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Review Article

Review of currently used standardized measures of quality of life after ventral incisional hernia repair: systematic review

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ABSTRACT

After advancements in surgical and anaesthetics expertise and increased life spans among patients with complex abdominal surgeries, clinicians are left with the next main challenge, to how to improve the quality of life in patients with incisional hernia resulted from previous complex abdominal surgeries. To date there is no consensus over the choice of instrument and time frame for its administration in the literature. The aim of this review was to search for the current literature on measurement of quality of life in patients with ventral incisional hernia repair and to explore how effective each QOL instrument was for measuring impact on quality of life after ventral incisional hernia repair. In accordance with PRISMA guidelines two independent clinicians searched for Mesh and specific terms related to quality of life in patients with ventral incisional hernia. Search was made on PubMed, Embase and other research databases. Trial registries were searched for any published or unpublished trials. Literature search came up with 461 articles. After scanning and removal of duplication, 200 articles were subjected to inclusion and exclusion criterion and 59 articles were selected for qualitative analysis. Different scales for the measurement of quality of life after ventral incisional hernia repair were found. The incidence of incisional hernia itself was found to be the biggest determinant of poor quality of life, regardless of timescale of follow up and type of surgery performed. No single instrument was found to be complete enough to address the wide-ranging health-related quality of life issues in patients after incisional hernia repair.

Keywords: Quality of life, Health related quality of life, Hernia, Abdominal hernia, Ventral hernia, Incisional hernia, Patient reported outcomes, Health surveys and questionnaires, Health related quality of life, Ventral hernia, Ventral incisional hernia repair

INTRODUCTION

Incisional hernias are often diagnosed within the first 3 years after initial laparotomy.[1] In Western world especially in UK, Incisional hernia and its effect on patient's quality of life is insidiously becoming a major problem for population and health system. Emergency laparotomy network in UK published a report in 2012 including 1853 patients from 35 institutions, showed 34.6% patients were less than 60 years of age, while 24.4% were more than 80 years of age. This data does not include elective procedures but gives an overlook of current trends.[2]

With more and more surgeries in younger population, we are inadvertently heading towards a situation with more IH surgeries in future. Age is not only one determinant. Obesity is making it more difficult to treat IH with

conventional manner and more complex procedures are evolving. There was a marked increase reported in obese population in UK from 13.2% in 1993 to 26.0% in 2013 for men, and from 16.4% to 23.8% for women.[3]

Our focus in this study is impact of HRQOL of patients with incisional hernia repair. IH is a common complications of midline abdominal incisions, with a reported incidence of 12.8% at 2 years of follow-up in a systematic review of 14,618 patients.[4] In colorectal cancer resection, the rate of incisional hernia has been reported as high as 39.9%, including both open and laparoscopic approaches (40.9% and 37.1%, respectively).[1]

QOL in the context of health is called HRQOL. As QOL is a multidimensional domain and measured in terms of physical, mental, social and emotional aspects, same is with HRQOL. HRQOL measures explore concepts beyond general health issues and look specifically for consequences caused by health-related matter or intervention.

The rising expectations of the community from surgical field in the past 150 years have led to a shift away from reviewing health in terms of survival, through a phase of defining it in terms of freedom from the disease, thence to an emphasis on the person's ability to perform his daily activities, and more recently to an emphasis on positive themes of happiness, social and emotional well-being, and QOL.[5]

REVIEW OF LITERATURE

Design

Qualitative systematic review of all available published primary literature in peer reviewed journals related to surveys and questionnaires assessing QOL in patients with ventral abdominal wall IHR.

Data source

Protocol was registered on PROSPERO (International prospective registry for systematic reviews) and conducted following PRISMA (Preferred reporting items for systematic reviews and meta-analysis) guidelines. Using PICO framework for devising literature search strategy, Mesh terms and keywords such as "quality of life", "surveys and questionnaires", "hernia", "abdominal or incisional or ventral hernia repair" and "patient reported outcomes" were searched on PubMed, Embase, Medline, PsychINFO and CINAHL databases from the dates of inception of these databases. Clinical trials registries (WHO, Clinicaltrials.gov, ISRCTN, ANZCTR, DRKS, EU-CTR, IRCT) were searched for any upcoming but unpublished results. Cochrane database of systematic reviews and Cochrane central register for clinical trials was also sought. All duplicates were omitted after cross referencing all data bases.

Eligibility criterion for study selection

We have included all articles related to QOL assessments in patients with VIHR where:

- Validated QOL questionnaires or surveys were used to determine patient reported quality of life outcome after VIHR.
- Standard but non-validated QOL questionnaires or surveys used.
- New questionnaires or instruments designed with internal or/and external validation.
- Validated pain scores were used, in conjunction with QOL questionnaire to assess the outcome of the surgery as a part of QOL assessment.
- Participants in trials were all adults, age more than 18 years.
- Where primary or recurrent incisional hernia repair was done.

All studies were excluded where:

- Main language was other than English.
- Participants of trial were less than 18 years of age.

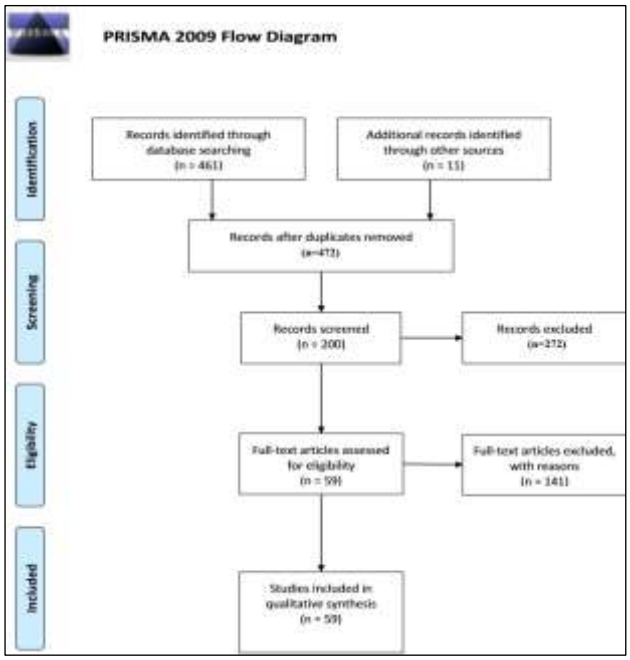

Figure 1: PRISMA flow diagram for literature selection for systematic review.

COMMENTARY ON QUALITY OF LIFE INSTRUMENTS

Generic QOL scales

SF36 (Short form-36): SF-36 is most commonly used instrument to measure QOL in the literature and regarded as a gold standard. SF36 is a set of generic, coherent and easily administrable quality of life measures. These

measures rely on patient reported outcomes and is based on patient perception of bodily pain, comfort and function. It is generic questionnaire with 36 questions in 8 domains consisting of physical and mental health summary.[6] The eight domains that the SF36 measures are as follows: physical functioning; role limitations due to physical health; role limitations due to emotional problems; energy/fatigue; emotional well-being; social functioning; pain; general health. Score ranges from 0 to 100%. Average time taken in some studies was five minutes. It is available in score of languages and proven to be culturally adaptive. It is in public domain and free to use.

SF-36 has its drawbacks as it is generic and does not address fully, issues related to hernia. Some researchers found it to be time-consuming and panned it for its inability to track back to patient's baseline function.

Short form 12 (SF-12)

SF-12 is a shorter version of SF-36, provides a solution to the problem faced by many investigators who must restrict survey length. The instrument was designed to reduce respondent burden while achieving minimum standards of precision for purposes of group comparisons involving multiple health dimensions. SF-12 is easily administrable, quicker to fill in and interpretation. It is also available in many languages and in public domain to use.

EQ-5D-3L (1990)

The 3-level version of EQ-5D (EQ-5D-3L) was introduced in 1990 by the EuroQol Group. The EQ-5D-3L essentially consists of 2 pages: the EQ-5D descriptive system and the EQ visual analogue scale (EQ VAS).

The EQ-5D-3L descriptive system comprises the following five dimensions: mobility, self-care, usual activities, pain/discomfort and anxiety/depression. Each dimension has 3 levels: no problems, some problems, and extreme problems.

It is available in various modes and 170 different languages (version April, 2017).

EQ-5D-5L

Improved version of EQ-5D-3L introduced in 2009 to increase the sensitivity and reduce the ceiling effect. Severity index, level of perceived problems per dimension and instructions to score were changed to increase the sensitivity and to make the whole process simpler.

15 D

The 15D is a generic, comprehensive (15-dimensional), self-administered instrument for measuring HRQOL among adults (age 16+ years). It combines the advantages of a profile and a preference-based, single index measure. A set of utility or preference weights is used to generate the 15D score (single index number) on a 0-1 scale. In most of the important properties the 15D compares favourably with other preference-based generic instruments.[7]

15D is a generic, 15-dimensional, standardized questionnaire, which describe 15 different dimensions: breathing, mental function, speech, vision, mobility, usual activities, vitality, hearing, eating, elimination, sleeping, distress, discomfort and symptoms, sexual activity, and depression. Completion time is 5-10 minutes.

Specific QOL Scales

Carolina comfort scale (CCS)

Carolinas Comfort Scale (CCS) developed by physician and researchers from Carolina laparoscopic and advanced surgery programme (CLASP), to monitor quality of life in patients undergoing hernia repair. It consists of 23 items on a scale of 0-5. severity of pain, sensation and movement limitations from the mesh in the following eight categories: laying down (LD), bending over (BO), sitting up (SU), activities of daily living (ADL), coughing or deep breathing (CB), walking (W), stairs (S), and exercise (E).

CCS and SF 36 are correlated as far as physical mental score summary are concerned and can be used in conjunction.

The gastrointestinal quality of life index (GIQLI)

This questionnaire is comprised of 36 items each with 5 response categories. Together they yield a total QOL score from 0 to 144.

The GIQLI is not a diagnostic tool. While it can moderately differentiate between patients with gastroenterological diseases and healthy individuals, it will not discriminate between diseases. GIQLI correlate slightly with other QOL instruments. But as it is specific to GI diseases and symptoms related to them, it cannot be applied generally in all situations.

Hernia related quality of life survey (HerQles)

Krpata and co-researchers designed a hernia-specific QofL instrument with a focus on abdominal wall function, evaluate its measurement properties, and assess the impact of VHR on QofL using this new instrument.[8]

HerQles is a hernia specific quality of life assessment tool, consisting of 12 items that patients score from 1 to 6. The 12-question QofL survey, HerQles, is reliable and valid and is the only incisional hernia specific questionnaire available to date.

Table 1: Comparison of different types of QOL instruments in tabloid form.

Instrument	Time used in literature	Hernia specific	No of questions/ components	Physical component	Mental component	Body image	Financial impact	Sexual life	Pros	Cons
Generic or non-specific QOL instruments										
SF-12 (Short Form 12)	5	No	12	Yes	Yes	No	No	No	Takes less time then SF36 gives same information, multi-language	Cannot track back to baseline QOL, time consuming
SF-36 (Short Form 36)	24	No	36	Yes	Yes	No	No	No	Coherent, generic, self-administered, statistically describe QOL.	Lack sexual component and body image
EQ-5D-3L	2	No	3	Yes	Yes	No	No	No	Generic, quick to do, quantitative measure of health outcome, multi-language, improved version of 5d-5L, easier to score	Non-specific cannot address specific aspects of complex abdominal hernia repair
EQ-5D-5L	0	No	5	Yes	Yes	No	No	No	Like EQ-5D-3L	Improved version 5D-3L is easier to use and score
Life orientation test	1	No	10	No	Yes	No	No	No	Research instrument, brief measure	Cannot be used in clinical situation
Hernia specific QOL instruments										
CCS (Carolina Comfort Scale)	15	Yes	23	Yes	No	No	No	No	Hernia specific instrument	Time consuming, applies to mesh related problems only
Hernia related QOL survey (HERQLES)	4	Yes	16	Yes	No	No	No	No	Measure abdominal wall function, ventral hernia specific, quick to perform	Lacks mental component and cosmetic aspects of QOL
Euro hernia specific QOL (EURAHS QOL)	0	Yes	3	Yes	Yes	No	No	No	Hernia specific, brief	Lacks components specific to abdominal wall repair
Pain specific instruments or questionnaires										
Brief pain inventory	2	No	9	Yes	Yes	No	No	Yes	Available in both short and long form, multilinguistic,	Addresses pain component only
MCGILL pain score	1	No	4	Yes	Yes	No	No	Yes	Generalized	Time consuming, specific to pain
VAS/ VRS (visual analogue or rating scale)	14	No	1	No	No	No	No	No	Simple and quick with no training required	No other component of QOL tested
VHPQ (ventral hernia pain questionnaire)	0	Yes	10	Yes	No	No	No	No	Specific to hernia repair	Specific to pain and activity
Functional and performance assessment scales and instruments										
AAS (activity assessment scale)	2	No	6	Yes	No	No	No	No	Generic, broad use	Non-specific
Modified AAS	1	No	6	Yes	No	No	No	No	Specific to activity used in physiotherapy	Non-specific
15 D	1	No	15	Yes	Yes	No	No	Yes	Multi-dimensional, generic,	Time consuming, non-specific
GIQLI (GI QOL index)	5	No	36	Yes	No	No	No	No	Specific to abdominal organs functions	Not in public domain, non-specific
KARNOFSKY performance status scale	1	No	3	Yes	No	No	No	No	Better in detecting limitation in activities then SF-36	Non-specific
Body image questionnaire										
BIQ (body image questionnaire)	1	No	8	Yes	Yes	No	Yes	Yes	Includes activity, function, cosmesis and sexual life	Nonspecific. To be used in conjunction with other QOL instruments

Pain scores

Measuring pain is a special challenge as it is a subjective feeling and cannot be measured objectively as physical disability. It is also hard to quantify pain and to define it as single entity. Pain is multidimensional and can be defined in terms of the intensity and patient's response to it. There is a strong relationship between pain and quality of life and in some circumstances used interchangeably though they are not synonym, as pain is only one of the aspects of quality of life.

In the literature review few pain scores were used namely: McGill pain questionnaire.[9] Verbal rating scale (VRS) and visual analogue pain rating scale (VAS).

Visual analogue rating scale (VAS)

VAS is the simplest way so far to quantify subjective estimates of pain. VAS is used in conjunction with other quality of life questionnaires in the review. There are different ways to measure pain with VAS but most common is using a line 10 cm long with no pain on one end while worst pain on the other end, and patient response is measured by difference between patients mark to lowest level of scale in millimetres. Its repeatability and validity are tested many a times and proved to be a sensitive measure of pain than verbal rating scale still used by paramedics and nursing staff in the hospitals.

Elder population finds it difficult to use VAS as it is difficult to grasp the idea of use of a continuous line. Numerical rating scale can be used instead or in conjunction in these cases.

McGill pain questionnaire

MPQ was designed to provide a quantitative profile of three aspects of pain namely sensory, affective and evaluative. It consists of pain intensity scale and questions related to pain to quantify pain that can be treated statistically.

In the literature, MPQ is used in conjunction with other questionnaire for assessment of quality of life in patients with abdominal wall repair.

Brief pain inventory (BPI)

Formerly the Wisconsin brief pain questionnaire is originally designed for cancer related pain but can also be applied to other diseases.[10] BPI includes 4 ratings of pain intensity and seven that measure the impact of pain.

Ventral hernia pain questionnaire (VHPQ)

The questionnaire comprises 20 questions and takes approximately 5 min to complete. The first six questions concern the level and duration of pain. The next seven questions relate to the impact on daily activities. The final questions deal with patient satisfaction and how physically demanding the patients regard their occupation.[11]

Activity assessment scale AAS

Generally used in physiotherapy in assessing freedom of movement and activity in patients recovering from stroke. The MMAS assesses the motor recovery of patients with stroke and is based on the motor components of activities of daily living. The MMAS is a modification of a motor assessment scale described by Carr et al.[12] The AAS is a widely utilized and validated 13-question abdominal wall specific QOL survey previously developed and validated in 2164 patients before and after hernia repair surgery. The questionnaire investigates patients' psychosocial QOL and abdominal wall function through questions covering mood, lifestyle, and physical activity. Similar alternative versions of this survey have been developed, most recently with the modified AAS, which is endorsed and utilized by the Americas Hernia Society13 and the ventral hernia outcomes collaborative.

Karnofsky performance status scale (KPS)

Generally, use for cancer patient but can be applied across different specialties. The Karnofsky scale ranges from 0-100 and higher score mean the patient can carry out daily activities. KPS can be used for diagnostic, evaluating and progress in changes in quality of life in patients.

Body image questionnaire (BIQ)

A new patient reported outcome instrument to measure patient satisfaction after body contouring procedures like abdominoplasty was devised in a study conducted by Danilla et al.[8] It consists of 5 domains and an internal validation showed it to be a reliable scale to measure body related QOL.[11,12] BIQ is a 19-items questionnaire to explore the dimensionality of perceptions, feelings and attitudes expressed towards one's body. A principal component analysis of the responses yielded an axis which is interpreted as general body satisfaction dimension.

DISCUSSION

Measuring quality of life in patients after incisional hernia repair is such a formidable task as treatment of the disease varies a great deal. Surgical outcomes of incisional hernia repair can differ depending on type of repair, so it is arduous to find a standard method to measure QOL.

There are generic and specific questionnaires to measure QOL, with no single instrument specific to VIHR. Generic instruments are useful in exploring basic life issues as well as providing grounds to explore more ideas. Generic QOL scales help researchers to determine the baseline QOL score for population to be used in

comparison to the population with actual disease. Disease specific instruments give better idea about complications related to specific clinical problem and procedure related to it. A generic validated QOL scale should be more acceptable to population and observers and should be consistent and acceptable in both short and long term follow up.[18-31]

Literature review has showed that, it is best to use a generic scale with a disease specific scale along with a validated pain scale that can cover the immediate post-operative period.[8,13,14] Pain scores should be used in the peri-operative period to determine if patient has developed any acute pain or his pre-operative pain is continuing and becoming a chronic pain. Long term follow-up for pain should be more specific and a QOL scale should be able to explore it.[13]

In our literature review, SF-36 is most commonly used, followed by Carolina comfort scale (CCS) and then SF-12, which is an abridged version of SF-36. Other commonly used scales were HerQles, Euro QOL-5D, AAS and GIQLI. Pain scores like VAS, McGill pain score, VRS, NRS, BPI and VHPQ were used in more than half of the studies. Body image questionnaires was used only in a single study.

Not all studies have compared the baseline quality of life between patients (cases) and normal population (control). Rationale given by the authors is that measuring baseline QOL score for normal population is not always necessary as it is always lower in affected patients.[15,16] Measuring pre-operative score of affected patients should be a part of all QOL measurements, as it helps to determine the change in QOL after VIHR and any return of score towards baseline should be taken seriously as it could predict recurrence.

Body image questionnaire (BIQ) is used in only one study in conjunction with other quality of life instruments.[17] There is no instrument with body image or cosmesis as one of its component or domains. Body cosmesis and sexual life are greatly affected with VHR procedures and it is of major concern in population with IH and can be detrimental to quality of life.[17] Unfortunately, not a single commonly used QOL instrument address this issue, and body image and sexual life is a rarely touched subject in the literature. With advancements in diagnostics more and more of younger population is going through multiple abdominal surgeries, which is a single major cause of development of IH. VHR in such population demands addressing such issues and incorporating these dimensions in determining patient's quality of life.

Time frame for follow up is the most diverged subject in the literature, where quality of life was measured as soon as next day of surgery to up to five years.[18-31] No consistency was found in the follow up period and in different studies it ranges from days to years. Literature review also did not help to conclude the best time for follow up. Although anywhere between 8 weeks to a year can give some sense to QOL data. Generally, any immediate follow up will bring out concerns with pain, mobility and limitation of activity while long term follow up will address issues related to long term complication of surgery like limitation in activity, body image, social and psychological stress. Average time taken by most studies was about six months, when QOL score did not change further afterwards.[13] The main determinant to cause significant change in the quality of life was found to be Recurrence of hernia.[13] In most of the patients, recurrence is found at the end of first year, so it is reasonable to measure quality of life after one year. And any significant change in QOL should be taken as impending or already established recurrence and patient should be examined in the clinics and should undergo some sort of imaging. Next question is what type of scales should be used. As disease specific scales are less sensitive initially but become more sensitive in longer follow ups, so first choice of scales should be a hernia specific questionnaire like CCS.[8,13]

Questionnaires should be mailed to remove the bias, but here researchers must deal with the low response rate from the patients. Telephonic surveys have a better response rate, but they are not always possible and can be affected with bias.[13]

CONCLUSION

So, a combination of generic and hernia specific quality of life measurement scale with baseline QOL measurement along with body image questionnaire should be used, with a long term follow up. Currently no QOL scale was found to encompass wide range of effects on patients QOL after incisional hernia repair. A more comprehensive, incisional hernia specific questionnaire which includes all the missing domains from current scales should be the next step for researchers.

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