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The Accuracy of the Modified Evan's Blue Dye Test in Predicting Aspiration

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Objectives/Hypothesis: **The modified Evan's blue dye test (MEBDT) is a relatively simple, inexpensive bedside procedure for the assessment of aspiration in the tracheotomized patient. Recent investigations have questioned its diagnostic accuracy. The purpose of the study was to evaluate the accuracy of the MEBDT in predicting aspiration among tracheotomized patients.** ***Study Design:*** **Prospective observational study.** ***Methods:*** **In the setting of a long-term acute care hospital, all persons with a tracheotomy tube undergoing a bedside swallowing evaluation between October 1, 2001, and March 31, 2002, were prospectively evaluated. All individuals underwent a MEBDT and a subsequent fiberoptic endoscopic evaluation of swallowing (FEES) using a standardized protocol. The sensitivity and specificity of the MEBDT in predicting aspiration were determined.** ***Results:*** **Thirty persons were evaluated. The mean age of the cohort was 65 years (SD ± 11 y). Sixty percent (18 of 30) were men. The sensitivity and specificity of the MEBDT for the entire cohort were 82% and 38%, respectively. The sensitivity of the MEBDT for patients receiving mechanical ventilation was 100% compared with 76% for individuals not receiving mechanical ventilation. The specificity of the MEBDT remained low, regardless of ventilator status (33%–40%).** ***Conclusion:*** **The sensitivity of the MEBDT in predicting aspiration among individuals in our cohort was 82%. The sensitivity was even higher (100%) when performed on persons receiving mechanical ventilation. These results support the use of the MEBDT as a screening tool for persons with a tracheotomy tube. The specific technique of performing the MEBDT is imperative, and the results of the study must be differentiated from other reports evaluating the MEBDT that use a different test protocol.** ***Key Words:*** **Tracheotomy, aspiration, modified Evans blue dye test, fiberoptic endoscopic evaluation of swallowing, dysphagia.**

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INTRODUCTION

Approximately 1,468,000 tracheotomies are performed each year.[1] Although chronic aspiration may be an indication for a tracheotomy, the presence of a tracheotomy tube alone can often cause more problems in regard to aspiration than it solves. The association between the presence of a tracheotomy tube and aspiration is a result of limitations in laryngeal elevation, reductions in laryngeal sensation and subglottic pressure, and problems with effective cough production.[2–8] In addition, the tracheotomy tube cuff can place pressure on the common wall with the esophagus, thus narrowing the esophageal lumen and creating a mechanical obstruction.[9] The obstructed esophageal lumen can cause bolus stagnation and regurgitation out of the esophageal inlet into the airway. Because of the potential problems posed by a tracheotomy tube on the swallowing mechanism, a high index of suspicion for aspiration must be maintained in all persons with a tracheotomy tube. Thus, an easily administered and effective screening tool for aspiration in tracheotomized individuals would be extremely valuable.

Evans blue dye (T-1824) is a diazo dye that has been the principal method of determining blood volume in humans and animals for more than 80 years. The dye was named after Herbert McLean Evans, an American anatomist and physiologist at the University of California, Berkeley, who published some of the early work on the use of this dye in calculating blood volume.[10] The Evans blue dye test for aspiration in tracheotomized persons was introduced by Cameron et al.[11] in 1973. The test is performed by placing four drops of 1% solution of Evans blue dye on the back of the patient's tongue every 4 hours. The patient is then placed on a schedule of suctioning for 48 hours, and the secretions are monitored for evidence of a blue tinge. The modified Evans blue dye test (MEBDT) introduces a slight variation on the original examination as described by Cameron et al.[11] Unlike the Evans blue dye test that is simply the administration of blue dye into the oral cavity, the MEBT involves the administration of test food materials, such as ice, liquid, or puree, impregnated with the dye.

Since its introduction almost 30 years ago, the accuracy of the blue dye test in documenting aspiration has been brought into question. In 1995, Thompson-Henry

and Braddock[12] reported the failure of the MEBDT in detecting aspiration in five unselected individuals. Brady et al.[13] and Donzelli et al.[14] reported a 50% false-negative error rate for the detection of trace aspiration. Thus, the use of this diagnostic test as a screening tool for aspiration may be no better than a coin flip. The technique of performing the MEBDT can vary depending on the protocol used to perform the test and by the institution or ancillary service administering the test. The purpose of the present investigation was to evaluate the accuracy of our technique of performing the MEBDT in predicting the presence of aspiration in patients with a tracheotomy tube.

PATIENTS AND METHODS

All patients with a tracheotomy tube admitted to a long-term acute care facility (Kindred Hospital, San Diego, CA) between October 1, 2001, and March 31, 2002, were prospectively evaluated. A MEBDT and a flexible endoscopic evaluation of swallowing (FEES) were performed on all individuals. Our technique of performing the MEBDT involves first deflating the tracheotomy tube cuff. Before cuff deflation, the patient's mouth and trachea are suctioned clear. If a cuffless tube is being used, this step is disregarded. A 45-ml amount of ice chips is impregnated with 0.5 mL blue dye (blue shade pure food color No. 4050, Dean Distributors, Burlingame, CA). One tablespoon (15 mL) is placed in the patient's oral cavity. The 15-mL bolus of ice chips is presented on three successive swallows so that a total amount of ice chips of 45 mL is given per complete trial. The patient's trachea is suctioned immediately after the third administration of 15 mL ice chips and on two more occasions, 30 and then 60 minutes afterward. This entire procedure (administration of 45 mL of ice chips followed by tracheal suctioning performed three times) is repeated on three separate occasions separated by at least 1 hour.

When the MEBDT was performed on patients requiring mechanical ventilation, the set pressure support from the ventilator was eliminated before suctioning. This was performed to minimize the airflow that is associated with pressure support which may affect true aspiration. Ice chips are used because they are less dangerous if aspirated and the thermal stimulation they elicit may stimulate the swallow. The presence of blue dye in any tracheal secretions signified a positive MEBDT. All MEBDT procedures were performed by a licensed speech-language pathologist (SLP). Our technique of FEES has been described elsewhere and is not reiterated.[15,16] The endoscopic presence of any food material below the level of the true vocal folds signified aspiration and a positive finding on FEES. Each FEES was performed by a licensed SLP in conjunction with a board-certified otolaryngologist (P.C.B.) within 24 hours of the last administration of ice chips. All data were coded and recorded into SPSS software, version 6.6, for the Macintosh (Chicago, IL). The prevalence of aspiration on the MEBDT was compared with the prevalence of aspiration on FEES. Using the FEES as the gold standard, the sensitivity and specificity of the MEBDT were calculated.

RESULTS

Thirty persons were prospectively evaluated. The mean age of the cohort was 65 years (SD ± 11 y). Sixty percent of the individuals (18 of 30) were men. Thirty-three percent (10 of 30) were receiving mechanical ventilation at the time of study. Seventy-three percent (22 of 30) of the entire cohort aspirated on FEES and 77% (23 of 30) aspirated on the MEBDT, reflecting the high acuity of the study population. The sensitivity and specificity of the MEBDT in predicting aspiration with puree, as determined by FEES, were 93% and 33%, respectively. The sensitivity and specificity of the MEBDT in predicting aspiration with thin liquids, as determined by FEES, were 86% and 43%, respectively. The overall sensitivity and specificity of the MEBDT were 82% and 38%, respectively. The sensitivity of the MEBDT for patients receiving mechanical ventilation was 100% compared with 76% for individuals not receiving mechanical ventilation. The specificity of the MEBDT remained low, regardless of ventilator status (33%–40%).

DISCUSSION

The limitations in swallowing function created by the placement of a tracheotomy tube necessitate that a high index of suspicion for aspiration be maintained in all tracheotomized individuals. The gold standard for the evaluation of swallowing and the documentation of aspiration remains uncertain. The FEES and the videofluoroscopic study or modified barium swallow (MBS) are the two most widely used diagnostic tools for this purpose. Although each study has certain advantages and disadvantages, multiple investigations have revealed that they are roughly equivalent in terms of diagnostic accuracy.[16–19] The advantages of the MEBDT over both the MBS and FEES are its relative ease of administration, the lack of need for special expertise in endoscopy or radiography, and the lack of need for expensive radiographic or endoscopic equipment. If the diagnostic accuracy of the MEBDT proved to be as appealing as its ease of administration and low cost, it would be the test of choice for the screening of aspiration in tracheotomized persons. However, the data from previous investigations evaluating the accuracy of the MEBD test have been disappointing.

Donzelli et al.[14] performed simultaneous FEES and MEBDT on 15 individuals with tracheotomies. The authors reported a 50% false-negative error rate for the MEBDT. These results are in agreement with those of Brady et al.,[13] who reported a 50% false-negative error rate for simultaneous MEBDT and videofluoroscopic swallow study. Both of these investigations showed increased sensitivity of the MEBDT in tracheotomized persons who aspirated more than trace amounts, suggesting that the quantity of the aspirated food bolus is associated with the accuracy of the test. In comparison to the 50% false-negative error rate in these investigations, the false-negative error rate of our study was only 18% (4 of 22). We chose not to differentiate between the aspiration of trace and gross amounts of material. Given the high acuity of our population, we consider even trace amounts of aspiration to be significant. Although the previous studies did not report the sensitivity and specificity of the MEBDT, the overall sensitivity of the MEBDT in our cohort of 82% is acceptable and supports the role of this study as a screening tool in persons with a tracheotomy tube. The sensitivity of the MEBDT (100%) in persons receiving mechanical ventilation suggests that the MEBDT may be the screening test of choice in these individuals. Based on these results, it is recommended that pressure support be discontinued before suctioning. The poor specificity of the MEBDT supports the notion that persons who fail this

test may be considered for FEES or MBS because the propensity for false-positive results with the MEBDT using our protocol is relatively high.

Several factors could account for the discrepancy between the results of our investigation and those of Donzelli et al.[14] and Brady et al.[13] The most likely explanation for the enhanced sensitivity reported in our study is the technique of performing the MEBDT. The type and quantity of food impregnated with blue dye that was administered were not specified in the study of Donzelli et al.[14] MEBDT performed with puree would not be expected to be as sensitive as a MEBDT performed with thin liquid or ice chips. Administering the examination on only one occasion, as was the case in the studies of Donzelli et al.[14] and Brady et al.[13], may also limit the sensitivity. Each person in our investigation received three separate trials of 45 mL of ice chips given over three consecutive 15-mL swallows as defined in our protocol. Each trial was separated by at least 1 hour. This is similar to the technique originally described by Cameron et al.,[11] who administered the dye every 4 hours for 48 hours. The type and quantity of dye placed in the food bolus may also influence the sensitivity. The study conducted by Brady et al.[13] used three to five drops of blue dye for every 4 ounces of barium-and-food mixture (puree, nectar-thick liquids, and thin liquids). However, if a particular mixture was judged by the swallowing study team to be unsafe, they deferred the administration of that food consistency. This would be expected to alter the sensitivity of their examination. By not administering substances deemed unsafe, the sensitivity of the blue dye test may be compromised. We used 0.5 mL of dye for each 45-mL bolus of ice chips. We think that the enhanced sensitivity of the MEBDT reported in our investigation is at least partly a result of the use of ice chips in our protocol. Using less dye (four or five drops per 4 ounces vs. 0.5 mL per 45 mL) or a different type of dye may also make identifying blue-tinged tracheal secretions more difficult. Thus, differences in MEBDT protocol preclude the direct comparison between data obtained from our study and previous investigations.

The enhanced sensitivity reported in our investigation is at the expense of specificity. The specificity of the MEBDT using our protocol was only 33% for individuals not receiving mechanical ventilation and 40% for individuals receiving mechanical ventilation. Placing 45 mL of ice chips in the oral cavity allows for the patient's secretions and saliva to become tinged as the person chews and sucks on the ice. This is especially true for patients with delayed oral preparation as frequently seen in our high-acuity study population. When the patient's trachea is suctioned, it may be the saliva and oral secretions that are coloring the tracheal secretions (and thus resulting in a positive MEBDT result), not the aspiration of food bolus. When the FEES was performed, a person with a positive MEBDT result by our criteria and protocol may not display any aspiration of liquid or puree bolus on endoscopic swallow evaluation. The "aspiration" documented on the MEBDT in some patients may in fact be due to normal mucociliary flow. Thus, when using the FEES as the gold standard, our protocol resulted in a high incidence of false-positive results. Because ice chips were given on three separate occasions, it was not possible to simultaneously administer the MEBDT and the FEES. Swallowing safety can show significant variability based on the time of day, level of fatigue, mental status, patient positioning, and the like. Although the FEES was performed within 24 hours of the last administration of ice chips, the time difference may also have influenced the determination of sensitivity and specificity.

CONCLUSION

The sensitivity of our MEBDT protocol in predicting aspiration among individuals in our cohort was 82%. The sensitivity was even higher (100%) when determined specifically in persons receiving mechanical ventilation. These results support the use of the MEBDT as a screening tool for persons with a tracheotomy tube. The specific technique of performing the MEBDT is imperative, and the results of the present study must be differentiated from other reports evaluating the MEBDT that use a different test protocol.

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