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Pressure Flow Analysis for Assessment of Pediatric Oropharyngeal Dysphagia

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Conflict of Interests

Authors Nathalie Rommel and Taher Omari hold a patent on Pressure Flow Analysis, AIMplot methods. All other authors have no conflict of interests to declare.

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Abbreviations list:

CP	Cricopharyngeus (muscle)
DDS	Dysphagia Disorders Survey
IBP	Intra-bolus Pressure
FI	Flow Interval
FOIS	Functional Oral Intake Scale
HRIM	High Resolution Manometry with Impedance
NI	Nadir Impedance
OPD	Oro-pharyngeal Dysphagia
PFA	Pressure Flow Analysis
PNI	Pressure at Nadir Impedance
PP	Peak Pressure
PSIR	Post Swallow Impedance Ratio
SRI	Swallow Risk Index
TNIPP	Time from Nadir Impedance to Peak Pressure
UES	Upper Esophageal Sphincter
UESNI	Upper Esophageal Sphincter Nadir Impedance
UESRES	Upper Esophageal Sphincter intra-bolus pressure during relaxation
VFSS	Videofluoroscopy Swallow Study

ABSTRACT

Objectives

Pharyngeal High Resolution Manometry with Impedance (HRIM) was performed in a heterogeneous group of children with signs of oropharyngeal dysphagia (OPD). The aim of this study was to determine which objective pressure-impedance measures of pharyngeal swallowing function correlated with clinically assessed severity of OPD symptoms.

Study Design

Forty five pediatric OPD patients and 34 non-OPD controls were recruited and up to 5 liquid bolus swallows were recorded using a solid state HRIM catheter. Individual measures of pharyngeal and upper esophageal sphincter (UES) function and a Swallow Risk Index composite score were derived for each swallow, and averaged data for OPD patients were compared against those of non-OPD controls. Clinical severity of OPD symptoms and oral feeding competency was based on the validated Dysphagia Disorders Survey (DDS) and Functional Oral Intake Scale.

Results

Those objective measures that were markers of UES relaxation, UES opening and pharyngeal flow resistance, differentiated patients with and without OPD symptoms. Patients demonstrating abnormally high pharyngeal intra-bolus pressures and high UES resistance, markers of outflow obstruction, were most likely to have overt DDS signs and symptoms (Odds Ratio 9.24, p=0.05, and 9.7, p = 0.016, respectively).

Conclusion

Pharyngeal motor patterns can be recorded in children using HRIM and pharyngeal function can be objectively defined using pressure-impedance measures. Objective measurements suggest that pharyngeal dysfunction is common in children with clinical signs of OPD. A key finding of this study was evidence of markers of restricted UES opening.

INTRODUCTION

Safe, effective and efficient swallowing throughout development relies on intricate sensory development, fine motor coordination of the swallowing musculature, and maturation of feeding skills to ensure airway protection and full bolus clearance from the oropharyngeal segment (1-3). Physiologically, pressure changes across the pharyngo-esophageal segment drive bolus movement during the swallowing process. Stimulation of mechanoreceptors in the base of tongue during bolus propulsion, and afferent pathways stimulated by bolus advancement into the oropharynx trigger the pharyngeal swallow response (4). The soft palate elevates to seal the nasal cavity; the cricopharyngeus (CP) muscle, which primarily generates the upper esophageal sphincter (UES) high pressure zone, relaxes in coordination with hyolaryngeal excursion to enable concomitant airway protection and UES opening. The pharyngeal stripping wave follows to clear any bolus residue. In cases where there is restriction at the level of the UES, bolus outflow from the pharynx is obstructed and intrabolus pressures increase, making post-swallow residue and risk of mid or post-swallow aspiration more likely.

Children with developmental disorders, neurological conditions, respiratory or cardiac problems, esophageal dysmotility or structural deficits such as cleft palate are at risk for oro-pharyngeal dysphagia (OPD) and potentially aspiration (5-13). The pathophysiology underlying OPD symptoms is important for diagnosis and management, however this is often difficult to determine in these children.

Objective assessment of oropharyngeal swallowing is challenging due to its mechanically complex nature (12). High resolution solid state manometry with impedance (HRIM) is a catheter-based diagnostic modality which overcomes some of the inherent limitations of existing assessment techniques. Used as an adjunct to videofluoroscopy swallow studies (VFSS), HRIM enhances biomechanical evaluation of oropharyngeal swallowing and

furthermore, pressure and impedance recordings generated during HRIM-measured swallows can be analysed using Pressure-Flow Analysis (PFA) (2, 13, 15-20). Published studies in adults and, to a lesser extent in children with pharyngeal dysphagia, have shown individual PFA measures and a global composite score of swallowing dysfunction, called the Swallow Risk Index (SRI), are able to discriminate consequences of swallowing pathophysiology, such as aspiration risk, the presence of post-swallow residue and abnormal pharyngeal distension-contraction timing in circumstances of poor oral containment and/or delayed swallow trigger (2, 13, 19, 20). Whilst PFA measures differ in relation to the radiological picture of severity, it remains to be determined which PFA measures correlate with the degree of swallowing impairment determined by accepted clinical assessment scales that are widely used amongst speech-language pathologists.

The aim of this study was to perform HRIM with PFA in a heterogeneous group of children with clinically recognised signs of OPD to investigate potential correlations with established clinical assessment scales, namely the Dysphagia Disorders Survey (DDS) (21), and the Functional Oral Intake Scale (FOIS) (22). We hypothesised that PFA metrics would differentiate OPD patients from non-OPD controls, and correlate with DDS and FOIS scores.

METHODS

All investigations were performed in the Gastroenterology Department at the Women's and Children's Hospital in Adelaide, Australia. Children over 2 years of age with dysphagia symptoms were recruited between December 2011 and June 2015. The Women's and Children's Health Network Human Research Ethics Committee approved the study protocol (HREC1367). Informed consent was obtained from the primary care giver for all participants. Due to ethical concerns, healthy children were not studied; instead, children who were referred for manometric investigation of esophageal motility were recruited as non-OPD

controls. If needed, these children were given extra boluses with the catheter re-positioned to capture pharyngeal motor patterns.

Measurement Protocol

A 10 French solid state HRIM catheter was used, incorporating 25 1cm-spaced unidirectional pressure sensors, and 12 adjoining impedance segments, each of 2 cm (Unisensor AG catheter, Attikon Switzerland). The catheter was positioned trans-nasally with sensors straddling the entire pharyngo-esophageal segment from velopharynx to proximal esophagus. A small amount of water-based lubricant was used at the tip and shaft of the catheter to assist with passage. Once positioned, the catheter was taped to the participant's cheek. The pressure and impedance data were acquired at 20 Hz (Solar Gastrointestinal acquisition unit Medical Measurement Systems, Enschede, The Netherlands). Patients were seated upright/semi-reclined for all swallows. The swallow material was offered via syringe or spoon and cervical auscultation was used to confirm swallow onset following bolus administration to the mouth. Liquid bolus swallows (saline 0.9% NaCl) of 2-5mls were recorded in each patient. Swallows acquired and analysed from HRIM recordings were for liquid swallows without thickener modifications. Note, the volume and number administered were determined on clinical grounds by the attending speech-language pathologist. Patient recordings were included in this study if at least 3 swallows of 2mls saline were acquired. All non-OPD controls provided at least 4 x 5ml liquid (saline 0.9% NaCl) swallows. Saline was used to enhance conductivity for reliable impedance measurements. In order to investigate the effects of age and volume on the PFA measures in this cohort patients were grouped for age (2-5yrs, 6-10yrs, 11-14yrs or 15-18yrs) and volume (2 - 3mls or 4 - 5mls).

Acquired HRIM recordings

As shown in Figure 1, pressure recordings during swallows are displayed as colour isobaric-contour plots. This provides a graphical representation of pressure changes in real time, from the velopharynx to the proximal esophagus during a swallow. Simultaneously acquired impedance measurements detect the movement of the propelled bolus through the pharynx and UES.

Pressure Flow Analysis

Following acquisition of the HRIM recordings, pressure and impedance data for each swallow were exported (csv file) and opened using purpose designed MATLAB-based software for PFA. (AIMplot.v1 software, copyright T Omari; version 7.9.0.529; MathWorks Inc., Natick, MA, USA). AIMPlot is used to derive swallow function metrics and a swallow risk index (SRI). Derivation of metrics and the SRI have been previously described (2, 13, 15-20). In brief, specific landmarks on the pressure topography space-time plot were selected (Figure 1) to define specific regions of interest (ROI) for analysis (Figure 2; online). The landmarks selected were: 1) swallow onset, 2) position of the UES proximal margin post swallow and 3) position of the velopharynx during the swallow.

Within each ROI, swallow function metrics were derived using automated algorithms. These metrics are: *pharyngeal peak pressure* (PP), defined as the maximum contraction of the pharynx during the swallow; the *pharyngeal nadir impedance* reading (NI), defined as a marker of the centre and diameter of the main body of the swallowed bolus; the *pressure at nadir impedance* (PNI), defined as the intra bolus pressure during maximal pharyngeal distension; the *time interval from nadir impedance to peak pressure* (TNIPP), measuring the time from bolus distension of the pharynx to the maximum pharyngeal contraction during the

stripping wave; and the *flow interval* (FI), defining pharyngeal bolus dwell time (15). Additionally, we measured the *UES nadir impedance* (UESNI) as a marker of UES opening diameter (13), and the *UES Resistance* (UESRES) defined by UES intrabolus pressures over the relaxation period (14). The post-swallow impedance ratio (PSIR) is an integrated ratio that relates post-swallow impedance to the impedance during pharyngeal bolus passage. PSIR has previously been shown to elevate with post swallow pharyngeal residue seen on VFSS (20).

The swallow risk index (SRI) is a separate composite score derived from four key swallow metrics previously found to differ in relation to aspiration risk (14). The SRI validation studies used simultaneous VFSS and HRIM with AIMplot analysis and showed a significantly higher SRI in patients with penetration-aspiration compared to patients without penetration or aspiration (13, 14). Therefore, the SRI aims to quantify the overall level of swallowing dysfunction potentially predisposing to aspiration risk. This study provides the first non-OPD pediatric reference range data for the SRI. Using estimated marginal means with 95% confidence intervals, the cut off for normality for these data is < 8.

The SRI is derived by the following formula:

$$SRI = \frac{FI \times PNI}{PP \times (TNIPP + 1)} \times 100$$

All swallow function metrics investigated in this work are summarised in Table 1; online.

Clinical Measures of Swallowing Dysfunction

A speech-language pathologist not involved in routine care of the participants independently reviewed the medical records, interviewed the primary care givers and performed the Dysphagia Disorders Survey (DDS) assessment to determine the DDS scores, Functional Oral Intake Scale (FOIS) score and aspiration status for each patient as described below.

Dysphagia Disorders Survey

The DDS was completed within one week of the HRIM recording. The DDS is a standardised dysphagia assessment tool used internationally for children 2 years and above (19). This two part test provides a raw score and equivalent Disability percentile rank based on binary scored items of feeding competency (for liquids, separate to chewable, separate to non-chewable food types). Note, the higher the DDS score, the greater the dysfunction. Specific items 13 (Oro-pharyngeal swallow) and 14 (Post-swallow) of the DDS were also used to dichotomously define presence/absence of clinical signs of OPD during liquid swallows (based on observations of 'promptness' of swallow response, gagging, multiple swallows for a single liquid bolus, presence of cough, and/or wet breath/voice sounds).

Functional Oral Intake Scale

Functional Oral Intake Scale (FOIS) is a standardised benchmarking method indicating tolerance of consistencies based on clinical recommendation/intervention (20). Level 1 = nil by mouth; 2= tube dependent with minimal attempts of food or liquid; 3 = tube supplements with consistent oral intake of food of liquid; 4 = total oral diet of a single consistency; 5 = total oral diet of multiple consistencies but requiring special preparation or compensations; 6 = total oral diet with multiple consistencies without special preparation, but with specific food limitations; 7 = full oral diet, no restrictions. The patient group was then dichotomously grouped 1-3 or 4-7 as patients with FOIS 1-3 were tube dependent. Note that a score of 1-3 indicates children with most severe oral intake restrictions. Separately, fluid restrictions (use of thickener) were also dichotomously assessed.

Aspiration Status

Aspiration status from non-concurrent VFSS was a secondary outcome measure. Patient data were included if the VFSS was performed within 12 weeks from HRIM investigations. Aspiration status was a binary retrospective measure based on clinical VFSS reports. Most clinical reports included Penetration Aspiration Scale scores which were independently reviewed for aspiration status by a speech-language pathologist who did not participate in the acquisition of VFSS or generation of reports. Patients were deemed aspirators if the clinical report outlined at least one episode of aspiration with thin fluids for all but one participant. For this one participant, thin fluids were not assessed as mildly thickened fluids were silently aspirated; this participant was included as an aspirator.

STATISTICAL ANALYSIS

All AIMplot software derived swallow function measures were averaged for each of the participants and non-OPD controls. A statistics package (IBM Corp. Released 2013. IBM Statistical Package for the Social Sciences (SPSS) Statistics for Windows, v. 22.0 Armonk, NY: IBM Corp) was used to investigate the data. Measurements were predominantly non-parametric therefore log transformations were completed prior to comparisons. DDS scores, as the only continuous outcome measure, were normally distributed for this cohort. Correlations used Pearson or Spearman's Rho Ranks; Group comparisons were based on Univariate Analysis, see Table 3; and Binary Logistic Regression was used for odds ratios and predictive values. Manual Bonferroni adjustments were calculated for all correlations ($p<0.005$) and SPSS Holm-Sidak adjusted p-values are quoted for multiple comparisons. A p-value <0.05 was considered to indicate statistical significance.

RESULTS

Patient Details

There were 45 OPD patients recruited for this study on the background of suspected or established aspiration risk (26 male: 19 female; mean patient age: 5yrs, range 2 – 18 years).

Of these participants, 15 had a neurological diagnosis [cerebral palsy (8); neurodegenerative disorders (3); acquired brain injury (1); metabolic disorders (2); CHARGE syndrome with tracheostomy (1)]. In addition, 15 patients presented with global developmental delays. There were 7 patients with other medical conditions predisposing to aspiration risk: cardiac conditions (3); and 4 with structural abnormalities [repaired tracheoesophageal fistula + esophageal atresia (1); laryngeal cleft (1); aberrant subclavian artery (1); and cleft palate repair (1)]. Additionally there were 8 children with no known cause for dysphagia symptoms. There were 34 non-OPD controls (13 male: 21 female; mean age 12yrs; range 2-18 years). These participants were recruited following clinical referral for lower esophageal investigation (e.g. gastro-esophageal reflux or rumination, or suspicion of esophageal motility disorder). These patients had no history of oropharyngeal dysphagia and/or aspiration and did not demonstrate overt signs or symptoms of OPD.

Relationship between Clinical Measures of Swallowing Dysfunction and PFA measures

The relationships amongst PFA measures, DDS score, DDS criteria for clinical signs of OPD, FOIS, patient age and bolus volume are presented in Table 2. A higher DDS, presence of OPD signs and lower FOIS correlated significantly with PFA measures of dysfunction. Smaller volumes were swallowed by patients of younger age and/or more severe dysphagia. Therefore, patient age and bolus volume were included as co-variates for all subsequent group comparisons based on clinical signs of OPD to ensure the PFA measures investigated were significant beyond these effects.

An overall comparison of controls and patients revealed four key differences in PFA measures; see Table 3. The SRI, a global measure of dysfunction, and the PSIR, marking post-swallow residue, were both significantly higher in patients vs. controls ($p<0.05$ and

$p<0.01$ respectively). Of individual PFA metrics, the FI was significantly longer ($p<0.05$) and the UESNI was significantly higher ($p<0.01$) in patients.

Amongst OPD patients, UES measures differentiated the patients with clinical signs of OPD on the DDS from those without clinical signs of OPD. Specifically, patients with clinical signs for OPD had higher UESRES and significantly higher UESNI compared to controls ($p<0.01$). UESNI identified patients who did not show signs of OPD ($p<0.05$). These findings are consistent with reduced relaxation and UES opening and contribute to OPD symptoms (Table 3).

Eleven OPD patients exhibited a FOIS of 1-3. These patients had a significantly higher UESRES, higher UESNI, and shorter TNIPP compared to non-OPD controls ($p<0.05$ for each respectively). Of the 45 OPD patients, 28 were recommended for thickened fluids as a management strategy for aspiration prevention. The PFA measures were not altered in these patients compared to patients taking thin liquids. A correlation between individual thickener levels and PFA metrics was intended, however of the patients whose thickener level was obtainable, the group sizes were unbalanced. The majority of patients were receiving nectar-thick fluids, while only 2 patients were receiving honey-thick and only a single patient was receiving spoon-thick fluids. The data were insufficient to allow comparisons for differences amongst the different thickener levels.

There were 14 patients (31%) with an SRI above the upper confidence interval boundary measured for controls (SRI >8). A raised pharyngeal intra-bolus pressure (PNI) was the only one of the four key PFA metrics used to derive the SRI to be significantly associated with clinical signs of OPD. Patients with an abnormal PNI were 9 times more likely to have clinical signs of OPD (Table 4). Regarding UES metrics, abnormal findings for UESRES and

UESNI were also significantly associated with clinical signs of OPD (Odds Ratio 9.7, p = 0.016 and 7.6, p = 0.023 respectively).

Aspiration status was gathered from clinical VFSS reports (performed within 12 weeks of HRIM study). Aspiration status could only be determined for 19 of 45 OPD patients. Of these 19 patients, 10 showed no aspiration. Six of these 10 patients were reported to present with penetration only. Nine of the total 19 patients were reported to have aspiration of thin fluids. No PFA measures differentiated patients reported to be aspirating from those who did not aspirate on previous VFSS. Furthermore, presence of DDS signs of OPD or FOIS did not significantly differentiate aspirating patients from non-aspirating patients (Fisher exact test p= 0.09, and p=1.00, respectively).

DISCUSSION

In this study we correlated objective PFA measures of swallowing function with clinically recognised signs of OPD in a heterogeneous cohort of children recruited with suspected or established aspiration risk. The majority of children with clinical signs of OPD had diagnosed neuro-myogenic conditions, such as cerebral palsy, muscular dystrophy, or clinically reported global developmental delays. OPD patients had higher SRI and PSIR, which are global PFA parameters consistent with greater risk of swallowing dysfunction.

Participants with and without clinical signs of OPD were assessed using PFA swallow metrics as a method to objectively quantify pharyngeal and UES motility and bolus flow patterns. The SRI, which defines overall pressure flow dysfunction, was abnormal (>8) in 25% of the patient cohort. Of the four key metrics used to calculate the SRI, abnormal pharyngeal intra-bolus pressure (PNI) was the only measure significantly linked to the incidence of clinical symptoms of OPD. Elevated pharyngeal intra-bolus pressure (as measured with PNI) is a marker of flow resistance when pharyngeal propulsion is adequate. Given that the majority of

patients (66 %) in this cohort presented with pharyngeal pressures suggestive of normal pharyngeal propulsion, the elevated PNI were most likely a consequence of resistance at the level of the UES. Results for PFA metrics specific to the UES high pressure zone provide further evidence of UES dysfunction. Patients with clinical signs of OPD and a poor functional oral intake score (FOIS score 1-3) showed residual UES pressures and significantly higher UES impedance recordings during bolus flow. These markers indicate restricted UES opening (23, 24).

Resistance at the level of the UES during swallowing is a clinically important finding as it increases the risk of mid or post-swallow aspiration and/or post-swallow residue in particular at the level of the pyriform sinuses. Consequently, assessment of UES dysfunction is considered essential for therapeutic decision making (27, 28). Whilst we demonstrate objective evidence that UES dysfunction is prevalent in this pediatric OPD cohort, there is conjecture regarding the prevalence of UES dysfunction in pediatric dysphagia. The literature is limited and mostly focused on previous case studies of extreme pathologies such as cricopharyngeal achalasia or in relation to hypertrophy and/or hyperactivity of the CP muscle secondary to gastroesophageal reflux disease (GORD) (25-30). Our data suggest that PFA metrics, specifically within the UES high pressure zone, may provide greater confidence for assessing and directing treatments for impaired UES opening.

Whilst PFA results from this study have demonstrated clear features of UES dysfunction in this pediatric cohort we acknowledge some limitations: HRIM recordings were performed without simultaneous VFSS which could provide an indication of lingual propulsion, hyolaryngeal excursion and reliable aspiration status. The aspiration status used in this study was included retrospectively as a secondary measure of clinical interest. Aspiration status may have varied between VFSS and HRIM studies (up to 12 weeks apart). Whilst there were

some weak correlations between PFA metrics and DDS scores/FOIS scores, we note that presence of DDS signs of OPD or FOIS did not significantly differentiate aspirating patients from non-aspirating patients. In the context of these limitations we also acknowledge the SRI did not differentiate aspirators and non-aspirating patients in this study. However, the main intention for this study was to focus on established clinical assessments, not radiological measures. We also note that a previous pediatric study with simultaneous VFSS and HRIM was able to show significantly different SRI results between aspirating and non-aspirating patients (2). Another limitation is that the non-OPD control group were not age matched to the OPD patient group. A true pediatric control group is not possible to obtain for ethical reasons; therefore children referred for clinical investigation of lower esophagus were included as pharyngeal controls and age matching was not possible. While volume effects have previously been demonstrated, showing increased pharyngeal peak pressure with increased bolus volume (16); in this study bolus volumes could not be standardised due to differences in age, size and OPD severity. To address this limitation, volume and patient age were included as covariates for statistical analysis. We intend to stratify the etiology for OPD in future cohorts, and investigate the types of clinical signs of OPD; however such statistical analysis was not reliable within this small sample size.

In conclusion, PFA is a promising research tool that may, in the future, be able to clinically assess pharyngeal and UES motor function during swallowing. HRIM is mobile and can be used at the bedside or in a community clinic setting. PFA offers objective profiling of bolus timing and efficiency of bolus clearance with integrated recordings of pressure activity in the pharynx and UES. PFA findings suggest a higher prevalence of UES dysfunction in pediatric OPD patients, which could be targeted for therapy.

FIGURES AND TABLES

Figure 1. Schematic of catheter in situ with illustration of pressure sensors detecting isobaric contour pressure plot with embedded impedance waveforms (pink lines). Specific landmarks are labelled 1: swallow onset; 2: proximal margin UES post swallow, and 3: position of velopharynx.

Figure 2; online. The isobaric contour pressure plot showing ROI 1 to calculate PP, PNI and TNIPP; ROI 2 to calculate FI; and ROI 3 to calculate UESNI and UESRES.

Table 1; online. Summary of Pressure Flow Analysis Swallow Function Metrics and Aggregate Scores (SRI and PSIR).

Table 2. Correlation of PFA measures with key study outcome measures: DDS raw score, DDS clinical signs, and FOIS. Data presented are R values for Spearman Rank or Pearson correlations (bold). Significance *** $p<0.005$ following Bonferroni adjustment for multiple correlations.

Table 3. Comparisons in relation to PFA measures for controls vs. patients; and in relation to Clinical Signs of OPD and Management Outcomes indicated by the FOIS. Data are estimated marginal means [95% Confidence Interval] compared using univariate analysis with age and volume as co-variables (with Sidak pairwise adjustments for multiple comparisons). [a]Patient group significantly different to control group. [b,c]Pairwise significance vs. controls [(b)] or No overt signs OPD/No aspiration[(c)]. ([a,b,c] $p<0.05$, [aa,bb,cc] $p<0.01$). Overt Signs OPD for liquid swallows according to the Dysphagia Disorders Survey (DDS) (21) i.e. presence of cough, wet breath/voice quality, multiple swallows, and/or delayed swallow sounds on cervical auscultation. Aspiration Presence based on VFSS conducted at WCH within a 12 week window from HRIM study. Oral Intake Status based on FOIS (22).

Table 4. Stratification of patients with/without OPD signs and symptoms based on normal/abnormal findings for key PFA metrics, which contribute to the SRI. Odds Ratios based on Binary Logistic Regression with age, volume and normal/abnormal PFA measures as co-variables.

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