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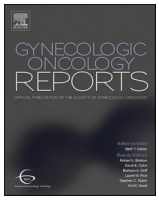

Short communication

Cost effectiveness of immunotherapy combination therapies for endometrial cancer

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ABSTRACT

Over the past five years (2019–2023), several new targeted therapies and immunotherapy has been approved in treating relapsed cervical, ovarian, and endometrial cancers. Concurrently, there has been growing recognition of financial toxicity associated with cancer care during this time period. As such, we reviewed FDA approvals from 2019 to 2013 and identified the following approvals in gynecologic oncology: pembrolizumab plus lenvatinib, pembrolizumab for recurrent endometrial cancer that is MSI-H/dMMR, tisotumab vedotin, dostarlimab as single-agent therapy, and dostarlimab plus chemotherapy. We focused on approvals for endometrial cancer, and conducted a cost-effectiveness analysis for combination options approved in treating recurrent or advanced endometrial cancer (i.e. pembrolizumab plus lenvatinib versus placebo; dostarlimab plus chemotherapy versus placebo), and found neither regimen was cost-effective at a willingness-to-pay of $100,000 per Equal Value of Life Years Gained (evLYG). While these costs may not necessarily be translated to an individual patient, these costs are absorbed by healthcare systems and insurance providers on a larger scale with downstream effects on individuals contributing to healthcare costs a whole.

1. Introduction

Financial toxicity has gained increasing attention for its deleterious effects in oncologic care. The term refers to the economic burden related to cancer care that is endured by individuals with cancer, as well as family members of those with cancer (Abrams et al., 2021). In addition, healthcare systems and insurance payors often occur significant costs in paying for cancer-directed therapies. Total costs related to cancer in the United States are anticipated to substantially increase from an estimated $183 billion to up to $246 billion by the year 2030 (Mariotto et al., 2020). With over 200 cancer drug approvals from the US Food and Drug Administration between 2016 and 2021, the costs of oncologic care from cancer-directed therapies alone is expected to rise with additional drug approvals in the future (Benjamin et al., 2022).

Previous studies have evaluated financial toxicity and cost-effectiveness of PARP inhibitors used in treating platinum-refractory ovarian cancer in which PARP inhibitors were found to cost from $16,327-$18,970 per month of progression free survival (Wolford et al., 2020). Two prior cost-effectiveness analyses of pembrolizumab plus lenvatinib in treating recurrent/advanced endometrial cancer found the combination therapy is not cost effective in comparison to chemotherapy (Ackroyd et al., 2021; Feng et al., 2022). A third study found that single agent pembrolizumab in treating chemotherapy-refractory endometrial cancer is cost effective similar to other single agent therapies (Barrington et al., 2019). However, to our knowledge, no cost effectiveness analysis has been conducted evaluating newly approved dostarlimab in combination with chemotherapy for recurrent/advanced endometrial cancer. As such, we sought to determine whether immunotherapy combinations are cost effective for this indication.

2. Methods

We reviewed the FDA's list of oncology (cancer) approval notifications to identify therapies approved in treating gynecologic cancers during a five year period from 2019 to 2023 (Research C for DE and. Oncology (Cancer) / Hematologic Malignancies Approval Notifications,

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2021). The search was conducted on August 1, 2023 and identified the following therapies: pembrolizumab plus lenvatinib for recurrent endometrial cancer that is not microsatellite instability high (MSI-H) or mismatch repair deficient (dMMR), pembrolizumab for recurrent endometrial cancer that is MSI-H or dMMR, tisotumab vedotin for recurrent or metastatic cervical cancer with disease progression or after chemotherapy, mirvetuximab soravtansine-gynx for platinum-resistant epithelial ovarian, fallopian tube, or primary peritoneal cancer, dostarlimab for recurrent or advanced endometrial cancer dMMR that has progressed on or following platinum-based chemotherapy, and dostarlimab plus chemotherapy for primary/advanced endometrial cancer that is dMMR or MSI-H. We then identified the corresponding clinical trial that led to approval to confirm drug dosing, number of cycles of each treatment, and any possible survival benefit (either progression

Table 1
Acquisition costs associated with FDA approved targeted therapies and immunotherapy in endometrial cancer between 2019–2023.

Drug Name	Mechanism of Action	Tumor Type and Treatment Setting	Time on Treatment	Cost per Unit/per cycle (Assuming BSA of 2 m2)	Body Weight	Total Cost	Survival Benefit
Pembrolizumab plus Lenvatinib vs. chemotherapy (docetaxel or paclitaxel)	Immune checkpoint inhibitor plus tyrosine kinase inhibitor	Advanced endometrial cancer after failure of platinum-based chemotherapy	Median dose of lenvatinib was 13.8 mg with median duration of treatment 231 days, and median number of cycles of pembrolizumab was 10 Median number of cycles of doxorubicin was 5 and median number of cycles of paclitaxel was 6	Lenvatinib 14 mg PO daily plus pembrolizumab 200 mg every 3 weeks Lenvatinib = $468.88 for each day of 14 mg treatment 1 mg of pembrolizumab = $54.811 = $10,962.20 per cycle Doxorubicin 60 mg/m2 every 3 weeks→120 mg every 3 weeks. Cost of 50 mg = $315.64 and 10 mg = $63.13. Each cycle of doxorubicin chemotherapy = $757.54. $757.54 * 5 (median number of cycles) = $3,787.70 Paclitaxel 80 mg/m2 (three weeks on, one week off) = 160 mg x 3 = 480 mg per cycle. Cost of per 6 mg/mL = $3.17*26.67 = $84.53 per 160 mg *3 = $253.60 per cycle. $253.60 * 6 (median number of cycles) = $1,521.60	N/A	Lenvatinib: $468.88 x 231 = $108,311.28 Pembrolizumab: $10,962.20 (10) = $109,622Total (Pembrolizumab and Lenvatinib) : **$217,933.28**Total (Doxorubicin) : **$3,787.70**Total (Paclitaxel) : **$1,521.60**	OS 17.4 months versus 12.0 months in pMMR population
Dostarlimab plus Chemotherapy (Carboplatin + paclitaxel) vs. Placebo plus Chemotherapy (Carboplatin + paclitaxel)	Immune checkpoint inhibitor plus chemotherapy	Primary/ advanced endometrial cancer that is dMMR or MSI-H	6 500 mg q3w cycles + 9.5 1000 mg q6w cycles = 12500 mg dostarlimab used for 15.5 cycles Carboplatin AUC 5 + paclitaxel 175 mg/m2 for first 6 cycles Median number of cycles of dostarlimab plus carboplatin + paclitaxel was 15.5 cycles. Median number of cycles of placebo plus carboplatin + paclitaxel was 8 cycles.	Dostarlimab: 500 mg Q3W for 6 cycles then 1,000 mg Q6W 10 mg =$226.95 = 6 (500/10)*226.95 + 9.5 (1000/10) *226.95= $68,085 (for first 6 q3w cycles)+ $215,602.50 (for subsequent q6w cycles) Carboplatin AUC 5 (based on 65 years old, 85 kg (based on 160 cm average height and average BMI of 33.2), creatinine of 0.8 mg/dL, female sex) = 595 mg. Cost of 10 mg/mL = $1.00- $5.80 → $3.40 per mL (based on average of range) = $3.40 * 59.5 = $202.30. $202.30* 6 = (number of cycles of carboplatin + paclitaxel with dostarlimab or placebo) = $1,213.80 Paclitaxel 175 mg/m2 * 2 m2 = 350 mg. Cost of per 6 mg/mL = $3.17* 58.33 = $184.92 per 350 mg. $184.92 * 6 (number of cycles of carboplatin + paclitaxel with dostarlimab or placebo) = $1,109.52	N/A	Total (Dostarlimab): **$283,687.50**Total (Carboplatin AUC 5) : **$1,213.80**Total (Paclitaxel) = **$1,109.52**Total (Dostarlimab + chemotherapy): $286,010.82Total (placebo + chemotherapy): $2,323.32	PFS 30.3 months versus 7.7 months (placebo)

free survival [PFS] or overall survival [OS]) (Coleman et al., 2021; Makker et al., 2022; Marabelle et al., 2020; Matulonis et al., 2023; Mirza et al., 2023; Oaknin et al., 2022). However, we omitted single-agent pembrolizumab and dostarlimab from cost analysis due to inability to calculate total estimated acquisition costs due to unavailable data on duration of treatment with each immune checkpoint inhibitor.

We used publicly available data for these approved therapies from the Centers for Medicare and Medicaid (CMS) Part B July 2023 Average Sales Price file, UpToDate average wholesale cost for lenvatinib and publicly available data on dostarlimab (ASP Pricing Files | CMS, 2023; FDA Gives Nod to Mirvetuximab Soravtansine, 2023; UptoDate. Lenvatinib - Drug Information, 2023). We calculated costs using these listed prices for each cycle of treatment and the median number of cycles or months on therapy in the corresponding clinical trial leading to drug approval. In addition, we utilized clinical trial data from KEYNOTE-775 to determine the median dose of lenvatinib while on therapy.

As there were two combination therapies for recurrent/advanced endometrial cancer, we analyzed the cost-effectiveness of these two studies. Costs were drawn from these studies and converted to 2023 US dollars (USD). Effectiveness in units of Equal Value of Life Years Gained (evLYG) were extrapolated from PFS or OS information for each trial, in most cases by converting monthly survival statistics into annual survival. The evLYG is a standardized measure of health utility according to the U.S. Institute for Clinical and Economic Review, which reflects a constant value of health utility equal to the average annual quality-adjusted life years (QALYs) for the U.S. general population (i.e. 0.851 QALYs per year) (Cost-Effectiveness, the QALY, and the evLYG. ICER, 2024). Patients are awarded an evLYG for each year of life in a non-death health state. These assumptions on clinical effectiveness promote greater health equity and are optimal to model in the case of cancer trials which are driven by survival rates. These data were used to calculate and interpret an incremental cost-effectiveness ratio (ICER) and net monetary benefit (NMB) at a willingness-to-pay threshold of $100,000 per evLYG.

3. Results

In KEYNOTE-775, lenvatinib was studied at 14 mg PO (by mouth) daily in combination with pembrolizumab at fixed dose of 200 mg IV (intravenous) every 3 weeks. Per clinical trial data, the median dose of lenvatinib was 13.8 mg with a median duration of treatment on the tyrosine kinase inhibitor being 231 days. In addition, the median number of cycles of pembrolizumab was 10. Acquisition costs associated with treatment on lenvatinib were $108,311 and on pembrolizumab were $109,622 leading to a total of $217,933 for the average patient on this combination therapy as shown in Table 1; this was compared to $3,787 for the patients receiving doxorubicin and $1,521 for patients receiving paclitaxel. The OS benefit achieved in individuals with dMMR tumors was 17.4 months in comparison to 12.0 months in the comparator arm (doxorubicin or paclitaxel). As such, the acquisition cost of this combination therapy was $39,656.59 per patient for each month of OS improved in comparison to doxorubicin chemotherapy, which adjusts to $475,879 per life year survival and $40,076.24 per patient for each month of OS improved in comparison to paclitaxel chemotherapy, which adjusts to $480,914.88 per life year survival.

In the RUBY trial, chemotherapy (carboplatin plus paclitaxel) was administered with either dostarlimab at a dose of 500 mg every 3 weeks for the first six cycles followed by 1,000 mg every six weeks with chemotherapy or placebo with chemotherapy, which consisted of the combination of carboplatin AUC 5 and paclitaxel 175 mg/m2 given once every 3 weeks for six cycles. As individuals in the therapeutic arm received a median of 15.5 cycles of dostarlimab, we calculated acquisition costs for dostarlimab as being $283,687.50, carboplatin AUC 5 as being $1,213.80 and paclitaxel as being $1,109.52 (Table 1). The trial reported a PFS benefit of 30.3 months with dostarlimab in combination with chemotherapy in comparison to 7.7 months with chemotherapy alone. Thus, acquisition costs for dostarlimab per patient for each month of PFS gained is $12,552.54, which adjusts to $150,630.48 per life year survival.

Table 2 summarizes the ICER and NMB associated with the combination therapies for recurrent/advanced endometrial cancer. As demonstrated, pembrolizumab plus lenvatinib (i.e. NMB of $-175,850/evLYG when compared to doxorubicin; NMB of $-178,116/evLYG when compared to paclitaxel) as well as dostarlimab plus chemotherapy (i.e NMB of $-123,416) all exceeded the willingness-to-pay threshold of $100,000 per evLYG, making their value only marginal based on survival statistics.

4. Discussion

There is considerable variation among estimated acquisition costs for targeted therapies and immunotherapy approved in treating gynecologic malignancies between 2019 and 2023. The acquisition costs per patient with recurrent/advanced endometrial cancer with data available to make calculations are as follows in descending order: dostarlimab when used in combination with chemotherapy ($286,011), lenvatinib plus pembrolizumab ($217,933).

While combination therapies pembrolizumab plus lenvatinib as well as dostarlimab plus chemotherapy are approved for use in different subset patient populations of endometrial cancer, there is a low probability that neither new approved combination therapy is cost-effective in treating women with endometrial cancer.

Several new therapeutic approaches in treating recurrent/advanced endometrial cancer are apparent in the horizon. For example, niraparib as well as niraparib plus dostarlimab has been studied in the phase II trial setting for recurrent serous or endometroid endometrial cancer (Madariaga et al., 2023). In addition, the US FDA granted Breakthrough Therapy designation for the HER2 antibody drug conjugate BNT323/DB-1303 in December 2023 based off a phase 1/2 study in immunotherapy-refractory endometrial cancer harboring HER2 mutations (SE, 2023). Previous literature has shown that PARP inhibitors when compared to intravenous chemotherapy ($6,412/PFS-month) were not cost effective when compared to different PARP inhibitors including niraparib ($18,970/PFS-month) in the recurrent ovarian cancer setting and as a maintenance therapy in ovarian cancer in which niraparib cost $235 K per PFS -life year (Wolford et al., 2020; Zhong et al., 2018). Meanwhile, while other HER-2 antibody drug conjugates such as trastuzumab deruxtecan have been consider practice changing in some solid tumors, the cost effectiveness remains an issue, as trastuzumab deruxtecan in an analysis in HER-2 positive metastatic breast cancer had just a 11.1 % probability of being cost-effective at a $100,000 per quality adjusted life years (QALY) willingness-to-pay threshold (Mudumba et al., 2024). Thus, while these two ongoing trials may ultimately lead to FDA approved therapies for refractory endometrial cancer, it is unclear whether these therapies will be cost effective or further contribute to financial toxicity in the treatment of advanced endometrial cancer.

There are several limitations to this study. First, acquisition costs are derived from estimates in US dollars, and may not be reflective of costs in other nations. Second, additional costs such as clinical follow-up evaluations, labs, imaging, and facility use fees are not accounted in these calculations. Finally, the study did not incorporate fees associated with management of adverse events with each corresponding treatment. The incidence of grade 3 or higher events was 88.9 % with lenvatinib plus pembrolizumab and 70.5 % with dostarlimab plus chemotherapy. Each corresponding grade 3 or higher adverse event may be associated with costs due to clinical follow-up evaluations, labs, imaging and hospitalization fees.

5. Conclusion

While newly approved therapies for gynecologic malignancies offer

Table 2
Incremental Cost-effectiveness Ratio (ICER) and Net Monetary Benefit (NMB) of Pembrolizumab/Lenvatinimb and Dostarlimab/Chemo compared to Placebo at a willingness to pay threshold of $100,000 per expected-value of Life Year Gained (evLYG) based on reporting of overall survival (OS) or progression free survival (PFS).

	Cost ($)	ΔCost ($)	OS/PFS (months)	ΔOS/ΔPFS (months)	ΔOS/ΔPFS (years)	ΔevLYG	ICER ($/evLYG)	NMB ($)
Pembrolizumab* + *Lenvatinib* vs. *Doxorubicin or Paclitaxel (OS)								
Doxorubicin or Paclitaxel	4,937		12.0					
Pembrolizumab + Lenvatinib	217,933	212,996	17.4	5.4	0.45	0.38	556,198	(174,700.95)
Dostarlimab* + *Chemo* vs. *Placebo (PFS)								
Chemotherapy only	33,880		7.7					
Dostarlimab + Chemotherapy	283,687	249,807	30.3	22.6	1.88	1.600	155,865	(89,535.73)

additional therapeutic options for individuals, the costs associated with these therapies continues to add to growing costs associated with cancer care in the United States and globally. We found that the two combination therapies (dostarlimab plus chemotherapy and pembrolizumab plus lenvatinib) had a low likelihood to be cost-effective at a willingness-to-pay threshold of $100,000 per evLYG in treating the subset of endometrial cancer for their respective indications. As cancer care costs have direct medical, psychological, and financial effects on individuals with cancer as well as their families, healthcare systems and societies as whole, it is critical for treating physicians and other clinicians to be aware of the wide-ranging effects. Further research is warranted in order to identify avenues to improve survival and quality of life in women with gynecologic malignancies in a cost-effective manner.

CRediT authorship contribution statement

David J. Benjamin: Conceptualization, Data curation, Investigation, Methodology, Supervision, Writing – original draft, Writing – review & editing. **William V. Padula:** Data curation, Formal analysis, Investigation, Methodology, Supervision, Validation, Writing – review & editing. **Robert C. Hsu:** Conceptualization, Data curation, Formal analysis, Investigation, Methodology, Supervision, Validation, Writing – original draft, Writing – review & editing.

Declaration of competing interest

The authors declare the following financial interests/personal relationships which may be considered as potential competing interests: DJB has the following disclosures: Consulting: Seagen. Speakers' Bureau: Merck. Travel and Accommodations: Merck. RH is a consultant for Targeted Oncology and received honoraria from DAVA Oncology and The Dedham Group. WVP declares personal fees and equity from Stage Analytics.

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