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Fertility and Risk Factors for Elevated Infertility Concern in 10-Year Hematopoietic Cell Transplant Survivors and Case-Matched Controls

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Abstract

Purpose—To describe fertility status and the prevalence of and risk factors for elevated infertility concern in 10-year adult cancer survivors who underwent myeloablative stem cell transplant (SCT).

Patients and Methods—Perceived fertility status, conception efforts, and infertility concern were reported before transplant and after 10 years by 120 cancer survivors who received myeloablative SCT and their case-matched controls.

Results—Respondents (including cases and controls) were predominantly white and married. Sex, age, race, ethnicity and education level were case matched. Four survivors (all males) conceived after completing cancer treatment, one with unassisted conception. Twenty-two percent of survivors compared with 9% of controls reported that they had looked into family-building options because of infertility ($P = .009$). Fourteen survivors (12%) compared with eight controls (7%) indicated that they had tried unsuccessfully to have children in the previous 10 years ($P =$ not significant). One quarter of survivors had moderate to high levels of concern about infertility, compared with 7% of controls. A majority of survivors younger than age 40 years ($n = 20$; 54%) expressed elevated infertility concern. Survivors without children before transplant had greater risk of elevated concern after 10 years (odds ratio, 3.41; 95% CI, 1.93 to 11.30; $P = .05$). Although female controls were more likely to express elevated infertility concern ($P = .007$), sex did not discriminate concern among survivors.

Conclusion—The prevalence of infertility and related concerns is higher among long-term SCT survivors than among age-, sex-, and education-matched controls. Younger SCT recipients and those without children have persistent fertility-related needs even 10 years after treatment.

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AUTHOR CONTRIBUTIONS

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INTRODUCTION

There are now 10.5 million survivors of cancer,¹ many of whom need vigilant follow-up care and surveillance for long-term and late effects of cancer treatment. Recent trends indicate that 25% of autologous transplants and more than 60% of allogeneic transplants are performed on recipients younger than age 40 years, with more than 12,000 per year on recipients age 20 years or younger.² The number of survivors who receive high-dose systemic cancer treatment continues to expand, and the quality of survival data indicates largely normal work and marriage lifestyle among these survivors.³ Permanent gonadal damage and infertility are known toxicities of high-dose systemic cancer treatment, including therapies used as preparative conditioning for patients undergoing stem cell transplant (SCT).⁴⁻⁸ Therefore, health care providers who treat cancer survivors must be informed of these long-term treatment consequences and familiar with the fertility-related treatment needs of survivors.⁹

Infertility is a late effect of particular concern as it has the potential to influence various medical and quality-of-life domains of survivorship. In fact, some survivors reported that their loss of fertility was as painful as facing cancer.^{10,11} SCT survivors are at almost certain risk for infertility (> 98%) secondary to the gonado-toxic myeloablative chemotherapy with or without total-body irradiation that they receive in preparation for stem-cell transplantation.^{4,6} However, survivor fertility status cannot be definitively known without testing. Long-term survivors' perceived fertility, their infertility concerns, and their conception-related behaviors remain largely unreported. Consequently, issues such as infertility impact need to be examined.

The purpose of this study was to describe the perceived fertility status, conception history, prevalence of infertility concern, and risk factors for elevated infertility concern in adult 10-year cancer survivors who received SCT as part of their cancer therapy. On the basis of infertility and survivorship literature, we hypothesized that risk factors for elevated concern would include patients younger than 40 years at the time of 10-year evaluation, without children before transplant, of lower income status (suggesting potentially reduced access to infertility or adoption options), married, with lack of recent major medical illness (to distract from fertility concerns), and with elevated infertility concern before transplantation.

PATIENTS AND METHODS

This was a prospective case-control cohort study involving recipients of SCT and sibling or friend controls not treated with SCT. At the time of consent for transplant, all recipients were informed of their high probability of infertility. When not precluded by prior treatment or prepubertal age, males were urged to store sperm. All patients signed written informed consent for this study, were enrolled consecutively, and were followed from before transplant to 10 years or death. Adult US residents (n = 446) who were preparing for a first SCT at the Fred Hutchinson Cancer Research Center (Seattle, WA) between March 1987 and March 1990 were invited to participate. Within 12 months after surviving 10 years, all consenting survivors were contacted by mail for follow-up. Of the 147 survivors, 137 participated in the 10-year assessment. Surviving participants were asked to identify a

sibling or friend within 5 years of the survivor's age, race/ethnicity, and sex. This control population was selected because transplant recipients were of higher socioeconomic and educational resource level and more commonly non-Hispanic white compared with the general US population. We thought it important to match for these demographic characteristics, which are potentially important influences on fertility outcomes. Additional information on participant and control selection and survey dissemination were explicitly described in a previous publication.³ These analyses only include data from the 120 survivors and their matched controls who responded to the three primary fertility-related outcomes of interest (current fertility status, children added to family after transplant, current infertility concern).

Measures

Medical records provided diagnoses, medical events, and death. Patient-reported outcomes, which have established reliability in SCT survivors,¹² were assessed through mailed surveys. Before transplant and at 10 years, standard self-report questions were asked about age, sex, race/ethnicity, education, income, marital status, whether the transplant recipients had children before SCT, and level of concern about infertility (scored from 0 = not at all to 10 = very much). At 10-year follow-up, survivors and controls also reported perceived fertility status (now are you: infertile, fertile, unsure), and whether "issues of how to have children influenced your life" (scored from 0 = no, not in any way to 4 = yes, extremely). Next, respondents were asked the extent to which infertility impacted "my emotions," "my spouse or partner relationship," or "how I feel about myself" (scored from 0 = extremely positive to 6 = extremely negative). Additionally, survivors and controls were asked whether they or their spouse had been pregnant in the last 10 years, whether infertility options or alternatives had been pursued successfully or unsuccessfully, and whether they had major illnesses in the previous year.³ Consistent with other categorizing of 0 to 10 numerical rating scales of symptom severity, infertility concern was coded into none-mild (0 to 4) or moderate-high (5 to 10).¹³ Similarly, we recoded impact questions as 0 = extremely positive to slightly negative versus 1 = somewhat or extremely negative.

Statistical Analysis

Descriptive and inferential analyses were performed using SPSS version 14.0 (SPSS Inc, Chicago, IL). To define clinically important problems and levels of concern, we distinguished between none or mild symptoms compared with moderate to severe symptoms. χ^2 and t tests were utilized to compare medical and demographic characteristics of the participating versus not participating 10-year survivors during the enrollment time frame and to compare outcomes of the transplant recipients to those of controls. Paired t tests, McNemar, and Wilcoxon signed ranks tests were used to examine differences between survivors' fertility-related concern before transplant with concern 10 years after transplant, as well as to compare survivors fertility and family-building (ie, receipt of fertility treatment or adoption services for the purpose of bringing children into the home to parent) outcomes to those of controls. To determine risk factors for elevated infertility concern in survivors, logistic regression was calculated for hypothesized univariate predictors of infertility concern. Those factors with $P = .2$ or lower were retained in testing of the final logistic regression model. Two-tailed α for the final model was set at .05.

RESULTS

Infertility Concerns and Perceptions of Impact

Demographic and fertility-related outcomes of transplant recipients are presented in Table 1. Among participants, 3% of transplant recipients versus 57% of controls reported they were fertile; 79% versus 26%, respectively, believed they were currently infertile, with the remainder unsure of fertility status. Whereas controls older than 45 years ($P < .02$) were significantly more likely to report current infertility, age was unrelated to report of infertility in survivors ($P = .57$). Infertility concern was significantly higher in survivors, with 26% reporting elevated levels compared with 7% of controls ($P < .001$). More survivors endorsed the belief that issues related to how to have children influenced their lives at least moderately (24%) compared with controls (5%; $P < .001$). With regard to impact of infertility on emotions and relationships, 18% of survivors compared with 8% of controls indicated that infertility impacted their emotions ($P = .02$), whereas 14% of survivors compared with 7% of controls felt that infertility issues influenced their spouse/partner relationships ($P = .08$). Twenty-six percent of survivors with elevated infertility concern felt that these issues had influenced their relationship ($P = .003$).

Conception After Cancer Treatment

Of the four survivors (all males) who conceived after completing cancer treatment, only one was an unassisted conception. Twenty-three survivors (19%) had added children to their families since transplant (nine through adoption and 10 through stepchildren or grandchildren joining the family), and 12% indicated that they still planned to have children. Twenty-two percent of survivors compared with 9% of controls reported that they had looked into family-building options including fertility treatment and adoption because of infertility ($P = .009$). Fourteen survivors (12%) compared with eight controls (7%) indicated that they had tried unsuccessfully to have children in the previous 10 years, a difference that was not significant. Three survivors (2.5%) attempted to conceive using donor gametes, five (4.2%) with cryopreserved sperm, and one (1%) using a cryopreserved embryo; other unsuccessful efforts were through adoption.

Risk Factors for Infertility Concern

Significant bivariate associations between elevated infertility concern and demographic characteristics of SCT recipients are shown in Table 2. Moderate to high levels of concern were more prevalent in survivors younger than 40 years, nonwhite race/ethnicity, annual income less than \$100,000, as well as those who believed they were infertile at the time of the survey, those who had no children before transplant, and those with elevated infertility concern before transplant (all $P < .2$). For controls, moderate to high levels of infertility concern were more likely with age younger than 50 years, female sex, nonwhite race/ethnicity, annual income of at least \$100,000, lack of major illness in the previous year, and uncertainty about current fertility status (all $P < .2$; Table 2). A separate logistic analysis evaluating the association between fertility concern and sex in survivors and controls younger than 40, 40 to 50 and older than 50 years failed to demonstrate sex differences by age (odds ratio = .744; $P = .531$). The final model for multivariate logistic regression (Table 3) examined all bivariate factors with a trend toward significance ($P < .2$) for independent

contributions to predicting elevated infertility concern. In the final model, the risk factors independently associated with elevated concern at 10 years in survivors were not having children before transplant ($P = .05$) and increased infertility concern pretransplant ($P = .02$). In the final model for controls, those with incomes of at least \$100,000 ($P = .007$) and females ($P = .05$) had increased risk for elevated infertility concern.

The correlation of infertility concern before and 10 years after transplant was $r = 0.58$. For 80 of the transplant recipients (72%), high versus low infertility concern did not change from before to 10 years after transplant. For 22 (20%), level of concern declined from elevated before transplant to not elevated at 10 years, and for 10 (9%) level of concern rose from not elevated before transplant to elevated after 10 years.

DISCUSSION

Ten years after SCT, fertility-related outcomes differed between adult transplant recipients compared with sibling or friend controls. Within the tested cohort of survivors, no women and few men had conceived after high-dose treatment, although almost one in five survivors added children to their families, usually through adoption or stepchildren. Twelve percent had been unsuccessful in efforts to build their families through adoption or infertility treatment.

Importantly, one in four survivors continued to have substantial concerns about their fertility 10 years after transplant. Survivors at elevated risk for long-term infertility concern were those without children before transplant and with greater pretransplant infertility concern. In addition, there was a trend suggesting elevated fertility concern for those under age 40. Although high infertility rates have been reported after SCT, elevated fertility concern has not been described as continuing in long-term survivors.⁶ These results are intriguing and merit further investigation because they suggest subgroups of survivors who may benefit from additional monitoring and intervention and improved patient-provider communication.

Consistent with the literature on this topic,^{10,14,15} younger survivors without children before cancer treatment were most likely to report elevated infertility concern. Although one quarter of SCT recipients reported elevated infertility concern, this concern was expressed by a majority of respondents in the youngest age category (< 40). Fertility distress was not statistically different between men and women survivors. Although women expressed greater concern in both cohorts, only among controls was this difference significant. It is possible that sex differences among survivors in infertility concern would have reached significance in a larger sample.

Several professional and policy focused groups including the American Society of Clinical Oncology, the Endocrine Society, and the 2006 National Institutes of Health Adolescent and Young Adult Progress Review Group and the ethics committee of the American Society of Reproductive Medicine have issued practice guidelines/recommendations to highlight the importance of informing reproductive-aged survivors about potential fertility compromise associated with cancer and its treatment and increasing research in this area.^{9,16–18} Although current standard practice is to inform patients of probable infertility before transplant, our

results support that repetition of this information is needed for long-term survivors who may forget, not process, or not fully understand this information.

For the majority of survivors (72%) 10-year concerns could be accurately projected from their level of concern before transplant. The strong correlation between level of infertility concern before and 10 years after completing cancer treatment clearly indicates that this issue does not resolve on its own for survivors. Only 20% reported a decline in concern. Furthermore, concern increased in nearly one in 10 survivors, mostly younger than 40, in the 10 years after completing treatment. This finding highlights that for younger survivors, infertility should be discussed even if concerns are not raised at the start of treatment. Providers such as medical oncologists should be cognizant that fertility-related concerns persist even beyond 10 years.

On the basis of previous research, we would expect that infertility rates would approach more than 98% in this SCT cohort.⁶ However, our analyses demonstrated the actual reported rates were eighty percent of survivors (79%). In addition, one quarter of controls (26%) believed they were infertile. Infertility rates among controls were higher than the national average of 7.4% for women between 15 and 44.¹⁹ In this study, controls were similar to cases with respect to age, race, and sex and were predominantly white and in their 40s. Likely, because controls were friends or relatives of cancer survivors, there were other unmeasured biologic factors or exposures placing them at greater risk of infertility compared with the general population. These findings are surprising and merit additional investigation.

As expected, more survivors than controls indicated infertility concerns and reported current infertility. However, our data suggest concern related to infertility may be similar among survivors and controls. For both groups, approximately one in four to five respondents who thought they were infertile indicated that this was an issue that negatively impacts their emotions and relationships. Thus, our data indicate that many people adapt to infertility restrictions in their lives.

It is also notable, given the projected rates of infertility after transplant, that 18% of survivors and 17% of controls were unsure of their fertility status. Surprisingly, 81% of controls and 91% of survivors who were unsure indicated low concern. Only one survivor who was unsure of fertility had attempted to conceive, and most survivors (81%) unsure about their fertility had children before SCT. This suggests that fertility was not an issue that these respondents felt a need to confirm. This may also indicate that there is a knowledge gap amenable to educational intervention and improved communication about fertility and other late consequences of cancer treatment before, during, and after treatment.

Respondents from nonwhite racial/ethnic groups and those with annual incomes of less than \$45,000 were more likely to report greater information needs about fertility after cancer than were white and higher-income survivors. Disparities based on such demographic factors exist in a variety of undesirable cancer and health-related outcomes.^{19,20} These findings are consistent with previous reports that nonwhite populations have higher comparative infertility and lower utilization of fertility treatment.^{21,22} Elevated fertility-related concern

among ethnoculturally diverse survivors may represent an area where culturally competent education and communication interventions should be developed and tested.

Fertility-related concern in hematopoietic stem-cell transplant recipients has been infrequently described in the literature.²³ Moreover, it has rarely been reported in studies that examine important quality of life end points and outcomes in survivors of specific types of cancer^{5,24,25} An important gap exists in our understanding about how the likelihood of infertility affects long-term concerns, how fertility-related concern is associated with other outcomes of cancer therapy, and which, if any, interventions are associated with lower levels of concern. Further, strategies for addressing the needs of survivors relative to family-building options have been essentially untested.

Several limitations may affect the generalization of our findings. First, ethnic and racial minorities, autologous SCT recipients, and patients with diseases other than leukemia are under-represented in our cohort. Secondly, despite the relatively large sample size for this longitudinal study in a population with high mortality rates, statistical power to detect differences in fertility-related outcomes such as the number of survivors or controls who sought assistance (fertility treatment or adoption), was limited. Also, the sample size limited our ability to explore possible confounding or effect modification with other factors. However, this is one of the few studies that has examined fertility-related concern in cancer survivors in detail, over time, and with a relatively large and case-controlled cohort.

The prevalence of infertility and elevated infertility concern is higher among SCT long-term survivors than among sibling or friend controls, and these concerns do not resolve over time. Although many survivors find ways to add children to their families, younger SCT recipients and those without children have persistent fertility-related morbidity 10 years after treatment. Foreknowledge of this toxicity of treatment and the trade-off of survival for fertility may not adequately address the loss-related needs of survivors who are unable to conceive biologic offspring. These findings suggest that all providers of survivorship care should communicate early and, if necessary, repeatedly with patients about the probability of fertility compromise to ensure that patients understand their risks and fertility-preservation and family-building options. Given the large numbers of cancer patients grappling with fertility issues, it may be appropriate to evaluate the fertility status of all reproductive-age survivors who have preferences for or against pregnancy. As the number of young long-term survivors expands, providers need to address psychological and relationship sequelae of cancer and iatrogenic infertility. These findings moreover highlight the importance of oncologists' being aware of and implementing existing guidelines for counseling and screening of outcomes such as infertility-related impacts, which might otherwise be overlooked as providers focus on more apparent physical health-focused care.

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Fig 1.

Flow of patients through the study. (*) One researcher consented and assessed patients.

When this researcher was on vacation or was booked with other appointments, new patients could not be consented to the study. SCT, stem cell transplant.

Table 1.

Demographic Characteristics of SCT Recipients and Controls

Characteristic	Survivor (n = 120)		Control (n = 120)	
	No.	%	No.	%
Age at 10 years, years				
Mean	44.6		44.0	
SD	8.21		8.25	
< 40	37	31	39	33
40–50	59	49	53	44
> 50	24	20	28	23
Age at SCT, years				
Mean	33.71			
SD	8.33			
< 40	98	82	NA	
40–50	19	16		
> 50	3	2.5		
Diagnosis				
Chronic myeloid leukemia	63	52.5	NA	
Acute leukemia	25	21		
Non-Hodgkin's lymphoma	19	16		
Myelodysplasia	9	7.5		
Other hematologic malignancies	4	3		
Treatment				
Chemotherapy only	13	11	NA	
Chemotherapy plus total-body irradiation	107	89		
Stem cell donor				
Autologous	13	11	NA	
Allogeneic, related	93	77		
Allogeneic, unrelated	14	12		
Sex				
Male	60	50	60	50

Characteristic	Survivor (n = 120)		Control (n = 120)	
	No.	%	No.	%
Female	60	50	60	50
Education				
< College	56	47	66	55
College	63	52	53	44
Missing	1	<1	1	<1
Race/ethnicity				
White, non-Hispanic	114	95	110	92
Nonwhite or Hispanic	6	6	8	7
Missing	0	0	2	2
Annual income				
< \$45,000	37	31	34	28
\$45,000 to < \$100,000	53	44	60	50
\$100,000	29	24	24	20
Missing	1	1	2	2
Marital status				
Married or living with partner	91	75	92	77
Not married or partnered	29	24	28	23
Major illness in past year				
No	81	67	99	82
Yes	38	32	20	17
Missing	1	<1	1	<1
Do you have any children? (patients only; before SCT)				
No	39	32.5	NA	
Yes	81	67.5		
Have you or your partner/spouse had a full-term pregnancy? (controls only)				
No	NA		21	17
Yes			98	82
Missing			1	<1
Have children been added to your family since your cancer?				
No	98	82	NA	

Characteristic	Survivor (n = 120)		Control (n = 120)	
	No.	%	No.	%
Yes	22	18		
Infertility-related concern (scored 0–10)				
0–4 (not at all-mild)	89	74	112	93
5–10 (moderate-very much)	31	26	8	7
Do you have issues about how to have children?				
“Not in any way” or “A little” (0–1)	103	86	117	97
“Moderately,” or “Quite a bit” (2–4)	17	14	3	3
Current fertility status				
Fertile	3	3	68	57
Infertile	95	79	31	26
Not sure	22	18	21	17

Abbreviations: SCT, stem cell transplant; SD, standard deviation; NA, not applicable.

Table 2.
All Examined Bivariate Risk Factors for Moderate to High Levels of Infertility Concern in 10-year Survivors and Controls

Factor	Infertility Concern in Survivors				Infertility Concern in Controls			
	None-Mild		Moderate-High		None-Mild		Moderate-High	
	No.	%	No.	%	No.	%	No.	%
Age, years								
< 40	17	46	20	54	34	85	5	15
40–50	49	83	10	18	50	92	3	8
> 50	23	95.8	1	4.2	28	100	0	0
Sex								
Male	47	78	13	22	58	97	2	3
Female	42	70	18	30	54	90	6	10
Education								
< College	43	77	13	23	61	90	5	10
College	45	71	18	29	50	94	3	6
Race/ethnicity								
White, non-Hispanic	86	75	28	25	104	96	6	4
Nonwhite or Hispanic	3	50	3	50	6	75	2	25
Annual income								
< \$45,000	23	62	14	38	32	94	2	6
\$45,000 to < \$100,000	39	74	14	26	59	98	1	2
\$100,000	26	90	3	10	19	79	5	21
Marital status								
Married or living with partner	68	75	23	25	86	93	6	7
Not married or partnered	21	72	8	28	26	93	2	7
Infertility concern before transplant*								
Low concern	60	86	10	14	NA		NA	
High concern	22	52	20	48	NA		NA	
Major illness in past year								
No	62	76	19	24	91	92	8	8
Yes	27	71	11	29	20	100	0	0

Factor	Infertility Concern in Survivors					Infertility Concern in Controls				
	None-Mild		Moderate-High		P for Association	None-Mild		Moderate-High		P for Association
	No.	%	No.	%		No.	%	No.	%	
Current fertility status										
Fertile	3	100	0		.07	64	94	4	6	.02
Infertile	66	68	29	32		31	100	0		
Unsure	20	91	2	9		17	81	4	19	
Had children before transplant (survivors) or full term pregnancy (controls)?										
None	18	46	21	54	<.0001	20	95	1	5	.70
One or more	71	88	10	12		92	82	7	7	

Abbreviation: NA, not applicable.

* Eight survivors did not have pretransplant infertility concern scores.

Table 3. Logistic Regression Final Models: Risk Factors for Elevated Infertility Concern in 10-Year Survivors and Controls

Factor	Survivors			Controls		
	Measure of Association	95% CI	P	Measure of Association	95% CI	P
Do you have children? (assessed before transplant): no, yes	3.41	1.03 to 11.30	.05	NA		NA
Infertility concern before transplant (continuous variable)	1.21	1.04 to 1.41	.02	NA		NA
Age, years: < 40, 40	2.21	0.65 to 7.51	.21	0.17	0.19 to 1.53	.12
Race/ethnicity: white, nonwhite	3.73	0.45 to 30.96	.22	2.75	0.25 to 30.89	.41
Annual income at 10 years: < \$100,000 v \$100,000	2.53	0.56 to 11.37	.23	51.27	2.99 to 880.57	.007
Perceived fertility status at 10 years: fertile (referent)			.45			.12
Infertile	0.00		.99	0.00		.99
Unsure	3.32	0.52 to 21.34	.21	10.09	1.12 to 90.50	.04
Sex: male, female	NA		NA	11.41	1.00 to 130.03	.05
Major illness: yes, no	NA		NA	0.00		.99

Abbreviation: NA, not applicable.