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## **Effect of Bolus Volume and Viscosity on Pharyngeal Automated Impedance Manometry Variables Derived for Broad Dysphagia Patients**

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**Abbreviations:**

<i>Peak P</i>	peak pressure
<i>PNadImp</i>	pressure at nadir impedance
<i>TNadImp-PeakP</i>	time from nadir impedance to peak pressure
<i>SRI</i>	swallow risk index
<i>UES</i>	upper esophageal sphincter
<i>UES RI</i>	UES relaxation interval
<i>NadUESP</i>	UES nadir relaxation pressure
<i>UES IBP</i>	UES intrabolus pressure
<i>PAS</i>	penetration-aspiration scale

## **Abstract**

**BACKGROUND:** Automated Impedance Manometry analysis (AIM) measures swallow variables defining bolus timing, pressure, contractile vigour and bolus presence which are combined to derive a swallow risk index (SRI) correlating with aspiration.

**AIM:** In a heterogeneous cohort of dysphagia patients, we assessed the impact of bolus volume and viscosity on AIM variables.

**METHODS:** We studied 40 patients (average 46 years). Swallowing of boluses was recorded with manometry, impedance and videofluoroscopy. AIMplot software was used to derive functional variables; peak pressure (PeakP), pressure at nadir impedance (PNadImp), time from nadir impedance to peak pressure (TNadImp-PeakP), the interval of impedance drop in the distal pharynx (flow interval), UES relaxation interval (UES RI), nadir UES pressure (NadUESP), UES intrabolus pressure (UES IBP) and UES resistance. The SRI was derived by the formula;

$$SRI = (FI * PNadImp) / (PeakP * (TNadImp - PeakP + 1)) * 100.$$

**RESULTS:** 173 liquid, 44 semisolid and 33 solid boluses were analysed. The SRI was elevated in relation to aspiration. Peak P increased with volume. SRI was not significantly altered by bolus volume. PNadImp, UES IBP and UES resistance increased with viscosity. SRI was lower with increased viscosity.

**CONCLUSIONS:** In patients with dysphagia, the SRI is elevated in relation to aspiration, reduced by bolus viscosity and not affected by bolus volume. These data provide evidence that pharyngeal AIM analysis may have clinical utility for assessing deglutitive aspiration risk to liquid boluses.

**KEY WORDS:** Respiratory aspiration; deglutition disorders; manometry; electric impedance.

## **Introduction**

Pharyngeal automated impedance manometry (AIM) analysis is a new methodology which can be used to analyze the patterns of flow and pressure generated during bolus swallowing. AIM analysis derives pharyngeal pressure-flow variables which are objective markers of deglutitive function and are altered in relation to ineffective swallowing and aspiration risk (1-4). Although the analysis methods are complex, they are simple to apply using a software platform such as *AIMplot* (4) which renders to the background any methodological complexity, whilst at the same time presenting outcomes in terms of numerical measures which can be compared to reference ranges to detect abnormality and predict aspiration risk through derivation of a swallow risk index (SRI) (2-4). AIM analysis also has high intra-rater and inter-rater reproducibility for derivation of pharyngeal pressure-flow variables and the SRI (4) and may therefore have clinical utility as an objective, reliable, non-radiological method for assessing deglutitive function.

With impedance-manometry becoming more readily available and the measurements obtained more standardised, due to solid state sensing within a standard catheter configuration, there is a greater opportunity for this technique to be used independently of videofluoroscopy. Videofluoroscopy is not always readily available and there can be inherent difficulties in achieving good quality studies in patients with mobility and neuro-cognitive impediments. Such patients could potentially benefit from AIM analysis which could be used in conjunction with routine clinical assessment of swallowing at the bedside.

It is well understood that, during normal swallowing, mechanisms of bolus propulsion and clearance adjust in relation to volume and viscosity of the bolus to be swallowed (5, 6). It is therefore reasonable to assume that bolus volume and consistency may influence pharyngeal AIM measurements. Furthermore the presence of structural resistance to bolus passage may also produce different results as has been demonstrated with manometry (7-10). We therefore assessed the impact of bolus volume and bolus viscosity in a broad cohort of patients with pharyngeal dysphagia who were referred for videofluoroscopy.

## **Methods**

### *Subjects*

A review of patients who were referred to the swallowing clinic at University Hospitals Leuven for a video-impedance-manometry study of the pharynx and esophagus was undertaken. Patients were included if they were administered boluses of at least two different consistencies or had received liquid boluses of 5ml and 10ml volume. This identified 40 dysphagic patients (24 males, mean age 46 yrs, age range 23-95 yrs). Underlying diseases/conditions were identified through a review of medical records. Eighteen patients had a neurological history (10 stroke and 2 Parkinson's disease, 1 Huntington's disease, 1 multiple sclerosis, 2 dementia, 1 spina bifida, and 1 post neurosurgery). Eight patients had underlying gastrointestinal disease (oesophageal motility disorders, GERD). Four patients had an oropharyngeal tumor. Six patients had pulmonary disease (COPD, lung abscess, pneumonia). The remaining four patients were post cervical surgery, Wegener disease, post septic shock and a diabetic. At the time of initial investigation, all patients were enrolled in study protocols that were approved by the Research Ethics Committee, University Hospitals Leuven, Belgium.

### *Measurement Technique*

Studies were performed in the Radiology Department, University Hospitals Leuven with a 3.2mm diameter solid state manometric and impedance catheter incorporating 25 1cm-spaced pressure sensors and 12 adjoining impedance segments, each of 2 cm (Model K102532-E-08XX, Unisensor USA Inc, Portsmouth, NH). Subjects were intubated after topical anaesthesia (lignocaine spray) and the catheter was positioned with sensors straddling the entire pharyngo-esophageal segment (velopharynx to proximal esophagus). Pressure and impedance data were acquired at 20Hz (Solar GI acquisition system, MMS, The Netherlands) with the patient sitting upright.

All patients were tested with liquid boluses (10 receiving only 5ml and 30 receiving both 5 and 10ml), 38 and 31 were also tested with semisolid and solid boluses respectively. The bolus

consistencies were standardised. A standard liquid contrast material (MicropaqueH™) was given as liquid bolus and used with thickener (Thick & Easy™ ) for semisolid boluses. A low osmotic hydrosoluble iodine compound (UltravistH™) was used when aspiration was suspected. The viscosity of the administered boluses was determined by a Rheomat 115 Viscometer. The Bingham viscosity of the liquid Barium (MicropaqueH™) was 0.22PA s and 450 PA s for the semisolid bolus. All bolus stock contained 1% NaCl to enhance conductivity.

### *AIM analysis*

Manometric recordings of swallows were reviewed and exported in text data format. Double swallows with a second swallow occurring within 2.0sec of the primary swallow were excluded at this point. Swallows followed by cough were not excluded.

AIM analysis of text data files was performed using *AIMplot*, a purpose-designed MATLAB-based analysis program developed to increase the applicability of the methodology for routine use (4).

Note: pressure and impedance data were smoothed by a cubic interpolation method which doubled the temporal data and increased the amount of spatial data by a factor of 10 (pressure) and 20 (impedance), hence achieving a virtual increase from 1 pressure and 0.5 impedance values per 1 cm sampled every 5msec (20Hz) to 10 pressure and impedance values per cm sampled every 2.5msec (40Hz).

To operate *AIMplot* the observer was required to define three space-time landmarks from a standard pressure iso-contour plot of the pharyngeal swallow. These were:

- i. The time of onset of pharyngeal swallow; defined by the onset of upper esophageal sphincter (UES) relaxation often associated with a proximal excursion of the UES high pressure zone.
- ii. The position of the UES proximal margin immediately post pharyngeal swallow.
- iii. The position of the velopharynx; defined as the pressure zone immediately above the propagated pharyngeal stripping wave.

Guided by definition of these landmarks, *AIMplot* then was able to automatically derive four pharyngeal pressure-flow variables based on our established methodology (1-4).

Pressure flow variables were as follows:

- a. time from nadir impedance to peak pressure (TNadImp-PeakP). This variable measures the time delay from maximum distension of the pharynx by the bolus and peak pharyngeal contraction and is a marker of strength of bolus propulsion.
- b. pressure at nadir impedance (PNadImp). This variable can be considered as equivalent to pharyngeal intrabolus pressure.
- c. peak pharyngeal pressure (PeakP).
- d. bolus flow interval (flow interval). This variable is an estimation of the duration of impedance drop within the distal pharynx using a curve shape analysis.

All four variables were then combined to derive a swallow risk index (SRI) which provides a global assessment of swallow function and aspiration risk. The SRI for each swallow was derived by the formula:

$$SRI = \frac{(sec \text{ flow interval} * mmHg \text{ PNadImp})}{(mmHg \text{ PeakP} * (sec \text{ TNadImp-PeakP} + 1))} * 100$$

In patients with a neurological basis for their dysphagia, an average SRI > 15 for liquid swallows has been determined to be the optimal cut-off criteria for detection of level of swallowing dysfunction predisposing to aspiration risk (2).

#### *UES Relaxation Variables*

UES relaxation characteristics were measured using the established method of Ghosh et al., 2006 (11) which objectively calculated UES relaxation interval (UES RI), the UES nadir relaxation pressure (NadUESP), the median intrabolus pressure (UES IBP) and the UES resistance (calculated as UES IBP/UES RI).



### *Fluoroscopy Analysis*

Fluoroscopic images of all swallows were blindly scored by an expert analyst (speech pathologist) for the occurrence of aspiration. A validated 8-point penetration-aspiration scale (PAS) (12), was used to assess the depth to which material passes in the airway and by whether or not material entering the airway is expelled during the swallow sequence (PAS score 1 = no aspiration, 2-5 = penetration, 6-8 = aspiration). Swallows of poor image quality, as determined by the expert analyst, were not included for analysis.

### *Statistical analysis*

Data gathered from multiple individual swallows recorded within different study patients were averaged and compared. Grouped data were non-parametric and therefore presented as medians [inter-quartile range]. The Mann-Whitney Rank Sum Test and, for multiple comparisons, Kruskal-Wallis ANOVA on ranks with pair-wise multiple analysis procedures (Dunn's method) were used. Paired data for 5ml vs 10ml volume were compared using Wilcoxon Signed Rank Test. Comparisons amongst patients receiving all bolus consistencies were performed using Friedman Repeated Measures Analysis of Variance on Ranks and Pairwise Multiple Comparison Procedures (Tukey Test). Prognostic value and agreement was determined through calculation of sensitivity, specificity and Cohen's kappa statistic ( $\kappa$ ). The scale for  $\kappa$  values is: 0.00 = no agreement, 0.00 – 0.2 = slight, 0.21-0.40 = fair 0.41-0.60 = moderate, 0.61-0.8 = substantial, 0.81-1.00 = almost perfect.

## Results

### *Bolus Volume and Consistency*

A total of 173 liquid boluses (99 x 5ml and 74 x 10ml), 44 semisolid and 33 solid boluses were analysed. The effect of volume could only be assessed for liquid boluses. In the 30 patients who received both 5ml and 10ml liquid, Peak P was the only individual variable that was altered in relation to volume with peak pressure significantly higher with the larger volume (Table 1). SRI was not significantly altered by bolus volume (Figure 1A). In the 31 patients who received all three bolus consistencies (data shown in Table 1), PNadImp, UES IBP and UES resistance were significantly increased with increased viscosity (ANOVA  $p=0.023$ ,  $p=0.002$ ,  $p=0.009$  respectively) and SRI was lower with increased viscosity (ANOVA  $p=0.024$ ) (Figure 1B).

### *Fluoroscopy Defined Penetration-Aspiration*

Thirty patients demonstrated penetration-aspiration on fluoroscopy (12 with penetration and 18 with aspiration of whom 11 had a maximum recorded PAS of 8). For liquid boluses, patients demonstrating penetration-aspiration had a higher PNadImp, shorter TNadImp-PeakP and longer flow interval during swallowing (Table 2). For semisolid boluses, PNadImp and TNadImp-PeakP were still significantly different and, for solid boluses, only TNadImp-PeakP was significantly different in relation to penetration-aspiration (Table 2). The SRI was significantly elevated in relation to penetration-aspiration for liquid and viscous boluses and, whilst elevated, did not reach statistical significance for solid boluses (Figure 1C). For liquid and semisolid swallows, higher SRI correlated with maximum PAS (Spearman Rank correlations  $r = 0.627$   $p<0.0001$ ,  $r = 0.334$   $p<0.05$ , respectively). For liquid boluses, current AIM based diagnostic criteria predictive of aspiration risk (SRI >15 for neurologically-based dysphagia) had and sensitivity/specificity of 0.70/0.82 and Kappa of 0.504 (moderate agreement) for detecting penetration to the level of the vocal cords (PAS 4+).

### *Effect of Swallow Number on Average SRI*

As our assessments to date have been based upon the average SRI determined from repeated swallows, we evaluated the reliability of averaging the SRI across increasing numbers of swallows. We based this assessment on data from a subgroup of 19 patients who had received five or more liquid boluses during videofluoroscopic assessment. Figure 2A shows the average SRI in relation to the number of swallows used to calculate it. Using diagnostic criteria of average SRI > 15 for predicting aspiration Figure 2B shows the level of agreement (Kappa) between the average SRI calculated for between 1 and 5 swallows and the average SRI determined for all swallows recorded in that patient. This analysis indicated that a minimum of four repeated swallows produces a reliable result ( $\kappa = 1.0$ ) for average SRI being above or below 15 (Figure 2B).

## Discussion

We measured pharyngeal pressure flow variables using AIM analysis in a heterogeneous group of pharyngeal dysphagia patients. Bolus volume and consistency increased some variables such as pharyngeal peak pressures and pressure at nadir impedance. Importantly, the global assessment of swallow function based on the calculation of the swallow risk index appeared less affected by bolus volume than viscosity and was elevated in patients with aspiration. In terms of clinical application, a reliable estimate of the SRI was achieved through the measurement of four or more liquid swallows.

This study confirms our previous findings that the SRI is elevated in relation to aspiration during liquid swallowing (2-4). SRI calculation takes into account several different measures of function and therefore potentially delivers an accurate global assessment of aspiration risk, even though, as is clearly the case in the studied cohort, the pattern of functional impairment may differ from patient to patient. One of the potential advantages of using multiple variables to generate a global index is that the overall influence of bolus related factors is reduced. By way of example, when bolus volume is increased variables such as Peak P and PNadImp (intrabolus pressure) are also likely to increase. However the net effect on the SRI is lessened by virtue of the fact that increasing the Peak P (SRI denominator) drives *down* the SRI whilst increasing the PNadImp (SRI numerator) drives *up* the SRI. We hypothesise that an abnormal liquid SRI finding is a true marker of aberrant swallowing and aspiration risk, irrespective of the bolus volume administered. We believe that our data support this however further studies are clearly needed in more homogeneous patient populations.

A major strength of the AIM analysis method is that it can be used independently of radiology, thus offering potential as a screening tool and allowing greater scope for swallow assessment in terms of the number and type of boluses that can be evaluated. However, whilst removing the constraints of radiological exposure, a conservative protocol of bolus administration may still be needed as dysphagic patients may be aspirating silently without any obvious clinical signs or symptoms. Our

experience to date suggests that combined impedance-manometry procedures are very well tolerated by dysphagic patients of all ages. In practise it may be possible to assess aspiration risk relatively quickly using a small number of liquid boluses which can be analysed with the catheter in situ. Subsequent to safe swallowing being determined, different bolus consistencies, swallowing manoeuvres and treatment regimes may then be employed.

We have previously observed that averaging the SRI calculations across multiple liquid swallows improves diagnostic accuracy (2). Our current findings show that the administration of 4-5 liquid boluses will produce an average SRI that is reliable for our current optimal predictor of dysfunction predisposing to liquid aspiration risk. With limited data from patients who aspirate semisolids and solids we are unable to say if the approach will in the end distinguish patients who aspirate these boluses with the same degree of prognostic accuracy as appears to be possible when using liquid boluses. However confirmation of a significant improvement in the SRI with thickened liquid, semisolid and solid boluses may be suggestive that a treatment strategy involving increasing bolus consistency may be of benefit. The effect of altering bolus consistency, in conjunction with specific swallowing manoeuvres, is currently under investigation.

Our study has some clear limitations in terms of a heterogeneous study cohort who underwent clinical investigation based upon the judgement of the attending specialist without a standardise protocol for bolus administration. As the primary clinical focus for fluoroscopic assessment was to determine aspiration risk on liquids, patients were given fewer (one or two) semisolid and solid boluses and this may have introduced the possibility of a Type 1 error with respect to variables that were not found to be statistically different in relation to bolus type. There was also no scope to assess volume effects of these more viscous boluses. Furthermore use of uni-directional pressure sensing may have influenced some of the parameters measured, particularly within the region of the UES high pressure zone which has been shown to demonstrate radial asymmetry (13). Nevertheless we were able to demonstrate significant changes in some parameters which allow confidence in these data. Most importantly we observed increased Peak P in relation to volume which has been

previously shown to increase with bolus volume (5, 6). As has already been shown, using combined high-resolution manometry and videofluoroscopy, intra-bolus pressures in particular are elevated in the presence of pathology that limits opening of the UES (7, 9, 10). Such patients were not well represented in our patient cohort and the impact of obstruction of AIM variables and the SRI is currently the subject of ongoing study. Hence our findings are consistent with physiological/pathophysiological expectations, despite there being inconsistencies in the protocol used for data capture in different patients.

The SRI cut-off that is most clinically relevant to patients with different pathologies still needs to be defined. Whilst we have defined an SRI >15 as being optimal for detecting aspiration risk in patients with a neurologically-based dysphagia (2, 4), we have purposefully chosen not to explore further diagnostic criteria until such time as we have sufficient data from patients with other dysphagia-causing diseases. Nevertheless we are encouraged that it may be possible to establish an SRI criterion that can be universally applied across different pathologies.

In conclusion we show that the SRI calculated in relation to liquid swallows was higher in patients with dysphagia who were found to demonstrate penetration-aspiration on radiology. Increased bolus viscosity reduced the SRI whilst the SRI to 5ml and 10ml liquid boluses was not different. Pharyngeal AIM analysis may allow assessment of deglutitive dysfunction in a broad range of patients with pharyngeal dysphagia.

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	<b>Liquid Bolus 5ml vs 10ml</b>		<b>Liquid Bolus</b>	<b>Semisolid Bolus</b>	<b>Solid Bolus</b>
	<b>5ml</b>	<b>10ml</b>			
Peak P mmHg	<b>130</b> [76, 200]	<b>136*</b> [85, 232]	<u>164</u> [96, 215]	<u>147</u> [97, 208]	<u>159</u> [102, 218]
PNadImp mmHg	22 [11, 33]	21 [15, 46]	<b><u>21</u></b> [15, 46]	<b><u>26#</u></b> [13, 35]	<b><u>30</u></b> [13, 38]
TNadImp-Peak msec	248 [189, 376]	288 217, 411]	<u>306</u> [200, 369]	<u>282</u> [169, 373]	<u>271</u> [228, 354]
Flow Interval msec	1308 [556, 1789]	1090 [542, 1577]	<u>1126</u> [631, 1473]	<u>923</u> [438, 1274]	<u>677</u> [288, 1283]
UES RI msec	715 [444, 980]	743 [500, 857]	<u>676</u> [455, 833]	<u>555</u> [359, 856]	<u>618</u> [486, 732]
UES IBP mmHg	21 [14, 30]	22 [16, 31]	<b><u>19</u></b> [13, 25]	<b><u>22</u></b> [13, 30]	<b><u>25#</u></b> [20, 34]
NadUESP mmHg	10 [4, 17]	11 [4, 18]	<u>10</u> [6, 18]	<u>8</u> [4, 19]	<u>12</u> [4, 26]
UES resistance mmHg/sec	26 [16, 55]	31 [15, 61]	<b><u>32</u></b> [20, 56]	<b><u>36</u></b> [18, 74]	<b><u>37#</u></b> [26, 108]

**Table 1. Effect of bolus volume and consistency on swallow function variables.** Data presented as median [IQR]. Data for 5ml vs. 10ml liquid are shown for patients who received both bolus volumes during fluoroscopy (n=30 patients). \*5ml liquid significantly different to 10ml liquid using Wilcoxon Signed Rank Test

( $p < 0.05$ ). Data for liquid, semisolid and solid boluses are only from who received all three bolus consistencies during fluoroscopy (n=31 patients). Variables with significant bolus-related effects using Friedman Repeated Measures Analysis of Variance on Ranks are shown in bold, # indicates significantly different to liquid bolus ( $p < 0.05$ ) using Pairwise Multiple Comparison Procedures (Tukey Test).

	<b>Liquid Bolus</b>		<b>Semisolid Bolus</b>		<b>Solid Bolus</b>	
	<b>No Aspiration</b>	<b>Aspiration</b>	<b>No Aspiration</b>	<b>Aspiration</b>	<b>No Aspiration</b>	<b>Aspiration</b>
Peak P mmHg	147 [86, 194]	104 [87, 224]	126 [97, 217]	138 [89, 198]	153 [99, 234]	159 [107, 218]
PNadImp mmHg	15 [11, 18]	36** [17, 57]	19 [4, 23]	27* [13, 39]	21 [15, 33]	31 [12, 39]
TNadImp-Peak msec	342 [311, 398]	235(0.065) [156, 364]	375 [281, 421]	255* [166, 356]	380 [290, 449]	253** [162, 283]
Flow Interval msec	596 [454, 652]	1429*** [1068, 2091]	810 [304, 1325]	1153 [707, 1410]	745 [338, 849]	648 [288, 1410]
UES RI msec	780 [718, 949]	595 (0.070) [428, 876]	635 [440, 813]	555 [356, 1006]	647 [611, 730]	590 [300, 791]
UES IBP mmHg	19 [17, 24]	21 [13, 27]	17 [12, 28]	27 [13, 32]	28 [21, 36]	25 [20, 34]
NadUESP mmHg	9 [6, 11]	12 [5, 19]	8 [6, 10]	8 [2, 22]	12 [6, 21]	14 [3, 26]
UES resistance mmHg/sec	24 [16, 38]	41 [19, 63]	29 [19, 58]	38 [18, 80]	42 [29, 57]	36 [21, 120]

**Table 2. Swallow function variables in dysphagic patients with and without penetration-aspiration.**

Data presented as median [IQR]. Aspiration defined by one or more swallow with a PAS>1 for any consistency.

\*patients with aspiration significantly different to those without aspiration using Mann-Whitney Rank Sum Test

(\*p<0.05, \*\*p<0.01, \*\*\*p<0.001, p-values 0.05-1.0 shown in parentheses).

## FIGURE LEGENDS

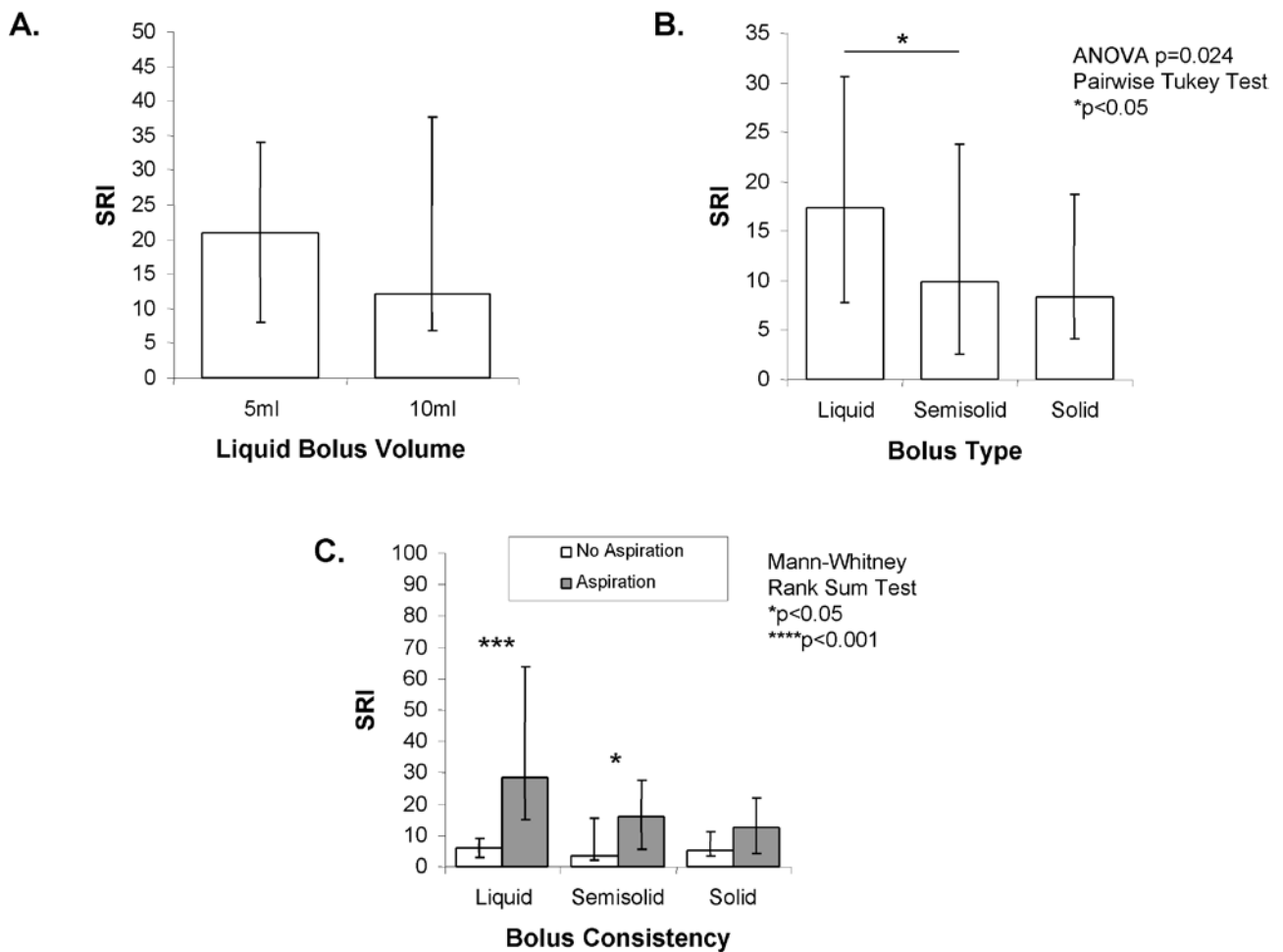
**Figure 1. Effect of bolus volume and consistency on the SRI.**

A. SRI in relation to liquid bolus volume.

B. SRI in relation to bolus consistency.

C. SRI in relation to the presence of penetration-aspiration.

Data presented as median [IQR].



**Figure 2. Effect of swallow number on the average SRI.**

A. The average SRI in relation to the number of swallows used to calculate it. Average SRI >15, used for predicting penetration-aspiration risk, shown as dotted line. B. The level of agreement (Kappa) between the average SRI calculated for 1-5 swallows being >15 and the average SRI determined for all swallows being >15. Note a minimum of four repeated swallows produces the most reliable result ( $\kappa = 1.0$ ).

