



Office-Based Cricopharyngeus Balloon Dilation for Post Chemoirradiation Dysphagia in Nasopharyngeal Carcinoma Patients: A Pilot Study

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Abstract

Dysphagia is a common sequela post chemo/radiotherapy for nasopharyngeal carcinoma (NPC), with cricopharyngeal dysfunction often a contributing factor. This study examined the impact of balloon dilation of the cricopharyngeus and cervical oesophagus on swallow competence for dysphagic patients with cricopharyngeal dysfunction post NPC. Patients with NPC were screened for dysphagia and cricopharyngeal dysfunction using fiberoptic endoscopic evaluation. Thirteen symptomatic patients, median 14.1 years post chemoradiotherapy for NPC, then underwent balloon dilation under local anesthesia. Before and 1 month post dilation, swallow function was assessed with fluoroscopy, and rated using the penetration–aspiration scale, temporal swallowing measures, and MBSImP pharyngoesophageal segment opening and esophageal clearance parameter. The MD Anderson Dysphagia Inventory (MDADI; Chinese version) and the Functional Oral Intake Scale (FOIS) were collected pre-, 1 month, and approximately 3 months post dilation. Post-dilation, significant improvements were noted in mean FOIS scores (5.00 to 5.62), duration of cricopharyngeus opening (0.42 s to 0.53 s), MBSImP pharyngoesophageal opening scores (1.61 to 1.08), penetration-aspiration scale scores (4.85 to 3.92) and MDADI Composite score (46.48 to 52.43). At 3 months post dilation, the MDADI Composite Score showed sustained benefit. The procedure was well tolerated and without complication. In patients with cricopharyngeal dysfunction post NPC, balloon dilation significantly improved swallow function, reduced aspiration risk and improved quality of life. Evidence from a larger cohort with long-term follow-up is warranted to determine sustained benefit.

Keywords Nasopharyngeal carcinoma · Dilation · Swallowing treatment · Cricopharyngeal dysfunction · Deglutition · Deglutition disorders

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Introduction

Modern treatment for NPC has contributed to improved rates of long-term survival, with age-adjusted mortality decreasing from 9.8 per 100,000 in 1983 to 2.8 per 100,000 in 2013 [1, 2]. Although mortality rates have reduced, survivors of NPC continue to face multiple long-term side effects from radiotherapy \pm chemotherapy (C/RT), and many experience significant physical, psychosocial and socio-economic impacts post treatment [2, 3]. Impaired swallow function (i.e. dysphagia) is a common negative consequence of NPC management [4]. In a study of 50 NPC patients, 76% of patients complained of dysphagia symptoms and 96% of patients had swallow function abnormality on instrumental assessment [5]. In particular, aspiration risk in this population is high, reported to range from 71.8% to 83.8% [6–8], and silent aspiration is prevalent [9].

The cause of aspiration risk and persistent dysphagia in NPC survivors tends to be multifactorial, with both oral and pharyngeal phase deficits reported [6, 8]. Within the deficits noted in the pharyngeal stage post C/RT for NPC, aberrant upper esophageal sphincter (UES) function is often reported [6, 8]. In a study of swallowing physiology in a cohort of 31 NPC patients, Wu et al. [8] postulated that the increased pharyngeal residue observed in 93.5% of their participants, was due to impaired pharyngeal constriction and imperfect UES relaxation. The authors also reported that UES dysfunction was one of the factors that led to aspiration in their cohort [8]. Cricopharyngeal dysfunction in this population is proposed to be due to relaxation failure, resulting from decreased muscle compliance caused by progressive fibrosis [6, 8]. In some cases, fibrosis after C/RT can lead to the formation of pharyngo-esophageal strictures [6]. Stricture can occur in up to 33% of patients with head and neck cancer (HNC) treated with radiation therapy [10], and can be an additional factor contributing to dysphagia.

For patients who present with significant cricopharyngeal dysfunction and/or stricture impacting on bolus flow, balloon dilation is one therapeutic technique that has been used successfully. In a recent systematic review [11], dilation was used in 6 of the 34 studied articles, across a range of clinical populations. The review revealed an average success rate of 81%, and concluded that dilation, along with myotomy and Botulinum toxin injection to the cricopharyngeus, can be employed with good outcomes and minimal morbidity [11]. Compared to using bougie, dilation using a control radial expansion (CRE) balloon imposes higher cost. Nevertheless, it may be off-set by the reduced risk of pharyngeal and esophageal tissue damage due to its minimal shearing force [12]. There are also

other patient comfort considerations for selecting balloon dilation over bougie. For example, the presence of trismus may prevent the bougie from inserting in a relatively straight direction down the pharynx into the oesophagus, creating a bend in the bougie which can impinge on the pharyngeal mucosa and cause severe discomfort to the patient.

Within the HNC population, balloon dilation has been used specifically to manage identified stricture following radiation therapy, and improved swallow function has been reported in 65–90% of patients [13–15]. Specifically, within the NPC population, a randomized control trial exploring balloon dilation to manage dysphagia associated with identified stricture compared to behavioral therapy showed superior swallowing improvements in the group who received both the neuromuscular stimulation and balloon dilation. However, although stricture may occur and impact swallowing in a small number of patients post NPC [16], for many patients, dysphagia is the result of factors other than a specific area of stricture. Rather, a degree of cricopharyngeal dysfunction has been proposed to be a contributing factor to poor bolus flow and pharyngeal residue [6, 8]. Although there is evidence to support balloon dilation as a treatment option for patients presenting with cricopharyngeal dysfunction in other clinical populations [17, 18], systematic study of the benefits of dilation post NPC for patients presenting with cricopharyngeal dysfunction has not been conducted. Hence, the aim of the current study was to evaluate the impact of balloon dilation to the cricopharyngeus and cervical esophagus on overall swallowing competence in a pilot cohort of NPC patients treated with C/RT and presenting with cricopharyngeal dysfunction.

Methods

Ethical approval was received from University of Hong Kong/Hong Kong Wester Cluster Institute Review Board (HKU/HKWC IRB No. UW 16-442) and The University of Queensland Human Research Ethics Committee (Approval No. 2018001228). All participants provided informed consent.

Participants

Participant recruitment involved a two-step process. All patients attending outpatient services of Queen Mary Hospital, Hong Kong, between January 2016 and June 2017, and reporting swallowing difficulty subsequent to C/RT for NPC, were identified for potential participation. Participants had to have received radiation therapy at least 1 year prior to study enrolment and have shown poor response to previous swallowing training. Potential participants were excluded if they

had current or prior medical history of any other neurological disorder that may affect swallowing function. Those who met initial suitability criteria had their swallowing function assessed via Fiberoptic Endoscopic Evaluation of Swallowing (FEES) from which similar to the criteria used by Halum et al. [19], if participants had significant pharyngeal residue at the pyriform fossa, while the tongue base propulsion and pharyngeal contraction were relatively intact, the participant was determined to have cricopharyngeal dysfunction. Participants with cricopharyngeal dysfunction on FEES, as determined by both the assessing ENT surgeon and speech pathologist, were eligible for dilation intervention.

Balloon Dilation

Dilations were performed under local anaesthesia with 10% xylocaine and endoscopic guidance in an office setting by an otolaryngologist (YWN). Procedures were standardized across participants and were based on an institutional protocol. A flexible laryngoscope was introduced at one nostril to provide direct visualization of the larynx, the cricopharyngeus and upper esophagus. Cook Medical Quantum TTC® 18 mm × 8 cm Controlled Radial Expansion (CRE)TM Balloon Dilator (Cook Medical, Bloomington, IN) was introduced through the other nostril. The long balloon allows some shifting during balloon inflation yet the balloon is still in the cricopharyngeus region. Dilation was performed at the right and left pyriform fossa and the post-cricoid region. For each dilation, the balloon was inflated to 3 atm for 2 min. Each patient received a total of 6 dilations in one treatment, with mean duration of dilation treatment being 25.4 min (range 15–43 min). All participants received a single dilation treatment session. Figure 1 is a screen capture showing the balloon dilation procedure as seen under the flexible video laryngoscope.

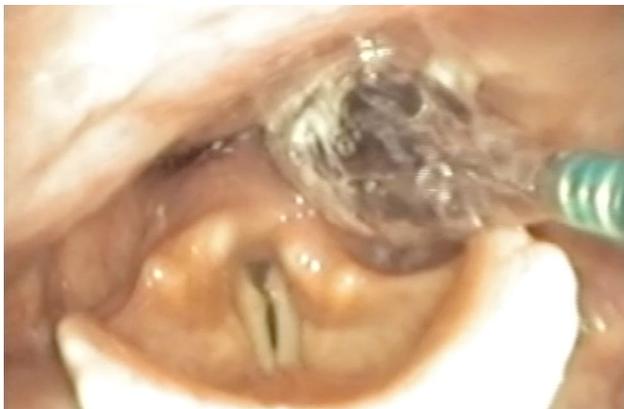


Fig. 1 Balloon dilation procedure at the left pyriform fossa

Pre-post Dilation Evaluation

All participants received a videofluoroscopic swallowing study (VFSS) 1 month pre-dilation (median = 20 days, range 1–85) and 1 month (median = 27 days, range 15–46) post dilation. VFSS procedures were performed by an experienced SLP using the Siemens AXIOM Luminos TF system, recorded using Sony DVO1000MD Medical Recorder. Participants were given two trials of thin liquid and semi-solids, via a 5 ml-teaspoon. Thin liquid boluses (20% w/v) were prepared by adding 104 g of E-Z-PAQUE (96% w/w; Manufacturer: EZEM, Cat. No. 747) powder to 473 ml of water. The barium coated semi-solids (30% w/v) were prepared by adding E-Z-PASTE (60% w/w; Manufacturer: EZEM, Cat. 770) to semi-solids at a 1:1 ratio. Examination was completed with the participant seated upright in a VFSS chair (Manufacturer: TransMotion Medical, Model: TMM3) and recordings made in the lateral view. Examinations were digitally recorded at 25 frames per second and then transcoded to MPEG-2 format using QuickTime Pro 7.0 (Apple Inc., Cupertino, CA) for further analysis. Only the second swallow for each consistency was used for analysis as per Frowen et al. [20] VFSS videos were analyzed using four temporal measures and two scales. Temporal measures include oral transit time, which is the duration from onset of bolus propulsion by the tongue until the bolus reaches the base of tongue, [21] pharyngeal transit time, which is the duration from onset of the bolus passing the tongue base until it reaches the upper esophageal sphincter [21], pharyngeal delay time, which is the duration from onset of the bolus reaching the pharynx until structural movements begin [21], and the duration of cricopharyngeal opening (DCO), which is the duration from onset of the opening of the upper esophageal sphincter until the closure of the sphincter [22]. The parameter has been shown to be sensitive in differentiating normal and individuals with cricopharyngeal problems [23]. Pharyngoesophageal segment opening was assessed using MBSImP component 14 (MBSImP PESO), a 0–3 interval scale where 0 = complete distension and duration of the opening of the pharyngoesophageal segment, 1 = partial distension and duration with partial obstruction of bolus flow, 2 = minimal distension and duration with marked obstruction of bolus flow and 3 = no distension [24]. Cervical esophageal bolus clearance was assessed using the MBSImP component number 17, Esophageal Clearance Parameter (MBSImP EC), a 0–4 interval scale where 0 = complete clearance, 4 = minimal to no esophageal clearance [24]. Penetration/aspiration was assessed using the penetration aspiration scale (PAS) [25], an 8-point scale documenting the presence and degree of penetration/aspiration, where 1–2 = normal, 3–5 = penetration, and 6–8 = aspiration.

At the time of VFSS, the patients' current functional oral intake was rated using the FOIS [26]. The FOIS is a 7-point ordinal scale used to document the functional level of oral intake of food and liquid, where 1 = tube dependence and nothing by mouth, 2–3 = tube dependence with gradual oral intake, 4–6 = total oral diet with gradually less restriction, and 7 = total oral diet with no restrictions [26]. Although initially developed for the stroke population [26], it has been used extensively in HNC research [27]. Participants also completed the Chinese version of the MD Anderson Dysphagia Inventory [28], a 20-item questionnaire exploring the effect of dysphagia on the quality of life in patients with HNC. A global score and a composite score (a weighted average of the subscale scores) were computed and expressed out of 100. Higher scores indicate quality of life is less affected. The FOIS and MDADI were repeated at follow-up assessment at 3 months post-dilation (median 88 days, range 46–122 days).

Statistical Analysis

All analyses were conducted using SPSS ver. 22.0 (IBM, Armonk, NY, USA). Inter and intra-rater reliability was calculated using the intra-class correlation coefficient ICC (average measures) for the four bolus flow measures, and Cohen's kappa was used for the PAS and MBSImp EC data. An ICC above 0.75 was considered as excellent correlation [29] and kappa values of 0.61 to 0.8 indicate substantial agreement while 0.81 to 1 indicates almost perfect agreement [30]. Outcomes from the VFSS assessments pre-post were compared using paired t-tests for the 4 temporal measures, Chi square test for changes in classification group (normal, penetration, aspiration) for the PAS, and Wilcoxon signed rank tests for the MBSImp scores. Results of the FOIS and MDADI scores from the 3 time points were analyzed using Friedman test (post hoc Wilcoxon signed rank test) and repeated measures ANOVA (post hoc paired *t* test) respectively. Significance was set at 0.05.

Results

Over the recruitment period, 27 patients underwent initial screening. Of these, 13 met all eligibility criteria. The majority of the cohort was male (85%) and median age at NPC diagnosis was 42 (range 23–65 years). The majority presented with T2–T3 tumors (77%; 7% T1) with nodal involvement (38% N1, 23% N2, 23% N0). Initial tumor staging was unknown for 16%. All had received primary non-surgical treatment (69% radiotherapy, 31% chemoradiotherapy). Two participants had local recurrence > 5 years prior and had surgery that did not involve the hypopharynx, the upper esophageal sphincter or the cervical esophagus. One had a history of neck recurrence managed with a radical neck dissection. Another participant with recurrence had additional C/RT (54 gray, cisplatin/5-fluorouracil). Time from diagnosis to dilation was a median of 14.7 years (range 3.92–27.3 years).

Impact of Dilation on Swallow Function

The dilation procedure was well-tolerated by the participants, and no significant adverse effects developed during treatment or the follow-up period. Pre-post dilation results from the 4 temporal swallowing measures are displayed in Table 1. Only the duration of cricopharyngeal opening on thin liquid was significantly ($p < 0.012$) improved post-dilation. On the PAS, there was significant change ($\chi^2(4) = 9.630$, $p = 0.047$) in the proportion of patients demonstrating aspiration on thin liquids post dilation (Fig. 2). There was no significant change ($\chi^2(4) = 2.095$, $p = 0.351$) observed for semi-solid boluses. Ratings for the MBSImp PESO for thin liquids pre ($M = 1.61$, $SD = 0.65$) were statistically improved ($Z = -2.333$, $p = 0.020$) post-dilation ($M = 1.08$, $SD = 0.49$). There was no change for semi-solids (mean pre = 1.33, $SD = 0.78$; mean post = 1.33, $SD = 0.78$; $Z = -1.414$, $p = 0.157$). Ratings for the MBSImp EC parameter for liquids pre ($M = 0.69$, $SD = 0.95$) and post ($M = 0.62$, $SD = 0.77$) revealed no significant change ($Z = -0.447$, $p = 0.655$). There was also no change for semi-solids

Table 1 Means of VFSS parameters for thin liquid and semi-solids pre- and post-balloon dilation

	Thin liquid ($n = 13$)			Semi-solids ($n = 12$)		
	Before dilation	1-month follow-up	<i>p</i> value	Before dilation	1-month follow-up	<i>p</i> value
Oral transit time (s)	0.2892	0.2585	0.837	1.1417	0.8667	0.461
Pharyngeal transit time (s)	1.4815	1.0892	0.217	2.0389	2.3633	0.607
Pharyngeal delay time (s)	0.8677	0.4308	0.222	1.3450	1.3033	0.925
Duration of cricopharyngeal opening (s)	0.4223	0.5323	0.012	0.5967	0.5867	0.873

Bold indicates a significant difference ($p < 0.05$)

Fig. 2 Distribution of penetration–aspiration ratings on thin liquid and semi-solid boluses pre- and post-dilation

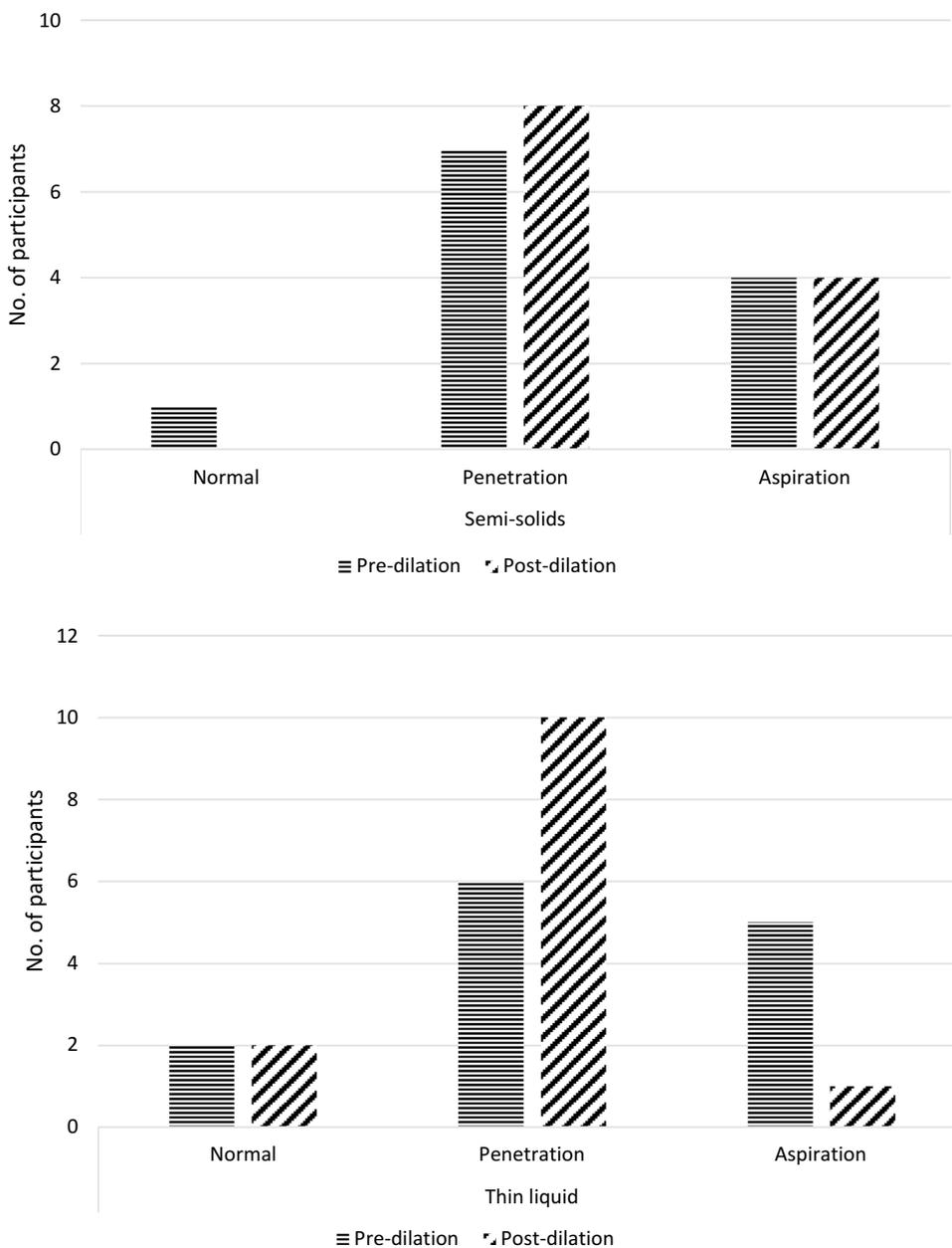


Table 2 Means and standard deviations of MDADI [39] scores across subscales pre-, post-balloon dilation and during follow-up

		Before dilation (n = 12)	1-month follow up (n = 12)	3-months follow up (n = 9)	p value
MDADI	Global score	36.67 (16.70)	43.33 (16.70)	40.00 (10.00)	0.157
	Composite score	46.48 (4.11)	52.43 (6.68)	52.87 (7.42)	0.001

Bold indicates a significant difference ($p < 0.05$)

(mean pre = 1.58, SD = 0.51; mean post = 1.42, SD = 0.51; $Z = 0.000$, $p = 1.000$).

FOIS scores revealed significant changes across the three timepoints (Table 2). Post hoc analysis data revealed a significant improvement ($Z = -2.333$, $p = 0.020$) in FOIS scores

pre-post dilation. At 3 months, this result was not significantly different to immediately post-dilation ($Z = -0.577$, $p = 0.564$). At an individual level, seven individuals experienced at least a 1 scale point improvement from pre- to post-dilation, while six remained unchanged. One patient

improved from being fully tube dependent pre-dilation to resuming some oral intake after dilation, while another changed from being tube dependent to resuming a full (modified) oral diet. On the 3-months post-dilation follow-up, five retained functional diet improvements with two regressing back to pre-dilation level.

There was no significant change in MDADI Global score, however the MDADI composite score was significantly different over time (Table 2). Post hoc analysis data revealed MDADI composite score significantly improved pre-post dilation ($t(11) = -3.601$, $p = 0.004$) and remained significantly above baseline ($t(8) = -3.118$, $p = 0.014$) and comparable to the post-dilation level ($t(8) = 0.504$, $p = 0.628$).

Discussion

Findings revealed that a single dilation session, using non-compliant CRE balloon, had positive functional impact on swallowing in this cohort of patients with dysphagia post NPC. The treatment effect was most apparent on thin liquid intake, with significant improvements in the duration of the cricopharyngeal opening noted on liquid trials. With balloon dilation, the UES is mechanically dilated [31] by the forcible fracture of the mucularis propria [32], and thus improvements in DCO is the intended outcome. Improvement in cricopharyngeal opening after balloon dilation have been reported in a small number of studies that have included the DCO as a treatment outcome. In a study of 30 brainstem stroke patients who received balloon dilation, Lan et al. [18] reported that the UES relaxation duration, as measured by high resolution manometry (HRM), was significantly lengthened. In that study, the increase in DCO was evident across consistencies of water, thick liquid and paste [18]. In contrast, the current study found no change in DCO of the semi-solid consistencies. Possible reasons for the differences in findings may be explained by the different underlying cause of UES dysfunction (neurological versus fibrosis) between the different clinical populations studied. From prior research it has been reported that the DCO of normal individuals from various studies for a 5 ml bolus ranged from 0.46 to 0.49 s [33, 34]. The pre-dilation DCO of our cohort had a mean of 0.42 s, which was lower than the normative values, and this value increased to 0.52 s after dilation. This tends to suggest that prior to dilation, the DCO was shortened, with potential for bolus transit through the UES to be incomplete.

On thin liquid trials, there was also a significant change in aspiration events noted. Positive reduction in aspiration events have also been reported in other balloon dilation studies. In a study of five patients with primary cricopharyngeal dysfunction, four no longer presented with aspiration after dilation [35]. In another study, 38 patients with

cricopharyngeal dysfunction due to brainstem infarction or encephalitis received balloon dilation, and all patients were reported to have no aspiration after dilation [36]. It is possible that with the significant increase in duration of sphincter opening, a greater portion of the bolus was allowed to pass through and clear the pharynx, possibly resulting in less residue retained in the pharynx [22]. Improvement in PAS score is an important clinical outcome particularly in the NPC population. Chronic aspiration is believed to be the main causes of late-onset pneumonia in patients with NPC [37]. In a large cohort study, 30% ($n = 63$) of 210 NPC patients who had aspiration pneumonia died within 2 months after the onset of pneumonia [37]. For those who survived the aspiration pneumonia episode, reliance on tube feeding to prevent future incidence of dysphagia-related pneumonia was indicated.

In addition to physiological changes, functional swallowing outcomes also showed significant improvement, as evidenced in prior studies [17, 18, 36]. For seven patients, there were clinically important improvements in functional oral intake level, with two patients resuming oral intake while previously being fully tube dependent. For the majority of participants in the current study, swallowing-related QoL also improved after dilation and was sustained at 3-months post dilation. Dysphagia is regarded to have the highest correlation to QoL measurements in patients with HNC [38]. In a study of 173 HNC patients, results on the University of Washington-QoL scale were found to be 11.5 points worse for patients with a gastrostomy tube than those without one, indicating that severe dysphagia requiring a gastrostomy tube had a negative impact on the survivors' QoL. The results of the current study confirm the positive benefits of the dilation treatment not only on actual swallow function, but also on swallowing-related quality of life.

Limitations

This was a pilot study and larger numbers are needed. The current cohort was heterogeneous in terms of age, duration post diagnosis and staging of the tumor. The effect of various clinical factors could not be further analyzed for this study. Patients only had one instrumental assessment after dilation and the short duration of follow-up did not allow the investigators to determine long-term effect. In addition, for six patients, no benefits were seen following a single dilation and a further two patients showed regression by the 3 month review. In the current study, the capacity to explore the effects of repeated dilations to achieve benefits for these patients was not examined. There is often a need of multiple dilations to achieve/sustain benefit [15, 31], and future studies are required to explore the benefit of multiple dilations. It is also recognized that using VFSS alone may have failed to accurately document smaller changes in UES pressures.

In future studies, the additional use of HRM to record pressure changes in the UES and the cervical esophagus pre- and post-dilatation and accurately document the maximum diameter and compliance of the UES during relaxation [39] is recommended. Larger bolus volumes should also be incorporated into the testing protocols to ensure that maximal UES opening and nature of UES dysfunction can be adequately assessed.

Conclusions

This pilot study showed that a single dilatation session of balloon dilatation to the cricopharyngeus and cervical esophagus had a positive and short-term sustained impact on swallow function in a small cohort of patients with chronic dysphagia following C/RT for NPC. The procedure can be done in outpatient setting and is well tolerated by patients. A larger scale clinical trial with more participants and longer follow-up to define the long-term benefit and cost effectiveness of balloon dilatation for managing this specific group of dysphagia patients is warranted.

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Compliance with Ethical Standards

Conflict of interest The authors declare that they have no conflict of interest.

Ethical Approval All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki Declaration and its later amendments or comparable ethical standards.

Informed Consent Informed consent was obtained from all individual participants included in the study.

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