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Identified Enrollment Challenges of Adolescent and Young Adult Patients on the Nonchemotherapy Arm of Children's Oncology Group Study ARST1321

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ARST1321, a trial of patients with advanced soft tissue sarcoma, was the first National Clinical Trials Network study codeveloped by pediatric and adult consortia with two treatment cohorts. We report on the findings of a survey to identify barriers to enrolling adolescent and young adult patients (15–39 years) onto the nonchemotherapy arm. The survey response rate was 31% with a 70% completion rate. Common identified reasons for low accrual in order of decreasing frequency included insufficient funding, lack of study awareness or interest, competing trials, toxicity concerns, philosophical differences in the therapy backbone, and regulatory and infrastructure barriers. Clinical Trials.gov ID: NCT02180867.

Keywords: enrollment barriers, NCTN, clinical trials, cooperative groups, survey

Introduction

Although the gap in outcomes for adolescent and young adults (AYAs) (15–39 years old) with cancer has begun to narrow, improvements in progression-free and overall survival continue to trail those of younger patients with select soft tissue and bone sarcomas.[1,2] Although the etiology of this gap is multifactorial, lower cancer clinical trial (CCT) participation remains a key factor.[3–5] Specifically, compared with enrollment rates >40%–60% in pediatric populations, enrollment rates of AYAs are <10%–20%.[6–9] In addition, AYAs tend to be cared for in community centers where resources and awareness of CCTs may be more limited.[10,11] This contrasts with children <15 years, >90% of whom are treated at National Cancer Institute (NCI)/Children's Oncology Group (COG)-sponsored institutions.[12]

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Compounding these issues is the dearth of CCTs for AYAs.[13] CCTs designed for either children or older adults often have age ranges limiting AYA participation.[14] Although age ranges widened in recent years, traditional referral patterns to adult- or pediatric-centers with little cross talk between medical and pediatric oncology limits accessibility.[15] This has led to underrepresentation in biospecimen repositories, impeding the ability to ask biologically relevant questions and understand differences in pharmacokinetics and pharmacodynamics.[8,16]

In 2014, the NCI transformed its long-standing cooperative group program, comprising the Alliance for Clinical Trials in Oncology (Alliance), Eastern Cooperative Oncology Group and American College of Radiology Imaging Network, National Surgical Adjuvant Breast and Bowel Project, Radiation Therapy Oncology Group, Gynecologic Oncology Group (NRG Oncology), Southwest Oncology Group, COG and the Canadian Cancer Trials Group, into the National Clinical Trials Network (NCTN) to address these issues by allowing cross-enrollment across cooperative groups.[17,18] ARST1321 (PAZNTIS), A Phase II/III Randomized Trial of Preoperative Chemoradiation or Preoperative Radiation Plus or Minus Pazopanib (NCT02180867), was the first NCTN study codeveloped by pediatric (COG) and adult (NRG Oncology) consortia to improve AYA enrollment.[19]

Opened in 2014, ARST1321 enrolled patients aged 2 years and older with unresectable sarcoma onto two treatment cohorts: chemoradiation+delayed surgery ± pazopanib (''chemotherapy arm'') versus radiation + delayed surgery ± pazopanib (''nonchemotherapy arm''). Based on enrollment patterns on prior COG and NRG oncology trials, adults were anticipated to contribute the majority of enrollment on the nonchemotherapy arm.[19] Although the chemotherapy arm accrued as anticipated (with accrual across the age spectrum), the nonchemotherapy arm had low enrollment (expected annual accrual rate 44; actual 15) leading to premature closure in 2017.[14,20] We report the results of a survey to assess AYA patient enrollment onto ARST1321, focusing on the nonchemotherapy arm.

Methods

An online survey administered through SurveyMonkey (Palo Alto, CA) was distributed to 161 providers representing medical, pediatric, surgical, and radiation oncology at NCTN-member sarcoma centers between November 12, 2019 and January 3, 2020 (full survey available as Supplementary Data S1). More specifically, the survey was distributed to 73 established large academic sarcoma centers in the United States identified through a publicly available listing of Sarcoma Alliance for Research through Collaboration (SARC) Centers (https://sarctrials.org/join-sarc/sarc-centers). The authors, who all have specific interest and expertise in sarcoma and collectively represent all the NCTN cooperative organizations, attempted to be as inclusive as possible by reaching out to medical, surgical, and radiation oncologists at as many of these institutions as possible. The survey was sent to more than one provider at a site but none within the same discipline. Since enrollment was primarily an issue with adult patients, we largely focused our survey on non-COG sites. When COG sites were selected, we chose to only survey surgeons and radiation oncologists knowing that most pediatric oncologists already enroll patients on COG-led trials. Respondents were asked up to 35 multiple-choice and free text questions pertaining to provider subspecialty and role; institution culture, resources, and affiliation; patient population; clinical trial infrastructure; and perceived barriers for opening and enrolling onto ARST1321. The goal response rate for this online questionnaire was 30%. Respondents were not required to answer every survey question and some questions permitted multiple responses.

Results

The survey response rate was 31% ($n = 50/161$) with a 70% completion rate. The respondents' demographics are summarized in Table 1. Nearly 50% of all respondents were medical oncologists ($n = 24/50$); the remainder were pediatric (6%; $n = 3/50$), general or orthopedic surgeons (24%; $n = 12/50$) and radiation oncologists (22%; $n = 11/50$). Thirty percent of respondents were from institutions affiliated with only adult consortia; the remainder were at institutions affiliated with both a pediatric and adult group. Most institutions were medical oncology centers within an academic medical center or NCI-designated cancer center (60%; $n = 30/50$); 30% of institutions were either a pediatric oncology center within an academic medical center ($n = 11/50$) or a free-standing children's hospital ($n = 4/50$). A significant portion of pediatric centers cared for patients up to the age of 29 years (70%; $n = 35/50$); 56% of adult centers cared for patients ≥ 18 years ($n = 28/50$). Most institutions (82%; $n = 41/50$) had >50 new cases of sarcomas annually in patients ≥ 18 years; only 16% ($n = 8/50$) of institutions treated >50 new cases of sarcomas annually in patients <18 years. Seventy percent of institutions had a formal collaboration between pediatric and medical oncology ($n = 35$); of those, 74% had a joint tumor board ($n = 26/35$), 23% had an integrated AYA clinic ($n = 8/35$), 60% had an integrated

Table 1. Demographics of Respondents and Institutions

	N (%)
Respondent discipline	
Medical oncology	24 (48)
Pediatric oncology	3 (6)
General or orthopedic surgery	12 (24)
Radiation oncology	11 (22)
Consortia affiliation	
Medical only	15 (30)
Both medical and pediatric	35 (70)
Institution type	
Medical center within academic medical center or NCI-designated center cancer	30 (60)
Pediatric center within academic medical center	11 (22)
Free-standing children's hospital	4 (8)
AYA features	
Formal collaboration between medical and pediatric oncology	35 (70)
Joint tumor board	26 (52)
Integrated AYA clinic	8 (16)
Integrated IRB	21 (42)
Medical and pediatric co-PIs	19 (38)

AYA, adolescent and young adult; NCI, National Cancer Institute.

Institutional Review Board (IRB; $n=21/35$), and 54% permitted pediatric and medical oncologists to serve as co-principal investigators on the same trial ($n=19/35$).

Seventy percent of respondent institutions opened ARST1321 ($n=35$). Of those, 75% ($n=26/35$) anticipated accruing at least one patient to the nonchemotherapy arm and 20% ($n=7/35$) anticipated accruing at least five patients. However, only 58% ($n=15/26$) of responding institutions enrolled at least one patient to the nonchemotherapy arm (and only one enrolled more than five). Only 35% of responding institutions used the central IRB to open ARST1321 ($n=9/26$); a similar number used a local IRB ($n=10$). The most significant anticipated barriers to opening ARST1321 reported included disagreement about therapy backbone and toxicity (23%; $n=6/26$); funding concerns, including reimbursement from cooperative groups and local institutions (38%; $n=10/26$); competing trials and lack of interest in ARST1321 (35%; $n=9/26$); and logistical issues, including IRB approval, infrastructure, and data requirements (35%; $n=9/26$).

Focusing specifically on enrollment onto the nonchemotherapy arm, the primary barriers were similar to those in opening ARST1321: competing trials or lack of interest (38%; $n=10/26$); funding concerns (12%; $n=3/26$); and logistical issues (15%; $n=4/26$). However, there were two key differences: eligibility and patient considerations (23%; $n=6/26$) and premature closure of the arm (12%; $n=3/26$; as reported in free text by institutions who opened ARST1321 after the nonchemotherapy arm was already closed) contributed significantly to limiting accrual. Concerns about therapy backbone and toxicity did not limit accrual to the nonchemotherapy arm. A summary of the most common enrollment barriers on ARST1321 are provided in Table 2.

Of the 11 institutions who never intended to open the trial, the principal barriers were concerns related to therapy backbone and toxicity ($n=5$) and lack of support, funding and awareness across disciplines ($n=7$).

Discussion

In 2011, COG and NRG Oncology separately proposed a clinical trial to investigate pazopanib in the neoadjuvant setting with either preoperative radiation or concurrent chemoradiation for locally advanced soft tissue sarcomas. Given the overlapping concepts, the Cancer Therapy Evaluation Program encouraged a joint trial between the two NCTN organizations with the study committee including representatives from key disciplines from both groups. ARST1321 was an ideal opportunity to improve AYA enrollment given close collaboration and codevelopment between pediatric and adult consortia without age restrictions. This helped to overcome the historically perceived bias among the cooperative groups in having one group have primary ownership over trial design, influencing staging, classification systems, and treatment paradigms. Despite this, the nonchemotherapy arm of ARST1321 closed prematurely due to low enrollment. From our survey results, many of the contributing reasons support previously described barriers: disagreement with proposed therapy backbone and concerns over toxicity; lack of interest, awareness and/or support for the trial or competing trials; logistical issues including regulatory and infrastructure barriers; funding concerns at the local and consortia level; and patient preference.[8,21]

Table 2. Most Common Reported Barriers to AYA Enrollment on ARST1321

	N[a] (%)
Opening ARST1321 (26 sites)	
Funding limitations	10 (38)
Competing trials and/or lack of interest in ARST1321	9 (35)
Logistical issues	9 (35)
Disagreement about therapy backbone and concerns over toxicity	6 (23)
Accrual to the nonchemotherapy arm of ARST1321 (26 sites)	
Competing trials and/or lack of interest in ARST1321	10 (38)
Eligibility and patient considerations	6 (23)
Logistical issues	4 (15)
Funding concerns	3 (12)
Premature closure of the nonchemotherapy arm	3 (12)

[a]Respondents were able to select more than one answer.

Although codeveloped, COG was designated the lead protocol organization (LPO), which made it less visible to NCTN groups outside of COG and dampened support from other consortia and institutions without COG representation. At the time of study closure, 56% of enrollments were credited to COG institutions, 31% NRG Oncology and 13% other consortia. By improving visibility of the study's joint leadership and more actively soliciting representation from other NCTN partners, cooperation and outreach could be improved significantly. This could increase awareness and willingness to prioritize trials based on NCTN consensus. Critically, this could allay concerns with the proposed therapy and perceived toxicities. Nearly a quarter of responding institutions anticipated that the therapy backbone may disincentivize trial accrual; of those institutions that did not open the trial, more than half stated disagreement with the backbone as the primary reason. Thus, by involving other NCTN partners earlier in the study development, support from more institutions could be achieved. Working groups with grassroots representation from all consortia could help spearhead this effort by serving as champions at both the national and local levels.[14,20,22] In addition, by altering the naming of clinical trials such that the name does not indicate the LPO, enrollment bias could be reduced (e.g., all COG clinical trial names begin with the letter ''A'' followed by the disease abbreviation, year, and trial phase).

Another significant obstacle reported was limited resources, particularly funding at the local level and per case reimbursement by the cooperative groups. By prioritizing trials deemed critical by all NCTN partners, scarce funding may be redirected to ensure completion of trials. Although this may limit the number of trials opened, it would allow for meaningful progress by focusing on those studies asking the most important questions. Interestingly, more than a third of institutions that opened ARST1321 reported competing trials as a hurdle to enrollment. Thus, by strategically directing available resources to those trials given priority by NCTN, such competition can be ameliorated. Although the greater fix is to increase funding for AYA oncology and better incentives for improving AYA engagement, we must be deliberate in working within the limitations of the current system. For

example, alternatives to financial incentives, such as academic credit (authorship, title promotions, etc.), may also encourage participation by institutions and providers. Moreover, engaging with independent nonprofit research organizations (e.g., SARC), philanthropic and patient advocacy groups and industry, can augment federal resources. These partner associations can sponsor trials and increase patient education and outreach.[20]

Furthermore, although academic centers were well represented among those institutions that opened ARST1321, the importance of engaging the NCI Community Oncology Research Program (NCORP) is critical as most older AYAs are cared for at community centers.[23] This could limit the barriers of travel and logistics for many AYAs. Understanding local institutional concerns and needs is also important. Central IRBs that assess protocols agnostic of age can facilitate trial approval; acceptance of these decisions by local IRBs can bypass regulatory delays.[24] Common registration, enrollment procedures, and timelines from a central group (e.g., Clinical Trials Support Unit) could minimize obstacles at the local level by standardizing the approach and training of CCT staff.

After the premature closure of the nonchemotherapy arm on ARST1321, the authors of this article created the NCTN/SARC Sarcoma AYA Clinical Trials Working Group with the goal of identifying and overcoming enrollment barriers through close communication and collaboration. Monthly meetings are held in which new sarcoma AYA trial concepts in early development are discussed and NCTN champions identified. This avoids overlapping trials, encourages perspective sharing, establishes consensus, and identifies barriers to enhance future cross-group enrollment and prevent activation of a trial with limited potential for completion.

As a survey-based study, there may be inherent limitations in the generalizability of findings. Although we achieved our goal response rate of 30%, this remains a limited sampling. As medical oncologists were overrepresented, the perspectives of surgical and radiation oncologists were not as well characterized. In addition, although free text options were included, respondent answers could not be further probed for better understanding of nuances between responses. The respondents also overrepresented academic centers. However, we purposely targeted such institutions as they have historically been the primary drivers of patient accrual to consortia trials. Notably, the barriers we report have been previously well described and thus reaffirm the central findings of our study. Furthermore, although the focus of this article has been on AYAs and how the aforementioned barriers relate to AYAs, remedies to these barriers would also enhance accrual of children and older adults as these issues are not necessarily unique to AYAs.

Table 3. Potential Opportunities to Improve Adolescent And Young Adult Accrual in National Clinical Trials Network Cancer Clinical Trials

Establish joint ownership of clinical trial beginning from concept design to trial conduct, avoiding one cooperative group as the lead protocol organization
Solicit champions from all cooperative groups at the national, local, and institutional levels
Create multidisciplinary grassroots working groups to increase awareness and raise support
Remove individual cooperative group-based clinical trial nomenclature and create a standard naming process for NCTN cosponsored clinical trials
Achieve consensus for clinical trial prioritization by all NCTN partners to ensure appropriate conduct, funding, and completion of trials
Engage with nonprofit patient advocacy and philanthropic groups to raise awareness, interest, and funding for clinical trials
Partner with community and resource-limited cancer centers to increase accrual catchment areas
Standardize use of central processes, including IRB review, trial conduct processes, and pathology confirmation

NCTN, National Clinical Trials Network.

Conclusions

ARST1321 was an important step in attempting to improve AYA enrollment and although cross-enrollment was observed, it was inconsistent. Although known barriers persisted, ARST1321 offers us a unique opportunity to evaluate possible solutions (Table 3): co-ownership of trials without single LPOs and group-neutral trial names; NCTN prioritization and funneling of limited resources to the most relevant CCTs; partnerships with nonprofit and philanthropic groups; incorporation of NCORP; harmonization of central and local processes; and earlier engagement and promotion between cooperative groups.

Disclaimer

The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health.

Author Disclosure Statement

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Supplementary Material

Supplementary Data S1

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