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# Role of blue dye test as an early predictor of post-laryngectomy pharyngocutaneous fistula

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## Abstract

**Background** Pharyngocutaneous fistula (PCF) is considered the most common suffering complication in laryngectomized patients. PCF occurs variably from 10 to 20% and sometimes reaches more than 60%, as a result of a combination of local and systemic factors related to poor tissue healing and wound breakdown. Development of PCF affects the restoration of normal life after laryngectomy that could potentially lead to major complications affecting patient survival.

**Aim of study** We studied the role of blue dye test in the early detection of PCF post-laryngectomy, which could potentially lead to optimum management which can reduce the duration of hospital stay as well as major complications out of salivary leakage.

**Results** Out of 64 patients who underwent TL from Jan 2020 till Dec 2021 at a Tertiary Head and Neck Cancer Center, 40 patients were included in the study. All these patients underwent blue dye test and barium swallow considered the standard postoperative leak test. Patients' characteristics as well as associated comorbidities have been studied as well as blue dye test findings compared to barium swallow, including median time for diagnosis of PCF, duration, management plan, additional leak tests, and length of hospital stay.

**Conclusion** Blue dye test gives a good clue for early detection with proper management of PCF, which could eventually result in early recovery and reduce cost, morbidity, and hospital stay. It can be repeatedly performed to establish a simple, reliable, and safe bedside tool for follow-up.

**Keywords** Laryngectomy, Pharyngocutaneous fistula, Blue dye test, Barium swallow

## Background

Pharyngocutaneous fistula (PCF) is considered the most common suffering complication in laryngectomized patients (1–3). It has been agreed that PCF occurs

variably in 10–20% cases, even sometimes it could reach more than 60% [1–5]. PCF results from combination of local factors like poor surgical technique, infection, prior irradiation or chemoradiation, positive margins, or tumor recurrence, in addition to systemic factors including malnutrition, anemia, diabetes, and hypothyroidism that have been implicated in poor tissue healing and wound breakdown [1–5]. Development of PCF unfortunately complicates the plan to resume normal life after laryngectomy; this is well explained by delay regarding starting oral intake, inflammation of the neck with delayed healing or even more breakdown, prolongation of hospital stay, the need for further medical and

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surgical interference, increase the cost spent for the cure, and in such a way delayed complementary radiation treatment in situation required, all that have a negative impact on the patient physical and psychological status or even can end with major complications that affect the patient survival [1, 2, 4–10].

Certainly, early prediction of fistula can help with more precise and time-specific management that alleviates the burden of its occurrence. Different parameters have been described in literature for expectation of the fistula formation, like preoperative risk factors, clinical features of local wound inflammation, fever, change of drain contents, salivary pooling from the wound, drain amylase measurements, tissue markers, barium, and other radiological testing [1, 3–5] that determine the decision of oral feeding initiation [11–14].

Our study aims to illustrate using an easy, convenient, and safe bedside blue dye test in early detection of PCF following laryngectomy in addition to assessing the impact of utilizing it in the diagnosis and management of PCF including the duration of hospital stay.

## Methods

It is a retrospective review to all post-laryngectomy cases that have been performed during the period from Jan 2020 till Dec 2021 at a tertiary Head and Neck Cancer Center where we utilized both post-operative blue dye test and barium study for all patients. A total of 64 patients were reviewed and only 40 patients were included in the study.

### Study protocol

Our institution protocol for postoperative testing includes doing a barium study on day 7 in primary cases and day 10 in salvage cases. In our study group, we used on blue dye test as an initial test followed by barium study that was considered a standard test for assessment. Subjects who did not have a postoperative blue dye test prior to barium swallow study evaluation were excluded from the study.

Patient information was collected, including age, sex, medical co-morbidities, tumor stage, history of radiation, margin status, and type of pharyngeal closure whether associated with reconstruction or not. Further details associated with the development of a PCF were recorded for that subset of patients including local neck insult whether infection or dehiscence, length of time of fistula, and management. This study was approved by the Institutional Review Board.

Our data includes both primary and salvage total laryngectomy with and without partial pharyngectomy; reconstruction was done mainly in salvage cases as overly flap for pharyngeal augmentation or to reconstruct a

pharyngectomy defect using pectoralis major musculocutaneous or supraclavicular pedicled regional flaps. All patients were kept on prophylactic antibiotics therapy with feeding through nasogastric or gastrostomy route for at least 1 week post-operatively.

Blue dye test was performed by using a diluted blue dye of food flavors 2 ml in 250-ml water and the patients drink a frequent sip of it by spoon or cup, hold it in the mouth for few seconds, then swallow it over a period of 4 h during which drain content and neck incision line or stoma opening observed for any dye leakage over 24 h. If immediate leakage occurs, the test stopped, or any leakage appeared over next 24 h then regarded as positive test and then repeated after interval of days. When no leakage occurs, the test is regarded as negative and a barium study is performed 1 to 2 days later.

Barium swallow study was undertaken by allowing the patient to swallow a liquid barium in an erect position during which a radiological assessment was done. Fistula was diagnosed in case there is a significant out pouching from the pharynx, or evident leakage of barium in the neck drain through a communicating tract with pharynx immediately or through the next 24 h.

As literature mentioned, most fistulae developed within the first 35 days of surgery and most of swallow study done after 2 weeks. A period of 21 days after swallow study appears to be a proper time for the development of a fistula. Any leaks that occurred beyond this time were accepted to be a new onset, "late" leaks, rather than fistulae that were missed on earlier assessment.

In our study, most patients underwent the blue dye test < 10 days postoperatively, except in some selected cases that were deferred based on surgeon decision to delay it beyond day 10 postoperatively.

Cases in which fistula was detected by blue dye test were managed conservatively by continuation nothing by mouth, antibiotics treatment with correction of any nutritional deficiency; however in cases that leakage site showed no response, surgical management was offered with direct closure with and without flap use. Barium swallow study in these cases were rescheduled later after repeating the blue dye test once or more to confirm closure of fistula.

### Statistical analysis

Analysis of data was carried out using the available statistical package of SPSS-28 (Statistical Packages for Social Sciences- version 28). Data were presented in simple measures of frequency, percentage, mean, standard deviation, and range (minimum–maximum values).

The significance of difference of different means (quantitative data) was tested using Students *t*-test for difference between two independent means. The significance

of difference of different percentages (qualitative data) was tested using Pearson chi-square test (c2-test) with application of Yate’s correction or Fisher exact test whenever applicable. Statistical significance was considered whenever the *P* value was equal or less than 0.05.

**Results**

Our study was performed on 64 patients who underwent total laryngectomy during the period from Jan 2020 till Dec 2021 at a tertiary Head and Neck Cancer Center; 40 patients were included in the study that had both post-operative blue dye test and barium swallow. We used to consider barium swallow as standard test to detect post-operative PCF as the situation offered for remaining 24 patients that had only barium swallow study.

Patients’ age group was more in less than and equal to 65 years for our study group (65%). Most of our

patients were male (97.5%, *n* = 39). There was a history of preoperative radiation in 16 (40%) patients; smoking was reported in 35 (87.5%) of patients while none of our patients was alcoholic in this study. Six patients were diabetic (15%) and 3 (7.5%) were hypothyroid postoperatively. PCF have occurred in 7 patients (17.5%). Pharynx was closed primarily in 36 (90%) of cases whereas flap was used in four (10%) cases, two (5%) of them had pectoralis musculocutaneous flap and other two patients had (5%) supraclavicular fasciocutaneous flap (Table 1).

Median time for diagnosis of fistula was nine (5–35) days, and five of the cases (12.5%) were managed conservatively while two cases (12.5%) required surgical intervention. Median time for healing was 22 (19–30) days in conservative cases and 54 (37–70) days in surgical cases (Table 1).

**Table 1** Patient characteristics

		Patients ( <i>n</i> = 40)	
		No	%
Age (years)	≤65y	26	65.0
	>65y	14	35.0
	Mean ± SD (range)	61.2 ± 10.3 (37–82)	
Sex	Male	39	97.5
	Female	1	2.5
Tobacco	Yes	35	87.5
	No	5	12.5
Alcohol	Yes	-	-
	No	40	100
Diabetes mellitus	Yes	6	15.0
	No	34	85.0
Hypothyroidism	Yes	3	7.5
	No	37	92.5
Tumor pT stage	T1-T3	-	-
	T4	40	100
Previous radiation treatment	Yes	16	40.0
	No	24	60.0
Pharyngeal closure	Primary	36	90.0
	Flap	-	-
	PMMC	2	5.0
Fistula	Supraclavicular	2	5.0
	Yes	7	17.5
	No	33	82.5
Diagnosis time (days)	Mean ± SD	19.1 ± 6.5	
	Median (Range)	9 (5–35)	
Management of fistula	Conservative	5	12.5
	Surgical	2	5.0
Median time for fistula healing (days)	Conservative Median (Range)	22 (19–30)	
	Surgical Median (Range)	54 (37–70)	

Factors that were correlated with fistula formation are shown in Table 2; statistical significance was found in cases with neck infection ( $n=5$ , 71.4%,  $p=0.0001$ ) and neck dehiscence ( $n=4$ , 57.1%,  $p=0.007$ ) as well as length of hospital stay which was >11 days ( $n=7$ , 100%,  $p=0.0001$ ) in all fistula cases, while most of non-fistula patients were <11 days ( $n=27$ , 81.8%). Although five out of seven patients who developed fistula were irradiated, it was statistically not significant that might be explained by small sample size.

**Table 2** Patient characteristics and relation to fistula

	Presence of fistula ( $n=7$ )		No fistula ( $n=33$ )		P-value
	No	%	No	%	
<b>Age, years</b>					
≤65 ( $n=27$ )	6	85.7	21	63.6	0.257
>65 ( $n=13$ )	1	14.3	12	36.4	
<b>Total laryngectomy closure</b>					
Primary ( $n=36$ )	5	71.4	31	94	0.071
Pectoralis ( $n=2$ )	1	14.3	1	3	
Supraclavicular ( $n=2$ )	1	14.3	1	3	
<b>Positive margin</b>					
Yes ( $n=5$ )	1	14.3	4	12.1	0.875
No ( $n=35$ )	6	85.7	29	87.9	
<b>Neck infection</b>					
Yes ( $n=9$ )	5	71.4	4	12.1	0.0001*
No ( $n=31$ )	2	28.6	29	87.9	
<b>Neck dehiscence</b>					
Yes ( $n=8$ )	4	57.1	4	12.1	0.007*
No ( $n=32$ )	3	42.9	29	87.9	
<b>Pre-operative radiotherapy</b>					
Yes ( $n=16$ )	5	71.4	11	33.3	0.062
No ( $n=24$ )	2	18.6	22	66.7	
<b>Length of hospitalization/days</b>					
≤11 ( $n=27$ )	-	-	27	81.8	0.0001*
>11 ( $n=13$ )	7	100	6	18.2	

\* Significant difference between proportions using Pearson chi-square test at 0.05 level

Regarding the outcome of patients with PCF as shown in Table 3, five (12.5%) of their blue dye test and barium swallow were positive while two of them showed negative results (5%). These patients were later presented with a clinical fistula. Median time for fistula diagnosis was 10 days when test was positive and 23 days when test was negative. Median time for closure of fistula was 23 days for the positive group and 45 days for the negative group. Conservative management was offered for five patients (12.5%) whereas surgical management was utilized in the remaining two patients (5%). Range of hospital stay for fistula closure was significantly longer in the negative group, calculated as 45 days. Further details for fistula cases are illustrated in Table 4.

**Discussion**

PCF is a common complication following total laryngectomy that makes a burden to the patients themselves and their family in addition to a significant cost of health care system [1–3, 15]. Multiple local and systemic factors contribute to development of fistula that have been documented in previous literature [1–3, 14, 16, 17]. In our study, PCF was reported in 7/40 of patients (17.5%) which matches the same percentage mentioned in literature [1–4, 17, 18]. Factors have been studied in correlation to fistula formation including age, pharyngeal closure, positive margins, neck infection, neck dehiscence, and preoperative radiotherapy. All factors showed poor correlation apart from neck infection and dehiscence that had statistical significance ( $p$ -value 0.0001 and 0.007). White et al. [14] confirmed that previous radiotherapy and hypothyroidism are important risk factors for PCF, while Sousa et al. [16], Amutta and Abdullahi [17], and Kiong et al. [3] show no statistical correlation with the studied factors.

While previous literature described different methods for the detection of PCF, initially fistula detection was based on clinical features [19–21]. Giordano et al. used barium study [22], White et al. tested using gastrografin instead [14], and Moses et al. relied on doing dysphagiogram for patients [23], while Kiong et al. added

**Table 3** Outcome of patients diagnosed with PCF

Outcomes	Blue dye test Positive ( $n=5$ )	Blue dye test Negative ( $n=35$ )
Evidence of PCF		
Presence of fistula ( $n=7$ )	5	2
No fistula ( $n=33$ )	-	33
POD of diagnosis (days) median (range)	10 (5; 12)	23 (12, 34)
Conservative management	4	1
Surgical closure	1	1
Time to closure of fistula (days) median (range)	23 (19; 38)	45 (20, 70)

**Table 4** Details of fistula patients

No	Diagnosis	Intervention	Risk factor	Comorbidities	Time of identification	Fistula management	Outcome
1	Persistent transglottic SCC/post chemo/XRT	Salvage total laryngectomy, Rt SND, Supraclavicular flap	Smoking	None	POD 34	Conservative	Clinical resolution with blue dye test at POD 54, gastrostomy dependent then total oral
2	Chondroradionecrosis post transglottic SCC/post chemo/XRT	Salvage total laryngectomy, Rt SND, & Primary closure	Smoking	Hypothyroidism	POD 12	Surgical debridement and closure	Radiographic resolution of fistula with barium swallow at POD 38, gastrostomy dependent then total oral feeding
3	Transglottic SCC T4a	Primary laryngectomy, BCND, PVMC flap	Smoking	None	POD 10	Conservative	Clinical resolution with blue dye test at POD 17 then confirmed by radiological resolution of fistula with barium swallow at POD 19, then the patient resumes full oral intake
4	Recurrent transglottic SCC/post chemo/XRT	Salvage total laryngectomy, BSND, primary closure	Smoking	None	POD 12	Surgical debridement and closure, then later dehiscence managed conservative	Clinical resolution with repeated blue dye test at POD 41, 54, and 70 with complete cure and resume full oral intake
5	Recurrent transglottic SCC/post chemo/XRT	Salvage total laryngectomy, BSND, primary closure	Smoking	None	POD 5	Conservative	Clinical resolution with repeated blue dye test at POD 16 and 23 with complete cure and resume full oral intake
6	Transglottic SCC T4a	Primary laryngectomy, RT MRND, LT SND, primary closure	Smoker	Hypothyroidism	POD 11	Conservative	Clinical resolution with blue dye test at POD 21 then confirmed by radiological resolution with barium swallow at POD 22
7	Recurrent transglottic SCC T4a/post chemo/ XRT	Salvage total laryngectomy, primary closure	Smoker	None	POD 6	Conservative	Radiological resolution of fistula with barium swallow at POD 30 then resume oral intake

POD Postoperative day

videofluoroscopy study to the assessment methods [3], Morton et al. tested the level of drain amylase [24], and Koob et al. relied on tissue marker measurement as a predictor for PCF formation [4]. Blue dye test have been used in other studies in the detection of PCF either using methylene blue dye like by Amutta and Abdullahi [17] or blue food dye by Kiong et al. [3] while Malfitano et al. used the grape juice for the same purpose [25].

Our institution protocol for postoperative leak testing was based on doing a barium study on postoperative day 7 in primary cases and day 10 in salvage cases. In this study, we utilized the blue dye test as initial test which was performed a day or two before barium study which is considered a reference standard for assessment. Subjects who did not have a postoperative blue dye test prior to barium swallow study evaluation were excluded from the study.

Blue dye test has been used in our study on multiple occasions; first, once the patient’s neck shows features of infection or dehiscence within the early days postoperatively, the swallowing of the dye can detect early fistula; second, as a leak test to check closure as an initial test before doing barium swallow to detect fistula and avoid complications of barium leakage in the neck once happened; third, in case of established fistula, the test can be repeated frequently till being negative before resuming oral feeding. Amin et al. [1] have been used a repeated barium swallow in some cases to confirm resolution or detection of fistula in patients with subtle signs of leak; Kiong et al. [3] depended on a repeated blue dye test in difficult or suspicious cases even if initially negative that later revealed evidence of fistula.

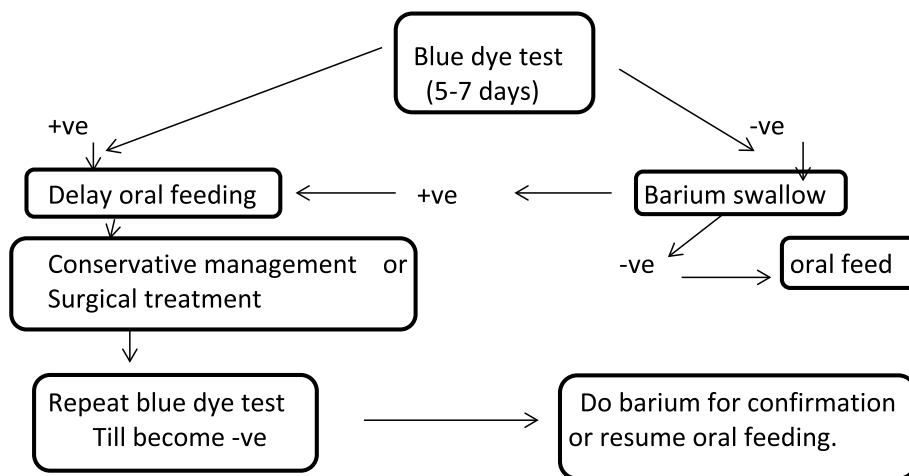
Blue dye test was capable of detection of fistula in most of our cases (4/7 = ≤ 11 days) as early as 5th postoperative day, so we started early management. Kion

et al. [3] and Amutta and Abdullahi [17] suggested early testing undertaken before 10th postoperative day. Most of the fistula cases were managed conservatively in the form of nothing by mouth, local care, systemic antibiotics, correction of the general conditions, and feeding by NG tube or gastrostomy especially in the early cases. Three cases have been reported in our data with delayed fistula, two of them managed by surgical debridement, primary closure of the fistula site, and overly myofascial flap for pharyngeal augmentation and one case managed conservatively and that have been undertaken in similar way in previous literature [17]. All that reflected on the hospital stay as early detection of the fistula as 10th day resulted in initiation of the management within a proper time so as shortening of hospital stay as short as 23 days in early cases compared to 45 days in late cases like what has been reported by Kion et al. [3] but with a longer period as 40 days and 76.5 days respectively as well as other series [7, 8, 14, 26–28] with its effects in the form of increasing the cost, morbidity, and delayed of resuming normal life activities.

As shown in our study, blue dye test contributed significantly to early detection of fistula with an appropriate management; however, that lacked statistical significance explained by small sample size. We established a simple flowchart (Fig. 1) to summarize our protocol in using the blue dye test in detection of PCF to facilitate the understanding of our idea.

**Conclusion**

Utilization of the blue dye test is very beneficial in early detection and consequently proper management of pharyngocutaneous fistula. That will lead to reduction of the hospital stay and its financial implications. It is a simple, safe, and reliable test that could



**Fig. 1** Flowchart of blue dye test in PCF

be repeated avoiding potential risks related to barium leakage in the neck. Further larger sample study is recommended to establish solid consensus for using blue dye test as standard leak test for laryngectomy patients.

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**Authors' contributions**

SA was the main and corresponding author, MZ participated in the literature review and data analysis, AT was a supervisor of research, and AY was a main author and participated in the data analysis, in addition to being a supervisor of the research.

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**Availability of data and materials**

The datasets generated and/or analyzed during the current study are available from the corresponding author on reasonable request.

**Declarations**

**Ethics approval and consent to participate**

This study was approved by the research ethical committee (REC), Alexandria University. Written consent was obtained from the patients prior to contribution to the study after clarifying the importance of the study.

**Consent for publication**

Not applicable.

**Competing interests**

The authors declare that they have no competing interests.

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