Reliability and Validity of the Thai Version of the Carolinas Comfort Scale

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Objective: To evaluate the reliability and validity of the Thai version of the Carolinas Comfort Scale (CCS) to measure health-related quality of life (HRQoL) in post-hernia repaired patients.

Materials and Methods: Three hundred twenty-eight patients that underwent the inguinal hernia repair procedure in Vajira Hospital were recruited in the present study. The Thai version of CCS (TCCS) was performed entirely by the patient, and the test-retest reliability was conducted at a 2-week interval.

Results: The TCCS's internal consistency reliability was excellent (Cronbach's alpha 0.89). The inter-rater reliability was found to agree with the intraclass correlation coefficient of 0.90. The test-retest reliability over two weeks was high, with an intraclass correlation coefficient of 0.92.

Conclusion: The Thai version of CCS was found to have adequate reliability and validity and could be used to measure HRQoL in Thai patients that undergo inguinal hernia repair.

Keywords: Reliability; Validity; Carolinas Comfort Scale; Thai version

Inguinal hernia repairs are the most common general surgical operation. According to the recommendation from the International Guidelines for Groin Hernia Management[1], the mesh-based repair is used to reduce the occurrence of inguinal hernia recurrence rate and chronic groin pain. Appropriate surgical techniques and the use of mesh decrease the incidence of surgical failure. In inguinal hernia surgery, primary measures of operative success are the recurrence rate, postoperative complications, and duration after which patients could return to their normal activities of daily living. The health-related quality of life (HRQoL) assessment is another outcome increasingly used to assess inguinal hernia surgery's effectiveness and subsequent improvement in clinical outcomes[2,3].

HRQoL is measured using standardized questionnaires, generic or disease-specific. The generic HRQoL covers a wide range of dimensions and can be used in various conditions such as the short-form 36 questionnaires (SF-36) and EQ-5D-5L. In contrast, disease-specific HRQoL is designed for a particular patient population[4].

Carolinas Comfort Scale (CCS)[5] is used to assess HRQoL and is developed by the Carolinas Laparoscopic and Advanced Surgery Program, Carolinas Medical Center, USA. It is an accurate tool statistically validated against other assessment tools and has become the gold standard for disease-specific quality of life (QoL) assessments in patients with inguinal hernia[6,7]. A recent comparison study reported that the CCS better assess the QoL and satisfaction of patients that underwent surgical inguinal hernia repair in comparison with the generic SF-36[8-10].

The CCS is used by surgeons in 19 US states and 39 countries and translated into multiple languages. The Thai version of the CCS (TCCS) has been used to assess QoL issues concerning inguinal hernia repairs with mesh in the Minimal Invasive Surgery Unit, Department of Surgery, Faculty of Medicine, Vajira Hospital, Navamindrahiraj University,

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Bangkok, Thailand. Therefore, the present study aimed to evaluate the reliability and validity of the TCCS.

Materials and Methods

The original CCS

The CCS consists of eight domains or activities, comprising 23 questions. Each question is graded at six levels with 0 for no symptoms, 1 for mild but not bothersome, 2 for mild and bothersome but not daily, 3 for moderate or daily symptoms, 4 for severe symptoms, and 5 for disabling symptoms. The total score ranges from 0 to 115. The interpretation will be using the mean or median scores in terms of activity score from each domain or activity, mesh sensation score from questions 1a, 2a, 3a, 4a, 5a, 6a, 7a, and 8a, pain score from questions 1b, 2b, 3b, 4b, 5b, 6b, 7b, and 8b, movement limitation score from questions 2c, 3c, 4c, 5c, 6c, 7c, and 8c, and total score from the 23 questions. A lower score indicates a favorable postoperative health status.

Translation process

Before initiating the present study, the Vajira Institutional Review Board had approved the study protocol (COA 78/2556), and the authors also officially contacted the Carolinas HealthCare System for a license agreement translated into the Thai language and the use of the questionnaire. The authors followed the guidelines for the process of cross-cultural adaptation of self-reported measures[11]. The translation process began with a forward translation from English to Thai languages by two bilingual translators. They compared, discussed, and synthesized the first Thai translation version. Next, the Thai version was back-translated to English by bilingual surgeons from Vajira Minimally Invasive Surgical Team. The English-translated version was compared with the original CCS version and checked for mistranslation and misunderstanding. The content validity was performed and reported. An expert committee validated the final Thai version from the Thai hernia society members, and then, the version was tested for reliability and validity.

Clinical validation process

Demographic and clinical data for each participant were collected using a predesigned questionnaire. Before each participant was discharged, the participant was briefly instructed on how to fill in the CCS questionnaires. At the 6-month follow-up periods, all participants completed the CCS questionnaires.

Clinical validity was assessed by content validity. Content validity evaluation was done, using the responses of two independent general surgeon and 10 nurses. The first draft questionnaire was reviewed in aspects of the understanding of questions and vocabulary and sequence of questionnaire.

Study designs, participants, and data collections

The cross-sectional study was conducted at the Department of Surgery, Faculty of Medicine Vajira Hospital, Navamindradhiraj University. The inclusion criteria were patients aged 20 to 70 underwent primary inguinal hernia repair with mesh as ambulatory or inpatient and understand and communicate in Thai language. Patients with a recurrent hernia, bilateral hernia, operated using the tissue repair hernia technique, and that underwent emergency setting operations were excluded. All patients were treated between January 2013 and December 2014, and the TCCS was administered to collect data postoperatively at six months.

Statistical analysis

Patient characteristics were demonstrated in frequency with percentage, ratio, mean ± standard deviation, depending on the type of variables. The test-retest reliability was assessed; all patients were asked to complete TCCS twice at a 2-week interval. Test-retest reliability was determined using the intraclass correlation coefficient. Reliability was determined by calculating Cronbach's alpha. The internal consistency estimated of more than 0.7 were considered acceptable.

The validity was determined by calculating Spearman's correlation coefficient. Correlation coefficients of 0.1 to 0.3, 0.3 to 0.6, and more than 0.6 were considered weak, moderate, and strong, respectively. All statistical analyses were performed using the Stata, version 14 (StataCorp LP, College Station, TX, USA).

Results

Three hundred twenty-eight patients returned for follow-up and completed the TCCS postoperatively at 6 and 6.5 months. No patient was lost during the follow-up, and no recurrence was observed in the present study. One patient had chronic groin pain but improved later with medication. All patient characteristics are shown in Table 1. The overall QoL with TCCS was excellent, with a score of 2.52±3.52 (Table 2).

The Thai version of CCS's internal consistency

Table 1. Patient's characteristics

Characteristics	Value
Sample size	328
Age (year); mean±SD	50.45±11.15
Sex: male; n (%)	318 (96.95)
Unilateral:Bilateral hernia	258:70
Open hernia repair:Laparoscopic hernia repair	194:134

SD=standard deviation

Table 2. The outcome score on Thai version Carolinas Comfort Scale

	Mean±SD	Median [IQR (P25, P75)]
Mesh sensation score	1.78±2.24	1.30 [0.94, 1.52]
Pain score	0.55±1.07	0.31 [0.21, 0.44]
Movement limitation score	0.49±1.44	0.50 [0.20, 0.36]
Total score	2.51±3.52	2.61 [1.33, 2.14]

SD=standard deviation; IQR=interquartile range

and reliability was excellent (Cronbach's alpha 0.89). The inter-rater reliability was found to agree with the intraclass correlation coefficient of 0.90. The test-retest reliability over two weeks was high, with an intraclass correlation coefficient of 0.92.

Discussion

An inguinal hernia is the most common problem in general surgical conditions, occurring in approximately one-third of men diagnosed with an inguinal hernia in their lifetime. An inguinal hernia's age distribution is bimodal, with the highest incidence during childhood and after 50 years of age[12]. The International Guideline for Groin Hernia Management recommends mesh-based hernia repair as the gold standard of care for symptomatic patients. Results used to assess the success of inguinal hernia repair are recurrence rate, pain, recovery time, and complication rate. Not only physically affecting, but also the QoL is another outcome that should be considered after an inguinal hernia surgery[13-15]. A generic QoL tool such as SF-36[16] has been used to evaluate the QoL in inguinal hernia. These generic tools have been beneficial in most situations but lack the specificity to capture some disease-specific details. In 2008, the Carolinas Hernia Center proposed CCS and reported outcome comparison of the generic and specific quality-of-life scales for mesh hernia repairs[5]. CCS questionnaires were evaluated postoperatively in the long term and assessed into the mesh sensation, pain,

movement limitation, and eight positions. The score can indicate post-hernia repair specificity. The CCS was widely translated into several languages.

In the present study, the authors translated TCCS and validated it in 328 patients. The internal consistency was high for all domains, suggesting strong reliability of this translated version.

The authors had followed the standard process of translation using the guidelines for cross-cultural adaptation of self-reported measures[11]. However, the present study was conducted in a single tertiary-care hospital, which may be considered a limitation. The other limitation of CCS was no evidence of CCS to assess emergency inguinal hernia repair. The authors are uncertain about applying this TCCS in a different population in a rural area, which may differ in daily life activities and activities. Furthermore, the authors plan to use TCCS in a large-scale multicenter study to complete a future assessment.

Conclusion

The original CCS was successfully translated to the TCCS, a reliable and valid tool for evaluating the specific QoL among Thai patients at post-inguinal hernia repair.

What is already known on this topic?

The CCS is the gold standard for HRQoL assessment in patients with inguinal hernia.

A recent comparison study reported that the CCS better assess the QoL and satisfaction of patients underwent surgical inguinal hernia repair in comparison with the generic SF-36.

What this study adds?

This study translates CCS into the Thai language and test for reliability and validity.

Conflicts of interest

The authors declare no conflicts of interest.

References

1. HerniaSurge Group. International guidelines for groin hernia management. Hernia 2018;22:1-165.
2. Tolver MA. Early clinical outcomes following laparoscopic inguinal hernia repair. Dan Med J 2013;60:B4672.
3. van Veen RN, Wijsmuller AR, Vrijland WW, Hop WC, Lange JF, Jeekel J. Randomized clinical trial of mesh versus non-mesh primary inguinal hernia repair: long-term chronic pain at 10 years. Surgery 2007;142:695-8.
4. Kristofferzon ML, Ternesten-Hasséus E. A study of two generic health-related quality of life questionnaires--Nottingham Health Profile and Short-Form 36 Health Survey--and of coping in patients with sensory hyperreactivity. Health Qual Life Outcomes 2013;11:182.
5. Heniford BT, Walters AL, Lincourt AE, Novitsky YW, Hope WW, Kercher KW. Comparison of generic versus specific quality-of-life scales for mesh hernia repairs. J Am Coll Surg 2008;206:638-44.
6. Abbas AE, Abd Ellatif ME, Noaman N, Negm A, El-Morsy G, Amin M, et al. Patient-perspective quality of life after laparoscopic and open hernia repair: a controlled randomized trial. Surg Endosc 2012;26:2465-70.
7. Ladurner R, Chiapponi C, Linhuber Q, Mussack T. Long term outcome and quality of life after open incisional hernia repair--light versus heavy weight meshes. BMC Surg 2011;11:25.
8. Heniford BT, Lincourt AE, Walters AL, Colavita PD, Belyansky I, Kercher KW, et al. Carolinas Comfort Scale as a measure of hernia repair quality of life: A reappraisal utilizing 3788 international patients. Ann Surg 2018;267:171-6.
9. Jalil O, Rowlands C, Ruddle A, Hassn A, Morcous P. Medium-term recurrence and quality of life assessment using the hernia-specific Carolinas Comfort Scale following laparoscopic inguinal hernia repair. J Laparoendosc Adv Surg Tech A 2015;25:477-80.
10. Forester B, Attaar M, Chirayil S, Kuchta K, Denham W, Linn JG, et al. Predictors of chronic pain after laparoscopic inguinal hernia repair. Surgery 2021;169:586-94.
11. Beaton DE, Bombardier C, Guillemin F, Ferraz MB. Guidelines for the process of cross-cultural adaptation of self-report measures. Spine (Phila Pa 1976) 2000;25:3186-91.
12. Primatesta P, Goldacre MJ. Inguinal hernia repair: incidence of elective and emergency surgery, readmission and mortality. Int J Epidemiol 1996;25:835-9.
13. Gitelis ME, Patel L, Deasis F, Joehl R, Lapin B, Linn J, et al. Laparoscopic totally extraperitoneal groin hernia repair and quality of life at 2-year follow-up. J Am Coll Surg 2016;223:153-61.
14. Bullen NL, Massey LH, Antoniou SA, Smart NJ, Fortelny RH. Open versus laparoscopic mesh repair of primary unilateral uncomplicated inguinal hernia: a systematic review with meta-analysis and trial sequential analysis. Hernia 2019;23:461-72.
15. Mier N, Helm M, Kastenmeier AS, Gould JC, Goldblatt MI. Preoperative pain in patient with an inguinal hernia predicts long-term quality of life. Surgery 2018;163:578-81.
16. Isil RG, Avlanmis O. Effects of totally extraperitoneal and lichtenstein hernia repair on men's sexual function and quality of life. Surg Endosc 2020;34:1103-11.