Achalasia: a 13-year, single-centre experience comparing endoscopic balloon dilatation and laparoscopic Heller myotomy

Alexander Huelsen, Ramadan Oumer, Anna Ashcroft, Ross H Roberts, Grant N Coulter, Steven J Kelly, Murray L Barclay

ABSTRACT

BACKGROUND: Idiopathic achalasia is a non-curable, primary motility disorder of the oesophagus. Most established long-term palliative treatment options are laparoscopic Heller myotomy (LHM) and endoscopic balloon dilatation (BD).

AIM: We aimed to compare the outcome of both therapies and the risk of serious complications, defined as perforation or death, in a single-centre series.

METHOD: In this retrospective study, patients with BD or LHM were identified from 1997–2010. The symptom score (modified Zaninotto score) before treatment and at time of interview was evaluated via a telephone questionnaire.

RESULTS: Ninety-nine patients fulfilled the inclusion criteria and treatment was provided with BD-only in 63, surgery-only in 23, BD crossover to surgery in 12, and surgery crossover to BD in one patient. Mean age was 62 years in the BD-only, and 39 years in the surgery-only group. One hundred and fifteen BD were performed on 76 patients with multiple dilatations required in 46 patients (38%). Sixty-four percent of all patients alive (n=81) were interviewed. Satisfactory outcomes were achieved in 79% in the BD group and in 88% in the surgery group, with a mean follow-up of 81 and 69 months, respectively. There was a single perforation in the BD group (0.9%) and no deaths occurred.

CONCLUSION: LHM and on-demand BD were safe and within the limitations of our study design both methods appeared similarly effective treatments for achalasia, resulting in a satisfactory outcome in 88% and 79% of patients with a mean follow-up of 69 and 81 months. Serious complications occurred in less than 1% of procedures and there were no deaths.

Achalasia is a rare and non-curable primary motility disorder of the oesophagus with an estimated incidence of 0.5–1.6 per 100,000/year.[1,2,3] Symptoms include dysphagia to solids and/or fluids, regurgitation, chest pain, heartburn and weight loss. The classical features are a hypertensive lower oesophageal sphincter (LES) with incomplete relaxation, as well as a lack of peristalsis in the oesophagus due to inflammatory degeneration of the myenteric plexus.[4] The established most effective treatment options are endoscopic balloon dilatation (BD) and trans-abdominal laparoscopic Heller myotomy (LHM) combined with an anti-reflux procedure.[5] The later is currently recognised as the more definite long-term treatment.[6,7] However, a recent interim report of a European, multicentre, randomised controlled trial showed that both therapies are similarly effective in the short term.[8] The follow-up data from this study aims to reveal the medium to long-term outcome over the next

decade, which may help to clarify the exact role of these therapies. Peroral endoscopic myotomy (POEM) is a further relatively new endoscopic treatment option developed in Japan in 2008. With this technique, the myotomy is performed endoscopically using a standard gastroscope, thus avoiding abdominal incisions. POEM is gaining fast and widespread popularity worldwide as a likely, similarly-effective minimally-invasive treatment option and may also be available in the near future in New Zealand. However, long-term outcome results of POEM and randomised trials comparing the three approaches will not be available for some years. Until such evidence becomes available, local data remains important to guide management, especially as BD is a relatively easy procedure that can be performed by any skilled endoscopist, whereas LHM can be technically challenging and requires adequate training and continuous exposure to achieve a good outcome. New Zealand is a small country, with a relatively low number of achalasia cases per surgeon compared to larger countries or centres. The great results reported by centres of excellence with a high-volume caseload might not be directly translatable to local clinical practice in hospitals with lower case volumes for surgeons.

The primary aim of this study was therefore to assess and compare symptom outcomes of the currently available treatments, LHM and BD, in a tertiary hospital in New Zealand. Secondary endpoints included serious complications defined as perforation or death and assessment of patient satisfaction with treatment.

Method

Christchurch Public Hospital is the largest hospital in the South Island of New Zealand, with a catchment area of over 450,000 people. The Christchurch Public Hospital endoscopy unit is the only service providing 30–40 mm balloon dilatation for achalasia in this region; consequently, all patients who underwent this procedure were identifiable through the endoscopy databases (Endoscribe v2.25 and Provation).

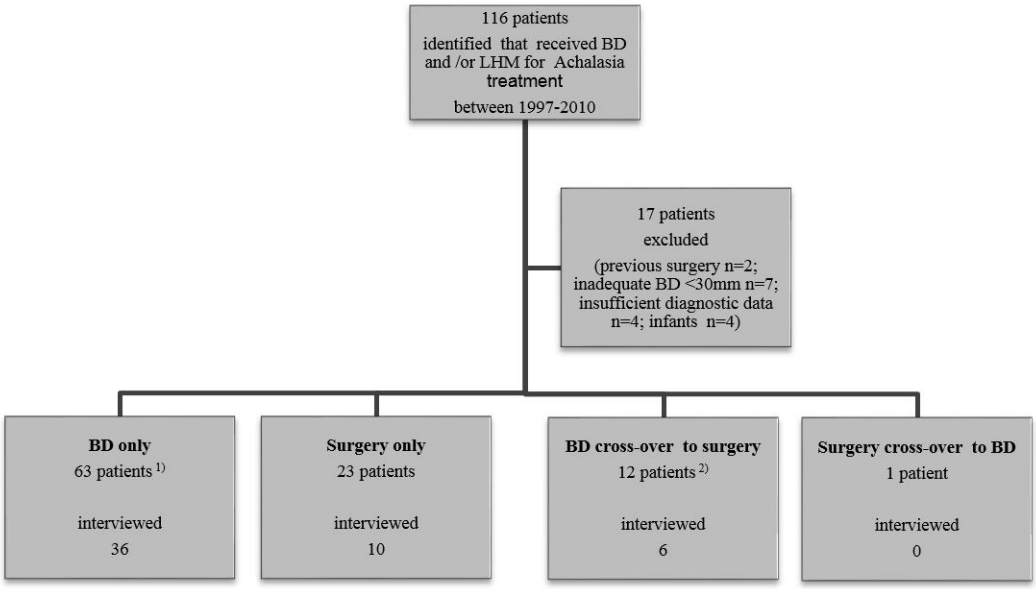
BD was provided following an "on demand" approach, starting with a 30mm diameter balloon (Rigiflex, Boston Scientific), with the option to increase balloon size on subsequent dilatations if there was ongoing or recurrent dysphagia. Generally, the balloon was inflated once—and in a few occasions twice—with 15 psi of air and held for 15–30 seconds. The decision to perform a primary or further BD, or to consider LHM, was made by the specialist (gastroenterologist and/or surgeon) on clinical grounds following a diagnosis of achalasia with manometry, and including the preference of the patient.

Over the defined study period, two upper GI specialist surgeons performed LHM in the Christchurch region, in both public and private hospital setting. This study excluded paediatric patients (< age 6) and not all private clinics could be incorporated; thus not all cases could be identified for certain. The LHM was performed largely following the method described by Hunter et al.[9] Both surgeons had performed less than 50 LHMs throughout their career. Patients treated in Christchurch Public Hospital were identified using the hospital clinical coding system, and patients treated in the private sector were identified through the clinical coding system of the private surgeons.

The clinical records of all patients were retrieved and reviewed in the first part of this study to determine demographic characteristics, gastroscopy and manometry results, interventional treatment methods and documented severe complications, defined as perforation or death. Patients were included in the study if the diagnosis of achalasia was based on manometry criteria (achalasia subtype classification was not available and not recognised standard at the time of our study period), and a gastroscopy did not reveal other pathology. Patients were excluded if they had prior oesophageal surgery, anti-reflux surgery or myotomy, or if they were less than six years of age at first treatment.

In the second part of this study, clinical outcome data were collected through a telephone interview with patients using a standardised questionnaire, after obtaining informed consent. The questionnaire was a modified version of the one described by Zaninotto et al to score relevant clinical symptoms pre-treatment and at the time of the telephone interview.[10] Patients who failed either surgical or endoscopic treatment, and crossed over to the other

Figure 1: Number of patients in each treatment group and numbers interviewed.



[1)] 18 patients (all in the BD-only group) were deceased at the time of interview. [2)] In three cases it remained unclear if balloon dilatation (BD) was adequate (≥30mm) as BD was performed prior to our study period and this information was not available.

treatment, were also interviewed regarding their symptoms prior to the second-line treatment. The symptoms evaluated were dysphagia, chest pain, heartburn and regurgitation, and these were scored according to their severity and frequency. An overall symptom score was calculated by combining the severity of each symptom (0 = none; 2 = mild; 4 = moderate; 6 = severe) with its frequency (0 = never; 1 = very occasionally; 2 = once a month; 3 = every week; 4 = twice a week; 5 = daily). The highest total score obtainable was 44.

All patients were also interviewed regarding their overall satisfaction with the treatment received (very unsatisfied; unsatisfied; satisfied; very satisfied).

Statistical analyses

The data collected were analysed using the Statistical Package for the Social Sciences (Windows version 11.5; SPSS Inc, Chicago, US). Continuous variables were expressed as medians with interquartile ranges (IQR), as the data showed significant skewing. Non-parametric tests were used to compare groups. Related-samples Wilcoxon signed-rank tests were used to compare before and after scores (both total and individual symptoms) within each group; Mann-Whitney U tests were used to compare overall differences between groups; and Kruskal-Wallis tests were used to compare individual symptom improvements and satisfaction across the three different treatment groups (BD only, BD prior to surgery and surgery only). A probability of <5% was considered to indicate statistical significance ($p<0.05$).

Results

Overall, 116 patients were identified through the database search, with 99 fulfilling the inclusion criteria. The number of patients in each treatment group, and number able to be interviewed for this study, are shown in Figure 1. Patient demographics are summarised in Table 1.

All but two LHM operations were combined with a fundoplication procedure. In three cases, a 360-degree fundoplication was used, and in all other patients, partial fundoplications, either Dor or Toupet, with varying wraps from 90 to 270 degrees, were performed.

Five intraoperative complications were reported, including: two gastric and one oesophageal perforation (all repaired, no subsequent leaks); one splenic tear (clipped); and one thoracic duct injury (clipped). Post-surgical convalescence was not affected. Following surgery, further treatments were required in 6 patients (17%) due to dysphagia or reflux (Table 2).

Four gastroenterologists performed 115 BD on 76 patients. Of these, 47 (62%) had only one BD during the study period and of these, 2 (2.6%) crossed directly over to LHM. More than one dilatation (2-4 BD) was

Table 1: Patient demographics.

Treatment Group	**Age in years** at first BD[§]/ LHM[¶] mean (range)	**Gender** M/F n
BD only	63 (9–95)	21/42
BD cross-over to surgery	45 (22–67)	6/6
Surgery only	39 (18–66)	14/9
Surgery cross-over to BD	65	1/0

[§]Balloon dilatation; [¶]laparoscopic Heller myotomy

Table 2: Treatments following laparoscopic Heller myotomy.

Patients (n)	**Symptom**	**Intervention**
3	dysphagia	2 x18mm BD,§ and 1 x Savary dilatation
1	dysphagia	Cross-over to BD
1	dysphagia then dumping syndrome	Open thoracic revision of myotomy and fundoplication; BD; esophagogastrectomy; jejunostomy
1	reflux	Partial fundoplication converted to Nissen fundoplication with subsequent redo

[§]Balloon dilatation

Figure 2: Number of balloon dilatations performed and balloon sizes used.

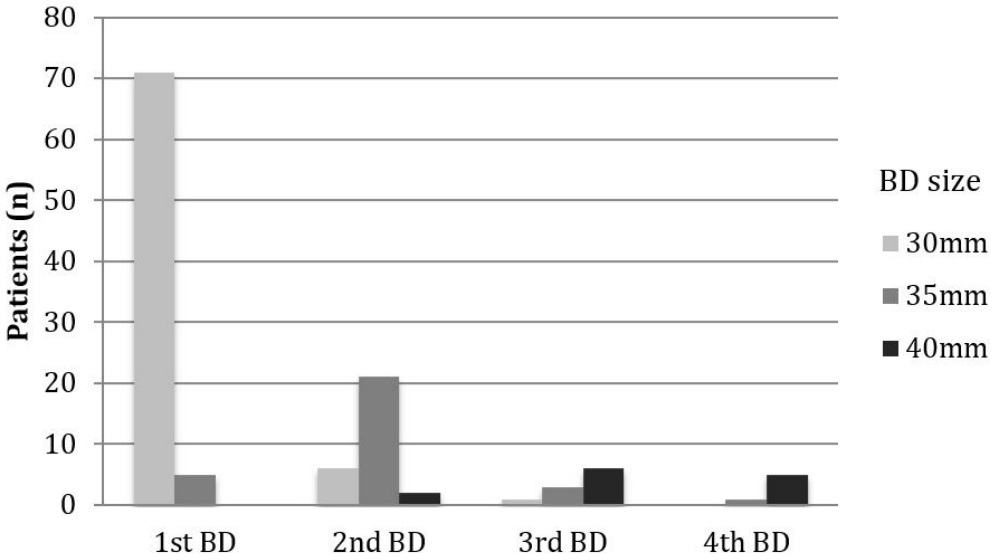
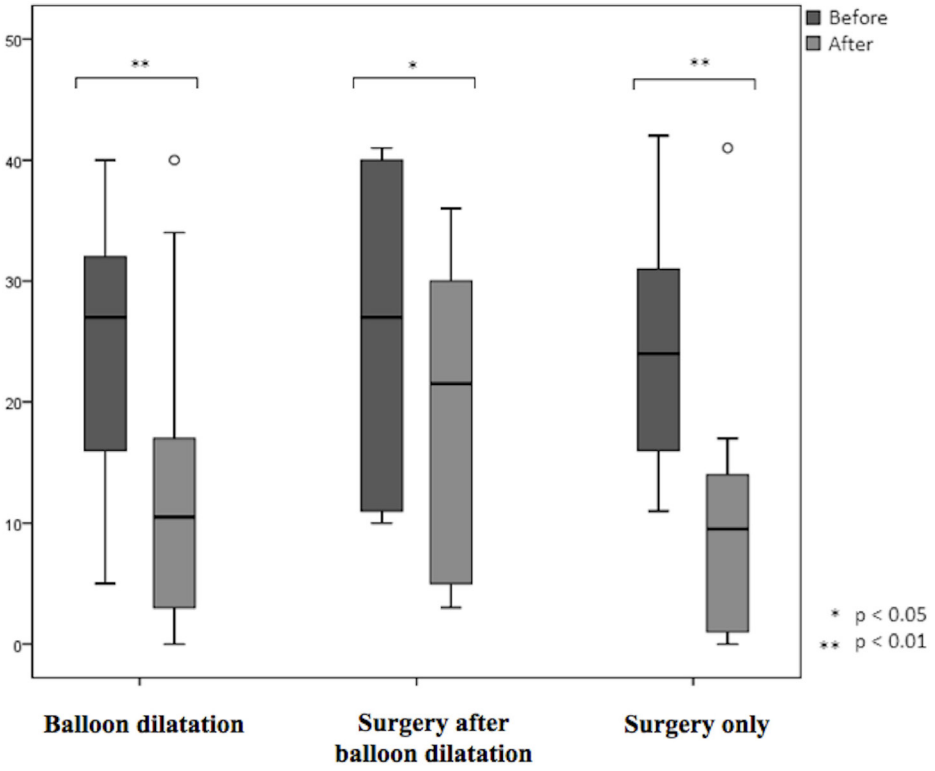


Figure 3: Pre- and post-treatment symptom scores (dark grey and light grey) in patient groups with BD (all BD patients), BD cross-over to surgery, and surgery only.



performed in 29 patients (38%), with the number of BD performed and balloon sizes shown in Figure 2.

In the group of patients requiring further dilatations, the median time to the second dilatation was 14 months (range 1–75), the median time to the third dilatation was 14 months (range 3–49), and the one patient with a fourth BD had this performed 11 months following the third BD.

In the BD group, one perforation occurred (0.9%) which was subsequently treated with open Heller myotomy the next day, without any further complications and a good clinical outcome. Overall, subsequent LHM was required in 12 patients (16%).

At the time of data collection, 18 patients had died, all belonging to the BD-only group. These cases were reviewed, and in none of the cases was death related to achalasia treatment. The mean age at death was 82 years (range 58–97).

Of the 81 patients alive at the time of data collection, 52 (64%) were contactable and consented to take part in a telephone interview and were included in the second part of the study (Figure 1).

The analysis of the standardised questionnaires revealed that, overall, symptom scores improved significantly in the BD group (including all patients that underwent BD) from a median of 27.0 (IQR 16–32) prior to BD, to 10.5 (IQR 3–17) after BD ($p<0.01$). The symptom scores of patients in the surgical group (including all patients that underwent LMH) also improved significantly ($p<0.01$) from a median of 26.0 (IQR 12–37.0) to 11.0 (IQR 4–23). No statistically significant difference was found in the degree of improvement between the two treatment groups ($p=0.48$).

Analysis of the surgery-only group and the 12 patients who had an initial BD prior to surgery, showed that both groups had significant improvements in symptom scores, with no statistically significant difference found between the two treatment groups ($p=0.35$). The surgery-only group demonstrated a median reduction of symptom scores (before-after) of 8 points (IQR: 5–24; $p<0.01$), with the group who had BD prior to surgery demonstrating a median difference of 6.5 points (IQR: 4–10; $p< 0.03$), as demonstrated in Figure 3.

The individual symptom score sub-categories dysphagia and regurgitation showed similar and significant improvement in the BD and surgery groups. Chest pain was significantly improved only in the BD group,

Figure 4: Sub-category symptom scores before (dark grey) and after (light grey) treatment in balloon dilatation patients.

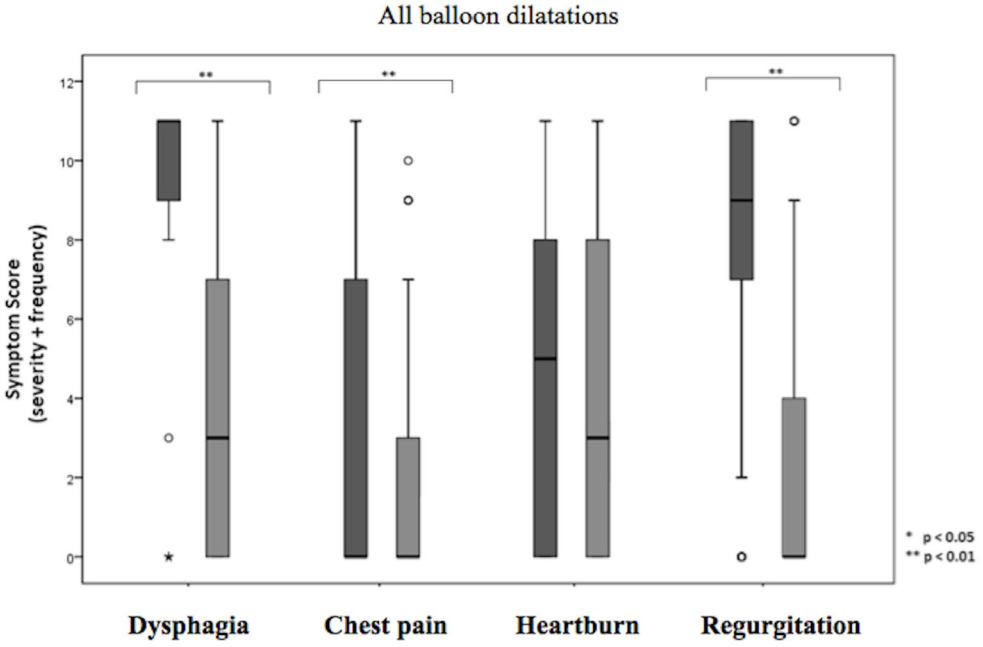
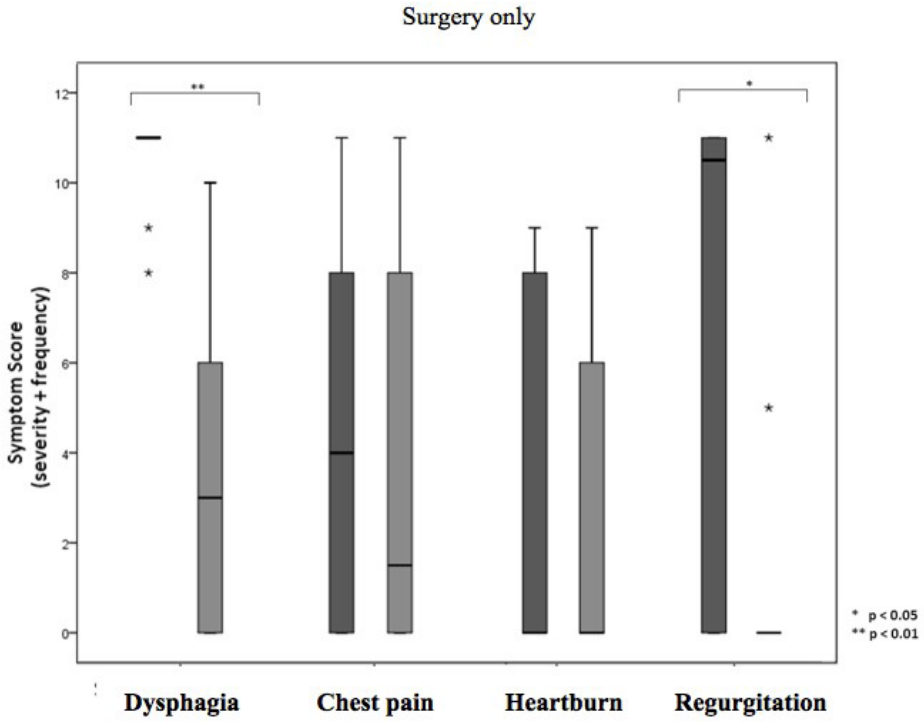


Figure 5: Sub-category symptom scores before (dark grey) and after (light grey) treatment in the surgery-only group.



whereas the sub-category heartburn did not show any significant improvement in either treatment group, as illustrated in Figures 4 and 5.

All interviewed surgical patients (n=16) had their surgery performed by one of two specialist surgeons, with similar improvements in symptom scores for each surgeon.

Participants reported their satisfaction with treatment as satisfied or very satisfied in 79% (n=33) in the BD group, with a mean follow-up of 81 months (median 81; IQR: 10–211), and in 88% (n=14) with LHM with a mean follow-up of 69 months (median 52; IQR: 11–141). No statistically significant difference was found in satisfaction rates between the treatment groups

Discussion

Some authors describe LHM as a more permanent and superior treatment for achalasia compared to BD, with excellent initial and medium-term success rates of 90%.[6] Supporting data are usually derived from specialised referral centres with highly experienced operators. However, published success rates may not be entirely translatable to centres with smaller patient numbers, such as in New Zealand. This concern was underlined by a large nationwide retrospective study from Canada that identified significantly higher retreatment requirements following LHM compared to high-volume specialist centres.[11]

The results of our study revealed that LHM was performed safely and achieved a satisfactory outcome in 88% of the interviewed patients after a mean follow up of 69 months, which is consistent with the data provided by specialised referral centres.[6] Interventional retreatment following LHM was required in 17% and was due to symptoms of reflux or dysphagia. Similar retreatment rates of 18–21% after a mean follow-up of 5–6 years have been reported in other studies.[12,13]

BD, on the other hand, has become somewhat less favoured since the introduction of LHM, due to higher symptom recurrence following a single dilatation. However, over the last decade it has become well recognised that a single BD should not be seen as sufficient to treat achalasia in the long-term in many cases.[14] Eckart et al found that after 5 years, up to 50% of patients will have symptom recurrence following a single BD. This was also demonstrated in our study, where 47% of our interviewed BD-only cohort required more than one dilatation to achieve on-going symptom control.[15]

Recent studies assessing BD with an on-demand and/or graded approach using repeat procedures with similar or increasing balloon sizes have provided excellent results, with success rates of over 90% after a follow-up of 6–10 years.[16,17] In our cohort, BD with an on-demand approach achieved a satisfactory outcome in 79% of the interviewed patients after a mean follow-up of 81 months.

Crossover to LHM was required in 16% of the BD patients, including the single perforation case that occurred during our study period. A recent single-centre study from a high-volume institution reviewed 184 patients in their 12-year treatment experience, and found 8.7% underwent LHM following BD, including one perforation following BD.[18] We speculate that in our institution, compared to higher volume centres, the threshold to crossover to LHM was possibly lower due to the predominant local opinion that LHM may offer a more definitive treatment.

Our study did not detect a statistically significant difference in outcome between our BD and LHM groups. However, it is important to note that the treatment groups were not equally matched in this retrospective study, and therefore success rates may not be entirely comparable. LHM was offered more frequently to younger male patients, following current evidence that male gender, and age under 40, are independent negative prognostic factors for BD.[15,17,19] In such cases, LHM may offer a more permanent resolution of symptoms. In addition, our crossover group from BD to LHM had an average age of 45 years, compared to 62 years in the BD-only group.

An ongoing, multicentre, randomised controlled trial from Europe comparing LHM with graded BD is suggested to have enough power to clarify the appropriate role of these procedures in achalasia treatment. First interim reports after a 2- and 5-year follow-up period of 196 patients supports our short-term findings, and showed equal success rates, suggesting that both procedures can be used as initial treatment.[8,20] Our results would also suggest that these results might be sustained in the medium-term.

BD has been reported to cause submucosal microhaemorrhages leading to local fibrosis that may increase the complication rate should a surgical myotomy then be attempted.[21,22] Some experts therefore argue that LHM should be regarded as the first line treatment for achalasia, and BD should be reserved as second-line treatment; however, available data is conflicting.[22,23,24] In our study, the crossover group showed significant improvement following LHM that did not differ statistically from the

LHM only group, however, the treatment cohorts were small with only 6 and 10 patients, respectively.

Looking at our symptom subcategories, there was no significant change in the rate of heartburn following either intervention. Heartburn is common in achalasia, and is usually not related to acid reflux episodes by pH monitoring prior to treatment; however, the development of gastro-oesophageal reflux disease (GORD) remains a concern in the long-term, especially following surgical treatment.[25] Our study was based on symptom assessment via questionnaire only and cannot provide further data regarding GORD occurrence.

Chest pain was significantly improved following BD, but not following surgery. There is no obvious explanation for this difference between the treatment groups, and this finding should not be over-interpreted given the small sample size interviewed post-surgery. The cause of chest pain in achalasia is not known and a previous study found that both BD and LHM had only a small effect on this symptom.[26] However, it was noted in this study that, in general, chest pain tended to improve in most patients over the course of several years, which may have also been the case in our study. Other studies found improvement in chest pain following LHM.[27,28]

The secondary aims of our study were assessment of treatment-related perforations and deaths, and both treatments were found to be very safe in this regard. There was only one perforation (0.9%) following BD requiring subsequent LHM, and three intraoperative mucosal perforations during LHM that were identified and treated at the time of the index operation, without any subsequent complications. These results are excellent and in keeping with the international literature reporting 1.9% (range 0–16%) of perforations following BD and 7–15% following LHM.[29]

No treatment-related deaths occurred during our study period, and the 18 patients in our study cohort that died prior to our data collection were on average 82 years old, which is in keeping with the current life expectancy in New Zealand. This finding is in line with previous reports that patients with achalasia have a normal life expectancy.[30]

Our study design was based on a standardised telephone interview on an achalasia treatment cohort identified retrospectively. Such a design is clearly inferior to a prospective randomised controlled study, consequently the results have to be considered critically. We identified that treatment groups were not matched and mirror pre-existing evidence that age <40 and male gender are negative prognostic factors for BD.[19,31] Furthermore, sample sizes were limited in several groups and sub-groups, which may impair statistical power in identifying small but clinically relevant differences. Treatment success or failure was not assessed objectively or pre-defined in this study compared to prospective trials, but rather assumed to correlate with the patient being satisfied or unsatisfied with the treatment result. One may speculate that patients may develop tolerance to symptoms that persist after treatment. On the other hand, satisfaction with treatment remains an important endpoint for any patient undergoing interventional treatment and therefore we believe our assessment of this is well justified.

Our research group modified the Zanninotto score to include chest pain as a well-recognised and distinct symptom of achalasia.[10] The Zanninotto score, however, has never been validated in this form.

Lastly, newer evidence emerged in 2008 that led to the classification of Achalasia into three subtypes based on high-resolution manometry criteria. This is of clinical relevance as the treatment outcome differs between subgroups, and over representation of one subtype in one treatment group would have likely significantly skewed the data.[32] High-resolution manometry with subtype classification is now standard in our unit, but was not available throughout the study period.

Conclusion

Our study in a medium-sized hospital setting in Australasia showed that LHM and on-demand BD were safe and within the limitations of our study design both methods appeared similarly effective for the treatment of achalasia. Satisfactory outcomes were achieved in 88% of the LHM group

and 79% of the BD group over a medium follow-up of 69 and 81 months, respectively. Treatment-related perforation occurred during BD in only a single case (0.9%), which was subsequently closed surgically without any further complications. LHM led to three perforations (8.3%), however these were repaired during the index operation. There were no treatment related deaths.

Competing interests:
Nil
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Author information:
Alexander Huelsen, Interventional Endoscopy Fellow, Gastroenterology and Hepatology Department, Princess Alexandra Hospital, Brisbane, Australia; Ramadan Oumer, Surgical Registrar, Department of Surgery, Christchurch Hospital, Christchurch; Anna Ashcroft, Research and statistics assistant, Department of Gastroenterology, Christchurch Hospital, Christchurch; Ross H Roberts, Consultant Surgeon, Department of Surgery, Christchurch Hospital, Christchurch; Grant N Coulter, Consultant Surgeon, Department of Surgery, Christchurch Hospital, Christchurch; Steven J Kelly, Consultant Surgeon, Department of Surgery, Christchurch Hospital, Christchurch, M Barclay, Consultant Gastroenterologist, Department of Gastroenterology, Christchurch Hospital, Christchurch and University of Otago Christchurch, Christchurch.
Corresponding author:
Alexander Huelsen, Interventional Endoscopy Fellow, Gastroenterology and Hepatology Department, Princess Alexandra Hospital, 199 Ipswich Rd, Woolloongabba, QLD 4102, Australia.
alexhuelsen@yahoo.com
URL:
www.nzma.org.nz/journal/read-the-journal/all-issues/2010-2019/2016/vol-129-no-1433-22-april-2016/6867

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