






ORIGINAL RESEARCH

Videofluoroscopic and manometric outcomes of cricopharyngeus balloon dilation for treatment of pharyngo-esophageal dysphagia associated with nasopharyngeal cancer: A case series

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Abstract

Background: Problems with pharyngo-esophageal bolus flow have been reported following nasopharyngeal cancer (NPC) treatment. While studies using videofluoroscopic assessment have shown balloon dilation can help address this impairment, the impact of dilation on pressure and bolus flow characteristics incorporating high-resolution pharyngeal manometry (HRPM) has not been reported.

Methods: Five cases with pharyngo-esophageal dysphagia post NPC underwent balloon dilation. Videofluoroscopic swallowing study (VFSS) and HRPM were completed before and 1 month post dilation. Oral intake and dysphagia related quality of life were reported to 3 months.

Results: VFSS, manometry and functional outcomes revealed positive benefits from dilation in two cases. In the other three cases, two showed improvements on VFSS only. These three failed to make functional swallowing gains.

Conclusions: Where there was functional gain, both fluoroscopy and HRPM recorded improvement to UES function. Across the cases, response to dilation was variable and further work is needed to determine which patients would receive most benefit.

Level of Evidence: 4.

KEYWORDS

balloon dilation, dysphagia, high resolution manometry, nasopharyngeal cancer

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1 | INTRODUCTION

Nasopharyngeal cancer (NPC), which includes carcinomas found in the region delineated superiorly by the skull base, inferiorly by the oropharynx, anteriorly by the nasal septum and apertures and posteriorly by the first two vertebra, is predominately treated with chemoradiation (CRT). As the structures affected by the cancer and its treatment involve those vital to safe and efficient swallowing, the prevalence of dysphagia (disordered swallowing) in this population has been reported to be as high as 93.5%.^{1,2} Penetration or aspiration risk has been reported to occur in most cases (eg, 91.6%¹), with silent aspiration noted to be a highly prevalent characteristic.³

The origins of aspiration risk and chronic dysphagia in patients post NPC management appear to be multifactorial,⁴ with compromise reported across all phases of swallowing.^{1,2,5-12} Oral phase problems such as impaired lingual control,⁷ and pharyngeal phase problems including poor pharyngeal contraction,^{1,2,5,7} reduced hyoid movement,^{1,5,8} impaired laryngopharyngeal sensation⁶ and cricopharyngeal dysfunction have been reported,^{10,11} as have issues with upper esophageal clearance¹¹ and esophageal stricture.⁹ These often co-existing deficits can contribute to poor bolus transit through the pharynx and upper esophageal sphincter (UES) and stasis in the upper cervical segment of the esophagus. In a recent study, impaired bolus transit in the cervical esophagus was observed in 83% ($n = 111$) of a group of 134 NPC patients during thin liquid swallows, and in 97% ($n = 130$) during semi-solid swallows.⁹ Bolus flow limitations in the esophagus have also been found to be associated with penetration and aspiration.⁹ Interventions that can assist trans-sphincteric bolus flow are therefore potential strategies to increase swallowing safety and efficiency in this population.

Balloon dilation is one such therapeutic option considered when patients present with cricopharyngeal dysfunction and/or stricture impeding bolus flow.^{10,12} Mechanical dilation applied to the cricopharyngeus and cervical esophagus has been shown to improve flow of thin fluids and reduce post-swallow pharyngeal residue and aspiration in the NPC population.¹⁰ This also translated to functional gains in swallowing and improved patient self-reports.¹⁰ Similar positive swallowing outcomes were observed in a randomized controlled trial of balloon dilation and electrical stimulation.¹²

Although existing evidence supports the use of balloon dilation for NPC patients post-CRT presenting with cricopharyngeal dysfunction, the evaluation of biomechanical changes in the pharynx and cervical esophagus associated with the observed functional swallowing outcomes have yet to be explored. One technique to evaluate changes in pharyngo-esophageal biomechanics during swallowing is high resolution pharyngeal manometry (HRPM) with impedance, a tool used for measuring pressure changes along the pharyngeal and proximal esophageal region.¹³ The combined analysis of pressure and bolus flow events based on manometric and impedance data provides quantifiable, objective and reliable insight into deglutitive swallowing biomechanics.^{14,15} HRPM has previously been used in patients with head and neck cancer¹⁶ but it has not yet been used to quantify changes in cross-sphincteric bolus flow following dilation within the NPC population.¹⁰ In this report, we present a case series of five patients presenting with

dysphagia due to NPC post CRT, whose swallowing function was assessed using videofluoroscopic swallowing study (VFSS), HRPM, functional swallowing outcomes and swallowing-related quality of life measurements before and after a single balloon dilation using a controlled radial expansion balloon. It was hypothesized that in addition to the VFSS and functional swallowing changes reported in prior studies,¹⁰ balloon dilation should lead to temporal and spatial improvement in UES relaxation measured on HRPM.

2 | METHODS

Ethical approval was received from the University of Hong Kong/Hong Kong West 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 written informed consent.

2.1 | Participants

Participants were recruited from the cohort of patients attending outpatient services at the Queen Mary Hospital, Hong Kong, between April and September 2018 for evaluation and treatment of chronic swallowing difficulties after CRT for NPC. To be eligible for inclusion, participants had to be at least 1 year post-CRT, have no current or prior medical history of neurological dysfunction that could affect swallowing, and be clinically suitable for balloon dilation as determined by an otorhinolaryngologist and a speech language pathologist. To be eligible for dilation intervention, assessment via fiberoptic endoscopic evaluation of swallowing (FEES) had to identify significant residue at the pyriform fossa, with relatively intact tongue base propulsion and pharyngeal contraction, implying cricopharyngeal dysfunction.¹⁷ The FEES footage was reviewed and eligibility for dilation determined jointly by an otorhinolaryngologist and a speech language pathologist.

A total of 12 patients from the clinic were identified as potential participants during the study period. Of these, seven met all criteria and consented to be part of the study. Unfortunately, two participants failed to complete multiple follow-up assessments, and therefore had insufficient data for analysis. Of the 5 remaining participants, 4 were male and 1 female, aged between 39 to 74 years at the time of dilation (mean = 59.3 years, SD: 12.5 years). All had received curative intent management for NPC between 5 and 20 years ago (mean = 14.7 years, SD: 6.4 years). Prior to participation, 2 participants were on gastrostomy tube for feeding and non-oral, whereas 3 were on oral feeding with modified diets.

2.2 | Balloon dilation

Dilations were performed in a single treatment session by an otorhinolaryngologist (NS) in an office setting under local anesthesia (10% xylocaine administered transnasally). Procedures were standardized

across participants and were based on an institutional protocol as published in a previous study¹⁰ using Cook Medical Quantum TTC 18 mm × 8 cm Controlled Radial Expansion (CRE) Balloon Dilator (Cook Medical, Bloomington, Indiana). Dilatation was performed with the tip of the balloon seen at the right and left pyriform fossa and the post-cricoid region, twice for each site, with the balloon length extending into the cervical esophagus.¹⁰ For each dilatation, the balloon was inflated to 3 atm for 2 minutes.

2.3 | Pre-post dilation evaluation

All participants completed a pre- and post-dilatation evaluation, that included: (1) HRPM, (2) VFSS, (3) assessment of functional swallowing outcome using the functional oral intake scale (FOIS¹⁸), and (4) completion of the Chinese version of the MD Anderson Dysphagia Inventory (MDADI¹⁹). All assessments were completed on the same day. The test battery was completed approximately 1 week before (median = 8 days, range 1-22) and 1 month after dilatation (median = 28 days, range 27-34). At a follow-up at 3 months post-dilatation, only the FOIS and MDADI were repeated (median = 90 days, range 77-94) to determine sustained functional gain.

2.4 | HRPM with impedance (HRPM)

HRPM was conducted using a solid state high-resolution manometry system (ManoScan360 Model A120, Sierra Scientific Instruments, Los Angeles) with a flexible 4.2 mm catheter incorporating 36 circumferential pressure sensors spaced at 1-cm intervals and 18 impedance channels spaced at 2-cm intervals (ManoScan Eso Z Catheter, Sierra Scientific Instruments, Los Angeles). The catheter was positioned transnasally without topical anaesthetic to the nares, with sensors straddling the entire pharyngoesophageal segment (ie, velopharynx to approximately 10 cm past the esophageal transition zone). Participants were seated upright for all swallows and were asked to swallow the liquid bolus in one attempt, as naturally as possible. Boluses were offered via a 20 mL syringe. Thin liquid (normal saline; 0.9% sodium chloride, IDDSI level 0) at 2 mL, 5 mL, and 10 mL, with three trials each, and three trials of 5 mL thickened saline (using starch-based thickener to achieve IDDSI level 3 consistency) were recorded.^{14,20} Saline was used to enhance conductivity for reliable and stable impedance measures. No solid boluses were tested under HRPM.

Pressure and impedance data captured for each swallow were exported and analyzed via the open access web-based portal, Swallow Gateway (swallowgateway.com; version 7; 2020). The pressure topography and impedance plots for each bolus swallow were individually analyzed by selecting the velopharynx to the transition zone (ie, the region between the smooth and skeletal muscles in the esophagus) as the region of interest. Whenever there was more than one swallow per bolus, which occurred in 22 out of the total of 120 swallows (18.3%), the impedance plots for all swallows associated with that bolus were examined and the primary swallow was defined as the one displaying

the largest impedance signature, corresponding with the majority of the bolus passing through the hypopharynx and the UES. This definition of the primary swallow was used in two previous studies.^{21,22} Only this swallow was included in the subsequent analysis. Landmarks to guide automated analysis were identified by visual inspection of the pressure topography plot by at least two investigators. Landmark markers were placed (Figure 1) to correspond with (1) UES opening, (2) post-swallow UES contraction, and the positions of (3) velopharyngeal proximal margin, (4) hypopharyngeal proximal margin, (5) UES apogee during the swallow and (6) UES distal margin, as described previously.²³ Analysis windows were automatically generated from the manually placed landmarks (Figure 2). Swallow function metrics were derived using the automatic algorithms underpinning the Swallow Gateway software portal as described in more detail elsewhere.²³ For the purposes of this study, five metrics as proposed previously were calculated for each swallow (see Table 1).²⁴ Of these, three metrics relate to UES relaxation and opening that would reflect changes in the UES attributable to dilatation: (1) UES integrated relaxation pressure (UES IRP), which is a measure of the extent of the relaxation; (2) UES relaxation time (UES RT), which reflects the duration of the UES relaxation; and, (3) the UES maximum admittance (UES Adm), which is reflective of the extent of the UES opening (Table 1).²³ In addition, (4) the pharyngeal contractile integral (PhCI) was used to evaluate changes in pharyngeal contraction in response to the dilatation. Finally, (5) intra-bolus pressure (IBP), reflecting the pharyngeal resistance encountered by the bolus at the time of maximal distension (based on impedance) in the hypopharynx 1 cm above the UES apogee, was also used in the analysis. Means across three

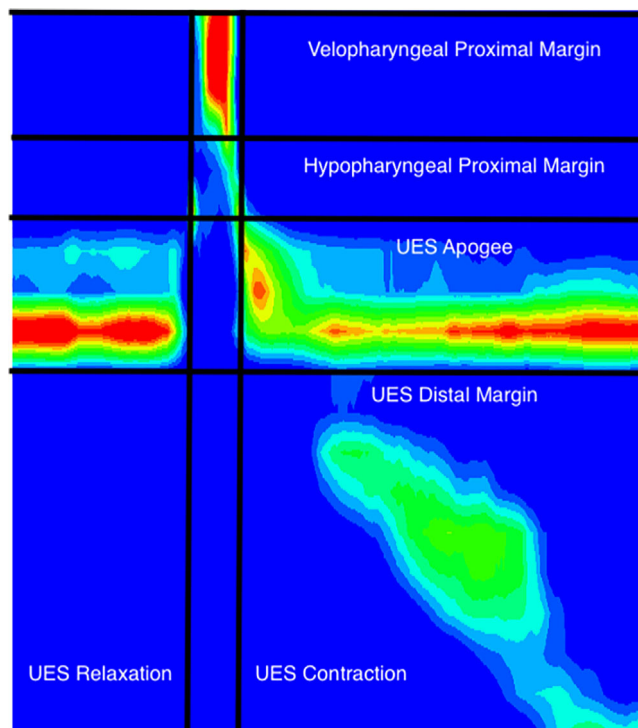


FIGURE 1 The pressure topography plot marked manually with 6 landmarks

swallow trials were calculated for each consistency and bolus volume. For balloon dilation to be considered effective, we hypothesized that on HRPM, UES integrated relaxation pressure and IBP would decrease, whereas UES relaxation time and UES maximum admittance would increase.²⁵

2.5 | VFSS

After the HRPM procedure, participants proceeded to VFSS, which was performed by an experienced SLP using the Siemens AXIOM

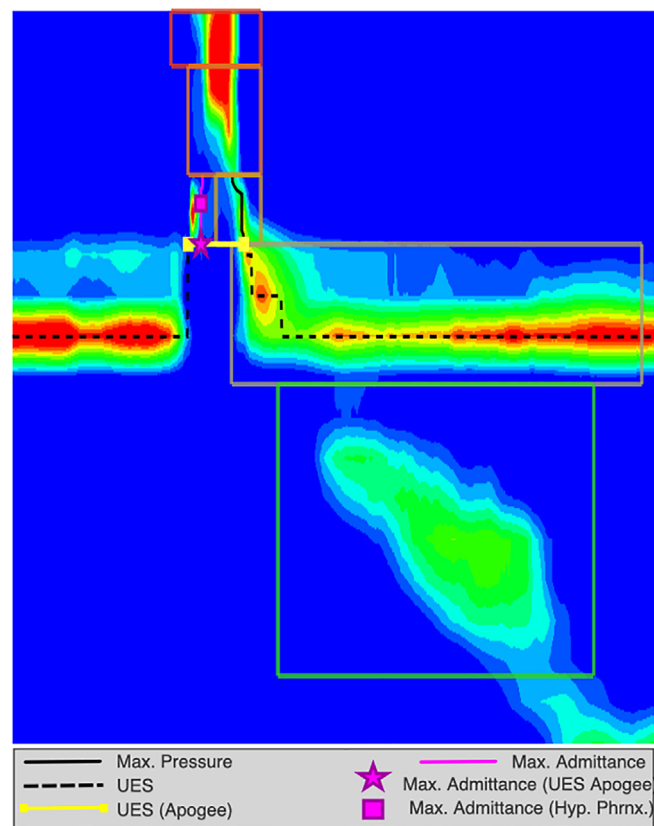


FIGURE 2 The pressure topography plot with regions of interest automatically identified

Luminos TF system, recorded using Sony DVO1000MD Medical Video Recorder at 25 frames per second. The procedures were in accordance with the MBSImP protocol, which is a standardized evaluation of 17 anatomical and physiological parameters related to swallowing function across a range of consistencies/textures in lateral and antero-posterior (AP) views.²⁶ VFSS analysis was conducted by a certified MBSImP clinician. As per MBSImP procedures, each parameter is scored on a Likert scale ranging from 3 to 5 points, with 0 indicating normal, and higher numbers corresponding to increasing degree of impairment.²⁶ The oral and pharyngeal sum scores were calculated by adding scores from parameters 1-6 and 7-16 respectively. Scores of “1,” indicating trace appearance of barium on structures on components 1, 5, 15 and 16, were not added to the oral and pharyngeal sum scores as per MBSImP guidelines.²⁶ The higher the score, the more severe the impairment. As this study aimed to elucidate the effect of dilation on swallow function, only seven of the 17 parameters (thought to reflect the changes associated with dilation) are reported on here: (1) Component 8—Laryngeal elevation (MBS8); (2) Component 9—Anterior hyoid excursion (MBS9); (3) Component 11—Laryngeal vestibular closure (MBS11); (4) Component 12—Pharyngeal stripping wave (MBS12); (5) Component 14—Pharyngoesophageal segment opening (MBS14); (6) Component 16—Pharyngeal residue (MBS16); and (7) Component 17—Esophageal clearance (MBS17).

Presence and degree of penetration and/or aspiration and temporal measurements were analyzed for single swallows performed in lateral view (ie, 8 of the 12 swallows). Sequential swallows of thin and thick liquid were excluded from these analyses as not all participants could tolerate these tasks. Penetration/aspiration was assessed using the penetration aspiration scale (PAS), an 8-point scale documenting the presence and degree of penetration/aspiration, where 1-2 = normal, 3-5 = penetration and 6-8 = aspiration.²⁷ Temporal measures included oral transit time (ie, the duration from onset of bolus propulsion by the tongue until the bolus reaches the base of tongue),²⁸ pharyngeal transit time (ie, the duration from onset of the bolus passing the tongue base until it reaches the upper esophageal sphincter),²⁸ pharyngeal delay time (ie, the duration from onset of the bolus reaching the pharynx until structural movements begin),²⁸ and the duration of cricopharyngeal opening (ie, the duration from onset of UES opening until UES closure).²⁹ These parameters have been shown to be sensitive in

TABLE 1 High resolution pharyngeal manometry with impedance metrics

Metric class	Metric	Acronym	Unit	Interpretation of the results
UES relaxation and opening	UES integrated relaxation pressure	UES IRP	mmHg	Higher value indicates UES restriction and impaired relaxation
	UES relaxation time	UES RT	s	Lower value indicates reduced opening period
	UES admittance	UES Adm	mS	Lower value indicates reduced opening extent
Pharyngeal lumen occlusive pressure	Whole pharyngeal contractile integral	PhCI	mmHg.cm.s	Lower value indicates weakness in region
Hypopharyngeal intrabolus distension pressure	Intrabolus pressure	IBP	mmHg	Higher value indicates pharyngeal resistance

Abbreviation: UES, upper esophageal sphincter.

differentiating individuals with cricopharyngeal problems from those with normal function.³⁰

2.6 | Functional oral intake

Food and fluid levels being consumed by each participant were mapped to the IDDSI standards of fluids (Level 0 = Thin liquid to Level 4 = Extremely Thick liquids) and foods (Level 3 = Liquidized puree to Level 7 = easy to chew/normal).³¹ Participant's functional oral intake was rated using the FOIS, a 7-point ordinal scale, 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.¹⁸ The rating was based on patient's self-report regarding their current ability for oral intake.

2.7 | MDADI

Participants completed the Chinese version of the MD Anderson Dysphagia Inventory (MDADI), a 20-item questionnaire exploring the effects of dysphagia on the quality of life in patients with head and neck cancer.¹⁹ A global score and a composite score [weighted average of subscale scores] were computed and expressed out of 100. Higher scores indicate that quality of life is less affected.

3 | RESULTS—CASE REPORTS

The results pre and post dilation are detailed case by case for the 5 cases with individual data presented in Tables 2–6, with post-intervention results bolded in the direction that is expected from dilation. Overall, across the 5 cases, 2 individuals showed positive impacts physiologically and functionally (cases 1, 2), 2 showed changes

physiologically but not functionally (case 3, 4) and 1 showed no changes in terms of swallow physiology and function (cases 5).

3.1 | Case 1

Case 1, a 60-year-old male, was 5 years post CRT for NPC and 4 years post recurrence requiring nasopharyngectomy at the time of enrolment in this study. He had been on non-oral feeding via gastrostomy for 18 months. The outcome of balloon dilation was positive, resulting in a substantial physiological and functional improvement in swallowing, leading to recommencement of modified oral intake with gastrostomy supplement.

At baseline, all nutritional intake was via gastrostomy (FOIS 1). VFSS revealed significant pharyngeal phase deficits, with a MBSImP pharyngeal sum score of 17 out of 29 (Table 2). There was silent aspiration (PAS 8) across all consistencies swallowed (Table 3). A MDADI global score of 20 and a composite score of 40 were consistent with quality of life being severely affected by the swallowing problem (Table 6).

Balloon dilation proceeded uneventfully. Postdilation VFSS assessment revealed improvement in the MBSImP scores of pharyngoesophageal segment opening and pharyngeal residue (Table 2). Airway response improved on thin liquid (5 mL) and thick liquid (5 mL and cup), from aspiration (PAS 8) to penetration (thin liquid: PAS 5; thick liquid: PAS 3) (Table 3). On VFSS, pharyngoesophageal segment opening improved from minimal distension/duration to partial distension/duration. The duration of cricopharyngeal opening was similar after dilation on thin liquid (5 mL), decreased on thick liquid (5 mL) and improved (increased) on puree (5 mL) (Table 3).

On HRPM, post dilation this case showed decreased UES IRP on all consistencies and volumes (Table 4), and increased UES RT on 5 mL (from 0.39 to 0.44 second) and 10 mL thin liquid (from 0.26 to 0.46 second), as well as UES Adm on 10 mL thin liquid (from 3.69 to 6.01

TABLE 2 Key parameters, oral and pharyngeal total sum scores of the MBSImP²⁴

Case #	Pre-/post-intervention	MBSImP parameter							Oral sum	Pharyngeal sum
		8	9	11	12	14	16	17		
1	Pre	2	1	1	1	2	3	1	13	17
	Post	2	1	1	1	1	2	1	12	14
2	Pre	1	1	1	0	2	1	2	10	7
	Post	2	1	1	1	1	1	0	7	7
3	Pre	1	1	1	0	1	2	0	2	8
	Post	1	1	1	1	1	1	0	1	8
4	Pre	1	1	0	1	1	2	2	11	12
	Post	0	1	0	0	0	2	1	10	7
5	Pre	2	1	1	1	2	3	2	13	17
	Post	2	1	1	1	2	2	2	12	16

Note: Results in post intervention bolded if it was in the direction expected from dilation.

TABLE 3 Penetration-aspiration scale²⁵ scores and the duration of cricopharyngeal opening on videofluoroscopic swallow studies

Case #	Pre-/post-intervention	Penetration-aspiration scale scores						Duration of cricopharyngeal opening (s)					
		Thin liquid		Thick liquid		Puree 5 mL	Soft	Thin liquid		Thick liquid		Puree 5 mL	Soft
		5 mL	Cup	5 mL	Cup			5 mL	Cup	5 mL	Cup		
1	Pre	8	N/A	8	8	8	N/A	0.44	N/A	0.48	0.36	0.32	N/A
	Post	5	3	3	3	8	3	0.44	0.60	0.36	0.32	0.52	0.32
2	Pre	7	8	8	3	8	8	0.56	0.56	0.40	0.44	0.52	0.44
	Post	3	3	8	3	3	8	0.40	0.52	0.56	0.48	0.48	0.44
3	Pre	1	1	3	1	3	8	0.48	0.48	0.32	0.44	0.48	0.52
	Post	1	3	3	3	3	3	0.56	0.68	0.52	0.60	0.56	0.68
4	Pre	1	2	1	1	1	1	0.68	0.52	0.76	0.76	0.68	0.60
	Post	1	1	1	1	1	1	0.76	0.76	0.40	0.64	0.60	0.60
5	Pre	5	8	8	8	8	N/A	0.44	0.48	0.32	0.44	0.44	N/A
	Post	5	8	8	5	8	8	0.44	0.40	0.40	0.40	0.40	0.32

Note: Results in post intervention bolded if it was in the direction expected from dilation.

Abbreviation: N/A, not applicable.

TABLE 4 High resolution pharyngeal manometry metrics on upper esophageal sphincter pre- and post-balloon dilation

Case #	Pre-/post-intervention	UES integrated relaxation pressure (mmHg)			UES relaxation time (s)			UES maximum admittance (mS)		
		5 mL thin	10 mL thin	5 mL thick	5 mL thin	10 mL thin	5 mL thick	5 mL thin	10 mL thin	5 mL thick
1	Pre	-1.81	-0.31	4.48	0.39	0.26	0.37	5.09	3.69	4.26
	Post	-2.83	-5.02	1.42	0.44	0.46	0.26	4.27	6.01	4.09
2	Pre	2.22	2.42	4.73	0.41	0.42	0.39	N/A	N/A	N/A
	Post	-6.40	-8.06	-1.55	0.41	0.41	0.34	N/A	N/A	N/A
3	Pre	6.29	4.48	9.09	0.51	0.46	0.47	3.59	3.56	3.96
	Post	6.29	4.51	8.75	0.52	0.48	0.44	3.59	3.56	3.04
4	Pre	7.61	10.06	5.41	0.72	0.57	0.62	5.16	5.27	5.04
	Post	5.6	-2.39	4.17	0.37	0.50	0.30	4.14	3.45	4.26
5	Pre	-2.0	-4.89	-2.69	0.35	0.42	0.45	3.03	5.14	3.19
	Post	10.06	5.45	-1.52	0.2	0.31	0.23	2.34	4.96	2.06

Note: Results in post intervention bolded if it was in the direction expected from dilation.

Abbreviations: N/A, not applicable; UES, upper esophageal sphincter.

mS). The IBP also decreased on 5 mL, 10 mL of thin liquid and 5 mL of thick liquid, indicating less resistance of the bolus flow in the pharynx post dilation (Table 5). The other HRPM metrics did not show a consistent pattern of change. Overall, HRPM data indicated improved opening of the UES in magnitude and duration during swallowing and corresponded to the reduction of the pharyngeal residue on VFSS and post-swallow aspiration.

The overall safety and efficiency of the swallow improved on thin and thick liquid to IDDSI level 3 (Table 6). After dilation, commencement of some oral intake of thick liquid (IDDSI level 3) in addition to gastrostomy intake, was recommended (FOIS 2). At 3 months post-intervention, case 1 was able to manage half of his oral intake needs via thick fluid (IDDSI level 2 and 3) and liquidized puree (IDDSI level 3), with supplement via gastrostomy tube (FOIS 3). With the resumption of oral feeding and less reliance on gastrostomy tube for feeding,

his quality of life improved as reflected by his improved MDADI composite score 1 months post, and sustained at 3 months postdilation (Table 6).

3.2 | Case 2

Case 2, a 74-year-old man, was 14 years post CRT for NPC. Similar to case 1, he had improvement post dilation, though to a lesser degree. At baseline, he was managing IDDSI level 0 fluids and level 6 foods (soft and bite-sized) (FOIS 6). The pre-intervention VFSS revealed a focal impairment of pharyngoesophageal opening and esophageal clearance (MBS14: minimal distension/duration; marked obstruction of flow; MBS17 esophageal retention with retrograde flow below the pharyngoesophageal segment), and aspiration (PAS 7-8) was noted in

TABLE 5 High resolution pharyngeal manometry metrics on pharyngeal contraction and intra-bolus pressure pre- and post-balloon dilation

Case #	Pre-/post-intervention	Pharyngeal contractile integral (mmHg.cm.s)			Intra-bolus pressure (mmHg)		
		5 mL thin	10 mL thin	5 mL thick	5 mL thin	10 mL thin	5 mL thick
1	Pre	25.98	7.10	21.67	-3.11	0.71	-3.12
	Post	13.19	8.40	2.30	-4.64	-2.85	-3.62
2	Pre	50.87	43.02	45.86	N/A	N/A	N/A
	Post	42.87	35.45	47.03	N/A	N/A	N/A
3	Pre	73.55	61.24	100.75	18.91	12.45	19.02
	Post	74.84	69.61	91.03	18.91	10.28	27.78
4	Pre	95.59	78.32	86.10	1.62	4.21	15.23
	Post	74.84	36.79	40.02	1.82	20.38	6.64
5	Pre	47.06	65.13	84.18	-7.09	-9.56	13.11
	Post	50.72	45.55	49.82	0.62	0.84	58.04

Note: Results in post intervention bolded if it was in the direction expected from dilation.

Abbreviation: N/A, not applicable.

TABLE 6 Liquid and food intake IDDSI level,²⁹ functional oral intake scale (FOIS¹⁸) scores and the MD Anderson Dysphagia Inventory (MDADI¹⁹) scores pre- and 1 and 3 months post balloon dilation

Case #	Pre-/post-intervention	IDDSI liquid level	IDDSI food level	FOIS	MDADI global	MDADI composite
1	Pre	N/A	N/A	1	20	40.00
	1 month post	3	N/A	2	20	54.74
	3 months post	2	3	3	40	58.29
2	Pre	0	6	6	20	45.26
	1 month post	0	7	7	40	68.42
	3 months post	0	7	7	60	61.05
3	Pre	0	6	6	40	52.63
	1 month post	0	6	6	40	56.84
	3 months post	0	6	6	40	59.16
4	Pre	0	6	6	40	62.13
	1 month post	0	6	6	40	62.11
	3 months post	0	6	6	40	73.68
5	Pre	N/A	N/A	1	20	41.05
	1 month post	N/A	N/A	1	40	44.21
	3 months post	N/A	N/A	1	20	43.18

Note: Results in post intervention bolded if it was in the direction expected from dilation.

Abbreviation: N/A, not applicable.

all consistencies except on cup drinking of thick liquid (PAS 3, Table 3).

Balloon dilation was completed uneventfully. Post-treatment VFSS showed improved pharyngoesophageal opening and cervical esophageal clearance (MBSImP 14 & 17, Table 2). Degree of pharyngeal residue remained consistent pre and post dilation (MBSImP 16). Penetration-aspiration improved post dilation for thin liquid (5 mL and cup—PAS 8 to 3) and puree (PAS 8 to 3) (Table 3). The duration of cricopharyngeal opening decreased on thin liquid (5 mL and cup) and puree (5 mL), increased on thick liquid (5 mL and cup) and had no change on soft solids (Table 3).

For this case, no impedance data were captured pre-intervention due to technical difficulties, therefore comparison could only be made on the pressure changes for this patient (Tables 4 and 5). However, this was positive with UES IRP improving on 5 mL (from 2.22 to -6.40 mmHg.cm.s) and 10 mL swallows of thin liquid (from 2.42 to -8.06 mmHg.cm.s) and 5 mL thick liquid (from 4.73 to -1.55 mmHg.cm.s), though UES RT remained similar. The other HRPM metrics remained unchanged. This suggests dilation improved UES opening in terms of magnitude but not in duration, which corresponded with the increased UES opening and

improved penetration-aspiration scores, but similar pharyngeal residue on VFSS.

Following dilation, functional oral intake improved, with the patient having easy to chew/regular food (IDDSI Level 7) no longer having any restriction (FOIS 7). This was maintained at 3 months postdilation. Dysphagia-related quality of life improved after treatment, and this was maintained 3 months post treatment (Table 6).

3.3 | Case 3

Case 3, a 40-year-old man, was 13 years post CRT for NPC. In contrary to cases 1 and 2, although some physiological changes on VFSS were noted post dilation, no changes were observed on manometry or in functional diet level. At baseline, case 3 was on soft and bite sized food and thin liquids (IDDSI Level 6 and FOIS 6). Pre-intervention VFSS revealed oral and pharyngeal phase deficits. The hyolaryngeal excursion was rated as partial (MBS8/9-1) and the pharyngoesophageal segment opening had a partial distension/duration, creating a partial obstruction of flow (MBS14-1). There was a collection of residue within or on the pharyngeal structures (MBS16-2). Penetration was detected on both Level 2 thick liquid and liquidized puree (PAS 3), and silent aspiration after the swallow due to overflow of residue (PAS 8) was noted on solids.

Balloon dilation was completed uneventfully. After the intervention, VFSS showed improvement with less pharyngeal residue across consistencies (MBS16-1). Penetration-aspiration status improved on solid swallows, from aspiration (PAS 8) to penetration (PAS 3) only. The duration of cricopharyngeal opening as measured by VFSS also improved on puree (5 mL; from 0.48 to 0.56 second) and soft solid swallows (from 0.52 to 0.68 second) (Table 3).

HRPM showed minor changes in UES relaxation or opening metrics (see Tables 4 and 5), the clinical relevance of which is not clear. This case is an example of improvements on pharyngeal residue and penetration/aspiration status noticed on VFSS, but not clearly reflected in changes on HRPM.

In terms of the functional outcome, case 3 remained on thin liquid (IDDSI Level 0), soft and bite sized food (IDDSI Level 6 and FOIS 6). Dilation failed to improve the functional swallow outcomes and quality of life measures remaining largely consistent across time points (see Table 6).

3.4 | Case 4

Case 4 was a 61-year-old man who had received CRT for NPC 20 years prior. Similar to case 3, he had no obvious functional changes with balloon dilation. He was on soft and bite sized food (IDDSI Level 6 and FOIS 6) and thin liquids. His baseline VFSS showed a mild degree of problem in the pharyngeal phase: partial hyolaryngeal excursion (MBS8/9-1), partial distension/duration of

the pharyngoesophageal segment leading to partial obstruction (MBS 14-1) resulting in collection of residue within/on the pharyngeal structures (MBS 16-2). There was esophageal retention with retrograde flow below the pharyngoesophageal segment (MBS17-2). However, there was no aspiration across consistencies (PAS 1-2).

Balloon dilation was completed uneventfully. Post-intervention assessment showed improvement in 5 out of 10 pharyngeal parameters on the MBSImP (Pharyngeal sum score—7 out of 29) and his cervical esophageal clearance also improved to only esophageal retention (MBS17-1). The duration of cricopharyngeal opening increased on thin liquid (5 mL and cup) but decreased on thick liquid (5 mL and cup) and puree (5 mL) (Table 3).

On HRPM, UES IRP improved on all swallows (see Table 4) but UES RT decreased (5 mL thin liquid from 0.72 second to 0.37 second; 5 mL thick liquid from 0.62 second to 0.30 second). The other HRPM metrics remained unchanged (see Table 5). Despite small improvement seen on VFSS and HRPM, case 4 was still on soft and bite-sized food (IDDSI Level 6), and his FOIS and MDADI scores remained unchanged at 1 month postdilation. Case 4 showed improvement in the MDADI composite scores at 3 months post-intervention despite having no changes on his liquid and food consistencies (IDDSI level 0 and 6) and FOIS score (Table 6).

3.5 | Case 5

Case 5 was a 60-year-old man who completed RT for NPC 20 years prior. As per case 4, balloon dilation did not have any measurable positive impacts on swallow biomechanics or functional outcome. At baseline, he had an episode of aspiration pneumonia about 6 months previously, and had been on gastrostomy tube feeding for 5 months (FOIS 1) prior to participation. Baseline VFSS showed significant pharyngeal impairment (Pharyngeal sum score—17 out of 29) and aspiration (PAS 8) across consistencies.

Dilation was completed uneventfully. Post-intervention assessment showed mild degree of improvement in laryngeal elevation and degree of pharyngeal residue, but penetration-aspiration status did not change on all consistencies (PAS 8) except on cup-drinking of thick liquid (PAS 5). There were no obvious changes to the duration of cricopharyngeal opening across consistencies.

On HRPM, UES IRP increased and UES relaxation time decreased across consistencies and volumes (see Table 4). PhCI decreased on 10 mL thin liquid (from 65.13 to 45.55 mmHg.cm.s), while IBP increased on 5 mL thin liquid (from -7.09 to 0.62 mmHg), 10 mL thin liquid (from -9.56 to 0.84 mmHg) and 5 mL thick liquid (from 13.11 to 58.04 mmHg) (see Table 5). Overall, HRPM suggested greater bolus flow resistance evidenced by reduced pharyngeal contraction and reduced UES opening. This was consistent with unchanged pharyngoesophageal segment opening and penetration-aspiration scores on VFSS. Case 5 remained dependent on gastrostomy tube for feeding after the intervention (FOIS 1) and MDADI scores showed minimal change at 1 and 3 months post-intervention.

4 | DISCUSSION

In this series of NPC patients with chronic dysphagia post CRT, changes in swallowing biomechanics, bolus flow and functional food intake in response to a single balloon dilation varied greatly across patients. Two out of 5 cases (case 1 and 2) showed obvious improvement in physiological swallowing outcomes, with improved safety reflected by improved penetration-aspiration status and functional oral intake. Two other cases (case 3 and 4), whose swallowing safety was only mildly compromised before dilation, showed slight improvement in their physiological swallowing outcomes, but this did not translate into improvements of their functional oral intake. The fifth case (case 5), who had a severely impaired swallowing function and safety, did not show any improvements in either physiological or functional outcomes after the dilation and remained feeding tube dependent. Overall, this series of case studies highlights that balloon dilation can provide benefits for some patients with bolus flow impairments across the UES, however, further work is needed to identify and stratify those patients who are going to be most likely to benefit from this intervention.

Our findings partially align with previous VFSS research that demonstrated increased cricopharyngeal opening, less pharyngeal residue and improved penetration-aspiration on liquids following balloon dilation in 13 NPC patients.¹⁰ In this case series, this was particularly evident in cases 1 and 2, where improved UES opening and penetration-aspiration scores on VFSS corresponded with improved pharyngeal contractile integral and bolus flow metrics on HRPM, for example, reduced IBP. A similar change has also been reported after myotomy.²⁵ Likewise, UES admittance values, which would be expected to be higher after dilation, were also increased in case 1 for the 10 mL thin liquid swallow. Overall in these patients, the improved trans-sphincteric bolus flow consequently resulted in improved functional oral intake and better swallowing-related quality of life.

In contrast to case 1, in the remaining cases who had impedance measurements (cases 3, 4, 5), all impedance-based measures remained similar or worsened after dilation. For example, cases 3 and 4 demonstrated less noticeable changes in swallowing biomechanics on VFSS and HRPM, which corresponded with a lack of consistent and noticeable changes in FOIS and MDADI scores. Finally, in case 5, initially severe physiological impairment was not improved by dilation on VFSS and worsened on HRPM, and this consequently also did not translate into functional gains or improved quality of life.

Overall, although VFSS revealed positive improvements in 4 of the 5 cases post dilation in the current study, HRPM only identified reduced UES IRP and increased UES RT for case 1, and reduced UES IRP with unchanged UES RT in case 2. Balloon dilation is also hypothesized to decrease IBP in the pharynx as the outflow obstruction at the UES level is alleviated. However, post dilation in the current 5 cases, IBP was only decreased in case 1, but not cases 3 and 4, whose IBP remained unchanged and case 5, whose IBP increased following dilation.

Therefore, in this case series we were unable to identify a consistent pattern of change across all assessed outcomes measures. Specifically, the severity of oral and pharyngeal deficits, as measured by the oral and pharyngeal sum scores of MBSImP, was similar in patients that responded to dilation and those who did not. Similarly, patients with better pharyngeal contraction, as measured by the PhCI²⁴ (cases 3 and 4), did not perform better on MBSImP than those with weaker pharyngeal contraction (cases 2 and 5). There were also no apparent differences in terms of patients' UES relaxation and opening prior to the dilation, as patients with a relatively elevated IRP at baseline (cases 3 and 4) did not show a more noticeable decrease after dilation. The predilation penetration-aspiration status also did not seem to affect the outcome of dilation. Specifically, cases 1 and 5 were very similar in their baseline VFSS, HRPM, FOIS and MDADI scores. However, while case 1 showed much greater physiological and functional improvement after the dilation that lasted until the 3 month follow up, case 5 demonstrated very little change and remained gastrostomy tube dependent.

The PhCI²⁴ is an indirect measurement of the pharyngeal contraction force and has been studied in normal adults³² and patients with dysphagia.³³ In our cohort, the PhCI ranged from 13.19 to 95.59 mmHg.cm.s for 5 mL thin liquid and 2.3 to 100.75 mmHg.cm.s for 5 mL thickened liquid. The values were much lower than the reported mean PhCI in healthy individuals (308 mmHg.cm.s for 5 mL thin liquid; 305 mmHg.cm.s for 3 mL pudding³²). The UES IRP is indicative of the completeness of UES relaxation and the compliance of the sphincter. The values obtained in our cohort were -6.4 to 10.06 mmHg for 5 mL thin liquid and -2.69 to 9.09 mmHg for 5 mL thick liquid. The values were comparable to the means obtained from healthy individuals (0 mmHg for 5 mL thin liquid and 3 mmHg for 3 mL pudding³²). Taken together, these findings suggest that in the patients presented here, reduced pharyngeal driving forces were a key characteristic of impaired swallowing biomechanics, while UES parameters remained relatively unaffected. This is in line with previous reports that patients with NPC may present with significant pharyngeal contraction problems.^{1,5} Balloon dilation did not specifically target improved pharyngeal contraction and hence could be one of the reasons why the results from this study in this respect are inconclusive. Further treatment studies in patients with NPC should seek to build upon the HRPM findings presented in this cohort to determine if improvements in pharyngeal contraction would translate to functional gains in swallowing.

This case series, therefore, demonstrates that even if NPC patients present with similar physiological problems in swallowing, their responses to mechanical dilation can be vastly different. The reasons for this are unclear. It is possible that muscle properties in the cricopharyngeal and cervical esophageal regions vary in the way they respond to CRT across individuals, which may influence the response to dilation and whether it is functionally effective or not. However, as we did not assess tissue properties, this hypothesis warrants further investigation. Another possible reason that led to difference in outcomes across patients were the differences in surgical history for each case. Case 1 was the only individual that received surgical

management for recurrent NPC. Although nasopharyngectomy has been associated with more severe dysphagia symptoms and restricted daily function,³⁴ the difference in how swallowing function is affected by the surgery as compared to CRT is unclear. Time post CRT (ie, 5 years for case 1 vs a minimum of 13 years for cases 2-5) may have also contributed to the differences in dilation outcomes. It is also possible that slight variations in the dilation procedure may have contributed to varying responses across patients. A strict protocol was in place to ensure consistency in how the procedure was carried out, but slight variations in placement of the balloon catheter due to anatomical differences across patients cannot be completely ruled out.

5 | CONCLUSION

In line with previous studies,^{10,12} this case series demonstrates that balloon dilation can be effective for some NPC patients with dysphagia after CRT. A trend as to who will benefit from balloon dilation after NPC treatment could not be clearly established from this case series. Where positive functional gains were achieved, both fluoroscopy and HRPM indicated improved UES function post dilation. Further large scale studies incorporating HRPM are needed to fully examine the impact of dilation on pharyngeal pressure metrics and bolus flow.

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CONFLICT OF INTEREST

The authors declare that they have no conflict of interest.

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