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Research article

Predicting acute odynophagia during lung cancer radiotherapy using observations derived from patient-centred nursing care



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ABSTRACT

During radiotherapy, lung cancer patients commonly experience pain while swallowing (odynophagia) of food and drink. Observations from patient-centred nursing practice have been used to generate predictive models for odynophagia needing prescription pain medication during external beam lung radiotherapy for non-small cell and small-cell lung cancer. Three multivariate logistic models were evaluated in repeat cross-validation: a manual-stepwise model and two supervised machine learning models. Overall predictive performance was good. Correct classification rates ranged from 0.82 to 0.84, and areas under the receiver operator curve ranged from 0.83 to 0.85. Model sensitivity (range: 0.92–0.97) was higher than model specificity (range: 0.58–0.63). Further validation of the models in clinical context is required. A predictive model for pain medication for odynophagia prior to commencement of radiotherapy would support Radiotherapy Technologists Nurses (RTNs) in directing nursing interventions towards patients at risk.

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Introduction

Chemoradiotherapy is well-established as a curative intervention for inoperable lung cancers. In external beam radiotherapy, the proximity of tumours to the esophageal tract increases the risk of damage to the mucosal lining of the esophagus. Concurrent chemotherapy [1–4] and bi-daily radiotherapy fractionation [5] are known to increase the risk of acute esophagitis. In routine clinical practice, esophagitis is not commonly assessed by objective endoscopy. Various different symptoms - such as odynophagia (painful swallowing), dysphagia (difficult swallowing), nausea, heartburn and anorexia - are widely used as clinical surrogates of esophagitis. Therefore, at mild and moderate levels of clinical severity, acute esophagitis is a highly subjective experience that varies greatly from one patient to the next.

Qualitative patient feedback in our clinic suggests that odynophagia (leading to appetite loss, dehydration and diet modi-

fication) is the dominant factor impacting on their perceived quality of life and treatment satisfaction. The objective of this investigation is to explore the incidence of low-grade acute esophagitis during lung cancer radiotherapy that manifests as patient-reported odynophagia, and hence to specifically predict when prescription pain medication may be required to manage this symptom.

Patient-centred care (PCC) is a guiding value in many clinics [6]. However, clinically meaningful PCC can only be achieved when care providers sustain systematic processes that (i) foster trust between patients and clinicians [7], (ii) enhance two-way communication about treatment effects that matter in patient lives' [8], and (iii) encourage patients to become active partners in medical decision-making [9].

Clinical scoring systems are used to objectively measure the clinical impacts of treatment-induced side-effects. However, passive observation and clinical scoring by themselves do not meet the aspirations of clinically meaningful PCC, since there is no opportunity to include a patient's own perception of the severity of side-effects or to offer them an opportunity to influence decisions about their nursing care. Sole reliance on patient self-scored outcomes may not be universally appropriate, since these

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may be modulated by social support, psychological resilience and treatment expectations.

Each radiotherapy patient in our clinic is treated by, and followed-up by, a designated Radiotherapy Technologist Nurse (RTN) team throughout their course of treatment. Teams consist of highly experienced clinical nurses that have completed an additional year of intensive training in radiotherapy. Continuity of team-based care fosters a high degree of trust needed for two-way communication with patients. Patients are encouraged to discuss any aspect of their treatment they find uncomfortable or unbearable. This qualitative information is used by RTNs to actively propose a nursing intervention before issues escalate into treatment disruptions or protocol deviations.

In a rapidly-learning healthcare system (RLHS), advanced computing uses clinical observations from routine practice to predict probable outcomes, test hypotheses and instigate improvements [10,11]. The combination of RLHS and PCC creates a virtuous cycle where routine care continuously improves and decisions (by practitioners and patients) are supported by data.

We have combined clinical, dosimetric and patient interview data to propose statistical models to predict whether a patient will require prescription medication for odynophagia during external beam radiotherapy treatment for lung cancer. Three candidate models have been developed and cross-validated. We discuss how such models can support decision-making by RTNs.

Material and methods

Outcomes registration

The outcomes were derived from semi-structured weekly in-person interviews with patients about treatment-related side-effects and how it has been impacting on his/her daily activities. A RTN actively listened if a patient made any allusion to odynophagia (for example, a persistent sore throat, pain while eating or drinking, or significantly altered dietary patterns). A hypothetical interview transcript is given in [Online Supplementary Materials \(Table E1\)](#). He/she probes into the severity of symptoms to assign a clinical nursing score for acute esophagitis according to department guidelines. The nursing score was derived from the Common Terminology Criteria for Adverse Events (CTCAE v4.0, see [Table 1](#)).

In keeping with PCC, the RTN also probes into medication needs from the patient's perspective. If both patient and nurse jointly arrive at a decision to begin a course of prescription medication due to odynophagia (PMO), the nursing notes will register a "PMO" event. A PMO event during radiotherapy ought to be closely correlated with the score for acute esophagitis, but these two observations are not interchangeable. Medication either prescribed prior to radiotherapy or for unrelated symptoms did not count as PMO, but the prescription medication was nonetheless noted.

PMO can only be registered either none or once during the course of radiotherapy; either a patient has not registered such an event, or an event was registered and PMO status must not be revoked even if symptoms resolve. In contrast, the esophagitis score ought to fluctuate over time. Though differences in scoring between observers cannot be ruled out, only the *maximum* score over all weeks was reported in the patient's notes.

Retrospective data screening

Electronic radiotherapy records were retrospectively screened for lung cancer treatments for either small-cell (SCLC) or non-small cell lung cancer (NSCLC). Records of patients completing their last radiotherapy fraction between January 2013 and March 2015 were reviewed. An unfiltered extract yielded 135 curative

Table 1
RTN scoring guideline for acute esophagitis during radiotherapy.

Score	Description
0	No changes in the mucosa of esophagus
1	Mild swallowing pain but capable of eating a normal diet Intervention not indicated
2	Moderate swallowing pain, not capable of eating sufficiently Oral supplements and/or pain medication indicated
3	Severe swallowing pain, limiting ADL. Strong medication indicated, tube feeding, TPN and intravenous fluids required
4	Requires hospitalization and treatment
5	Death

Table 2
Characteristics of the patient cohort.

Age (years)	Median Range	68.0 (35–86)
Sex	Female Male	67 (51.1%) 64 (48.9%)
Histology	Non-small cell Small cell	101 (77.1%) 30 (22.9%)
Node status	Positive Negative	73 (55.7%) 58 (44.3%)
Chemotherapy	Concurrent Sequential None Unspecified	89 (67.9%) 32 (24.4%) 8 (6.1%) 2 (1.5%)
Prescribed dose	60–66 Gy 45 vGy 45 Gy (b.i.d.)	101 (77.1%) 7 (5.3%) 23 (17.6%)

cases. Of these, 3 were excluded that had been treated for lung cancer earlier than 2013, but had since returned for additional treatment. One case was excluded because a palliative dose-fractionation had been given.

All 131 remaining cases were used in statistical analysis. SCLC were treated once daily (45 Gy in 25 fractions) or bi-daily (45 Gy in 30 fractions), including either concomittant or sequential combination chemotherapy (carboplatinum and etoposide). NSCLC cases were prescribed doses between 60 and 66 Gy in daily 2 Gy fractions, with either concomittant or sequential combination chemotherapy (carboplatinum and vinorelbine). However, eight NSCLC patients (i.e. only 6% of the cohort) were not given any chemotherapy (see [Table 2](#)). Hence, there were insufficient frequency of events to stratify the effect of no chemotherapy.

Case reports were compiled in SurveyXact (v7.1, Ramboell Consulting, Aarhus, Denmark) using information in nursing notes, doctors notes and hospital electronic journals. SurveyXact forms were linked with treatment planning system data (Oncentra External Beam v4.3, Elekta AB, Stockholm, Sweden) and oncology information system data (MosaiQ v2.50, Elekta AB, Stockholm, Sweden). Data merging, pre-processing and statistical modelling were carried out in R (v3.3). Details specific to data processing are provided in [supplementary materials \(Table E2\)](#).

As a surrogate for esophageal exposure, the as-approved treatment plans were used. All patients were treated as a single-phase plan; in certain cases, anatomical changes in the vicinity of the tumour detected mid-treatment necessitated some combination of either re-contouring, re-simulation or re-planning. Therefore, the beam arrangement in subsequent plans was assumed to be only a minor perturbation from the initial plan. Where multiple radiotherapy treatment plans per patient were located, a consistent arbitration rule was thus applied - the cumulative dose-volume histogram (cDVH) from the treatment plan delivered on the majority of the first 15 fractions was used. In all but one case,

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