Braz J Otorhinolaryngol. 2015;81(4):394–401

Brazilian Journal of
OTORHINOLARYNGOLOGY
www.bjorl.org

ORIGINAL ARTICLE

Derivation of a clinical decision rule for predictive factors for the development of pharyngocutaneous fistula postlaryngectomy☆,☆☆

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Received 20 March 2014; accepted 21 September 2014
Available online 10 June 2015

KEYWORDS
Postoperative complications;
ENT surgical procedures;
Laryngeal neoplasms;
Laryngectomy;
Surgical wound dehiscence;
Salivary gland fistula

Abstract
Introduction: Pharyngocutaneous fistula after larynx and hypopharynx cancer surgery can cause several damages. This study's aim was to derive a clinical decision rule to predict pharyngocutaneous fistula development after pharyngolaryngeal cancer surgery.
Methods: A retrospective cohort study was conducted, including all patients performing total laryngectomy/pharyngolaryngectomy ($n = 171$). Association between pertinent variables and pharyngocutaneous fistula development was assessed and a predictive model proposed.
Results: American Society of Anesthesiologists scale, chemoradiotherapy, and tracheotomy before surgery were associated with fistula in the univariate analysis. In the multivariate analysis, only American Society of Anesthesiologists maintained statistical significance. Using logistic regression, a predictive model including the following was derived: American Society of Anesthesiologists, alcohol, chemoradiotherapy, tracheotomy, hemoglobin and albumin pre-surgery, local extension, N-classification, and diabetes mellitus. The model's score area under the curve was 0.76 (95% CI 0.64–0.87). The high-risk group presented specificity of 93%, positive likelihood

☆ Please cite this article as: Cecatto SB, Monteiro-Soares M, Henriques T, Monteiro E, Moura CIFP. Derivation of a clinical decision rule for predictive factors for the development of pharyngocutaneous fistula postlaryngectomy. Braz J Otorhinolaryngol. 2015;81:394–401.

☆☆ Institution: Work conducted at the Portuguese Institute of Oncology, city of Oporto (IPOPFG-EPE, Oporto), Department of Otolaryngology, under the sphere of the Master's Degree Program in Evidence and Decision Making in Healthcare – part of a Master's thesis defended by the main author in November 2012 at Medicine School, University of Oporto – Portugal.

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http://dx.doi.org/10.1016/j.bjorl.2014.09.009

ratio of 7.10, and positive predictive value of 76%. Including the medium-low, medium-high, and high-risk groups, a sensitivity of 92%, negative likelihood ratio of 0.25, and negative predictive value of 89% were observed.
Conclusion: A clinical decision rule was created to identify patients with high risk of pharyngocutaneous fistula development. Prognostic accuracy measures were substantial. Nevertheless, it is essential to conduct larger prospective studies for validation and refinement.

PALAVRAS-CHAVE
Complicações pós-operatórias;
Procedimentos cirúrgicos otorrinolaringológicos;
Neoplasias laríngeas;
Laringectomia;
Deiscência da ferida operatória;
Fístula das glândulas salivares

Derivação de uma regra de decisão clínica para predição de desenvolvimento de fístula faringocutânea pós laringectomia

Resumo
Introdução: Fístula faringocutânea após cirurgia de câncer de laringe e hipofaringe causa diversos danos. Nosso objetivo foi derivar uma regra de decisão clínica (RDC) para predizer o desenvolvimento da fístula faringocutânea após cirurgia.
Método: Estudo de coorte retrospectivo incluindo todos os pacientes submetidos à laringectomia total e faringolaringectomia (n = 171). Analisou-se a associação entre as variáveis pertinentes e o desenvolvimento da fístula e foi proposto um modelo preditivo.
Resultados: Na análise univariada, a ASA, quimioradioterapia (QRT) e traqueostomia antes da cirurgia foram associadas à fístula. Na análise multivariada, somente a ASA manteve-se estatisticamente significante. Por regressão logística, derivamos um modelo preditivo incluindo: ASA, álcool, QRT, traqueostomia, hemoglobina e albumina pré-operatórias, extensão local, N, DM. A curva ROC do modelo foi 0,76 (95% CI 0,64–0,87). O grupo de alto risco teve especificidade 93%, *Likelihood* positivo 7,10 e valor preditivo positivo 76%. Incluindo os grupos de médio baixo, médio alto e alto risco, temos sensibilidade de 92%, *Likelihood* negativo 0,25 e valor preditivo positivo 89%.
Conclusão: Criamos uma RDC para identificar os pacientes de alto risco ao desenvolvimento da fístula faringocutânea. As medidas de acurácia prognóstica foram substanciais. Entretanto, é essencial conduzir estudos prospectivos maiores para validação/refinamento do modelo.

Introduction

Larynx and hypopharynx cancer represents almost 45% of all treated diseases in this tertiary care hospital's department of otolaryngology, specialized in oncology.

Prevalence of pharyngocutaneous fistula after larynx and pharyngolarynx cancer surgery is reported to be between 9% and 25%.[1,2] Its occurrence vastly increases these patients' length of stay and consequently the treatment cost.[3] Moreover, its occurrence can cause, among other physical and psychological damages, the delay in onset of complementary therapies (such as radiotherapy/chemotherapy), consequently delaying recovery.

Until now, no study has proposed a clinical decision rule (CDR) for predicting pharyngocutaneous fistula after total laryngectomy and primary or rescue pharyngolaryngectomy, with or without neck dissection, and major predictive factors were scarcely assessed.[4] Thus, the goal was to derive such a CDR in a sample of patients from this hospital. Its creation is intended to encourage clinical behavior modification in order to avoid development of this complication and thus facilitate the reduction of unnecessary costs as well as improve patients' quality of life.

Methods

A retrospective cohort study was conducted (longitudinal historical cohort study), consecutively including all the patients performing total laryngectomy/pharyngolaryngectomy, due to cancer of the larynx and hypopharynx, in the Otolaryngology Department of this hospital, from February of 2006 to June of 2011. All patients diagnosed with laryngeal and pharyngolaryngeal cancer were evaluated by the team before final treatment. Only procedures consistent with total laryngectomy with or without partial pharyngectomy and primary closure of the pharyngeal defect were considered in this study. The operations were performed by four different surgeons, two with ten or more years of experience, and two with less.

This study conduction was approved by the Ethics Committee of this hospital.

Data collection

All variables and outcome occurrence were collected by the principal investigator (SC), between August of 2011 and