

Clinical Paper

# Patient Reported Outcomes Following Laparoscopic Surgery for Benign Upper Gastrointestinal Disease

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## ABSTRACT

Patient reported quality of life (QOL) outcomes are important tools for measuring the success of surgical intervention. This is of particular relevance in benign disease when surgery is specifically indicated primarily to treat symptoms and improve QOL. In upper gastrointestinal disease, common conditions such as achalasia, gastro-oesophageal reflux disease and para-oesophageal hernias can have a significant impact on patient's quality of life. The aim of this study was to compare QOL scores before and after surgery for these conditions, and to assess patient satisfaction.

Patients who underwent laparoscopic paraoesophageal hernia (POH) repair, laparoscopic cardiomyotomy or laparoscopic fundoplication over a 7 year period (2006-2013) by one surgeon were asked to assess their symptoms before and after surgery using the Gastro-oesophageal Reflux Disease-Health Related Quality-Of-Life (GORD-HRQOL) Score and The Royal Adelaide Dysphagia (RAD) Score, and to rate their satisfaction.

All procedures were carried out electively, with no 30-day mortality, and an absence of any major peri-operative morbidity.

Responses were received from 121 patients (68 female and 53 male). This comprised of 34 POH repairs, 39 cardiomyotomies and 48 funduplications.

Median GORD scores improved significantly for all groups; POH 20.5 to 2, ( $p < 0.0001$ ), Fundoplication 24.5 to 6.5 ( $p < 0.0001$ ), and Cardiomyotomy 21 to 10 ( $p = 0.0008$ ).

Dysphagia scores improved significantly for Cardiomyotomy, 7.5 to 30 ( $p < 0.0001$ ), and POH, 25 to 40.5 ( $p = 0.044$ ), but not with Fundoplication 45 to 35.25 ( $p = 0.17$ ).

64% of patients were 'satisfied' or 'very satisfied' with their current condition. 77% were 'satisfied' or 'very satisfied' with the procedure itself.

This study has shown that there is a high rate of patient satisfaction following laparoscopic surgery for benign upper GI disease.

## INTRODUCTION

Benign upper gastrointestinal (GI) diseases including achalasia, gastro-oesophageal reflux disease (GORD) and para-oesophageal hernias (POH) result in a number of overlapping symptoms that can significantly impact upon a patient's quality of life (QOL). Approximately 89% of patients with GORD complain of heartburn. Bloating, flatulence and dysphagia are also commonly reported symptoms<sup>2</sup>. The prevalence of GORD in Europe is amongst the highest in the world at 23.7%<sup>3</sup>, and is known to have a significant adverse impact on QOL<sup>4</sup>. Achalasia has an annual incidence of 1 in 100,000 and causes symptoms of progressive dysphagia and regurgitation<sup>5,6</sup>. Hiatal hernias are common<sup>7</sup> with most being the sliding type (type 1)<sup>8</sup>. Para-oesophageal hernias (types 2-4) account for 5% of all hiatal hernias<sup>7</sup>. These may present with a variety of symptoms, including heartburn, regurgitation, dysphagia, and chest pain. They can also present acutely with gastric volvulus. All of these conditions can now be effectively managed laparoscopically<sup>9</sup>.

Patient reported outcomes are important tools for measuring the success of surgical interventions. This is of particular relevance in benign disease when surgery is specifically indicated primarily to treat symptoms and improve QOL. There are a number of validated tools for assessing QOL in benign upper GI disease<sup>10</sup>. The GORD-HRQOL developed by Velanovich et al.<sup>11</sup> is one such tool that has been used for GORD specifically and has been validated in a number of other studies<sup>12,10</sup>.

The dysphagia score used in this study was first devised by Dakkak et al<sup>1</sup> (Table 1) and has subsequently been used in a number of other studies reporting outcomes following laparoscopic fundoplication<sup>13,14</sup> and following laparoscopic cardiomyotomy and anterior Dor fundoplication for achalasia<sup>6</sup>.

The aim of this study was to compare QOL scores before and after laparoscopic surgery for achalasia, GORD and POH and to determine overall patient satisfaction scores. Responses were received from 121 of 184 individual patients.

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## MATERIALS AND METHODS

All patients undergoing elective laparoscopic surgery for the three conditions by a single surgeon over a seven year period from 2006-2013 were included. There were a total of 184 individual patients, incorporating 59 cardiomyotomies for achalasia, 89 funduplications for GORD and 43 POH repairs. Of these, five patients had re-do cardiomyotomies, and two had release of fundoplication due to symptoms related to dysphagia. All the procedures were completed laparoscopically.

A review of the procedures revealed no operative or 30 day mortality. However, given the time period involved, 3 patients died of other causes.

A 7cm cardiomyotomy with an anterior Dor fundoplication was performed in all patients with achalasia. A Nissen fundoplication without division of the short gastric arteries was performed in patients with GORD. POH repair was undertaken by primary crural repair without a mesh after complete reduction of the sac. A 360° fundoplication was also undertaken in this group.

Patients were asked via postal questionnaire to grade GORD symptoms using the GORD-HRQOL score with 0 equal to no symptoms and a maximum of 50 to indicate the most symptomatic.

Dysphagia symptoms were assessed using the previously described scoring system by Dakkak et al<sup>1</sup>, with a maximum score of 45 indicating no difficulty swallowing any of the foods included and a score of 0 indicating difficulties swallowing all of the foods in question including water. Therefore a score of 0 represents the most severely symptomatic.

Patients were also asked to rate their overall satisfaction with their current condition and with the procedure undertaken.

Of those who responded, 102 patients completed the online survey or returned the questionnaire via post. Non-responders were contacted via telephone and asked the same set of questions verbally to increase the response rate. A further 19 patients were reached this way. The individual who contacted the patients via telephone worked within the department, but had not been personally involved with any of the procedures or clinic follow-ups.

Results were analysed according to procedure and sex. The Mann-Whitney Test was used to compare median pre-operative and post-operative scores for each of the three groups which were expressed with their interquartile range (IQR).

## RESULTS

121 responses (68 females and 53 males) were received. The overall response rate was 66%. The mean follow-up times for the three groups were 62.9 months for the cardiomyotomy group, 50.2 months for the fundoplication group and 32.2

months for the POH group. The range for follow-up was 4 – 84 months.

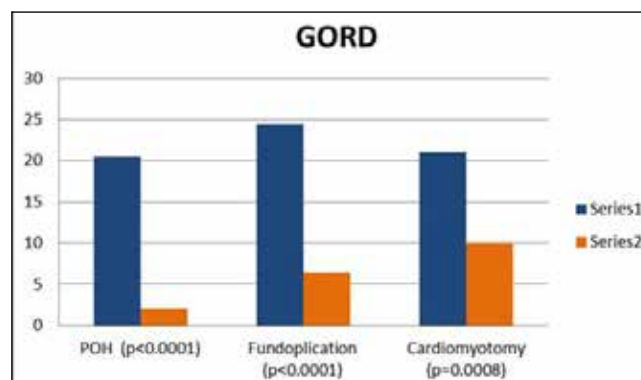


Fig 1. Incidence of GORD symptoms in pre (series 1) and post (series 2) treatment patients.

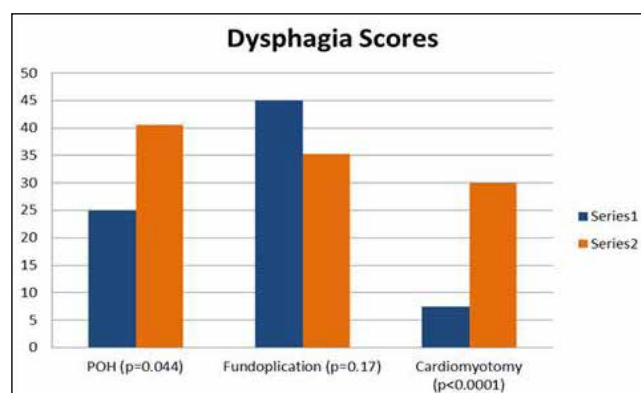


Fig 2. Dysphagia scores in pre (series 1) and post (series 2) treatment patients.

In the cardiomyotomy group there were 39 responses from a possible 58 (67%), 20 men and 19 women. This group showed a significant improvement in both symptom scores with the median pre-operative GORD-HRQOL score of 21 (IQR: 8, 27) significantly improved to 10 (IQR: 2, 15) following surgery ( $p=0.0008$ ). RAD scores improved from 7.5 (IQR: 3, 13.5) pre-operatively to 30 (IQR: 20, 41) post-operatively ( $p<0.0001$ ). 64% of respondents rated themselves as either “Satisfied” or “Very Satisfied” with their current condition and 90% said they were “Satisfied” or “Very Satisfied” with the surgical procedure.

In the fundoplication group there were 48 responses from a possible 84 (57%), 23 men and 25 women. This group showed an expected significant improvement in GORD symptoms with median pre-operative GORD-HRQOL score of 24.5 (IQR: 18.5, 33) compared to 6.5 (IQR: 2.25, 14.5) postoperatively ( $p<0.0001$ ). There was also a non-significant trend towards more dysphagia symptoms following fundoplication with RAD scores falling from 45 (IQR: 27.5, 45) pre-operatively to 35.25 (IQR: 21.75, 45) post-operatively ( $p=0.17$ ). 54% of respondents rated themselves as either “Satisfied” or “Very Satisfied” with their current condition and 63% said they were “Satisfied” or “Very Satisfied” with the surgical procedure.

In the POH group there were 34 responses from a possible 42 (81%), 10 men and 34 women. A significant improvement in GORD symptoms was also noted in this group, with median pre-operative GORD-HRQOL scores improving from 20.5(IQR: 10.25, 27.75) pre-operatively to 2(IQR: 0, 10.25) post-operatively ( $p < 0.0001$ ). Median RAD scores also improved from 25 (IQR: 8.74, 45) preoperatively to 40.5(IQR: 23.38, 45) post-operatively ( $p = 0.044$ ). 68% of respondents rated themselves as either "Satisfied" or "Very Satisfied" with their current condition and 82% said they were "Satisfied" or "Very Satisfied" with the surgical procedure.

## DISCUSSION

This study using patient reported outcome measures has shown that symptoms of dysphagia and GORD can be significantly improved following laparoscopic surgery for achalasia and POH. (Figures 1&2). The fundoplication group, as expected, showed a significant improvement in GORD scores but a non-significant worsening of dysphagia scores. Satisfaction scores were also high across all the groups following surgery but lowest in the fundoplication group, possibly as a result of some patients having a degree of dysphagia. This may also help to explain why the response rate was lower in this group. However, the overall response rate in this study is in keeping with what would be expected from similar studies. It is accepted that the lower the response rate, the lower the effective sample size and the greater the risk of bias.<sup>15</sup>

In the achalasia group, it is clearly expected that dysphagia scores would be significantly better after surgery. It is interesting in this study that QOL in terms of GORD symptoms was also significantly better in this group. Ponce et al showed that symptoms of GORD were relatively common in patients following open cardiomyotomy for achalasia but despite this the QOL scores using the Short Form (SF)-36 were equivalent to that of the general population and satisfaction levels remained high due to the reduction in dysphagia<sup>16</sup>. Chan et al compared laparoscopic cardiomyotomy combined with an anterior Dor fundoplication to endoscopic balloon dilatation and showed that surgery resulted in better overall QOL scores also using the SF-36<sup>17</sup>. They also showed that QOL was significantly worse in patients who reported GORD symptoms postoperatively. This was more common after balloon dilatation but was not statistically significant. In our study, symptoms of GORD were relatively high preoperatively in the achalasia group; this may be due to the non-specific character of many of these symptoms. Anderson et al showed that symptoms of heartburn were relatively high both before and after surgery in patients with achalasia but that this was a poor predictor of objective GORD on pH studies<sup>18</sup>. Irrespective of the mechanism, it is reassuring to note that GORD related symptoms did significantly improve with surgery in our study.

The group of patients undergoing fundoplication for GORD in our study reported low dysphagia scores preoperatively. In a review incorporating open and laparoscopic studies,

Wills et al reported average dysphagia rates across all the included studies with 41% of patients reporting dysphagia preoperatively. 34% still reported some dysphagia within 3 months of surgery, falling to 6% at 76 months with 4% of patients requiring further intervention for dysphagia<sup>19</sup>. Our low reports of dysphagia preoperatively may be due to recall bias in this retrospective study and this may explain the non-specific trend towards a worsening in of dysphagia scores in this group of patients. Patient satisfaction rates were generally lower in our study in the fundoplication group. This may be a reflection of the higher postoperative dysphagia rates as previously noted. Kellokumpu et al reported 10-year follow-up (median 10.2 years) of outcomes after laparoscopic fundoplication. Of those who were considered cured at 10 years (72.2%), QoL scores were equal to those of the general population and overall 83% reported satisfaction with the procedure and their current condition at 10 years<sup>20</sup>.

Para-Oesophageal Hernias may present with a variety of symptoms as noted previously. Our study revealed that symptoms of GORD and dysphagia both significantly improved in this group of patients after laparoscopic repair. Louie et al similarly revealed a sustained improvement in GERD-HRQL scores and low rates of dysphagia following laparoscopic repair at median follow up of 1.3 years. They also showed a significant improvement of QOL scores<sup>21</sup>. Parameswaran et al also showed a significant improvement in symptoms of abdominal pain, GORD and indigestion scores following laparoscopic repair using validated symptom specific scores<sup>22</sup>. They also demonstrated high rates of patient satisfaction after surgery in keeping with those reported in our study.

We conclude that our study using patient reported outcome measures has shown that laparoscopic surgery for achalasia, GORD and POH repair results in generally high rates of patient satisfaction and improvement in QOL. Patients with achalasia and para-oesophageal hernias reported significant improvement in QOL in terms of symptoms of both dysphagia and GORD.

## AUTHORS DISCLOSURES

Drs. Dobson, Thompson, and Kennedy have no conflicts of interest or financial ties to disclose.

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