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Pharyngeal pouch: comparison of surgical treatment with botulinum toxin injection to the cricopharyngeus

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Abstract

Background. Pharyngeal pouch surgical treatments can be carried out via an endoscopic or open approach. Injection of botulinum toxin into the cricopharyngeus was first described as an alternative treatment to the more invasive surgical procedures performed for cricopharyngeal dysfunction. It has not been previously described as a treatment option for pharyngeal pouch.

Objectives. To compare operative time, average stay, complication rates and symptom control between endoscopic laser diverticulotomy, botulinum toxin injection and open procedures for pharyngeal pouch patients.

Methods. The medical records for 66 pharyngeal pouch procedures, carried out on 47 patients treated between 2011 and 2017, were identified and reviewed.

Results. The mean operative time was 21 minutes for botulinum toxin injection, 38 for endoscopic laser diverticulotomy and 104 for open surgery. The mean hospital stay was 0.6 days for botulinum toxin injection, 4.7 for endoscopic laser diverticulotomy and 4 for open surgery. The improvement in Reflux Symptom Index scores was statistically significant for both endoscopic laser diverticulotomy and botulinum toxin injection. Botulinum toxin injection had a 0 per cent complication rate.

Conclusion. Botulinum toxin injection is a safe and effective treatment for pharyngeal pouch.

Introduction

Pharyngeal pouch occurs mainly in older people, with an estimated overall incidence of about 1 per 100 000 per year.[1] Surgical treatment can be carried out via either an endoscopic or open surgical approach.[2] Endoscopic treatment of pharyngeal pouches is reported to be quicker and less invasive than an open approach, with shorter hospital stays and fewer complications.[3,4] However, there are cases where endoscopic access can be difficult or impossible (regardless of pouch size), or the pouch may simply be too small for an endoscopic procedure.

Injection of botulinum toxin into the cricopharyngeus was first described as an alternative treatment to the more invasive myotomy treatment procedures performed for cricopharyngeal dysfunction.[5] Though this injection is now conducted routinely for cricopharyngeal dysfunction, it has not been described as a treatment option for pharyngeal pouch.

Endoscopic treatment can take the form of laser diverticulotomy or stapling. In our unit, endoscopic laser diverticulotomy has been the preferred treatment choice (if suitable) for patients with symptomatic pharyngeal pouches.

On one occasion, a patient was encountered who had significant co-morbidities and a very high anaesthetic risk. She had troublesome symptoms from her pharyngeal pouch, and when she was finally prepared and assessed for a general anaesthetic, she was consented to undergo endoscopic laser diverticulotomy. The patient had stated clearly that her symptoms were severely affecting her life, and that she was willing to accept a risk to her life by having an anaesthetic. On the operating table, however, she was found to be unsuitable for endoscopic laser diverticulotomy as she had a large pulsating artery in the cricopharyngeal bar. It was felt, after discussion between the surgeon, anaesthetist and senior nursing staff, that some form of treatment should be offered during the anaesthetic. Hence, the decision was made to inject botulinum toxin into her cricopharyngeus, which is our standard treatment for cricopharyngeal dysfunction. Her symptoms improved remarkably after the procedure and did not recur. Since then, it has become our practice to offer botulinum toxin injection as another treatment option for pharyngeal pouches.

Materials and methods

At our unit, patients diagnosed with a pharyngeal pouch requiring an otolaryngology review are referred to a single consultant otolaryngologist (MGW). All patients referred

Main Article

Miss K Lau takes responsibility for the integrity of the content of the paper

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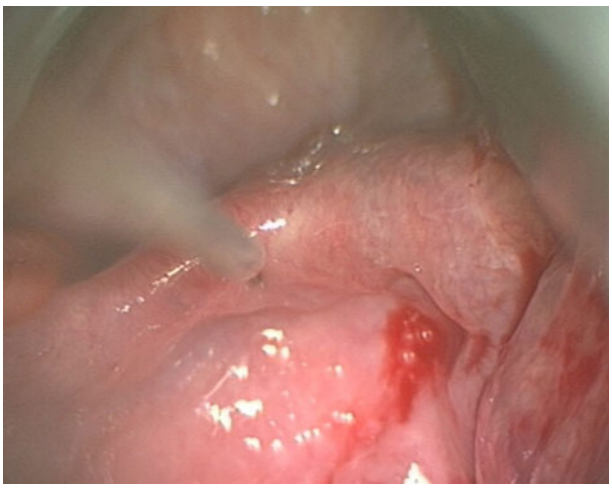

Fig. 1. Botulinum toxin injected into cricopharyngeal bar under direct vision.

between 2011 and 2017 were identified via the surgeon's database. All paper and electronic medical records were reviewed.

Endoscopic laser diverticulotomy procedures were carried out using a Weerda diverticuloscope, an operating microscope (×16 magnification) and a carbon dioxide laser, set at 2–3 W, in superpulse mode. Following a midline mucosal incision into the cricopharyngeal bar, all visible cricopharyngeal muscle fibres were divided. Monopolar diathermy was used as required for haemostasis. Nasogastric tube feeding was routinely employed for the following 72 hours until a contrast swallow confirmed no evidence of a leak, at which point oral intake was resumed.

Botulinum toxin injections were carried out during rigid pharyngoscopy. After careful identification of the pouch and cricopharyngeal bar, 100 units of botulinum toxin (Xeomin; Merz Pharma, Elstree, UK) were injected into the bar under direct vision (50 units to the midline, 25 to each side) (Figure 1). Rigid pharyngoscopy allows for definite identification of the cricopharyngeal bar prior to injection, as inadvertent injection into the post-cricoid region and posterior cricoarytenoid muscle must be avoided. Patients were allowed to eat and drink 2 hours after the procedure, and were usually allowed home the same day.

The data collected included gender, age, co-morbidities, presenting symptoms, pre-treatment Reflux Symptom Index and Eating Assessment Tool 10 scores (if available), treatment option, operative time, length of hospital stay, any complications, post-treatment Reflux Symptom Index and Eating Assessment Tool 10 scores, and need for revision surgery following endoscopic laser diverticulotomy, botulinum toxin injection and open procedures.

The Fisher exact test was used to compare the improvement between the groups treated with endoscopic laser diverticulotomy versus those treated with botulinum toxin injection (residual symptoms *vs* no symptoms). Significance levels were set at $p < 0.05$. The paired *t*-test was used to calculate for any statistical difference between the pre- and post-treatment Reflux Symptom Index scores for endoscopic laser diverticulotomy, botulinum toxin injection and open surgery patients. The unpaired *t*-test was used to calculate for any statistical difference between: (1) the mean operative time for endoscopic laser diverticulotomy and botulinum toxin injection; and (2) the pre- and post-treatment Reflux Symptom Index scores for endoscopic laser diverticulotomy versus botulinum toxin injection, botulinum toxin injection versus open procedures, and endoscopic laser diverticulotomy versus open procedures.

Results

Fifty-six patients with pharyngeal pouches were identified. Nine patients were managed conservatively using medical treatment with anti-reflux medication (twice daily dispersible lansoprazole and Gaviscon Advance), and were therefore excluded from the analysis. Forty-seven patients were managed surgically.

A total of 66 pharyngeal pouch procedures, carried out on 47 patients from 2011 to 2017, were identified. Twenty-nine patients were male and 18 were female (male-to-female ratio = 1.6:1). The age range was 50–93 years, with a median age of 70 years. The main complaints were dysphagia, regurgitation and weight loss. The patients' demographics, procedures undertaken and American Society of Anesthesiologists physical status grades are shown in Tables 1–3, respectively.

The mean operative time was 38 minutes for endoscopic laser diverticulotomy, 21 minutes for botulinum toxin injection and 104 minutes for open surgery (Table 4). Unpaired *t*-test results showed a statistical difference between the mean operative times of endoscopic laser diverticulotomy and botulinum toxin injection, with a two-tailed *p*-value of less than 0.0001 (95 per cent confidence interval (CI) = 11.87 to 22.28). Statistical analysis comparing the mean operative time for open surgery was not carried out, as the numbers were small.

The mean hospital stay was 4.7 days for endoscopic laser diverticulotomy, 0.6 days for botulinum toxin injection and 4 days for open surgery (Table 4). There were no complications in the botulinum toxin group. Three out of 28 patients in the endoscopic laser diverticulotomy group had complications (2 asymptomatic minor post-operative leaks, detected on routine post-operative contrast swallow, which were treated conservatively with nasogastric feeds and by withholding oral intake for a few more days, and 1 post-operative chest infection), but no patients developed mediastinitis. One of two patients in the open surgery group had a post-operative wound haematoma (Table 4).

When reviewed in the out-patient clinic (usually at two months post-procedure), patients were asked if any subjective residual symptoms were present. In the endoscopic laser diverticulotomy group, 2 out of 24 patients remained symptomatic to some degree, compared with 11 out of 18 in the botulinum toxin group. The null hypothesis is that the probability of treatment resulting in symptom improvement (symptomatic *vs* asymptomatic) is the same whether or not we treat with endoscopic laser diverticulotomy or botulinum toxin. The Fisher exact test statistical value was 0.0111. The result is significant, with a *p*-value of less than 0.05. Our results show that a higher percentage of patients in the botulinum toxin group remained symptomatic post-treatment, and the Fisher exact test result shows evidence of a statistically significant difference in the proportions of patients with symptom improvement between the two treatment groups.

However, in a more detailed analysis of patient symptom findings (pre- and post-operative Reflux Symptom Index scores; Table 5), the paired *t*-test results revealed a statistical difference between pre- and post-treatment Reflux Symptom Index scores for both endoscopic laser diverticulotomy ($p <$ 0.0001, 95 per cent CI = 6.37 to 15.80) and botulinum toxin

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Table 1. Patient demographics

Parameter	Value
Males (*n*)	29
Females (*n*)	18
Male : female ratio	1.6:1
Median age (years)	70
Age range (years)	50–93

Table 2. Breakdown of procedures

Procedure	*n*
Attempted endoscopic laser diverticulotomy, poor access	3
Endoscopic laser diverticulotomy	24
Endoscopic laser diverticulotomy revision	4
Botulinum toxin injection	32
Open excision & myotomy	2
Cricopharyngeal dilatation	1
Total procedures	66

Table 3. ASA grade of patients

ASA grade	Patients (*n*)
1	15
2	26
3	6

ASA = American Society of Anesthesiologists physical status

injection ($p < 0.0001$, 95 per cent CI = 18.80 to 26.29). The paired *t*-test results revealed no statistical difference between pre- and post-treatment Reflux Symptom Index scores for open surgery ($p = 0.0614$, 95 per cent = CI −3.56 to 34.56). However, the number of such procedures was very small ($n = 2$).

Comparisons of the improvements in Reflux Symptom Index scores were conducted between: the botulinum toxin and endoscopic laser diverticulotomy groups, the botulinum toxin and open procedure groups, and the endoscopic laser diverticulotomy and open procedure groups. The unpaired *t*-test showed no statistical difference between the pre- and post-treatment Reflux Symptom Index scores in all groups (botulinum toxin *vs* endoscopic laser diverticulotomy $p = 0.103$ (95 per cent CI = −11.5 to 1.1), botulinum toxin *vs* open procedure $p = 0.506$ (95 per cent CI = −16.7 to 8.4), and endoscopic laser diverticulotomy *vs* open procedures $p = 0.9126$ (95 per cent CI = −18.9 to 21.1)).

Thirty-three per cent of patients who underwent endoscopic laser diverticulotomy required revision surgery, compared with 60 per cent of patients who underwent botulinum toxin injection (Table 6). Access was difficult in 40 per cent of patients in the botulinum toxin group, and these patients would not have been good candidates for endoscopic laser diverticulotomy anyway (Table 6).

Discussion

The mean operative time for botulinum toxin injection was 45 per cent shorter than that for endoscopic laser diverticulotomy, with a statistically significant difference. Given the patients' mean age of 70.5 years and the fact that most of our patients (68 per cent) were categorised as having mild or moderate systemic disease, cricopharyngeal injection of botulinum toxin has a distinct appeal in patients who are not ideal candidates for longer general anaesthesia.

Patients who undergo endoscopic laser diverticulotomy are usually admitted as in-patients. They are kept nil by mouth for

Table 4. Mean operative times, hospital stay and complication rates

Group	Total *n*	Mean operative time (minutes)	Mean hospital stay (days)	Complications (*n* (%))
Endoscopic laser diverticulotomy (all)	28	38	4.7	3/28 (11)*
Botulinum toxin injection	32	21	0.6	0/32 (0)
Open surgery	2	104	4	1/2 (50)†

*Two post-operative leaks (asymptomatic) and one post-operative chest infection. †One post-operative wound haematoma

Table 5. RSI and EAT-10 scores

	Pre-operative score (average)		Post-operative score (average)	
Group	RSI	EAT-10	RSI	EAT-10
Endoscopic laser diverticulotomy (all)	28	NA	5	NA
Botulinum toxin injection	30	26	19	15
Open surgery	31	NA	15	NA

RSI = Reflux Symptom Index; EAT-10 = Eating Assessment Tool 10; NA = not applicable

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Table 6. Revision surgery and difficult access rates

Group	Revision surgery (*n* (%))	Difficult access (*n* (%))
Endoscopic laser diverticulotomy (all)	7/21 (33)	NA
Botulinum toxin injection	12/20 (60)	8/20 (40)
Open surgery	0 (0)	NA

NA = not applicable

3 days, until they have a water-soluble contrast on day 3 post-operatively to ensure there is no leak, after which they are commenced on an oral diet. The mean operative hospital stay in this group was therefore longer than that for the group who received botulinum toxin injection, which is normally carried out as a day-case procedure. Overnight admission in this latter group is usually only required for social reasons. The advantages of day-case procedures include a reduced risk of hospital-acquired infections, the lower cost and no need for contrast studies post-operatively.

Although botulinum toxin has not previously been described as a treatment option for pharyngeal pouch, our study has shown that botulinum toxin injection for pharyngeal pouch is safe, can be conducted as a day-case procedure and results in good symptomatic improvement. Rigid pharyngoscopy allows for safe identification of the cricopharyngeal muscle prior to injection. Although percutaneous techniques have been described for cricopharyngeal injection, avoiding the need for general anaesthesia, there is a risk of posterior cricoarytenoid injection even in expert hands.[6] Although the revision rate is higher compared to the endoscopic laser diverticulotomy group, many patients, when offered, prefer to have the least invasive treatment to start with, accepting that they may need to undergo a second procedure when the botulinum toxin wears off eventually.

For all three treatment groups, there was no statistical difference between the improvements in Reflux Symptom Index scores. Therefore, we cannot conclude that any of the three treatments is superior in treating pharyngeal pouch, although the need for a subsequent procedure is higher for botulinum toxin patients.

The authors acknowledge that the Eating Assessment Tool 10 score is a more validated scoring system for dysphagia than the Reflux Symptom Index score. However, the Reflux Symptom Index scores for each patient were readily available in their medical records, as the clinic nurses who prepare the notes automatically hand out Reflux Symptom Index sheets to any new or follow-up patients with any swallowing problems. In the last year, this issue has been identified; for the last 12 months of this study, the Eating Assessment Tool 10 score has been used before and after treatment. This may give a more accurate assessment of symptom improvement than the Reflux Symptom Index scores alone.

- Pharyngeal pouch surgical treatments can be carried out via an endoscopic or open approach
- Botulinum toxin injection into the cricopharyngeus has not been described as a treatment option for pharyngeal pouch
- The botulinum toxin injection technique is described in this paper
- The botulinum toxin technique is associated with a quick operative time and short hospital stay, with significant symptom improvement
- Botulinum toxin injection has a low complication rate, and was found to be a safe and effective treatment for pharyngeal pouch

Taking into account the low complication rate, the quicker surgical time and shorter hospital stay, the authors conclude that botulinum toxin injection is a quick, safe and effective treatment for pharyngeal pouch, and should be offered to patients as a potential treatment option.

Competing interests. None declared

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