HERQL, a Mobile App to Enhance the Long-term Follow-up of Hernia Patients

Ching-Shui Huang
Cathay General Hospital
Heng-Hui Lien
Cathay General Hospital
Feng-Chuan Tai
Cathay General Hospital
Jia-Uei Wong
Fu-Jen Catholic University Hospital
Chi-Cheng Huang (chishenh74@gmail.com)
Taipei Veterans Genreal Hospital

Research Article

Keywords: HERQL, Hernia Patients, Long-term Follow-up

Posted Date: October 20th, 2021

DOI: https://doi.org/10.21203/rs.3.rs-964218/v1

Abstract

Purpose:

Hernia repair is one of the most commonly performed surgical procedures worldwide with long-term outcomes less appraised, mainly due to high loss of follow up rate and poor patients' compliance, which result in a biased estimate of recurrence, complication, and patients' subjective quality-of-life perception. To overcome these limitations, we developed a novel mobile app to enhance the follow up and outcomes assessment of hernia patients.

Materials and Methods:

The mobile app was empowered by a cloud-based corroborative system. Hernia patients could administer a quality-of-life measuring instrument, HERQL, to assess outcomes of hernia repair. The HERQL questionnaire comprises a 4-item summative pain score measuring pain and discomfort resulted from various strenuous activities. Symptomatic burden, functional domains, and post-operative satisfaction and potential complications were evaluated.

Results:

During the one year's enrollment period, 2615 patients who had their hernias repaired at our hospital were identified from medical records and an invitation was sent through post. Response rate was 11.9% (311 patients followed the instruction, successfully logged on and completed HERQL survey). There were 93 ventral/incisional hernias, 202 groin hernias, and 16 both. The earliest repair took place more than 13 years ago. Overall recurrence rate was 0.96% (n=3), and 88.7% (n=276) of participants rated their last hernia repair as satisfactory/very satisfactory. Around seventy percent of patients (n=213, 68.5%) reported no discomfort relevant to hernia repairs, and 61.1% (n=190) never experience mesh foreign body sensation.

Conclusion:

The establishment of the mobile app platform could enhance the quality of care for hernia patients and facilitate outcomes research for this common disease with a more comprehensive and complete follow up. The experiences learnt from this study could project to other surgical diseases as well.

Introduction

Hernia repair is one of the most common surgical procedures performed worldwide. With the development of prosthetic mesh and tension free techniques, the recurrence rate following hernia repair has been reduced drastically [1–7]. Outcomes research of hernia surgery should concentrate on post-operative quality of life and complications [8–9]. The long-term outcomes of hernioplasty, however, are not thoroughly evaluated. High loss of follow up rate and poor compliance from patients result in a biased evaluation of recurrence, complication, and patients' subjective quality-of-life.

In past few years, we have developed a hernia-specific quality of life assessment instrument, HERQL, for both groin and abdominal wall hernias [10–11]. The validation study was conducted from 386 HERQL surveys from 183 groin hernia patients. Internal reliability of the multi-item summative pain score domain was indicated by Cronbach's alpha coefficient of 0.85. Criterion validity was evidenced by substantial to moderate correlations of HERQL with EQ-5D-5L in pain/discomfort and health impact subscales [12]. Clinical validity was ascertained from the worse hernia protrusion, pain during mild to heavy exercise, activity restriction and health impairment scores reported from pre-operative than those reported from follow-up patients. Clinical responsiveness was indicated by the time effect of -1.63 in summative pain score from repeated measures [10].

As previously mentioned, low compliance and high loss of follow up of hernia patients compromised outcomes evaluation of hernioplasty, especially when long-term outcomes were pursued. Indeed, there remains an unmet need to deliver a precise estimate of hernia recurrence, as well as the associated complications and subjective wellbeing [13]. To overcome these limitations, we purposed a novel mobile app to enhance the follow up and outcomes assessment of hernia patients.

Materials And Methods

Study design

The full study protocol had been reviewed and approved by IRB of Cathay General Hospital (protocol number: CGH-P102069). Patients who had underwent hernia repair at our hospital were identified from medical records. Both groin and abdominal hernias, the latter including primary ventral and incisional hernias, were eligible. The latest hernia surgery should be performed at least one-year prior to the starting date of the study. The enrollment period was between Apr 1, 2016 and Mar 31, 2017. Identified cases were contacted through post using the address from medical chart. Patients who completed both HERQL questionnaire and signed informed consent wound receive a remuneration of 200 New Taiwan dollar (approximately equal to 7 USD at the year 2016) by post. All methods were carried out in accordance with relevant guidelines and regulations. Informed consent was obtained from all participants.

HERQL instrument

A hernia-specific quality of life assessment instrument, HERQL, has been described elsewhere [10]. In brief, HERQL comprised a 4-item summative pain score measuring pain and discomfort resulting from various strenuous activities (rest, mild, moderate or heavy activities). In the meantime, symptomatic burden and functional domains, as well as post-operative satisfaction and potential complications were assessed concurrently.

Pain and activity restriction due to pain or discomfort were rated with a 0-10-point Likert-type scale in each item while symptomatic and functional domains (hernia protrusion, analgesic usage, hernia's impact on health, economic burden and subjective quality of life/global health) were evaluated with a 5-

point Likert-type scale. An auxiliary post-operative module, also equipped with 5-point Likert-type scales, was designed to decipher potential complications following hernia repairs; these items included mesh foreign body sensation, severity of complications, overall satisfaction for hernia repair, confidence that hernia will not recur and quality-of-life improvement by hernia repair. All scales were arranged with the order of higher values representing compromised functionality or worse symptoms.

Mobile app

The mobile app was empowered by a cloud-based corroborative system. The mobile app version of HERQL assessing patients' quality of life, was launched for index cases identified form medical records, and an invitation was sent by post for those who had undergone hernia repairs at our institute at least one year before the study began. Both Android (https://play.google.com/store/apps/details?id=com.Synerfun.SynerfunPC68/) and iOS (https://itunes.apple.com/TR/app/id913626455/) platforms were supported, and an URL linked to an online Google Documents-based questionnaire (http://goo.gl/FMHlCt) was provided as an alternative for those not equipped with a smart phone but with an internet access. Fig. 1 shows the Quick Response (QR) code for HERQL mobile app and Fig. 2 shows screenshots from an iOS-based device capturing all steps from log-on to the end of questionnaire. A corresponding google site (https://sites.google.com/site/herqlsurvey/) was established for communication and education purpose (Supplementary Fig. 1). The mobile app system was developed in corporation with SynerFUN Technology Cooperation (Hsinchu City, Taiwan). A preset combination of unique ID and password was sent to each invitee via mail and electronically signed informed consent was obtained with HERQL app through built-in signature module (Supplementary Fig. 2). A carbo copy of informed consent was sent to the e-mail provided by each subject for preservation as well.

Results

Study population

During the one year's enrollment period, 2615 patients who had their hernias repaired at our institute were invited through the post. Among them, there were 2245 males and 370 females. The mean age was 60 years-old (median: 62, ranged 1-95), and standard deviation was 15. The response rate was 11.9% (311 patients followed the instruction, with successful log on and completed the HERQL survey). There were 93 abdominal wall (incisional/ventral) hernias, 202 groin hernias, and 16 with both abdominal wall and groin hernias. The earliest hernia repair took place more than 13 years ago (mean: 5.5, median: 5.4, range: 1-13.6). Most responders were within 5 years of hernia repairs. Table 1 shows types of prosthetic mesh adopted during hernioplasty.

Table 1
Types of prosthetic mesh used for hernia repairs.

Mesh type	Groin hernia(n=218*)	Abdominal wall hernia(n=109*)
Composix/Ventrio	0	38
Kugel/Modified Kugel	60	11
PHS/UHS	57	11
Paritex	2	0
Mesh plug	77	9
Laparoscopy	13	2
Others	9	38
*Including 16 with both groin/abdominal wall hernias.		

Mobile app platform

The mobile app was empowered by a cloud-based corroborative system. The system comprised a data management and storage subunit, and a security information subunit. Hernia patients could administer HERQL, to report their outcomes of hernia repair. The platform provided an easy and efficient way for patients reporting any discomfort to their surgeons, which was designed to enhance the long-term follow up and compliance of hernia patients.

Long-term follow up of hernia repairs

The overall recurrence rate was 0.96% (Q19, n=3), and 88.7% (n=276) of participants rated their last hernia repair as satisfactory or very satisfactory (Q18). Two hundred thirteen patients (68.5%) reported no discomfort related with hernia repairs (Q16), and 61.1% (n=190) never experience mesh foreign body sensation (Q15). Quality of life improvement following hernia repairs was ascertained in 90.4% (n=281) of enrolled subjects (Q20).

Subgroup Analysis

Comparisons were conducted between 77 patients with mesh plug and 57 with PHS/UHS from groin hernia group. Mesh plug hernia repairs reported higher analgesic usage than those with PHS/UHS (1.2 vs 1, P=0.009, Q08), worse health impaction (1.9 vs 1.5, P=0.025, Q11), economic burden (1.4 vs 1.2, P=0.036, Q12), foreign body sensation (1.8 vs 1.4, P=0.002, Q15), discomfort severity (1.5 vs 1.2,

P=0.005, Q17), less satisfaction (1.7 vs 1.4, P=0.03, Q18), less confidence in hernia repair (2.2 vs 1.9, P=0.009, Q19) and compromised quality of life improvement (1.4 vs 1.1, P=0.025).

Conceptual structure of HERQL

Figure 3 shows the conceptual of HERQL with and without auxiliary post-operative module.

Discussion

Hernia repair is one of the long-lasting surgical procedures performed day by day, which can be traced back to the era of ancient Egypt [14]. Recurrence following hernia repairs has improved enormously, thanks to the invention and wide adaption of tension-free mesh repair. For ventral/incisional hernias, recurrence rate could be reduced from 50% of primary repair to 10-23% with a prosthetic mesh [15]. With the reduced rate of recurrence equal or less than 1% for groin hernia repair, more attention should be paid to complications which may bother patients' long-term wellbeing such as chronic pain [16].

To understand treatment outcomes further, a valid tool to assess the multi-factorial quality of life should be sought by surgical communities. There are several quality of life instruments specific for hernia disease, such as Caroline Comfort Scale (CCS), HerQLes, EuraHSQoL, COMI-hernia, Inguinal Pain Questionnaire and Brief Pain Inventory (BPI), to name a few [17–22]. Our published HERQL targets both abdominal wall and inguinal hernia, traditional open and minimally invasive surgeries, and various mesh materials [10–11]. HERQL deciphers hernia-related multi-dimensional quality of life aspects, including symptomatic physical or psychological burden and functionalities. One merit of using HERQL for hernia outcomes research is the determination of the causal relationship between formative symptomatic scales and reflective functional indicators, which is elaborated through the pathway analysis of structural equation modeling (SEM) [23–25].

In current study, the experience of developing a mobile app to facilitate the long-term follow up of hernia patients was reported. The cloud-based system eliminated the need of returning hospital visits for subjects who had undergone hernia repairs as early as a decade ago, which in turn wound augment the follow up condition. Hernia is one of surgical diseases with compromised long-term follow-up as there is neither periodic surveillance nor medicine prescription once the defect is repaired. In addition, patients with recurrent disease may seek second opinions and reoperation from surgeons other than the one with failed repair. Therefore, an easy to assess reporting system will be of great value for patients to present their immediate abdominal or groin conditions and for surgeons to update treatment outcomes.

Under these hypotheses, we sent inviting mail to subjects who had their hernias repaired at our institute more than one year ago, with these cases identified from medical records. With enclosed preset ID and password, they could easily download the iOS or Android version of mobile app, complete quality of life survey and electrical signature within a few minutes. For those not familiar with mobile app, a Google

Forms survey provided an on-line alternative. The response rate was 11.9%, or slightly more than one-tenth of identified candidates.

Taking the study conducted by Heniford et al. as an example, CCS questionnaire was mailed to 1,048 patients and their response rate was 12.9% [17]. We invited hernia patients who completed surgery more than one year before the enrollment, and our response rate was like that of CCS study while a much longer time interval between hernioplasty and questionnaire survey was pronounced in current study. One major reason for low response rate was loss of contact due to wrong address resulting in undelivered mails. With longer follow up, migration occurred naturally while some subjects might have passed away, and these patients finally became unapproachable. Although compensation was arranged, lack of incentive, worry about fraud and reluctance to participate might compromise recovery of HERQL survey substantially, which constituted another reason for low response.

Despite the fair response rate of slightly more than one-tenth, successful HERQL assessment was performed for 311 patients with majority diagnosed with groin hernias, reflecting the clinical scenarios of hernia population. Our results suggested that most hernia patients enjoyed a relatively low recurrence rate (less than 1%), and around 90% of them reported a satisfactory/very satisfactory hernia repair experience. Only slightly more than 30% of surveyed subjects reported hernioplasty-related discomfort, and less than 40% experienced mesh foreign body sensation. Most importantly, 90.3% of hernia patients ascertained improvement in quality of life following hernia surgeries, indicating that elimination of hernia-related symptoms might be the main contributor of such improvement.

In our previous study, 192 mesh plug groin hernia repairs were compared with 234 PHS repairs. Postoperatively the mesh plug group had higher incidence of chronic non-disabling groin pain [26]. In current study, subgroup analysis was conducted comparing prosthetic devices of plug and PHS/UHS. Corresponding to our previous study, mesh plug did hamper hernioplasty outcomes with worse symptoms and compromised functionality. Worse (higher) symptomatic scores were reported from analgesic usage, health impact, economic burden, foreign body sensation and discomfort severity as well as compromised functionalities in less satisfaction, confidence in hernia repair and quality of life improvement.

Conceptual structure of HERQL with and without of the auxiliary post-operative module displayed satisfactory model fit indices (Fig. 3), further augmenting the superiority of SEM approach of HERQL. Fayers et al. initiated the efforts to use SEM for conceptual structure of quality of life measuring instrument, who aimed to separate causal variables (symptoms) from effect indicators (functional domains) [23]. The causal and indicator variables model proposed by Fayers et al. and Boehmer et al. formed the basis of HERQL structure [10–11, 24–25]. The critical rationale underpinning the causal-indicative duality was that hernia-associated symptoms impaired subjective quality of life perception, which was subsequently reflected in functional domain indicator variables, as well as in patients' satisfaction from the postoperative module. Elaboration on causal/indicator duality recognized one-way causal effects of symptomatic scales upon functional domains, but not vice versa [18].

There were some limitations of the study. First, retrospective design inevitably brought recall bias, especially for those with longer follow up. Second, not all clinical and demographic data were available through chart reviews, such as body mass index and fascia defect size, which could hamper post hoc and multi-variate analysis considerably. Third, some elderly patients might not be able to complete the survey without an assistant, and there was no printed questionnaire if mobile app was not properly installed. Fourth, no further remind mail or phone call was attempted if there was no response from the initial inviting mail.

Experience learnt from the study can translate into further hernia outcomes research design. For example, to establish an updated Hernia Registry which includes a novel mobile app to enhance the follow up of hernia patients, and a cloud-based database for both surgeons and hernia patients. The corroborative database is suitable for surgeons to collect clinical and operative details from hernia surgeries and provides a platform for real-time communication between surgeons and hernia patients to enhance post-operative follow up and outcomes assessment. Surgeons could enter the clinical and operative data immediately after completion of hernia repairs with mobile devices while sensitive clinical data were secured and restricted to authorized personnel. On the other hand, hernia patients could review their clinical and operative details in a well-designed and self-explanatory manner. Hernia patients could also record the post-operative events, such as visual analog pain scale, wound condition and complications, as well as administer HERQL periodically, to assess the outcomes of hernia repair. Finally, the instant message communication subunit provides an easy and efficient way for patients reporting any discomfort to their surgeons and a proper response from the latter could enhance the long-term follow up compliance rate of hernia patients.

Conclusion

The establishment of the mobile app could enhance the quality of care for hernia patients and facilitate outcomes research for hernia disease with a more comprehensive and complete follow up. The experiences learnt from this project could propagate into other common surgical procedures [27-28]. This study will facilitate hernia outcomes research and enhance the quality of care for this common disease by providing a validated HERQL instrument with enhanced sensitivity.

Declarations

Acknowledge:

All authors declare that they have no competing interests. The work was supported in part by MOST-103-2314-B-281-004-MY2 and CGH-MR-A10510. This study contained materials presented at the 39th Annual International Congress of European Hernia Society, during May 24-27, 2017, Vienna, Austria.

References

1. Lomanto, D. *et al.* Inguinal hernia repair: toward Asian guidelines. *Asian J Endosc Surg*, **8** (1), 16–23 (2015 Feb).
2. Simons, M. P. *et al.* European Hernia Society guidelines on the treatment of inguinal hernia in adult patients., **13**, 343–403 (2009).
3. Huang, C. S. The evolution of groin hernioplasty, an update. *Formos J Surg*, **43**, 278–284 (2010).
4. Mason, R. J., Moazzez, A., Sohn, H. J., Berne, T. V. & Katkhouda, N. Laparoscopic versus open anterior abdominal wall hernia repair: 30-day morbidity and mortality using the ACS-NSQIP database. *Ann Surg*, **254**, 641–652 (2011).
5. Nguyen, M. T. *et al.* Comparison of outcomes of synthetic mesh vs suture repair of elective primary ventral herniorrhaphy: a systematic review and meta-analysis. *JAMA Surg*, **149**, 415–421 (2014).
6. Scott, N. W. *et al.* Open mesh versus non-mesh for repair of femoral and inguinal hernia.Cochrane Database Syst Rev. 2002;CD002197.
7. Woods, B. & Neumayer, L. Open repair of inguinal hernia: an evidence-based review. *Surg Clin North Am*, **88**, 139–155 (2008).
8. Jensen, K. K., Henriksen, N. A. & Harling, H. Standardized measurement of quality of life after incisional hernia repair: a systematic review. *Am J Surg*, **208** (3), 485–493 (2014 Sep).
9. Sandø, A., Rosen, M. J., Heniford, B. T. & Bisgaard, T. Long-term patient-reported outcomes and quality of the evidence in ventral hernia mesh repair: a systematic review., **24** (4), 695–705 (2020 Aug).
10. Huang, C. C. *et al.* Quality of life of inguinal hernia patients in Taiwan: The application of the hernia-specific quality of life assessment instrument.PLoS One. 2017 Aug17;12(8):e0183138.
11. Huang, C. C. *et al.* the hernia-specific quality-of-life assessment instrument, to extend the clinical applicability for abdominal wall hernias., **24** (4), 771–780 (2020 Aug).
12. Herdman, M. *et al.* Development and preliminary testing of the new five-level version of EQ-5D (EQ-5D-5L). *Qual Life Res*, **20** (10), 1727–1736 (2011 Dec).
13. Harji, D. *et al.* NoSTRA HarMoNY. A systematic review of outcome reporting in incisional hernia surgery. BJS Open 2021 Mar 5;5(2):zrab006.
14. Legutko, J., Pach, R., Solecki, R., Matyja, A. & Kulig, J. [The history of treatment of groin hernia]. *Folia Med Cracov*, **49** (1-2), 57–74 (2008).
15. Fränneby, U., Sandblom, G., Nordin, P., Nyrén, O. & Gunnarsson, U. Risk factors for long-term pain after hernia surgery. *Ann Surg*, **244** (2), 212–219 (2006 Aug).
16. Luijendijk, R. W. *et al.* A comparison of suture repair with mesh repair for incisional hernia. *N Engl J Med*, **10** (6), 392–398 (2000 Aug).
17. Heniford, B. T. *et al.* Comparison of generic versus specific quality-of-life scales for mesh hernia repairs. *J Am Coll Surg*, **206**, 638–644 (2008).

18. Krpata, D. M. *et al.* Design and initial implementation of HerQLes: a hernia-related quality-of-life survey to assess abdominal wall function. *J Am Coll Surg*, **215**, 635–642 (2012).
19. Staerkle, R. F. & Villiger, P. Simple questionnaire for assessing core outcomes in inguinal hernia repair. *Br J Surg*, **98**, 148–155 (2011).
20. Chung, L. & O'Dwyer, P. J. Pain and its effects on physical activity and quality of life before operation in patients undergoing elective inguinal and ventral hernia repair. *Am J Surg*, **208**, 406–411 (2014).
21. Muysoms, F. *et al.* EuraHS: the development of an international online platform for registration and outcome measurement of ventral abdominal wall hernia repair., **16**, 239–250 (2012).
22. Fränneby, U. *et al.* Validation of an Inguinal Pain Questionnaire for assessment of chronic pain after groin hernia repair. *Br J Surg*, **95**, 488–493 (2008).
23. Fayers, P. M., Hand, D. J., Bjordal, K. & Groenvold, M. Causal indicators in quality of life research. *Qual Life Res*, **6**, 393–406 (1997).
24. Fayers, P. M. & Hand, D. J. Factor analysis, causal indicators and quality of life. *Qual Life Res*, **6**, 139–150 (1997).
25. Boehmer, S. & Luszczynska, A. Two kinds of items in quality of life instruments: 'indicator and causal variables' in the EORTC QLQ-C30. *Qual Life Res*, **15**, 131–141 (2006).
26. Huang, C. S., Huang, C. C. & Lien, H. H. Prolene hernia system compared with mesh plug technique: a prospective study of short- to mid-term outcomes in primary groin hernia repair., **9** (2), 167–171 (2005 May).
27. Wu, J. M. *et al.* Tablet PC-enabled application intervention for patients with gastric cancer undergoing gastrectomy. *Comput Methods Programs Biomed*, **119** (2), 101–109 (2015 Apr).
28. McCarthy, M. Jr *et al.* Assessment of patient functional status after surgery. *J Am Coll Surg*, **201**, 171–178 (2005).

Figures

Figure 1

Quick Response (QR) code for HERQL mobile app.

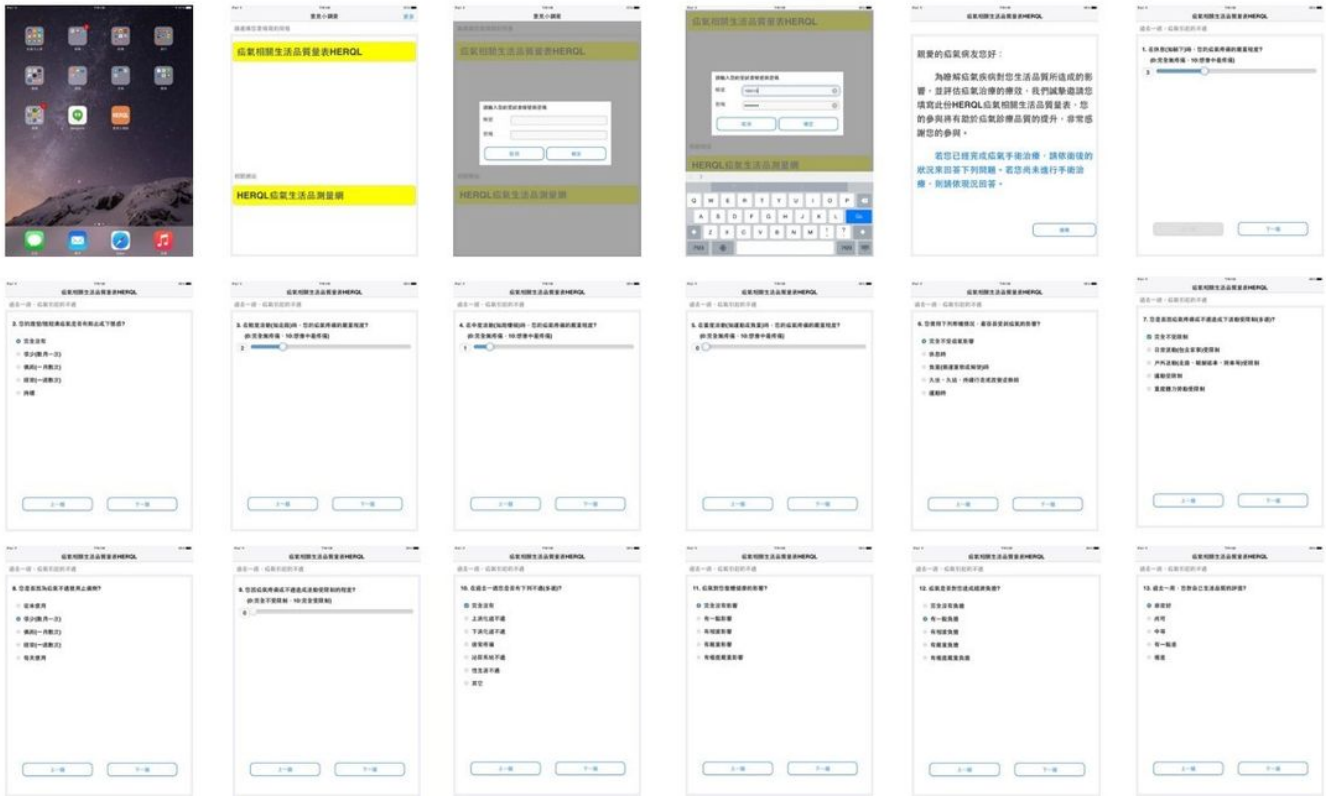
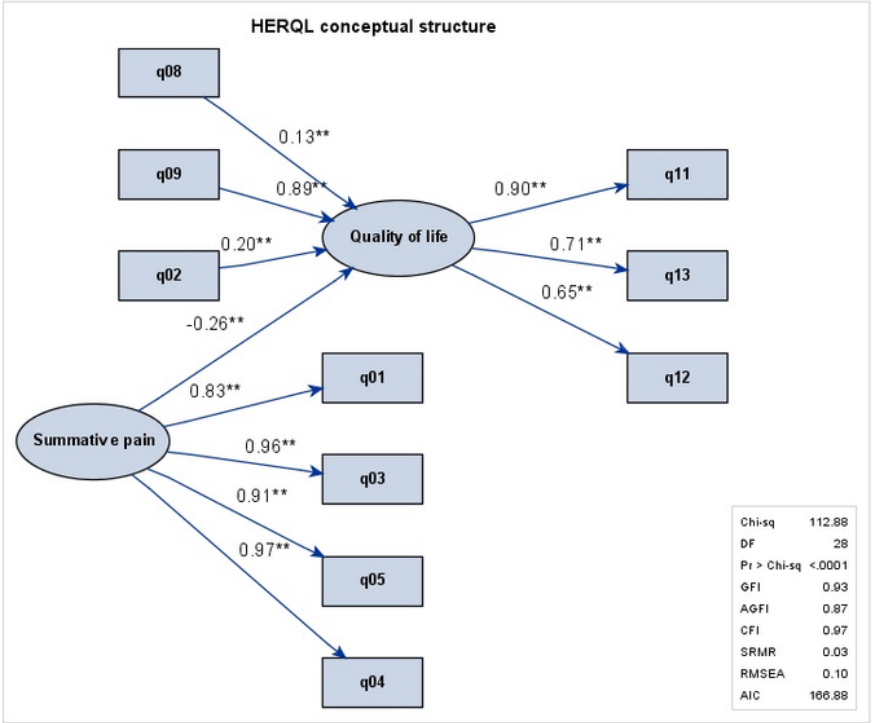


Figure 2

Screenshots of HERQL mobile app from an iOS-based device.



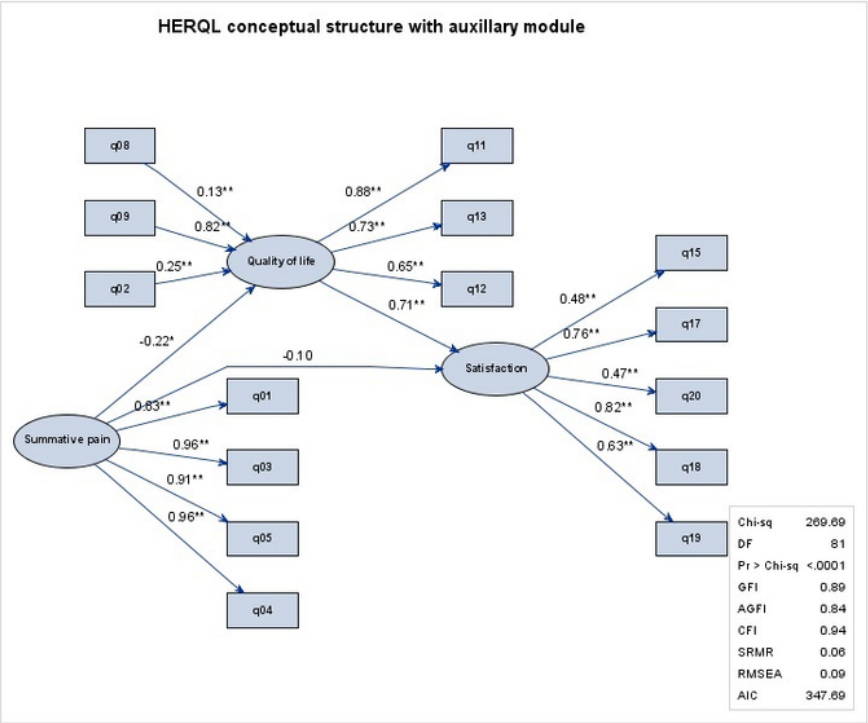


Figure 3

Conceptual structure of HERQL without (top) and with (bottom) the auxiliary post-operative module. Circles: latent factors, rectangles: measured variables (questionnaire items). Q01: pain at rest, Q02: hernia protrusion, Q03: pain from mild activity, Q04: pain from moderate activity, Q05: pain from heavy activity, Q08: analgesic usage, Q09: activity restriction, Q11: hernia's impact on health, Q12: economic burden, Q13: quality of life/global health, Q15: foreign body sensation, Q17: complication severity, Q18: overall

satisfaction, Q19: confidence in hernia repair, Q20: quality of life improvement by hernia repair. Arrows indicate the direction of regressive relationships. Numeric values are regression weights. *P<0.05, **P<0.01.

Supplementary Files

This is a list of supplementary files associated with this preprint. Click to download.

- Supplementarymaterials.docx