Relationship between hot flashes and distress in men receiving androgen deprivation therapy for prostate cancer

Erin Winters Ulloa1,2,*, Raoul Salup1,2,3, Stephen G. Patterson1,2 and Paul B. Jacobsen1,2

1University of South Florida, Tampa, FL, USA
2H. Lee Moffitt Cancer Centre and Research Institute, Tampa, FL, USA
3James A. Haley Veterans’ Hospital, Tampa, FL, USA

Abstract

Objective: Side effects of cancer treatment have been found to have a significant impact on patients’ psychological well-being. Each of the primary treatment options for prostate cancer is associated with significant side effects that can have a dramatic impact on quality of life. Hot flashes are a notable side effect of androgen deprivation therapy (ADT) and a potential source of distress due to their episodic nature and low frequency in a normal aging male population. The current study sought to examine the relationship between hot flashes and cancer-related distress during the first three months of ADT.

Methods: Participants were 68 men with various stages of prostate cancer scheduled to begin ADT for the first time. Study measures were completed at the beginning of treatment and 3 months later.

Results: Repeated measures ANOVA indicated that men who did not experience hot flashes had a significant decrease in total cancer-related distress and avoidance over the 3-month period, while men with hot flashes exhibited no change in distress. Among men with hot flashes, results of hierarchical regression analyses indicated that a worse experience with hot flashes was a significant predictor of greater increases in intrusion and total cancer-related distress over the 3-month period.

Conclusions: These results suggest that hot flashes serve to maintain levels of distress during the treatment period. Further research should extend these findings by lengthening the follow-up period and using ecological momentary assessment to refine measurement of these constructs and provide evidence for the direction of causality between hot flashes and distress.

Keywords: prostate cancer; oncology; androgen deprivation therapy; hot flashes; cancer-related distress

Introduction

It is estimated that one out of every six men will develop prostate cancer in his lifetime, making this the most common non-skin cancer among men in the United States [1]. When prostate cancer is diagnosed in the early stages, a number of effective treatment options are available, including surgery, radiotherapy (external beam or brachytherapy), and watchful waiting. Factors such as treatment side effects, disease characteristics (e.g. Gleason score), age, and comorbid health conditions are often considered when determining the optimal treatment approach. Androgen deprivation therapy (ADT) is an additional form of treatment that is used to treat patients at varying stages of disease. Although the specific indications for the use of ADT are the focus of ongoing debate, the American Society of Clinical Oncology recommends these agents as the initial treatment for patients with symptomatic metastatic prostate cancer and considers them to be of potential benefit in three other groups: patients with rising prostate-specific antigen (PSA) levels following surgery or radiotherapy, patients with node positive disease who are asymptomatic for metastases, and patients who are asymptomatic for metastases but have evidence of metastases on imaging studies [2]. In determining when to initiate ADT, the rate at which PSA levels increase (i.e. PSA velocity) is considered to be a more useful indicator of disease progression than the actual PSA value itself [3]. The large number of patients who will receive ADT is reflected in an estimate that each year, upwards of 50,000 US men with prostate cancer enter the rising PSA category alone [4].

ADT typically involves the use of a class of drugs known as luteinizing hormone-releasing hormone (LHRH) agonists. LHRH agonists are administered as a depot injection that is slowly released...
into the body over the course of several months. The primary therapeutic mechanism of action of this class of agents is a reduction of testosterone to levels similar to those achieved with surgical castration [5]. As a direct result, ADT can produce several undesirable side effects, such as loss of libido, erectile dysfunction, hot flashes, gynecomastia, weight gain, osteoporosis, anemia, changes in mood and cognitive function, and fatigue [6]. This constellation of side effects has been associated with significant psychological distress and declines in several aspects of quality of life [7–12]. Unlike most of the effects listed above, hot flashes are not a common result of male aging. Consequently, when men with prostate cancer experience a hot flash, they may be reminded of their diagnosis and treatment and of the impact it has had on their lives. These reminders may function as intrusive thoughts, with the potential to contribute to heightened cancer-related distress. Symptoms and side effects of treatment have been found to predict post-treatment cancer-related distress in women with breast cancer [13]. This relationship appears to be driven by the influence of symptoms and side effects on intrusive thoughts. Whether a similar relationship exists among men receiving treatment for prostate cancer is unclear.

Although hot flashes are a commonly recognized side effect of ADT, research on the psychosocial impact of this gender-inconsistent symptom is limited. Numerous investigations have examined the impact of ADT on quality of life in men with prostate cancer; however, no studies could be identified that specifically focus on the relationship between hot flashes and psychological distress. Most of the research in oncology on hot flashes and their impact on psychological well-being has been conducted with women with breast cancer. In addition to naturally occurring menopause, women with breast cancer are susceptible to hot flashes as a consequence of treatment (i.e. oophorectomy or chemotherapy-induced menopause). In this population, hot flashes have been associated with higher levels of mood disturbance and greater negative affect [14–16].

The current study had two primary aims. First, we sought to describe the frequency and severity of hot flashes within the first 3 months of treatment with ADT. Second, we sought to examine the relationship between hot flashes and cancer-related distress during this time period. Based on existing research on the impact of ADT in men with prostate cancer and the impact of hot flashes in women with breast cancer, the following hypotheses were proposed: (1) men with hot flashes would report greater increases in cancer-related distress over the 3-month follow-up period than men without hot flashes; and (2) among men with hot flashes, a worse experience of hot flashes would be associated with greater increases in cancer-related distress over the 3-month follow-up period.

**Method**

**Participants**

Participants were scheduled to receive ADT for the treatment of prostate cancer for a period of at least 3 months at the H. Lee Moffitt Cancer Center (HLMCC) or James A. Haley Veterans’ Hospital (JAHVH). Additional eligibility criteria were as follows: (1) no clinical evidence of metastatic disease; (2) no prior experience with ADT; (3) greater than 18 years of age; (4) able to speak and read English; and (5) completion of at least six years of formal education. Patients with evidence of metastatic disease were excluded from the present study in an attempt to minimize variability in the outcomes that might be associated with disease severity.

**Procedure**

Eligible patients were identified with the assistance of medical staff and review of computerized medical records. Patients were approached during a clinic visit prior to the initiation of ADT. Men who provided informed consent were asked to complete a questionnaire assessing the variables described below. This questionnaire, which was completed within one week of the patient’s first hormonal treatment, served as a baseline measure for the variables of interest. Testosterone levels typically fell into the castrate range by 10 days after the injection [17]; therefore, participants were given this window in which to report on their pre-treatment side effects. Participants were contacted by telephone approximately 6 weeks after the initiation of ADT to obtain ratings of hot flash frequency, severity, and interference. Participants then completed a second questionnaire similar to the baseline questionnaire approximately 3 months after the baseline assessment. This project was reviewed and approved by the Institutional Review Board (IRB) at the University of South Florida, as well as by analogous internal review boards at JAHVH and HLMCC. All procedures were compliant with the Health Insurance Portability and Accountability Act (HIPAA).

**Measures**

**Demographic and clinical data**

The following demographic variables were assessed via self-report: date of birth, race, marital status, income, and education. Computerized medical records were reviewed to obtain information on date of cancer diagnosis, disease stage, recent PSA
values, and other relevant disease and treatment characteristics.

Hot flashes

Hot flash frequency and severity were assessed using methods similar to those used by Carpenter and colleagues [14] in their evaluation of hot flashes in post-menopausal women treated for breast cancer. Specifically, participants were asked if they had experienced hot flashes in the previous 2 weeks; if so, they were asked to estimate the number of hot flashes experienced during this time period and to rate their severity using a four-point scale (1 = mild; 4 = very severe). This information was collected at three time points (baseline, 6-week follow-up, 3-month follow-up). As in prior research [18], a total hot flash score was calculated by multiplying hot flash frequency by hot flash severity. This method is preferred because it takes into account both frequency and severity, providing an outcome measure that is sensitive to changes in either variable. Data collected at the first assessment were used to confirm that men were not experiencing hot flashes prior to initiation of ADT. As noted below, men reporting hot flashes at the baseline assessment were eliminated from the analyses in order to provide a homogeneous sample in terms of prior experience with the variable of interest.

Hot flash interference

The Hot Flash-Related Daily Interference Scale (HFRDIS) [19] is a 10-item scale that assesses the degree to which hot flashes interfere with a variety of daily activities and overall quality of life. Interference is rated on an 11-point scale (0 = do not interfere; 10 = completely interfere). The validity of the HFRDIS has been demonstrated in breast cancer survivors and healthy women [19]. This measure was administered at the 6-week and 3-month follow-up assessments. Reliability coefficients (alpha) at these two assessments were 0.86 and 0.98, respectively.

Cancer-related distress

The Impact of Events Scale (IES) [20] consists of 15 items that measure subjective distress related to a particular event with a focus on intrusive and avoidant responses. Examples of intrusive experiences include unwanted or inescapable thoughts and feelings, or images of the event. Avoidant experiences include behaviors that allow individuals to avoid reminders of the event or to dull their emotional reactions to it. In the current study, participants rated the frequency with which each item was true for them with respect to their cancer and its treatment (0 = not at all; 1 = rarely; 3 = sometimes; 5 = often). Item responses were summed to arrive at an intrusion score, an avoidance score, and a total distress score, which is the sum of the two subscales. Previous research has supported the use of the IES as a measure of cancer-related distress [21]. This measure was administered at the baseline and 3-month follow-up assessments. Reliability coefficients (alpha) for the total scale, intrusion subscale, and avoidance subscale at these assessments ranged from 0.68 to 0.91.

Results

Participant characteristics

A total of 103 men were invited to participate in the current study. Of these men, 4 (4%) declined participation, 5 (5%) were determined to be ineligible, and 18 (17%) were eliminated because they did not return questionnaires within the allowable time frame or returned questionnaires with considerable missing data, thus yielding a 74% response rate. No significant (p < 0.05) differences were found between these 27 men and the 76 remaining men with regard to any of the demographic or clinical characteristics assessed.

At the baseline assessment, eight participants reported hot flashes in the previous 2 weeks. In order to maintain a homogeneous sample in terms of initial experience with hot flashes, these men were dropped from the remainder of the analyses. The 68 men who comprised the final sample ranged from 50 to 90 years of age (M = 73.45, SD = 10.06). They were predominantly Caucasian (90%) and currently married (77%). The majority had at least a partial college education or specialized training (70%), were retired (73%), and reported an annual household income of under $40 000 (60%). See Table 1 for complete demographic information.

Time since prostate cancer diagnosis ranged from 0 (day of enrollment in the study) to 18.33 years (M = 3.23, SD = 4.60). Twenty-six men (38%) received ADT as a result of a rising PSA subsequent to primary treatment. Of the remaining participants, 17 men (25%) received an LHRH-agonist as their primary form of treatment, and 25 men (37%) received this form of treatment in addition to, or in preparation for, another form of treatment (e.g. prostatectomy or radiation). Average PSA values at the time of recruitment ranged from 0.6 to over 1000 ng/mL (M = 25.37, SD = 121.17). 3-month follow-up PSA values were available for 57 of the 68 men (83%). At this time point, average PSA values ranged from below 0.1 ng/mL (undetectable) to 97.40 ng/mL (M = 2.46, SD = 12.66). Eleven (16%) men were prescribed an antiandrogen agent (bicalutamide) prior to...
to initiation of an LHRH-agonist. At the 3-month follow-up assessment, two of the participants reported that they had sought medication or herbal remedies to alleviate hot flashes. See Table 2 for complete clinical and treatment information.

Participants’ experience of hot flashes

Six weeks after the initiation of ADT, 36 men (53%) reported experiencing hot flashes. These men reported an average severity rating of 1.81 (SD = 0.82), which most closely corresponds to a moderate level. The number of hot flashes reported at this time ranged from 1 to 154 (M = 43.81, SD = 46.77) in the previous 2 weeks. By the 3-month follow-up, 47 men (69%) were reporting hot flashes. The average severity rating was 2.02 (SD = 0.74), with the number of hot flashes reported ranging from 2 to 336 (M = 55.81, SD = 67.28) in the previous 2 weeks.

Participants’ experience of distress

Ratings of cancer-related distress ranged from 0 to 42 (M = 11.54, SD = 11.53) at baseline and from 0 to 51 (M = 10.00, SD = 13.17) at the 3-month follow-up. There were no statistically significant changes in distress for the group as a whole across the 3-month study period, *t*(67) = 1.23, *p* > 0.05. Subscale scores were categorized as mild (score ≤ 8), moderate (scores of 9–18), and severe (scores ≥ 19) according to Horowitz’s recommendations (see Table 3).

Demographic and clinical correlates of hot flashes and distress

Prior to examining the relationship between hot flashes and distress, correlations were computed to identify demographic or clinical variables that might confound this relationship. Age was significantly associated with ratings of total distress (*r* = −0.25, *p* < 0.04) and intrusion at the 3-month follow-up (*r* = −0.33, *p* < 0.01), with younger participants reporting greater total distress and greater intrusion. All other relationships of demographic or clinical variables with hot flashes or distress were non-significant (*p* > 0.05). In order to control for the potential confounding influence of age, it was included as a covariate in subsequent analyses.
Changes in cancer-related distress in men with and without hot flashes

The first hypothesis proposed that men who experienced hot flashes would demonstrate greater increases in cancer-related distress over the 3-month study period than men without hot flashes. To evaluate this hypothesis, the data were entered into repeated measures analysis of variance designs and the Group (Hot Flashes vs No Hot Flashes) × Time (Baseline vs 3-Month Follow-up) interaction effects were calculated to compare changes in IES scores over the 3-month study period for men with and without hot flashes. Age was included as a covariate in these analyses. Results yielded the expected significant group-time interaction, \( F(1, 65) = 5.34, p = 0.02 \) for IES total score. Tests of simple effects indicated a significant decrease in IES total score between the baseline (\( M = 11.71, SD = 11.81 \)) and 3-month follow-up (\( M = 5.81, SD = 9.63 \)) for men without hot flashes, \( F(1,66) = 7.34, p = 0.01 \). Among men with hot flashes, the change in IES total score between baseline (\( M = 11.47, SD = 11.54 \)) and follow-up assessments (\( M = 11.87, SD = 14.17 \)) was not significant, \( F(1,66) = 0.08, p = 0.78 \). A similar pattern was observed for the avoidance subscale. The group × time interaction for IES avoidance scores was significant, \( F(1, 65) = 4.70, p = 0.03 \). Tests of simple effects within the two hot flash groups showed a significant decrease in avoidance scores over time among men without hot flashes (\( F(1,66) = 5.98, p = 0.02 \)), but not in men with hot flashes (\( F(1,66) = 0.04, p = 0.84 \)). The group × time interaction for intrusion scores was not statistically significant, \( F(1, 65) = 3.05, p = 0.09 \).

Impact of intensity of hot flashes on change in cancer-related distress

Hierarchical regression analyses were conducted to test the second hypothesis that, among men reporting hot flashes, a worse experience with hot flashes would be related to greater increases in cancer-related distress between the baseline and 3-month follow-up assessments. Age and baseline levels of total cancer-related distress were entered together on the first step and each of the hot flash variables was entered on the second step in two separate regression equations (see Table 4). After accounting for age and baseline levels of distress, the hot flash score (frequency × severity) accounted for 5% of the remaining variance in total cancer-related distress at the 3-month follow-up assessment (\( p = 0.02 \)). Hot flash-related interference did not meet the criteria set for significance when evaluated in a separate regression equation (\( p = 0.06 \)).

Analyses were then conducted to examine the relationship between hot flashes and IES subscale scores (see Tables 5 and 6). As in the previous analyses, age and baseline levels of each subscale were entered on the first step followed by hot flash score and hot flash-related interference on the second step in separate regression equations. After controlling for age and baseline levels of intrusion, the hot flash score accounted for 15% of the remaining variance in intrusion scores at the 3-month follow-up (\( p < 0.0001 \)). In a separate regression equation, hot flash interference accounted for 7% of the remaining variance in intrusion scores (\( p < 0.01 \)). Identical procedures were used to evaluate the relationship between hot flashes

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and IES avoidance subscale. Neither of the hot flash variables accounted for a significant portion of the variance in avoidance scores after controlling for age and baseline levels of avoidance ($p = 0.41$).

**Discussion**

The goal of the current study was to increase our understanding of men’s experience of hot flashes during the first 3 months of ADT for prostate cancer. Hot flashes are an unusual experience for most men and little is known about their impact on psychological functioning. The present findings add to the growing body of research documenting a relationship between receipt of ADT and psychological distress [7,9,11]. To date, most studies conducted with men receiving ADT have not attempted to differentiate among the constellation of side effects that occur as a result of this form of treatment. Of particular interest in the current study was the impact of hot flashes on increases in distress over the 3-month period following the initiation of ADT. Although other studies have found strong relationships between frequency and/or severity of hot flashes and measures of psychological distress in women with breast cancer [14,15], these relationships are not as well defined in men with prostate cancer.

It was hypothesized that men with hot flashes would report greater increases in cancer-related distress over the 3-month study period than men without hot flashes. Although men with hot flashes reported significantly higher levels of distress at the 3-month follow-up than men without hot flashes, the longitudinal course of distress did not unfold as expected. While levels of distress remained stable among men with hot flashes, men without hot flashes reported a significant decline in cancer-related distress between baseline and 3-month follow-up assessments. This suggests that the experience of hot flashes contributes to the maintenance of distress during this treatment period. Potential explanations for this relationship were not explored in the current study; however, it is possible that a consistent experience of hot flashes prevents patients from engaging in the cognitive processing that may be necessary for distress reduction [23]. Disruptions in the sleep cycle may be another potential explanation for these findings. Further research is necessary to explore these proposed causal mechanisms.

As predicted, among men with hot flashes, a worse experience of hot flashes was associated with greater increases in cancer-related distress. This was particularly salient for ratings of intrusion, for which the hot flash score accounted for 15% of the variance after accounting for age and baseline levels of intrusion. These findings are in line with other research showing that side effects of breast cancer treatment predict both cancer-related distress and intrusion post-treatment [13]. These findings also lend support to the notion that side effects of treatment serve as reminders of a patient’s cancer diagnosis, which, in turn, contribute to elevated levels of distress.

Average distress ratings in the current sample were comparable to those reported in samples of men with localized prostate cancer and survivors of testicular cancer [24,25]. As shown in Table 3, at least 20% of men in the current sample reported a moderate to severe level of cancer-related distress based on categorizations developed by the author of the IES [22]. Some researchers suggest that older men may be hesitant to report distress; therefore, the current findings may underrepresent the prevalence of distress in this population [26,27]. Recognized cutoff scores for clinically significant levels of distress have not been established for the IES; however, other brief screening tools, such as the Distress Thermometer, have been found to be an efficient way to identify prostate cancer patients in need of additional support services [27].

Studies have shown that hot flashes do not generally subside as time since treatment increases [28,29]; therefore, it is important to recognize the impact of this treatment-related side effect and to develop appropriate and effective remedies. Evidence supports the use of pharmacological agents, such as selective serotonin reuptake inhibitors (SSRIs), to reduce hot flashes in men [30,31]. Although these medications can be associated with side effects such as nausea, dry mouth, sexual problems, and constipation, the likelihood of side effects may be reduced when used in the lower doses typically prescribed for hot flashes. Behavioral interventions can be used as an alternative or as an adjunct to pharmacological approaches given their benign side effect profile. Research in this area is limited; preliminary results suggest that cognitive behavioral intervention leads to modest improvements in subjective ratings of hot flash bother, severity, and interference with daily activities among women with breast cancer [32]. In general, psychological interventions have proven to be effective at reducing levels of distress among cancer patients, particularly those involving a relaxation component [33–35]. Few studies have been conducted that evaluate interventions of this nature among men with prostate cancer, but existing research has documented improvements in physical functioning, positive health behaviors, and quality of life following participation in structured support groups [36,37].

Approximately 20–38% of men in the present sample reported moderate-to-severe symptoms of distress. In addition to the detrimental impact on quality of life, inadequately managed distress can adversely affect medical care. Among patients with
chronic illness, psychological distress has been associated with negative health behaviors such as non-adherence to prescribed treatment recommendations and overuse of medical services [38–41]. Among men with prostate cancer, behaviors such as attending follow-up appointments and routine PSA testing are necessary to monitor potential disease progression. Should cancer-related distress interfere with these behaviors, patient care may suffer.

Although this study represents an advance over much of the previous cross-sectional research on hot flashes in prostate cancer patients, certain limitations should be considered when evaluating the results. First, because this is the initial study to longitudinally evaluate the role of hot flashes in the development of distress, the results should be considered preliminary and in need of replication. Because the sample size was relatively small, the ability of these results to generalize to the broader population of prostate cancer patients is unknown. The current sample was diverse with regards to disease characteristics, including time since diagnosis, Gleason score, and other prostate cancer treatment received. Despite this heterogeneity, ratings of hot flashes and cancer-related distress were not associated with any of the clinical variables assessed, which minimizes the possibility that these characteristics exerted significant influence on either of the primary study variables. Conversely, the sample was fairly homogeneous in terms of demographic characteristics. The majority of participants were Caucasian, married, and retired. Although demographic characteristics were not associated with hot flashes or distress in this sample, the small number of participants in the minority groups prohibits a thorough examination of differences. The experience and impact of hot flashes among men belonging to different segments of the population (e.g. those actively working) remain unclear. Additionally, potential confounding variables such as comorbid medical conditions, premorbid psychological distress, and use of other medications associated with hot flashes (e.g. SSRIs) were not accounted for. While only two men reported accessing pharmacologic treatment for hot flashes, it is possible that some participants were prescribed SSRIs for other purposes, which may have minimized their experience of hot flashes. Further research is needed to clarify these issues and extend these findings to the broader population of men receiving ADT for prostate cancer.

The 10-day window participants were given to complete the baseline assessment chosen for practical and logistical reasons. This time frame may have been adequate for capturing a baseline level of physical side effects; however, certain aspects of patients’ psychosocial functioning may have been impacted by the initiation of treatment. Assessment of psychosocial variables would therefore not be reflective of baseline levels. The degree to which this occurred is thought to be minimal, but should be taken into consideration when interpreting these results.

It should also be noted that the hot flash variables (predictors) and distress (outcome) were assessed concurrently; therefore, causal relationships among these variables cannot be conclusively determined. It is possible that men with greater distress at the outset of treatment were inclined to report hot flashes that were more intense, frequent, and disabling than men with lower levels of pre-treatment distress. The current data do not allow us to adequately test this alternative hypothesis; however, future research should employ more frequent assessments in order to disentangle the temporal relationship between hot flashes and distress. Incorporation of daily diaries or real-time data collection technology (i.e. ecological momentary assessment) would allow for more precise evaluation of the temporal relationship between hot flashes and psychological distress [42].

In sum, these findings provide evidence for the impact of hot flashes on psychological distress among men receiving ADT for prostate cancer. Results suggested that hot flashes may prevent men from experiencing the decline in distress reported by men without this troubling side effect. Hot flashes were a prevalent side effect in this sample, affecting approximately 70% of patients. The results of this study highlight the need for additional attention to hot flashes as a notable consequence of ADT. Future research should explore the potential causal mechanisms for this relationship in order to tailor psychological intervention to promote distress reduction in this population.

Acknowledgements

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