Factors associated with receipt of second-line recurrent or metastatic cervical cancer treatment in the United States: A retrospective administrative claims analysis

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ABSTRACT

Purpose: Contemporary, real-world data on eligible patients receiving treatment following progression on first-line (1L) recurrent or metastatic cervical cancer (r/mCC) therapy are needed to inform treatment algorithms and identify potential gaps in the r/mCC care continuum.

Methods: This study estimated the prevalence and predictors of second-line (2L) r/mCC therapy among 1L-treated patients using the 2015–2020 IBM MarketScan® commercial claims database. Women ≥18 years diagnosed with cervical cancer and treated with first-line systemic therapies were identified and followed for 12 months from their 1L therapy end date. Women with claims for a new therapy after 60 days but no later than 365 days from the end of 1L treatment were identified as those who progressed and received 2L therapy for r/mCC. Descriptive statistics examined baseline cohort characteristics and multivariable logistic regression model examined the factors associated with receiving 2L treatment.

Results: We identified 384 1L-treated patients with r/mCC with ≥12 months of follow-up post-1L treatment. During follow-up, over half (51.0%) of the 1L-treated r/mCC patients received 2L therapy. Patients from the South and Midwest had a lower likelihood of receiving 2L treatment compared with those living in the Northeast (adjusted odds ratio [aOR] = 0.43; 0.23–0.84) and (aOR = 0.52; 0.28–0.95, respectively). Patients not treated with bevacizumab in 1L were also less likely to receive 2L therapy (aOR = 0.65; 0.43–0.99).

Conclusion: Additional research and targeted outreach efforts are needed to understand geography-, population-, or practice-specific barriers impacting access to 2L therapy among patients with r/mCC.

1. Introduction

An estimated 14,100 women will be diagnosed with invasive cervical cancer in 2022 in the United States (US), with approximately 16% metastatic at diagnosis, and up to 61% of patients with earlier stage diagnosis will develop metastatic cervical cancer within the first 2 years of completing treatment (National Cancer Institute: Surveillance, Epidemiology, and End Results (SEER) Program, 2022a, 2022b;
Although the recurrent or metastatic cervical cancer (r/mCC) setting has been characterized by poor prognosis with limited treatment options, recent approvals offer new treatment options to address the unmet needs for first-line (1L) or second-line or later (2L+) r/mCC patients (National Cancer Institute: Surveillance, Epidemiology, and End Results (SEER) Program, 2022a; Marabelle et al., 2020; Colombo et al., 2021; U.S. Food Drug Administration, 2021).

In 2018, the U.S. Food and Drug Administration granted accelerated approval to pembrolizumab as monotherapy for previously treated patients with r/mCC whose tumors express PD-L1 (Marabelle et al., 2020). In 2021, pembrolizumab received full approval for use in combination with chemotherapy +/- bevacizumab for patients with PD-L1 expression in the 1L r/mCC setting (Colombo et al., 2021). Also in 2021, tisotumab vedotin-tftv, an antibody-drug conjugate targeting tissue factor, was granted accelerated approval for treatment of patients with r/mCC with disease progression on or after chemotherapy (U.S. Food Drug Administration, 2021).

As the r/mCC treatment landscape continues to evolve, quantifying the proportion of patients needing 2L therapy and the predictors of 2L therapy uptake will help inform treatment algorithms, identify potential gaps in the care continuum, and provide insights into underlying drivers of r/mCC treatment continuity for future research. Data on these aspects of r/mCC treatment are so far limited. Therefore, the objective of this study was to determine the prevalence and predictors of 2L therapy among 1L treated patients with r/mCC.

2. Methods

We analyzed the 2015–2020 IBM MarketScan® commercial claims database. The database comprises member enrollment information consisting of demographic variables such as age, sex, geographic location (identified as four census regions, Northeast, Midwest, South, or West), and health plan enrollment/disenrollment dates, as well as medical and prescription drug claims. We utilized a previously-validated claims-based algorithm to identify patients with r/mCC (Musa et al., 2022). Briefly, a cohort design was used; we identified women ≥ 18 years with one or more inpatient claim or two outpatient claims with a diagnosis for malignant neoplasm of the cervix (identified by the International Classification of Diseases 9th and 10th Revisions, Clinical Modification Codes, 180.XX and C53.XX), followed by utilization of one or more systemic therapy indicative of 1L r/mCC treatment. Therapies that included concomitant radiation therapy or surgery within 60 days were excluded. The last recorded date of 1L treatment was assigned as the index date for each patient. Continuous enrollment criteria of a minimum 3-month pre-index and 12-month post-index were applied (Fig. 1). Women with claims for a new therapy after 60 days but no later than 365 days from the end of 1L treatment were identified as those who received subsequent r/mCC therapy.

3. Results

A total of 1080 patients with 1L-treated r/mCC were identified, of whom 384 met the study criteria (Fig. 2). The cohort comprised women with a mean age of 54.5 years, largely enrolled in a non-health maintenance organization health plan (88.8 %), and most women had no comorbid conditions (55.0 %). Approximately 40 % of these women were previously treated with bevacizumab (Table 1).

Post-1L treatment, 196 (51.0 %) patients initiated a subsequent therapy within a median duration of 122 days from the end date of 1L therapy. The baseline characteristics of patients who received 2L treatment were generally similar to those who did not receive 2L therapy (Table 2).

Fig. 2. Study sample flow. 1L, first-line; 2L, second-line; r/mCC, recurrent or metastatic cervical cancer.

We used descriptive statistics to examine the baseline characteristics of the final analytical cohort. A multivariable logistic regression model examined the factors associated with receiving 2L treatment. All analyses were performed using SAS®, Cary, NC. P-value was tested at 0.05.
bevacizumab treatment were also less likely to receive subsequent therapy (Alholm et al., 2022). To our knowledge, these are the only two studies so far that estimated real-world receipt of 2L therapy and its predictors among patients not receiving 2L r/mCC therapy. Taken together, results suggest that the difference across the US in proportion of patients receiving subsequent therapy are likely influenced by both local- and patient-level factors. Further investigation into these relationships will help in understanding more clearly drivers of treatment and health disparities in r/mCC.

Patients without prior exposure to bevacizumab were also less likely to receive 2L treatment for r/mCC. Previous reports have suggested that factors associated with the likelihood of receiving 2L r/mCC treatment were similar to those predicting survival, including prior bevacizumab exposure (other factors cited included disease stage, histology, metastases, tumor size, and tumor burden) (Tewari et al., 2014; Kim et al., 2012; Chen et al., 2021; Kato et al., 2021; Zhang et al., 2018; Endo et al., 2015; Rose et al., 2015), although we were unable to directly assess such an association due to data limitations. Future studies should seek to understand patient characteristics or other factors influencing bevacizumab inclusion in a patient’s treatment.

Our study findings should be interpreted within the context of study limitations. Claims databases do not contain information on pathology, biomarkers, and qualitative indicators pertaining to treatment; therefore, our model does not account for these factors. Patients who may have initiated a subsequent line of therapy beyond the 12-month follow-up duration study were not captured in our analysis. Finally, our cohort was derived from a nationwide sample of women enrolled in a commercial health plan, which precludes generalizability to uninsured patients and patients enrolled under public health insurance plans.

Despite limitations, our study points to clear contributors of eligible patients not receiving 2L r/mCC therapy. Taken together, results suggest that the difference across the US in proportion of patients receiving subsequent therapy are likely influenced by both local- and patient-level factors. Further investigation into these relationships will help in understanding more clearly drivers of treatment and health disparities in r/mCC.

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**CRediT authorship contribution statement**

Kalyani Sonawane: Conceptualization, Methodology, Investigation, Supervision, Validation, Writing – original draft, Writing – review & editing. Tara Castellano: Conceptualization, Methodology, Investigation, Supervision, Validation, Writing – original draft, Writing – review & editing. Christina Washington: Methodology, Validation, Writing – review & editing. Jie Ting: Conceptualization, Methodology, Investigation, Supervision, Validation, Writing – original draft, Writing – review & editing. Andy Surinach: Investigation, Data curation, Data analysis, Writing – review & editing. Carol Kirshner: Investigation, Data curation, Data analysis, Writing – review & editing. Jagpreet Chhatwal: Conceptualization, Methodology, Project administration, Validation, Visualization, Writing – original draft, Writing – review & editing. Turgay Ayer: Conceptualization, Methodology, Project administration, Validation, Visualization, Writing – original draft, Writing – review & editing. Kathleen Moore: Conceptualization, Methodology, Investigation, Supervision, Validation, Writing – original draft, Writing – review & editing.

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**Table 1**

Demographic characteristics of 1L-treated patients with r/mCC.

| Characteristics                        | N   | Percent |
|----------------------------------------|-----|---------|
| Total                                   | 384 | 100.0   |
| Age at Index, years, mean (SD)          | 54.52 | 11.38  |
| **Index year**                          |     |         |
| 2015                                    | 100 | 26.0    |
| 2016                                    | 78  | 20.3    |
| 2017                                    | 82  | 21.4    |
| 2018                                    | 68  | 17.7    |
| 2019                                    | 56  | 14.6    |
| **Region**                              |     |         |
| Northeast                               | 62  | 16.2    |
| Midwest                                 | 93  | 24.2    |
| South                                   | 183 | 47.7    |
| West                                    | 46  | 12.0    |
| **1L contains bevacizumab**             |     |         |
| 1L                                       | 155 | 40.4    |
| **CCI categories**                      |     |         |
| 0                                        | 211 | 55.0    |
| 1                                        | 97  | 25.3    |
| 2                                        | 40  | 10.4    |
| 3                                        | 36  | 9.4     |
| **Baseline comorbidities**              |     |         |
| Myocardial infarction                    | 8   | 2.1     |
| Congestive heart failure                 | 8   | 2.1     |
| Peripheral vascular disease              | 23  | 6.0     |
| Dementia                                | 1   | 0.3     |
| Chronic pulmonary disease                | 45  | 11.7    |
| Rheumatic disease                       | 5   | 1.3     |
| Peptic ulcer disease                     | 3   | 0.8     |
| Liver disease                           | 50  | 13.0    |
| Diabetes without complications           | 58  | 15.1    |
| Diabetes with complications              | 16  | 4.2     |
| Paralysis                               | 2   | 0.5     |
| Renal disease                           | 29  | 7.6     |
| AIDS                                    | 1   | 0.3     |

1L, first-line; AIDS, acquired immunodeficiency syndrome; CCI, Charlson Comorbidity Index; HMO, health maintenance organization; r/mCC, recurrent or metastatic cervical cancer.

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4. Discussion

Our finding that nearly half of 1L-treated patients with r/mCC received 2L therapy is consistent with a recent study that followed patients with r/mCC from 2014 to 2020 in the US Oncology Network, reporting that 48% of 1L-treated patients received 2L therapy (Alholm et al., 2022). To our knowledge, these are the only two studies so far that estimated real-world receipt of 2L therapy and its predictors among contemporary patients with r/mCC. Collectively, these data provide highlight potential gaps in the r/mCC care continuum.

We found that geography is an important predictor in the receipt of 2L treatment. Due to data limitations, however, it was not possible to capture geographic-level factors contributing to a lower likelihood of receiving 2L r/mCC treatment for patients living in the South and the Midwest, compared with those in the Northeast. Previous studies have pointed to a high correlation between treatment discontinuation and/or interruption due to longer travel times, lack of gynecologic oncology workforce, and suboptimal treatment with patients’ area of residence and distance from the care facility (Barrington et al., 2016; Temkin et al., 2015; Ricci et al., 2017; Hung et al., 2020). Southern and Midwestern states were reported to have fewer gynecological oncologists and fewer National Cancer Institute (NCI)-designated cancer centers compared with the Northeast (Alimena et al., 2021). Spees et al. also reported that travel time of ≥15 miles from residence is associated with a nearly 30% higher risk of lack of timely cervical cancer treatment (Spees et al., 2019). It is possible that patients with r/mCC in our study who live in the South or the Midwest experienced these barriers, which decreased their likelihood of receiving 2L treatment. More granular patient- and geography-level indicators of healthcare access are needed to better understand drivers of geographic disparities in r/mCC treatment.

Patients without prior exposure to bevacizumab were also less likely to receive 2L treatment for r/mCC. Previous reports have suggested that factors associated with the likelihood of receiving 2L r/mCC treatment were similar to those predicting survival, including prior bevacizumab exposure (other factors cited included disease stage, histology, metastases, tumor size, and tumor burden) (Tewari et al., 2014; Kim et al., 2012; Chen et al., 2021; Kato et al., 2021; Zhang et al., 2018; Endo et al., 2015; Rose et al., 2015), although we were unable to directly assess such an association due to data limitations. Future studies should seek to understand patient characteristics or other factors influencing bevacizumab inclusion in a patient’s treatment.

Our study findings should be interpreted within the context of study limitations. Claims databases do not contain information on pathology, biomarkers, and qualitative indicators pertaining to treatment; therefore, our model does not account for these factors. Patients who may have initiated a subsequent line of therapy beyond the 12-month follow-up duration study were not captured in our analysis. Finally, our cohort was derived from a nationwide sample of women enrolled in a commercial health plan, which precludes generalizability to uninsured patients and patients enrolled under public health insurance plans.

Despite limitations, our study points to clear contributors of eligible patients not receiving 2L r/mCC therapy. Taken together, results suggest that the difference across the US in proportion of patients receiving subsequent therapy are likely influenced by both local- and patient-level factors. Further investigation into these relationships will help in understanding more clearly drivers of treatment and health disparities in r/mCC.
Declaration of Competing Interest

Kalyani Sonawane has received consulting fees from, and has held a leadership role with Value Analytics Labs; Jie Ting is an employee of, and holds stock in Seagen Inc.; Andy Surinach is an employee of Genesis Research, which received consulting fees from Seagen Inc. in connection with this study; Jagpreet Chhatwal received funding from Seagen Inc. in connection with this study, and has received consulting fees and honoraria from Novo Nordisk, and Bayer; Turgay Ayer received funding from Seagen Inc. in connection with this study, and holds a leadership role with Value Analytics Labs; Kathleen Moore has received consulting fees from Green Fire Bio, and payment or honoraria from, and participated in data monitoring or advisory boards for AstraZeneca, Aravive, Alkerme, Addi, Blueprint pharma, Clovis, Elevate, Eisai, EMD Serono, GSK/Tesaro, Genentech/Roche, Hengrui, Immunogen, Inxmed, iMB, Merck, Mercola, Myriad, Mereo, Novartis, OncXerna, Onconova, SQZ, Tarveda, VBL Therapeutics and Versastem, received support for attending meetings with AstraZeneca and GSK/Tesaro and holds a leadership role with GOG partners; Tara Castellano, Christina Washington and Carol Kirshner have no competing interests to disclose.

Table 2
Baseline characteristics of 1L treated patients with r/mCC with and without 2L therapy during follow-up.

| Characteristics               | Total   | Percent | Total   | Percent |
|------------------------------|---------|---------|---------|---------|
|                              | N       |         | N       |         |
| Total                         | 384     | 100.0   | 188     | 100.0   |
| Age at index, years Mean (SD)| 54.52   | 10.65   | 54.41   | 12.13   |
| Index year                    |         |         |         |         |
| 2015                          | 100     | 29.1    | 43      | 22.9    |
| 2016                          | 78      | 20.4    | 38      | 20.2    |
| 2017                          | 82      | 23.0    | 37      | 19.7    |
| 2018                          | 68      | 15.3    | 38      | 20.2    |
| 2019                          | 56      | 12.2    | 32      | 17.0    |
| Region                        |         |         |         |         |
| Northeast                     | 62      | 20.4    | 22      | 11.7    |
| Midwest                       | 93      | 20.9    | 52      | 27.7    |
| South                        | 183     | 45.9    | 93      | 49.5    |
| West                          | 46      | 12.8    | 21      | 11.2    |
| Index line contains bevacizumab|         | 100.0   |         | 100.0   |
| No                            | 229     | 55.1    | 121     | 64.4    |
| Yes                           | 155     | 44.9    | 67      | 35.6    |
| Providers seen in 60 days prior to index | | | | |
| Oncologist                    | 180     | 45.9    | 90      | 47.9    |
| Gynecologist                  | 122     | 32.7    | 58      | 30.9    |
| Others                        | 193     | 49.5    | 96      | 51.1    |
| Charlson Comorbidity Score Mean (SD) | 0.82     | 0.79    | 1.22    | 0.85    |
| 0                             | 211     | 57.1    | 99      | 52.7    |
| 1                             | 97      | 24.0    | 50      | 26.6    |
| 2                             | 40      | 9.2     | 22      | 11.7    |
| 3+                            | 36      | 9.7     | 17      | 9.0     |
| Baseline comorbidities        |         |         |         |         |
| Myocardial infarction         | 8       | 2.6     | 3       | 1.6     |
| Congestive heart failure      | 8       | 2.0     | 4       | 2.1     |
| Peripheral vascular disease   | 23      | 5.1     | 13      | 6.9     |
| Cerebrovascular diseases      | 13      | 2.6     | 8       | 4.3     |
| Dementia                      | 1       | 0.0     | 1       | 0.5     |
| Chronic pulmonary disease     | 45      | 12.2    | 21      | 11.2    |
| Rheumatic disease             | 5       | 2.0     | 1       | 0.5     |
| Peptic ulcer disease          | 3       | 0.5     | 2       | 1.1     |
| Mild liver disease            | 50      | 14.3    | 22      | 11.7    |
| Diabetes without complications| 58      | 14.3    | 30      | 16.0    |
| Diabetes with complications   | 16      | 3.6     | 9       | 4.8     |
| Paralysis                     | 2       | 0.5     | 1       | 0.5     |
| Renal disease                 | 29      | 12.6    | 17      | 9.0     |
| AIDS                          | 1       | 0.5     | 0       | 0.0     |

1L, first-line; 2L, second-line; AIDS, acquired immunodeficiency syndrome; CCI, Charlson Comorbidity Index; HMO, health maintenance organization; r/mCC, recurrent or metastatic cervical cancer.

Table 3
Likelihood of receipt of 2L treatment among 1L treated patients with r/mCC.

| Effect                      | Odds Ratio* | 95 % Confidence Limits | P-value |
|-----------------------------|-------------|------------------------|---------|
| Age                         | 1.01        | 0.99 1.04              | 0.33    |
| Region                      |             |                        |         |
| South versus Northeast      | 0.43        | 0.23 0.84              | 0.03    |
| Midwest versus Northeast    | 0.52        | 0.28 0.95              | 0.01    |
| West versus Northeast       | 0.64        | 0.29 1.40              | 0.26    |
| Plan type (Non-HMO vs HMO)  | 1.23        | 0.64 2.38              | 0.53    |
| Group type (Medicare vs. commercial) | 0.79  | 0.35 1.75 | 0.55  |
| Bevacizumab history (No vs Yes) | 0.65       | 0.43 0.99  | 0.04  |
| Charlson Comorbidity Index  | 0.96        | 0.81 1.14              | 0.65    |

*Odds ratio and 95% confidence limits for multivariable logistic regression model simultaneously adjusted for age, region, plan type, group type, bevacizumab treatment history, and comorbidity index.

1L, first-line; 2L, second-line; HMO, health maintenance organization; r/mCC, recurrent or metastatic cervical cancer.

1L, first-line; 2L, second-line; AIDS, acquired immunodeficiency syndrome; CCI, Charlson Comorbidity Index; HMO, health maintenance organization; r/mCC, recurrent or metastatic cervical cancer.
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