TITLE PAGE

Article title

Impact of nasogastric tubes on swallowing physiology in older, healthy subjects: a randomized controlled crossover trial

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ABSTRACT

Background & Aims: The presence of a nasogastric tube (NGT) affects swallowing physiology but not function in healthy young adults. The swallowing mechanism changes with increasing age, therefore the impact of a NGT on swallowing in elderly individuals is likely to be different but is not yet known. The aims of this study were to determine the effects of NGTs of different diameter on (1) airway penetration-aspiration, (2) pharyngeal residue, and (3) pharyngeal transit, in older healthy subjects.

Methods: Randomized controlled crossover design. Healthy elderly volunteers underwent 3 modified barium swallow studies in which multiple diet and fluid consistencies were swallowed under the following conditions: (A) no NGT (control), (B) fine bore NGT, and (C) wide bore NGT. The control condition was assessed first to establish baseline swallowing function, then NGT order was randomly allocated.

Results: Of the 15 volunteers (median age 65 years, range 60-81) complete data sets were obtained for 9 (4 with allocation order ABC; 5 with ACB). Wide bore NGT data could not be obtained for 6 volunteers mainly due to tube intolerance. The presence of a NGT was associated with: (i) an increase in airway penetration-aspiration (fine bore NGT with serial liquid swallows and puree) ($p<0.01$); (ii) increased pharyngeal residue ($p<0.05$) in the pyriform sinus (fine bore NGT with puree); and in the valleculae (both fine and wide bore NGT with soft solids); and (iii) an increase in pharyngeal transit duration regardless of consistency ($p<0.01$), with longest swallowing durations with the widest tube.

Conclusions: NGT presence increases airway penetration-aspiration, pharyngeal residue and prolongs transit through the pharynx in older healthy individuals. Consideration of NGT impact on swallowing during concurrent oral and enteral feeding is recommended, with

further systematic investigation required in elderly patients recovering from critical illness.

Keywords

Aspiration, elderly, enteral nutrition, nasogastric tube, supplemental feeding, swallowing

Abbreviations and definitions used in text

DPR – duration of pharyngeal response

DPT – duration of pharyngeal transit

DST – duration of stage transition

DUESO – duration of upper oesophageal sphincter opening

NGT – nasogastric tube

PAS – penetration-aspiration scale

RCT – randomized controlled trial

UES – upper oesophageal sphincter

Clinical trial registry

Australia & New Zealand Clinical Trials Registry (ACTRN12613000577718)

TEXT

1. Introduction

Nasogastric tubes (NGTs) are widely regarded as a safe short term strategy to administer tube feeding, hydration and/or medications to patients who are unable to eat and drink, or to maintain adequate nutrition.[1,2] Presence of a NGT however is not without complication risk.[1] Fine bore feeding tubes are assumed to be more comfortable for the patient and minimize the risk of mucosal ulceration[3] while wide bore NGTs are preferred for drainage or to check gastric residuals during tube feeding.[2]

As a patient transitions from enteral to oral feeding with improving condition and/or bulbar function, combined oral intake and NGT nutrition may be administered to increase calorie delivery. Furthermore, the timing of NGT removal is often dependent on achieving adequate oral nutrition, yet clinical experience suggests this may be difficult for some patients while the NGT remains in the pharynx.

Investigations of the impact of pharyngeal tubes (nasogastric or manometry) on the swallowing physiology of healthy volunteers[4-6] or clinical populations[7-10] are limited, with considerable methodological variation. To date evidence does not suggest that NGT presence increases aspiration risk[4-10] however the impact on swallowing physiology and function remains unclear.[4-7,10] Durational changes (i.e. a change in timing of swallowing events) associated with tube presence have been reported in two studies[5-6] with one (a randomized controlled trial [RCT] on young volunteers) documenting an effect associated with tube size – i.e. the wider the tube, the greater the change.[5] Another RCT on normal aging reported an age effect:[6] in the presence of a manometry tube, durational changes were observed amongst all age groups but in the oldest participants they noted an increased frequency of airway penetration while drinking.[6] Observed changes in swallowing patterns in the elderly may be attributed to the effects of aging on the swallowing mechanism, which is already slower, weaker, and more susceptible to airway penetration and aspiration.[11-14]

As the aging population accounts for a large proportion of hospitalised and enterally fed patients, there is a need to understand any potential impact NGTs may have on the swallowing mechanism against a background of an aging swallow. To clarify this issue, the current study was designed to assess the impact of both a fine bore NGT and wide bore NGT on swallowing in older healthy volunteers. Specific aims were to determine if NGT presence, including NGTs of different diameters, would affect: (1) airway penetration-aspiration, (2) pharyngeal residue, and (3) pharyngeal transit when swallowing multiple different food and fluid consistencies.

2. Materials and Methods

The study was a randomized controlled crossover design of fine and wide bore NGTs (control, no tube) and the effect on swallowing in older healthy volunteers. The study was approved by the Royal Adelaide Hospital Research Ethics Committee for 12 months recruitment and carried out in accordance with the Helsinki Declaration of 1975 as revised in 1983 (Australian & New Zealand Clinical Trials Registry ACTRN12613000577718).

Healthy older volunteers were recruited through advertisement, provided signed informed consent, and received an honorarium reimbursement payment for participation in the study. A total of 19 individuals were screened for inclusion although only 15 underwent testing **(Figure 1)**. Participants underwent 3 modified barium swallow studies on a single day in which swallowing was examined in each of the 3 required study conditions: (1) control - without a NGT; (2) fine bore NGT in-situ *(8French gauge, 91cm length, medical grade polyurethane, Corpak MedSystems, Wheeling, USA)*, and (3) wide bore NGT in-situ *(Levin 16Fr 125cm length, polyvinylchloride, Unomedical, Sydney, Australia)* (Figure 1). Both NGTs included in the study were selected due to their predominance of use in the participating hospital. The control condition was completed first to establish a normal baseline swallow. After the control assessment, the order of NGT insertion (fine or wide) was randomized using a random allocation set generated by the third investigator (PLC) who was independent of the data collection process. Sequential numbered opaque envelopes were pre-sealed and later opened by the testing clinician in the predetermined sequence to establish NGT insertion order (wide then fine bore, or fine then wide bore).

A cotton swab coated with 4 metered sprays of co-phenylcaine® forte (*lignocaine 5% with phenylephrine 0.5%*) was applied to the anterior nostril of each participant prior to all swallow studies, including the control. This was required to minimize discomfort on NGT insertion; however its use in the control condition was to maintain procedural consistency. A non-anaesthetic lubricant gel was used during NGT insertion by a trained health professional. Each NGT was in-situ for 20 minutes with radiological confirmation of placement prior to the modified barium swallow. There was a 30 minute break between the baseline and first experimental condition, and NGT insertions were separated by 60 minutes.

A Siemens Axiom Artis multipurpose floor unit was used to record each study in the radiology suite of the participating hospital. Digital images were stored in 300 frame loops enabling frame by frame analysis of 15 per second (i.e. 1 frame = 0.067 seconds). During each study, participants were instructed to feed themselves and swallow in a normal manner for the following consistencies: (A) 3 single sips of thin liquid, (B) serial swallows of 100ml thin liquid, (C) 3x15ml puree fruit, and (D) 3x15ml diced fruit, all mixed with liquid polibar barium sulphate suspension at ratio 2:1 for fluids, and 3:1 for solids. Liquids and solids were taken via a straw and spoon respectively. Each study was performed in the erect lateral position with neutral head position, allowing views of the oral cavity, pharynx, larynx, trachea, oesophagus and cervical spine. Screening commenced as the bolus entered the oral cavity and ceased following passage of the bolus through the upper oesophageal sphincter (UES). Study consistencies were presented in order ABCD and images saved to digital file.

Analysis included continuous and categorical data. The 8-point Penetration-Aspiration Scale (PAS)[15] was the primary outcome measure **(Table 1)** with an increase in PAS indicating a decline in airway protection. Secondary outcome measures were pharyngeal residue and duration of pharyngeal transit. Pharyngeal residue was rated using a validated 3-point severity scale[16] (*mild, moderate, severe*) which was modified to include a fourth point (*nil*). The overall duration of pharyngeal transit (DPT) and the duration of the component phases: duration of stage transition (DST), duration of pharyngeal response (DPR) and duration of upper oesophageal sphincter opening (DUESO) were calculated using previously outlined procedures and definitions.[17] Durations were calculated in seconds by multiplying the number of radiological frames per stage by 0.067 (i.e. the duration of 1 frame). Duration measures were not obtained for serial liquid swallows.

The radiographic analyses were performed by an experienced senior speech pathologist independent to the research study. This clinician received training in outcome measure definitions prior to undertaking the analysis. A second senior speech pathologist independently rated 25% of the sample, and the main clinician re-rated 25% of the sample three months later with inter and intra-rater reliability calculated using intraclass correlation coefficients for exact agreement.

Ordinal scale measures, PAS and pharyngeal residue, were analysed by non-parametric repeated measures analysis of variation (ANOVA), using the Skillings-Mack modification of the Friedman test to allow for missing data, with relevant between group comparisons using the Wilcoxon signed-rank test. Continuous measures such as pharyngeal transit durations were log-transformed prior to repeated measures ANOVA, with between group comparisons by paired t-tests. Significance was established at $\alpha = 0.05$. All analyses were performed using Stata/SE 12.1 (StataCorp LP).

3. Results

Complete data sets were collected for 9 participants (Figure 1) with 4 in one arm (control, fine bore, wide bore NGT) and 5 in the other (control, wide bore, fine bore NGT). Fifteen participants completed 2 conditions: control and the fine bore NGT. Wide bore NGT data was unavailable for 6 subjects mainly due to intolerance of tube insertion.

The median group age was 65 years (range 60-81) and 8 of the 15 participants were male. All had functional dentition and were within the normal weight range for age, with median body mass index 26.3 (range 21.1 to 29.1). All had normal speech, swallowing and oromotor function, as assessed by a speech pathologist with 10 years clinical experience (LNP).

Inter-rater reliability between clinician 1 and 2 was 1.0 (continuous data 96% exact agreement, categorical data 100% exact agreement); and intra-rater reliability for the main rating clinician was 1.0 (continuous data 98% exact agreement, categorical data 100% exact agreement).

3.1 Penetration-Aspiration Scale (PAS - Figure 2): The presence of a fine bore NGT was associated with increased penetration-aspiration ratings compared to the control condition, during serial liquid and puree swallows. Aspiration events (PAS scores ≥6) were exclusive to liquids and included those without reflexive cough (PAS = 8).

3.2 Pharyngeal residue (Figure 3a, 3b): Valleculae residue increased with both NGTs in-situ compared to the control during swallows of diced fruit. There was no difference in valleculae residue with liquid or puree swallows. More pyriform sinus residue was found during puree swallows with the fine bore NGT compared to the control**.**

3.3 Swallowing duration (Figure 4): ANOVA showed an interaction between the type of NGT and duration of pharyngeal transit (DPT) ($p<0.01$) with a pattern of prolonged swallowing duration across consistencies with increasing NGT diameter. Post-hoc analysis revealed longer pharyngeal transit durations during single liquid sips with both the fine and wide bore NGT, and during diced fruit swallows with the wide bore NGT, when compared to the control. Descriptive analysis of sub-components of DPT revealed increasing mean durations for stage transition (DST), pharyngeal response (DPR) and UES opening (DUESO) with increasing NGT diameter across all consistencies, with duration of stage transition (DST) appearing to contribute most strongly to the overall increase in pharyngeal transit duration **(Figure 5).**

Gender, age, randomisation order, and consistency of bolus swallowed did not influence these results.

4. Discussion:

The key findings from this study were that the presence of a nasogastric tube in older individuals was associated with increased penetration or aspiration of the bolus into the airway, greater pharyngeal residue post-swallow, and prolonged duration of bolus transit through the pharynx. These data have implications for the initiation of oral feeding while a nasogastric tube is in place and for nasogastric supplementation of oral feeding to increase calorie delivery.

The most concerning finding was the increase in airway penetration-aspiration with liquid and puree swallows in the presence of a fine bore NGT. The presence of the wide bore NGT also appeared to increase aspiration and penetration but did not reach significance, which may reflect the diminished sample size with one third of subjects lost due to tube intolerance.

No other study has statistically shown increased airway penetration or aspiration risk due to tube presence. Our findings are similar to the descriptive reports for older subjects (over 70 years) by Robbins *et al* [6] in which 77% of airway penetration events when drinking occurred in the presence of a pharyngeal manometry tube. Other studies have suggested that the presence of a NGT does not increase aspiration risk[4,5,7-10] but these studies differ from the current study in population[5,7-10] and methodology.[4,7-10] Methodological differences across studies relate to use of fibreoptic endoscopic evaluation of swallowing[4,7-9] as compared to modified barium swallow.[5-6,10] While both procedures are considered equivalent in detecting aspiration,[18] modified barium swallow allows additional information to be captured on swallowing duration hence its use in the current study. Most other investigations were observational studies of clinical populations with dysphagia,[7-10] therefore different from the normative data presented in this RCT. Furthermore, prior studies used a binary,[8-10] modified[7] or condensed rating scale[4] of penetration-aspiration which is not as sensitive in capturing subtle changes in swallowing function as the validated 8 point PAS[15] which spans the continuum of penetration to aspiration. The only other study to analyse data using the 8 point scale[5] found no difference in penetration-aspiration, however the subjects were young healthy volunteers. It is plausible that NGTs may have no effect on the swallowing function of a young healthy adult but may have a clinically important impact in the aged. Hence our study may be the most robust to date examining the effect of the presence of a NGT on swallowing mechanisms in the elderly.

A further methodological difference between this and previous studies is the investigation of tube impact during serial liquid swallows (i.e. repeated swallowing without taking breath). A liquid consistency,[4,12] increasing bolus volume[14] and advanced age[19] are independently associated with higher PAS ratings. This, combined with the nature of serial swallowing (typically initiated deeper in the pharynx),[20] subtle changes in the swallowing-respiratory pattern[21] and reduced laryngopharyngeal sensitivity with increasing age,[22] may have contributed to the deeper laryngeal penetration and aspiration events observed almost exclusively with liquids in our study. In contrast, only the extent of airway penetration increased when swallowing puree with a NGT in-situ. The degree of change was small (i.e. an increase from PAS rating 1 to 2) and implied good airway protective mechanisms; however the change was noted in almost half the healthy subjects (47%). The increased aspiration during oral feeding in the presence of a NGT has obvious implications for patient safety. Aspiration during feeding can lead to deteriorating respiratory function which can impact on survival. We know changes in lung function occur with age,[23] immunity diminishes[24] and risk factors for pneumonia (e.g. poor oral hygiene, systemic disease, medical comorbidities) increase.[25] Greater incidence and/or severity of penetration/aspiration in an elderly, deconditioned critically ill patient with impaired nutritional status (requiring NGT feeding) could therefore have more serious consequences.

Further functional change was observed in the effectiveness of pharyngeal clearance. Pharyngeal residue is a feature of normal aging, and an independent predictor of aspiration.[26] This is the first study to report increased residue in the presence of a NGT, related to eating. However we have confirmed previous reports of absent pharyngeal residue while drinking.[5,10] Pyriform residue occurs more commonly in an older person due to changes in bolus acceleration through the hypopharynx[11] compounded by reduced relaxation and smaller opening of the UES,[19] therefore the presence of a NGT may increase residue by partially obstructing a UES already narrowed with age[27] with residual material in close proximity to the open and unprotected airway after the swallow. Higher in the pharynx, valleculae residue can result from reduced base of tongue contact against the posterior pharyngeal wall, along which path the NGT traverses, and may reflect incomplete epiglottic deflection over the airway during the swallow. As the epiglottis becomes stiffer and less compliant with increasing age[13] it is possible NGT presence may exacerbate age-related changes.

Lastly, our study found an association between the type of NGT and the overall duration of pharyngeal transit (DPT) regardless of consistency swallowed. This result was consistent with findings from earlier normative RCTs[5-6] including longest swallowing durations with the widest diameter tube in-situ, and has clinical implications for swallowing efficiency in the presence of a NGT. Descriptive analysis would suggest that changes in the duration of stage transition (DST) relating to a delay in swallowing initiation make the greatest contribution to this result, which contrasts to the quicker pharyngeal initiation reported in young healthy volunteers.[5] This may reflect diminished pharyngeal sensation in the older population.

Overall there was not one consistency that appeared "safer" to swallow than another, as each was associated with some degree of physiological or functional change in keeping with prior research that suggests bolus volume and viscosity affect swallowing differently.[28] While our study found significant changes in swallowing physiology and function due to NGT presence there was not a dominant pattern of change across every participant, consistency and/or tube condition. The small sample size is an acknowledged limitation however this variability in swallowing safety, effectiveness and efficiency may also be a phenomenon attributed to the elderly cohort under examination. Additional limitations primarily reflect ethical considerations adopted to minimize distress and discomfort for our volunteers. Firstly NGT placement was only short-term therefore maladaptive behaviour cannot be discounted. Furthermore, the 2 tubes differed in material (as well as diameter) which may have influenced the high attrition of subjects with the stiff polyvinylchloride wide bore NGT due to discomfort passing through the nostril. Future research would need to consider longer-term adjustment periods in patients to confirm clinical applicability, and the properties of the tubes examined. Secondly, a topical anaesthetic was applied to the nostril. The evidence for and against anaesthetic impact on the pharyngeal swallow is mixed.[29-30] However, precautions were followed to contain the anaesthetic effect locally to the nares, and the swab was applied prior to all swallowing studies including the control, therefore it is unlikely that differences in swallowing outcome measures resulted from anaesthetic use. Raters could not be blinded to condition (control versus NGT) or consistency, as these were visually obvious on the radiographic images. However, there was near complete agreement between multiple raters supporting the reliability of analysis. Lastly, statistical analysis was limited by the small sample size which was further compounded by missing data in the wide bore NGT condition due to a third of the group not tolerating insertion. Similar patterns of swallowing change were observed with the wide bore NGT and indeed there was some indication the wide bore

NGT may have had greater impact on swallowing but significance was lost through loss of subject numbers.

Conclusions: Though limited by sample size, the current data contributes to our current understanding of how swallowing physiology can be altered by presence of a NGT. Our results suggest the presence of a NGT when eating and/or drinking can increase airway penetration-aspiration and pharyngeal residue, and prolong the duration of pharyngeal transit in older healthy adults. As such, consideration of NGT impact on swallowing during combined oral and NGT feeding is recommended. This warrants further systematic examination in elderly patients without dysphagia who are recovering from critical illness or undergoing treatment in which supplemental tube feeding is required.

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Contributors and authorship

LNP, ECW, PLC, SNO and MJC conceived and designed the study; LNP, ECW and SNO conducted the research; MEF performed statistical analysis; LNP, ECW, PLC and MJC wrote the paper; LNP had primary responsibility for final content. All authors read and approved the final manuscript.

Conflict of interest

None declared.

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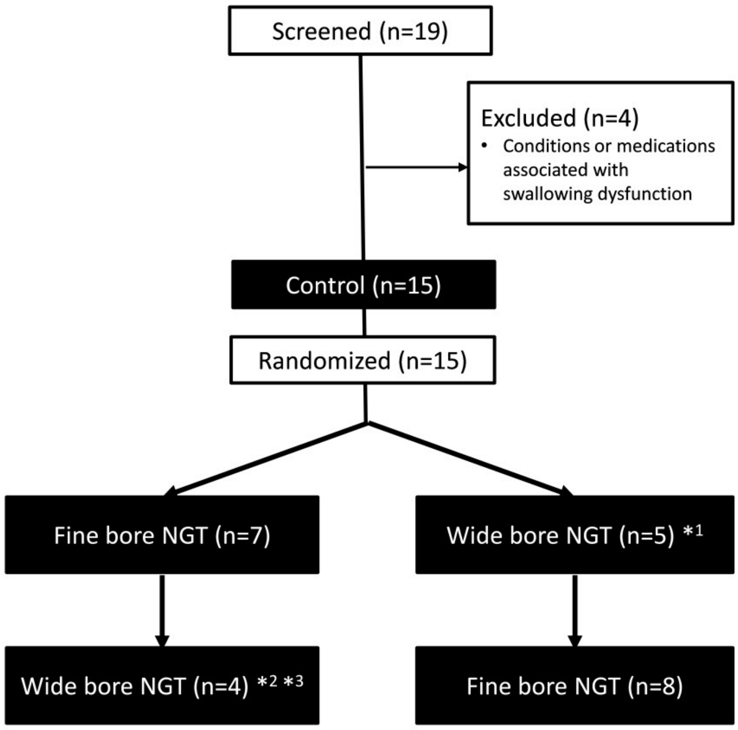
FIGURE & TABLE LEGENDS

TABLE 1.
8-Point Penetration-Aspiration Scale[15]

1. Material does not enter the airway
2. Material enters the airway, remains above the vocal folds, and is ejected from the airway
3. Material enters the airway, remains above the vocal folds, and is not ejected from the airway
4. Material enters the airway, contacts the vocal folds, and is ejected from the airway
5. Material enters the airway, contacts the vocal folds, and is not ejected from the airway
6. Material enters the airway, passes below the vocal folds and is ejected into the larynx or out of the airway
7. Material enters the airway, passes below the vocal folds, and is not ejected from the trachea despite effort
8. Material enters the airway, passes below the vocal folds, and no effort is made to eject



*1 Did not tolerate insertion of the wide bore NGT (n=3)

*2 Did not tolerate insertion of the wide bore NGT (n=2)

*3 Data lost prior to analysis (n=1)

FIGURE 1. CONSORT diagram of enrolment to study completion: 9 subjects completed the control condition and both experimental arms; 6 subjects completed the control and one experimental arm (fine bore NGT) due to drop-out or data loss with the wide bore NGT.

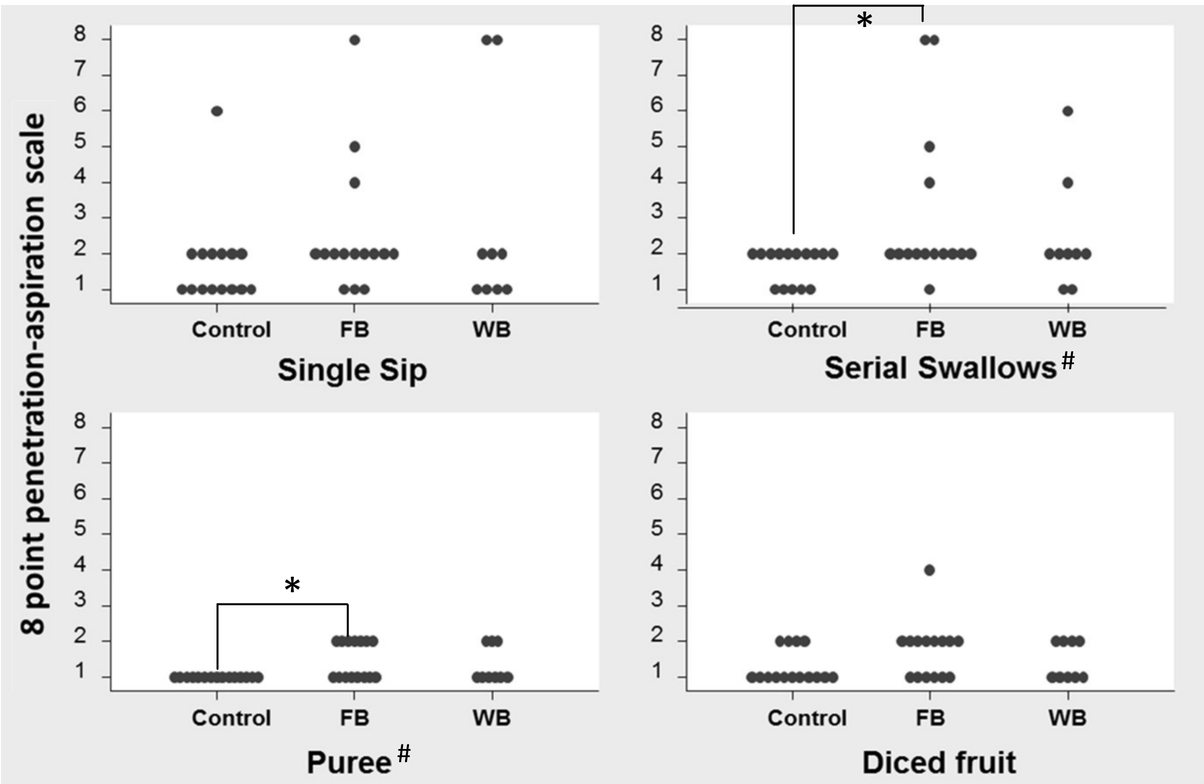


FIGURE 2. Penetration-aspiration scale (PAS). Worst PAS scores compared across control (no NGT) and experimental (fine bore NGT, wide bore NGT) conditions for each consistency using the Skillings Mack modification of the Friedman test ($^{\#}p<0.01$) with post-hoc Wilcoxon's (*p<0.01).

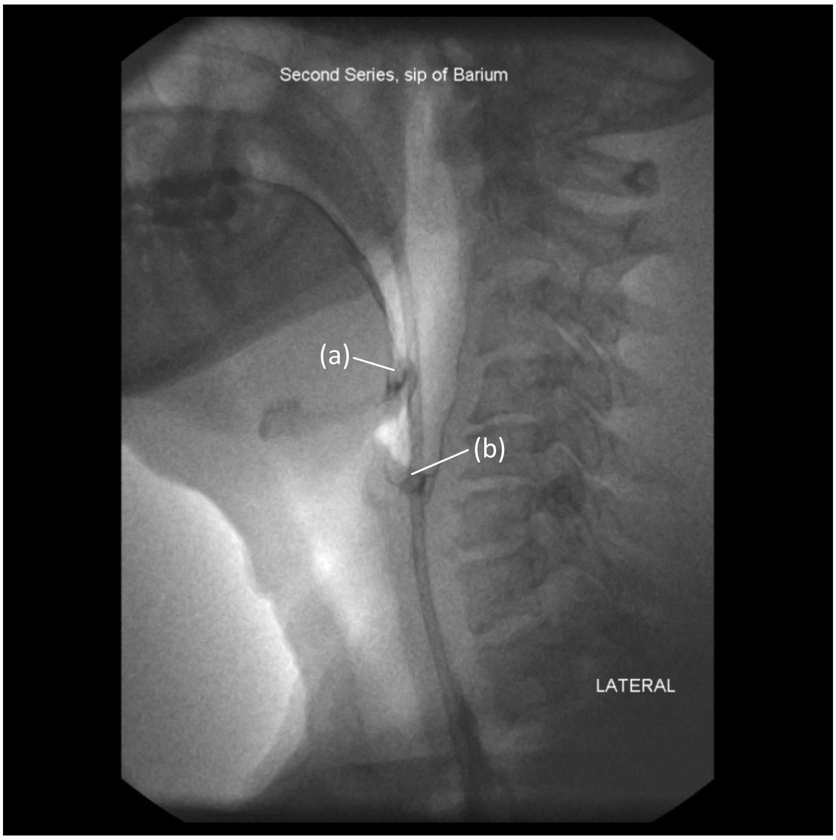


FIGURE 3a. Site of pharyngeal residue: (a) valleculae and (b) pyriform sinus.

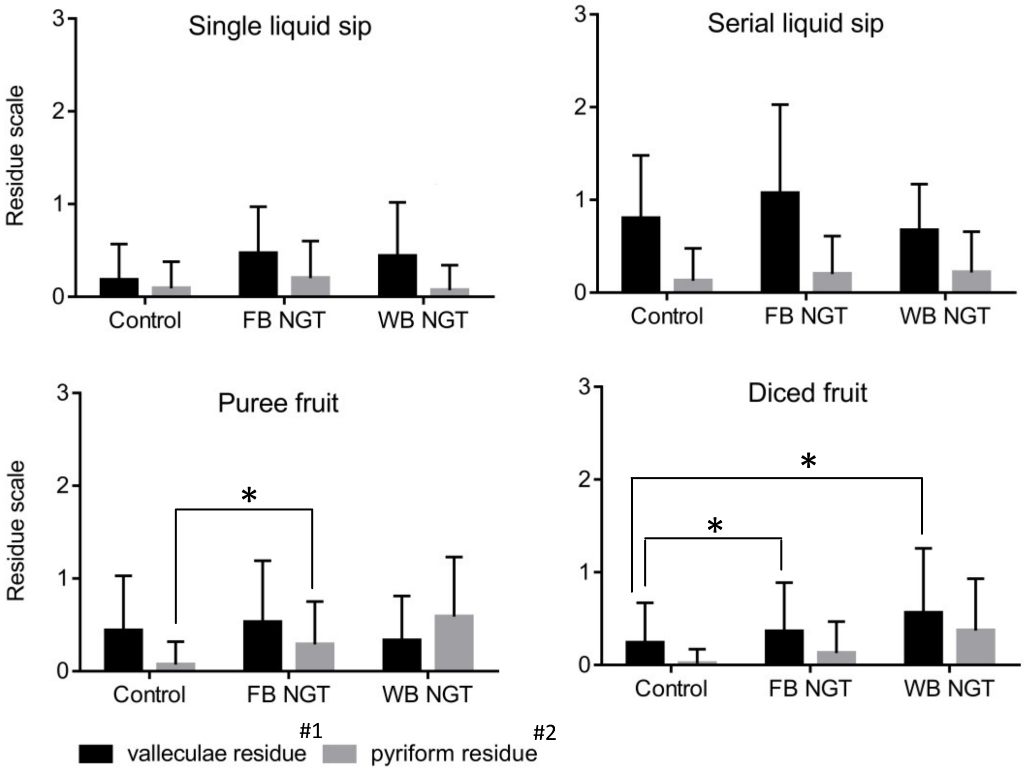


FIGURE 3b. Pharyngeal residue. Mean (+/-SD) ratings of valleculae and pyriform sinus residue for each consistency compared across control (no NGT) and experimental (fine bore NGT, wide bore NGT) conditions using the Skillings Mack modification of the Friedman test ([#1]$p<0.01$, [#2]$p<0.05$) with post-hoc Wilcoxon's (*$p<0.05$).

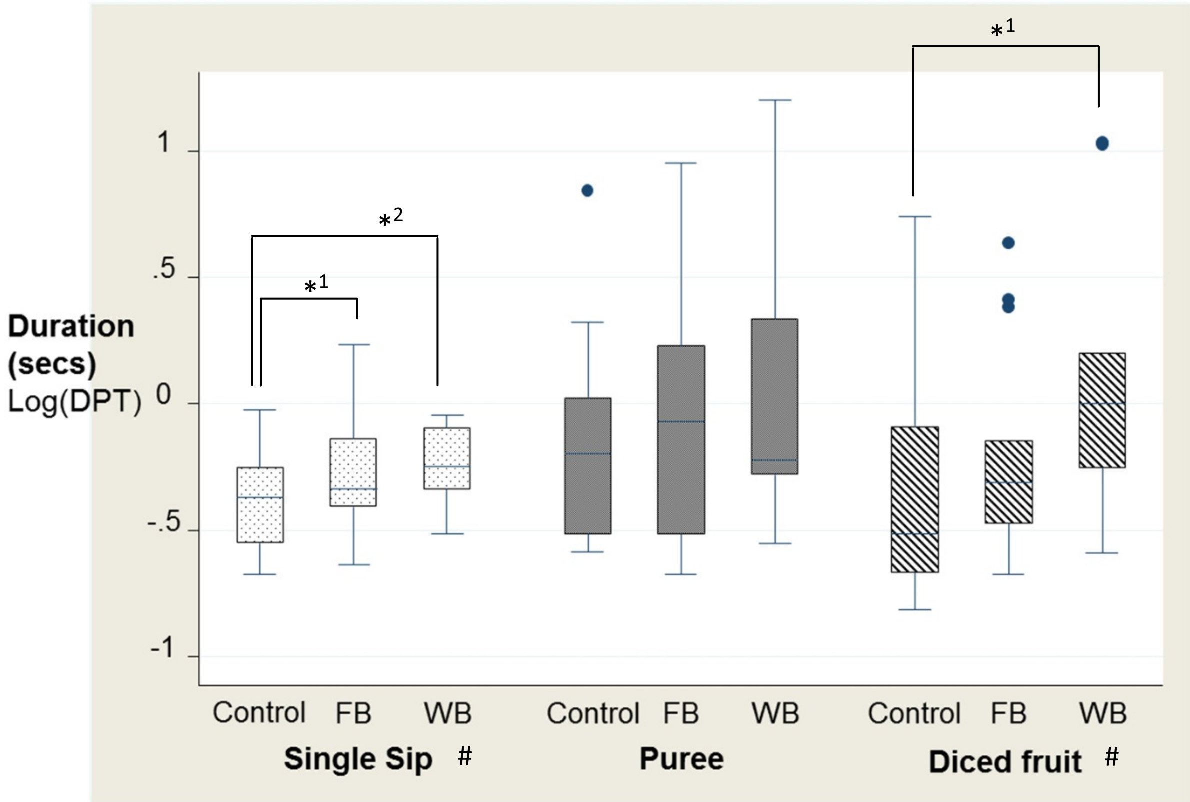


FIGURE 4. Overall swallowing duration. Mean (+/-SD) duration of pharyngeal transit (DPT, seconds) for single liquid sips, puree fruit and diced fruit swallows compared across control (no NGT) and experimental (fine bore NGT, wide bore NGT) conditions. Data log-transformed prior to repeated measures ANOVA ($^{\#}p<0.01$) and post-hoc paired t-tests ($*^{1}p<0.05$, $*^{2}p<0.01$).

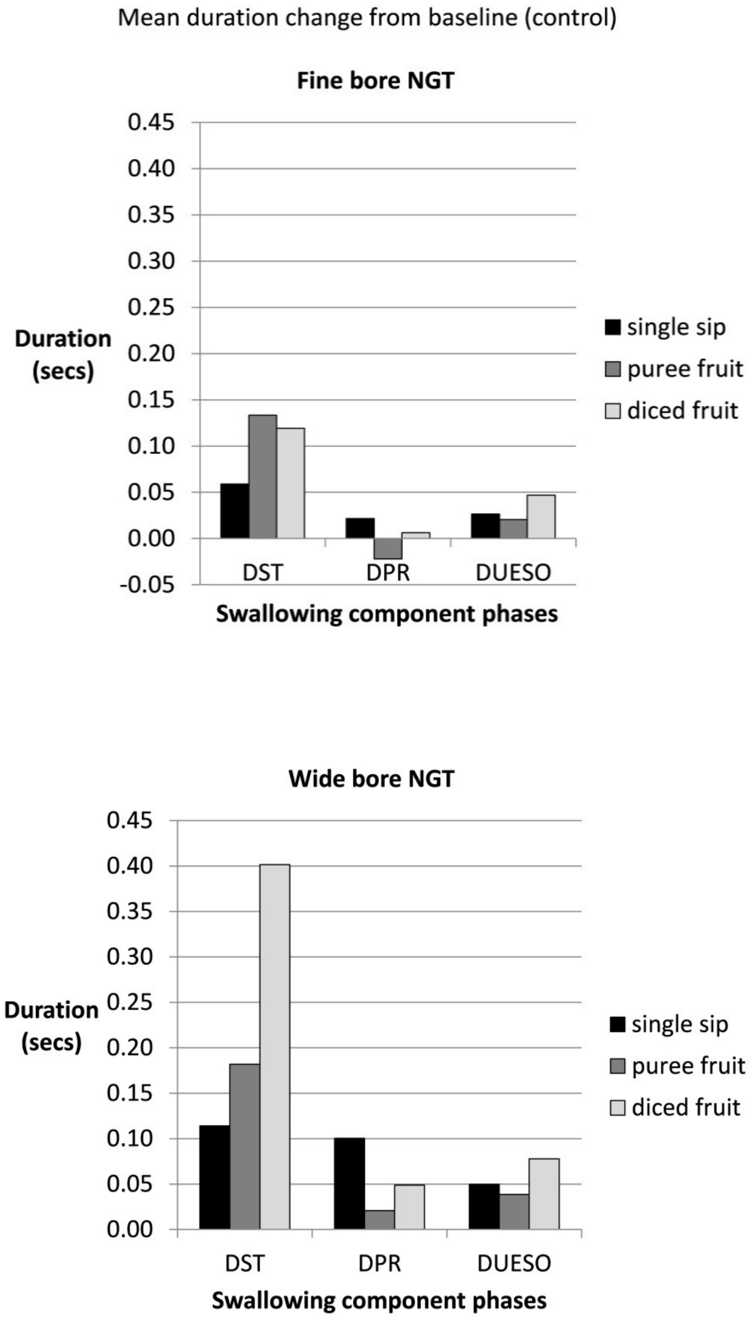


FIGURE 5. Change in swallowing duration (from baseline) with a nasogastric tube in-situ. Mean duration change (seconds) from baseline (control) with fine bore NGT and wide bore NGT in-situ for component phases within overall pharyngeal transit. DPR, duration of pharyngeal response; DST, duration of stage transition; DUESO, duration of upper esophageal sphincter opening.