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Research Paper
Head and Neck Oncology

Identification of appropriate outcome indices in head and neck cancer and factors influencing them

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Abstract. Audit of early postoperative outcomes adjusted for patient case mix is still in its infancy in head and neck surgery. Nevertheless the role for audit of early postoperative outcomes is obvious. The primary outcome measure of this study was to identify factors that are associated with early mortality or morbidity after surgery for head and neck squamous cell carcinoma (HNSCC). The secondary outcome measure was to develop a pilot score that allows for risk-adjustment of outcome data to facilitate departmental audit. In this series the mortality rate was low (2.8%), in keeping with other published series. Complications, including those causing death, occurred after 38.1% of operations. Independent risk factors for mortality on logistic regression were shown to be previous HNSCC ($P = 0.03$), estimated blood loss (l) ($P = 0.03$), and extracapsular spread ($P = 0.05$). Age ($P = 0.01$), tracheostomy ($P < 0.01$), estimated blood loss (l) ($P = 0.05$), and duration of anaesthesia ($P < 0.01$) were independent predictors of complications. Models predicting for risk demonstrated good discrimination (area under the curve statistics) for mortality (0.86) and morbidity (0.81). These pilot scores need external validation and may herald a means of facilitating risk-adjustment in the audit of early outcomes, allowing meaningful comparison of surgeons and their units over time.

Keywords: morbidity; mortality; HNSCC; audit; outcomes.

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Routine presentation of early surgical outcomes for public consumption has become mainstream in the UK in 2013. In the UK, head and neck surgeons are now requested to submit to the Department of Health both 30-day mortality data and return to theatre data for patients receiving primary operative treatment for head and neck squamous cell carcinoma (HNSCC). The results will highlight the performance of a given surgeon and unit. A key reservation with this process is that without proper risk adjustment for case mix, the presentation of crude data is meaningless and even harmful. Risk adjustment is unusually important for patients with HNSCC.

Demographic and lifestyle factors that adversely affect cardio-respiratory or liver function are highly variable in the patient population being studied. Studying the influence of these factors on outcome is therefore desirable in the head and neck patient population. In addition the patient's homeostatic mechanisms are

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further taxed by operative procedures in complex anatomical areas of the body. Physical alterations of the oral environment can compromise the airway and affect deglutition. Wound healing is an ever present problem.

Mortality incidence is relatively low in the international literature (1.4–3%),[1–3] making rigorous investigation of causes a protracted endeavour. We speculate that morbidity is a more appropriate early outcome measure of unit performance. Reported morbidity is common and seems to vary widely between centres (15–55%),[4–6] but making comparisons is challenging. The literature on this topic is currently too focused on specific subgroups of operation or outcome. Different classification systems and time points at which complications are measured further compound comparisons.

Early morbidity contributes to hospital costs by increasing both intensive care unit stay and hospital stay.[7] Hospital commissioners considering purchasing may infer quality of care from these factors.

A scientifically based and validated weighting system based on patient risk factors, disease burden, operative intervention, and early outcomes may act as a safeguard against inappropriate crude outcome analysis. Ultimately such a score will facilitate outcome audit and permit comparison of a unit's performance.

The primary outcome measure of this study was to highlight factors associated with early mortality or morbidity after head and neck surgery. The secondary outcome measure was the development of a risk index or score that allows for case-mix adjustment of outcome data.

Materials and methods

During the period 1992–2009, a database modelled on the British Association of Head and Neck Oncologists (BAHNO)[8] minimum dataset was commenced in the oral and maxillofacial unit of a UK hospital. The details of 1173 patients were collected prospectively. In order to improve data content, a retrospective case note evaluation was conducted, including inspection of microfiched data by two junior researchers between 2009 and 2010. Mortality data, namely date of death, was finalized in May 2010 using the National Cancer Registry, using name, date of birth, National Health Service (NHS) unique identifier, and postcode.

Inclusion criteria for this study included resection of biopsy proven squamous cell carcinoma and NHS surgical treatment performed between 1992 and 2010 by the senior author.[4] Patients who met the inclusion criteria with incomplete data were excluded, but details of those excluded were compared to the included group to explore any biases resulting from their omission.

Tumour factors were staged using the 2002 American Joint Committee on Cancer/Union Internationale Contre le Cancer (AJCC/UICC) staging guidelines. Patient performance status was documented according to the Eastern Cooperative Oncology Group (ECOG)/World Health Organization (WHO) classification.[9] Operative interventions were recorded specifically, dated and classified by BUPA operative severity grade into minor (operation lasting <1 h), intermediate (operation lasting 1–6 h), and major interventions (operations over 6 h, with or without regional/free tissue reconstruction).

Blood loss was estimated to the nearest 500 ml, as this is an approximation that coincides with well described changes in the physiology of shock. Anaesthetic duration was derived from anaesthetic intraoperative monitoring charts.

Complications were classified using the Clavien–Dindo system, graded 1–5.[10] The current study chose 30 days post-surgery as the cut-off period following the example of other major UK surgical outcome reports, largely POSSUM (physiological and operative severity score for the enumeration of mortality and morbidity) variants.[11–15] Morbidity and mortality outcomes were analyzed separately using univariate logistic regression testing of each demographic or co-morbidity factor. Univariate analyses were carried out to determine associations with mortality and morbidity. Those variables with a P-value ≤ 0.05 were selected and entered into a multivariate logistic regression model to get a best (final) model for mortality and morbidity. The best models for each outcome were selected on the basis of the log-likelihood ratio test comparisons (not shown in the tables) until the best predictive set of factors for defining a predictive equation could be chosen. Discrimination of the predictive models was tested using receiver operating characteristic (ROC) curve analyses for each outcome for mortality and morbidity.

Results

Four hundred and seventy-five of the 1173 individuals had a recorded diagnosis of HNSCC; complete data were available for 317/475 (66.7%) individuals having 396 operations within the NHS. Fifty-two of the 1173 individuals had a recorded HNSCC but had other outcomes besides surgical treatment, including chemo/radiotherapy ($n = 22$) and referral to palliative care ($n = 21$), or were lost to follow-up ($n = 7$) or died before planned treatment ($n = 2$). The remaining 646 of the 1173 individuals had non-HNSCC disease.

One hundred and fifty-eight of the 475 individuals with a diagnosis of HNSCC were excluded because of insufficient data in one or more of the following fields: demographic ($n = 20$), operative ($n = 87$), anaesthetic ($n = 39$), or histopathology data ($n = 22$). Patients missing these crucial fields were grouped and compared to those entered into the analysis (Table 1); patients missing data in more than one field resulted in percentages not totalling 100%. No inference procedure was used to fill these data points. Inadequacy of the microfiching process, limited access to archived histology results, and incomplete records accounted for the high exclusion rate.

Of 396 interventions on 317 individuals, 55.3% were on males (219/396). The mean age of the cohort was 62 years (standard deviation 14 years). Fifty-three percent of interventions were major procedures (211/396), with 24.2% (96/396) including a free tissue transfer procedure; 26.0% were intermediate procedures (103/396) and 20.7% minor procedures (82/396).

There were 12 deaths within 30 days of the operation. Of these, 11 patients had a documented postoperative complication, representing a 30-day surgical mortality rate of 2.8% (11/396). One patient committed suicide after discharge (8 uneventful days postoperatively). Reasons for death were intraoperative arrest due to myocardial infarction ($n = 1$), cardiac dysrhythmia and arrest ($n = 2$), respiratory distress provoking cardio-pulmonary arrest ($n = 2$), myocardial infarction and arrest ($n = 1$), pulmonary embolism and subsequent cerebrovascular accident ($n = 1$), carotid blowout ($n = 1$), tracheostomy tube blockage and cardiac arrhythmia ($n = 1$), disseminated intravascular coagulation leading to multiorgan failure ($n = 1$), and intestinal obstruction ($n = 1$) with no further details (the operation was done in 1994).

The median time period between surgery and the first complication was 4 days, between first complication and death was 2.5 days, and between surgery and death was 7.5 days.

Overall 30-day morbidity was common at 38.1% (151/396). Where a complication occurred, the Clavien–Dindo grade was

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