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A multi-centre analysis of a decade of endoscopic pharyngeal pouch surgery in Cheshire and Merseyside

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Main Article

Mr T Hampton takes responsibility for the integrity of the content of the paper

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Abstract

Background. There are sparse data on the outcomes of endoscopic stapling of pharyngeal pouches. The Mersey ENT Trainee Collaborative compared regional practice against published benchmarks.

Methods. A 10-year retrospective analysis of endoscopic pharyngeal pouch surgery was conducted and practice was assessed against eight standards. Comparisons were made between results from the tertiary centre and other sites.

Results. A total of 225 procedures were performed (range of 1.2–9.2 cases per centre per year). All centres achieved 90 per cent resumption of oral intake within 2 days. All centres achieved less than 2-day hospital stays. Primary success (84 per cent (i.e. abandonment of endoscopic stapling in 16 per cent)), symptom resolution (83 per cent) and recurrence rates (13 per cent) failed to meet the standard across the non-tertiary centres.

Conclusion. Endoscopic pharyngeal pouch stapling is a procedure with a low mortality and brief in-patient stay. There was significant variance in outcomes across the region. This raises the question of whether this service should become centralised and the preserve of either tertiary centres or sub-specialist practitioners.

Introduction

Zenker's diverticulum is the most common type of pharyngeal pouch. It occurs when the mucosa and submucosa of the pharynx herniates through the muscles of the pharyngeal wall. This typically occurs at Killian's dehiscence and is more common in older people.[1] Elevated swallowing pressures and cricopharyngeal dysfunction are purported to be the underlying aetiology.[2]

The estimated overall incidence of pharyngeal pouch is 1–2 per 100 000 per year.[3,4] Surgical management can be divided into open and endoscopic approaches, and is dependent largely on patient choice, patient factors and local surgical expertise.[3]

Before the introduction of contemporary endoscopic techniques, an external cervical approach with diverticulectomy or diverticulopexy was the standard of care. In recent decades, however, the cohort of patients undergoing operative intervention has become older,[5] and there has been a shift towards less invasive techniques such as rigid endoscopic stapling or flexible endoscopic division.[3,6]

Though first reported in the literature in 1993,[7,8] endoscopic stapling of pharyngeal pouches was first endorsed in the UK by the National Institute for Health and Care Excellence (NICE) in 2003.[9] It is believed to be the approach of choice in most UK units, although a survey of behaviour and preference amongst UK surgeons has not been published since 2004.[10]

UK national guidance issued by NICE specifies that endoscopic stapling should be performed by surgeons trained in that specific procedure, and working in specialist units, rather than by all ENT surgeons.[9] Moreover, the 1996–7 annual Report of the National Confidential Enquiry into Peri-Operative Deaths also recommended that this procedure be the preserve of sub-specialists.[11]

Following its introduction, endoscopic stapling has been reported to be quicker and less invasive than open approaches. It is also perceived to be safe and offer satisfactory outcomes in terms of symptom resolution and reduced in-patient stay.[12]

Objectives

Despite NICE guidelines for the audit of outcomes, and the attempt by Leong *et al.* to define appropriate benchmark standards in 2012,[5] NICE themselves have not yet suggested their own standards, and there remains a dearth of any UK audit data published since then.

Therefore, the endoscopic pharyngeal pouch outcomes for each hospital in the region were retrospectively compared against a pre-determined benchmark for this procedure.

A secondary aim of the study was to compare variation in outcomes between secondary and tertiary care units.

Materials and methods

The study was registered and approved by clinical information and audit departments at all six participating sites. Patient identifiable data were held locally by designated site leads, and only fully anonymised data were handled and analysed by the lead author.

We identified a suggested audit standard first proposed in the 2012 meta-analysis by Leong *et al.*[5] In this meta-analysis of 585 patients, the following standards or domains were suggested: 92.3 per cent were successfully stapled; 7.7 per cent procedures were abandoned intra-operatively (the most common reason for abandonment was difficulty assessing a small pouch); 92 per cent had resumed oral intake by the 2nd post-operative day; 87 per cent were discharged by the 2nd post-operative day; 90 per cent reported resolved or significantly improved (patient-reported) symptoms; and there was a 4.8 per cent overall perforation rate (perforation should be confirmed on imaging); a 9.6 per cent overall complication rate; and a 0.2 per cent mortality rate.

Study design and setting

A retrospective analysis of patient records for the predefined 10-year period (1 January 2009 to 31 December 2018) at all six sites was conducted by the six appointed site leads. Patients were identified using coding for pharyngeal pouch (International Statistical Classification of Diseases 10th Revision, code Q38.7) or the Office of Population Censuses and Surveys' Classification of Surgical Operations and Procedures 4th Revision code (E24.3 – endoscopic stapling of pharyngeal pouch, E23.2 – pharyngeal pouch operations or Y26.3 – stapling of organ not otherwise classified, and Y76.3 – endoscopic approach to other body cavity).

Regarding the inclusion criteria, any patient undergoing successful or attempted endoscopic pharyngeal pouch stapling was included. The exclusion criteria included procedures abandoned as no pouch found.

We planned to perform a degree of subgroup analysis by comparing the local tertiary head and neck centre results with all other centres in the region, to see if there was any significant variance in outcomes. Any cases identified with incomplete data may have invalidated our conclusions regarding outcomes; hence, these affected cases were excluded from the relevant analysis.

Results

Overall results

In the 10 years (1 January 2009 to 31 December 2018) of our audit, the total number of endoscopic stapling procedures performed in our region was 225. Revision surgery represented 42 of the total procedures performed (18.7 per cent).

Region wide

For all cases combined, successful stapling occurred in 199 out of 225 procedures (88 per cent). Oral intake on the 2nd post-operative day was possible in 217 out of 225 cases (96 per cent). Symptom improvement or resolution occurred in 209 out of 225 cases (93 per cent). The median age of our patients was 71 years and the age range was 31–102 years. Men underwent 147 procedures (65 per cent of the total). Post-operative complications occurred for 16 of 225 patients (7 per cent), including 7 perforations (3 per cent). Four perforations were managed conservatively and three were managed surgically, all within 24 hours, at the tertiary centre. There were no recorded peri-operative deaths.

Tertiary centre

When the tertiary centre cases were analysed separately, 94 procedures were performed at the tertiary head and neck centre. This included 21 revision procedures (primary procedure at tertiary centre after previous attempt abandoned elsewhere). Of the tertiary cases, 87 of 94 (93 per cent) were successful. Of these 87 successful cases, oral intake was achieved by the 2nd post-operative day in 85 cases (98 per cent). Eighty-one patients were discharged by the 2nd post-operative day (93 per cent). Symptoms improved or resolved in 81 patients (93 per cent). The recurrence rate was 5 per cent (4 out of 87). The perforation rate was 3 per cent (3 out of 94). All outcomes achieved the proposed standard.

Tertiary centre – revision cases

In the revision group performed at the tertiary referral centre, successful stapling and symptom resolution was achieved in 19 out of 21 cases. Unfortunately, because analysis of primary or revision procedures was not part of the intended study outcomes, there were incomplete data regarding the previous procedure location and outcomes for the cohort of patients who were undergoing repeat revision (second or revision) surgery at a secondary centre. For this reason, this revision surgery cohort was excluded from the final analysis and assessment against the benchmark standard. Given the direct referral to the tertiary centre from other units, the data for revision cases performed at the tertiary centre were complete and have been analysed separately from the primary cases.

In the tertiary centre, the revision stapling failures were attributed to prominent teeth and osteophytes of the cervical spine, confirming the difficulties reported (where recorded) in the secondary centres. Both cases were managed with an external approach.

Oral intake was achieved by the 2nd post-operative day in all cases. Hospital discharge was possible by the 2nd post-operative day in 18 out of 19 cases. In addition, symptom improvement or resolution was attained in all cases.

There was one further perforation (4.8 per cent perforation rate in this subgroup); this patient returned to the operating theatre the same day for external repair and diverticulectomy, with good results. There were no other complications.

Outcomes versus the audit standard are presented in Table 1.

Discussion

Key findings

Endoscopic pouch stapling is a safe but relatively uncommon procedure: over a period of one decade at our six centres, the number of primary pharyngeal pouch stapling procedures

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Table 1. Results in tertiary centre and pooled secondary centres versus benchmark standards

Variable	National standard	Tertiary centre: primary surgery*	Tertiary centre: revisions†	Pooled secondary centre: primary surgery‡	Statistical difference between primary surgeries
Abandoned endoscopic stapling rate	7.7	6.8	9.5	16.4	$X^2 = 3.61$; $p = 0.06$
Oral intake resumption (within 2 days) rate	92.0	97.2	100	93.6	$X^2 = 1.23$; $p = 0.27$
Hospital stay <2 days rate	87.0	92.6	94.7	91.8	–
Overall complication rate	9.6	2.7	4.8	3.6	–
Iatrogenic perforation rate	4.8	2.7	4.8	3.6	Fisher's exact = 1
Mortality rate	0.2	0.0	0.0	0.0	–
Symptom improvement rate	91.0	91.2	100	82.7	$X^2 = 2.42$; $p = 0.11$
Recurrence rate	12.8	4.4	5.3	13.0	$X^2 = 1.27$; $p = 0.26$

Data represent percentages, unless indicated otherwise. *$n = 73$; †$n = 21$; ‡$n = 110$

ranged between 1.2 and 9.2 cases per year. Many of the eight audited domains were satisfactory. Furthermore, all centres achieved 90 per cent resumption of oral intake within 2 days. The pooled data across all centres achieved the less than 2-day hospital stay standard. However, initial success, symptom resolution and recurrence rates all failed to meet the standard across pooled secondary centres, but did so at the tertiary centre. Although these differences are arguably of clinical significance, statistical significance was not reached ($p = 0.06$, $p = 0.11$ and $p = 0.26$ respectively). Standardised post-operative symptom assessment does not occur at any centre and may be a focus for future studies.

Our pooled mortality and perforation rates were superior to the recommended standard. Our tertiary centre outcomes were superior to audit standards on all eight measured domains (Leong *et al.*).[5]

We excluded 21 revision procedures from the pooled secondary care case analysis. This is because we sought to compare primary cases against the benchmark standard, and revision surgery patients represent a discrete patient cohort. We are aware that this may have introduced further bias into our results and conclusions, but primary versus secondary subgroup analysis was not a pre-determined aim of this study.

For reference, if the revision cases are included in a pooled secondary centre cohort, the symptom improvement rate is 81.6 per cent (*vs* 82.7 per cent for primary case outcomes alone), so we feel the take-home message of our study is not significantly altered by this decision.

It is also worth noting that there was a higher success rate for revision surgery at the tertiary centre for patients who had undergone abandoned procedures at the secondary centres, even with repeat endoscopic stapling. Perforation rates were similar regardless of centre; however, at the head and neck centre, when a perforation did occur (3.2 per cent), all patients returned to the operating theatre for external repair (within 24 hours) and had no further complications.

Our study suggests that endoscopic pharyngeal pouch stapling is performed less than twice a year in some centres. It is noteworthy that there was still no significant discrepancy between numbers of perforations in our series, despite in-patient stay being prolonged in those managed conservatively; our numbers are too small to draw meaningful conclusions about this.

Although lower volume centres have low mortality rates and brief in-patient stays, the symptom resolution and procedure abandonment rates fell below our standard. We suggest that this may represent conservative surgical decision-making related to the full spectrum of treatment options being less readily available.

- Over 1 decade at our 6 centres, 225 endoscopic pharyngeal pouch stapling procedures were performed
- The number of primary pharyngeal pouch stapling procedures ranged between 1.2 and 9.2 cases per year
- There was a non-statistically significant difference between outcomes versus benchmark standards achieved at regional tertiary and non-tertiary centres
- The adoption of standardised post-operative assessment is recommended
- Other UK units should be encouraged to audit their own pharyngeal pouch practice, against our results and the proposed standards

Where problems performing the procedure occurred, this was usually because of patient issues such as dentition or limited mouth opening. In these instances, the multidisciplinary teams based at the tertiary centre allowed for alternative and successful management strategies (e.g. dental extractions and subsequent dental implants, or open surgery). These findings raise the question of whether such a service should be centralised, with pouch procedures becoming the preserve of specialist high-volume centres or specialist practitioners.

The observed (but not statistically significant) discrepancy between procedure abandonment rates at the tertiary centre and the majority of other hospitals may represent an intentional, conservative approach adopted by surgeons out of consideration for the population in question (regarding age, frailty, co-morbidities, anaesthetic risk, etc.). These demographic and peri-operative issues are part of the reason endoscopic techniques first gained traction, when compared to open surgery. However, these same patients may be at risk from undergoing repeat or recurrent general anaesthesia if one or more surgical procedures are abandoned or symptoms recur. A conservative 'mindset' or risk-averse approach may also contribute to incomplete or partial resolution of the pouch and higher symptom recurrence rates. Whilst this is speculative, some operative notes in our series do record narrative comments to this effect. Furthermore, a large proportion (90.5 per cent) of the failed or recurrent symptom cases underwent successful endoscopic stapling at first attempt at the tertiary centre, which may also support our inference regarding differing approaches to risk. Although not a truly testable hypothesis, we surmise that this only lends further credence to the notion of centralisation of service.

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Over recent years, many surgical specialties within the UK have embraced the concept of Getting It Right First Time ('GIRFT'; the National Health Service quality improvement project addressing variation of care). Recommendations from the most recent Getting It Right First Time report[13] suggest the development of surgical outcome metrics that are not yet covered by existing audits. Pharyngeal pouch surgery is an area within our specialty that could benefit from such an approach, and it would be considerably worthwhile for other regions to present their figures in accordance with the standards used here.

Study strengths and limitations

Our adopted audit standard was taken from the benchmarks suggested in a previous UK pooled analysis;[5] therefore, this standard may well be subject to publication bias, with truly representative outcome figures potentially being less favourable.

There are also limitations inherent to retrospective data analysis. This study was non-randomised, and there was no comparison or control group. In addition, across the six centres, operative technique and experience of the individual operative surgeons were not assessed or recorded, and this will have potentially affected the reproducibility of our conclusions. Furthermore, eight cases had incomplete datasets and were excluded from the initial analysis. In such a small cohort, these outcomes could have significantly skewed the overall performance against the audit standard, and therefore influenced the fidelity of our findings and external validity of some of our conclusions.

An alternative option would have been to include all cases in our analysis, regardless of data completeness, but this could potentially underestimate the incidence of significant events (e.g. perforations) and would introduce the potential for confounding bias in our analysis. Although patients who have undergone unsuccessful procedures are routinely referred to the tertiary centre, our recurrence rate is also affected by patients who may be lost to follow up. For instance, if symptoms recurred, some patients may have been referred to another tertiary centre.

There may also have been cases lost to coding, which could lead to follow-up and selection biases in our series. Abandoned procedures, for example, may simply have been coded as pharyngoscopy. We sought to minimise this, however, by including International Classification of Diseases 10th Revision diagnostic codes in our data capture criteria, rather than simply searching on the basis of Office of Population Censuses and Surveys' Classification of Surgical Operations and Procedures codes.

Unfortunately, in our region, there was no uniform recording of patient-reported outcomes using, for example, symptom-specific tools like the Eating Assessment Tool-10 ('EAT-10'),[14] the M D Anderson Dysphagia Inventory[15] (originally validated in head and neck cancer) or a more generalisable score like the Glasgow Benefit Inventory.[16] This could be facilitated through dedicated speech and language team involvement, which could be streamlined as part of a specialist service. It is important to consider multifactorial contributions to dysphagia in an ageing and complex patient population, and there is no guarantee that successful endoscopic or open surgery will lead to complete resolution of swallowing difficulty.[2] Nonetheless, we conducted a crude assessment of patient-reported symptom improvements; this was not the primary purpose of this study, however, as the efficacy of endoscopic stapling from a patient-reported outcome measure perspective has been previously assessed elsewhere.[5,14]

Despite these critiques of our study design, the authors were unable to identify any other prospective or retrospective multi-centre audits of outcomes against pre-determined standards for endoscopic pharyngeal pouch surgery in the literature. To our knowledge, there are no other comparable studies of pharyngeal pouch cohorts with a larger sample size.

Comparisons with other studies

In 1997, Koay *et al.* published the findings of a postal survey study which demonstrated that more than 75 per cent of surgeons (308 surgeons responded) who operated on pharyngeal pouches performed three or fewer pouch operations per year.[17] In 2004, Siddiq and Sood reported that, in their postal survey ($n = 227$), only 1 per cent of surgeons performed more than 20 procedures per year, and 65 per cent performed 5 or fewer procedures per year.[10]

The findings of a 10-year UK retrospective series, published in 1995, revealed a similar incidence to our study. In that study of 103 patients, 35 had conservative treatment and 68 underwent external surgery (but with a fistula rate of 8.9 per cent and median hospital stay of 7 days).[18] In the intervening 25 years, these numbers seem largely unchanged, with relatively low mean numbers of annual endoscopic pouch surgical procedures undertaken by our peripheral units compared to our tertiary unit (four and nine procedures respectively). These numbers are comparable to annual pharyngeal pouch procedure numbers reported in recent case series from other parts of the world, including Las Vegas ($n = 8$),[19] Montreal ($n =$ less than 3),[20] Tel Aviv ($n = 8$),[21] Sydney ($n = 11$),[22] Victoria (Australia) ($n = 11$),[23] Hull (UK) ($n = 8$)[24] and Oxford ($n = 13$).[25]

We can compare the trends demonstrated in these publications with current trends in Hospital Episodes statistics. The latter actually suggest that numbers of procedures performed on pharyngeal pouches (Office of Population Censuses and Surveys' Classification of Surgical Operations and Procedures codes E23.3 and E24.3) in England since 2000 has risen from approximately 325 to approximately 750 in 2019.[5,26]

Presuming these numbers are similar across the rest of the UK, the NICE and Confidential Enquiry into Perioperative Deaths recommendation for the centralisation of pharyngeal pouch surgery, limited to a few specialist high-volume surgeons or centres, could be an appropriate option for surgeons and patients, similar to the hub-and-spoke system used in head and neck cancer surgery. This would concentrate expertise and offer targeted training for registrars, whilst hopefully improving patient outcomes.

Dutch, Swiss and German surgeons have minimal operative numbers for certification and licensing, and North American surgeons have recommendations. There is a precedent in ENT for expected operative numbers from the British Thyroid Association, which suggests that surgeons who operate on patients with thyroid cancer should perform a minimum of 20 thyroidectomies per year.[27] Adam *et al.* found that the risk of permanent vocal fold paralysis after thyroid surgery decreases with the number of cases performed at the treating hospital. The best results (study of 17 000 patients operated on by 5000 surgeons) were achieved at an annual operating frequency of over 25 operations per surgeon.[28]

Bauer and Honselmann conducted a review of 35 systematic reviews of minimum operative numbers, and found a volume–outcome relationship, with two-thirds of studies relating this to hospital and physician volumes. The higher the number

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of cases, the more likely that good treatment results were achieved, across a variety of different surgical procedures.[29]

Markar *et al.* found that once a consultant surgeon performed 15 operations, they achieved a 50 per cent reduction in mortality.[30] They found that a plateau of optimised long-term results in oesophageal surgery was achieved only after performing 35–59 operations. The patient threshold for improved mortality was 5 annual cases for oesophageal perforation, but 11 annual cases for paraesophageal hernia.[31] Similarly, another study by Markar and colleagues found that high-volume endoscopists have a significantly reduced 30-day mortality rate after endoscopic mucosal resection, and that endoscopist volume is of greater importance than hospital volume. The initial stage of endoscopist competency gain was found to be the most critical, and there was significant association with mortality in the first five cases.[32]

In the UK, there is also precedent for reorganisation of ENT surgical services delivery from both the head and neck cancer hub-and-spoke model and the cleft palate service. Cleft lip and/or palates have a greater annual incidence than pharyngeal pouch (approximately 1.6 per 1000 in UK). Akin to the head and neck 'hub-and-spoke' model, all cleft surgery takes place at the 'hub' centres, allowing those specialist centres to perform between 80 and 100 procedures per year.[33]

Some authors have assessed pouch size,[25,34] although there does not appear to be consensus for pouch size reporting between Morton and Bartley[35] (small = less than 2 cm, medium = 2–4 cm, and large = more than 4 cm) and Overbeek and Groote[36] (vertebral bodies – small = less than one vertebrae, and large = more than three vertebrae) grading. Although radiological data were available for determining pouch size, this was not part of our study. An analysis including pouch size, position and patient-reported long-term functional outcome assessment (e.g. Eating Assessment Tool-10) should be the focus of future studies of pharyngeal pouch outcomes if ethical approval is granted.

Conclusion

Our study has demonstrated variations in procedure abandonment rate, symptom resolution and need for revision surgery for patients undergoing endoscopic stapling of a pharyngeal pouch in our region over the last decade. The apparent variability between secondary care and a higher volume tertiary care unit invites scrutiny of the provision of pharyngeal pouch surgery. Interpretation, however, should be made in light of the acknowledged limitations of our study design, and our conclusions may not necessarily extrapolate to other regions within the UK where different patterns of service provision and sub-specialisation may exist. As per the NICE recommendations, we would encourage units to audit their own pharyngeal pouch practice against our results and the standards proposed in this paper.

Competing interests. None declared

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