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British Journal of Oral and Maxillofacial Surgery 54 (2016) 141–150

BRITISH Journal of Oral and Maxillofacial Surgery

www.bjoms.com

Refining the head and neck cancer referral guidelines: a two centre analysis of 4715 referrals

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Accepted 14 September 2015

Abstract

Our aim was to identify the set of referral criteria that will offer optimal diagnostic efficacy in patients suspected to have head and neck cancer (HNC) in the primary care setting. We analysed the referral criteria and outcomes from two tertiary care cancer centres in the United Kingdom. Between 2007 and 2010, 4715 patients were referred via the fast track system with a suspected HNC. The main outcome measures were the parameters of diagnostic efficacy, a multivariate regression model to calculate estimated probability of HNC and the area under the receiver operating characteristic curve (AUROC). We found that the majority of referring symptoms had a positive predictive value higher than the 3% cut-off point stated to be significant for HNC detection in the 2015 NICE recommendations. Nevertheless, our multivariate analysis identified 9 symptoms to be linked with HNC. Of these, only 4 are included in the latest NICE guidelines. The best fit predictive model for this dataset included the following symptoms: hoarseness>3 weeks, dysphagia>3 weeks, odynophagia, unexplained neck mass, oral swelling >3 weeks, oral ulcer >3weeks, prolonged otalgia with normal otoscopy, presence of blood in mouth with concurrent sensation of lump in throat, and presence of otalgia with concurrent lump in throat sensation. Intermittent hoarseness and sensation of lump in throat were negatively associated with HNC. The AUROC demonstrated that our model had a higher predictive value (0.77) compared to those generated using the NICE 2005 (0.69) and 2015 (0.68) referral criteria ($p<0.0001$). An online risk calculator based on this study is available at http://www.orlhealth.com/risk-calculator.html. This paper presents a significantly refined version of referral guidelines which demonstrate greater diagnostic efficacy than the current NICE guidelines. We recommend that further iterative refinements of referral criteria be considered when referring patients with suspected HNC.

Keywords: Head and neck cancer; 2-week-wait clinic; NICE guidance

Introduction

Each year approximately 8000 new cases of head and neck cancer (HNC) are diagnosed in the UK.[1] The incidence of certain HNCs has risen significantly over the past two decades with oropharyngeal cancer having increased two fold.[2]

Despite the rising numbers, mortality rates have fallen or remained stable depending on the cancer site. Oropharyngeal and laryngeal cancers have had a 50% and a 33% fall in mortality respectively between 1990 and 2006, with small variations across the country.[2] The combination of surgical and non-surgical treatment with improvements in perioperative and supportive care of head and neck cancer is thought to have contributed to this.[3]

In 2000 the Department of Health (DoH) developed the UK National Guidelines for referring suspected HNC (fast track - 2 week pathway). According to the guidelines, all

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http://dx.doi.org/10.1016/j.bjoms.2015.09.022

suspected cancer patients should be seen by a specialist within 14 days.[4] This move seemed to be an important step forward in early detection and management. However, several audits across the country showed a low cancer detection rate for the 2 week referral system with a significant number of inappropriate referrals. The cancer detection rate was not significantly different when compared to the non-urgent referrals and no early cancers were being identified in patients diagnosed with cancer via this referral pathway.[5–11] As a result, the National Institute for Health and Care Excellence (NICE) updated the guidelines for HNC in 2005.[12]

Following the 2005 update new audits and research papers failed to show any significant improvement in cancer detection rate, highlighting poor compliance to guidelines.[13,14] These papers also identified the need for further education of primary care physicians in the appropriate use of the urgent Two-Week referral proforma.[15,16] Additionally, it was recommended that a standardised national proforma be developed based on specific signs and symptoms which have a proven correlation with HNC.[17,18]

In June 2015 NICE updated again the HNC referral guidance, classified by organs sites. In this iteration the positive predictive value (PPV) was used to determine high risk symptoms for HNC. Only data from studies within a primary care setting were used to formulate the new guidance as it was felt that these were representative of the population the guidance is targeted at. The Guideline Development Group (GDG) state that they have included in the new guidance all symptoms with a PPV threshold of 3% or higher. The previous guidance included only few symptoms with PPV less than 5%. It was felt that by decreasing the percentage the diagnosis of cancers would occur at earlier stages. The GDG concluded that this change would neither overwhelm clinical services nor cause over-investigation of healthy individuals, even though at the time of setting the threshold figure no good quality health-economic studies were available to help formulate the guidance.[19] Risk factors for cancer such as increased age, smoking, alcohol and family history have been excluded, except for the laryngeal cancer guidance, where age more than 45 is considered a significant risk factor. The NICE guidance group rightly considered that while risk factors increase the chance of cancer, they do not alter the presenting symptoms and are not relevant for the individual patient.[19]

The aim of this work is to identify and refine the set of referral criteria that will provide optimal diagnostic efficacy using data obtained from a large cohort of patients who were referred using the previous iteration (2005) of fast track criteria with a suspected HNC by applying well defined statistical techniques.

Methods

This study was conducted from the data obtained at two tertiary hospitals. All suspected HNC patients who were seen in a 2 week wait (2WW) clinic between January 2007 and December 2010 at Newcastle upon Tyne Hospitals and between July 2009 and July 2010 in the Queen Elizabeth Hospital Birmingham were included. The dataset included demographic details, smoking status, presenting symptom(s) that triggered the referral and the final diagnosis.

Rare symptoms which presented in less than 10 patients were excluded from further analysis as this would cause large systematic errors.[20] Presence of pain in the head and neck associated with otalgia and normal otoscopy was divided into two separate variables in order to check for presence of interactions with the other symptoms as these were combined in previous iterations of the guidance. Smoking variable was not included in the analysis due to missing data for more than half of the patients.

Data collection was undertaken by two authors. This was performed prospectively at the Newcastle upon Tyne Hospital and retrospectively in the Queen Elizabeth Hospital Birmingham. The collected data were entered into a single excel file for analysis.

Statistical analysis

Results are expressed as mean (95% CI or ±SD) for continuous variables and as a percentage for categorical variables. Univariate analysis of risk factors using Pearson's chi-square test or Fisher's exact test where appropriate for categorical variables was performed. The sensitivity, specificity and PPV were calculated as markers of diagnostic efficacy of the presenting symptoms.

Statistics modelling was performed using the 'proc logistic' function in the 'SAS® 9.3. Cary, NC, USA: SAS Institute Inc.' statistical package. A multivariate binary logistic regression analysis was conducted to identify the symptoms that contribute significantly to the diagnosis or not of malignancy. The variables tested included patients' gender, age and presenting symptoms. Presence of interactions between the independent variables was also tested. Following a stepwise elimination process only the statistically significant variables were included in the final model. A variable was considered statistically significant if it reached the 0.05 level of significance. Presence of 2 and 3 way interactions were checked for inclusion in the final model. When a significant interaction was identified the main effects were included in the model even if not significant. In the presence of significant interactions the odds ratio (OR) and confidence interval (CI) of the main effects could not be directly calculated.[20]

The same cohort of patients was used to identify the performance of the current and previous NICE referral guidance using standard parameters for diagnostic efficacy. We performed further multivariate binary logistic regression analyses of the referral criteria as defined by the 2005 and the 2015 iterations of the NICE guidelines using our dataset in order to externally validate the 2005 and 2015 NICE guidances and identify which of these models explains best the sample variation.