Research Paper

Rationale and Design of a New Zealand-wide Electronic Registry for Complex Basal Cell Carcinoma

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Abstract

Basal cell carcinomas are a common skin lesion that can often be managed with local therapy, both surgical and otherwise. A subgroup exists that is atypical in its development, progression, and effects. These atypical cancers previously lacked an adequate definition by which to meaningfully study them. We have produced a robust definition from the existing data and have established a nationwide registry for such lesions.

Background: Many nations worldwide collect data regarding the incidence of cancer. Despite their preponderance, the global burden of basal cell carcinoma (BCC) is not known. A disproportionate burden on patients and health care systems results from a small subgroup of basal cell carcinomas that display atypical features. **Materials and Methods:** We identified the features that will enable further research into these cancers and improve overall health care with regard to skin cancer. BCCs are not included in the new American Joint Committee on Cancer, 8th edition, TNM system. **Results:** We completed a review of the published data regarding the high-risk features of BCCs. These have been assembled to form a new definition for "complex basal cell carcinoma." We also developed an electronic database for lesions identified using this classification system. **Conclusion:** We have used a robust, user-independent definition for "complex BCCs" (the Auckland classification) to create an electronic registry of complex BCCs within New Zealand. We anticipate approximately 600 lesions annually within New Zealand, equivalent to an estimated 1% of all BCCs nationwide.

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Introduction

Cutaneous basal cell carcinoma (BCC) is the most common cancer in humans, accounting for approximately 80% of all non-melanoma skin cancer cases globally.[1] These cancers result primarily from overexposure to ultraviolet radiation, with higher rates evident in nations with greater levels of sunlight exposure. Typical BCCs are slow-growing, locally invasive lesions that can be cured by surgical excision in > 95% of cases.[2] The metastasis risk increases with the duration of disease but, overall, is exceedingly rare, with rates of 0.0028% to 0.55% reported.[3] Although local invasion occurs in a 3-dimensional manner, destruction of surrounding structures is uncommon. However, a small subgroup of BCCs exists that do not behave as typical BCCs. These are characterized by aggressive local invasion and distant metastasis or by a genetic predisposition.[4] Such lesions have variably been described in published studies as "advanced," "giant," or "severe" BCCs, although no universally accepted definition exists for these terms.[2,3,5] The new 8th edition of the American Joint Committee on Cancer TNM staging system does not include BCC.[6] Locally or metastatically advanced BCCs have been thought to result from either delayed access to primary treatment or an inherent aggressiveness of the cancer itself,[3] with histologic subtypes such as basosquamous lesions more commonly implicated.[2] BCCs that behave in atypically are responsible for a disproportionate amount of patient morbidity and mortality and place a considerable financial burden on the health care system.

The extent of this health care burden in New Zealand and internationally, although expected to be significant, is unreported and, therefore, unknown. Mandatory reporting of all primary malignant disease enabled the formation of the New Zealand Cancer Registry (NZCR) in 1948. This was established with the dual goals of providing information on the incidence and mortality of cancer and serving as a basis for cancer survival studies and

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research programs. From 1958 onward, cutaneous basal and squamous cell carcinomas were excluded from the registry because of "resource considerations."[7] Thus, although nationwide reporting of most cancers has been excellent, it has been difficult to access meaningful data regarding the incidence or effect of BCCs in New Zealand. This problem is not unique to New Zealand; globally, no uniform reporting process is in effect for BCC, with a subsequent lack of accurate epidemiologic data.[3] Resource constraints are an inevitability of any health care system, and these particular constraints are, for the most part, acceptable. Because the management of most BCCs is uncomplicated, their reporting would be, at best, academic. However, the complete exclusion of all BCCs has included the more complex lesions, which is problematic for several reasons. First, these cancers often require multidisciplinary input and collaboration among specialists. Registration of these lesions would enable relevant specialists to be aware of them and reduce the risks resulting from inadequate treatment. Second, complex BCCs are less likely to respond to standard treatment options and to require adjunctive treatment. Failure to identify the patients who are more likely to benefit from these treatments will reduce access to treatment, result in inappropriate and costly usage of adjunctive treatment, and hamper ongoing research into targeted BCC therapy. Third, the burden of disease continues to be an unknown quantity, which has implications in terms of appropriately allocating health care funding. To address these concerns regarding the current management of BCCs in New Zealand, we have designed a database by which to monitor and study the more complex lesions throughout the nation.

Methods and Materials

Study Protocol and Ethics

We received ethical approval for the creation of a new electronic database for complex BCCs as defined by the Auckland classification. This was granted according to a precedent established by the Auckland Breast Cancer Register.[8] As such, individual patient consent was not required for inclusion in the complex BCC registry.

Registry Design and Data Entry

The New Zealand-wide electronic registry (e-registry) for complex BCCs is an electronic database with password protection stored securely within Waitemata district health board's data warehouse and, therefore, subject to the same levels of security as other clinical applications. Subject logs are held on site, not within the database, and all data are entered relative to a subject number requiring Windows authentication.

The registration of patients in the complex BCC registry is not mandated by law. We will, therefore, rely on the cooperation from relevant health care professionals throughout New Zealand, who will be identifying and submitting patients' data to the registry. We are now recruiting patients from each of the 20 district health boards in New Zealand. The most likely sources of new patient data are anticipated to be pathologists, nurse specialists, dermatologists, cutaneous oncologic surgeons, head and neck surgeons, and medical and radiation oncologists.

When a patient is identified as having a complex BCC in accordance with the study definition, details of the patient's case can be sent to a study coordinator for entry into the database. At first, individual health care providers will not be able to input patient data directly into the database but will be required to submit information to an administrator. The Health and Disability Ethics Committee provided ethical approval. Details from the registry will only be made known to relevant medical practitioners after assessment by a clinical governance group. Access to de-identified information stored in the database will be available on request to relevant health care professionals. The study group will also use the data stored in the registry to compile accurate data regarding burden and management of complex BCCs in New Zealand.

We reviewed the data points collected by existing registries such as the NZCR to identify the relevant information required for lesions in our own registry. The data recorded for each patient diagnosed with a complex BCC in accordance with our inclusion criteria are listed in Table 1. Each patient has a single entry in the e-registry, under which individual lesions are registered. The registry includes the capacity for multiple lesions per patient.

Clinical Endpoints

Data regarding treatment, complications, and clinical endpoints will be recorded in the registry (Table 2). These data demonstrate the key treatment-related information to be recorded for each lesion included in the registry.

Inclusion Criteria

All patients accessing health care within New Zealand are eligible for inclusion in our registry. To be registered, they must have a diagnosis of a histologically confirmed BCC that meets 1 of the 4 criteria listed in Table 3.

Results

Review of Published Data

A review of the available data revealed that the terms "advanced" and "severe" BCCs have been used extensively in previous research, with no accepted consensus on the definitions of these terms. Most definitions previously used were limited by their subjectivity, potential for interuser variability, and their inability to consider various aspects of disease pathology. This variation makes the comparison of results between groups very difficult. The primary aim of our published data search was to identify the various terms and definitions previously used to define BCCs that do not behave

Table 1 Data Included in E-registry for Each Patient With a Complex Basal Cell Carcinoma

Factor
Patient age (at diagnosis)
Gender
Ethnicity
History of proven diagnosis of genetic condition associated with BCC (eg, xeroderma pigmentosum, Gorlin syndrome, Rombo syndrome, Bazex-Dupre-Christol syndrome, Rothmund-Thompson syndrome, Oley syndrome)
Immunocompromised status
Region of domicile at the initial diagnosis

Abbreviation: BCC = basal cell carcinoma.