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Is non-operative management warranted in ventral hernia patients with comorbidities? A case-matched, prospective 3 year follow-up, patient-centered study☆

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ABSTRACT

Background: We hypothesized that long-term quality of life (QoL) is improved among patients with ventral hernias (VHs) and comorbid conditions managed operatively than with non-operative management.

Methods: This was the 3-year follow-up to a prospective observational study of patients with comorbid conditions and VHs. Primary outcome was change in QoL measured utilizing the modified Activities Assessment Scale (AAS), a validated, hernia-specific survey. Outcomes were compared using: (1)paired *t*-test on matched subset and (2)multivariable linear regression on the overall cohort.

Results: In the matched cohort (n = 80; 40/group), the operative group experienced a significantly greater improvement in QoL compared to the non-operative group (28.4 ± 27.1 vs. 11.8 ± 23.8,p = 0.005). The operative group, had 10 (25.0%) reported recurrences while the non-operative group, reported 4/15 (26.7%) recurrences among the 15 (37.5%) patients that underwent repair. On multivariable analysis of the whole cohort (n = 137), operative management was associated with a 19.5 (95% CI7.0–31.9) point greater improvement in QoL compared to non-operative management.

Conclusions: This is the first long term prospective study showing the benefits of operative as opposed to non-operative management of patients with comorbid conditions and VHs.

Introduction

Comorbid conditions such as obesity increase the likelihood of developing a ventral hernia and significantly increase the risk of complications after hernia repair.[1] Other comorbid conditions such as poorly controlled diabetes and smoking have been strongly correlated to long-term complications and hernia recurrence.[2–4] These patients are at high surgical risk and often treated non-operatively.[5]

With continued emphasis in our healthcare system on surgical outcomes and quality improvement, the best treatment strategy for patients with comorbid conditions is still undetermined.[6,7] We previously reported the 1-year results of a prospective study comparing management strategies in patients with a medical co-morbidity and a ventral hernia. This study found that among patients with comorbid conditions, elective repair demonstrated improvement in hernia-related quality of life (QoL) and functional status compared to those managed non-operatively.[8] However, the impact of possible long term complications, such as hernia recurrence, on patient's QoL remains unknown as well as the impact of long-term watchful waiting since patients were followed for one year.[9]

Experiencing a complication, such as a recurrence, puts patients

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at risk for entering a vicious cycle of repair, complication, and reoperation. Unfortunately, patients who experience a recurrence have a lower average QoL than patients who have a ventral hernia that has never been repaired.[10]

The aim of this study is to determine the difference in patient's QoL and functional status between patients with comorbid conditions and a ventral hernia who are managed operatively and those managed non-operatively three years after enrollment. We hypothesized that in the long term, QoL is better among patients with ventral hernias managed operatively than those managed non-operatively.

Methods

After obtaining Institutional Review Board approval, patients presenting to a single academic center hernia clinic between June 2014 to June 2015 were prospectively enrolled. Inclusion criteria included patients presenting with a comorbid condition such as body mass index (BMI) > 33 kg/m^2, poorly controlled diabetes (glycosylated hemoglobin >8.0%), current smokers, or patients with end-stage organ disease (e.g. advanced cardiac, pulmonary, or hepatic disease). Patients were then managed with elective or non-operative repair based on co-morbidities, patient choice, and surgeon discretion.

Outcomes

Primary outcome was change in QoL/functional status. This was measured using a validated, hernia-specific survey created from a modified Activities Assessment Scale.[11] Patients completed the survey during study enrollment at their first clinic visit, 1 year, and again at 3 years during a structured follow-up phone call. The survey contained twelve QoL questions measuring functional status using a 10-point Likert-type scale, 1 indicated poor satisfaction and 10 high satisfaction. Scores were normalized to a 1–100 scale, where 1 indicated poor function and 100 indicated high function. Changes of 7 points or more are considered clinically significant.[12]

Secondary outcomes included change in pain score over time, abdominal wall satisfaction, abdominal wall cosmesis, need for surgery, elective surgery versus emergent surgery, emergency room visit, and hernia recurrence. Pain scores were assessed using the visual analog scale at baseline and at follow-up, this was based on a 1–10 scale where 1 indicated no pain, and 10 indicated severe pain. Abdominal wall satisfaction and cosmesis were assessed using a 1–10 scale where 1 was highly dissatisfied and 10 highly satisfied. Need for surgery, elective surgery versus emergent surgery, emergency room visits were determined by patient report and checking electronic medical records. Hernia recurrence was determined by self-report.

Statistical analysis

The study population was analyzed in two ways. First, patients from the initial non-operative and operative groups were individually matched in a 1:1 fashion. Characteristics used for matching included BMI within 3 points, baseline pain score within 2 points, smoking, diabetes mellitus, prior ventral hernia repair, and hernia width on computer tomography (CT) scan within 1 cm.[1,5,8] These were chosen since they were thought to be important in determining what treatment the patient would receive. For this cohort, QoL scores were compared using a two-tailed paired *t*-test.

Second, the entire cohort (all patients who completed 3 year follow-up) was evaluated using multivariable linear regression to identify factors associated with change in QoL score at 3 years. Preset variables included in the initial model included race, gender, smoking, diabetes, baseline pain score, hernia width on radiologic imaging, hernia type (primary versus secondary), American Society of Anesthesiologist (ASA) score, and treatment group (non-operative or operative). The model with the lowest Akaike information criterion was chosen.

Results

A total of 195 patients were initially enrolled and 137 patients (non-operative = 85; operative = 52) completed follow up at a median (range) of 37.3 (23.9–51.6) months (Fig. 1). Eighty patients (40 from each group) were matched. Baseline and hernia characteristics were similar between the matched cohorts (Tables 1 and 2).

There was no difference in QoL scores between groups at baseline or at three year follow-up. When analyzing the change from baseline, the operative group had a significantly greater average improvement in QoL compared to the initial non-operative group; but both groups experienced clinically significant average improvements in QoL (Table 3 and Fig. 2). Patients in the operative group had a significantly greater improvement in abdominal wall satisfaction and cosmesis scores at 3 years follow-up (Table 3). However, there was no difference in change in pain scores over time.

In the operative group, 10 (25.0%) patients self-reported a hernia recurrence and 5 (12.5%) had one or more emergency room visits. For the initial non-operative arm, 11 (27.5%) had one or more emergency room visits while 15 (37.5%) patients underwent ventral hernia repair: 12 elective and 3 emergent. Among these patients 4/15 (26.7%) experienced a hernia recurrence.

Patients who self-reported a recurrence following ventral hernia repair from either study group reported a significantly lower baseline and 3 year QoL scores compared to those with no hernia recurrence (Table 4, eTable 1 and 2). Surprisingly however, the average change in QoL significantly improved among these patients. Patients who remained non-operative experienced no clinically significant change in QoL while those who converted to surgery experienced substantial improvements in QoL regardless of recurrence.

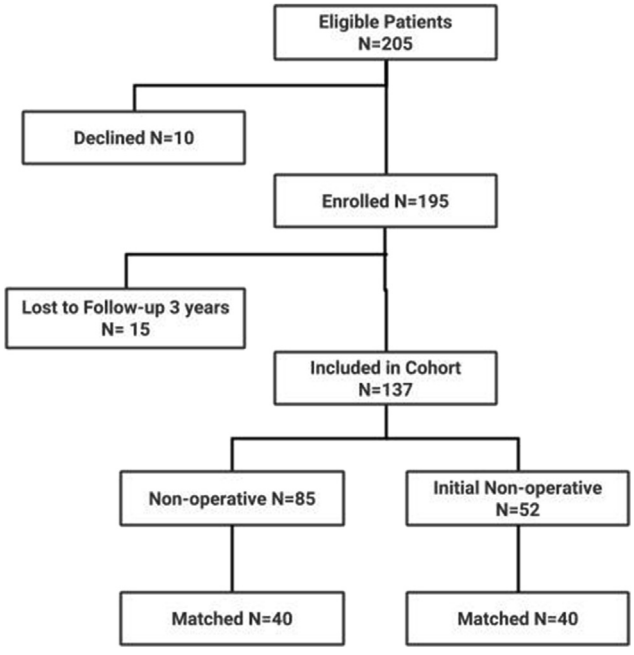

Fig. 1. Patient Flowchart.

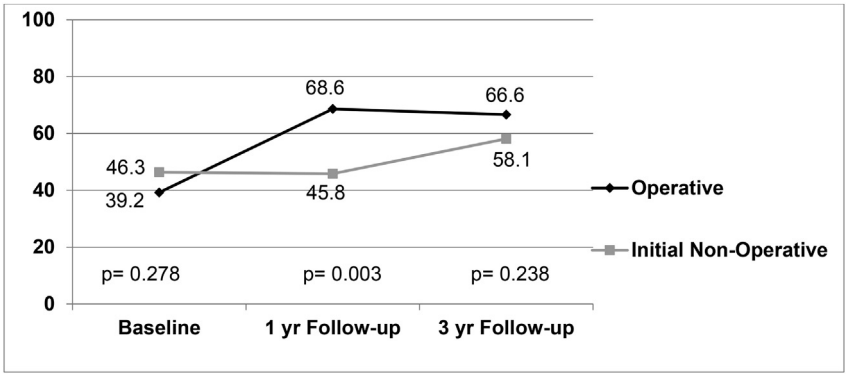

Fig. 2. QoL scores over time between the operative and initial non-operative groups.

Table 1
Baseline characteristics.

Characteristics	Total N = 80	Operative N = 40	Initial Non-operative N = 40	P value
Age[a]	52.2 ± 10.5	50.1 ± 13.9	54.2 ± 9.6	0.077
Sex- Female	47 (58.8%)	23 (57.5%)	24 (60.0%)	0.820
Race				1.000
White	9 (11.3%)	4 (10.0%)	5 (12.5%)	
Underserved minority: Non-white	71 (88.8%)	36 (90.0%)	35 (87.5%)	
BMI[a]	30.7 ± 4.2	29.8 ± 0.5	31.6 ± 0.8	1.000
Less than 30	32 (40.0%)	16 (40.0%)	16 (40.0%)	
Greater than 30	48 (60.0%)	24 (60.0%)	24 (60.0%)	
Comorbidities				
Active Smoker	14 (17.5%)	7 (17.5%)	7 (17.5%)	1.000
Ascites	1 (1.3%)	0 (0.0%)	1 (2.5%)	1.000
COPD	2 (2.5%)	1 (2.5%)	1 (2.5%)	1.000
Immunosuppressed	6 (7.5%)	2 (5.0%)	4 (10.0%)	0.675
DM	12 (15.0%)	7 (17.5%)	5 (12.5%)	0.755
Prostate disease	4 (5.0%)	2 (5.0%)	2 (5.0%)	1.000
ASA class				0.141
1	4 (5.0%)	3 (7.5%)	1 (2.5%)	
2	49 (61.3%)	28 (70.0%)	21 (52.5%)	
3	26 (32.5%)	9 (22.5%)	17 (42.5%)	
4	1 (1.3%)	0 (0.0%)	1 (2.5%)	
Prior SSI	7 (8.8%)	4 (10.0%)	3 (7.5%)	1.000
Number of prior abdominal surgeries[b]	2 (1,3)	2 (1,3)	2 (2,3)	0.894
Prior ventral hernia repair	15 (18.8%)	8 (20.0%)	7 (17.5%)	1.000
Previous mesh	11 (13.8%)	8 (20.0%)	3 (7.5%)	0.193

ASA: American Society of Anesthesiologists, BMI: Body Mass Index, COPD: Chronic Obstructive Pulmonary Disease, DM: Diabetes Mellitus, SSI: Surgical Site Infection.
[a] Mean ± Standard Deviation (SD).
[b] Median (Interquartile Range (IQR)).

Overall cohort

In the operative group from the overall cohort, there were 13 (25.0%) recurrences. Thirty one (36.5%) patients in the initial non-operative group later underwent operative management because they met goals set out for them to qualify for elective surgery (11, 12.9%), went to a different provider (12, 14.1%), obstruction or acute incarceration (8, 9.4%). Among these patients, there were 4 (4.7%) recurrences.

On multivariable analysis of the whole cohort, operative management was associated with a 19.5 (95% CI 7.0–31.9) greater change in QoL compared to initial non-operative management (Table 5).

Discussion

This is the first long term prospective study that evaluates the effects of management strategy on patient's QoL. Patients in the operative group, on average, had a significant improvement in QoL scores at follow-up, while patients in the initial non-operative group experienced a slight improve in QoL. Patients seeking surgery for both elective and emergent indications drove most of the improvement in QoL in the initial non-operative group.

On subgroup analysis, patients who underwent repair and self-reported a recurrence had two surprising findings: (1) these patients had very low initial QoL score and (2) regardless of a recurrence, these patients reported significant improvements in QoL. On average, patients with recurrences had hernias similar in size to patients who did not suffer a recurrence. One possible explanation for a baseline lower QoL could be the duration of the hernia prior to repair. Even though our study did not evaluate this, it is possible that patients with chronic hernias may report lower QoL scores. On the same idea, since these recurrences may have occurred more recently patients may still report an increase in QoL. There is a chance that these recurrences could get worse over time and could probably cause a bigger effect a patient's QoL over time. Also, there may be some association between patients with low baseline QoL score being more likely to self-report a recurrence. There is a possibility that patients may mistake a bulge, or abdominal wall laxity as a hernia when surveyed and in reality they do not truly have a recurrence.

Table 2
Baseline hernia characteristics.

Characteristics	Total N = 80	Operative N = 40	Initial Non-operative N = 40	P value
Hernia Width (cm)[a]	3.6 ± 0.4	4.0 ± 0.7	3.1 ± 0.5	0.276
Hernia Length (cm)[a]	4.5 ± 0.5	5.0 ± 0.9	4.0 ± 0.6	0.374
Area (cm^2)[a]	25.0 ± 5.4	33.6 ± 9.9	16.5 ± 4.4	0.117
Hernia Type				0.633
Primary	26 (32.5%)	14 (35.0%)	12 (30.0%)	
Incisional	54 (67.5%)	26 (65.0%)	28 (70.0%)	
Recurrent	15 (18.8%)	8 (20.0%)	7 (17.5%)	1.000

[a] Mean ± Standard Deviation (SD).

Table 3
Change in QoL scores and patient centered outcomes among patients with ventral hernias in the operative and initial non-operative group (3 years post-enrollment).

Scores	Operative N = 40	Initial Non-operative N = 40	P value
QoL Scores			
Baseline QoL score[a]	39.2 ± 26.6	46.3 ± 30.8	0.278
Follow up QoL score[a]	66.6 ± 30.9	58.1 ± 33.2	0.238
Change QoL[a]	28.4 ± 27.1	11.8 ± 23.8	0.005
Change in Patient Centered Outcomes			
I am satisfied with my abdomen (your belly)[b]	4.0 (2.7–5.3)	0.90 (−0.16 to 1.96)	0.001
I am satisfied with how my abdomen (your belly) looks now[b]	4.4 (3.07–5.73)	1.1 (−0.11 to 2.32)	0.000
My typical abdominal wall (your belly) pain is:[b]	0.97 (−0.32 to 2.27)	−1.13 (−2.13 to −0.12)	0.917

[a] Mean ± Standard Deviation (SD).
[b] Mean and (95% confidence interval). 1 = poor satisfaction, no pain; 10 = high satisfaction, severe pain.

Table 4
QoL score stratified by study group, surgery, and recurrence.

Mean (±SD) QOL Scores	Operative (N = 40)		P	Non-Operative (N = 40)			P
	Operative: No Recurrence (N = 30)[a]	Operative: Recurrence (N = 10)[a]		Remained Non-Operative (N = 25)[a]	Non-Operative Converted to Operative (N = 15)[a]		
					No Recurrence (N = 11)[a]	Recurrence (N = 4)[a]	
Baseline[b]	46.6 ± 25.4	17.9 ± 17.2	0.002	50.5 ± 31.2	50.5 ± 26.1	8.6 ± 13.3	0.001
1 year	75.0 ± 23.4	49.3 ± 26.6	0.012	42.2 ± 32.9	89.1 ± 4.8	1 ± 1.0	0.001
3 years	76.0 ± 27.5	38.5 ± 23.1	0.001	54.8 ± 32.3	74.2 ± 30.1	20.8 ± 16.0	0.001
Change[c]	30.9 ± 28.4	20.6 ± 22.4	0.303	4.3 ± 19.9	21.7 ± 23.6	27.1 ± 37.3	0.001

[a] Number of patients in this category at 3 years follow up, this may not be same number of patients per category at 1 year follow up.
[b] Baseline for matched patients.
[c] Change in score from baseline to 3 year follow up.

Table 5
Multivariable analysis showing variables associated with change in QoL scores in patients with ventral hernia (overall cohort).

QoL Scores		
Independent Variable	Coefficient (95% CI)	P value
Race	−9.1 (−18.0, −0.2)	0.046
Chronic Abdominal wall Pain	2.1 (0.3, 3.9)	0.022
Hernia Width on CT scan	1.5 (0.1, 2.9)	0.041
Operative Management	19.5 (7.0, 31.9)	0.002

When comparing patients with recurrences from each group, those in the operative group had greater improvement in QoL scores than those in the initial non-operative group who then underwent repair and also had a recurrence. Of those patients who converted to operative repair but suffered from a recurrence, 75% reported emergency room visits related to their hernia and 25% reported undergoing an emergent repair. In the operative group only 20% reported an emergency room visit related to their hernia. Dealing with factors such as emergency room visits or emergent repair may put patients at risk for lower satisfaction and QoL scores.

Non-operative management still has a significant role in ventral hernia care. The results of this study suggest that poor surgical candidates or patients not interested in surgical repair may be safely managed non-operatively. However, the risks must be discussed with the patient. The incidence of acute incarceration is still present as well as converting to operative management. In our study 36.5% of patients converted to operative management in three years. Our results appear to be slightly higher that those reported in the literature for emergent surgery at 9.4% and an average 12% cross-per year. In addition, there is a high likelihood that patients will just seek care elsewhere when they are managed non-operatively, 14.1% of our patients underwent surgical repair elsewhere.

Other observational studies in different populations suggest that non-operative management or "watchful waiting" may be safe for patients with ventral hernias. These are mostly short-term follow up.[13–15] In addition, there are ongoing randomized controlled trials evaluating operative versus non-operative management hoping to provide more clear guidance on the optimal treatment options (clinicaltrials.gov: NCT02263599, NCT01349400).[16,17] The next step in the management of patients with comorbid conditions and ventral hernias is to conduct a randomized controlled trial in patients considered low, moderate, and high risk comparing operative versus non-operative management.

There are several limitations to this study. This was not a randomized study and is subject to selection bias. However, case matching and risk-adjusted analysis was used to develop similar groups for comparison. In addition, this study only followed patients for three years after enrollment. Studies have suggested that the vast majority of hernias occur within the first three years, however over time, additional recurrence can continue to occur and erode the benefits of surgery.[10,18] Furthermore, recurrences were identified by patient self report only. However, Jekeel et al. found that a survey can identify a hernia recurrence without the need for imaging. [19] Finally, only low to moderate risk patients were compared. Patients considered high risk, e.g. patients with very high BMI, were not matched since they had no operative counterpart.

Conclusions

This is a long term follow-up to a prospective study comparing management strategies in patients with comorbid conditions and ventral hernias. Elective repair was associated with improved hernia related QoL in the long term. In addition, over one third of patients treated non-operatively will crossover and undergo ventral hernia repair. In patients who undergo repair, even if they self-report a recurrence, they still experienced an improvement in their quality of life compared to their baseline scores. Therefore, optimization of patients with comorbid conditions and ventral hernia repair should be preferred over non-operative management.

Disclosures

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Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.amjsurg.2019.07.044.

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