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ANTERIOR 90^{O} PARTIAL vs NISSEN FUNDOPLICATION - 5 YEAR FOLLOW-UP OF A SINGLE CENTRE RANDOMIZED TRIAL

David I Watson[1]

Peter G Devitt[2]

Lorelle Smith[1,2]

Glyn G Jamieson[2]

Flinders University Department of Surgery, Flinders Medical Centre, Bedford Park, Adelaide South Australia[1]

and

Discipline of Surgery, University of Adelaide, Royal Adelaide Hospital, Adelaide, South Australia[2]

AUTHOR FOR CORRESPONDENCE:
Professor David I Watson
Head, Flinders University Department of Surgery
Room 3D211, Flinders Medical Centre
Bedford Park
South Australia 5042
AUSTRALIA

Ph: +61 8 8204 6086
Fax: +61 8 8204 6130
Email: david.watson@flinders.edu.au

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SUMMARY

Introduction

Nissen fundoplication can be followed by side effects, and this has driven modifications, including partial fundoplications. We previously reported early outcomes from a randomised trial of Nissen vs anterior 90^0 partial fundoplication. This paper reports 5 year follow-up outcomes to determine whether anterior 90^0 fundoplication achieves a satisfactory longer term outcome.

Methods

From February 1999 to August 2003, 79 patients were randomized to Nissen vs. Anterior 90^o fundoplication. Patients were followed yearly using a standardized clinical questionnaire which included symptom scores to assess heartburn, dysphagia, other post-fundoplication side effects, and overall satisfaction with the outcome. Five year clinical outcomes were analysed.

Results

Seventy four patients were available for follow-up at 5 years. There were no significant differences for: heartburn or satisfaction, although more patients used antisecretory medication after anterior 90^0 fundoplication (29.7% vs 8.1%). Dysphagia was greater after Nissen fundoplication when measured by an analog score for solid food and a composite dysphagia score. Symptoms of bloating were more common following Nissen fundoplication (80.0% vs 32.4%), and less patients could eat a normal diet (78.4% vs. 94.6%). Re-operation was undertaken in 4 patients after Nissen fundoplication (dysphagia – 3, hiatus hernia -1) vs. 3 after anterior 90^0 fundoplication (recurrent reflux – 3).

Conclusions

At 5 years, Anterior 90^0 partial fundoplication was associated with less side effects, offset by greater use of antisecretory medication. Reflux symptoms and overall satisfaction were similar to Nissen fundoplication. Laparoscopic anterior 90^0 partial fundoplication is an effective treatment for gastro-esophageal reflux.

INTRODUCTION

Laparoscopic fundoplication is well established for the treatment of gastro-esophageal reflux disease, and good outcomes are obtained for the majority of patients who undergo this surgery. However, Nissen fundoplication, whilst achieving good long term outcomes in 80-90% of patients[1], is followed by troublesome side effects such as dysphagia and gas related symptoms in some individuals, and in an attempt to improve clinical outcomes the Nissen fundoplication procedure has been progressively modified. One approach has been to construct a partial fundoplication, and this approach appears to have the greatest potential to minimise side effects. The commonest partial fundoplication technique entails the posterior approach, and randomized trials have consistently shown that this reduces the risk of gas related side effects[2,3]. However, the results of trials have been more variable for dysphagia, and a proportion of patients continue to report this problem after posterior partial fundoplication[2,3].

Anterior partial fundoplication is an alternative approach, and randomised trials have also shown that these techniques also reduce the risk of wind related side effects, as well as consistently reducing the risk of post-fundoplication dysphagia[4,5,6,7]. A range of techniques have been described, including anterior 180^0, anterior 120^0 [7] and anterior 90^0 [4,6]. Each technique differs with respect to the extent of anchorage of the gastric fundus to the right hiatal pillar. The anterior 180^0 partial fundoplication entails anchoring the fundus firmly to the right hiatal pillar[4,5], whereas with the other techniques the fundus is anchored only to the left side and anterior aspects of the esophagus and the hiatal rim[6,7]. Two randomized trials have shown excellent results at up to 10 years follow-up for the anterior 180^0 partial fundoplication approach[5,8]. However, results from randomized trails which have evaluated

anterior 120^0 and anterior 90^0 partial fundoplication techniques report more mixed results, with the reduced risk of side effects traded off against a greater risk of recurrent reflux during follow-up in some trials[6,7].

We have previously reported 5 year clinical outcomes from a multicentre Australia and New Zealand trial of Nissen fundoplication with short gastric vessel division vs. Anterior 90^0 partial fundoplication[6]. This showed more reflux, less side effects, but equivalent overall satisfaction with the outcome of surgery after anterior 90^0 partial fundoplication[6]. After completing the enrolment phase of this trial, we commenced a second randomized trial of anterior 90^0 partial fundoplication vs. Nissen fundoplication without short gastric vessel division, and undertook this trial in a single centre[9]. The results at up to 12 months follow-up in this trial have been reported previously, and they demonstrated reduced side effects following anterior 90^0 fundoplication, and equivalent reflux symptom control[9]. This suggested that the early outcome following anterior 90^0 fundoplication was at least as good as for Nissen fundoplication. However, in the absence of longer term outcomes, there has been understandable reluctance to consider the anterior 90^0 partial fundoplication for the treatment of gastro-esophageal reflux outside clinical trials. Hence, we determined and analysed the longer term (5 year follow-up) outcomes for patients enrolled in this trial, and these results are reported in this paper.

PATIENTS AND METHODS

The protocol and methods for the randomized controlled trial have been fully described previously[9]. In brief, patients with proven gastro-esophageal reflux disease (ulcerative esophagitis at endoscopy and/or an abnormal 24 hour pH study) were considered for entry into the trial. Exclusion criteria included an esophageal motility disorder which precluded a Nissen fundoplication, the need for a concurrent abdominal procedure, previous antireflux surgery or age greater than 75 years. Patients were investigated pre-operatively with esophageal manometry and endoscopy, and 24 hour pH monitoring was performed selectively for patients who did not have both typical reflux symptoms and ulcerative esophagitis at endoscopy. Informed consent was obtained from all patients.

Patients were randomized to undergo either laparoscopic Nissen or anterior 90^0 partial fundoplication. Randomization occurred in the operating room after the induction of general anesthesia, by opening a pre-sealed envelope. Patients were blinded during follow-up to which procedure had been performed. The surgical techniques have been described in detail elsewhere[10,11]. Posterior hiatal repair was performed in all patients. For Nissen fundoplication, the short gastric vessels were not divided and a 1.5 to 2cm long loose 360^0 total fundoplication was constructed, with a 52-Fr intra-esophageal bougie in situ. Anterior 90^0 partial fundoplication entailed suturing the posterior esophagus to the right hiatal pillar, re-creation of the angle of His by suturing the fundus to the left side of the esophagus, and construction of a fundoplication which was secured to the anterior hiatal rim, thereby covering only the left anterolateral intra-abdominal esophagus (Figure 1). A bougie was not used, and short gastric blood vessels were not divided during the partial fundoplication procedures.

Early outcomes at up to 12 months follow-up have been reported elsewhere[9]. For the current study 5 year follow-up outcomes were determined and analysed. Patients were followed yearly by a research nurse who used a standardized clinical questionnaire. To maximize the completeness of follow-up, the questionnaire was applied either by telephone interview or mail. The research nurses managing the follow-up were blinded to the type of fundoplication which had been constructed.

The questionnaire investigated the symptoms of heartburn, dysphagia and other post-fundoplication side effects[9]. Questions entailed yes / no questions asking whether "heartburn" or "dysphagia for solids" was present or absent, and the use of antisecretory medications was sought. Antisecretory medications were considered to be in use in any individual who reported either continuous or intermittent use over the previous 4 weeks. Patients were also asked to grade symptoms of heartburn, dysphagia for liquids, and dysphagia for solids using separate 0 to 10 analog scales (0 = symptom absent, 10 = severe symptoms). A previously described dysphagia score[12] was also used. This scoring system generated a composite score from each patient's ability to swallow nine index liquid or solid foods (0 = no dysphagia, 45 = total dysphagia). Additional yes / no questions were asked about symptoms of upper abdominal bloating and the ability to belch normally. Overall satisfaction with the outcome of surgery was determined using another 0 to 10 analog scale (0 = highly unsatisfied, 10 = highly satisfied). Patients were also asked whether if faced with similar preoperative circumstances they still considered their original decision to undergo surgery to be correct.

This trial was designed to identify differences between the two procedures for recurrent reflux and dysphagia. Preliminary power calculations determined that 80 patients (40 in each group)

would be needed to demonstrate a 15% difference in outcomes at a significance level of $p < 0.05$ and power of 80%. Data analysis was undertaken using InStat version 3.1a (GraphPad Software Inc) and performed on an intention to treat basis, with all patients remaining in their initial allocated group for this analysis. Fisher's exact test was used to determine the significance of 2 x 2 contingency tables, the Chi-squared test for larger contingency tables, and a two-tailed Mann-Whitney test was used to assess differences between sets of non-parametric data. This trial was approved by Human Research Ethics Committee of the Royal Adelaide Hospital.

RESULTS

From February 1999 to August 2003, 79 patients were enrolled in this trial. Forty were randomized to undergo anterior 90^0 partial fundoplication vs. 39 to undergo Nissen fundoplication. Seventy four (94%) patients provided follow-up data at 5 years follow-up – 37 in each group (Figure 2). In the anterior 90^0 partial fundoplication group, 1 patient died from breast cancer 3 years after fundoplication and 1 withdrew from the trial. Three further patients were lost to follow-up (Nissen – 2, Anterior 90^0 – 1). Demographic details for both study groups have been reported previously[9], and are summarized in Table 1. Both groups were well matched at enrolment. Overall, 54.4% of patients were male.

Table 2 summarizes the outcome for heartburn, dysphagia and other side effects. At five years follow-up, there were no statistically significant differences between the 2 groups for the symptom of "heartburn", or for the analog scores for heartburn. However, the use of antisecretory medication was significantly higher in the anterior 90^0 partial fundoplication group (29.7% vs. 8.1%). Three of the 4 measures used to assess dysphagia were significantly lower after anterior 90^0 partial fundoplication at 5 years follow-up, including the yes/no question (29.7% vs. 70.3%), the composite dysphagia score (mean 6.4 vs. 14.1) and the analog score for solids (mean 1.6 vs. 3.7). Only the difference for the analog score for liquids (mean 0.9 vs 1.9) failed to reach statistical significance. Abdominal bloating was significantly less common (32.4% vs 80.0%) and more patients could eat a normal diet after anterior 90^0 partial fundoplication (94.6% vs 78.4%). There were no significant differences between the groups for the ability to belch and the ability to relieve bloating symptoms.

The overall clinical outcome for the two groups was similar (Table 3). There were no statistically significant differences between the groups for the satisfaction score (mean 7.6 vs 6.7), or for the yes/no question (83.8% vs 75.7%) which assessed satisfaction with the original surgical decision making, although the trends were towards higher levels of satisfaction after anterior 90^0 partial fundoplication.

Seven (8.9%) patients underwent re-operation during the 5 year follow-up period All revision operations were undertaken laparoscopically. Four of these patients originally underwent a Nissen fundoplication, and persistent dysphagia was the indication for revision surgery in 3 of the 4 patients in this group (undertaken at, 4, 6 and 9 months). In 2 of the operations undertaken for dysphagia, the Nissen fundoplication was converted to a partial fundoplication, and in the other the diaphragmatic hiatus was widened and the fundoplication left intact. The other revision procedure in the Nissen fundoplication group was for an acute para-esophageal hiatus hernia occurring 2 days after the original surgery. All 3 revision operations in the anterior 90^0 partial fundoplication group were undertaken for recurrent reflux, with surgery entailing conversion to a Nissen fundoplication. This was undertaken at 7 months, 9 months and 2 years following the original operation.

DISCUSSION

Whilst most patients report a successful outcome following antireflux surgery, troublesome side effects occur in some patients following Nissen fundoplication, and this has led to technical modifications, such as partial fundoplication techniques, in an attempt to reduce the risk. Unfortunately, the results from randomized trials of posterior partial vs. Nissen fundoplication show that some patients are still troubled by side effects such as dysphagia and bloating after posterior partial fundoplication, even though the risks might be less than following the Nissen procedure[2,3]. In an attempt to further minimise the risk of these side effects, we have developed and evaluated techniques for anterior partial fundoplication.

In 1996 we commenced a randomized trial of Nissen vs Anterior 180^0 partial fundoplication, and we have reported 5 and 10 year follow-up from this trial[5,13]. This demonstrated similar levels of reflux control, but significantly less dysphagia and wind related side effects after Anterior 180^0 partial fundoplication, although a small group of patients still reported side effects. In 2000, we took this concept further and developed a new technique for Anterior 90^0 partial fundoplication[14]. The early laboratory and clinical outcomes confirmed that this created a more "anatomical" repair, rather than an overcompetent valve at the gastro-esophageal junction[14,15]. Two randomised controlled trials of Anterior 90^0 partial vs Nissen fundoplication have been undertaken to evaluate this further. The first, entailed a multicentre trial, conducted in 6 cities in Australia and New Zealand, and the results at 5 years follow-up demonstrated similar levels of satisfaction with the overall outcome for the 2 procedures, less side effects after Anterior 90^0 partial fundoplication, but offset by a higher incidence of recurrent reflux[6,15]. The Nissen fundoplication performed in this trial included division of the short gastric vessels.

To compare the outcome for Anterior 90^0 partial fundoplication with a Nissen fundoplication in which the short gastric vessels were not divided, we commenced the current trial[9]. Enrolment was limited to a single centre, and commenced after the recruitment phase for the first trial was completed. All surgery was undertaken by or under the direct supervision of 3 surgeons (DIW, GGJ & PGD). The initial results at 6 to 12 months follow-up were promising, demonstrating less side effects, but similar reflux control after Anterior 90^0 partial fundoplication[9]. With longer term follow-up, our current study has shown acceptable outcomes to 5 years. These results clearly demonstrate less dysphagia and wind related side effects after Anterior 90^0 fundoplication, and reflux symptoms, as measured by the heartburn score, were similar for the two groups, even though the use of antisecretory medication and the rate of revision surgery for recurrent reflux were both higher following Anterior 90^0 fundoplication. This suggests less effective, but still adequate control of reflux at 5 years follow-up. It should be recognized, however, that even though there was an apparent excess of reoperations for recurrent reflux in the Anterior 90^0 fundoplication, this was fully offset by re-operative surgery for dysphagia after Nissen fundoplication, and the overall satisfaction with the clinical outcome at 5 years was at least as good after Anterior 90^0 fundoplication. These results are consistent with results from all other trials of Anterior partial vs. Nissen fundoplication[4,5,6,7,8], as well as a recent meta-analysis[16].

The outcomes for the yes/no questions used in this study might initially seem to show unusually high rates of side effects such as dysphagia or bloating. However, it is important to recognize that the way a question is structured impacts on how it is answered. In our study patients were only allowed to answer “yes” or “no”, and a “yes” was given, even if symptoms occurred only occasionally. Previous trials using this approach have also reported similar high

rates of response, both during follow-up and also before surgery[5,6]. It is important, therefore, to focus on the differences between response rates for each question, and it is not appropriate to compare absolute percentages with outcomes from other studies in a non-randomised fashion.

In the current trial we have shown a significant difference between the 2 groups for the usage of antisecretory medications. Whilst, this is informative about the relative risk of recurrent reflux symptoms for each procedure, we have also shown previously that only 1/3 of antisecretory medication use at late follow-up after fundoplication is actually for recurrent reflux, and approximately 2/3's of patients use antisecretory medications for other reasons[17]. The rate of PPI consumption 5 years after anterior 90^0 partial fundoplication in our current study was similar to the 33% PPI use rate reported at mean 5.9 years after Nissen fundoplication in 525 patients enrolled in a medication usage study[17]. The 8.1% rate of PPI use at 5 years after Nissen fundoplication in our current trial is actually much lower than is usually reported at late follow-up in other studies[17]. Despite this, it is difficult to interpret the difference in medication usage as showing anything but a difference in reflux control. How is this rationalized with other data, such as the similar heartburn symptom scores and satisfaction scores? The heartburn scores assessed the status of symptoms at 5 years, and these might be controlled by surgery alone, medication alone (if reflux has recurred), or by a combination of surgery and reflux. Most patients enrolled in our trial had reflux symptoms which were not controlled by medication at the time of entry into the trial, and for them a partial failure of reflux control after surgery which requires the use of medication to now achieve full symptom control appears to actually be acceptable to many of these patients, whereas full reflux control offset by ongoing dysphagia is often not acceptable.

The follow-up in our trial was obtained using standardized clinical questionnaires, and we did not measure objective outcomes using pH monitoring, impedance, manometry or endoscopy at late follow-up. Whilst objective data might strengthen the conclusions drawn, repeated objective investigations are not acceptable to most asymptomatic Australian patients following antireflux surgery. We did undertake pH monitoring, esophageal manometry and endoscopy at 6 months after surgery, and data from these studies were reported elsewhere[9]. The results were consistent with the early clinical outcomes in this trial. Our experience with conducting several trials in this area confirms that the clinical assessment scores are quite informative about outcomes and differences, and that the global satisfaction scores probably better assess the actual outcome as perceived by the patient, whereas the results of objective tests are often of less relevance to the clinical outcome as perceived by the individual patient.

The 5 year follow-up outcomes from our randomized trial of Anterior 90^0 partial vs. Nissen fundoplication suggests equivalent overall outcomes, with a significantly lower rate of side effects after Anterior 90^0 partial fundoplication, but a greater likelihood of recurrent reflux. Rates of satisfaction and actual reflux symptoms were similar for the 2 procedures at 5 years follow-up. In clinical practice, we currently undertake a mix of Anterior 90^0, Anterior 180^0, and Nissen fundoplication, and often tailor the type of fundoplication to the perceived risk of side effects. In particular, we now always prefer an anterior partial fundoplication in individuals who are at a higher risk of post-fundoplication side effects, and as longer term outcome studies show good reflux control following Anterior 180^0 fundoplication[5], this has been the commonest procedure performed in our departments over recent years. Whilst awaiting the outcomes from the randomized trials of Nissen vs. Anterior 90^0 fundoplication, we have tended to use the Anterior 90^0 partial fundoplication in the more elderly patient group undergoing surgery primarily for very large hiatus hernia, in whom reflux is often less

of an issue, but in whom side effect minimization is important. The results of our current trial, however, suggest that Anterior 90^0 partial fundoplication is an effective operation for the surgical treatment of gastro-esophageal reflux disease, and this data supports a wider application for this procedure in clinical practice.

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TABLES

TABLE 1

Preoperative patient characteristics

	Nissen fundoplication (n=39)	**Anterior 90^0 fundoplication** (n=40)	**P value**
Age (yrs)	45.7 (42.4, 49.1)	45.8 (42.1, 49.4)	0.775
Gender (M/F)	19M:20F	24M:16F	0.370
Height (cm)	168 (163, 172)	171 (167, 176)	0.203
Weight (kg)	88.1 (82.5, 93.7)	83.0 (75.2, 90.7)	0.238
Previous upper abdominal surgery	6 (15.3%)	6 (15.0%)	0.766

All figures are mean (95% confidence intervals) or No. (%).

TABLE 2

Clinical outcomes at 5 years for heartburn, dysphagia and other side effects

	Nissen fundoplication (n=37)	**Anterior 90^0 fundoplication** (n=37)	**P value**
Reflux symptoms			
Heartburn present	14 (37.8%)	11 (29.7%)	0.624
Heartburn analog score	2.00 (1.05, 2.95)	1.703 (0.91, 2.49)	0.921
Using antisecretory medications	3 (8.1%)	11 (29.7%)	0.035
Dysphagia assessment			
Dysphagia for solids	26 (70.3%)	11 (29.7%)	0.0010
Dysphagia analog scores			
Liquids	1.92 (0.94, 2.90)	0.92 (0.27, 1.57)	0.107
Solids	3.70 (2.62, 4.79)	1.60 (0.80, 2.39)	0.0019
Composite dysphagia score	14.14 (10.41, 17.86)	6.38 (3.48, 9.28)	0.0010
Other side effects			
Abdominal bloating	27 (80.0%)	12 (32.4%)	0.0010
Able to relieve Bloating	24 (64.9%)	21 (56.8%)	0.482
Ability to Belch normally	22 (59.5%)	29 (78.4%)	0.131
Able to eat a normal diet	29 (78.4%)	35 (94.6%)	0.047

All figures are mean (95% confidence intervals) or No. (%).

TABLE 3

Overall outcome assessment at 5 years

	Nissen fundoplication (n=37)	**Anterior 90^0 fundoplication** (n=37)	**P Value**
Analog score of "satisfaction"	6.68 (5.58, 7.78)	7.65 (6.56, 8.74)	0.114
Satisfaction score 0-3	7 (18.9%)	6 (16.2%)	
Satisfaction score 4-6	6 (16.2%)	3 (8.1%)	
Satisfaction score 7-10	24 (64.9%)	28 (75.7%)	0.500
"Would choose operation again"	28 (75.7%)	31 (83.8%)	0.564

All figures are mean (95% confidence intervals) or No. (%).

FIGURE LEGENDS

Figure 1

Completed anterior 90^0 partial fundoplication. The anterior fundus is sutured half way across the front of the esophagus, leaving the right antero-lateral wall of the esophagus uncovered. The fundus lies adjacent to 25-30% of the wall of the intra-abdominal esophagus.

Figure 2

Consort diagram for randomized trial. Five year follow-up data is reported in the current paper. Earlier follow-up reported elsewhere[9].

Figure 1

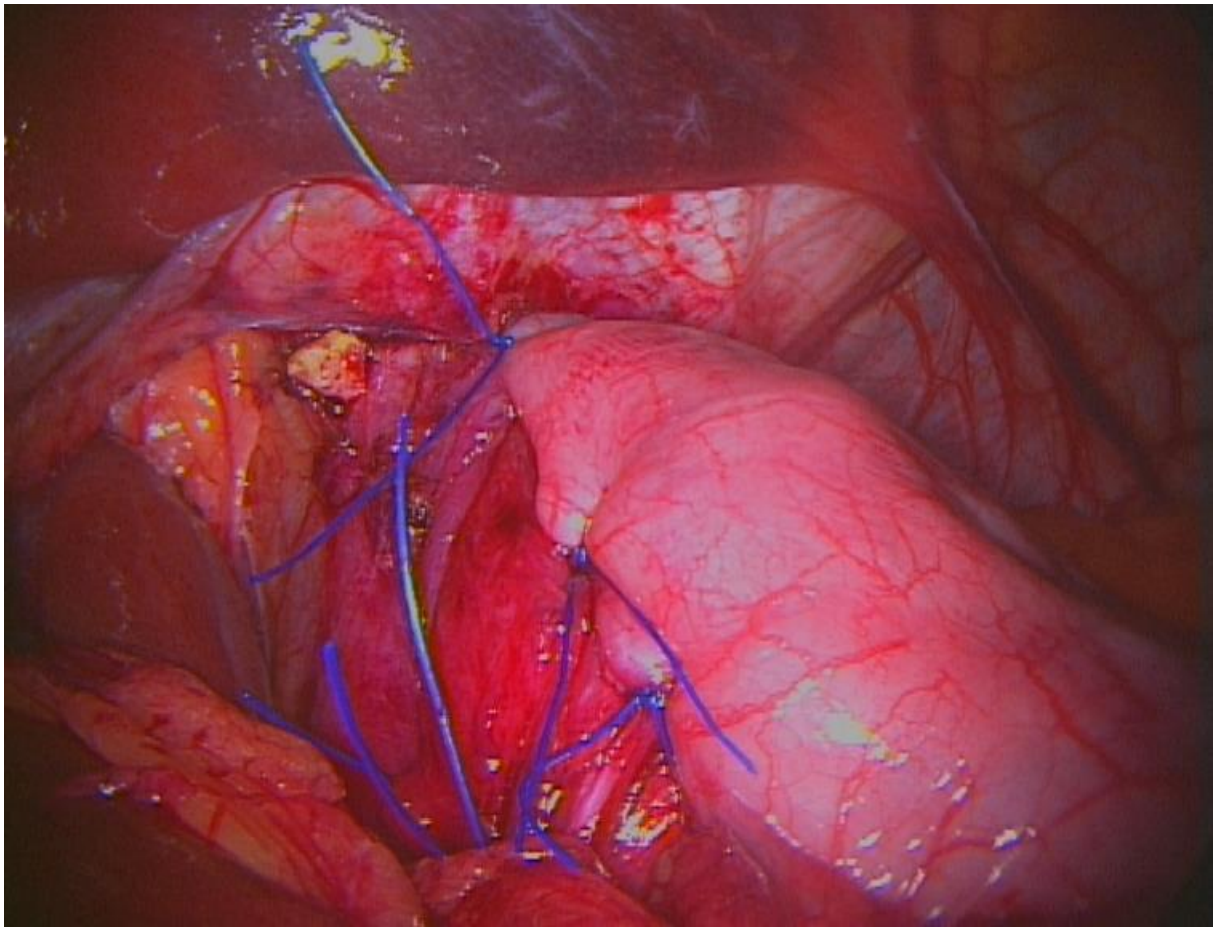

Figure 2