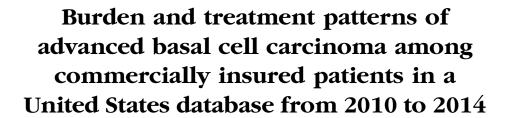
## **ORIGINAL ARTICLE**



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Background: The burden of advanced basal cell carcinoma (aBCC) is not fully understood.

Objective: To compare BCC disease burden and treatment patterns for aBCC with those for non-aBCC.

**Methods:** A retrospective, insurance claims—based study design was used. Adults with  $\geq 2$  claims associated with a BCC diagnosis (ICD-9-CM 173.x1) separated by  $\geq 30$  days on or after October 1, 2011, were classified as aBCC or non-aBCC by using an algorithm based on metastasis diagnosis, radiation therapy use, and medical oncologist/other specialist use. Non-aBCC and aBCC patients were matched 1:1 on the basis of age, sex, and region, and assigned the same index date (date of first qualifying diagnosis or event). Comparisons were made using Wilcoxon signed-rank (continuous variables) and McNemar's (categorical variables) tests.

**Results:** In total, 847 matched aBCC/non-aBCC patient pairs were selected (mean age 75 years; 57% men; locally advanced BCC, n = 826; metastatic BCC, n = 21). During the 12-month study period following the index date, aBCC patients had a significantly higher mean Charlson Comorbidity Index (P = .0023), significantly higher mean numbers of outpatient/dermatologist/medical oncologist visits (all P < .0001), and significantly higher mean total/medical/inpatient/outpatient/BCC treatment costs (all P < .005).

*Limitations:* This study only included information from a database on commercial insurance and Medicare claims. The algorithm criteria might have restricted patient numbers; data were not fully reflective of targeted therapy era.

**Conclusions:** aBCC patients had a higher disease burden than non-aBCC patients. Cost differences were largely driven by higher BCC treatment costs, specifically radiation therapy. (J Am Acad Dermatol http://dx.doi.org/10.1016/j.jaad.2017.02.050.)

Key words: basal cell carcinoma; burden; costs; healthcare utilization; treatment.

B asal cell carcinoma (BCC), a subset of nonmelanoma skin cancer (NMSC), is the most commonly diagnosed cancer in the

United States, with an annual incidence of 2.8 million cases. <sup>1,2</sup> Most BCCs can be treated effectively with excision, Mohs micrographic surgery, curettage and

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Conflicts of interest: Dr Migden has received honoraria for advisory boards from Eli Lilly, Genentech, and Novartis. Dr Xie and Ms Tang are full-time employees of Analysis Group. Ms Wei was a full-time employee of Analysis Group at the time the study was

conducted. Drs Palmer and Herrera are full-time employees of Novartis.

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electrodessication, cryosurgery, radiation, or topical therapy. In some cases, however, BCCs substantially increase in size, infiltrate deeply into structures below the skin, and progress to advanced BCC (aBCC), which can result in significant disfigurement and morbidity or death.<sup>3,4</sup>

Advanced BCC includes locally advanced BCC

(laBCC), which is not amenable to surgery or radiation therapy, and metastatic BCC (mBCC), which has spread discontinuous other sites and is considered to be incurable.<sup>5</sup> aBCC incidence estimates vary widely, reflecting a lack of uniform reporting requirements, as well as a lack of widespread use of staging systems. Based on available data, aBCC is estimated to account for approximately 1%-10% of all BCC cases, with mBCC representing

0.003%-0.5% of all cases<sup>7-9</sup>; a recent retrospective database analysis reported a projected age-adjusted incidence and prevalence for the US population of 4399 and 7940 patients, respectively, for laBCC, and 108 and 384, respectively, for mBCC.<sup>10</sup>

Current National Comprehensive Cancer Network guidelines for the treatment of BCC not appropriate for (further) surgery or radiation, which is consistent with the aBCC population, recommend multidisciplinary tumor board consultation (with consideration of hedgehog signaling pathway inhibitor therapy or clinical trial enrollment). 11 Vismodegib, an oral hedgehog signaling pathway inhibitor, was shown to produce tumor responses in patients with laBCC and mBCC. 12,13 On the basis of these data, vismodegib was approved by the US Food and Drug Administration (FDA) in January 2012 for the treatment of adults with mBCC, adults with laBCC that has recurred after surgery, and adults who are not candidates for surgery or radiation therapy. 14 Sonidegib, another oral hedgehog signaling pathway inhibitor, was recently shown to produce marked tumor responses in patients with aBCC. 15 This agent was approved by the FDA in July 2015 for the treatment of adults with laBCC that has recurred following surgery or radiation therapy and adults who are not candidates for surgery or radiation therapy. 16

The burden and real-world treatment patterns of aBCC remain poorly understood. The release of BCCspecific ICD-9-CM (International Classification of Diseases, Ninth Revision, Clinical Modification) codes in October 2011 has made it possible to distinguish between BCC and NMSC in administrative claims databases. Dacosta Byfield et al<sup>17</sup> developed an algorithm to classify patients with NMSC into subgroups with locally advanced and metastatic disease. For our study, this algorithm was adapted and used in conjunction with BCC-specific ICD-9-CM codes to

identify patients with BCC, and classify them into aBCC and non-aBCC subgroups. Our objectives were to compare the BCC disease burden with respect to comorbidities, health care use, and costs for patients with aBCC versus those with non-aBCC and compare treatment patterns in these 2 populations.

# CAPSULE SUMMARY

- The burden of advanced basal cell carcinoma (aBCC) is not fully understood.
- Analysis of matched pairs of aBCC/nonaBCC patients demonstrated that aBCC patients had significantly greater comorbidities and healthcare resource utilization/costs.
- Patients with aBCC had a higher disease burden than those with non-aBCC, underscoring the need for new treatments.

#### **METHODS**

This was an observational, retrospective, insuranceclaims based cohort study using data from the Truven

Health MarketScan database with cut-points from January 1, 2010, to June 30, 2014. The MarketScan database captures the medical experiences of approximately 30 million employees, dependents, and retirees with primary or Medicare supplemental coverage through privately insured fee-for-service, point-of-service, or capitated health plans. It covers all US census regions, but predominantly the South and North Central (Midwest). We classified adults with  $\geq 2$  claims for BCC diagnosis (ICD-9-CM 173.x1) separated by  $\geq 30$  days on or after October 1, 2011, were classified as having aBCC or non-aBCC using an algorithm based on metastasis diagnosis, radiation therapy use, and medical oncologist/other specialist visits. Non-aBCC and aBCC patients were matched 1:1 based on age, sex, and region, and assigned the same index date (date of first qualifying diagnosis or event). Comparisons were made using Wilcoxon signed-rank (continuous variables) and McNemar's (categorical variables) tests. Full details regarding patient identification and classification, study variables, and statistical analyses are provided in the Supplementary Appendix (available at http://www.jaad.org).

#### **RESULTS**

#### Patient characteristics

In total, 847 patients with aBCC (21 with mBCC and 826 with laBCC) were identified meeting the algorithm selection criteria (Fig 1). These patients were matched 1:1 with patients with non-aBCC on

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