Simultaneous Modified Barium Swallow and Blue Dye Tests: 
A Determination of the Accuracy of Blue Dye Test 
Aspiration Findings

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Abstract. The overall objective of this pilot study was to determine blue dye test reliability and validity for the identification of aspiration of secretions, food, and/or drink in 50 simultaneously administered blue dye (BDT) and modified barium swallow (MBS) tests of tracheostomized individuals. With the MBS as an objective test of aspiration, BDT sensitivity and specificity identifying aspiration were less than 80% and 62%, respectively. Certain tracheostomy tube conditions and food consistencies were associated with more accurate BDT aspiration results than others. Characteristics of the aspiration episodes, interpretation of the results, and needs for further research are discussed.

Keywords: Aspiration — Blue dye — Tracheostomy — Videofluoroscopy — Dysphagia — Deglutition — Deglutition disorders.

Individuals who have tracheostomies are described as being at increased risk for swallowing problems [1,2]. These problems include decreased swallow and cough reflexes [3–6], decreased laryngeal elevation and anterior rotation [7], and reduced glottic closure [8]. The presence of any or all of these problems may result in aspiration [3,9–11], which a recent study of acute care tracheostomized patients concluded is not caused by the tracheostomy or tracheostomy tube per se but by other factors such as patient medical status and neurological condition [12]. Recurrent aspiration may be associated with aspiration pneumonia, which is more common in medically vulnerable populations than medically stable ones [9,11,13].

Blue dye tests have been used to assess aspiration in individuals with a tracheostomy since the 1970s. In the original blue dye test, the Evans Blue Dye Test (EBDT), drops of Evans blue dye are placed on the tongue every four hours and the trachea is suctioned at set intervals; blue-tinged tracheal secretions suggest aspiration [14]. The Modified Evans Blue Dye Test (MEBDT) is conducted similarly but with blue food coloring mixed into semisolid food and liquids [2]. Currently, blue dye tests are used (1) as an aspiration screening tool prior to an objective test of swallowing [11,15], (2) because a clinical team feels that their at-risk patient cannot tolerate an objective swallowing assessment, (3) and/or because of lack of easy, timely access to an objective swallowing assessment [11,15,16]. Advantages of blue dye tests include the following: they can be conducted at the patient’s bedside and in a timely fashion, they are relatively inexpensive, with as few as one team member and only suctioning equipment needed [17], and they do not expose the patient to any radiation [11,18].

Blue dye test (BDT) accuracy has been questioned since the 1980s [19]. It was first investigated in a 1995 retrospective study of five subjects who received the MEBDT, followed by an objective test of swallowing—either a modified barium swallow
MBS study, also known as videofluoroscopy, or a fiberoptic endoscopic evaluation of swallowing (FEES) [2]—using methods which were subsequently considered flawed [20,21]. Flaws included a small number of subjects and widely ranging time intervals between procedures within and across subjects.

A 1999 prospective study to determine if MBS aspiration corresponded with simultaneous MEBD study aspiration across 20 subjects and three per os (oral) consistencies reported that the MEBD had a 50% false-negative error rate [16]. That is, the MEBD identified all four cases of greater than trace aspiration (10% or more of the bolus) and failed to identify all four cases of trace aspiration (less than 10% of the bolus). However, because subjects were not suctioned following a swallow if aspiration was not observed on MBS, it is not known if absence of aspiration on MBS corresponded with the same on MEBD. Also, results were not analyzed separately for each per os consistency.

Based on simultaneous MBS–BDT aspiration results of a 2001 study in which 20 subjects were presented one per os consistency, BDT sensitivity was 45% [95% confidence interval (CI) = ±8%] and specificity was 100% [17]. The authors discussed that positive BDT aspiration results provide useful information but that negative BDT aspiration results should be viewed cautiously. Although mechanisms to explain false negative BDT results were not offered, the authors discussed the possibility of a revised, more accurate BDT protocol with continued research.

In summary, clinicians administer blue dye tests to detect aspiration without strong evidence of their accuracy. The primary purpose of this pilot study was to determine the accuracy of the BDT across 50 tracheostomized patient assessments. The null hypothesis was that aspiration results of simultaneous MBS and BDT procedures would be unrelated. The experimental hypothesis was that aspiration results of simultaneous MBS and blue dye procedures would be identical across the 50 assessments—that is, that identification of aspiration during each MBS would correspond to identification of aspiration during the simultaneous BDT and that absence of aspiration during each MBS would correspond to absence of aspiration during the simultaneous BDT. In the event that MBS and BDT aspiration results were not identical across assessments, the secondary purpose of this study was to identify tracheostomy tube conditions, per os consistencies, and characteristics of aspiration which were associated with MBS–BDT aspiration agreement.

### Materials and Methods

#### Subjects

Subjects completed 50 simultaneous MBS–BDT procedures. Because the agreement between aspiration results of each of the 50 MBS–BDT studies was independent of the agreement between aspiration results of the other 49 simultaneous procedures, subjects were allowed to participate in this study up to three different times. Thirty-seven acute rehabilitation hospital tracheostomized inpatients participated in this study. A patient was eligible for study participation after being referred for a BDT. Subject ages ranged from 22 years 5 months to 87 years 5 months, with a mean age of 55 years 3 months. Twenty-six subjects (70%) were male, and 11 subjects (30%) were female. Subjects had anatomic, cardiovascular, neuromuscular, and/or pulmonary medical diagnoses.

Based on the subject’s overall medical condition and the reasons for the BDT referral, each subject’s clinical team determined the tracheostomy tube conditions under which each MBS–BDT study was completed. High aspiration-risk patients, whose cuffed tracheostomy tubes were inflated to reduce risk for deeper aspiration below the inflated cuff, were included as subjects so that BDT accuracy in identifying aspiration in these patients could be investigated.

Tracheostomy tube inner diameters ranged from 5 to 8.5 mm; outer diameters ranged from 7 to 12.6 mm. During 32 of the 50 studies (64%), the tracheostomy tube was nonfenestrated. The tracheostomy tube was cuffed during 33 of the 50 studies (66%), with the cuff deflated during 30 of these 33 studies (91%). During 6 of the 50 studies (12%), the tracheostomy tube was unoccluded; during 32 of the 50 studies (64%), a speaking valve was worn; and during 12 of the 50 studies (24%), the tracheostomy tube was buttoned.

#### Procedures

All MBS studies were conducted by a radiologist and a speech-language pathologist (SLP), each with over 10 years of instrumental swallowing diagnostic experience. For multiple years prior to this study, the clinicians conducted MBS studies according to institutional protocol. These clinicians were trained in and deemed competent to follow the MBS protocol for this study. All simultaneous BDT studies were conducted by an occupational therapist (OT) and a respiratory therapist (RT), each with over 5 years of clinical swallowing experience. For multiple years prior to this study, the clinicians conducted BDT studies according to interdisciplinary institutional protocol. They were trained in and deemed competent to follow the BDT protocol for this study.

Prior to the initiation of each MBS–BDT study, a lemon glycerin swab was dipped in liquid barium and blue food coloring for secretions assessment, and 6–8-oz servings of liquid barium-mixed pureed solid, thick nectar liquid, and thin liquid consistencies were each colored with 6–8 drops of blue food coloring. Sequence of stimulus presentations was: lemon glycerin swabbing to bilateral anterior faucial arches (4–5 strokes per side) and tongue (3–5 strokes), pureed solids (3 cc), thick nectar liquids (5 cc), and thin liquids (5 cc). Based on his or her judgment of how well a subject was tolerating the research protocol, any participating clinician could terminate the subject’s participation in the study at any time.

For each consistency presented, the radiologist and SLP each independently documented presence (+) or absence (−) of aspiration; rated airway entry using the Penetration–Aspiration (P–A)