



ORIGINALES

A cultural adaptation and validation of the Self-care Questionnaire in patients with left ventricular assist device

Adaptación cultural del Cuestionario de autocuidado en pacientes con asistencia ventricular definitiva

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ABSTRACT:

Introduction. In order to achieve an optimal life, patients with permanent implantable left ventricular assist devices face complex treatment regimens; they require acquiring knowledge and developing skills to guide their care. This makes it necessary for the nursing professional to have tools that allow them to identify the self-care level as a starting point to promote positive behaviors that allow adherence to their new lifestyle.

Objective. To determine the equivalent version of the self-care questionnaire for patients with permanent ventricular assistance in Colombia.

Material and methods. Methodological study. The process was carried out in six stages to guarantee the equivalence of the adapted instrument through a first translation, synthesis of translations, reverse translation, review by the expert committee, trial of the pre-final version and presentation of the instrument to the authors.

Results. Translation and back-translation of the instrument were performed. 77% of the experts mentioned that all the items were understandable and clear, but 33% reported that items 3,5,6,7,8,10 and 11 required form adjustments.

Conclusions. The cross-cultural adaptation of the self-care questionnaire in patients with permanent ventricular assistance for the Colombian environment was obtained, preserving the experiential, conceptual, idiomatic and semantic equivalence of the original instrument.

Keywords: Heart failure, adaptation, Self-care, Patient.

RESUMEN:

Introducción. Con el fin de alcanzar una vida óptima, los pacientes con dispositivos de asistencia ventricular izquierda implantables de forma permanente se enfrentan a regímenes de tratamiento complejos; requieren adquirir conocimiento y desarrollar habilidades para orientar su cuidado. Esto hace necesario que el profesional de enfermería cuente con herramientas que permitan identificar el

nivel de autocuidado como punto de partida para promover comportamientos positivos que permitan adherirse a su nuevo estilo de vida.

Objetivo. Determinar la versión equivalente del cuestionario de autocuidado para pacientes con asistencia ventricular definitiva en Colombia.

Material y métodos. Estudio de tipo metodológico. Se llevó a cabo en seis etapas, con el propósito de garantizar la equivalencia del instrumento adaptado por medio de traducción inicial, síntesis de las traducciones, traducción inversa, revisión por parte del comité de expertos, presentación del instrumento a los autores y prueba de la versión prefinal.

Resultados. Se realizó la traducción y la retrotraducción del instrumento. El 77 % de los expertos mencionaron que todos los ítems eran comprensibles y claros, pero el 33 % refirieron que en los ítems 3,5,6,7,8,10 y 11 requerían ajustes de forma.

Conclusión. Se obtuvo la adaptación transcultural del cuestionario de autocuidado en pacientes con asistencia ventricular definitiva para el medio colombiano, conservando la equivalencia experiencial, conceptual, idiomática y semántica del instrumento original.

Palabras claves. Insuficiencia cardiaca, autocuidado, adaptación, paciente.

INTRODUCTION

Advanced heart failure is present in approximately 4% to 6% of patients and is associated with more symptoms, increased comorbidity and mortality (up to 75% per year). At this point, conventional therapies have failed or are refractory and decisions need to be made to establish more advanced treatments. One of these treatments are the left ventricular assist devices (LVAD) ⁽¹⁾.

For many of these patients, heart transplantation would be the ideal option; unfortunately, however, the waiting list for heart transplantation is growing and the number of transplantable heart donors is very limited. For this reason, permanently implantable left ventricular assist devices (LVADs) have become an alternative treatment option as a bridge-to-transplant or destination therapy ⁽²⁾.

LVADs ⁽³⁾ are mechanical pumps that mechanically support circulation by increasing blood flow from the left ventricle to the aorta. These have five main components: a blood pump with two inner tubes, a system controller, a system monitor, a driveline and a power source.

The blood pump is the component responsible for increasing cardiac output by ejecting blood directly into the aorta. Blood enters the pump from an inflow tube placed in the patient's left ventricle and exits the pump through a second tube implanted in the patient's aorta. A pneumatic system, consisting of a sensor inside the pump and a venting orifice, is responsible for the movement of blood in and out of the pump into the systemic circulation.

The blood pump and pneumatic system are regulated by an external electronic system controller. The controller, considered the "brain" of the LVAD, is a microprocessor-based unit connected to the blood pump through the percutaneous tube, called the driveline. The system controller, in addition to initiating pump action, also provides information on device functionality and battery status. The controller also provides visual and audible alarms that signal improper operation ⁽³⁾.

Ventricular assist devices decrease mortality, increase survival and improve quality of life ⁽⁴⁾. However, in order to achieve optimal life, patients are faced with complex treatment regimens and require knowledge and skills to guide their care in the

prevention of percutaneous line exit site infections, lifestyle changes, anticoagulation adherence, battery management and alarm response.

For this reason, a multidisciplinary team should provide permanent and comprehensive support to the patient. Similarly, the implementation of interventions to promote a high degree of self-care is required.

High levels of self-care will allow patients to prolong their lives by reducing the risk of infection, bleeding and other device-related complications ^(5,6).

Studies have been conducted to develop educational tools for patients and to describe the learning process of acquiring new skills and knowledge related to LVAD ^(7,8). However, only a few have comprehensively evaluated self-care so far. In addition, there are no scales with validity and reliability to measure self-care in patients with LVAD. These scales can play an important role in the evaluation of future educational interventions or to guide practice regarding the education and counseling of patients and their caregivers ⁽⁸⁾.

In order to address this need, Kato NP et al. ⁽⁹⁾ developed the *Self-Care Questionnaire in Patients with Definitive Ventricular Assistance (LVAD)*, which is based on the mid-range theory of self-care in chronic illnesses ⁽¹⁰⁾ and includes feedback from both healthcare professionals and patients. It has 33 items, where 19 items are related to self-care maintenance, activities associated with device maintenance and lifestyle. It also has 10 self-care monitoring items, addressing the surveillance of the percutaneous line, infection and heart failure symptoms, plus 4 items measuring self-care performance regarding alarm management and coping with their new lifestyle with the device.

It has a Likert-type response scale that evaluates how often they perform the self-care behavior, where 1 is equivalent to *never* and 5 to *always*. Their overall range goes from 165 to 33; the higher the score, the better self-care. It is self-administered and takes approximately 10 minutes to complete. It has been culturally adapted in countries such as Japan, Israel and Italy. In Germany the evaluation study of psychometric properties is in progress ⁽⁹⁾.

This questionnaire becomes a fundamental tool for providing information more objectively, contributing to making appropriate decisions regarding the care of this group of patients. However, it has been developed and adapted in Anglo-American cultures, so it requires a special adaptation process to be applied safely and efficiently in other countries and cultures ⁽¹¹⁾.

The adaptation of an instrument into another language is a complex process -a situation generated by cultural differences- and a simple translation is not possible; for this reason, technical, linguistic and semantic aspects must be taken into account. To ensure the cultural adaptation of the instruments in a methodologically correct manner, systematized standards have been proposed in the international literature ⁽¹¹⁾.

In Spanish-speaking countries, particularly in Colombia, there is no adapted version of this scale. Based on this, it is understood why it is necessary to develop psychometric studies that allow its integration into the daily assessment of patients with LVAD.

The objective of the study was to determine the equivalent version of the *Self-Care Questionnaire in patients with definitive ventricular assistance (LVAD)* for Colombia.

MATERIALS AND METHODS

The design used for this study was methodological since it allows the development and adaptation of reliable, effective and functional instruments that can be used to improve research and practice ⁽¹²⁾. The cultural adaptation of the *Self-Care Questionnaire in patients with definitive ventricular assistance (LVAD)* for the Colombian context was carried out.

The methodological development of the study was based on international guidelines for cultural adaptation ⁽¹¹⁾ through five stages.

First stage: The initial translation was performed by two certified professional translators who were native Spanish speakers.

Second stage: A synthesis of the translations was developed. Both translators, plus an observer, compared the results in order to make the necessary adjustments and reach a unified version that maintained technical, semantic and content equivalence.

Third stage: The scale was back-translated into Spanish and then translated into English by two other translators who had not participated in the first stage.

Fourth stage: A committee of experts was assembled, consisting of two nurses specialized in the area and the translators, where the translations were compared until the final version was obtained.

Fifth stage: The final version of the translated scale was submitted to the author for approval.

Sixth stage: After the author's approval, a pilot test of the final version was carried out to verify the interpretation and cultural relevance of the items, as well as the ease of understanding.

Regarding ethical aspects, the authors authorized the adaptation of the instrument. Authorization was also obtained from the ethics committees of both the study from which the original instrument was derived -code: 10947-(3)- and the committee for the adaptation process -number: 9413-. The international and national guidelines that regulate health research were taken into account.

RESULTS

Stage 1 and 2. Initial translation and synthesis of translations. Two translators with a certificate of competency participated in these stages. One of the translators had experience in the self-care construct and the second translator was only an expert in languages. A meeting was held to inform them of the objective of the study and the proposed methodology for the cultural adaptation of the questionnaire. Both translators worked separately to minimize bias. Subsequently, a meeting with them was held in

order to resolve disagreements and generate the synthesis of the translations into Spanish.

Stage 3: Reverse Translation. Two different certified translators with English as their mother tongue were selected. They were sent the Spanish version resulting from the synthesis of the previous stages. Subsequently, back-translation was carried out individually by each of the translators in order to generate the English version of the measurement instrument. With these two versions, the team of researchers and translators met to reach a final consensus that consolidated the most appropriate version (see table 1).

Stage 4: Expert Committee. At this stage, the preliminary version of the *Self-Care Questionnaire in Patients with Definitive Ventricular Assist Devices (LVAD)* was reviewed. Three nursing professionals with extensive experience in the care of patients with advanced heart failure, assist devices and in the English language participated in its development. Additionally, two translators participated, one of them with an academic background in philology, an aspect that favored the semantics, syntax and phonetics of the translation and back translation of the instrument.

77% of the experts mentioned that all items were understandable and clear, but 33% stated that in items 3,5,6,7,8,10 and 11, the standardized term for one of the parts of the device *-driveline-* should be replaced for *percutaneous line*. In item 6 it is suggested to specify the term *support* using *anchorage*; in item 9, the abbreviation PI was complemented by its meaning *-pulsatility index-* for better understanding. Item 31, which states *I measure my blood pressure*, was reconsidered since, in Colombia, this cannot be evaluated. The reason is that the taking of this vital sign must be done with a *Doppler device*. The device has a linear flow; having access to this *Doppler* at home is very expensive and is not yet covered by the health system.

Stage V: Submission of the final version of the questionnaire to the author. The adjustments suggested by the committee of experts were made and both back translations and the final version in Spanish were sent to the author for approval. It was emphasized that in the Colombian context, question 31 was very difficult to assess. The author approved the final version of the instrument and noted that the relevance of the question (either keeping it or withdrawing it) would be determined by the results achieved from the psychometric analysis of the questionnaire, which was initiated in the first semester of 2022 and is still under development.

Stage VI: Pilot Test. At this stage, the final version of the adapted instrument was reviewed by a small group of patients and professionals specialized in assist devices, who reported that the instrument was clear and that each of the questions was properly understood.

DISCUSSION

The process of cultural adaptation of the questionnaire resulted in an instrument of 33 items, equivalent in the Colombian Spanish language variant in experiential, conceptual, idiomatic and semantic ways, through a rigorous follow-up of the guidelines established by the theoretical references that support this methodology.

It proved to be easily understandable and adaptable to the language and culture. Its simplicity in the items and its quick administration make it a promising tool in the assessment of self-care in patients with LVAD.

Patients who have an LVAD implanted are responsible for administering a daily care regimen to maintain normal device function, and to improve health and quality of life. Casida JM et al. (11) point out that success in device retention and increased survival depends on achieving high levels of self-care with the therapeutic regimen. In order to achieve adequate levels of self-care, instruments are required to identify previous positive behaviors, in order to strengthen them, or negative behaviors that require reinforcement and monitoring.

Patients need specific education and personalized training to enable self-management and self-development in the care of their device and their daily life routine ⁽¹²⁾.

Likewise, Casida JM et al. ⁽¹³⁾ mention that the integration of self-care scales into the patient's care plan is essential to assess the patient in a comprehensive manner, facilitate decision making and predict treatment outcomes.

The quality of the final version of the adapted questionnaire depends on the rigorosity of each of the stages, which makes back-translation a very important process in the cultural adaptation of an instrument. This made it possible to obtain a version that felt absolutely natural when read in English. A translation is considered to be good to the extent that it does not appear to have been translated, but looks as if it was originally written in the language in which it is being read ⁽¹⁵⁾.

Another aspect that contributed to the quality of the final version was the expertise of the members from the expert committee, reflected in their knowledge about the preparation of these patients and the recognition of the self-care construct as a central axis in both the recovery and maintenance of health. Since this is a relatively new topic and the number of patients is limited, not all practitioners could be able to support this step ⁽¹⁶⁾.

Different authors mention that the adaptation of instruments into Spanish is understood without difficulty by most Spanish speakers, regardless of their country of origin or the regions of the country which they come from ^(17,18).

In this way, the administration of the self-care questionnaire (LVAD) will become a tool to be used during the hospital stay, resulting from the implantation of the device and to help outpatient monitoring.

Eventually, this study may become the starting point to continue with the validation process and further research in order to have a Spanish-language scale that can be routinely applied by nursing personnel for the identification and monitoring of self-care.

CONCLUSION

- The equivalent version of the Self-Care Questionnaire in Patients with Definitive Ventricular Assist Device (LVAD) obtained in this study ensures conceptual equivalence with the original instrument and guarantees its cross-cultural applicability.

- The methodological development implemented in the study through the six stages favors the reliability and quality of the instrument and minimizes possible biases that may occur during clinical assessment.
- The ease, clarity and comprehensiveness of the questionnaire reported by experts and patients make it a promising tool to be implemented in the care and monitoring of patients with LVAD.

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Table 1

Equivalent version. Self-care Questionnaire in Patients with Definitive Ventricular Assist Device (LVAD).

Original English version Self-Care Questionnaire in Patients with Definitive Ventricular Assistance (LVAD)	Final Spanish version Cuestionario de autocuidado en pacientes con asistencia ventricular definitiva (DAVI)
1. I clean the controller, batteries, and battery connection.	1. Limpio el controlador, las baterías y la conexión de la batería.
2. I make sure the electrical power source and batteries are always at hand, and that they work properly.	2. Verifico que la fuente de energía eléctrica y las baterías estén siempre a la mano y que funcionen correctamente.
3. When I go to sleep, I keep the percutaneous line (<i>driveline</i>), the controller and the power supply in a safe position.	3. Cuando me voy a dormir, mantengo en posición segura la línea percutánea (<i>driveline</i>), el controlador y la fuente de energía.
4. I carry the backup batteries and the controller with me.	4. Llevo conmigo las baterías de repuesto y el controlador.
5. I avoid bending, pulling or moving the percutaneous line (<i>driveline</i>) in the area where it exits.	5. Evito doblar, halar o mover la línea percutánea (<i>driveline</i>) en la zona por donde sale.
6. I use a (anchorage) bracket to hold the percutaneous line (<i>driveline</i>) in place and prevent excessive movement in the area where it exits.	6. Uso un soporte (anclaje) para mantener la línea percutánea (<i>driveline</i>) en su lugar y evitar un movimiento excesivo en la zona por donde esta sale.
7. I keep clean and dry the percutaneous line (<i>driveline</i>) and the area where it exits.	7. Mantengo limpia y seca la línea percutánea (<i>driveline</i>) y la zona por donde esta sale.
8. I follow the steps or instructions to change the bandage in the area where the percutaneous line (<i>driveline</i>) exits.	8. Sigo los pasos o instrucciones para cambiar el vendaje en la zona por donde sale la línea percutánea (<i>driveline</i>).
9. I check and record the speed, flow, power, and IP (pulsatility index) of the LVAD	9. Verifico y registro la velocidad, el flujo, la potencia y el IP (índice de pulsatilidad) del DAVI todos los días.
10. I inspect the percutaneous line (<i>driveline</i>) on its entire path in search of dirt or damage.	10. Inspecciono la línea percutánea (<i>driveline</i>) en todo su trayecto en busca de suciedad o daños.
11. I evaluate and monitor the site where the percutaneous line (<i>driveline</i>) exits in search of infection or drainage, the same way I was explained.	11. Evalúo y monitoreo el sitio por donde sale la línea percutánea (<i>driveline</i>) en busca de infección o drenaje, tal y como se me explicó.
12. I monitor myself to find signs of infection such as fever, chills, or night sweats.	12. Me monitoreo a mí mismo(a) para detectar signos de infección como fiebre, escalofríos o sudores nocturnos.
13. I monitor myself to find blood in my nose, color change in urine, or blood in stool.	13. Me monitoreo a mí mismo(a) para detectar si tengo sangre en la nariz, cambio de color en la orina o sangre en las heces.

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| <p>14. I regularly check my INR at home or at the clinic as stated by the medical instructions.</p> <p>15. I contact the group of ventricular assist professionals in case of alarms or problems with the equipment.</p> <p>16. I have someone to talk to about how to handle the ventricular assist device (LVAD), or how to cope with my health problem.</p> <p>17. I check myself to detect if swelling in my legs appears or increases.</p> <p>18. I monitor myself to detect whether my difficulty to breath worsens.</p> <p>19. I monitor myself to see if fatigue gets worse.</p> <p>20. I monitor my weight.</p> <p>21. When I feel sad or worried I talk to the group of ventricular assist professionals or someone else.</p> <p>22. I adjust my physical activities depending on my symptoms.</p> <p>23. I take my medications the same way they were ordered.</p> <p>24. I exercise regularly.</p> <p>25. I consume a heart-healthy diet.</p> <p>26. I comply with the consumption of the daily-recommended amount of fluid.</p> <p>27. I limit my alcohol consumption to 1 unit a day, for women, or 2 units a day, for men. (1 unit, for example, a 500 ml beer bottle; a 180 ml glass of wine)</p> <p>28. I avoid cigarettes and tobacco smoke.</p> <p>29. I sleep enough.</p> <p>30. I contact the group of ventricular assist professionals in case I have symptoms.</p> <p>31. I measure my blood pressure.</p> <p>32. I monitor myself to detect symptoms of cerebrovascular accident.</p> <p>33. I attend the scheduled medical appointments.</p> | <p>14. Reviso regularmente mi INR en casa o en la clínica según las instrucciones médicas.</p> <p>15. Me contacto con el grupo de profesionales de asistencia ventricular en caso de alarmas o problemas con el equipo.</p> <p>16. Tengo con quién hablar sobre cómo manejar el dispositivo de asistencia ventricular (DAVI) o cómo afrontar mi problema de salud.</p> <p>17. Me reviso para detectar si hay aparición o aumento de la hinchazón de las piernas.</p> <p>18. Me monitoreo para detectar si empeora la dificultad para respirar.</p> <p>19. Me monitoreo para ver si la fatiga empeora.</p> <p>20. Monitoreo mi peso.</p> <p>21. Cuando me siento triste o preocupado hablo con el grupo de profesionales de asistencia ventricular o con alguien más.</p> <p>22. Ajusto mis actividades físicas dependiendo de mis síntomas.</p> <p>23. Me tomo los medicamentos igual a como me los ordenaron.</p> <p>24. Hago ejercicio regularmente.</p> <p>25. Consumo una dieta saludable para el corazón.</p> <p>26. Cumpló con el consumo de la cantidad diaria recomendada de líquidos.</p> <p>27. Limito mi consumo de alcohol a 1 unidad al día para las mujeres o a 2 unidades al día para los hombres. (1 unidad, por ejemplo, una botella de cerveza de 500 ml; una copa de vino de 180 ml)</p> <p>28. Evito los cigarrillos y el humo del tabaco.</p> <p>29. Duermo lo suficiente.</p> <p>30. Me contacto con el grupo de profesionales de asistencia ventricular en caso de presentar síntomas.</p> <p>31. Me tomo la presión arterial.</p> <p>32. Me monitoreo para detectar síntomas de ataque cerebrovascular.</p> <p>33. Voy a las citas médicas programadas.</p> |
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Source: results derived from the cross-cultural adaptation process of the LVAD scale.

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