Is the Botulinum Toxin Injection Into the Cricopharyngeal Sphincter Precipitate Laryngopharyngeal Reflux Symptoms in Patients With Retrograde Cricopharyngeal Dysfunction?☆

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SUMMARY: Objective. To investigate the potential relationship between retrograde cricopharyngeal dysfunction (R-CPD) and laryngopharyngeal reflux disease (LPRD) at baseline and whether cricopharyngeal sphincter paralysis botulinum toxin injection (BTI) is associated with an increase of LPRD symptoms in treated R-CPD patients.

Methods. Patients with clinical diagnosis of R-CPD were prospectively recruited from two European hospitals. Controls included individuals unable to burp without troublesome symptoms (CT1) and healthy subjects able to burp (CT2). All participants completed the Burp Score and Reflux Symptom Score-12 (RSS-12) at baseline. R-CPD patients underwent office-based electromyography-guided BTI followed by a 3- to 6-month follow-up evaluation.

Results. Forty-two R-CPD patients and 133 gender- and age-matched controls (30 CT1, 103 CT2) completed baseline evaluations. Burp scores were significantly higher in the R-CPD and CT1 groups compared to CT2, with CT1 subjects presenting mild symptom scores significantly exceeding CT2 levels. No significant differences in RSS-12 total scores were observed between R-CPD and CT2 subjects. Among 38 R-CPD patients completing postBTI evaluation (22 responders), RSS-12 total scores remained stable. Dysphonia and dysphagia scores significantly increased post treatment, potentially representing BTI-related adverse events.

Conclusion. This preliminary clinical study supports that R-CPD and LPRD are distinct clinical disorders, with BTI treatment improving R-CPD symptoms without significantly increasing LPRD symptoms.

Key Words: Laryngopharyngeal reflux–Retrograde–Cricopharyngeus dysfunction–Cricopharyngeal–Otolaryngology–Voice.

INTRODUCTION

Retrograde cricopharyngeal dysfunction (R-CPD) is a newly described syndrome associated with a constellation of troublesome symptoms, such as abelchia, gargling noise, hiccups, chest pain, excessive flatulence, and bloating.[1,2] R-CPD is related to absent or incomplete cricopharyngeal sphincter relaxation in response to abrupt esophageal distention by gastroesophageal gas reflux.[1–3] The current etiology of R-CPD remains unknown, with gastroesophageal reflux disease (GERD) in childhood suspected as a potential trigger.[4,5] Because of the hypertonicity of the cricopharyngeal sphincter, the current therapeutic standard of care consists of the injection of botulinum toxin (BTI) into the cricopharyngeal sphincter or the surgical incision of the sphincter (myotomy),[6,7] both resulting in the ability to evacuate the gas accumulated in the esophagus and relieve symptoms. A potential theoretical adverse event of cricopharyngeal paralysis or myotomy is the development of laryngopharyngeal reflux disease (LPRD),[4,5] which may be associated with the deposit of gastroduodenal enzymes into the upper aerodigestive tract mucosa through the relaxation of both lower and upper esophageal sphincters.[8,9] Indeed, the baseline tonicity of the cricopharyngeal sphincter is a key protective factor against esophago-pharyngeal reflux events, limiting the reflux process into the esophagus (full column).[10]

The aims of this preliminary study were to investigate the potential relationship between R-CPD and LPRD at baseline and whether cricopharyngeal sphincter paralysis (BTI) is associated with an increase of LPRD symptoms in successfully treated R-CPD patients.

MATERIALS AND METHODS

Subjects and setting

Three types of subject populations were consecutively recruited: patients with a clinical diagnosis of R-CPD,[1,2] subjects with an inability to burp without complaining from troublesome symptoms, and healthy individuals able to burp without digestive disorder (healthy individuals). R-CPD patients were recruited from two European hospitals (Foch Hospital, Paris, France; EpiCURA Hospital, Baudour, Belgium) between September 2024 and April 2025. The R-CPD diagnosis was based on the presence of an inability to belch associated with at least one of the

Accepted for publication August 15, 2025.
☆ The authors declare that they have no relevant financial interests.

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Journal of Voice, Vol xx, No xx, pp. xxx–xxx
0892-1997

https://doi.org/10.1016/j.jvoice.2025.08.021

following symptoms: gurgling noise, flatulence, bloating, and chest pain.[11] Individuals of the two control groups were recruited from a public call at the University of Mons (Belgium). The three groups were matched for gender and age. The following exclusion criteria were considered: neurological disorders affecting swallowing, psychiatric illness, Zenker's diverticulum, achalasia, vagal neuropathy, autoimmune disease affecting the esophagus or pharynx, history of head and neck radiation, cancer, or esophageal/laryngopharyngeal surgery. The presence or history of GERD or LPRD was not an exclusion criterion in any group regarding the aim of this study. All individuals completed a questionnaire to investigate the presence of the exclusion conditions described above and were excluded if one or more exclusion criteria were met.

The local ethics committee approved the study protocol (n°2022039). Subjects were invited to participate, and informed consent was obtained.

Data collection

R-CPD patients and controls completed an online questionnaire collecting the following information at baseline: gender, age, and comorbidities. Patients and controls completed the Reflux Symptom Score-12 (RSS-12)[12] and the Burp Score.[11] RSS-12 is a valid and reliable patient-reported outcome questionnaire assessing the frequency and severity (five-point scale) of the 12 most common LPRD symptoms, including seven ear, nose, and throat symptoms, three digestive symptoms, and two respiratory symptoms. For each item, the severity score is multiplied by the frequency score to get a symptom score ranging from 0 to 25. The sum of these symptom scores is calculated to obtain the RSS-12 final score, ranging from 0 to 300. An RSS-12 ≥ 13 was suggestive of potential LPRD.[12]

Burp Score is a valid and reliable patient-reported outcome questionnaire assessing the 10 most prevalent symptoms found in R-CPD patients.[11] Regarding the variability of clinical presentation of R-CPD, the Burp Score includes an evaluation of both severity (five-point scale) and frequency (three-point scale) of each symptom. The frequency and severity scores are multiplied to obtain a symptom score ranging from 0 to 15, and a total score ranging from 0 to 150 (Figure 1).

Botulinum toxin injections (BTIs)

The office-based electromyography (EMG)-guided BTI was a unilateral injection of Incobotulinum toxin A (dilution of 100 U/0.45 mL; Natus Dantec Keypoint, Focus).[4] Briefly, subjects were placed in a neutral supine position. The posterior left side of the cricoid cartilage was used to locate the cricopharyngeal sphincter through the EMG needle. The needle tip position was confirmed on the EMG tracing through swallowing (loss of signal with sphincter relaxation followed by motor unit recruitment with post-swallow contraction), the sustained vowel /i/ (to avoid thyrocricoid muscle injection), and a sniffing maneuver (to avoid posterior cricoarytenoid muscle injection). RSS-12 and Burp Score were completed after 3-to-6-month postBTI in R-CPD patients. At the follow-up consultation, patients had to specify if the treatment was effective or not. For patients with partial improvement, the MCID (11 points) of the Burp score was considered to classify the patient as responder or not.[11]

Statistical methods

Statistical analyses were performed using the Statistical Package for the Social Sciences for Windows (SPSS version 29.0; IBM Corp, Armonk, NY, USA). The patient and control group clinical findings, including item and total RSS-12 and Burp scores were compared at baseline using the Kruskal-Wallis test. Comparisons of scores between two groups were performed with the Mann-Whitney U test. The proportion of females/males across groups was compared with Chi-square. The preBTI to postBTI changes in RSS-12 and Burp Score were evaluated with the Wilcoxon Rank test in responders and non-responders. The pre-treatment to post treatment comparison of RSS-12 item and total scores was used to evaluate the potential increase of LPRD symptoms after BTI. Spearman correlation coefficient was used to investigate potential associations between baseline and post treatment clinical outcomes. A level of significance of $P < 0.05$ was used.

RESULTS

Patients and settings

Forty-two R-CPD patients and 133 controls completed the baseline evaluations. Of the controls, 30 (22.6%) subjects reported being unable to burp since childhood without presenting troublesome symptoms, and 103 (77.4%) were able to burp (Table 1). The gender proportion and age were comparable across groups.

Baseline clinical findings

The Burp item and total scores were significantly higher in R-CPD patients compared to controls. Subjects who are unable to burp reported significantly higher Burp total score compared to controls able to burp ($P = 0.001$). Similar observation was found for the following symptoms: inability to burp ($P = 0.001$), gargling noises ($P = 0.001$), chest pain ($P = 0.003$), bloating ($P = 0.002$), nausea ($P = 0.005$), hiccups ($P = 0.005$), difficulty vomiting ($P = 0.018$), and hypersialorrhea ($P = 0.024$).

R-CPD patients and asymptomatic controls (able to burp) reported similar RSS-12 scores (Table 1). When considering the RSS-12 symptoms, R-CPD patients demonstrated significantly higher scores compared to both control groups for the following symptoms: dysphagia, globus sensation, excess throat mucus, heartburn, abdominal pain, and indigestion; most of these scores being the lowest in the asymptomatic group and highest in the R-CPD group, while the control group composed of subjects with an inability to burp without complaining from troublesome symptoms reported intermediate scores (Table 1).

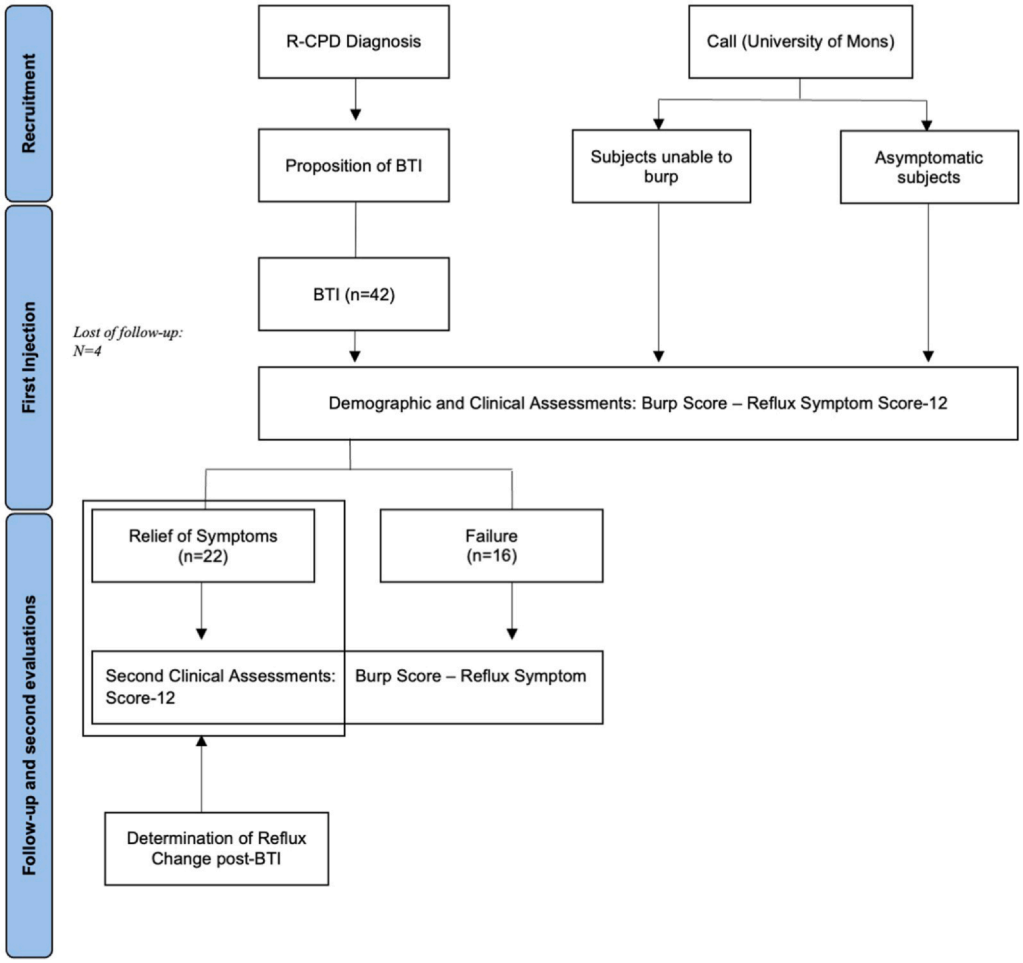

FIGURE 1. Chart flow. *Abbreviations:* BTI, botulinum toxin injection.

Clinical finding changes throughout treatment

Of the 82 R-CPD patients, 38 completed the preBTI to postBTI evaluations at the end of the study. There were 22 responders (57.9%) after one BTI. The pretreatmen to post treatment evolutions of the Burp score and RSS-12 in responders and non-responders are described in Table 2. Most Burp symptoms significantly decreased in the responder group, whereas they did not change in the non-responder group. The RSS-12 total score did not change from preBTI to postBTI in both groups. Among the RSS-12 symptoms that are specific to LPRD and not commonly found in both R-CPD and LPRD, only the dysphonia and dysphagia scores demonstrated significant increases from pretreatment to post treatment. Of the common R-CPD and LPRD symptoms, abdominal pain and indigestion/abdominal distension scores showed significant decreases in responder group (Table 2).

The association analysis reported a significantly positive association between the 3-month inability to burp score (Burp Score) and the dysphonia score (RSS-12; $r_s = 0.400$; $P = 0.001$). The 3-month Burp Score was strongly associated with the ability to burp (item 1) at postBTI ($r_s = 0.808$; $P = 0.001$).

DISCUSSION

The primary findings of this preliminary clinical study demonstrated that R-CPD patients reported similar baseline RSS-12 scores to healthy individuals who can burp, with significant differences only in non-specific symptoms found in both R-CPD and LPRD. The lack of evidence of high proportion of reflux in R-CPD patients corroborates the findings of Anderson et al who prospectively investigated the esophageal (high-resolution manometry) and reflux (reflux symptom index) findings in 85 R-CPD patients.[13] Authors revealed that the barium swallow was abnormal in 53% of cases, with a mild-to-moderate proportion of reflux esophagitis (15.4%) and hiatus hernia (21.5%) as the most common findings,[13] which was not greater than the incidence of hiatal hernia and GERD in Western countries.[14] Concerning the LPRD symptoms, the RSI mean score was 11.3, which was lower than the threshold (> 13) suggesting LPRD, while the authors reported that a few outliers with high RSI scores required medical management.[13] In a prospective uncontrolled study, Mailly et al reported a GERD prevalence of 6.6% in 106 R-CPD patients treated with office-based BTI,[4] with more than 90% of patients reporting a RSS-12 > 11 (mean RSS-12 score at 35.0) at the

TABLE 1.
Baseline Clinical Findings

	R-CPD $n=82$	Unable to burp $n=30$	Asymptomatics $n=103$	*P* value
Age (range, years)	18-32	18-28	18-25	NS
Gender				
Females	46 (56.1)	23 (76.7)	65 (63.1)	NS
Males	36 (43.9)	7 (23.7)	30 (36.9)	
RSS-12 items				
1. Voice disorder	0.78 ± 2.97	0.57 ± 1.83	0.91 ± 3.49	NS
2. Throat pain or odynophagia	1.94 ± 3.51	0.64 ± 1.25	1.36 ± 3.99	NS
3. Dysphagia	3.19 ± 5.99	0.79 ± 1.81	0.97 ± 3.56	0.001
4. Throat clearing	3.88 ± 6.19	3.25 ± 6.53	3.72 ± 7.25	NS
5. Globus sensation	4.27 ± 6.50	1.64 ± 4.97	1.55 ± 4.29	0.001
6. Excess throat mucus	4.56 ± 6.36	1.46 ± 4.73	2.37 ± 5.68	0.001
7. Halitosis	2.08 ± 3.88	1.93 ± 4.94	1.54 ± 4.86	NS
8. Heartburn, regurgitations, burps, nausea	5.91 ± 6.80	3.61 ± 6.84	2.02 ± 5.36	0.001
9. Abdominal pain or diarrheas	8.89 ± 8.30	3.29 ± 6.72	2.54 ± 6.04	0.001
10. Indigestion, abdominal distension and/or flatus	11.89 ± 8.11	6.07 ± 9.38	2.69 ± 6.38	0.001
11. Cough after eating/lying down or daytime troublesome cough	1.92 ± 3.90	1.32 ± 4.09	1.69 ± 5.29	NS
12. Breathing difficulties, breathlessness, or wheezing	3.31 ± 5.65	2.96 ± 6.89	1.87 ± 4.90	NS
RSS-12 total score	52.60 ± 37.02	27.53 ± 35.98	48.88 ± 30.96	0.001
Burp Score				
1. Inability to burp	12.80 ± 3.35	4.39 ± 4.66	0.00 ± 0.00	0.001
2. Gargling noises	13.80 ± 17.39	2.58 ± 3.86	0.64 ± 1.96	0.001
3. Chest pain	4.76 ± 3.88	1.55 ± 2.00	0.70 ± 1.36	0.001
4. Bloating and/or abdominal pain	9.88 ± 5.05	4.13 ± 4.75	1.57 ± 2.26	0.001
5. Excessive flatulence/gas	10.26 ± 4.70	2.81 ± 4.38	1.86 ± 3.22	0.001
6. Nausea	2.99 ± 3.19	2.45 ± 3.64	0.95 ± 1.75	0.001
7. Troublesome or painful hiccups	4.30 ± 3.89	0.77 ± 1.02	0.44 ± 1.53	0.001
8. Sensation of globus pharyngeus	4.23 ± 4.35	1.23 ± 2.84	0.58 ± 1.31	0.001
9. Difficulty vomiting	4.68 ± 5.87	1.03 ± 3.16	0.49 ± 1.95	0.001
10. Hypersialorrhea	3.64 ± 4.06	0.93 ± 2.05	0.47 ± 1.67	0.001
Burp total score	71.34 ± 27.67	21.87 ± 19.90	7.70 ± 8.88	0.001

Abbreviations: BTI, botulinum toxin injection; NS, non-significant; R-CPD, retrograde cricopharyngeal dysfunction; RSS-12, reflux symptom score-12.

time of BTI. Similarly to the present study, the high RSS-12 score may be attributed to elevated scores of non-specific symptoms found in both LPRD and R-CPD, leading to a higher RSS-12 total score. Indeed, in the present study, the symptom analysis showed that the significantly higher RSS-12 symptom scores found in R-CPD patients especially concerned R-CPD/LPRD common symptoms rather than symptoms that are commonly found in LPRD rather than R-CPD (dysphonia, throat pain, throat clearing, halitosis, cough, and breathing disorders).

The occurrence of reflux after BTI in cricopharyngeal dysfunction was initially suspected by Bastian and Smithson.[1] Recently, Jonsson and Plaschke failed to identify substantial association between R-CPD and reflux in their systematic review of 13 studies, but they suggested that reflux may be a complication of R-CPD injection, reaching 35.4% of cases in some studies.[15] Importantly, in most studies included in this review, reflux was reported as a mild and transient complication, while no study assessed either GERD or LPRD at 3- to 6-month post treatment using valid and reliable patient-reported outcome questionnaires or objective impedance-pH testing.[2,15] The investigation of reflux as a postBTI complication makes particular sense because cricopharyngeal sphincter myotomy, balloon dilatation, or BTI remain the primary therapeutic approaches for treating R-CPD patients.[4,6,7,16] From a pathophysiological standpoint, the paralysis or section of the cricopharyngeal sphincter may lead to a theoretically higher risk of developing LPRD regarding its primary defense role in the progression of distal to proximal reflux events to the pharynx.[10,17] The application of this theoretical point to R-CPD-treated patients was not supported by the findings of the present preliminary study. Indeed, R-CPD patients reporting both a successful feeling after BTI and a significant reduction of Burp score (MCID) did not report significant increase of RSS-12. This lack of LPRD-symptom changes was particularly found in symptoms that are found in LPRD and not in R-CPD, including throat pain, throat clearing, globus sensation, excess throat mucus, halitosis, heartburn/regurgitations, cough and breathing difficulties.[2,18] Interestingly, dysphonia and dysphagia were the only two symptoms reporting a significant

TABLE 2.
PreBTI to PostBTI Changes in Symptoms in R-CPD Patients

	Responders to BTI			Non-responders to BTI		
RSS-12 items	PreBTI	PostBTI	*P* value	PreBTI	PostBTI	*P* value
1. Voice disorder	0.01 ± 0.01	4.06 ± 6.84	0.043	2.13 ± 5.44	4.06 ± 6.84	NS
2. Throat pain or odynophagia	1.40 ± 2.95	1.19 ± 2.37	NS	1.40 ± 2.90	1.19 ± 2.37	NS
3. Dysphagia	3.85 ± 6.75	10.31 ± 7.22	0.009	4.80 ± 7.90	10.31 ± 7.22	NS
4. Throat clearing	5.85 ± 7.87	4.69 ± 4.16	NS	2.87 ± 5.76	4.69 ± 4.16	NS
5. Globus sensation	3.70 ± 6.67	5.88 ± 7.38	NS	2.20 ± 5.23	5.88 ± 7.38	0.046
6. Excess throat mucus	5.45 ± 8.53	5.50 ± 7.72	NS	3.27 ± 5.65	5.50 ± 7.72	NS
7. Halitosis	1.95 ± 3.78	1.44 ± 4.97	NS	1.73 ± 3.97	1.44 ± 4.97	NS
8. Heartburn, regurgitations, burps, nausea	7.67 ± 8.86	5.50 ± 5.59	NS	5.51 ± 5.21	5.50 ± 5.59	NS
9. Abdominal pain or diarrheas	10.15 ± 8.67	2.75 ± 4.28	0.004	12.93 ± 8.87	2.75 ± 4.28	NS
10. Indigestion, abdominal distension and/or flatus	11.88 ± 8.04	5.06 ± 4.57	0.009	15.87 ± 8.29	5.06 ± 4.57	0.027
11. Cough after eating or lying down or daytime troublesome cough	1.60 ± 3.23	0.75 ± 1.24	NS	1.90 ± 4.53	0.75 ± 1.24	NS
12. Breathing difficulties, breathlessness, or wheezing	4.20 ± 6.23	1.75 ± 2.67	NS	2.93 ± 6.39	1.75 ± 2.67	NS
RSS-12 total score	57.69 ± 45.88	48.88 ± 30.96	NS	57.54 ± 37.50	48.88 ± 30.96	NS
1. Inability to burp	13.14 ± 3.48	4.10 ± 4.00	0.001	13.31 ± 3.28	13.30 ± 2.47	NS
2. Gargling noises	12.18 ± 3.43	5.24 ± 4.13	0.001	12.25 ± 3.58	10.75 ± 4.78	NS
3. Chest pain	3.86 ± 3.76	0.95 ± 1.91	0.001	4.44 ± 4.41	3.25 ± 4.78	NS
4. Bloating and/or abdominal pain	9.77 ± 5.48	3.71 ± 4.10	0.003	11.25 ± 4.60	10.75 ± 4.78	NS
5. Excessive flatulence/gas	10.14 ± 4.49	4.62 ± 3.74	0.001	12.44 ± 3.60	11.50 ± 4.13	NS
6. Nausea	3.14 ± 3.88	1.38 ± 2.87	0.007	2.00 ± 2.07	2.75 ± 3.96	NS
7. Troublesome or painful hiccups	5.50 ± 4.87	1.24 ± 2.17	0.001	3.62 ± 3.42	3.25 ± 2.18	NS
8. Sensation of globus pharyngeus	4.55 ± 4.47	2.90 ± 3.15	NS	2.56 ± 3.39	4.38 ± 4.88	NS
9. Difficulty vomiting	6.82 ± 6.69	2.71 ± 4.45	0.020	3.87 ± 5.52	4.06 ± 5.51	NS
10. Hypersialorrhea	4.55 ± 4.58	1.81 ± 3.20	0.007	3.19 ± 4.18	4.06 ± 4.97	NS
Burp total score	73.64 ± 22.98	28.67 ± 24.43	0.001	68.94 ± 17.97	68.06 ± 13.96	NS

Abbreviations: BTI, botulinum toxin injection; NS, non-significant R-CPD, retrograde cricopharyngeal dysfunction; RSS-12, reflux symptom score-12.

increase in their score after BTI, which may be attributed to an adverse event of BTI rather than LPRD-induced symptoms. According to studies, dysphonia and dysphagia are both primary adverse events of office-based EMG-guided BTI, with an incidence ranging from 3.0% to 13.2%, and 20% to 75%, respectively.[2] The preBTI to postBTI use of RSS-12 may therefore support that dysphagia and dysphonia are both primary long-lasting adverse events, which are important to mention to R-CPD patients before BTI. Moreover, in non-responder patients, the RSS-12 globus sensation score significantly increased after BTI, which may be attributed to an additional adverse event symptom related to the toxin diffusion into the eso-pharyngo-laryngeal tissues. Among other RSS-12 symptoms highlighting significant changes throughout treatment, the reduction of abdominal pain and indigestion/abdominal distension mean scores may be attributed to the effect of BTI; both symptoms being non-specifically found in R-CPD and LPRD patients.[2,12,15,18]

To the best of our knowledge, this study is the first investigation of preBTI to postBTI change in LPRD symptoms, which is its primary strength. Based on these clinical observations, we may reasonably suggest that R-CPD BTI and the related paralysis of the cricopharyngeal sphincter is not clinically associated with a significant increase of LPRD-induced symptoms. The consideration of individuals who cannot burp without reporting troublesome symptoms is an additional strength because there is no study in the literature investigating this group of subjects who may present mild R-CPD symptoms without requiring medical care/intervention. The administration of the Burp Score in this group demonstrated that they may present an intermediate phenotype with mild symptoms and no identified significant relationship with LPRD. This observation strengthens the need to investigate the digestive physiology of this group of pauci-symptomatic subjects and compare with the findings of R-CPD patients.[5]

Despite the absence of significant association between LPRD and R-CPD symptomatology at initial clinical presentation, it remains challenging to definitively exclude reflux disease as a potential etiological factor in R-CPD pathogenesis. This uncertainty stems from the lack of longitudinal reflux assessment during childhood neurodevelopment—the critical period during which R-CPD typically manifests—precluding comprehensive evaluation of the temporal relationship between these conditions. The lack of hypopharyngeal-esophageal multichannel intraluminal impedance-pH testing is an

additional limitation of the study. This diagnostic approach is the gold standard for confirming the LPRD diagnosis through the objectification of esophago-pharyngeal reflux events.[9,18] However, regarding its cost and moderate tolerance, our team preferred conducting this preliminary clinical study based on patient-reported outcome questionnaires rather than immediately spending money for pH probes without having a high probability to achieve significant results. The low number of both subjects unable to burp without complaining of troublesome symptoms and R-CPD patients achieving the preBTI to postBTI evaluations are two additional limitations.

CONCLUSION

This preliminary clinical investigation suggests that R-CPD and LPRD are distinct clinical entities with overlapping non-specific symptoms rather than causally related conditions. BTI effectively addresses R-CPD symptoms without precipitating significant LPRD-specific symptoms, though transient dysphonia and dysphagia may occur as treatment-related adverse events. The identification of individuals with subclinical inability to burp presenting intermediate symptom severity warrants further exploration of the pathophysiological spectrum underlying cricopharyngeal dysfunction through comprehensive objective reflux assessment methodologies.

CRediT authorship contribution statement

Jerome R. Lechien, Marie Mailly, and Stephane Hans: design, acquisition of data, data analysis and interpretation, drafting, final approval, and accountability for the work; final approval of the version to be published; agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

Acknowledgments

Denis Deltenre for the matrix.

Sponsorships

None.

Declaration of Competing Interest

The author has no financial interest in the subject under discussion.

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