Spotlighting Social, Emotional Needs in Underserved Populations With Cancer

Matthew Gavidia

WHEN CONSIDERING THE PHYSICAL and mental effects of cancer diagnosis and recovery, several psychological and emotional needs have been cited in previous research as exacerbating patient outcomes in the past.

Despite in-person/virtual support groups and therapy seeking to address the mental challenges of cancer, such as feelings of depression and loneliness, significant gaps remain in managing the personalized issues that present to populations often underserved in oncology care and clinical research, according to experts interviewed by The American Journal of Managed Care®.

In an email exchange with AJMC®, Michael Roth, MD, co-director of the Adolescent and Young Adult (AYA) Oncology Program at the University of Texas MD Anderson Cancer Center, noted the myriad developmental challenges that face even AYAs without cancer who are becoming or learning how to become more independent, such as going away for school, starting their first job in their careers, starting a family, or developing new relationships.

Unmet Needs in AYAs With Cancer

Defined as people between 15 and 39 years old, Roth said that AYAs are often overlooked in cancer care and that significantly more attention is given to younger children and older adult patients.

Notably, the 90,000 AYAs who receive a cancer diagnosis each year and the more than 500,000 AYA cancer survivors currently living in the United States today have to manage the challenges brought by their diagnosis while delaying normal growth opportunities in life.

“AYAs need a special focus on their education, vocational training in their careers, and how cancer impacts or halts that progression. AYAs need special attention on their mental health and psychosocial

Factors of Ipilimumab/Nivolumab Success in Metastatic Melanoma Identified

Jared Kaltwasser

A NEW ANALYSIS OF THE USE OF ipilimumab (Yervoy) and nivolumab (Opdivo) to treat patients with advanced metastatic melanoma found a lower real-world overall survival (OS) rate than previous studies. However, it also identified factors that may boost an individual’s chance of success with the therapy.

As immune checkpoint inhibitors (ICIs) have become an important part of melanoma treatment, the strategy of combining anti–CTLA-4 agents, like ipilimumab, with anti–PD-1 agents, like nivolumab, has gained traction. However, the study authors noted that many patients do not respond to ICIs and there is a lack of clear biomarkers that can be used to predict which patients will and will not respond, as well as which types of therapy would be ideal.

In a new study in Clinical and Translational Oncology, the investigators looked back at OS and related biomarkers in a cohort of 44 patients who had advanced melanoma and received at least 1 dose of an ipilimumab/nivolumab regimen between 2016 and 2020. All of the study enrollees were patients at the same institution.

“In addition, we evaluated the baseline clinical characteristics, molecular variables, and peripheral blood laboratory values to determine the [OS] in this cohort and explore biomarkers associated with clinical benefit,” they wrote.

Most of the patients in the study (86.4%) had cutaneous melanoma, about half each had BRAF mutant cancers and high lactate dehydrogenase (LDH) values at presentation. Twenty-three patients had at least 3 disease sites, and 10 patients had brain metastases.

Most of the patients (63.6%) were treatment naïve, 9 patients had received BRAF and MEK inhibitors, 5 had been on anti-PD-1 therapy, and 2 had received other therapies.
With a median follow-up of 37.7 months, the investigators calculated a median OS of 21.1 months (95% CI, 8.2-not reached). When the authors separated out patients with central nervous system (CNS) metastases, they found an overall response rate (ORR) of 39.4% among patients without CNS metastases and a 10% ORR among those with CNS metastases; there was no difference in median OS.

“This value is lower than that of previous studies likely because of the inclusion of 22% of patients with brain metastases, most with > 3 brain lesions, half of whom required corticosteroid treatment,” the authors wrote.

When they performed a multivariate analysis, they found patients with Eastern Cooperative Oncology Group scores of zero, those with normal LDH levels, those without liver metastases, and those with neutrophil-to-lymphocyte ratios less than 5 had significantly longer OS. These factors were then used to classify patients into 3 prognostic risk groups.

“The model proposed allowed the identification of patient subgroups with different prognoses following ipilimumab-plus-nivolumab treatment, with 31.8% of patients presenting favorable values in all 4 factors, and the median OS was not reached,” they said. “In contrast, the prognosis was poor in individuals with 0-1 favorable factors, and the median OS was not reached,” they said. “In contrast, the prognosis was poor in individuals with 0-1 favorable factors, and the median OS was not reached.”

The investigators said their study offers potential new biomarkers that could be used to guide treatment decisions, although they said their findings would need to be verified in future prospective trials.

Reference

health. They need special attention on their sexual health and relationships,” said Roth. “All of these life issues, which are challenging without cancer, just become much more complicated, and unfortunately, many providers do not ever address any of these issues. AYAs are often left on their own to struggle through these issues as they struggle through cancer treatment.”

In a soon-to-be published analysis co-authored by Roth, only approximately 20% of phase 3 trials were found to capture quality of life (QOL) information among AYAs with cancer during and before treatment, indicating a significant gap in comprehension regarding these populations.

Adding that providers do not typically do a sufficient assessment of patients’ QOL, which often correlates with important cancer care implications such as symptom burden and treatment tolerance, Roth said that very little is known about the health and health-related QOL outcomes of AYAs with cancer.

“That’s why it’s so important that we have patients provide their own perspectives through the use of inventories that measure patient-reported outcomes. If we don’t ask, we’ll never know what’s happening with our patients. And most importantly, we’ll never know how we can intervene and improve their short-term and long-term outcomes.”

These concerns fueled the recent implementation of the AYA Patient-Reported Outcomes Task Force, a new task force co-chaired by Roth that was launched last year by the Children’s Oncology Group and funded through the National Cancer Institute’s (NCI) Childhood Cancer Data Initiative.

Bringing together experts from across the NCI’s clinical trials network, both pediatric and medical oncology, Roth said that the goal of the task force is to standardize and harmonize the patient-reported outcomes captured in AYA cancer clinical trials to try to understand what happens to patients who receive a cancer diagnosis and go through their cancer journey.

With minimal information available on how AYAs do in terms of their symptoms, toxicity

“Measuring these data through patient-reported outcomes is absolutely essential, and now’s the time to start doing it so we really can understand how we can improve and maximize patients’ health and long-term QOL.”

in health throughout treatment, and well after treatment into survivorship, Roth said that the task force wants to better understand the similarities and differences across various cancer diagnoses and treatment approaches.

“Until we have this basic data, it’s really challenging to intervene to improve patient outcomes, because we’re starting from a place where we just don’t understand what the trajectory of health outcomes are for this population, which we believe is at high risk for toxicity and poor long-term health-related QOL,” said Roth.

“Measuring these data through patient-reported outcomes is absolutely essential, and now’s the time to start doing it so we really can understand how we can improve and maximize patients’ health and long-term QOL.”

Prioritizing Communication in Cancer Care

With increasing diversification being reported in 2020 US Census Bureau data, a report issued recently by AMN Healthcare indicated that more than 50 languages other than English were commonly used in daily encounters between patients and health care providers—spearheaded by Spanish, which was used in 74% of discussions.

Despite the linguistic and cultural needs of US patient populations, services to accommodate non–English-speaking patients, who are more likely to be immigrants and of lower
“The outcomes from these minor interventions are so large that it begs the question: Why aren’t we all doing this? And why aren’t hospital systems investing more in these social mitigation tools that can not only improve outcomes, but also be cost-effective?”

socioeconomic status, have largely lagged in adoption. In fact, prior research found that more than half of patients with limited English proficiency reported lack of access to medical interpreters and translated materials.

What impact can these gaps in communication and information have on health outcomes?

Seeking to investigate social needs and their influence as mediators of social determinants of health, Abdulrahman K. Sinno, MD, director of surgical research and education at University of Miami Health System, and fellow authors conducted a prospective, survey-based cohort study of 135 female patients with gynecologic cancer, who were primarily immigrants and of lower socioeconomic status, from a public safety-net hospital in Los Angeles.

In assessing patients for unmet social needs and distress, factors known to affect QOL and survival in patients with cancer, 65.2% and 36.3% of patients were associated with each outcome, respectively. Moreover, those linked with these variables were found to be at greater risk for emergency department (ED) visits, hospital admissions, and treatment interruptions.

“In this population, we were able to find the most prevalent social needs, including needing help reading hospital materials (30.4%), lack of transportation (8.9%), food insecurity (12.6%), and housing instability (13.3%),” said Sinno.

Although some issues that contribute to disproportionate health care access and equity may not be able to be resolved by physicians, such as poverty or immigration status, Sinno highlighted that many of the social needs cited by patients can be improved through provider interventions.

“Whether a patient is Black, White, or Hispanic, if she’s an immigrant, if she’s poor or rich, if she has poor transportation, I can intervene and provide transportation,” noted Sinno. “If a patient can’t make it to the clinic, then they’re not going to come and tell you about the worsening symptoms that they have. It’s way cheaper to pay for a $20 Uber ride than a $5000 ED visit for something that could have been mitigated.”

Speaking further on the study, Sinno said that although the study authors were not initially planning on intervening, they identified so many patients with food insecurity that they started to connect participants with existing services that provide food assistance, such as Meals on Wheels and Project Angel Food.

“It might not be like sending a patient 5 meals a week, but that could be the difference between some of the patients not eating enough so that their family can eat and them eating enough to be able to tolerate their treatments.”

Integrating a registered dietitian was also cited by Sinno, whose clinical practice took a proactive approach in providing patients with nutrition advice that can improve care outcomes, including what to and what not to eat, how to prevent nausea, and how to increase calorie intake when experiencing malignancy in the abdomen.

With countless interventions available to address social determinants of health, screening for these social needs is ultimately the only way to recognize risk and develop mitigation tools.

“The first tenet of consent is that the patient understands what you’re saying. It’s unfair that only patients who have low socioeconomic status end up not understanding what they are getting. And also on a practical level, if you’re giving them these sorts of instructions, and they don’t understand their discharge instructions, they’re going to end up in the ED again,” concluded Sinno.

“The outcomes from these minor interventions are so large that it begs the question: Why aren’t we all doing this? And why aren’t hospital systems investing more in these social mitigation tools that can not only improve outcomes, but also be cost-effective?”
German Study Shows Savings Using ClonoSEQ to Guide Multiple Myeloma Treatment

Mary Caffrey

A STUDY FUNDED by the makers of the clonoSEQ test to detect minimal residual disease (MRD) found the test could achieve significant savings if used to treat patients with multiple myeloma, especially if used over longer periods, based on a model using Germany’s health care system.

The authors found use of the MRD diagnostic would allow “more efficient use of high-cost drugs” in the treatment of multiple myeloma, and that “therapy decisions can be better and more precisely controlled if the MRD status of patients is known before the next therapy phase.”

The authors acknowledged that their findings might not directly apply to a health care system that relies on private coverage, such as the system found in the United States. Other adjustments for demographic factors and care settings that differ by location might affect the precise experience by country, but the authors felt the key takeaways would hold up:

- Knowing a patient’s MRD status can help pinpoint the right multiple myeloma therapy to improve overall and progression-free survival.
- MRD testing through next-generation sequencing can help payers by putting downward pressure on the overuse of high-cost drugs, especially in multiple myeloma, which is often treated for a period of 10 years or more.

The cost-effectiveness of clonoSEQ was modeled based on Germany’s statutory insurance program. The authors started with clinical data derived from recent trials and expert opinion, with the primary data source being a 2009 phase 3 trial conducted at 69 centers involving the 3-part regimen known as RVD, for Revlimid (lenalidomide), Velcade (bortezomib), and dexamesthasone.

Following induction, stem cell mobilization with cyclophosphamide and granulocyte colony-stimulating factor was performed in all patients. For consolidation, one group (RVD-alone group) received 5 cycles of RVD with a reduced dose of dexamethasone; the other arm, the transplant group, received melphalan plus autologous stem cell transplant and 2 cycles of RVD, followed by maintenance, which continued for a year or until consent was withdrawn. The RVD-alone group could receive salvage transplant therapy.

The primary end point was progression-free survival; 350 patients were assigned to each group. In the RVD group, 331 patients entered consolidation in the RVD-alone group and 321 reached maintenance; in the transplant group, 323 received a transplant and 315 received RVD therapy after transplant and 311 entered maintenance.

“Based on the underlying model, clonoSEQ can support German health insurance funds to use high-cost drugs more efficiently in the treatment of myeloma,” the authors concluded.

A cost impact analysis of clonoSEQ was then derived, using these data and the available literature. Investigators created a Markov model that consisted of 6 healthy states, with every patient beginning at the start of maintenance, using an MRD arm and one without clonoSEQ testing. The therapies included in the model were lenalidomide for maintenance and carfilzomib, lenalidomide, and dexamethasone for relapse.

Over a period of 10 years, the analysis showed a total cost of €279,483 ($330,533) for patients using clonoSEQ compared with €356,623 ($421,867) for simulated patients without MRD testing. The main drivers of the cost differences are the cost savings from patients being able to take a “drug holiday,” based on MRD testing. The savings per patient in 1 year are €18,396 ($21,761). Savings after 3 years are €69,991 ($82,775) per patient. Savings after 10 years are €77,140 ($91,230) per patient.

“Based on the underlying model, clonoSEQ can support German health insurance funds to use high-cost drugs more efficiently in the treatment of myeloma,” the authors concluded.

Funding for the study was provided by Adaptive Biotechnologies.

Reference
Multidisciplinary Approach Important for Successful HCC Care

Laura Joszt, MA

HEPATOCELLULAR CARCINOMA (HCC) is the fastest-growing cause of cancer-related deaths in the United States, but HCC is challenging to diagnose because clinical presentation varies, and symptoms often appear late in the disease course. The unique challenges of HCC diagnosis necessitates a multidisciplinary approach to ensure high-quality care and the best patient outcomes, according to a study published in Clinical Liver Disease. Because the majority of HCC cases have a background of cirrhosis, gastroenterologists are pivotal for screening, for instance.

The treatment landscape continues to evolve, and finding the right treatment requires “expertise in the various therapeutic modalities from a number of different specialties, including hepatology, hepatobiliary surgery, transplant surgery, radiation oncology, medical oncology, interventional radiology, and palliative care specialists, among others,” the authors explained.

Although HCC can be cured with liver transplantation, surgical resection, or thermal ablation, nearly 70% of patients are not candidates and need alternative treatment options. A common practice for multidisciplinary care in cancer is to conduct regular meetings, known as multidisciplinary tumor boards (MTBs), to present cases and review relevant treatments. The authors noted that patients discussed at MTBs had improved treatment and better outcomes, including overall survival and a greater likelihood of undergoing liver transplantation.

“Moreover, recent studies have also shown that MTB frequently leads to changes in imaging interpretation, thus impacting potential treatment recommendations,” they added.

Another model of multidisciplinary care is a centralized group clinic model where patients see the appropriate providers concurrently. These appointments can either occur in person (space permitting) or virtually. This approach is patient centered and allows patients to actively participate in the discussion of their care. These clinics have resulted in shorter time to treatment and improved survival.

Although HCC can be cured with liver transplantation, surgical resection, or thermal ablation, nearly 70% of patients are not candidates and need alternative treatment options.

In addition to treatment benefits, such multidisciplinary approaches have resulted in improved patient satisfaction, specifically related to communication and confidence in their physician, the authors wrote.

There are multiple challenges to effectively implementing successful multidisciplinary care, but they can be successful even in resource-scarce regions, they noted, with one study showing successful implementation in a small community environment. Success of multidisciplinary care is reliant on administrative support, effective leadership, and team dynamics, they added.

“In today’s evolving landscape with newly available cancer treatments readily available, the importance of an integrated multidisciplinary approach to HCC care is vital,” the authors concluded.

Reference
CONVERTING PATIENTS FROM REFERENCE pegfilgrastim, either the prefilled syringe form (Neulasta) or the on-body injector (Neulasta Onpro), to a biosimilar version could lead to significant cost savings for payers and greater access to FOLFIRINOX (folinic acid, fluorouracil, irinotecan, oxaliplatin) chemotherapy for patients with metastatic pancreatic cancer, according to a recent study.

The study, published in Future Medicine, provides insight into how switching patients from the more expensive reference product to biosimilar pegfilgrastim-cbqv (Udenyca) as a febrile neutropenia prophylaxis could generate enough savings to allow for patients to have budget-neutral access to chemotherapy treatments.

“As the more affordable of the pancreatic cancer treatment regimens in most markets, the scale of expanded access to FOLFIRINOX that is achievable through the reallocation of savings from conversion to biosimilar pegfilgrastim-cbqv is significant—providing thousands of additional patients with cancer treatment on a budget-neutral basis,” wrote the investigators.

Throughout the COVID-19 pandemic, the use of pegfilgrastim has risen for patients with cancer at risk for developing febrile neutropenia, and this trend is expected to continue once the crisis has subsided. Currently, there are 4 FDA-approved pegfilgrastim biosimilars.

Although many cost-efficiency analyses are being done for multiple biosimilar products, less is known about the potential for expanded access to other medications, including chemotherapy regimens, as a result of biosimilar cost savings. All of the agents in FOLFIRINOX have generic equivalents for the treatment of metastatic pancreatic cancer.

The investigators chose to focus their research on pancreatic cancer because it is the 11th most prominent cancer in the United States and ranks fourth in terms of cancer mortality rates. It is also regularly diagnosed in late stages and has a 5-year survival rate of 3.0% in the United States.

By developing a simulation model among a panel of 2500 patients with metastatic pancreatic cancer treated with FOLFIRINOX, the investigators analyzed the effects of varying treatment duration and conversion rates to estimate cost savings and additional doses of FOLFIRINOX that could be budget neutral. The study consisted of 4 stages of analysis:

- Per-patient cost savings from converting to pegfilgrastim-cbqv across 1 to 12 cycles (up to 3 months) of prophylaxis
- Cost savings extrapolated to the patients over varying degrees of biosimilar conversion from 10% to 100% and over 1 to 12 cycles
- The number-needed-to-convert (NNC) from the reference product to the biosimilar for 1 patient to receive 1 cycle, 1 month, or 6 months of FOLFIRINOX
- The savings generated to calculate additional FOLFIRINOX cycles, months, and full 6-month regimens that could be purchased on a budget-neutral basis

The investigators combined the average sales price (ASP) and wholesale acquisition cost (WAC) of reference pegfilgrastim and pegfilgrastim-cbqv, to arrive at $4014.77 and $3439.16, respectively, for the third quarter of 2020. For 1 cycle of FOLFIRINOX for the same quarter, the total was $238.93.

Converting 1 patient from reference pegfilgrastim to the biosimilar generated savings of $575.62 for 1 cycle and $6907.41 for 12 cycles of prophylaxis. If the entire 2500-patient panel was converted, savings would jump to $1,439,043 for 1 cycle and $17,268,519 for 12 cycles.

The NNC analysis showed that 0.42 patients need to convert to the biosimilar for 1 pegfilgrastim cycle to purchase 1 additional cycle of FOLFIRINOX on a budget-neutral basis. To purchase an additional full 6-month regimen, 4.98 patients need to switch to the biosimilar.

If 100% of the panel was converted to the biosimilar across the 6-month duration, an additional 72,273 additional cycles of FOLFIRINOX could be purchased, which corresponds to 36,137 months of treatment or 6023 full 6-month regimens. If 50% of the panel converted for 6 months, 36,137 additional chemotherapy doses could be purchased, which translates to 18,068 months of treatment or 3011 full 6-month regimens.

The investigators listed the use of the blended ASP and WAC rate, the fact that ASP changes over time, the analysis of only 1 pegfilgrastim biosimilar, and the omission of costs associated with hospitalization and other treatments as limitations of the study. Additionally, costs associated with on-body injector failures were not included in the analysis.

Reference
Study Will Collect Patient Preferences for NSCLC Treatments

Jaime Rosenberg

A NEW STUDY IS AIMING to collect information on patient preferences for treatments for non–small cell lung cancer (NSCLC). The study protocol comes amid a paradigm shift in the treatment of advanced-stage NSCLC, following the emergence and uptake of immunotherapy, which created options that consist of immunotherapy monotherapy, chemotherapy monotherapy, or a combination of those treatments.

“In the last few years, patient preference (PP) for treatment outcomes has been receiving increasing attention as a relevant source of complexity. Specifically, PP heterogeneity arises when patients differ in how they value specific treatment attributes or outcomes,” wrote the researchers.

Their update was published in a recent issue of Frontiers in Medicine.

The data will offer insights into how patients prioritize certain attributes that vary between treatments. For example, chemoimmunotherapy regimens are often administered intravenously over a 4- to 5-hour period while immunotherapy alone is administered over approximately 1 hour. Immunotherapy also tends to be more well tolerated than chemotherapy, the authors noted.

In their paper, they outline their plan for initiating an online survey among over 500 patients through 2 dissemination methods:

• Discrete choice experiment (DCE): a quantitative method that has study respondents state their preference of hypothetical alternative scenarios defined by different levels of several characteristics; responses are used to determine the value they place on each attribute
• Swing weighting (SW): a newer quantitative method used for determining patient preferences, which asks respondents to choose which attribute they would prioritize to improve, ranking them from the worst to best

The data will offer insights into how patients prioritize certain attributes that vary between treatments.

“SW and DCE are 2 widely used PP methods in the field of health. Notwithstanding, research directly comparing DCE and SW is particularly lacking. Methods such as SW that do not force patients’ simultaneous trade-offs between multiple attributes are considered simpler,” explained the researchers. “Otherwise, others suggested that direct comparisons in a DCE can be easier for patients. Therefore, the aim of this study is to compare the performance and results of DCE and SW in a common preference context through empirical research.”

Attributes that patients included in the survey they say they will react to include how the treatment is administered, odds of 5-year survival, change of long-term skin problems, chance of extreme fatigue, and severity of hair loss.

Once the data are collected the researchers will analyze how similar the results are between the 2 methods and pinpoint the strengths and weaknesses of each when it comes to identifying and profiling treatment options.

The survey will also assess how demographics—like age, sex, and education level, as well as clinical factors like cancer stage and line of treatment—will sway or explain patient preferences.

Reference

THE BIDEN ADMINISTRATION Thursday released its plan to reduce prescription drug prices, which would include the use of models to test value-based payments in Medicare Part B.

The goal, said the administration, is “to foster innovation, increase competition, and improve the market environment, all in pursuit of reduced drug spending for consumers and throughout the health care system.”

The blueprint supports drug price negotiation with manufacturers, promotion of biosimilars and generics, and research that promotes the discovery of new therapies, while cracking down on patent thickets and pay-to-delay deals.

Negotiated drug prices in Medicare Parts B and D would be “available to commercial plans (including the Marketplace) and employers who want to participate.”

Giving the government power to negotiate drug prices is one that has strong public bipartisan support, the May 2021 KFF Health Tracking Poll has shown.

The plan also calls for:
• Medicare Part D reform, including a cap on catastrophic spending
• Legislation to slow price increases on existing drugs
• Legislation to encourage the use of biosimilar and generic drugs by speeding their entry into the market, thereby shortening the period of exclusivity, and policies in Medicare Part B to increase biosimilar uptake
• Investment in basic and translational biomedical research through a new agency within the National Institutes of Health called the Advanced Research Projects Agency for Health

The plan also calls on the CMS Innovation Center to explore various value-based models that could be open to other payers as well, including employer and Marketplace plans as well as state Medicaid programs. Payment could be tied to improved patient outcomes, reductions in health disparities, increased patient affordability, and lower overall costs.

The goal, said the administration, is “to foster innovation, increase competition, and improve the market environment, all in pursuit of reduced drug spending for consumers and throughout the health care system.”

It also suggested the use of shared-savings models, where Medicare Part B savings from using biosimilars, generics, or other high-value therapies are shared between prescribing providers and the government. Both beneficiaries with supplemental benefits and those without would benefit from either lower premiums or reduced out-of-pocket (OOP) costs, the plan said.

The plan also calls for bundled payment for treatment episodes that aim to reduce Medicare Part B drug spending through the use of biosimilars and generics, along with drug administration services, devices, and related assistance over a period of time. The models could include incentives for use of biosimilars, generic drugs, and “high-value single source product,” the plan said.

The plan also proposes to collect data from payers and pharmacy benefit managers about prices, rebates, and OOP spending.