Validation of definitions of the indicators for Nursing Outcomes Classification outcomes: Self-management cardiac disease

Agueda Maria Ruiz Zimmer Cavalcante
Camila Takao Lopes
Elizabeth Swanson
Sue Ann Moorhead
Maria Márcia Bachion
Alba Lucia Bottura Leite de Barros

Abstract

Objective: To validate conceptual and operational definitions of the indicators for NOC outcomes: cardiac disease self-management.

Methods: This consensus-validation study was developed in three steps: integrative literature review, development of conceptual and operational definitions of the indicators for NOC outcome: cardiac disease self-management, and consensus-validation of definitions by 20 nursing specialists. A binomial test was conducted to analyze the proportion of nursing specialists who agreed on the relevance and clarity of definitions. P-values lower than 0.05 indicated a significant difference of the opinion among nursing specialists concerning the relevance and clarity of definitions.

Results: After the reviewing by nursing specialists, the conceptual definitions of 43 indicators for clarity and 43 for relevance had a p > 0.05. Operational definitions of 36 indicators presented for clarity and 43 for relevance had a p-value >0.05. Indicators showing p <0.05 were adjusted accordingly to reflect the opinion of nursing specialists.

Conclusion: To establish conceptual and operational definitions for NOC indicators turn the assessment process more, and guide the clinical practice towards better results. Once validated, these indicators may provide higher precision and increase effectiveness in clinical practice.

Keywords
Heart failure; Patient outcome assessment; Nursing assessment; Validation studies

Resumo

Objetivo: Validar definições conceituais e operacionais para os indicadores do resultado NOC “Autocontrole da doença cardíaca”.

Métodos: Estudo metodológico de validação consensual desenvolvido em três etapas: revisão integrativa da literatura, elaboração de definições conceituais e operacionais para os indicadores do resultado NOC “Autocontrole da doença cardíaca” e validação das definições por consenso de 20 especialistas. Foi realizado teste binomial para análise da proporção de especialistas que concordaram que as definições elaboradas eram relevantes e claras. Valores de p inferiores a 0,05 indicavam diferença significativa na opinião dos especialistas quanto à relevância e à clareza das definições.

Resultados: Na avaliação dos especialistas, as definições conceituais de 43 indicadores apresentaram valores de p > 0,05 para clareza e 43 para relevância. Nas definições operacionais 36 indicadores apresentaram valor de p>0,05 para clareza e 43 para relevância. Para indicadores com o p<0,05 reajustes foram feitos conforme as sugestões dos especialistas.

Conclusão: O estabelecimento de definições conceituais e operacionais para indicadores NOC torna o processo de avaliação mais confiável, orientando a prática clínica em direção a melhores resultados. Quando validados, esses indicadores podem oferecer maior precisão, aumentando a efetividade da prática clínica.
Resumen

Objetivo: Validar definiciones conceptuales y operativas para los indicadores del resultado NOC “Autocontrol de la enfermedad cardíaca”

Métodos: Estudio metodológico de validación consensual realizado en tres etapas: revisión integradora de la literatura, elaboración de definiciones conceptuales y operacionales para los indicadores del resultado NOC “Autocontrol de la enfermedad cardíaca” y validación de las definiciones por consenso de 20 especialistas. Se realizó test binomial para analizar la proporción de especialistas que estaba de acuerdo con que las definiciones elaboradas eran relevantes y claras. Valores de p inferiores a 0,05 indicaban diferencia significativa en la opinión de los especialistas con relación a la relevancia y claridad de las definiciones.

Resultados: En el análisis de los especialistas, las definiciones conceptuales de 43 indicadores presentaron valores de p > 0,05 respecto a la claridad y 43 a la relevancia. En las definiciones operativas, 36 indicadores presentaron valores de p > 0,05 respecto a la claridad y 43 a la relevancia. Con relación a los indicadores con p < 0,05, se realizaron ajustes según las sugerencias de los especialistas.

Conclusión: Establecer definiciones conceptuales y operativas para indicadores NOC permite que el proceso de evaluación sea más confiable, lo que orienta la práctica clínica a la obtención de mejores resultados. Al validarlo, estos indicadores pueden ofrecer mayor precisión y aumentar la efectividad de la práctica médica.

Introduction

Among quality indicators for care services in health institutions, we highlight health status or quality of life outcomes reported by patients. These indicators comprise an essential dimension to establish assessment, analysis, and decision making parameters as they improve patient care in various settings.

Defining the expected outcomes for the patient’s medical condition and verifying their impact are at the third and final steps of the nursing process, i.e., planning and assessing patient care. In the assessment phase, nurses analyze the efficacy of interventions performed to guide replanning and to provide information that allow assessing the final care outcomes.

For this information to be consolidated and managed, the use of standardized language is required. Classifications such as the Nursing Outcomes Classification may be used to describe nursing outcomes. This classification defines a nursing-sensitive patient outcome as an individual, family or community state, behavior, or perception in response to nursing interventions. Each outcome has an associated group of definitions and indicators. Indicators are defined as a state, behavior, or observable perception or assessment reported by patient in more concrete level.

Each indicator includes a five-point Likert scale consisting of options to demonstrate variability in the state, behavior, or perception described by the patient. NOC outcomes show how patients respond to interventions and they aid to determine whether changes in care are warranted. Indicators, however, need to be further refined and present definitions that allow healthcare providers to estimate the reliability of changes in patients.

Well-defined and clear indicators contribute to the understanding and collecting information, by describing the state of a phenomenon, and/or guiding nursing actions. Such clarity is desirable to increase accuracy in the use classification systems. Thus, outcome indicators require conceptual and operational definitions to become applicable to the medical practice.

Studies have been conducted in different medical settings to validate and add reliability to NOC outcomes, providing standardization of patient assessment in medical practice.

In the context of patients with heart failure, the outcomes of nurse-provided care are shown by the individuals’ clinical improvement and decrease of acute episodes in the patient’s condition, by adherence to drug and non-drug therapies, and by the decrease in hospital readmissions.

Heart failure is one of the world most prevalent chronic non-communicable disease, affecting more than 23 million people. In Brazil, in 2018, there were 1,151,050 admissions due to circulatory system diseases. Of these, 200,694 was due to heart failure, and 22,328 deaths due to heart failure. Despite advancements in medical care, patients still have high risk for hospital admission due to exacerbation of this medical condition, which leads to a decrease in quality of life and an increase in mortality. The purpose of self-management interventions is to improve patient’s knowledge and skills in self-care, therefore, helping them to adhere to treatment,
to promote changes in life style, to monitor signs and symptoms, and consequently, to prevent ex-acerbation.\(^{15}\)

Nurses play a critical role in performing interventions that empower patients to adhere to the treatment, identifying complications, signs and symptoms of worsening, and making decisions in emergency situations.\(^{16}\) In this setting, chronic disease management is conducted by various institutions, where nurses follow patients, teaching and empower them to manage their own disease.

The NOC outcome Self-management: Cardiac Disease defined as personal actions to manage heart disease, its treatment, and to prevent disease progression and complications - supports the recommendations of a number of programs for chronic diseases management. This outcome belongs to the NOC domain Health Knowledge and Behavior and to the Class Health Behavior, and includes 45 indicators that have not been previously validated.\(^{5}\)

Although few studies using NOC outcomes for the care of patients with heart failure at outpatient and home settings, the NOC outcome: Self-management: Cardiac disease was mentioned only once.\(^{2,17-19}\) These indicators of outcomes reflect national and international guidelines for this population.\(^{20-23}\)

In a detailed analysis, the outcomes mentioned in these studies, such as Knowledge: cardiac disease management, Weight maintenance behavior, Knowledge: medication, Symptom control, Fluid balance, Activity tolerance, and Energy conservation—are included in the Self-management: Cardiac Disease indicators. This means that a proper assessment of a heart failure patient’s state can be obtained using only this outcome.\(^{2,17-19}\)

Considering the importance to assess and measure patients’ health outcomes using indicators, as well as by using standardized language, the objective of this study was to validate conceptual and operational definitions for the indicators of NOC outcome: Self-management: Cardiac Disease.

Methods

This was a consensus-validation study for the conceptual and operational definitions of the Self-management: Cardiac Disease indicators that was developed in three steps: literature review, development of conceptual and operational definitions of the indicators along with operational definitions for individual ratings in the quantification scale, and also validation by nursing specialties.\(^{24}\)

The following databases were used for the literature review: Latin American and Caribbean Health Sciences Literature (LILACS), Medical Literature Analysis and Retrieval System Online (MEDLINE), Cumulative Index to Nursing and Allied Health Literature (CINAHL), and Cochrane Database of Systematic Reviews. We included studies about self-care of heart failure patients published in English, Portuguese, or Spanish from 2009-2015. The initial period for inclusion (2009) was limited based on our interest in studies published after the implementation of the theory of self-care of heart failure patients.\(^{25}\)

Based on the literature review,\(^{25}\) we elaborated conceptual and operational definitions for the indicators, as well as individual definitions for each of the five points in the Likert scale.

Conceptual definitions are connected to words used in the indicators, a synthesis of a concept. They are defined purely by the meaning of words. Operational definitions attributed meaning to a given word, specifying how a given concept should be measured or assessed.\(^{26}\) In this investigation, the conceptual and operational definitions of indicators were analyzed for relevance and clarity by nursing specialists.

These specialists were initially selected from the Brazilian National Council for Scientific and Technological Development (CNPq) Lattes Platform (http://lattes.cnpq.br) using the term “NOC outcome” followed by the snowball sampling, i. e., those who accepted our invitation to join the study suggested other colleagues.

We considered nursing specialists those who had a score greater than or equal to 6, based on the following criteria: hold a PhD in nursing and/
or cardiology (2 points), Master’s degree in nursing and/or cardiology (2 points), specialization in cardiac care nursing (2 points), those who had published papers on nursing and/or cardiology as a result of a thesis or dissertation (2 points), those who published papers on nursing and/or cardiology (2 points), those who had teaching experience in terminology and/or cardiology (2 points). (23) Additionally, nurses should meet at least one of the following criteria: minimum 2-year of medical experience in cardiology (2 points) or at outpatient clinic in health education experience (2 points). (27) Therefore, in our study, we defined that a score greater than or equal to 8 (or at least 4 criteria) was enough to consider a participation a nursing expert. The recruiting of potentially eligible nurses occurred in September 2014, and validation was carried out in 2015.

A total of 65 nurses were invited to participate in the study. Of these, 30 accepted but 2 nurses did not meet the 8 points.

The instrument for assessing conceptual and operational definitions for the NOC outcome indicators was e-mailed to 28 nursing specialists. Of these, 20 responded. In terms of eligibility, nursing specialists scored from 10-16 points, with an average of 12.75 ±2.22.

To assess relevance and clarity in conceptual and operational definitions, nursing specialists scored with -1 (inadequate), 0 (unclear), or +1 (adequate). (28) Similarly, the relevance and clarity in operational definitions for individual ratings in the Likert scale were assessed.

With the obtained score, a binomial test was performed to analyze the proportion of nursing specialists who agreed on the relevance and clarity of definitions. Adequacy was obtained at ≥85%. (24)

A p-value <0.05 was used to indicate statistical significance when percent agreement did not reach 85%. Definitions showing a lower p-value were revised based on nursing specialists’ reviews.

This study was approved by the Institutional Ethics and Research Committee, CAEE number 42990214.40000.5505. An informed consent was obtained from all participants. Careful was taken to guarantee privacy and confidentiality of data.

Results

Literature review allowed us to elaborate conceptual and operational definitions for each 45 indicators of the NOC outcome: Self-management: Cardiac Disease, in addition to operational definitions for individual ratings.

Most definitions were considered clear and relevant. In operational definitions, we noticed that clarity had lower scores than relevance dimension (Table 1).

Nursing specialists suggested changes in several definitions for improvement which were subsequently changed accordingly for adequacy.

Conceptual definitions of indicators “Monitors pulse rate and rhythm” and “Follows recommended diet” were revised for clarity/relevance and clarity, respectively (Table 1).

Operational definitions of the following indicators were revised for clarity: “Accept diagnosis”; “Participates in prescribed cardiac rehabilitation”; “Performs treatment regimen as prescribed”; “Monitors symptom persistence”; “Monitor symptom severity”; “Reports signs and symptoms of depression”; “Monitors pulse rate and rhythm”; and “Uses energy conservation techniques”. The definition of the indicator “Uses energy conservation techniques” was revised for relevance.

Given limitations to present all conceptual and operational definitions for each of the 45 indicators, charts 1 and 2 show conceptual and operational definitions for indicators “Follows recommended diet” and “Monitors pulse rate and rhythm” to illustrate the final product of the validation process.

These indicators were selected based on relevance in medical practice and to show that, despite their significant p-value, nursing specialist suggestions were considered for improving definitions.
Table 1. Agreement between nursing specialists on relevance and clarity of conceptual and operational definitions of the indicators for NOC outcome: Self-management: Cardiac disease

<table>
<thead>
<tr>
<th>Self-management: Cardiac disease</th>
<th>Conceptual definition</th>
<th>Operational definition</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>P-value* (%**)</td>
<td>P-value* (%**)</td>
</tr>
<tr>
<td>Indicators</td>
<td>Relevance</td>
<td>Clarity</td>
</tr>
<tr>
<td>161701 – Accepts diagnosis</td>
<td>0.82(90.0)</td>
<td>0.17(75.0)</td>
</tr>
<tr>
<td>161702 – Seeks information about methods to maintain cardiovascular health</td>
<td>0.96(95.0)</td>
<td>0.60(85.0)</td>
</tr>
<tr>
<td>161703 – Participates in health care decisions</td>
<td>1.00(100.0)</td>
<td>0.60(85.0)</td>
</tr>
<tr>
<td>161704 – Participates in prescribed cardiac rehabilitation</td>
<td>1.00(100.0)</td>
<td>0.96(95%)</td>
</tr>
<tr>
<td>161705 – Performs treatment regimen as prescribed</td>
<td>0.96(95.0)</td>
<td>0.60(85%)</td>
</tr>
<tr>
<td>161706 – Monitors symptom onset</td>
<td>0.96(95.0)</td>
<td>0.82(90%)</td>
</tr>
<tr>
<td>161707 – Monitors symptom persistence</td>
<td>0.82(90.0)</td>
<td>0.82(90%)</td>
</tr>
<tr>
<td>161708 – Monitors symptom severity</td>
<td>1.00(100.0)</td>
<td>0.82(90.0)</td>
</tr>
<tr>
<td>161709 – Monitors symptom frequency</td>
<td>0.96(95.0)</td>
<td>0.96(95.0)</td>
</tr>
<tr>
<td>161710 – Reports symptoms of worsening disease</td>
<td>0.82(90.0)</td>
<td>0.82(90.0)</td>
</tr>
<tr>
<td>161711 – Reports signs and symptoms of depression</td>
<td>0.35(80.0)</td>
<td>0.82(90.0)</td>
</tr>
<tr>
<td>161712 – Uses diary to monitor symptoms over time</td>
<td>0.17(75.0)</td>
<td>0.35(80.0)</td>
</tr>
<tr>
<td>161713 – Uses preventive measures to reduce risk of complications</td>
<td>0.82(90.0)</td>
<td>0.60(85.0)</td>
</tr>
<tr>
<td>161714 – Uses symptom relief methods</td>
<td>1.00(100.0)</td>
<td>1.00(100.0)</td>
</tr>
<tr>
<td>161715 – Obtains health care when warning signs occur</td>
<td>0.82(90.0)</td>
<td>0.35(80.0)</td>
</tr>
<tr>
<td>161716 – Monitors pulse rate and rhythm</td>
<td>0.35(80.0)</td>
<td>0.02(65.0)</td>
</tr>
<tr>
<td>161717 – Monitors blood pressure</td>
<td>0.96(95.0)</td>
<td>0.35(80.0)</td>
</tr>
<tr>
<td>161718 – Limits sodium intake</td>
<td>0.96(95.0)</td>
<td>0.60(85.0)</td>
</tr>
<tr>
<td>161719 – Limits fat and cholesterol intake</td>
<td>0.96(95.0)</td>
<td>0.96(95.0)</td>
</tr>
<tr>
<td>161720 – Follows recommended diet</td>
<td>1.00(100.0)</td>
<td>0.35(80.0)</td>
</tr>
<tr>
<td>161721 – Follows fluid restrictions</td>
<td>0.96(95.0)</td>
<td>0.82(90.0)</td>
</tr>
<tr>
<td>161722 – Monitors effects of stimulants</td>
<td>0.60(85.0)</td>
<td>0.07(70.0)</td>
</tr>
<tr>
<td>161723 – Monitors body weight</td>
<td>0.96(95.0)</td>
<td>0.82(90.0)</td>
</tr>
<tr>
<td>161724 – Uses effective weight control strategies</td>
<td>0.96(95.0)</td>
<td>0.35(80.0)</td>
</tr>
<tr>
<td>161725 – Maintains optimum weight</td>
<td>0.96(95.0)</td>
<td>0.96(95.0)</td>
</tr>
<tr>
<td>161726 – Follows recommendations for alcohol use</td>
<td>0.96(95.0)</td>
<td>0.07(70.0)</td>
</tr>
<tr>
<td>161727 – Participates in smoking cessation regimen</td>
<td>1.00(100.0)</td>
<td>0.96(95.0)</td>
</tr>
<tr>
<td>161728 – Participates in recommended exercise</td>
<td>0.96(95.0)</td>
<td>0.82(90.0)</td>
</tr>
<tr>
<td>161729 – Uses energy conservation techniques</td>
<td>0.02(65.0)</td>
<td>0.60(85.0)</td>
</tr>
<tr>
<td>161730 – Balances activity and rest</td>
<td>0.60(85.0)</td>
<td>0.60(85.0)</td>
</tr>
<tr>
<td>161731 – Performs usual life routine</td>
<td>1.00(100.0)</td>
<td>1.00(100.0)</td>
</tr>
<tr>
<td>161732 – Follows recommendations for sexual activity</td>
<td>0.60(85.0)</td>
<td>0.82(90.0)</td>
</tr>
<tr>
<td>161733 – Obtains required medication</td>
<td>0.96(95.0)</td>
<td>0.96(95.0)</td>
</tr>
<tr>
<td>161734 – Uses medication as prescribed</td>
<td>1.00(100.0)</td>
<td>0.96(95.0)</td>
</tr>
<tr>
<td>161735 – Monitors prescribed medication therapeutic effects</td>
<td>1.00(100.0)</td>
<td>0.60(85.0)</td>
</tr>
<tr>
<td>161736 – Uses only non-prescription medication approved by health professional</td>
<td>0.96(95.0)</td>
<td>0.07(70.0)</td>
</tr>
<tr>
<td>161737 – Uses stress management strategies</td>
<td>0.96(95.0)</td>
<td>0.96(95.0)</td>
</tr>
<tr>
<td>161738 – Obtains influenza and pneumonia vaccine</td>
<td>0.82(90.0)</td>
<td>1.00(100.0)</td>
</tr>
<tr>
<td>161739 – Uses health care services congruent with needs</td>
<td>0.96(95.0)</td>
<td>0.96(95.0)</td>
</tr>
<tr>
<td>161740 – Participates in screening for cholesterol</td>
<td>0.60(85.0)</td>
<td>0.60(85.0)</td>
</tr>
<tr>
<td>161741 – Reports need for financial assistance</td>
<td>0.82(90.0)</td>
<td>1.00(100.0)</td>
</tr>
<tr>
<td>161742 – Keeps appointments with health professional</td>
<td>1.00(100.0)</td>
<td>1.00(100.0)</td>
</tr>
<tr>
<td>161743 – Maintains plan for medical emergencies</td>
<td>1.00(100.0)</td>
<td>0.96(95.0)</td>
</tr>
<tr>
<td>161745 – Adjuts life routine for optimal health</td>
<td>0.82(90.0)</td>
<td>0.60(85.0)</td>
</tr>
</tbody>
</table>

* Binomial test; ** Percent agreement on adequacy
Validation of definitions of the indicators for Nursing Outcomes Classification outcomes: Self-management cardiac disease

### Discussion

In this study, the Self-Management: Cardiac Disease indicators were validated by consensus of nursing specialists. Of the 44 indicators, operational definitions for 8 indicators were improved and the conceptual definition for 1 indicator had improved, for accuracy.

The use of standardized nursing language in various settings of patient care represents a challenge for nurses, and studies that encourage and clarify such standardized language support this practice. For this reason, the development of conceptual and operational definitions of an outcome does not invalidate the use of other outcomes, however, it contributes to more accurate assessments.
The indicators that were developed and validated in this study can be used to assess self-care behavior before and after implementation of interventions, and they can also help nurses to select adequate interventions to further motivate patients and nurses in the search for continuous management of illnesses. Nurses may select a group of adequate indicators for a certain patient by estimating a goal that can be assessed over a given period of time. In serial assessment in follow-up program may be performed with precise indicators for each strategy implemented by professional. Therefore, even if the NOC outcome includes a predetermined number of indicators, they can be selected as needed.\(^{(5)}\)

Several indicators are considered indispensable for cardiac disease management, especially as in this study, for patient with heart failure. We highlight indicators for monitoring symptom onset, persistence, severity, and frequency; identifying of worsening signs of the disease; obtaining health care in the face of red flags; limiting the ingestion of sodium; monitoring body weight; using medication as prescribed; and obtaining pneumonia and influenza vaccines.

Indicators in the Nursing Interventions Classification system, such as the NOC, require refined specifications and descriptions of scientific rigor and little subjectivity.\(^{(9)}\) The development of definitions aids to establish the level of patient improvement or worsening and provides higher accuracy in measuring selected indicator ratings, which, in turn, makes indicators more sensitive and representative and less subjective of patient response to interventions, thereby advancing the use of taxonomy in clinical practice.\(^{(7,29)}\)

The justification of the NOC elements has been suggested in different studies as a pathway for further elaborating and validating outcome indicator definitions, which contributes to decrease the subjectivity factor.\(^{(6,9,10,29)}\) The development of conceptual and operational definitions is essential for this process, and it contributes to study reproducibility and inconsistency reduction in nursing assessments.\(^{(10)}\)

Given that many indicators lack a detailed description in the published literature, a critical analysis on the part of nursing specialists is essential for improving these definitions. The definitions designed for indicators are often based on individual researcher considerations and on extensive scientific revision of subject matter and related studies. This issue is intensified when establishing definitions for the Likert scale items, given differentiation between levels that must reflect patient improvement or worsening based on an expected outcome. Establishing a level for patient state/behavior based on an outcome is mandatory, but the absence of clear definitions may make it difficult to register this information and use the scale for indicating severity level.\(^{(5)}\)

A study conducted by a group of nurses for consensus selection of NANDA-I diagnosis, NIC interventions, and NOC outcomes for home care of heart failure patients reported 6 diagnosis, 11 interventions, and 7 outcomes. The proposed outcomes are the following: Activity Tolerance; Energy Conservation; Knowledge: Treatment Regimen; Symptoms Management; Knowledge: Medication; Fluid Balance; and Family Participation in Professional Care.\(^{(19)}\) The indicators contained in the Self-management: Cardiac disease outcome reflect these outcomes, except for “Family Participation in Professional Care”. In this context, we should reflect about what is more appropriated for nursing science and practice of clinical nursing, i.e., broad or more specific outcomes.

A study analyzed 101 papers describing self-management among individuals with chronic conditions, which defines self-management as a dynamic and interactive daily process of engagement for disease control. The study identified three categories for self-management: 1-Focussing on illness needs; 2-Activating resources; and 3-Living with chronic illness. For each category, a set of tasks and skills were defined to obtain strategies for disease control.\(^{(30)}\) Outcome indicators investigated in this study can be also considered tasks and skills required by an individual for heart failure management, with the advantage of including an assessment scale and a description for each score.

Despite attempts to include the highest possible number of nursing specialists, 20 specialists participated in the study, which can be considered...
a small number, and a potential limitation of our study. The definitions were assessed by nurses only once, we did not seek a second consultation for reassessment of the revised version, which also can be considered a limitation. New assessments would contribute to greater accuracy, however, the results obtained are a significant starting point for further researches and for clinical studies to validate cardiac disease self-management outcome.

**Conclusion**

Conceptual and operational definitions were established and consensual validated by group of specialists for the NOC outcome Self-management: Cardiac disease indicators. Most definitions were considered clear and relevant. Only one of the definitions was not considered relevant, because information contained was believed to be obtained from another indicator. Some definitions were refined based on nursing specialist reviews, thus become clearer and facilitating clinical assessment. This NOC outcome and its indicators may aid healthcare providers in planning health care and provide useful information on the topics required for the assessment of individuals with the disease. For this reason, researchers should be strongly encouraged to develop indicator definitions that can be easily applied. Once conceptual and operational definitions are established for these indicators, the assessment and follow-up process become more accessible and reliable, even when performed by different healthcare providers, which reduce ambiguities and guide clinical practice to pursue better outcomes.

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**Collaborations**

Cavalcante AMRZ, Lopes CT, Swanson E, Moorhead AS, Bachion MM, and Barros ALBL contributed to the conception of the study, analysis and interpretation of data; drafting of the manuscript, critical review relevant for intellectual content, and approval of the final version to be published.

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