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Implementation of the ArteraAI Prostate Test in Clinical Practice: A Single-Center Experience

Developed with
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Introduction

Radiation Oncologists, P.A./ChristianaCare Practice Overview

Radiation Oncologists, P.A. (ROPA) provides specialized radiation oncology services as part of ChristianaCare, a large medical network in the Northeastern United States. Comprising nine radiation oncologists, including three who specialize in prostate cancer, the practice operates out of the Helen F. Graham Cancer Center, serving patients in Delaware and Southeastern Pennsylvania. The geographic positioning, alongside a high referral volume from multiple urology groups, has established the practice as a primary center for prostate cancer care, seeing approximately 15 to 30 new prostate cancer patients each week.

The practice collaborates closely with a large urology group and additional urologists within the ChristianaCare network, totaling over ten urologists, ensuring a robust referral system and strong continuity of care. To address the complexities of prostate cancer management, ROPA employs a multidisciplinary approach through weekly genitourinary tumor board meetings, bringing together urologists, medical oncologists, radiologists, and pathologists. This high-level collaboration, paired with access to a strong brachytherapy program and advanced technologies like CyberKnife, enables comprehensive, personalized care for each patient.

ArteraAI Prostate Test

The ArteraAI Prostate Test is a guideline-recommended, artificial intelligence (AI)-derived biomarker test designed to support risk-based clinical decision-making for patients with localized prostate cancer.[1-3] By analyzing digital histopathology images from hematoxylin and eosin (H&E)-stained slides, along with a limited set of clinical variables provided by the clinician, the test offersinsights for both prognostic and predictive purposes. The prognostic biomarker estimates a patient's 10-year risk of distant metastasis and prostate cancer-specific mortality, while also helping determine if active surveillance (AS) may be a suitable management option. For patients with National Comprehensive Cancer Network (NCCN) intermediate-risk disease, the predictive biomarker evaluates the potential benefit of adding short-term androgen deprivation therapy (ST-ADT) to radiation therapy.

The test's prognostic biomarker was trained and validated using data from thousands of patients with localized prostate cancer enrolled in large-scale, randomized phase 3 clinical trials, with follow-up periods of up to 20 years.[3,4] Numerous studies have since confirmed its ability to effectively stratify risk across the spectrum of localized prostate cancer.[5-12] The predictive biomarker for ST-ADT was developed and validated using data from four prospective, randomized phase 3 trials, including the RTOG 9408 trial, which examined the efficacy of radiation therapy with or without ST-ADT.[2]

The ArteraAI Prostate Test, available as a laboratory-developed test, is processed at Artera's Clinical Laboratory Improvement Amendments of 1998 (CLIA)–certified laboratory in Jacksonville, Florida, with results typically available within 24 to 36 hours of specimen receipt. The Centers for Medicare & Medicaid Services has also established a payment rate for the test.[13] This quick turnaround and streamlined process make the ArteraAI Prostate Test a practical and valuable tool for timely, personalized prostate cancer care.

Implementation of the ArteraAI Prostate Test at ROPA

ROPA has cultivated a culture of innovation and an openness to adopting new tools that provide added precision in patient care. The ArteraAI Prostate Test, offering predictive and prognostic insights, aligns with this forward-thinking approach, particularly in guiding decisions around ST-ADT for intermediate-risk prostate cancer patients.

Prior to its commercial launch in January 2024, the ArteraAI Prostate Test was available through the ArteraAI Early Access Program, which provided clinicians with precommercial access to support real-world evaluation and feedback for seamless integration into clinical care. Although the underlying AI algorithms and ArteraAI Prostate Test results were the same from 2023 to 2024, Artera made meaningful changes to the ordering and billing process throughout the Early Access Program, in part based on customer feedback.

The practice participated in the Early Access Program in 2023 to help address the critical need of identifying which intermediate-risk prostate cancer patients would most benefit from hormone therapy. The team was drawn to the test's potential to refine treatment recommendations for this group, particularly as many patients prefer to avoid hormone therapy due to its side effects[14]. Initially focused on unfavorable intermediate-risk cases, the ArteraAI Prostate Test has since become integral in helping stratify patients and guide therapy choices, allowing clinicians to confidently tailor treatment.

Over time, the practice expanded the use of the ArteraAI Prostate Test to other patient groups, including favorable intermediate-risk patients considering AS and high-risk patients needing additional risk stratification. The test's seamless ordering process and fast turnaround time (see table 3) fits easily into the clinic's workflow, ensuring results are ready for timely consults. The fast response and lack of tissue consumption support the ability to make timely treatment recommendations, whether patients are considering active surveillance, radiation therapy alone, or in combination with androgen deprivation therapy (ADT). The report's visual format is also valuable in facilitating patient-centered discussions, enabling patients to make informed choices with clear risk information.

The test's ease of use has also been beneficial for the clinic's busy nurses, who can manage orders with minimal added workload. This efficiency has led to high adoption rates across the practice, establishing the ArteraAI Prostate Test as an essential part of their treatment planning and patient engagement efforts.

Summary of Clinical Experience

Between February 2023 and August 2024, the ArteraAI Prostate Test was ordered for 127 patients at ROPA and were included in this analysis. Of the 127 patients, 59 patients underwent testing during the Early Access Program (prior to January 2024), whereas 68 were tested after the commercial launch (from January 2024 onward). The majority of patients were classified as having NCCN intermediate-risk disease, with 60% (76/127) categorized as unfavorable intermediate risk and 28% (35/127) as favorable intermediate risk (Table 1).

Table 1. Baseline characteristics (n=127)

Variable	Value, n (%)
Gleason Score	
6	11 (9)
7 (3+4)	66 (52)
7 (4+3)	44 (35)
8	3 (2)
9	3 (2)
NCCN Risk Group	
Very low	4 (3)
Low	5 (4)
Favorable intermediate	35 (28)
Unfavorable intermediate	76 (60)
High	7 (6)
Very high	0 (0)
MMAI Risk Group	
Low	106 (83)
Intermediate	21 (17)
High	0 (0)

MMAI, multimodal artificial intelligence; NCCN, National Comprehensive Cancer Network.

Prognostic Biomarker

Based on MMAI results, 83% (106/127) of patients were categorized as having low-risk disease and 17% (21/127) as having intermediate-risk disease, with no patients categorized as having high-risk disease. Among patients classified as having NCCN low-risk disease (n=9), all were confirmed as being low risk by MMAI. In the NCCN intermediate-risk group (n=111), 86% (95/111) were reclassified as MMAI low risk (Figure 1). Notably, in the NCCN high-risk group (n=7), 71% (5/7) were reclassified as MMAI intermediate risk and 29% (2/7) were reclassified as MMAI low risk. Overall, 80% (102/127) of patients were reclassified to a lower-risk group by MMAI, with no patients being reclassified to a higher-risk group. These findings align with previously published analyses demonstrating that MMAI often and accurately reclassifies patients into lower-risk groups while rarely shifting them to higher-risk groups, which can enhance precision in treatment decision-making.[4]

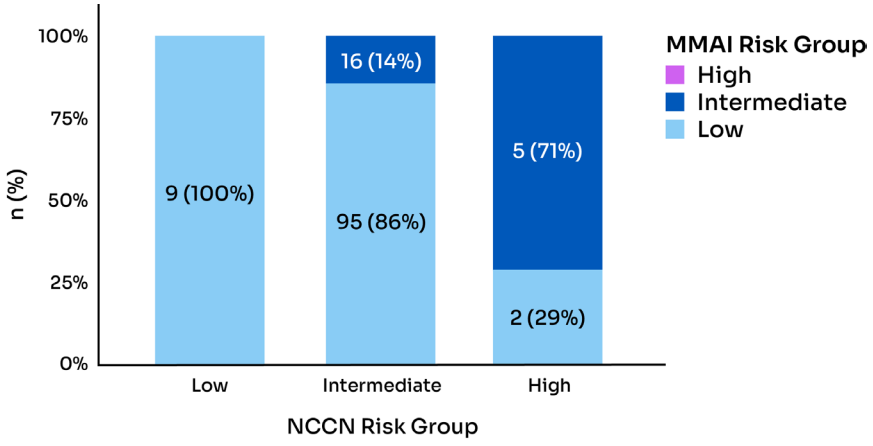


Figure 1. Reclassification of patients by MMAI prognostic biomarker. MMAI, multimodal artificial intelligence; NCCN, National Comprehensive Cancer Network.

Summary of Clinical Experience

Predictive ST-ADT Biomarker

Patients with NCCN intermediate-risk disease receive predictive ST-ADT biomarker results from the ArteraAI Prostate Test to provide insight into whether the addition of ST-ADT to radiation therapy) RT may be beneficial. Among the 93 patients who had NCCN intermediate-risk disease and underwent RT, 88 (95%) had a predictive ST-ADT biomarker result of negative, indicating no likely benefit from adding ST-ADT, whereas 5 patients (5%) had a positive result, suggesting potential benefit (Table 2).

Of the 67 patients with NCCN unfavorable intermediate-risk disease who received RT, 64 (96%) had a negative predictive ST-ADT biomarker result, and 3 (4%) had a positive result. Among those with a negative predictive ST-ADT biomarker result, 83% (53/64) did not receive ADT, aligning with the biomarker's recommendation. Among those with a positive ST-ADT biomarker result, 100% (3/3) received ADT, reflecting alignment to the biomarker's guidance. These results underscore how the predictive ST-ADT biomarker can support personalized treatment decisions, helping clinicians and patients weigh the benefits of ADT based on individual risk profiles. Over time, ROPA clinicians showed increased confidence in the ST-ADT biomarker results, resulting in more frequent alignment between the ArteraAI Prostate Test guidance and the resulting treatment.

Table 2. ADT usage by predictive ST-ADT biomarker status in patients who were treated with radiation therapy

	Favorable Intermediate		Unfavorable Intermediate	
ADT Usage	**ST-ADT (+)** [n=2]	**ST-ADT (-)** [n=24]	**ST-ADT (+)** [n=3]	**ST-ADT (-)** [n=64]
Received ADT	0 (0%)	7 (29%)	3 (100%)	11 (17%)
≤6 months	0 (0%)	7 (29%)	3 (100%)	9 (14%)
≥12 months	0 (0%)	0 (0%)	0 (0%)	2 (3%)
Did not receive ADT	2 (100%)	17 (71%)	0 (0%)	53 (83%)

ADT, androgen deprivation therapy; ST-ADT, short-term ADT.

Summary of Clinical Experience

Ordering

Figure 2. High-level overview of workflow.

The timing of order submission and report turnaround for the ArteraAI Prostate Test has improved over time, reflecting advancements in workflow and efficiency (Table 3; Figure 2). During the Early Access Program, the median time from order creation to submission was 3.8 minutes. After the Early Access Program, the ordering process was streamlined to enhance efficiency and ease of use. Accordingly, the median time from order creation to submission has since decreased to 2.3 minutes following commercialization. Similarly, the median time from order submission to the Artera lab receiving the sample for AI analysis decreased from 11.0 days during the Early Access Program to 8.0 days in the commercialization phase, indicating improved logistics for slide submission. These enhancements demonstrate how the ArteraAI Prostate Test integrates seamlessly into clinical workflows, ensuring clinicians receive timely, actionable results to guide treatment planning without delays.

Table 3. Timing of Ordering

	Early Access Program (2023)	Early Commercialization (1/2024-4/2024)
Time from order creation to submission, median	3.8 minutes	2.3 minutes
Time from order submission to AI analysis, median	11.0 days	8.0 days
Time from AI analysis to report, median	19.1 hours	3.2 hours

AI, artificial intelligence.

Case Studies

To illustrate the clinical application of the ArteraAI Prostate Test, three representative case studies highlighting how the test results were utilized in diverse clinical scenarios are presented. These cases demonstrate the test's ability to guide personalized treatment decisions, whether for patients considering AS, RT, or the addition of ST-ADT. By offering actionable insights tailored to individual risk profiles, the test supports both clinicians and patients in selecting the appropriate treatment strategies.

Case Studies Demonstrating Utility of the ArteraAI Prostate Test

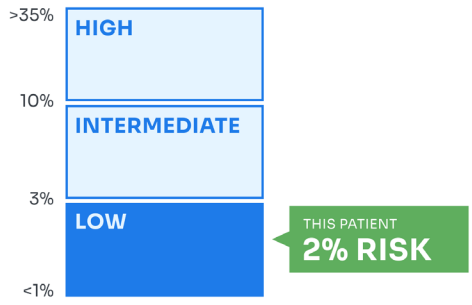
Patient 1

Clinical Tumor Stage	cT1c
Prebiopsy PSA	4.5 ng/mL
Gleason Score	7 (3+4)
Patient Age at Order Date	67
NCCN Risk	Favorable Intermediate

PROGNOSTIC RISK

LOW

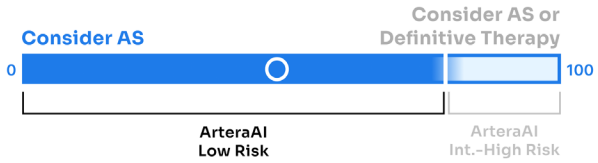
10-YEAR RISK OF DISTANT METASTASIS



10-YEAR RISK OF PROSTATE CANCER SPECIFIC MORTALITY 1%

ACTIVE SURVEILLANCE (AS) INSIGHTS

This patient's relative risk of adverse pathology at radical prostatectomy (RP) is in the **50th percentile** of a cohort of patients managed with AS who had RP.



ST-ADT BIOMARKER

Positive

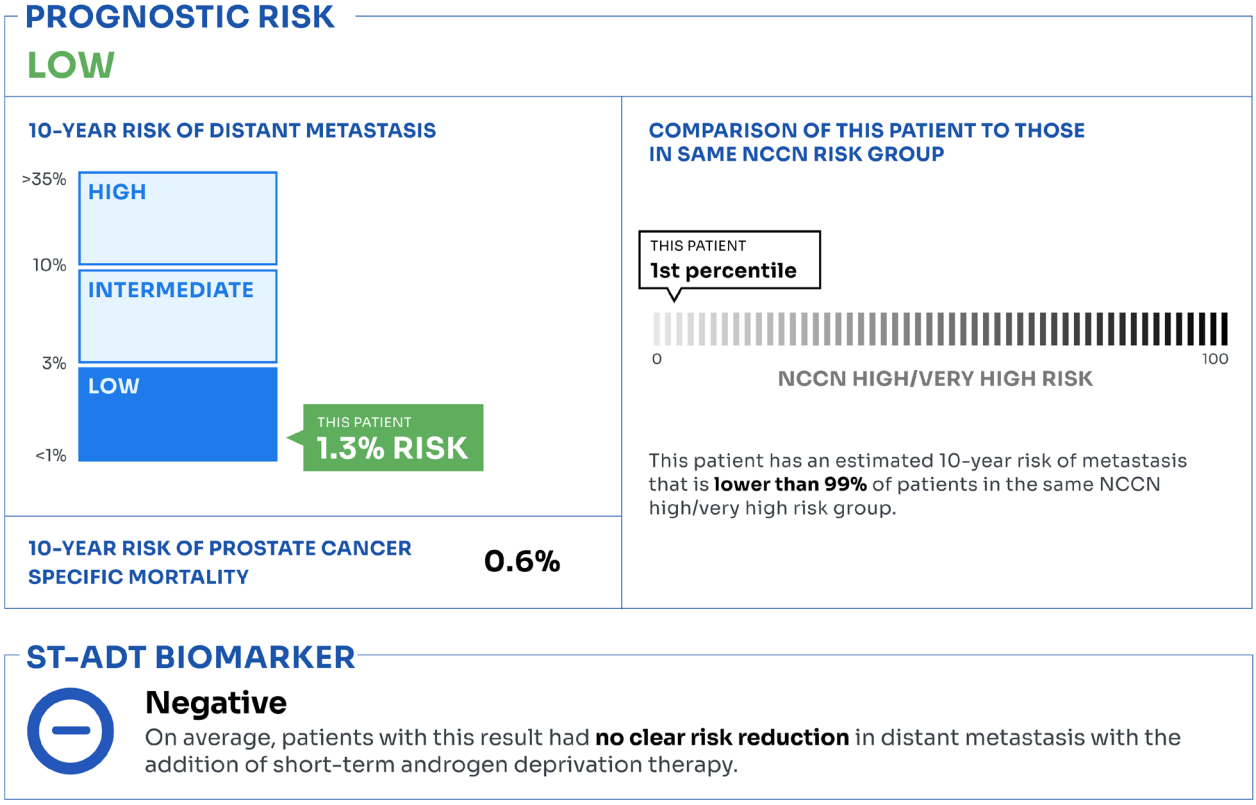
On average, patients with this result had **significant risk reduction** in distant metastasis with the addition of short-term androgen deprivation therapy.

After initial staging, this 67-year-old patient with NCCN favorable intermediate-risk disease sought additional insights into his treatment options, as he wanted to consider AS. Due to insufficient tissue, genomics testing was not feasible. However, the ArteraAI Prostate Test results provided valuable guidance, indicating a low prognostic risk. Given the favorable risk assessment from ArteraAI, **the patient felt confident in opting for AS**, allowing him to avoid immediate definitive treatment while closely monitoring his condition. The patient also received a predictive ST-ADT biomarker positive result, suggesting that if his disease were to progress during AS and the patient chose RT, he may benefit from the addition of ST-ADT.

Case Studies Demonstrating Utility of the ArteraAI Prostate Test

Patient 2

Clinical Tumor Stage	cT1c
Prebiopsy PSA	10.2 ng/mL
Gleason Score	7 (3+4)
Patient Age at Order Date	75
NCCN Risk	Unfavorable Intermediate

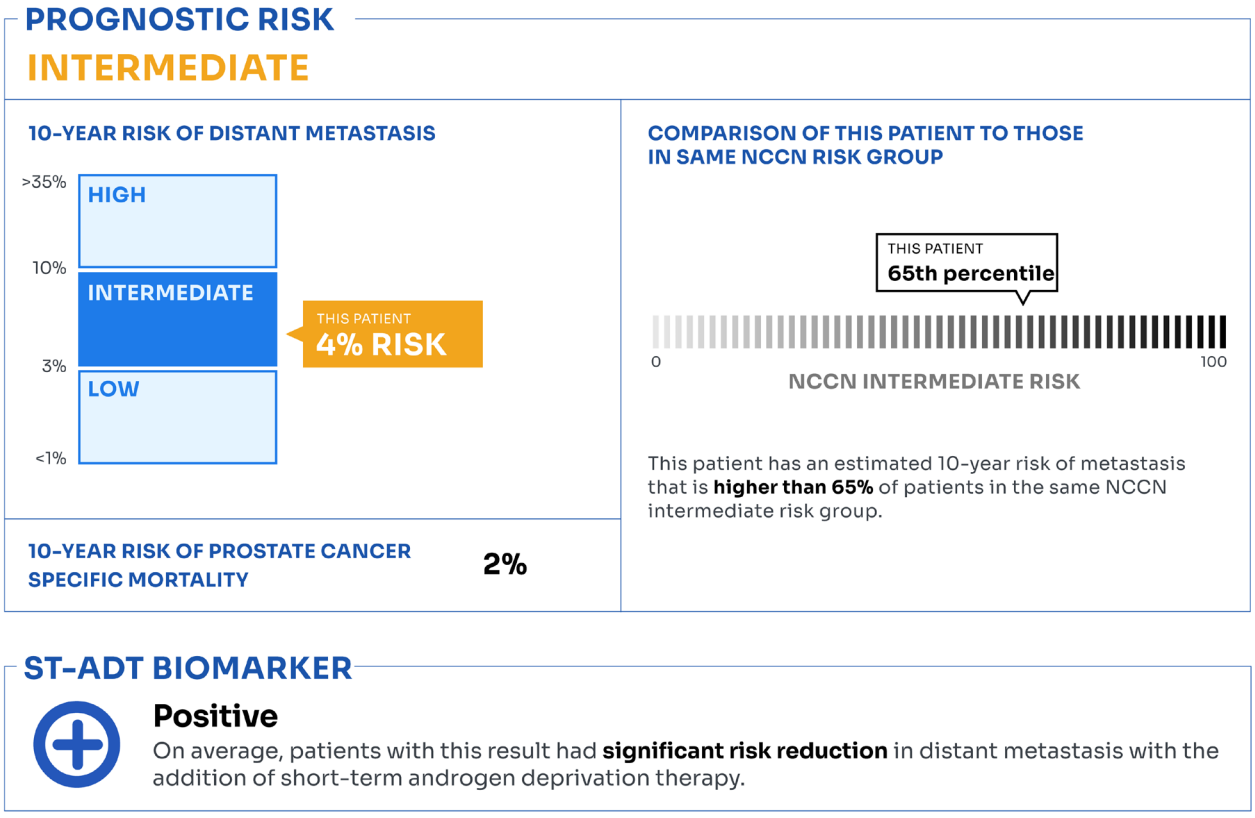


This 75-year-old patient, presented with NCCN unfavorable intermediate-risk disease and was initially considering adding ST-ADT to radiation therapy. However, given his concerns about the side effects associated with ADT, he and his care team sought further insight through the ArteraAI Prostate Test to evaluate if ADT could be avoided. The test results revealed a low 10-year risk of distant metastasis. Additionally, the ST-ADT biomarker was negative, indicating that ADT was unlikely to provide additional benefit in reducing metastasis risk. Armed with these results, **the patient opted to proceed without ST-ADT**, focusing on a management plan that aligned with his personal preferences and quality-of-life goals.

Case Studies Demonstrating Utility of the ArteraAI Prostate Test

Patient 3

Clinical Tumor Stage	cT1c
Prebiopsy PSA	6.2 ng/mL
Gleason Score	7 (4+3)
Patient Age at Order Date	82
NCCN Risk	Unfavorable Intermediate



This 82-year-old patient presented with NCCN unfavorable intermediate risk-disease and was considering whether ST-ADT would be necessary in his treatment plan. The ArteraAI Prostate Test provided further clarity, showing an intermediate 10-year risk of distant metastasis at 4%. Of importance, the ST-ADT biomarker was positive, indicating that ST-ADT may reduce his risk of metastasis. Based on this evidence, the **patient elected to proceed with a 4-month course of ADT**, aligning his treatment approach with the ArteraAI results to maximize risk reduction.

Summary

We have incorporated the ArteraAI Prostate Test into the management of patients with localized prostate cancer at ROPA, to help enable more personalized, evidence-based treatment decisions. With its predictive and prognostic insights, rapid turnaround time, and ease of use, the test has become a valuable tool for guiding therapy choices, particularly around ST-ADT for intermediate-risk patients. This implementation underscores the practice's commitment to innovation and precision medicine, enhancing both clinical outcomes and patient quality of life.

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Disclaimer

This case study was prepared by Dr. Timothy Kegelman based on his own personal experience with the ArteraAI Prostate Test and those of his colleagues at Radiation Oncologists, P.A. (ROPA). Artera has ensured that all references and citations for claims that can be substantiated have been documented appropriately. Non-substantiated claims should be considered personal opinions expressed by Dr. Kegelman, and may not be representative of all users. He was compensated for his time and effort in preparing this case study for publication.

The ArteraAI Prostate Test is a Laboratory Developed Test that is now clinically available through a single CLIA-certified laboratory in Jacksonville, Florida. This test has not been cleared or approved by the US Food and Drug Administration.

Please consult with your health care provider for personalized medical advice and determine if the ArteraAI Prostate Test is appropriate for you.

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Dr. Kegelman is a board-certified radiation oncologist, practicing in Delaware and Pennsylvania. He completed his training at the University of Pennsylvania after earning dual doctorates in the MD-PhD program at the Medical College of Virginia/Virginia Commonwealth University. In addition to medical education, he completed a PhD in Human and Molecular genetics, researching a novel protein target in glioblastoma and using a small molecule inhibitor in combination with radiation. Dr. Kegelman performed Internal Medicine internship at the Hospital of the University of Pennsylvania before his residency in Radiation Oncology at the University of Pennsylvania, where he was selected as chief resident. Prior to his medical training, Dr. Kegelman completed undergraduate training at the University of Notre Dame, majoring in Chemical Engineering while serving as the captain of the men's swim team.

He takes pride in providing excellent care to his patients and has clinical interests including prostate and other genitourinary cancers, cancers of the head and neck, liver, pancreas, lung and thoracic malignancies, breast and gynecologic cancers, oligometastatic disease, as well as other disease sites. He was the first in Delaware to treat osteoarthritis with low dose radiotherapy. Dr. Kegelman continues research through clinical trials as an investigator, achieving high accrual to national NRG research studies. He has published numerous peer-reviewed journal articles and presented at national and international meetings. He is a member of multiple professional societies and organizations, including the American Society for Radiation Oncology, the American College of Radiation Oncology, and the Medical Society of Delaware.

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