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ORIGINAL ARTICLE

The assessment of quality of life in a trial on lightweight mesh fixation with fibrin sealant in transabdominal preperitoneal hernia repair

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Abstract
Background Chronic pain is a major concern in open and laparoscopic hernia repair. Study groups have adopted a variety of tools to assess postoperative (postOP) pain and quality of life (QoL). Unfortunately, modifications of existing tests and self-designed questionnaires are common, yielding unvalidated results and making comparison of data difficult. The aim of this study was to assess the QoL in transabdominal preperitoneal mesh repair (TAPP) with fibrin sealant (FS) for lightweight mesh fixation, applying the standardised Short Form 36 (SF36) questionnaire in its unmodified design. The SF36 has already been validated and implemented in a large number of studies. In this trial the physical-health-component summary measure (PHM), summarising the physical health-related scales, served as the primary outcome parameter.
Materials and methods After informed written consent was obtained, TAPP with fibrin mesh sealing was performed in 11 non-selected consecutive patients by a single surgeon. A direct control group (e.g. TAPP with staples) was not enrolled, because a favourable change in the QoL in patients subjected to the mesh sealing approach was the tested hypothesis and not the comparison of techniques. The macroporous mesh (TI-Mesh, GfE, Germany) was fixed with 1 ml of FS (FS, Tisseel, Tissucol, Baxter Biosciences, Austria), and the QoL and pain were assessed preoperatively and 1 year postOP using the SF36 survey and the visual analogue score (VAS).
Results After 12 months, recurrences or complications were observed. The analysis of the unmodifed SF36 revealed a highly significant improvement in the PHM, based on significant changes of all physical-health-related scales. The scale 'social functioning' (SOCIAL), which belongs to the mental-health-related scale, had also significantly improved. The VAS was significantly reduced after 1 year.
Conclusions Despite a small number of patients ($n = 11$), a strikingly significant improvement in physical health and reduction of pain was detected with the unmodified SF36 and the VAS 1 year after TAPP repair with fibrin-sealed lightweight meshes. We suggest the use of the unmodified SF36 for QoL in hernia repair in order to assess all aspects of recovery (physical and mental) and to facilitate comparison of data.

Keywords TAPP · Mesh sealing · Fibrin sealant (FS) · Quality of life (QoL) · SF36 · Chronic pain

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Introduction

During the past decade, laparoscopic hernia repair has been constantly improved and is now considered by many leading experts as equal or even superior to open mesh reinforcing techniques. Extensive investigations were made to elucidate recurrence rate and patient satisfaction after inguinal hernia repair [4, 14]. While recurrences seem to appear in as few as 2% of patients at specialised centres, unacceptably high rates of chronic pain have been reported after both open and laparoscopic techniques [4, 14]. The development of chronic pain has repeatedly been contributed to perforating fixation devices, due to the risk of iatrogenic trauma to nerves, vessels or bowel which is imminent in the case of misplacement (e.g. in the so-called triangle of doom or triangle of pain) [7, 10, 17, 24]. Experimental as well as clinical investigations have demonstrated the efficacy of fibrin sealant (FS) for mesh fixation in inguinal as well as incisional hernia repair and suggested the potential to reduce postoperative (postOP) pain [8, 11, 19]. These reports add to the growing number of studies which have included the assessment of the quality of life (QoL) in hernia research since the late 1990s [25]. However, a large number of otherwise well-designed studies in the field presented modified versions of available standardised tests and/or self-designed questionnaires. Recent studies on mesh sealing using FS in transabdominal preperitoneal mesh repair (TAPP) or totally extraperitoneal mesh repair (TEP) are examples in which modifications of the QoL tests were performed [12, 15, 16, 18, 22]. However, these modifications, generally emphasising postOP pain, do not provide the validity and reliability of the standardised, unmodified psychometrical measurements, e.g. the Short Form 36 (SF36) [1].

The lack of preoperative QoL data is another major concern and so the comparison of QoL between similar trials seems practically impossible [1, 25].

Therefore, this study was designed to assess the impact of lightweight, macroporous meshes with FS fixation in TAPP with standardised, unmodified QoL tools (e.g. the SF36). The main objective was to emphasise the importance of the existing guidelines by providing reliable and reproducible QoL data for the controversial mesh sealing approach [6, 9]. This investigation in a small cohort of patients was performed as a pilot study prior to a randomised controlled trial comparing FS versus staple mesh fixation in TAPP repair by our department. Secondary points of interest were the scales of the SF 36, the mental-health-component summary measure (MHM) and the perception of pain assessed with the VAS.

Materials and methods

The clinical research on FS mesh fixation in TAPP at our surgical department began in February 2005 and was planned in consecutive three steps. At first the FS fixation technique was performed in 25 patients, who were assessed at short intervals for recurrences or complications for a period of 3 months. As neither adverse effects nor recurrences were observed, the decision was made, as a second step, to investigate the QoL after this procedure in a prospective pilot trial without a control group (e.g. staple fixation). The permission of the local ethical committee was granted. Patients were eligible if they were 18 years of age or older, reported no comorbidities associated with chronic pain or impairment of physical function, e.g. recent operations or symptomatic degenerative diseases, and did not score IV or V on the American Society of Anaesthesiologists Score (ASA) [20]. In total 11 male patients with primary inguinal or femoral hernias who consulted our ward were recruited, and informed written consent was obtained. With no exclusion criteria applying, these patients could be consecutively included in the trial and presented a non-selected cohort.

At admission (1 day prior to scheduled surgery), patients completed the unmodified SF36 and were additionally asked to specify the perceived pain on the visual analogue score (VAS). All participants were operated on by a single surgeon (R.F.) using the TAPP technique in a prospective protocol. The mean age was 47 years (22–64 years) and all but one patient were in the ASA class I (one patient was scored ASA II). Laparoscopic repair was performed on nine lateral and five medial primary hernias, which were classified intraoperatively according to the classification by Schumpelick [26].

The meshes used were TiMesh extralight (TMxl, 16 g/m^2) for lateral hernias and TiMesh light (TML, 35 g/m^2) for medial hernias (all GfE, Nuremberg, Germany). The heavier TML (although still lightweight by definition) was chosen for medial hernias due to its increased stiffness, which allowed an excellent adherence to the inverted fascia of the transverse abdominal muscle. One milliliter of Tisseel FS per side was applied with a Duplocath MIC 35 laparoscopic catheter for mesh fixation (both Baxter Bioscience, Vienna, Austria). Patients were examined clinically every day during their hospital stay (and asked for the VAS) and then 10 days, 3 months and 1 year postOP. The clinical follow-up at 1 year postOP included ultrasound imaging.

Based on the excellent results obtained in this small cohort of patients, the third step—a randomised controlled trial comparing FS and staple mesh fixation in TAPP repair—began in July 2006 (aiming to include 100 patients in total).

Operation/mesh sealing

TAPP repair was conducted in a standardised manner under general anaesthesia by a single surgeon (R.F.) experienced in this procedure. The operation was performed by three-port

technique (one 10-mm trocar subumbilically, two 5- to 10-mm trocars bilaterally of the umbilicus), after establishing a pneumoperitoneum (11 mm/Hg). Starting with the incision of the peritoneum at the level of the superior spina iliaca, attention was paid to meticulous preparation of the affected groin with identification of all relevant anatomical structures, as well as precise haemostasis. In case a medial hernia was encountered, the hernia sac was dissected and the fascia of the transverse abdominal muscle inverted and fixed with a single suture (PDS 2/0, Ethicon, Norderstedt, Germany). All meshes were 10 × 15 cm and not tailored. In the case of bilateral repair, the two meshes overlapped medially. TMxl was used for the reinforcement of all lateral hernias; the stiffer TM was chosen for medial defects. FS was applied in spots, moving the catheter clockwise around the whole perimeter of the mesh, beginning in the upper medial quadrant in order to allow the FS to disperse. The mesh was gently approximated to the underlying tissue with the tip of the application catheter. Finally the peritoneum was closed with a slowly resorbable, running suture (2/0 PDS, Ethicon, Norderstedt, Germany). Trocar sites were closed in anatomical layers. No antibiotic prophylaxis was administered preoperatively.

Assessment of recurrences and complications

Normal urination was verified in all patients before discharge. Ultrasound examination was routinely performed by the surgeon 1 year postOP to verify the correct position of the mesh implant. The titanised polypropylene mesh delivers a distinct signal, facilitating its identification.

Hospital stay

All patients were dismissed 4 days postOP. This delay was based on the reimbursement system by the public healthcare provider. In contrast to other publications, the hospital stay does not serve as indicator for the quality of treatment in this setting [3].

Assessment of quality of life

The unmodified SF36 is a multi-purpose health survey based on 36 questions. It consists of eight multi-item dimensions (= scales), each of which generates a score between 0 and 100. Higher scores relate to better health perceived by the patient. Because the SF36 is a generic measure, it has been found very useful in assessing the QoL in general and for specific conditions and populations. It allows the comparison of the burden of disease and the differentiation of benefits due to various different treatments. The unmodified SF36 has been translated into more than 50 languages and has been used to assess more than 200 diseases and conditions [1, 2]. Extensive data are available about the normal distribution of score results in a healthy population.

For the purpose of this study, the standard form of the German version 2.0 of the unmodified SF36 was used in which patients are asked to report changes in their health status over the past 4 weeks [1]. All enrolled patients had to be fluent in the German language and completed the questionnaire in the absence of the performing surgeon. The measurement model of the unmodified SF36 is based on eight scales derived from 36 items and is illustrated in Table 1. These scales combine to higher-ordered clusters (physical-health-component and mental-health-component summary measures). Higher scores relate to better levels of health perception. The physical-health-component summary measure (PHM) summarises the scales ‘physical function’, ‘role physical’, ‘bodily pain’ and ‘general health’. The mental-health component summary measure (MHM) summarizes ‘mental health’, ‘role emotional’, ‘social function’ and ‘vitality’.

The visual analogue score

The VAS consists of a simple indicator scale on which patients are asked to rate their pain from 0 (no pain) to 100 (the worst pain imaginable). The VAS was assessed preOP, on day 10, at 3 months (data not presented) and 1 year postOP. The VAS has successfully been used in hernia patients [6, 13].

Table 1 The differences in pre- and 1 year post-operative values of all eight items and two summary measures of the SF36 quality-of-life questionnaire

SF36 measures	Mean	SD	Median	Minimum	Maximum	Range	*P* value[a]
Physical function	14.1	20.0	5.0	−10.0	55.0	65.0	0.0352
Role physical	36.4	39.3	25.0	0.0	100.0	100.0	0.0313
Bodily pain	39.5	19.4	38.0	16.0	69.0	53.0	0.0010
General health	8.9	10.6	5.0	0.0	33.0	33.0	0.0078
Vitality	3.6	21.5	0.0	−30.0	50.0	80.0	0.7969
Social function	18.2	22.6	12.5	0.0	62.5	62.5	0.0313
Role emotional	21.2	45.4	0.0	−33.3	100.0	133.3	0.2500
Mental health	6.2	12.6	4.0	−8.0	32.0	40.0	0.2109
Physical summary	10.8	6.4	8.6	2.4	19.6	17.2	0.0010
Mental summary	2.6	8.7	−0.4	−8.1	20.1	28.2	0.5771

[a] Values <0.05 indicate a statistically significant improvement in measures 1 year post-operative compared with pre-operative values

Statistical analysis

The statistical analysis was performed by an independent investigator (F.K.) from the Department of Statistics at the Vienna Medical School. For the unmodified SF36 scores, mean, standard deviation, median, minimum and maximum were calculated per group (pre- and post-operatively). This was also done for the differences between the preOP and postOP values. In the text, mean ± standard deviation are reported. The primary outcome parameter was PHM. Additionally we analysed the MHM and all physical- and mental-health-related scales. To check for differences in the unmodified SF36 scores between preOP and postOP, Wilcoxon signed-rank tests were performed. A P value <0.05 was considered to indicate statistical significance.

Results

Complications and recurrences

A seroma was observed in one patient, which resolved spontaneously within 3 months and required no intervention. No other complication occurred during the observation period and no recurrence were observed. The correct position of mesh implants could be verified in all patients by ultrasound.

Short form 36

The differences and significances of the pre- and postOP values of all scales of the SF36 are summarized in Table 1.

Physical-health-component summary measure (PHM)

The PHM was the primary outcome parameter and improved significantly in all patients ($P < 0.0010$; Fig. 1). The significant amelioration shown in Fig. 1 reflects the complexity of the handicap linked to hernia disease and the widespread recovery after laparoscopic surgery in this study. It is noteworthy that patient no. 8 performed worse in all items, including those referring to mental and psychological well-being. The mean value was 55.8 ± 4.3 1 year postOP (vs. 45 ± 8.7 preOP). According to literature the mean value in the male, healthy and German-speaking reference population is 51.4 ± 9.6 (n = 1,236; values not directly comparable).

Bodily pain (PAIN)

All patients included in this study reported substantial pain at admission to our department. A significant improvement of pain was perceived after surgery in all patients (Fig. 2). As indicated, patients who were substantially suffering preoperatively reported to be free of pain 1 year after TAPP repair. The mean value of 'bodily pain' was 93.3 ± 12.7 postOP (vs. 53.7 ± 21.8 preOP) and therefore highly signficant ($P < 0.0010$).

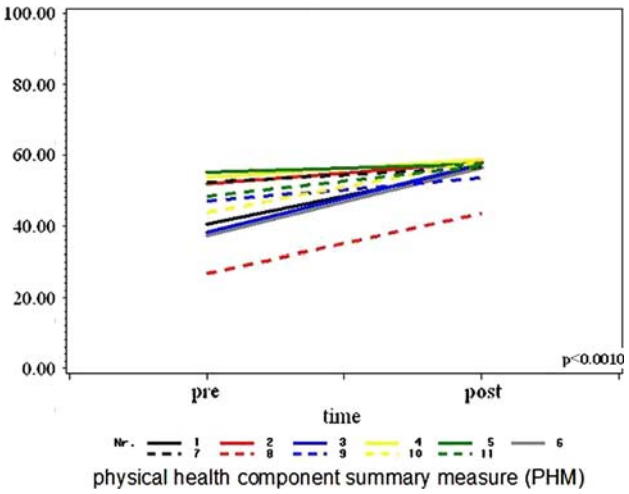

Fig. 1 Changes in the physical-health-component summary measure (PHM). The PHM reflects the individual rating of all physical items of the SF36

General health profile (GHP)

The 'general health profile' scale significantly improved ($P = 0.0078$) to a mean value of 83.3 ± 17.2 postOP (vs. 74.4 ± 21.7 preOP).

Physical functioning index (PFI)

The PFI improved significantly to a postOP mean value of 96.4 ± 10.5 (P < 0.035) from a baseline level of 82.3 ± 18.2.

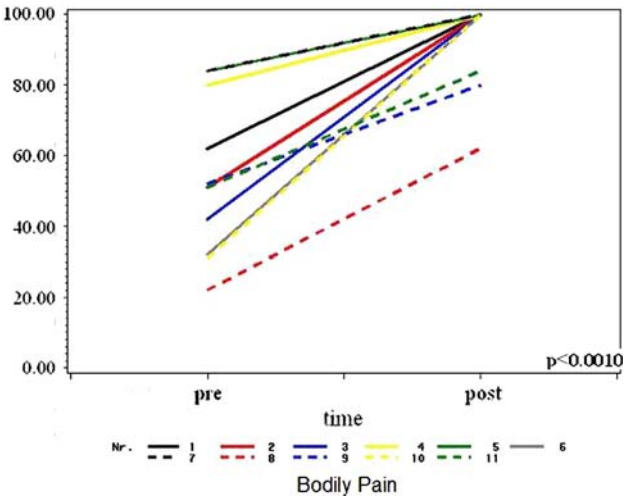

Fig. 2 A significant decrease in pain was perceived 1 year after surgery in all patients. This figure shows the significant improvement of the scale 'bodily pain'

Role physical (ROLPH)

The ROLPH was significantly better 1 year postOP at 97.7 ± 7.5 (vs. 61.4 ± 42.4). The *P* value for the analyis of RP was <0.031.

Social function (SOCIAL)

This mental-health-related scale improved significantly to a mean value of 95.5 ± 8.4 postOP (vs. 77.3 ± 23.7 preOP; $P < 0.031$; Fig. 3). Although mental-health-related items showed no significant differences, Fig. 3 is presented to create an awareness of the importance of the mental and psychological issues included in the SF36. In larger trials data obtained may show significant changes after surgery.

Mental-health-component summary measure (MHM)

MHM was not significantly improved ($P < 0.577$) because all related scales besides SF showed no significant difference.

The visual analogue score (0–100)

Results showed a significant reduction in pain in patients after 1 year ($P < 0.05$). Whereas all patients suffered from pain or at least perceived permanent discomfort prior to the surgery, 7 out of 11 patients reported a VAS of 0 1 year after the operation. The mean value preOP was 28.6 ± 24.4 versus 2.7 ± 4.9 postOP.

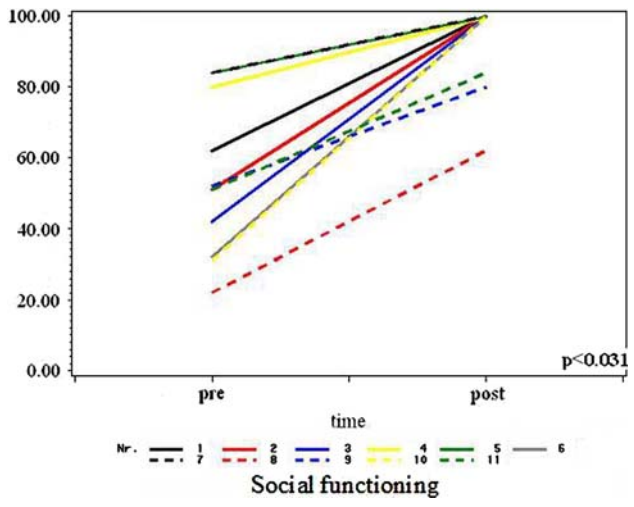

Fig. 3 Changes in mental-health-related items were observed during the observation period after TAPP. This figure shows a trend toward amelioration of the scale 'social functioning' due to the good recovery of TAPP patients subjected to fibrin mesh sealing

Discussion

The aim of this study was to assess the change in the QoL (with special emphasis on physical health) using the unmodified SF36 in patients who underwent TAPP repair with fibrin-sealed lightweight, macroporous meshes. As the benefits of fibrin sealing in both open and laparoscopic hernia repair have already been demonstrated in recent publications, a control group (e.g. TAPP with staples) was not included in this study [12]. This decision was also based on a large clinical study by Hindmarsh who has identified staple placement as a significant risk factor for the development of postOP pain [12]. However, the data presented in the TAPP study comparing FS versus staple mesh fixation by Lovisetto was produced with a modified version of the SF36, which spared mental-health-related items and scales, changing the text of questions and answers of the remaining physical health and pain assessment scales [12].

With regard to the methodology and design of pain and QoL studies in hernia repair, it must be noted that modifications of highly specialised psychometrical measurements require sound verification, otherwise they may lose their reliability and validity. Several publications in the field have failed to present proof of the reliability and validity of arbitrarily modified questionnaires [12, 25]. The use of the established name 'Short Form 36' and its abbreviation 'SF36' should exclusively be reserved for the unmodified version, which so far has been used in more than 5,000 publications on over 200 acute and chronic diseases; its quality has been demonstrated by an impressive body of secondary literature [1, 2, 9].

The results of our own study demonstrate that the recovery of TAPP patients is not only restricted to the dimension of pain, as significant changes were noted for all physical-health-related scales, and also on one mental-health-related scale. The significant improvement in the scale SOCIAL in our study indicates that the assessment of mental well-being could be important in future trials (Fig. 2). It seems obvious that favourable physical outcomes facilitate the return to a normal social life and productivity. Although social and psychological impairment has already been observed in hernia patients, these aspects of recovery have so far been neglected by the surgical research [4, 14]. The unmodified SF36 allows the detection and interpretation of the complex burden of hernia disease. We think that these facts encourage its use with the intent to build a comparable and standardised body of QoL data in hernia research. To the best of our knowledge, this study on mesh sealing is unprecedented in providing preoperative unmodified SF36 data, which is mandatory to understand the effect of the treatment. Considering the small cohort of patients included in this trial, the highly significant results are remarkable and indicate the strong effect of treatment, which could not be

expected based on the reported incidence of chronic pain in open and laparoscopic hernia repair.

The significant improvement in the VAS reflected the possibility of obtaining reliable data on chonic pain after hernia repair with this simple scale [5]. The use of the VAS is a minimalistic alternative to the unmodified SF36, when its assessment is considered too time consuming in the clinical routine. However, the growing body of literature emphasises the importance of QoL assessment in future studies on hernia repair [9, 12, 14, 25].

In the setting of our study we suggest that the use of fibrin-sealed lightweight meshes has positively influenced the results observed 1 year postOP. With regard to the data on pain development by the placement of tacks in the pubic tubercle, the avoidance of tissue perforation by mesh sealing seems to be the crucial advantage of this technique [12]. Both types of TiMeshes were especially appropriate for the FS-sealing approach [21, 23]. The hydrophilic titanised surface adheres well to the underlying tissue and allows binding of the FS to the mesh fibres where the large pore size facilitates its use. We regret that even an indirect comparison of our results with the data derived from a modified 'SF36' in a publication by Lovisetto using heavier polypropylene meshes with a different pore size is not possible. Therefore, the likely impact of different mesh types in combination with FS on the QoL and pain has yet to be elucidated.

Conclusions

Based on our experiences of QoL assessment in a small patient population we emphasise the use of standardised and unmodified psychometrical tools, such as the SF 36. Although benefits of mesh sealing in TAPP have already been previously reported, this study, revealing highly significant results of important scales, has been unprecedented in providing the comparison of intraindividual pre- and postOP QoL data.

We hope that our work will contribute to the awareness of creating reliable and reproducible data on patient satisfaction after hernia surgery.

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