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Original Article

Real-world Impact of Age at Diagnosis on Treatment Patterns and Survival Outcomes of Patients with Metastatic Pancreatic Ductal Adenocarcinoma

Rawad Elias[1,*], Paul Cockrum[2], Andy Surinach[3], Shu Wang[3], Bong Chul Chu[3], Armin Shahrokni[4]

[1]Hartford HealthCare Cancer Institute, Hartford, CT, USA
[2]Ipsen, Cambridge, MA, USA
[3]Genesis Research, Hoboken, NJ, USA
[4]Memorial Sloan Kettering Cancer Center, New York, NY, USA

*Corresponding author: Rawad Elias, Hartford HealthCare Cancer Institute, Hartford Hospital, 85 Retreat Ave, Hartford, CT 06106, USA. Tel: 860-249-6291. Email: Rawad.Elias@hhchealth.org

Abstract

Background: Sixty-eight percent of patients with pancreatic ductal adenocarcinoma (PDAC) are 65 years and older. Older adults are under-represented in clinical trials and their care is complicated with multiple age-related conditions. Research suggests that older patients can experience meaningful responses to treatment for PDAC. The objective of this study was to evaluate the characteristics, rate of treatment, and survival outcomes of patients with metastatic PDAC (mPDAC) based on age at diagnosis.

Materials and Methods: Data were extracted for patients diagnosed with mPDAC between January 1, 2015, and March 31, 2020, from the Flatiron Health database. Patients were stratified into 3 age groups: <70 years old, 70-79 years, and ≥80 years. The proportion of patients who received first-line therapy, the types of regimens received in the metastatic setting, overall survival (OS) from the start of treatment were evaluated.

Results: Of the 8382 patients included, 71.3% (n = 5973) received treatment. Among patients who received treatment 55.5% (n = 3313) were aged <70 years at diagnosis, 33.0% (n = 1972) were 70-79 years, and 11.5% (n = 688) were ≥80 years. Patients ≥80 years of age were more likely to receive gemcitabine monotherapy and less likely to receive FOLFIRINOX. Among first-line treated patients, median OS significantly decreased with age. However, when comparing patients treated with the same first-line regimen, no significant differences in median OS were observed by age.

Conclusions: This study highlights that older adults with mPDAC can benefit substantially by receiving appropriate levels of treatment.

Key words: pancreatic neoplasms; geriatric assessment; drug therapy; survival analysis.

Implications for Practice

Age at the time of diagnosis can affect treatment choice and outcomes for patients with metastatic pancreatic ductal adenocarcinoma (mPDAC). This real-world retrospective analysis shows that the rate of treatment for metastatic pancreatic cancer decreases with age. The median overall survival significantly decreased for older patients but there were no significant differences observed among different age groups when comparing outcomes for patients treated with the same first-line regimen. Survival outcomes by treatment are similar for all age groups among patients with mPDAC; older adults may benefit from appropriate levels of systemic treatment which can inform treatment selection.

Introduction

Metastatic pancreatic ductal adenocarcinoma (mPDAC) is primarily diagnosed in older adults with a median age at diagnosis of 70 years.[1] The prognosis is poor for mPDAC, with a 5-year survival rate of approximately 2.9%. The highest mortality rate is observed in older patients, who have a 5-year survival rate of 4.7%, independent of stage at diagnosis.[1] The number of older adults (aged ≥65 years) in the US is expected to increase to 73.1 million by 2030, accounting for more than 20% of the general population and recent estimates suggest the incidence of PDAC is increasing about 1% per year.[1,2]

The American Society of Clinical Oncology (ASCO) published updated treatment guidelines for metastatic pancreatic cancer in 2020.[3] The recommended treatment varies depending on the Eastern Cooperative Oncology Group Performance Status (ECOG PS) and comorbidity profile of the patient. For patients with an ECOG PS of 0 to 1 and favorable comorbidity profile, FOLFIRINOX (leucovorin,

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fluorouracil, irinotecan, and oxaliplatin) is recommended as first-line treatment, or gemcitabine plus nab-paclitaxel for patients with a relatively favorable comorbidity profile. Gemcitabine monotherapy is recommended for patients with an ECOG PS of 2 or a comorbidity profile that precludes the use of more aggressive treatment regimens.[3]

Aging-related conditions complicate the care of older adults with cancer.[4,5] However, aging is heterogeneous process and chronological age alone is a poor indicator of the true physiological status.[6,7] Functional assessments of the older adult population can facilitate informed treatment decision-making.[6-9] Guidelines from ASCO and the National Comprehensive Cancer Network (NCCN) recommend a baseline geriatric assessment (GA) for older patients receiving chemotherapy.[10,11] A GA can provide a comprehensive understanding of the functional and physiological status of older patients with cancer and allows the detection of vulnerabilities that may not be captured in routine oncology assessments.[10] Furthermore, GA can predict the risk of severe treatment-related toxicity and survival outcomes.[8]

Adults over the age of 65 years account for more than 50% of all cancer cases in the US,[1] but comprise less than one-third of participants in oncology clinical trials[12,13] and continue to be underrepresented.[14,15] Despite the limited data guiding the management of older adults with cancer, research has indicated that older patients who receive appropriate treatment for pancreatic cancer can experience meaningful response and survival outcomes.[16-19]

We evaluated the patient characteristics, rate of treatment, and survival outcomes for patients with mPDAC based on age at diagnosis.

Materials and Methods

Study Design

A retrospective, observational study of patients from the Flatiron Health database diagnosed with mPDAC between January 1, 2015, and March 31, 2020.

Data Source

This study used the nationwide Flatiron Health database, a longitudinal, demographically and geographically diverse database derived from electronic health record data. The database includes data from over 280 cancer clinics (~800 sites of care), representing more than 2.2 million active patients living with cancer in the US. Most patients in the database originate from community oncology settings. Patient-level data include structured data (eg, laboratory values and prescribed drugs) and unstructured data collected via technology-enabled chart abstraction from physician's notes and other documents. The data are de-identified and subject to conditions to prevent reidentification and protect patient confidentiality.

Patient Population

Patients included in the data source were those with a diagnosis code for pancreatic cancer (International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM): 157.x or ICD-10-CM: C25.x), 2 documented clinical visits, on separate days, on or after January 1, 2014, had pathology consistent with adenocarcinoma of the pancreas, and were diagnosed with stage IV disease or were diagnosed with earlier-stage pancreatic cancer and subsequently developed recurrent or progressive disease on or after January 1, 2014. Patients were included in the study if they met the following criteria: were ≥18 years of age at metastatic diagnosis date, diagnosed with mPDAC between January 1, 2015, and March 31, 2020, had a recorded activity (visit/treatment administration) on or after the metastatic diagnosis date, received a systemic treatment regimen in the metastatic setting, and had a follow-up activity recorded in the database after the start of systemic treatment.

Baseline Characteristics

The following clinical and demographic characteristics were assessed for the study population: age at metastatic diagnosis (<70 years, 70-79 years, ≥80 years), sex, race, region, index year, stage at initial diagnosis, practice type, ECOG PS (closest score within 30 days prior/7 days after the start of systemic treatment), presence of surgery any time prior to treatment, and surgery type.

Study Outcomes

The proportion of patients that received first-line, second-line, and third-line treatment was assessed. The most frequently received treatment regimens by line of therapy were assessed for each age group. Overall survival (OS) was assessed from the start of each line of therapy. Patient deaths were assigned the 15th day of the month of death as the event date, and patients without a death recorded in the database were censored at their last recorded clinical activity (visit or treatment administration).

Statistical Methods

Categorical variables were described with frequencies and percentages. Summary statistics were generated for continuous variables. Kaplan-Meier methods were used to calculate median OS. The log-rank test was used to compare OS between age groups. The $\chi 2$ test was used to assess differences between categorical variables. A P-value < .05 was considered statistically significant. Analysis was conducted using R (version 4.0.0).

Results

Study Cohort

There were 8382 patients identified with a diagnosis of mPDAC between January 1, 2015 and March 31, 2020. Of these patients, 5973 received treatment in the metastatic setting and met all other inclusion criteria (Fig. 1). Baseline characteristics are described in Table 1. Fifty-5 percent of patients were <70 years of age (n = 3313), 33% were 70-79 years (n = 1972), and 12% were ≥80 years (n = 688). Sex was similar between all age groups in the first-line setting (P = .2). Younger patients that received treatment were more likely to be treated at an academic center than older patents (15%, n = 506, vs. 11%, n = 78; P = .009). Patients in the age group ≥80 years had the highest proportion of ECOG PS scores ≥2 (21%, n = 147; P < .001).

Treatments

Overall, 71.3% (n = 5973) of patients received first-line treatment, 38.3% (n = 2289) received second-line treatment, and 33.2% (n = 761) of patients treated in second-line received third-line treatment. The proportion of patients receiving treatment decreased with age, and older patients were less likely to receive subsequent lines of therapy (Table 2). A

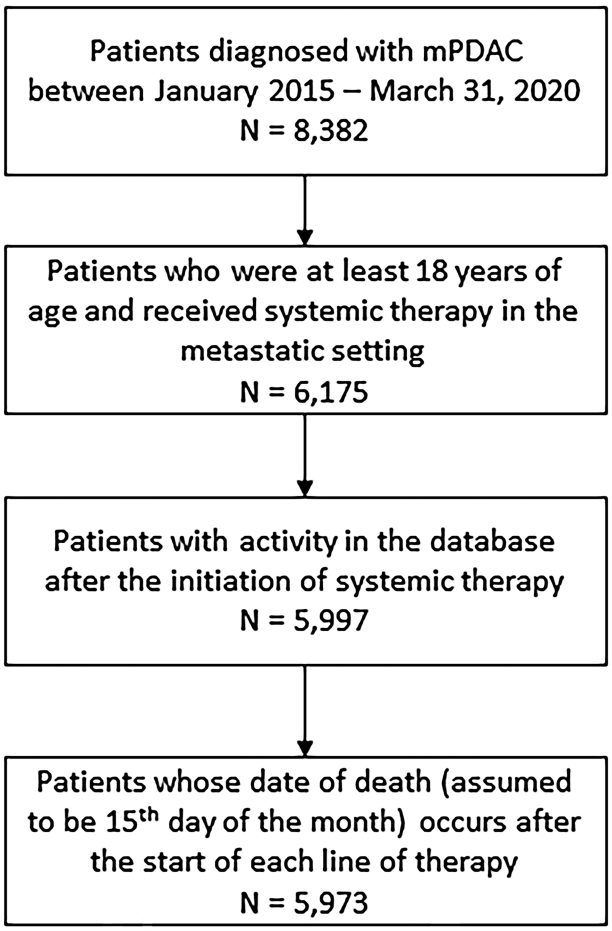

Figure 1. Cohort attrition diagram.

significant difference was not observed in third-line treatment rate between age groups (P = .3158).

First-line treatment regimens received according to age group are presented in Table 3. Across all age groups, the most common first-line treatment was gemcitabine plus nab-paclitaxel. Monotherapy with gemcitabine accounted for almost a quarter of the treatment regimens received in the first-line by patients ≥80 years of age but was less commonly administered to patients <80 years of age. Only 4.7% (n = 32) of patients aged ≥80 years received FOLFIRINOX, compared to 34% (n = 1131) of patients aged <70 years and 18% aged 70-79 years.

Overall Survival

The median OS significantly decreased with age among patients who received at least first-line treatment (Fig. 2). Patients aged less than 70 years had a median OS of 7.9 months (95% CI, 7.6-8.3 months) compared to 6.8 months (95% CI, 6.3-7.2 months) for patients 70-79 years, and 6.2 months (95% CI, 5.5-6.8 months) for patients ≥80 years (Table 4), P < .0001. However, when comparing survival outcomes by treatment regimen, median OS was similar across the age groups (Table 4).

Discussion

The results from this large, retrospective study suggest that older adults with mPDAC can benefit from systemic treatment as much as their younger counterparts. Although older patients were less likely to receive first-line and subsequent lines of therapy compared to younger patients, there were no significant differences in median OS by age when comparing patients treated with the same first-line regimen (Table 4). These results are consistent with previous studies, which suggested that older patients who receive appropriate treatment for pancreatic cancer can experience meaningful response and survival outcomes.[16-19]

A recent Dutch study reported that older patients with locally advanced pancreatic cancer are less likely to receive chemotherapy, but when treated their median OS is similar to younger patients.[20] A retrospective analysis of patients diagnosed with unresectable pancreatic cancer at 10 centers in Japan found that the median survival time of patients treated with chemotherapy was not significantly different between patients ≥65 years and <65 years of age.[16] Another study conducted in China showed that age (<70 vs. ≥70 years) did not affect treatment outcomes but older adults were more likely to experience adverse events highlighting the importance of patient selection to inform treatment decisions.[19]

Older adults receiving chemotherapy should be evaluated using a GA as recommended by the ASCO and NCCN guidelines.[10,11] The GA provides a comprehensive understanding of the functional and physiological status of patients, and facilitates informed decision making regarding treatment choice.[6-10] A systematic review assessing the effect of geriatric evaluations on treatment decisions for older patients with cancer showed that the GA led to a modification of the treatment plan for 39% of patients, mostly to a less intensive treatment strategy which may have preserved quality of life.[9] An analysis of a randomized study of older adults with non–small cell lung cancer showed that a GA-based treatment strategy led to different treatment selection with a higher rate of combination therapy (46% vs. 35%), less single-agent treatment (31% vs. 65%), and increased use of best supportive care (23% vs. 0%).[21] Importantly, the was no difference in OS across the study arms although a higher rate of patients on the GA arm received best supportive care only (23% vs. 0%). These results emphasize the role of geriatric evaluations in improving treatment selection and outcomes.[22]

Several randomized studies evaluating the impact of geriatric interventions on the outcomes of older adults with cancer receiving chemotherapy were recently reported.[23-25] These studies showed that the implementation of the GA and interventions led to an improvement in outcomes with reduced treatment-related toxicity, improved quality of life, and lower rates of unplanned hospitalizations.

The importance of patient selection when planning the treatment of advanced pancreatic cancer was highlighted in a retrospective review that showed improved tumor response and survival in older patients treated with FOLFIRINOX compared to other regimens, albeit at the risk of increased toxicity.[17]

The results of our study suggest that although OS differs by age group because older adults tend to receive less intensive treatment, OS is similar among patients of all age groups when treated with the same regimen for mPDAC. GAs should be used consistently to inform decision making for the treatment of older patients with mPDAC and identify patients that may benefit from appropriate levels of systemic treatment.

Table 1. Baseline characteristics at the start of first-line therapy among patients with mPDAC.

Characteristic	<70 years old	70-79 years old	≥80 years old	*P*[a]
Patients, *n* (%)	3313 (55)	1972 (33)	688 (12)	
Index year, *n* (%)				
2014	1 (<0.1)	0 (0)	0 (0)	<.001
2015	541 (16)	298 (15)	106 (15)	
2016	640 (19)	297 (15)	116 (17)	
2017	661 (20)	398 (20)	134 (19)	
2018	680 (21)	408 (21)	127 (18)	
2019	629 (19)	429 (22)	162 (24)	
2020	161 (4.9)	142 (7.2)	43 (6.2)	
Sex, *n* (%)				
Male	1831 (55)	1054 (53)	359 (52)	.2
Female	1482 (45)	918 (47)	329 (48)	
Race, *n* (%)				
White	2241 (68)	1361 (69)	480 (70)	.002
Black or African American	308 (9.3)	140 (7.1)	35 (5.1)	
Asian	59 (1.8)	27 (1.4)	16 (2.3)	
Hispanic or Latino	9 (0.3)	4 (0.2)	1 (0.1)	
Other race	416 (13)	242 (12)	77 (11)	
Unknown	280 (8.5)	198 (10)	79 (11)	
Region, *n* (%)				
Northeast	457 (14)	300 (15)	127 (18)	.005
Midwest	380 (11)	223 (11)	91 (13)	
South	1428 (43)	855 (43)	289 (42)	
West	449 (14)	284 (14)	92 (13)	
Unknown	599 (18)	310 (16)	89 (13)	
Stage at initial diagnosis, *n* (%)				
Stage IV	2268 (68)	1306 (66)	439 (64)	.033
Other	1045 (32)	666 (34)	249 (36)	
Practice type, *n* (%)				
Academic	506 (15)	260 (13)	78 (11)	.009
Community	2807 (85)	1712 (87)	610 (89)	
ECOG PS, *n* (%)				
0	849 (26)	430 (22)	127 (18)	<.001
1	1159 (35)	729 (37)	218 (32)	
2+	381 (12)	309 (16)	147 (21)	
Missing	924 (28)	504 (26)	196 (28)	

[a]Statistical test performed: chi-square test of independence.
Abbreviations: ECOG PS, Eastern Cooperative Oncology Group Performance Status; mPDAC, metastatic pancreatic ductal adenocarcinoma; *n*, number.

Table 2. Proportion of patients receiving first-line, second-line, and third-line treatment.

	Overall (*n* = 8382)	<70 years old (*n* = 4425)	70-79 years old (*n* = 2780)	≥80 years old (*n* = 1117)	*P*[a]
First-line, *n*; % (95% CI)	5973; 71.3% (69.5%-73.1%)	3313; 74.9% (72.3%-77.5%)	1972; 70.9% (67.8%-74.1%)	688; 58.4% (54.2%-63.0%)	<.0001
Second-line, *n*; % (95% CI)[b]	2289; 38.3% (36.8%-39.9%)	1424; 43.0% (40.8%-45.3%)	681; 34.5% (32.0%-37.2%)	184; 26.7% (23.0%-30.9%)	<.0001
Third-line, *n*; % (95% CI)[c]	761; 33.2% (30.9%-35.7%)	490; 34.4% (31.4%-37.6%)	213; 31.3% (27.2%-35.8%)	58; 31.5% (23.9%-40.7%)	.3158

[a]Statistical tests performed: chi-square test of independence.
[b]Percent of patients receiving second-line uses first-line treated patients as the denominator.
[c]Percent of patients receiving third-line uses second-line treated patients as the denominator.
Abbreviation: CI, confidence interval.

Table 3. First-line treatment regimen summary.

Regimen, *n* (%)	<70 years old (*n* = 3313)	70-79 years old (*n* = 1972)	≥80 years old (*n* = 688)
Gemcitabine + nab-paclitaxel	1343 (41)	964 (49)	340 (49)
Gemcitabine monotherapy	146 (4.4)	175 (8.9)	167 (24)
FOLFIRINOX	1131 (34)	362 (18)	32 (4.7)
5-FU + liposomal irinotecan	41 (1.2)	50 (2.5)	20 (2.9)
Other regimens	652 (20)	421 (21)	129 (19)

Abbreviations: 5-FU, 5-fluorouracil; FOLFIRINOX, leucovorin, fluorouracil, irinotecan, and oxaliplatin.

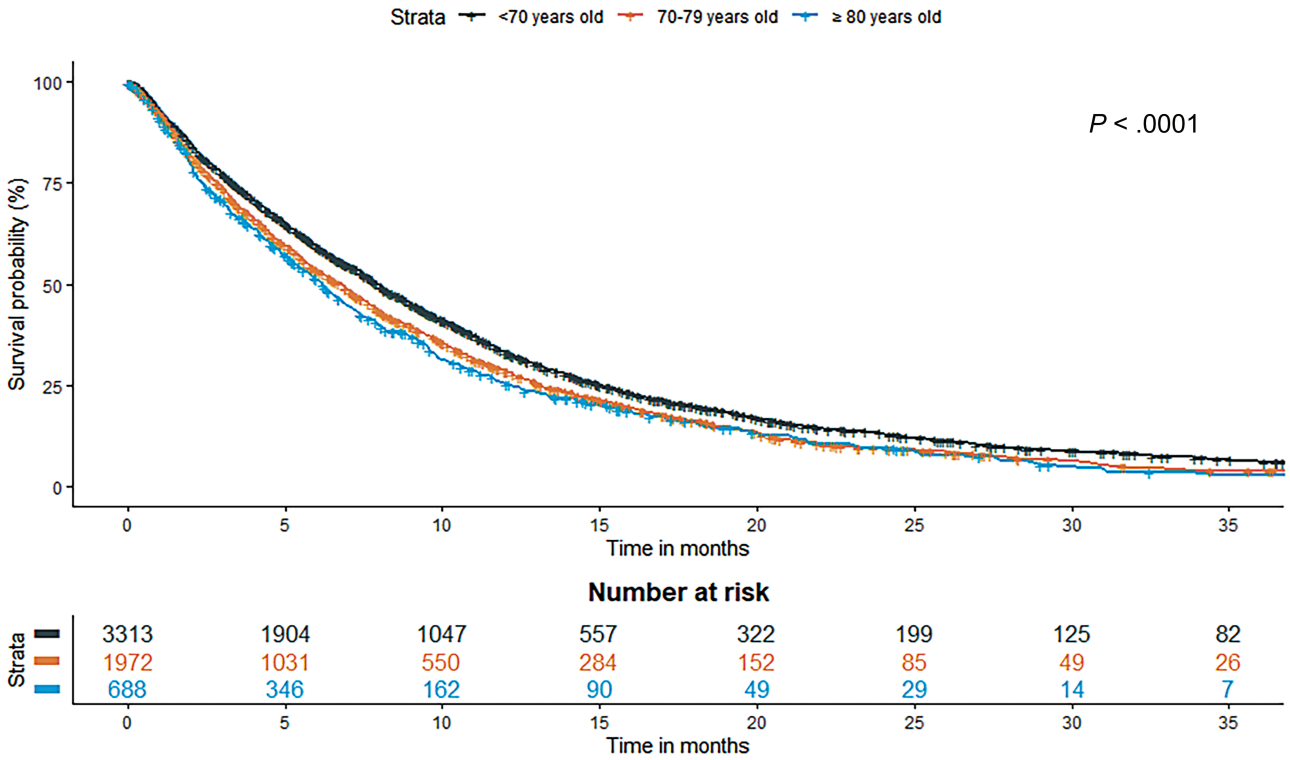

Figure 2. Kaplan-Meier survival analysis by age at diagnosis from first-line treatment initiation.

Table 4. Median OS by age at diagnosis and first-line treatment received.

	<70 years old			70-79 years old			≥80 years old			*P*
	N	mOS	95% CI	*N*	mOS	95% CI	*N*	mOS	95% CI	
Overall first-line	3313	7.9	7.6-8.3	1972	6.8	6.3-7.2	688	6.2	5.5-6.8	<.0001
Gemcitabine + nab-paclitaxel	1343	6.9	6.4-7.5	964	6.5	5.8-7.1	340	6.8	5.9-8.7	.25
Gemcitabine monotherapy	146	3.0	2.2-4.1	175	4.0	3.1-5.2	167	4.4	3.3-5.7	.72
FOLFIRINOX	1131	9.8	9.0-10.4	362	9.6	8.2-11.2	32	6.6	2.3-13.6	.064
5-FU + liposomal irinotecan	41	7.0	4.7-12.8	50	6.9	5.3-8.6	20	6.8	4.5-NR	.75

Abbreviations: 5-FU, 5-fluorouracil; CI, confidence interval; FOLFIRINOX, leucovorin, fluorouracil, irinotecan, and oxaliplatin; mOS, median overall survival; NR, not reached; OS, overall survival.

Limitations

Limitations of this study include the retrospective collection of data, which was obtained from routine clinical care rather than research purposes which may lead to missingness of important clinical variables (eg, ECOG PS). Treated patients were subject to nonrandom allocation, and the reason to forgo treatment either due to the patient or the physician was unavailable. Data were primarily from the community setting and may not be generalizable to other settings of care. Data on GAs were not available in the database, so it is not known

how often these assessments were used for the patients included in this study. The presence of comorbidities, which may have served as a proxy for the GA, were underreported in the EHR. Due to the small sample size of older adults receiving certain treatment regimens, we may not have had enough power to detect a significant difference in survival. Finally, the recording of patient age in the Flatiron Health database is capped at 85 years to protect patient confidentiality; the true age of some older patients with mPDAC and associated clinical outcomes could not be determined.

Conclusion

This study highlights that older adults with mPDAC can benefit substantially by receiving appropriate levels of treatment.

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Conflict of Interest

Paul Cockrum: Ipsen (E, OI); **Andy Surinach, Shu Wang, Bong Chul Chu**: Genesis Research (E, OI). The other authors indicated no financial relationships.

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Author Contributions

Conception/design: R.E., P.C., A. Surinach, B.C.C. Provision of study material/patients: P.C. Collection and/or assembly of data: A. Surinach, S.W., B.C.C. Data analysis and interpretation: R.E., P.C., A. Surinach, S.W., B.C.C., A. Shahrokni. Manuscript writing: R. E., P. C., A. Surinach, S.W., B.C.C., A. Shahrokni. Final approval of manuscript: All authors

Data Availability

The data underlying this article will be shared on reasonable request to the corresponding author.

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