. The latter are due to the systematic use by the scientific guild in the different scientific researches that have vast verification. For the fulfillment of this, the analysis of confidence intervals was taken into account.[9]

According to the documentary revision and literature reviewed, there are no instruments for the identification of labor and ergonomic risks in the management of ERCP in the Cuban context.

For the aforementioned reasons, the authors aimed to validate the instruments for the identification of occupational and ergonomic risks in the management of Endoscopic Retrograde Cholangiopancreatography, by statistical methods of competence coefficient, Aiken's V and calculation of confidence intervals.

METHOD

Content validity was performed by the statistical methods described in the period from February to April 2025.

The authors selected a total of nine experts for the validation of instruments, but only seven of them presented knowledge and mastery of the subject under investigation, with values between medium and high, as evidenced by the statistical method of competence coefficient.

Table 1. Evaluation of the experts' competence

Expert	Kc	Ka	K	Rating
1	0,7	0,60	0,65	Medium
2	0,7	0,90	0,8	High
3	0,9	1,00	0,95	High
4	0,8	1,00	0,9	High
5	0,7	1,00	0,85	High
6	0,8	0,60	0,7	Medium
7	0,8	0,90	0,85	High
8	0,2	0,80	0,5	Low
9	0,3	0,80	0,55	Low

Legend:
Kc: Coefficient of knowledge of competence.
Ka: Argumentation coefficient.
K: Coefficient of competence.

The selection was taken into account according to the expertise of each professional according to their area of knowledge. Distributed as follows:

1 Bachelor in Spanish Literature, 1 Doctor Epidemiologist, 1 1st degree Specialist in Biostatistics, 1 Bachelor in Health Technology, 1 Dr. C of Medical Education, 1 Bachelor in Nursing Head of the ERCP service, 1 Gastroenterologist of the ERCP service. They gave their informed consent to participate in the study.

The authors took into account the diversity of specialists in the group of experts given the contribution to knowledge based on the criteria for the analysis of the contents and appearance in the instruments of occupational and ergonomic risks in the management of ERCP. The seven specialists marked having knowledge on an increasing scale from 1 to 10 according to the experience in the realization of instruments or information related to the subject under investigation.

The authors of the research also performed documentary analysis and verification of the veracity of the Curriculum Vitae of each specialist, corroborating the expertise in the topics related to the assessment of ergonomic and occupational risks in the management of ERCP.

Subsequently, the instruments of occupational and ergonomic risks in the management of ERCP were sent to be validated by the specialists in terms of clarity, objectivity, timeliness, organization, sufficiency, relevance, consistency, coherence, methodology and applicability, for a total of 10 indicators, based on the instruments seen as a construct. The specialists analyzed the instruments on a verifiable scale from 1 to 5, where 1 is considered as terrible, 2 as bad, 3 as regular, 4 as good and 5 as perfect, translated into percentages from 0 % to 100 % respectively, as evidenced in Aiken's V statistical method.

Instruments

The first instrument proposed for the validation of contents by experts describes by dimensions the occupational risks that may be present in the management of ERCP.[10]

The specialty was considered given its relationship with the degree of exposure. The indicators are grouped into 4 dimensions (physical risks, biological risks, chemical risks and organizational risks) and a total of 24 indicators related to risk exposure to a greater or lesser extent during the performance of ERCP, distributed in three types of Likert response. Easy-to-use instrument to be filled out by the specialist who is part of the multidisciplinary ERCP team. It has a legend for better understanding and analysis.

The second instrument proposed is based on ergonomic risks in the management of ERCP. Gender, age, specialty, time dedicated to the service and health problems related to their work were considered as important elements in the data analysis and will allow researchers to assess the impact of risk exposure in the working population. These ergonomic risk factors were grouped in the following dimensions: postures, frequency of movements and handling of loads, as important elements in this therapeutic procedure according to Blanco Vela CI[11] and Marín Vargas BJ et al.[12] The instrument presents a total of 10 indicators and three types of Likert responses (always, sometimes, never) translated into high, medium and low exposure to risk. For the realization of both instruments the authors counted on the approval of international researchers[11,12] in the evaluation and analysis of the contents to be included and put into practice in the Cuban context.

Procedure

For the application of the methodology, a database was created in Excel, for the calculation of the statistical methods as described in the literature. The formulas of the statistical methods and their use are shown below:

Competition coefficient: it was used to determine the choice of judges.

$$k = 0{,}5(k_c + k_a)$$

$$k_c = n(0{,}1) \qquad k_a = N\mathrm{i} \qquad N_i = \sum n$$

Where:
Kc: coefficient of competence knowledge
n1 to n5: scoring form of the expert evaluation to calculate the argumentation coefficient.
Ni: value corresponding to the source of argumentation.
Ka: argumentation coefficient.
K: competence coefficient.

Aiken's V coefficient: used for content validation of the instruments.

$$v = \frac{s}{\left(n(C-1)\right)}$$

Where:
S: Sum of yes
Si: value assigned by the judge
n: number of judges
c: number of values in the rating scale.

Confidence intervals: used to check the validation of the instruments.

$$L = \frac{2nkv + z^2 - z\sqrt{4nkv(1-v) + z^2}}{2(nk + z^2)}$$

$$U = \frac{2nkv + z^2 + z\sqrt{4nkv(1-v) + z^2}}{2(nk + z^2)}$$

Where:
n: number of judges.

k: difference between the highest and lowest scores of the judges.
v: Aiken's V value.
z: chosen standard distribution (95 %).
L: lower limit.
U: upper limit.

Ethical Aspects

Informed consent was given based on the Helsinki principles where the experts were free to withdraw from the research without repercussions among the interested parties. The research ethics committee of the National Institute of Workers' Health (INSAT), as the center executing the project, approved the study.

RESULTS

After performing the Aiken V formula, the results of the validation of the instrument were obtained in an integral manner, attending to occupational risks, 0,98 for 98,21 %, while the validation of the ergonomic risks instrument provided an overall value of 0,99 for 98,93 %, which places them in the good range, above 75 %, as shown below.

Table 2. Integral validation of the instrument of occupational risks in the management of Endoscopic Retrograde Cholangiopancreatography by V of Aiken

Indicators		Judge 1	Judge 2	Judge 3	Judge 4	Judge 5	Judge 6	Judge 7	V aiken
Clarity	1	1	1	1	1	1	1	1	1
Objectivity	2	1	1	1	1	1	1	1	1
News	3	1	1	1	1	1	1	1	1
Organization	4	1	1	1	1	1	1	1	1
Sufficiency	5	0,75	1	1	1	1	1	1	0,96
Relevance	6	0,75	1	1	1	1	1	1	0,96
Consistency	7	0,75	1	1	1	1	1	1	0,96
Consistency	8	1	1	1	1	1	1	1	1
Methodology	9	1	1	1	1	1	1	0,75	0,96
Application	10	0,75	1	1	1	1	1	1	0,96
V Aiken Total									0,98
Final value:									98,21 %

Table 3. Integral validation of the ergonomic risk instrument in the handling of Endoscopic Retrograde Cholangiopancreatography by V of Aiken.

Indicators		Judge 1	Judge 2	Judge 3	Judge 4	Judge 5	Judge 6	Judge 7	V aiken
Clarity	1	1	1	1	1	1	1	1	1
Objectivity	2	1	1	1	1	1	1	1	1
News	3	1	1	1	1	1	1	1	1
Organization	4	1	1	1	1	1	1	1	1
Sufficiency	5	1	1	1	1	1	1	1	1
Relevance	6	0,75	1	1	1	1	1	1	0,96
Consistency	7	0,75	1	1	1	1	1	1	0,96
Consistency	8	1	1	1	1	1	1	1	1
Methodology	9	1	1	1	1	1	1	1	1
Application	10	0,75	1	1	1	1	1	1	0,96
V Aiken Total									0,99
Final value:									98,93 %

SCALE TO CHECK					
5	4	3		2	1
1	0.75	0.5		0.25	0
100%	75%	50%		25%	0%
PERFECT	GOOD	GOOD	PROPER	BAD	PÉSIMO

Figure 1. Scale to check the results

For the verification of the result obtained in the content validation of the occupational hazards instrument, the upper and lower limits were calculated by the confidence interval method, with a minimum value of L= 0,58 and a maximum of U= 1,39, with a value of Aiken's V in the permissible range. V= 0,98.

Similarly for the verification of the result obtained in the content validation of the ergonomic risk instrument the results were as follows:

L= 0,51 and a maximum of U= 1,48, with a value of Aiken's V in the permissible range. V= 0,99.

Suggestions after the first round of peer review

Suggestion 1. It was recommended to specify the principles of biosafety, universality, use of barriers and waste disposal management in indicator 8, occupational hazards instrument.

Suggestion 2. Separate the indicators by type of Likert response analysis in both instruments according to the legend presented, to avoid errors in the interpretation of the results and statistical analysis in data processing.

Given the importance of the suggestions, it was necessary to carry out two rounds of content validation, which made it possible to carry out a table work and adapt the occupational and ergonomic risk instruments with indicators related to the principles described above and to provide improvements to the legend, for data processing in an appropriate manner.

DISCUSSION

Reliable information in research is an indispensable element and guarantees the validity of the results obtained. Regarding the validation of the instruments to be used in a research, it provides tools that favor the quality of the construct and subsequent applicability in a given context with the least amount of risks in terms of comprehension, clarity, objectivity, organization, consistency, sufficiency, coherence, methodology, sufficiency and relevance of the instruments used.

The authors agree with Ventura León J and Mamani Benito O, regarding the results of the experts' judgment and the importance they attribute to their suggestions in the quality of the instruments designed and validated. They also agree on the design of their instruments by dimensions for a better understanding.[13]

The authors affirm together with Merino Soto C et al. the need to evaluate the clarity of the content with the methodology proposed in the study, given the implication it brings for the subsequent application of the instruments proposed in the study and they recognize it as a formal component in the evaluation of the content of the indicators.[14]

On the other hand, the authors agree with Balderas Sanchez AV et al. on the need to carry out an integral evaluation of the instrument, they call it "Global" with the inclusion of sociodemographic data, and the level of adequacy of each indicator with respect to the object of study; the latter grouped in dimensions and indicators for their analysis.[15]

In the study given by Roble Garrote P et al. considerations were taken from the methodological point of view, following the observations made by the experts. In addition, a testable statistical method was used given the low number of judges consulted in the validation process of the instrument in the two research comparisons described, as well as the consensus of agreement among the judges.[16]

Another consideration that differs from the aforementioned authors is the one addressed by Herrera Masó JR et al. since they propose the need to carry out three statistical testing methods to achieve the proposed objective of content validity and the determination of the number of experts. They consider that not only the judge's expertise is necessary, but also the competence index must be calculated to determine if the judges present sufficient cognitive mastery to work in the validation process and achieve a positive attitude towards the task assigned by the main researcher.[17]

In view of the above, the authors affirm the need to calculate confidence intervals in the study, in order to show statistical significance. It decreases the range of errors of the instruments validated by Aiken's V and determines the relevance of the results. They provide more information than a point estimate.

An article on procedures for estimation by confidence intervals in biomedical research highlighted that 95 % confidence intervals were mostly used, representing greater robustness in the analysis and application of the results.[18,19]

The authors agree with what was stated by Landaeta Mendoza CJ, that scientific research requires valid, objective and reliable measuring instruments to obtain accurate results, with vital importance in the quality of the data and credibility of the research.[20]

Strengths and limitations of the study

Strengths

Among the strengths is the diversity of specialists, as experts in the research, which allowed the variety of criteria, points of view, in terms of the evaluation of the instrument as a construct. Its generalization in terms of the possible applicability in all the institutions where ERCP is performed in the country and includes a center for performing ERCP in Ecuador, which is integrated by specialists trained in Cuba in postgraduate education. The instruments require little time and effort on the part of the professional who fills them out.

Limitations

Its generalization in other contexts that do not coincide with the characteristics of the ERCP rooms in Cuba, as well as the specialists involved in the procedure. Sometimes ERCP is performed after surgical interventions such as cholecystectomy either by general or laparoscopic surgery and in this sense, the instrument does not take into account the identification of occupational and ergonomic risks in these combined procedures.

CONCLUSIONS

The validation of the instruments for the identification of labor and ergonomic risks in the management of Endoscopic Retrograde Cholangiopancreatography in the Cuban context was performed by the experts' competence coefficient, Aiken's V for the validation of the instruments' contents and their confidence intervals, as a verifying statistical method. The suggestions made by the experts were considered in terms of the quality of the content of the instruments for their subsequent applicability.

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CONFLICT OF INTEREST

The authors declare that there is no conflict of interest.

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