British Journal of Applied Science & Technology
7(5): 429-435, 2015, Article no.BJAST.2015.161
ISSN: 2231-0843

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Sensitivity of the Blue Dye Food Test for Detecting Aspiration in Patients with a Tracheotomy

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Authors' contributions

Author SB designed the study, collected data, performed the statistical analysis, wrote draft of manuscript. Authors RK, MW, JD and MP assisted with the protocol design and data collection. All authors read and approved the final manuscript.

Article Information

DOI: 10.9734/BJAST/2015/11652
Editor(s):
(1) Singiresu S. Rao, Department of Mechanical and Aerospace Engineering, University of Miami, Coral Gables, USA.
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(1) Roberto Oliveira Dantas, Department of Medicine, Medical School of RibeirãoPreto, University of São Paulo, Brazil.
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Complete Peer review History: http://www.sciencedomain.org/review-history.php?iid=774&id=5&aid=8246

Original Research Article

Received 27th May 2014
Accepted 23rd July 2014
Published 24th February 2015

ABSTRACT

Aims: To explore the sensitivity and specificity values for aspiration with the blue dye food test (BDFT) in tracheotomized patients undergoing inpatient rehabilitation and explore what impact, if any, the accumulated oropharyngeal secretion level has upon the accuracy of the BDFT.
Methodology: Simultaneous BDFT and fiberoptic endoscopic evaluation of swallowing (FEES) procedure were conducted with 21 tracheotomized patients. The patient's accumulated oropharyngeal secretion level was evaluated first using a 5-point secretion severity scale. The patients then received ice chips and various boluses which were dyed blue. The BDFT was

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considered positive for aspiration when blue tinged material was present upon tracheal suctioning, around the stoma site, or on the tracheotomy tube upon its removal. The FEES was considered positive for aspiration when the bolus passed through the vocal folds as observed by nasal endoscopy. In cases where no blue material was observed on the BDFT, the additional step of subglottal viewing through the tracheostoma was performed.

Results: Results revealed the sensitivity of the BDFT for the detection of aspiration was only 0.4 when compared to the FEES during simultaneous examinations. Statistically significant differences were observed between secretion severity level and a positive BDFT as Group 1 (true positive BDFT) mean secretion level was 4.5, Group 2 (false negative BDFT) was 2.33, and Group 3 (true negative BDFT) was 2.0 ($F=8.143$, $p=0.003$).

Conclusion: Results further support that the BDFT demonstrates poor sensitivity for aspiration detection in patients with a tracheotomy. Results reveal for the first time the potential influence accumulated oropharyngeal secretions may have upon the likelihood of a positive BDFT. Results do not support use of the BDFT in isolation for definitive detection of aspiration. Potential uses for the BDFT in a clinical setting are discussed.

Keywords: Deglutition; dysphagia; endoscopy; swallow; tracheotomy.

1. INTRODUCTION

Using blue dye to detect aspiration in patients with a tracheotomy was first described by Cameron, Reynolds, and Zuidema [1]. In that study they described using four drops of 1% solution of Evans blue dye on tongues of patients with a tracheotomy to document the incidence of aspiration of their oropharyngeal secretions. If blue tinged secretions were suctioned through the tracheotomy tube, then it was considered positive for aspiration [1]. The blue dye food test (BDFT) used today in clinical practice with patients with a tracheotomy is based upon the original Evans blue dye test and uses food coloring (FD & C Blue No. 1) mixed with food and liquid. Similar to the original Evans blue dye test, the BDFT is considered positive for aspiration when blue dye/tinged secretions are suctioned through the tracheotomy tube [2].

The usefulness of the BDFT was questioned by Thompson-Henry and Braddock [3] as they reported five cases where the BDFT had failed to detect aspiration in patients with a tracheotomy tube when compared to a subsequent videofluoroscopic swallow study (VFSS). Brady and colleagues [2] were the first to report performing simultaneous BDFT and VFSS with rehabilitation patients who had a tracheotomy in order to evaluate the accuracy of the BDFT. During the simultaneous examinations, they reported in cases of known aspiration as documented by the VFSS, the BDFT was only 50% accurate in the detection of aspiration for patients undergoing inpatient rehabilitation. Follow-up studies by other research teams conducting simultaneous VFSS and BDFT found a sensitivity rate ranging from 38% to 79% for the detection of aspiration by the BDFT as compared to the VFSS [4,5].

The accuracy of the BDFT as compared to the fiberoptic endoscopic evaluation of swallowing (FEES) has also been documented in previous research [6]. The FEES allows for an evaluation of the anatomic structures, secretion levels, swallowing ability, and sensory ability. Donzelli, Brady, Wesling, and Craney [6] used simultaneous FEES and BDFT to evaluate the aspiration detection rate of the BDFTin rehabilitation patients with a tracheotomy. Again, they found that in cases of known aspiration as documented by FEES, the BDFT was only 50% accurate in detection of aspiration. Other investigators have reported a higher sensitivity rate for the detection of aspiration on the BDFT as compared to the FEES; however, those studies were completed without the added advantage of simultaneous exams [7,8].

One of the advantages of conducting the FEES as compared to the VFSS is the ability to evaluate the presence and location of accumulated oropharyngeal secretion levels [9]. Previous research conducted on secretion scales has demonstrated a relationship between the presence of accumulated oropharyngeal secretion levels and subsequent aspiration of food and/or liquid during the (FEES) [9-11]. While all of the various secretion scales share some similar qualities, the 5-point secretion scale [9] demonstrates an advantage for ease of use as it does not allow for a “transition” score for the secretion level. The score the patient receives is the point of maximum secretions present. A

score of a 1 on the 5-point secretion severity scale represents normal secretion level whereas a score of 5 indicates the presence of secretions at the level of the vocal folds and aspiration of secretions. Additionally, the 5-point secretion scale also distinguishes between laryngeal penetration and aspiration of secretions as a score of 4 reflects the presence of laryngeal penetration but not aspiration of secretions. A score of 2 or 3 on the scale represents progressively larger amounts of accumulated oropharyngeal secretions, however, no invasion into the laryngeal vestibule or airway.

Given the mixed research findings regarding the accuracy of the BDFT for aspiration and the limited information available regarding the relationship between accumulated oropharyngeal secretion levels and the BDFT, further research is needed to determine if secretion levels may play a role in the overall accuracy of the BDFT. Therefore, the purpose of this follow-up study is to further explore the accuracy of the BDFT as compared to the FEES with patients undergoing inpatient rehabilitation. The specific objectives are as follows: 1) to determine the sensitivity and specificity values for aspiration with the BDFT as compared to the FEES which is the gold standard; 2) to explore what impact, if any, accumulated oropharyngeal secretion levels have upon the accuracy of the BDFT; and3) to explore the added value viewing the lower airway through the tracheostoma has upon the accuracy of the BDFT.

2. METHODS

2.1 Subjects

A convenience sample of adult patients with a wide variety of medical diagnoses (i.e., brain injury, stroke, status post cardiac surgery, status post respiratory arrest) with a tracheotomy tube were the subjects of this investigation. These patients were referred for a FEES at a free standing rehabilitation hospital. Inclusion criteria included patients with a tracheotomy who were able to tolerate brief removal of the tracheotomy tube and accept food and/or liquid into their mouth, as well as participate in the FEES protocol. Exclusion criteria included patients unable to tolerate placement of the nasal endoscope in order to evaluate the swallow and/or tolerate removal of the tracheotomy tube. All patients were non-ventilator dependent.

2.2 Procedure

The patients underwent the standard FEES protocol based upon the original protocol of Lang more and colleagues [12] and also previously described by the investigators of this current project [5,9,13,14]. If a patient had a tracheotomy tube cuff, it was deflated prior to the FEES procedure. Prior to the presentation of an ice chip or any food/liquid boluses, the patient's accumulated oropharyngeal secretion level was evaluated using a previously published 5-point secretion severity scale [9]. Table 1 provides a summary of the 5-point secretion scale.

Table 1. Marianjoy five-point secretion severity scale [9]

Secretion Level	Description
Level 1: Normal	Thin, clear secretions; less than 10% pooling in pyriform sinuses and/or vallecular space
Level 2: Mild	Pooling of pharyngeal secretions from 10-25% in pyriform sinuses and/or vallecular space.
Level 3: Moderate	Pooling of pharyngeal secretions greater than 25% in pyriform sinuses and/or vallecular space; no endolaryngeal secretions present.
Level 4: Severe Level	Endolaryngeal secretions are present. Laryngeal penetration of secretions above the level of the true vocal cords; intermittent laryngeal penetration of secretions upon inhalation; but no aspiration of secretions observed.
Level 5: Profound Level	Secretions present at or below the level of the vocal cords.

Adopted with permission from the Annals of Otology, Rhinology, & Laryngology

Following the evaluation of the accumulated oropharyngeal secretion level, the patient received ice chips as well as various bolus types and consistencies that had been dyed blue with FD & C Blue No. 1. Four to five drops of blue dye were mixed with each four ounce amount of food and liquid to ensure adequate visualization. Bolus sizes for liquids ranged from as small as 1mL presented via teaspoon to as large as 60mL presented via cup or straw in uncontrolled, consecutive sips. For the pureed and solid boluses, bolus sizes ranged from ¼ of a teaspoon to a full teaspoon amount. If a particular consistency or bolus size was deemed unsafe, it was not presented. This was subsequently documented on the data collection sheet. A consensus opinion between the physicians and speech language pathologists was used to determine the presence or absence of aspiration during the FEES. All exams were recorded on digital disc for further review. The FEES was considered positive for aspiration when the bolus passed through the vocal folds as observed by nasal endoscopy with the endoscope positioned in the nasopharynx.

Following the bolus presentations, patients under went suctioning of their tracheotomy tube. The BDFT was considered positive if blue tinged material (e.g. secretions or bolus) was present either upon tracheal suctioning, around the stoma site, or on the tracheotomy tube upon its removal. In cases where no blue material was observed, the additional step of subglottal viewing through the tracheostoma was performed. Subglottal viewing was completed with the tracheotomy tube removed. The endoscope was inserted into the tracheostoma and flexed downward to view the lower airway and then flexed upward to view the area between the stoma and the subglottal structures to potentially observe aspirated material that was not detected utilizing the BDFT. This technique has been previously reported by these investigators [6]. Fig. 1 presents an illustration of the subglottal viewing. This study was approved by the Institution's Review Board.

2.3 Data Analysis

Statistical analyses were completed using the Statistical Package for the Social Sciences (SPSS) computer software version 21.0. The alpha level of significance was set at 0.05.

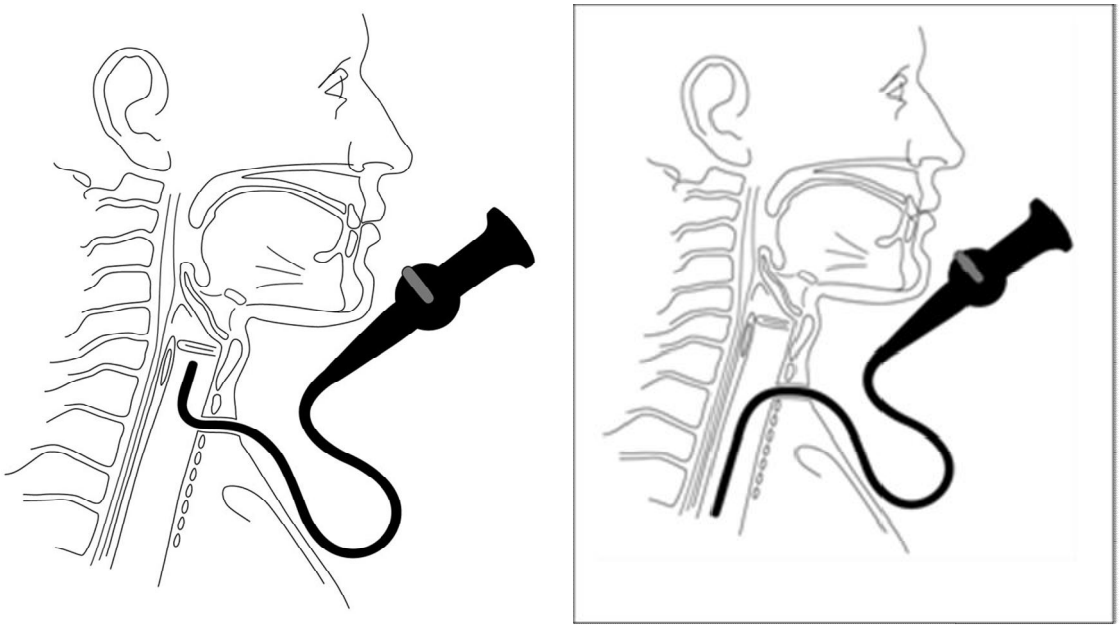

Fig. 1. Subglottal viewing through tracheostoma (images reprinted with permission from *Laryngoscope*)

3. RESULTS

Twenty-one patients participated in this study with ages ranging from 20 to 89 years and a mean age of 60 years (SD=17.5 years). Of the 21 patients, 13 were males and eight were females. Tracheotomy tubes in this study were manufactured by both Bivona and Shiley.

Tracheotomy tube size ranged from four to eight, and only three patients had a cuffed tracheotomy tube in place. The majority of the patients (95%, 20/21) had adequate bilateral vocal fold mobility. One patient had a unilateral right fold paralysis in the lateral position. Overall, aspiration as detected by the FEES was present in 71% (15/21) of the exams and 67% (10/15) of the time the aspiration was silent (no cough response).

3.1 Sensitivity and Specificity

Sensitivity and specificity analysis were completed for the BDFT using the FEES as the gold standard. The study sample was divided into three cohorts with group assignment based upon performance during the simultaneous FEES and BDFT as outlined below:

Group 1(n=6) - True Positive BDFT: Aspiration was observed on the FEES and upon tracheal suctioning or inspection of the tracheostomy tube blue dye material was observed. These patients were aspirators who were correctly identified as such by the BDFT.

Group 2 (n=9) - False Negative BDFT: Aspiration was observed on the FEES but no blue dye material was observed upon suctioning. However, upon subglottal viewing through the tracheostoma, blue tinged material was observed in the airway either above or below the stoma site. These patients were aspirators who were incorrectly identified as non-aspirators by the BDFT.

Group 3(n=6) - True Negative BDFT: No aspiration was observed on the FEES and no blue dye material present upon tracheal suctioning, inspection of the tracheostomy tube, or upon subglottal viewing. These patients were non-aspirators who were correctly identified as such by the BDFT.

By the operational definitions of this study, it was not possible for a patient to demonstrate a false positive error for the BDFT as compared to the FEES during simultaneous exams since any blue tinged material present in the lower airway would only be possible following an aspiration event.

Table 2 presents the contingency table and results for sensitivity and specificity values of the BDFT for the detection of aspiration. The sensitivity, or true positive rate, of the BDFT as compared with the FEES was 0.4. The specificity, or true negative rate, of the BDFT as compared to the FEES was 1.0.

3.2 Secretion Level Analysis

On the 5-point accumulated oropharyngeal secretion scale, there was a statistically significant difference between mean secretion levels for each study group. The mean secretion level of Group 1 was 4.5, Group 2 was 2.33, and Group 3 was 2.0 ($F=8.143$, $p=0.003$). In cases of known aspiration as documented by the FEES (i.e. Group 1 and Group 2), patients with higher accumulated oropharyngeal secretions were more likely to demonstrate a positive BDFT as compared to patients with a lower secretion levels.

3.3 Subglottal Viewing Results

When the BDFT was negative (i.e. Group 2 and Group 3), the additional step of subglottal viewing with the tracheotomy tube removed was performed. For the Group 2 participants, all nine cases (100%) where the BDFT was a false negative, no blue tinged material was present when the endoscope was flexed downward (inferior) to view the lower trachea and bronchus. However, with 89% (8/9) of these false negative cases, the blue tinged material was only visible when the endoscope was flexed upward (superior) to view the area from the level of the tracheostoma to the level just underneath the vocal folds. The one remaining patient (1/9) in this group demonstrated aspiration on the FEES with the bolus passing below the vocal folds; however, this elicited a spontaneous cough which expelled the aspirated material out of the airway prior to suctioning and subglottal viewing. Therefore, as the aspirated material had been expelled, no blue-tinged material was observed upon subglottal viewing. For group 3 (no aspiration on the FEES), no blue tinged material was observed with any of the participants upon subglottal viewing with the endoscope flexed downward or upward following insertion into the tracheostoma.

Table 2. Contingency table

	Disease Present (Aspiration)	No Disease (No Aspiration)
Positive Test	6 (a)	0 (b)
Negative Test	9 (c)	6 (d)

Sensitivity = a / (a + c) = 0.40, Specificity = d / (b + d) = 1.0, Positive Predictive Value = a / (a + b) = 1.0
Negative Predictive Value = d / (c + d) = 0.375

4. DISCUSSION

Dysphagia is an impairment of swallowing function caused by many diseases/conditions (e.g. cancer, stroke, Parkinson's disease) and is commonly seen with patients participating in inpatient rehabilitation. The patient with a tracheotomy tube may be at higher risk for silent aspiration due to laryngeal desensitization and therefore accurate identification of dysphagia and aspiration risk is vital with this patient population [15]. Furthermore, it is important to understand the rationale for conducting a BDFT with patients with a tracheotomy and to determine the potential added value of using a blue coloring agent to detect aspiration.

The purpose of the swallow screen is to identify individuals who require a comprehensive instrumental assessment of the swallow and to determine whether a patient is appropriate for further diagnostic follow-up for dysphagia. While the results of this study indicate low sensitivity values of the BDFT for detection of aspiration when compared to FEES, the use of a coloring agent during a swallowing screening in patients with a tracheotomy may still offer some clinical advantages. For example, despite low sensitivity values, BDFT may be of some value at positively identifying aspiration that is silent or might otherwise go undetected during a routine clinical swallowing assessment conducted at bedside. In addition, in clinical situations when the patient demonstrates a positive BDFT, the timing of further swallowing diagnostic exams (i.e., FEES) may be deferred until the patient is able to pass the BFDT. That is not to imply that all patients who demonstrate a positive BDFT should not undergo additional testing until they pass the screen, but rather the referral for instrumental swallow examination may be deferred until the clinician feels it would add additional diagnostic information and change current diet recommendations or treatment planning. This may be a consideration especially in situations or facilities where instrumental assessment is costly or not readily available. However, while using blue dye during a swallow screen may provide some additional value to assist the clinician with identifying the presence of aspiration, it should not be a substitute for sound clinical judgment, and should only be used with extreme caution and with full recognition of its limitations as a screening tool. As indicated by the results of this study, absence of aspiration is not to be implied following a negative BDFT given its low sensitivity rate for detection of aspiration. Instrumental assessment (i.e. FEES and/or VFSS) is warranted prior to initiation of oral feedings for patients with a tracheostomy undergoing inpatient rehabilitation.

This study identified an additional factor, accumulated oropharyngeal secretions levels, which may also influence the sensitivity of the BDFT. The potential role the accumulated oropharyngeal secretion level may have upon the accuracy of the BDFT has not been previously reported. In cases of known aspiration, patients with higher secretion levels were more likely to demonstrate a positive BDFT as compared to patients with lower secretion levels. Previous studies have found that individuals with a tracheotomy may be at increased risk for higher levels of accumulated oropharyngeal secretion levels [9,13]. This follow-up study provides support for the association between increased secretion levels and a positive BDFT.

One strength of this investigation was that the protocol included subglottal viewing through the tracheotomy site which provided valuable information regarding the exact location of the aspirated material. A recognized limitation of this study was safety protocols taken to minimize the risk of aspiration. These safety protocols are in place with all dysphagia clinical research studies at this institution and are a requirement of the Institutional Review Board.

5. CONCLUSION

The sensitivity of the BDFT as compared to the FEES was 0.4. Patients with a tracheotomy tube participating in inpatient rehabilitation who demonstrate higher accumulated oropharyngeal secretions were more likely to demonstrate a positive BDFT as compared to patients with

lower secretion levels. Results indicate that the BDFT has limited value in isolation as a screening tool for aspiration. Clinicians must be aware of its limitations, utilize sound clinical judgment, and act judiciously when deciding whether to implement this protocol into their routine bedside dysphagia screening procedure. For detection of aspiration in patients with a tracheostomy, BDFT should not be utilized as a substitute for gold standard instrumental assessment such as FEES or VFSS.

COMPETING INTERESTS

Authors have declared that no competing interests exist.

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Peer-review history:
The peer review history for this paper can be accessed here:
http://www.sciencedomain.org/review-history.php?iid=774&id=5&aid=8246