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UNIVERSITY OF MIAMI

PSYCHOSOCIAL CORRELATES OF PSYCHOLOGICAL DISTRESS AND AROUSAL IN PROSTATE CANCER SURVIVORS UNDERGOING ACTIVE SURVEILLANCE

By

Natalie Escobio Bustillo

A THESIS

Submitted to the Faculty of the University of Miami in partial fulfillment of the requirements for the degree of Master of Science

Coral Gables, Florida

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UNIVERSITY OF MIAMI

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Natalie Escobio Bustillo

Approved:

Frank J. Penedo, Ph.D. Associate Professor of Psychology Terri A. Scandura, Ph.D. Dean of the Graduate School

Michael H. Antoni, Ph.D. Professor of Psychology

Suzanne C. Lechner, Ph.D. Research Assistant Professor of Psychiatry and Behavioral Sciences



BUSTILLO, NATALIE ESCOBIO

<u>Psychosocial Correlates of Psychological Distress</u> and Arousal in Prostate Cancer Survivors <u>Undergoing Active Surveillance.</u>

Abstract of a thesis at the University of Miami.

Thesis supervised by Associate Professor Frank J. Penedo. No. of pages in text. (118)

Active Surveillance (AS) for the clinical management of prostate cancer (PC) is a treatment option for men with low-risk PC. Screening procedures have led to the overdetection of PCs that would have never caused problems. Active treatment (e.g., surgery or radiation) for these non-aggressive tumors may not be necessary given the slow-growing nature of PC. AS provides a way to monitor the disease and delay treatment-related compromises on quality of life until clinically indicated (e.g., rising PSA level). However, the intensive monitoring in AS may be a stressful experience and lead to greater anxiety, an emotional state that has been associated with undergoing active treatment despite physician recommendation for AS. The current study aimed to identify psychosocial correlates of anxiety in men undergoing AS. Using Mishel's Reconceptualized Uncertainty in Illness Model as a framework, the proposed study aimed to examine the relationships between perceived stress management skills, PC psychosocial concerns, and anxiety/arousal. Hierarchical multiple regression analyses were conducted on a sample of 71 men undergoing AS, who were on average 65.40 years old (SD=7.85) and ethnically diverse (52% non-Hispanic White; 31% Hispanic; 17% African American). Results indicated that greater PSMS were significantly associated with less IES-R anxiety (β =-.28, p<.04). PSMS were not significantly associated with PC



concerns (β =-.02, p>.05), but greater PC concerns were significantly associated with greater IES-R anxiety (β =.61, p<.01) and PSA anxiety (β =.42, p<.01). These associations held after controlling for relevant covariates. The results suggest a possible role for stress management skills as perceived ability to manage stress was related to less anxiety in the AS experience. Future studies should examine the relationship among these factors in longitudinal designs and whether greater stress is associated with unnecessary active treatment in low-risk PC.



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Chapter 1: Introduction

Prostate Cancer

Prostate cancer (PC) is the most common non-skin cancer diagnosed in American men (American Cancer Society, 2010; ACS). It is estimated that approximately 217,730 men will be diagnosed with PC in 2010. PC accounts for the second leading cause of cancer-related death in American men, with an estimated 32,050 expected to die in 2010. Due to the prevalence and mortality of this disease, men are often subject to screening even before symptoms are present. PC screening is defined as having a prostate-specific antigen (PSA) test and digital rectal exam (DRE) before symptoms arise. No clear cut-off value exists to distinguish between a normal and abnormal PSA result. However, a value greater than 4 ng/mL is used as guideline to indicate PC may be present (ACS, 2010). A DRE is also conducted to palpate the prostate gland and detect any abnormalities (e.g., bumps). The goal of PC screening is to detect cancers at early stages in order to increase the possibility of curing the disease. Because PC screening is not definitive, men with abnormal results are recommended to undergo a biopsy to determine whether or not cancer is present. Biopsies are associated with several risks, such as discomfort, infection, and bleeding (ACS, 2010).

PC Screening Guidelines

The ACS recommends that men with a minimum life expectancy of 10 years should discuss the potential risks and possible benefits of screening for PC with their physicians (Wolf et al., 2010). The timing of the discussion depends on age and risk of developing PC. Men at average risk are encouraged to discuss screening at 50 years of age, while those who are at higher risk (e.g., African American or have a family history



1

of PC) should begin the discussion at age 45 (ACS, 2010). The American Urological Association (AUA) recommends offering PSA screening beginning at 40 years of age to all men with a minimum 10-year life expectancy in order to obtain a baseline PSA value. The guidelines specify that PSA may be affected by age-related enlargement of the prostate and not necessarily indicate the presence of PC (AUA, 2009). Although their screening guidelines vary slightly, the AUA and ACS both agree that men should make an informed decision about whether or not they would like to be screened and those with a life expectancy of less than 10 years should not receive PC screening.

Unfortunately, PC screening is not always an effective method in detecting cancer. It is possible to have abnormal screening results when cancer is not present (false positive) and have normal screening results when cancer is present (false negative; ACS, 2010). Some men may be subjected to biopsies when cancer is not present. The National Cancer Institute (NCI; 2009) estimates that 65% to 75% of men who receive elevated PSA results do not have cancer. On the other hand, PC may go undetected even after men with elevated PSA levels undergo a biopsy. One study estimated the incidence of false negative biopsies to be 23% (Rabbani, Stroumbakis, Kava, Cookson, & Fair, 1998). Another problem is that screening procedures do not provide information on how aggressive a PC tumor is. Aggressiveness can only be determined after a biopsy is conducted and the tumor is graded using a grading system determined by a Gleason score. Multiple cores are taken from the prostate gland and the tissue is examined for the two most common patterns. Values between one (cancer tissue closely resembles normal prostate tissue) and five (cancer tissue lacks normal features) are assigned to the two patterns and are then summed to equal the Gleason score, which may range from 2 to 10.



Gleason scores indicate the likelihood that a tumor will spread beyond the prostate, with higher scores indicating more aggressive tumors with more poorly-differentiated tissue (NCI; 2008).

Once a PC diagnosis is confirmed via biopsy, doctors use a combination of PSA value, DRE results, and Gleason score to stage the cancer. Staging determines the extent to which the cancer may have spread outside of the prostate (ACS, 2010). PC stages range from T1 (early-stage) to T4 (advanced stage). Stage I indicates the tumor is confined to the prostate gland without spread to lymph nodes, while stage IV indicates the tumor has spread to the lymph nodes and tissues beyond the prostate gland (ACS, 2010). Five-year relative survival rates are near 100% for early-stage cancers as well as for cancers that have only spread to lymph nodes near the prostate. However, stage IV tumors that have spread to organs beyond the prostate gland have a 31% 5-year relative survival rate (ACS, 2010). Cancer stage and Gleason score are essential components of the treatment decision process. In addition, age, medical comorbidities, and potential treatment-related side effects are also taken into consideration when making a treatment decision (NCI, 2005).

High-risk versus Low-risk PC and Treatment Options

High-risk PC refers to having a PSA level > 20 ng/mL, a Gleason score between 8 and 10, or clinical stage T2c (AUA, 2007). Treatment options for high-risk PC depend on whether the cancer is detected at an early or advanced stage. In early stage cancers, men may choose among several curative treatment options, such as active surveillance (AS), radical prostatectomy, and radiation therapy (AUA, 2007). However, even at early stages, men with high-risk PC are more likely to suffer from recurrence compared to men with



low-risk PC (AUA, 2007). For this reason, the AUA recommends that men with high-risk PC undergo an active treatment instead of AS.

In contrast, low-risk PC is defined as a having a PSA level ≤ 10 ng/mL, Gleason score of 6 or less (no pattern 4 or 5), and clinical stage T1c or T2a (AUA, 2007). All lowrisk PCs are early stage cancers and men who receive this diagnosis may benefit from curative treatment or AS. Radical prostatectomy and radiation therapy are the most commonly used treatment options for men with low-grade disease (NCI, 2005). Although effective, men who undergo these treatment types often report urinary, bowel, and sexual dysfunction (AUA, 2007). Risks and side effects of radical prostatectomy include: infection and heart problems during surgery, longer recovery time compared to radiation, and urinary incontinence and erectile dysfunction immediately after surgery. Men who undergo radiation treatment often report bowel dysfunction during treatment, such as loose bowel movements and rectal bleeding or irritation (NCI, 2005). Contrary to the immediate sexual dysfunction commonly experienced by men who undergo radical prostatectomy, 50% of men who receive radiation experience sexual dysfunction within 5 years of treatment.

Treatments such as surgery and radiation are not appropriate for the risk that lowrisk tumors pose and AS may serve as a good alternative to traditional treatments (Soloway et al., 2007). When making a treatment decision, men take personal and spousal preferences as well as doctors' recommendations into consideration (O'Rourke, 2007). The treatment decision process can be a stressful event, as men decide whether immediate or delayed treatment is best for them. Men must also weigh the advantages and disadvantages of active treatments versus AS. While some men may choose to delay



treatment-related side effects, other men may prefer to avoid the anxiety associated with living with an active cancer. There is no right or wrong treatment option, as men who meet criteria for AS are also candidates for surgery and radiation.

Active Surveillance

Controversy remains regarding PC screening practices and overtreatment. After the onset of PSA testing in the late 1980s, screening has increased dramatically. Although screening is a method to detect PC before it causes symptoms, overuse of PSA testing leads to the detection of cancers that would have never caused problems due to the slowgrowing nature of the disease (Penson, Rossignol, Sartor, Scardino, & Abenhaim, 2008). The majority of men diagnosed with PC have low-risk disease where immediate treatment is unnecessary and could result in severe decrements in quality of life. Also, men with comorbid medical conditions, such as cardiovascular disease, are more likely to die from comorbidities than PC. For example, Daskivich et al. (2010) reported that men with congestive heart failure were four times more likely to die of a non-PC-related cause than of PC. One of the most influential studies in highlighting the over-diagnosis and treatment of PC examined the effect of PSA testing on PC mortality (Schröder et al., 2009). The researchers found that 1,410 men would need to be screened and 48 men would have to be treated in order to prevent a single death from PC. The over-diagnosis of PC provides support for the use of AS as a treatment option for men with low-risk disease.

AS is a type of clinical management recommended for men with low-risk PC that involves monitoring disease status while delaying curative treatment for early stage



disease. Men diagnosed with PC who elect this treatment type are subject to PSA testing and DREs every three months for the first two years post-diagnosis, PSA testing and DREs every six months after two years, and biopsies every six to twelve months (Soloway et al., 2007). AS serves two purposes. First, it allows a patient to delay treatment and its side effects until the disease progresses, while still providing the option of receiving a curative treatment. Frequent monitoring is a necessary aspect of AS as it provides a way for doctors to assess whether the cancer is progressing or not. Monitoring is extensive (i.e., PSA testing, DREs, and biopsies) as there is no single test that can detect the exact probability of progression. For men that have evidence of progression, frequent monitoring allows doctors to detect it as soon as possible so that cancer remains at an early stage with curative treatment options. Men with a life expectancy of at least 10 years may still receive curative treatment after undergoing AS (AUA, 2007; Parker, 2004). Second, AS prevents some men with low-risk disease from ever experiencing treatment-related side effects. PC is typically a slow-growing disease that does not always require active treatment to prevent death.

Prior to the development of AS early in the 21st century, men who did not receive active PC treatment were said to be on watchful waiting. AS was first introduced by Choo et al. (2002) as a derivation of the watchful waiting option and was referred to as a "selective delayed intervention". Choo et al. concluded that it would be feasible to evaluate disease progression in men undergoing watchful waiting in order to spare men with low-risk PC from unnecessary treatment and provide delayed curative treatment to those who show progression. Due to the relatively new concept of AS as a treatment option, watchful waiting is sometimes used interchangeably with AS in clinical practice.



However, there is a clear distinction between them. The AUA (2007) distinguishes them by stating that men who undergo watchful waiting will not benefit from curative treatment. Instead, these men are offered palliative treatment for local or metastatic PC. The decision to undergo watchful waiting may be made based on the person's age, medical comorbidities, and a life expectancy of less than 10 years (ACS, 2010). AS is a more aggressive form of disease monitoring. The present study focused on AS with the underlying assumption that the men will be monitored until disease progresses and curative treatment will remain a viable option.

AS in Clinical Practice

The treatment decision process between doctors and PC survivors is an important factor as it relates to the likelihood of a man choosing to undergo AS and remaining on AS until there is evidence of clinical progression. Davison et al. (2009) found that most men chose to undergo AS because it was recommended by their doctor as the best treatment approach. Men were further comforted with their decision to undergo AS by their doctor's recommendation to receive a second opinion from another physician who also recommended AS. When physicians recommend AS as a PC treatment option, men are presented with the advantages and disadvantages to delaying active treatment (O'Rourke, 2006). An emphasis is placed on the benefits of delaying PC-specific quality of life impairments, while highlighting the ongoing monitoring prescribed by AS. A critical component of the presentation of AS is that doctors describe it as an "individualized" type of clinical management (Soloway et al., 2007). Doctors assure patients that they have autonomy over their treatment decisions and may choose to initiate active treatment at any time in their AS management.



Only men who have low-grade PC (i.e., Gleason score of 6 or less) are recommended to undergo AS (AUA, 2007; ACS, 2010). Therefore, risk of disease progression is relatively low among men who choose AS. In a study that evaluated the incidence of disease progression in men undergoing AS, investigators found that 19 out of 262 men (7%) experienced disease progression (Eggener et al., 2009). Four out of 19 men refused active treatment upon detection of progression and remained metastasis-free between 10-25 months post-progression. The authors suggest that although the incidence of disease progression is low, it remains a possible risk factor that doctors should discuss with their patients when making a treatment decision.

Several studies have compared the number of men that meet criteria for AS to the number of men that actually choose it. However, it is important to note that investigators have not reported on whether men who qualify for AS and elect active treatment instead were ever offered AS as a treatment option. Roemeling et al. (2006) conducted a study where they examined the medical records of over 1,000 men who had been screened for PC. Of the 293 men that met criteria for AS, only 22.0% elected AS. This result is further evidenced by findings from the CaPSURE study. CaPSURE is a longitudinal, observational study examining general and disease-specific quality of life trajectories, health care use and satisfaction, and economic outcomes of men diagnosed and treated for PC (Lubeck et al., 1996). Results from the CaPSURE study revealed that of the 16.4% of men that met criteria for low-risk disease, over 90.0% of them elected a curative treatment rather than AS after a PC diagnosis (Barocas, Cowan, Smith, Carroll, & the CaPSURE Investigators, 2008).



There are several barriers to the uptake of AS, which may explain the low percentage of men eligible for AS who go on to elect it as their treatment type. Some of the psychosocial barriers to the uptake of AS include anxiety and uncertainty in in response to no active treatment and fear of possible disease progression (Pickles, Ruether, Weir, Carlson, & Jakulj, 2007). Although meeting eligibility for AS suggests that men have a slow-growing tumor that is unlikely to metastasize, there is also great psychological distress associated with living with an active cancer. An additional barrier may be the physician's description of AS as an alternative to immediate active treatment (Davison, Oliffe, Pickles, & Mróz, 2009). The comfort with which a physician presents AS may influence a patient to elect it, with doctors that take their time to explain the advantages and disadvantages being more successful at making patients feel confident about AS. Having greater confidence in one's physician's recommendation to undergo AS may serve as a buffer to potential lack of PC knowledge and emphasizes the importance of a high-quality relationship between patient and doctor.

In a study that examined the advantages and disadvantages of undergoing AS, investigators found that the most common advantage was delay of treatment-related side effects and the most common disadvantage was risk of disease progression (van den Bergh, van Vugt, et al., 2009). However, the nature of AS is to eventually receive curative treatment. Men are aware that they are putting off side effects in the present time, but may have to face them in the future. Because there is no way of predicting how quickly the disease may progress, some men think about active treatment options while undergoing AS. Men who report looking for treatment options have higher levels of anxiety than those who do not (Davison et al., 2009). In a study that examined treatment



satisfaction in men two years after a diagnosis of localized PC, men who elected active treatment reported greater treatment satisfaction compared to those who chose AS (Hoffman, Hunt, Gilliland, Stephenson, & Potowsky, 2003). Greater treatment satisfaction was associated with the perception of being free of cancer. In sum, there are several barriers to AS associated with living with an active cancer, which include psychological distress, uncertainty, and fear of progression (Oliffe, Davison, Pickles, & Mróz, 2009; Roos, 2003).

Psychological Distress and Arousal

It is well documented that individuals diagnosed and treated for cancer experience varying levels of psychological distress. Zabora, BrintzenhofeSzoc, Curbow, Hooker, and Piantadosi (2001) reported the prevalence of distress among the most commonly diagnosed cancers is approximately 35%. Psychological distress was measured using the Brief Symptom Inventory (BSI) with T-score values ≥63 on the Global Severity Index or on two of the subscales indicating significant distress (Derogatis & Melisaraatos, 1983). In this study, greater prevalence of distress was associated with cancers that had poorer prognoses. For example, lung cancer survivors reported greatest level of psychological distress (43.4%). Cancers with the highest mean anxiety levels were pancreatic, lung, and liver cancers. PC survivors reported the second lowest levels of psychological distress overall (30.5%) and the lowest mean anxiety levels when compared to other cancers. Given the high 5-year survival rates (near 100%) observed in localized disease as a result of effective treatments, it is understandable how overall levels of psychological distress are low in PC survivors.



Although levels of overall psychological distress are low when compared to other cancers, PC survivors are more likely to experience symptoms of traumatic stress and anxiety than symptoms of depression. Symptoms of anxiety have been reported more frequently than symptoms of depression in men with recently diagnosed early stage PC who have not received active treatment as well as in men undergoing AS (Bisson et al., 2002; Burnet, Parker, Dearnaley, Brewin, & Watson; 2007).

Elevated anxiety near the time of screening has been well documented in the literature. In a review, Dale et al. (2005) reported that levels of anxiety in PC survivors depended on factors related to uncertainty, such as screening and biopsy, with increased anxiety before these procedures and normal levels after. Similarly, Roth, Weinberger, and Nelson (2008) reported that in men who undergo active treatment for PC, anxiety is highest after treatment is complete and men return for PSA tests. This finding suggests that men undergoing AS may not experience continuous elevated levels of anxiety; instead, anxiety may rise at particular times in the management process. Although anxiety is elevated at the time of PSA testing and biopsy, there is a need to examine the factors that make some men susceptible to experiencing greater anxiety.

PSA testing as well as rising PSA levels have been associated with increased anxiety in men undergoing AS (van den Bergh, Essink-Bot, et al., 2009). For men that choose to undergo AS, anxiety is a predictor of receiving unnecessary treatment (Latini et al., 2007). Men enrolled in the CaPSURE study who chose AS and had anxiety data within three years of diagnosis were included in the study. Anxiety was measured using three items selected by Latini et al. from the "Memorial Anxiety Scale for Prostate Cancer" (Roth et al., 2003). The items were specific to the AS experience; for example,



"My fear of having my cancer getting worse gets in the way of my enjoying life". The investigators assessed the relationship between change in anxiety and active treatment onset and found that increased anxiety predicted treatment above and beyond rising PSA levels. Whereas the purpose of AS is to delay treatment until deemed clinically necessary, anxiety may increase the likelihood that men receive treatment soon after diagnosis.

In addition to increased anxiety, rising PSA levels is one of the most common reasons men discontinue AS (Ercole, Marietti, Fine, & Albertson, 2008). Patel et al. (2004) examined men diagnosed with low-risk PC who underwent AS. They followed men as they received repeat PSA tests and biopsies to determine whether curative treatment onset was associated with clinical indications of progression. The results suggested that 55% of the men that received active treatment had evidence of disease progression (i.e., Gleason pattern 4 or 5, PSA velocity increase greater than 0.75 for 2year period, new prostate lesion detected by DRE, and biopsy result of greater than four cores with cancer). However, approximately 23% of the men received treatment without evidence of disease progression due to anxiety and fear of progression. This finding is important as it is estimated that 20-30% of men who undergo AS receive treatment after 3-5 years (Dall'Era & Carroll, 2009). For men that have lower levels of anxiety and are able to withhold active treatment, this is a considerable amount of time that men can delay the side effects of treatment.

Nonetheless, research findings on psychological distress experienced by men on AS have been mixed. Whereas some studies report elevated levels of distress, others do not. For example, van den Bergh et al. (2010) assessed psychological distress over a 9-



month period in a Dutch sample of PC survivors who underwent AS. Results indicated that distress remained low for the first nine months. At the 9-month follow-up, only nine out of 108 participants discontinued AS and received a curative treatment. Seven of those men discontinued AS due to evidence of disease progression, while only two of those men discontinued AS for non-clinical reasons. This small number may be due to relatively low levels of distress in the sample at the beginning of the study relative to the general population of men undergoing AS. The findings were valuable in that they supported the idea that when distress levels remain low, the likelihood of receiving unnecessary treatment decreases.

As self-report measures can sometimes lead to inconsistent results, physiological markers of arousal may be useful in determining levels of distress. Cortisol, a hormone involved in the stress response and used as a measure of hypothalamic-pituitary-adrenal (HPA) axis functioning, has been examined as an indicator of stress in cancer populations (e.g., Carlson Speca, Faris, & Patel, 2007; Cruess et al., 2000; Phillips et al., 2007). For example, significantly increased nocturnal cortisol levels and decreased cortisol variability were found in ovarian cancer survivors when compared to women with benign disease and to healthy women, suggesting impaired stress regulation in women with malignant disease (Weinrib et al., 2010). Elevated levels of serum cortisol have also been found in men at the time of PC screening compared to a sample of men who did not undergo screening (Gustafsson et al., 1995; Kunkel, Bakker, Myers, Oyesanmi, & Gomella, 2000). This finding suggests that even men without PC may experience elevated physiological arousal when going through the screening process.



Gustafsson et al. (1995) also examined serum cortisol levels in men who underwent biopsies after an abnormal screening result. The first cortisol measure was taken two weeks after screening (before receiving their biopsy results) and the second measure was taken at 4 and 16 weeks post screening (after receiving their results). Men showed highest cortisol levels immediately prior to receiving biopsy results. Cortisol levels decreased to normal baseline levels after receiving their results, regardless of the whether the biopsy results were positive or negative. These findings suggest that the uncertainty of upcoming results is more anxiety provoking than the actual test results. This finding is salient in the AS experience as it is not the results of PSA testing, DREs, or biopsies that leads to higher arousal, but rather the suspense of awaiting results is what may contribute to greatest arousal.

Demographic and Clinical Characteristics Associated with Anxiety

There are various demographic and clinical characteristics that have been found to impact men diagnosed with cancer. For example, Hurria et al. (2009) found that having greater than three medical comorbidities was associated with greater distress in cancer survivors. Age and time since diagnoses have both been found to be significantly associated with anxiety in PC survivors, where younger men reported greater anxiety than older men and more time since diagnosis was also associated with greater anxiety as measured by the HADS anxiety scale (Burnet et al., 2007). The finding that younger men reported greater levels of anxiety compared to older men has been further supported in other research studies of PC survivors (Bisson et al. 2002; Carlsson et al., 2007). The receipt of an elevated PSA result and rising PSA values have also been associated with elevated PSA anxiety (Carlsson et al. 2007; van den Bergh et al., 2009). Furthermore,



greater distress has been associated with the report of a greater need for information about cancer (i.e., lack of knowledge; Mesters, van den Borne, De Boer, & Pruyn, 2001). The findings suggest that these demographic and clinical variables should all be accounted for when examining anxiety in cancer populations.

Prostate Cancer Psychosocial Concerns

The diagnosis of a chronic illness, such as cancer, can lead to illness perceptions that may impact emotional well-being. Traeger et al. (2009) conducted a study examining the impact of negative illness perceptions and perceived stress on emotional well-being in men treated for PC who were experiencing sexual dysfunction. Among significant results, fewer perceived negative consequences of PC on life were associated with greater emotional well-being and this relationship was moderated by life stress. This finding suggests that PC concerns more greatly affect emotional well-being in men with poor ability to manage stress compared to men with richer coping mechanisms. Several studies have shown that negative illness perceptions about the severity and consequences of the disease are associated with poorer recovery, independent of the initial medical prognosis (Petrie & Weinman, 2006). Therefore, it is important to explore the perceptions and concerns cancer survivors have about their illness.

Spencer et al. (1999) examined the concerns that were most important to breast cancer survivors who had been treated with surgery within the past year. The researchers also examined which concerns were associated with quality of life. Breast cancer survivors showed the greatest concern over life and pain issues (e.g., not seeing children and grandchildren grow up) and the least concern with social rejection issues (e.g.,



avoidance from friends). Emotional distress was predicted by life/pain concerns and sexuality concerns. To date no previous study has examined the relationship between PCspecific concerns and psychological distress. There is a need to examine PC psychosocial concerns in men undergoing AS due to the nature of the low-risk cancer that is usually free of symptoms. The way men perceive concerns about their current treatment decision may have implications for how they will adjust to the disease. In a hypothetical example of a man who believes future active treatment will result in financial burden, anxiety may increase throughout the monitoring of the disease at the thought of having to cover treatment-related costs. These types of perceptions are greatly influenced by the coping resources one has. Using the same hypothetical example, a man with greater ability to deal with stressful situations may be able to plan in advance for future difficulties and experience fewer concerns. In addition, a PC survivor's ability to relax, seek support, and use cognitive reframing may alleviate the psychosocial concerns associated with undergoing AS (Reese, Keefe, Somers, & Abernethy, 2010). These stress management skills are may be directly related to PC concerns in that one who is able to relax and reframe negative aspects of AS may not feel as burdened by potential consequences, which may result in experiencing less distress (Penedo et al., 2006). Similarly, greater ability to seek support from family and friends may result in fewer concerns about social alienation (Christie, Meyerowitz, Giedzinska-Simons, Gross, & Agus, 2008).

Perceived Stress Management Skills

The effects of stress management interventions on quality of life are well documented in the breast cancer and PC populations. In men treated for localized PC, the



development of perceived stress management skills through the participation in cognitive behavioral stress management (CBSM) programs has improved quality of life and benefit finding (Penedo et al., 2006; Penedo et al., 2004). Development of perceived stress management skills has important implications for improved quality of life. Specifically, perceived stress management skills were found to mediate the relationship between optimism and positive mood (Penedo et al., 2003). This finding indicates that mood depends on one's perception of having the ability to use adaptive coping strategies when faced with difficult situations, such as cancer. However, to this date no study has examined the relationship between perceived stress management skills and psychological well-being in men undergoing AS for PC. Given the results of the previous studies, the impact of perceived stress management skills on psychological distress is important to explore in men undergoing AS as the ability to manage stress may alleviate treatment uncertainty and improve well-being. No previous study has examined this relationship in individuals diagnosed with localized disease prior to receiving active treatment.

While interventions have been associated with improvements in quality of life, the majority of the research focuses on adjustment after treatment for cancer. For example, Antoni et al. (2006) found that a CBSM intervention improved various aspects of quality of life in breast cancer survivors, including emotional well-being, benefit finding, and positive affect. In the study, the positive outcomes of the intervention on quality of life were explained by perceived ability to relax at will. This study provides evidence for the beneficial outcomes of psychosocial interventions through their effect on improving stress management ability. Greater perceived stress management skills have also been shown to buffer the effects of stress by lowering levels of anxiety and depression and



improving quality of life above and beyond relevant demographic covariates in cancer patients prior to initiating treatment (Faul, Jim, Williams, Loftus, & Jacobsen, 2009). However, the sample consisted mostly of non-Hispanic White females, diagnoses of breast or lung cancer, and advanced stage disease. In order to fully understand the impact of perceived stress management on emotional well-being prior to treatment, studies should include an ethnically diverse sample. The generalizability of Faul et al.'s finding is further limited by only including women with advanced disease, as the psychosocial experience of a cancer diagnosis at an advanced stage is remarkably different from that of localized disease.

The relationship between stress management skills and physiological stress response has also been examined. Specifically, studies have examined the effects of a CBSM intervention on serum cortisol. Phillips et al. (2008) found that compared to women in a control group, women that participated in a CBSM intervention experienced decreases in serum cortisol levels over a one-year period, suggesting that stress management skills learned through participation in the intervention may have reduced levels of physiological stress. Other studies have also found similar results, where participation in a CBSM intervention resulted in reduced serum cortisol levels (e.g., Antoni et al., 2009; Cruess et al., 2000). However, the current literature lacks information on the relationship between perceived stress management skills and cortisol in PC survivors. Evidence from prior studies of the benefits of CBSM interventions on the stress response provides support for the examination of whether perceived stress management skills are related to physiological stress as measured by cortisol in men undergoing AS.



Uncertainty in Illness Theory

PC survivors who undergo AS are exposed to elevated levels of illness-related uncertainty (Bailey, Wallace, & Mishel, 2007). The appraisal of uncertainty is one of the factors that contributes to cancer adjustment (Wright, Afari, & Zautra, 2009). According to the Reconceptualized Uncertainty in Illness Model, uncertainty may persist throughout the course of an illness, but the appraisal of the uncertainty may change over time (Mishel, 1990). Uncertainty can be appraised as a danger or as an opportunity depending on whether a person expects a negative or positive outcome, respectively. Appraisals of danger consist of the perceived potential of experiencing poor quality of life, worry, mood disturbance, and poor social functioning, whereas appraisals of opportunity consist of greater perceived self-efficacy, decreased perceived threat, and better functional quality of life (Mishel, 1990).

Bailey, Wallace, and Mishel (2007) used Mishel's reconceptualized theory of uncertainty to explore uncertainty about PC and treatment, as well as appraisal processes in a qualitative study of men who underwent watchful waiting. Issues surrounding uncertainty about disease and treatment were focused on concern over lack of symptoms and insecurity over PSA levels as accurate markers of disease progression. Treatment decision was mainly appraised as a danger; some men were not sure if AS was best option and if they should have opted for a curative treatment instead. For example, one man thought about his PC every time he urinated and attributed changes in his urine stream to possible PC progression. Opportunity appraisal also occurred in some men who recognized the positive aspects of undergoing AS. For example, they viewed it as a way to keep their options open and kept in mind that they were dealing with a slow-growing



disease that was less likely to cause problems compared to other serious conditions, such as cardiovascular disease. There are various ways to appraise PC concerns, with appraisals of opportunity associated with improved quality of life and appraisals of danger as risk factors for poorer adjustment. It is important to note the distinction between watchful waiting and AS in addition to how the literature uses the terms interchangeably. It is unknown whether the participants in the previous descriptive study were actively monitoring the disease with the potential of curative treatment (i.e., AS) or if they were undergoing a less stringent regimen without the possibility of a cure (i.e., watchful waiting). The appraisal processes for men on AS versus watchful waiting may be different given the likelihood of ever being symptom free or cured.

In addition to appraisal, one's ability to manage the uncertainty is also essential for adjustment to cancer (Mishel, 1988). Psychosocial resources, such as the ability to manage stress and the use of effective coping strategies, play an important role when faced with the uncertainty of AS. Bailey, Mishel, Belyea, Stewart, & Mohler (2004) conducted an intervention in a small sample of men undergoing watchful waiting for PC. Again, caution must be taken when interpreting the results due to the difference between the watchful waiting and AS experiences. During the 5-week intervention, participants received phone calls from a nurse that taught men how to use cognitive reframing to make appraisals more positive. The intervention phone calls allowed the men the opportunity to talk about their uncertainties with the nurse and have questions answered (e.g., men that were confused about the meaning of PSA fluctuations received information from the nurse that helped reduce confusion). Improvement in quality of life was associated with men's ability to deal with concerns. The intervention taught



participants stress management skills that helped PC survivors incorporate uncertainty into their lives and aided in the reevaluation of the importance of life events, which may ultimately affect well-being. This study provides evidence for the beneficial effects of adaptive coping strategies on quality of life. It also highlights the importance of discussing PC concerns to improve well-being.



Chapter 2: Proposed Study

Men who undergo AS for the clinical management of PC often report elevated levels of anxiety. Anxiety is associated with the burden of living with an active disease and the frequent monitoring that accompanies AS (i.e., PSA tests, DREs, and biopsies various times per year (e.g., Barocas et al., 2008; Pickles et al., 2007; Roemeling et al., 2006). Previous research has shown that anxiety is a predictor of unnecessary active treatment for PC, which often leads to compromises in general and disease-specific quality of life (Latini et al., 2007; Patel et al., 2004). Few studies have examined correlates of anxiety in this population. Although the current literature provides evidence for medical correlates of anxiety in AS (e.g., PSA testing; Bisson et al., 2002; Dale et al., 2005; Kunkel et al., 2000), a gap remains in understanding how psychosocial factors may play a role. The current study aimed to identify psychosocial factors associated with anxiety/arousal in men diagnosed with PC and undergoing AS. Given the uncertainty associated with living an active cancer, the role of perceived stress management skills and PC concerns in anxiety/arousal was examined.

Although greater perceived stress management skills and fewer PC concerns have been associated with greater well-being in men diagnosed and treated for PC (e.g., Oliffe et al., 2009; Penedo et al.; 2003), the current literature lacks information on the impact of these psychosocial variables on psychological distress in men undergoing AS. The current study proposed that greater perceived stress management skills are associated with less anxiety/arousal and this relationship is mediated by PC psychosocial concerns. The transactional model of stress provides support for the examination of the relationship between perceived stress management skills and anxiety/arousal mediated by PC



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concerns. This model proposes that the perception that one does not have adequate resources to manage a difficult situation may result in increased stress (Holroyd & Rizzo, 1972; Folkman, 1982). The subjective experience of stress further depends on the appraisal of the severity of the stressor and the identification of controllable aspects of the stressor. Stressors are more likely to be appraised as less severe and more controllable when confidence about using adaptive coping strategies to deal with difficult situations is greater. PC survivors have reported several areas of concern, such as mortality and treatment side effects, suggesting there are multiple stressors associated with the AS experience (Oliffe et al., 2009). The current study conceptualized perceived coping resources as perceived stress management skills and appraisal of uncertainty as PC psychosocial concerns. Having greater perceived stress management skills (e.g., ability to cope effectively with difficult situations) may decrease amount of stress experienced by way of fewer PC concerns. Given the lack of research in this area for men undergoing AS for the clinical management of PC, the proposed study aimed to examine psychosocial correlates of psychological distress and arousal. Such knowledge may provide clinical implications for designing psychosocial interventions to reduce psychological distress and physiological arousal in men undergoing AS.

The proposed study used hierarchical multiple regression analyses to evaluate the relationship between perceived stress management skills and anxiety/arousal mediated by PC concerns. The overall conceptual model that was examined is shown in Figure 1.

For the proposed study, the following hypotheses were tested:

Specific Aim 1: To examine the relationship between perceived stress management skills and anxiety/arousal in men undergoing AS.



Hypothesis 1a: Greater perceived stress management skills are significantly associated with less anxiety.

Hypothesis 1b: Greater perceived stress management skills are significantly associated with less cortisol area under the curve with respect to ground (AUC_G) .

Specific Aim 2: To examine the relationship between perceived stress management skills and PC psychosocial concerns in men undergoing AS.

Hypothesis 2: Greater perceived stress management skills are significantly associated with fewer PC psychosocial concerns.

Specific Aim 3: To examine the relationship between PC psychosocial concerns and anxiety/arousal in men undergoing AS.

Hypothesis 3a: Fewer PC psychosocial concerns are significantly associated with less anxiety.

Hypothesis 3b: Fewer PC psychosocial concerns are significantly associated with less cortisol AUC_G.

Specific Aim 4: To examine whether PC psychosocial concerns mediate the relationship between perceived stress management skills and anxiety/arousal in men undergoing AS.

Hypothesis 4a: PC psychosocial concerns meditate the relationship between perceived stress management skills and anxiety.

Hypothesis 4b: PC psychosocial concerns meditate the relationship between perceived stress management skills and cortisol AUC_G .



Chapter 3: Method

Participants

Participants were enrolled in a National Institute of Health (NIH) funded study (Ethnicity and Determinants of Quality of Life Following Prostate Cancer Treatment; NCI grant R01-CA114412). The purpose of the study was to examine how ethnic group membership affects disease-specific and general quality of life in men diagnosed with PC. More specifically, the study aimed to assess how men from various ethnic backgrounds cope with the diagnosis and treatment of PC and to explore the factors that were associated to their quality of life. Full participation in the study included five faceto-face psychosocial interviews over a period of 18 to 24 months.

A total of 675 men were screened to participate in the NIH-funded study. Out of the 675 men that were screened, 301 were ineligible to participate in the study. The most common reasons for ineligibility were: having a history of non-skin cancer and initiating treatment prior to enrollment in the study. Of the 374 men that were deemed eligible to participate in the larger study, 249 enrolled in the study (i.e., they signed an informed consent form). The remaining 125 men were eligible to participate in the study, but refused to enroll. The most common reasons men gave for not participating in the study were: having no time to participate, living far away from study sites, and not being able to take time off from work. For men that chose to undergo AS at the time of screening, the refusal rate to participate in the larger study was approximately 24% (i.e., 22 out of 93 men on AS who were eligible to participate in the larger study refused). Refer to Figure 2 for a depiction of how the final sample was achieved.



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The current study had a cross-sectional design and only used the baseline assessment. A subset of participants from the larger study was selected. Specifically, only men undergoing AS were included in the current study. None of the participants included in the current study had undergone active treatment at the time of the baseline assessment. Medical records were examined to confirm eligibility criteria for those men who reported they were undergoing AS for the clinical management of PC. Out of the 249 participants enrolled in the larger study, 71 men were confirmed to be undergoing AS and were included in the current sample.

Active Surveillance

AS is a type of clinical management for the treatment of PC that may be chosen by men with early stage disease. The purpose of this treatment type is to delay the negative side effects associated with invasive treatments, such as surgery or radiation. Clinical management involves routine PSA tests, DREs, and biopsies. According to the current study's physicians, eligibility criteria for undergoing AS included: being less than 80 years of age; having a PSA \leq 15 nanograms per milliliter of blood (ng/mL) at diagnosis; Gleason score \leq 6 with no pattern 4 or 5 (i.e., cancer tissue that lacks normal features and is poorly differentiated); no more than two positive cores out of total number of cores taken; no more than 50% tumor in each positive core; and clinical stage T1 to T2a (Soloway et al., 2007). AS eligibility criteria for all participants were confirmed upon review of their medical records.

Inclusion/Exclusion Criteria

Participants were required to be at least 21 years of age and not have received any type of active treatment for PC prior to the assessment visit. Participants were also


required to have a minimum of a sixth grade reading level and be fluent in English or Spanish in order to ensure comprehension of study purpose and questionnaires. However, men that did not meet the sixth grade reading level were not excluded from the study. All documents (including the informed consent form) were read out loud in their entirety to ensure that participants understood the purpose of the study, what their participation involved, and their rights as a participant. Men were excluded if they had a history of cancer other than skin cancer, active psychiatric disorders (e.g., dementia, psychotic disorder, panic disorder, and alcohol/substance dependence disorder), symptoms of psychosis, active suicidal ideation, were not interested in participating, or had severe cognitive impairments as determined by the Mini Mental State Exam (MMSE; Folstein, Folstein, & McHugh, 1975),.

Measures

All measures were available in English and Spanish. Spanish measures were administered for Spanish-monolingual participants or those that preferred to complete assessments in Spanish. All control, predictor, mediator, and outcome measures were translated by an IRB-approved translation company. Based on previous experience of bilingual staff working with the Hispanic population, translated measures were reviewed and final edits were made to address Hispanic word use variability. The internal consistency of the items in each measure was evaluated using coefficient alpha.

Control Variables

Information regarding sociodemographic variables was collected using standard questionnaires in an interview format. Sociodemographic variables that were included in



the analyses were: age, ethnicity, partner status, highest degree earned in the United States or in country of origin, total combined household income, and access to healthcare. Access to healthcare was assessed with one item that asked "How long has it been since you last had had health care coverage?". Medical variables that were included in the analyses were: most recent PSA level (within 6 months of the assessment), time since diagnosis, and comorbid medical conditions. Medical comorbidity was assessed using the Charlson Comorbidities Index, a measure consisting of 13 medical conditions that yields a weighted index that takes into account the number of and severity of comorbid conditions (Charlson, Pompei, Ales, & MacKenzie, 1987). PSA level and time since diagnosis were derived from the participants' medical records, after they each signed an "Authorization for 3rd Party Disclosures- Short Form" document. The authorization document specifically requested disclosure of information related to the diagnosis and treatment of PC.

In addition, the current study used a 27-item measure to assess PC knowledge. The measure was comprised of the 12-item PC Knowledge Scale developed by Wilkinson, List, Sinner, Dai & Chodak (2003), which assessed PC knowledge in African American men. An additional 15 items were included in the measure based on information from the ACS (see Appendix for a copy of the measure used). All 27 items had "True", "False", or "Don't Know" response choices. Sample items included: "Prostate cancer is the most common cancer, excluding skin cancer, in men living in the U.S." and "A Gleason score indicates how large a prostate cancer tumor is". The PC knowledge composite score was used as a control measure in all primary analyses. Internal consistency of the PC Knowledge Scale (English and Spanish versions



combined) was adequate (i.e., Cronbach's alpha= .79). However, the reliability of the measure was much lower when only Spanish-monolingual participants were included in the analyses (i.e., Cronbach's alpha= .50).

Perceived Stress Management Skills

The Measure of Current Status (MOCS) Part A was used to measure participants' perceived stress management skills (Carver, 2006). MOCS Part A is a 20-item self-report scale that includes four subscales (relaxation, awareness of tension, assertiveness about needs, and confidence in using adaptive coping strategies) and a composite score (see Appendix for a copy of the measure used). Participants were asked to indicate the degree of confidence they had in doing each of the items on a 5-point scale ranging from "I cannot do this at all" to "I can do this extremely well". Sample items in this measure included "I am able to use muscle relaxation techniques to reduce any tension I experience" and "I notice right away whenever my body is becoming tense". The internal reliability for the MOCS Part A was adequate when testing English and Spanish versions combined (i.e., Cronbach's alpha=.91) as well the Spanish version alone (i.e., Cronbach's alpha= .92). Given the high internal consistency of the measure, which suggests that it assesses a unitary construct, the present study used the composite score as the measure of perceived stress management skills. Previous studies have found similar results (i.e., high degree of internal consistency in the MOCS Part A) and have also used the composite score instead of the subscale scores (e.g., Penedo et al., 2003 and Penedo et al., 2006).



Prostate Cancer Psychosocial Concerns

The Profile of Concerns about Prostate Cancer (PCPC), adapted from the Profile of Concerns about Breast Cancer (PCBC), was used to assess PC-related psychosocial concerns (Spencer et al., 1999). A factor analysis conducted in a sample of women treated for early-stage breast cancer with a mean age of 53 years found that the PCBC yielded three factors: Life and pain Issues, Rejection Issues, and Sexuality Issues (Spencer et al., 1999).

The PCPC is a 25-item self-report measure designed to assess the concerns men may have when faced with a PC diagnosis (see Appendix for a copy of the measure used). Participants were asked to use a 5-point scale ranging from "Not at all concerned" to "Very concerned" to describe how concerned they were about each listed issue. Participants were instructed to answer for how they currently felt, not how they felt at the time they were diagnosed with PC. The PCPC composite score was tested as a mediator in the present study. The internal reliability for the PCPC was adequate when testing English and Spanish versions combined (i.e., Cronbach's alpha= .92) as well the Spanish version alone (i.e., Cronbach's alpha= .92).

Psychological Distress and Arousal

In the current study, three measures were used to assess anxiety/arousal. Two of the measures were self-report: the Impact of Event Scale-Revised (IES-R) and the PSA Anxiety Scale. The third measure, salivary cortisol AUC_G, was used to assess psychophysiological response to stress.



IES-R

The IES-R is a 22-item self-report measure that assesses distress caused by traumatic events (Weiss & Marmar, 1997). Participants were asked to rate their level of distress for each item (with respect to their PC) during the past seven days using a 5-point scale ranging from "Not at all" to "Extremely" (see Appendix for a copy of the measure used). The IES-R is comprised of three subscales: Intrusion, Avoidance, and Hyperarousal. The measure also yields a total score that ranges from 0 to 88, where a higher score indicates greater disturbance. Sample items included: "Any reminder brought feelings about it" (Intrusion), "I stayed away from reminders about it" (Avoidance), and "I was jumpy and easily startled" (Hyperarousal). The IES-R demonstrated adequate psychometric properties and internal consistency in the current study for English and Spanish versions combined (i.e., Cronbach's alpha= .92). Due to the high internal consistency of the measure, which suggests that it assesses a unitary construct, the present study used the composite score of the IES-R as a measure of anxiety.

PSA Anxiety Scale

The PSA Anxiety Scale, developed for the current study, was used as a measure of PC-related anxiety. The PSA Anxiety Scale is comprised of seven items (see Appendix for a copy of the measure used). The first three items are qualitative and assess whether or not the participant had his PSA tested in the past week, the date of his last PSA test, and the PSA level the last time his PSA level was tested. The four remaining items were adapted from the HADS, which is a self-report measure that has been well-validated in previous studies using cancer populations (Zigmond & Snaith, 1983).



The current study calculated a composite score for this measure. Only the four items adapted from the HADS anxiety subscale were used to assess PSA-related anxiety. These four items were selected for the calculation of the composite score due to their quantitative nature. A total score for the participants' responses to the four quantitative items was calculated to generate a PSA anxiety score, where a higher score indicated greater anxiety. The methodology of the calculation of the composite score can be found in the "Preliminary Analyses" section. The PSA Anxiety Scale demonstrated adequate internal consistency in the current study for English and Spanish versions combined (i.e., Cronbach's alpha= .92) and Spanish version alone (i.e., Cronbach's alpha= .94).

Salivary Cortisol

Salivary cortisol was used as a measure of arousal to assess participants' reaction to stress. Participants collected samples of their saliva four times per day for the two consecutive days prior to their assessment visit: immediately after waking up in the morning, 30 minutes post wake-up, between 16:00 h and 17:00 h, and between 21:00 h and 22:00 h. Participants were provided with detailed instructions on how to collect their saliva and sealable plastic tubes (Salivettes), which they used to collect saliva. The first and second salivary samples were collected before breakfast, coffee, and brushing their teeth. Participants were instructed to refrain from eating, consuming caffeine, and exercising for the 30 minutes prior to collecting each sample. Participants collected each salivary sample by gently chewing on a cotton swab for 1 to 2 minutes, placing it in the Salivette, labeling the tube with the date and time of collection, and storing it in their refrigerator. A total of eight salivary tubes were collected from participants during their assessment visit. Salivary tubes were stored in a -80°C freezer until they were shipped to



the Dresden University of Technology in Dresden, Germany for analysis. Luminescence Immunoassay was used for the determination of salivary cortisol (IBL International, 2009). The salivary cortisol was assayed by thawing the frozen samples, then mixing and centrifuging the samples for 10 minutes at 2000 - 3000 x g.

Reportable ranges of salivary cortisol are 0.005 - 4.000 micrograms per deciliter $(\mu g/dL)$. Cortisol values were converted from the International System of Units form (nanomoles per liter, nmol/L) to the conventional unit form $(\mu g/dL)$ by using the conversion factor of 27.59 (IBL International, 2009; Society for Biomedical Diabetes Research, 2010). Specifically, cortisol results reported in nmol/L were divided by the conversion factor of 27.59 to convert to $\mu g/dL$ for interpretation. The current study used cortisol AUC_G as a measure of arousal. Cortisol AUC_G accounts for the total area under the curve of all measurement points with respect to zero. Two pieces of information are provided by cortisol AUC_G: distance of each measurement from the ground (i.e., intensity) and distance of each measurement from one another (i.e., sensitivity). According to Fekedulegn et al. (2007), cortisol AUC_G is one of the best measures of total hormonal secretion. Only the cortisol AUC_G for Day 2 was included in the current study due to the high quantity of missing values for Day 1 and for both days combined. Out of the 71 men that participated in the current study, only 34 had complete Day 2 saliva collection. The Day 2cortisol AUC_G calculation procedures can be found in the "Preliminary Analyses" section.



Procedure

Recruitment

Participants were recruited from various urology clinics in South Florida. The majority of the participants were recruited from the University of Miami (UM) Sylvester Comprehensive Cancer Centers located in Miami, FL (Miami-Dade County) and Deerfield Beach, FL (Broward County). Participants were also recruited from Jackson Memorial Hospital (JMH) and from the Miami Veterans Affairs (VA) Medical Center, which are both located in Miami-Dade County. These sites are unique in that attending urologists promote AS as an alternative to active treatment to patients who meet eligibility criteria. At least one research associate from the study team was present at the urology clinics in each location. When a research associate was unable to be physically present at a clinic, the urology personnel provided a member of the study team with the contact information for potential participants, which were later contacted by phone. All study participants were directly referred by their urologist. Contacts were not made without consulting with the attending physician at each clinic. After potential participants visited with their urologists, they were referred to speak to the available research associate. The research associate provided potential participants with a brief description of the study and asked for their consent to screen. All procedures were approved by the Institutional Review Board (IRB) and were in full accordance with the Health Information Portability and Accountability Act (HIPAA) guidelines at UM, JMH, and Miami VA Medical Center.



Screening

Initial eligibility screening was conducted in person at the urology clinics or by phone. The screener questionnaire assessed whether men endorsed items related to alcohol/substance abuse and other current active psychiatric symptoms (e.g., panic attacks, psychosis, and dementia). When a potential participant endorsed presently experiencing any one of these psychiatric symptoms within the past 6 months, he was excluded. Men excluded for current psychiatric symptoms were referred appropriate mental health resources prior to the end of the screening interview. Those men that met eligibility criteria were provided with more detailed information about the purpose of the study, given a study flyer with contact information, and given a copy of the informed consent form. Men who expressed interest in the study were scheduled to come in to one of our study locations. Men recruited from the UM sites and JMH were given a choice between the Clinical Research Building at the UM Miller School of Medicine or the UM Sylvester Comprehensive Center in Deerfield Beach sites to complete assessments, regardless of where they were recruited from. This provided men with greater flexibility and less burden, as they were able to choose the site that was most convenient. Due to VA policy, men recruited from the Miami VA were only scheduled for assessment visits at the Miami VA.

During the assessment visit, potential participants signed the IRB-approved informed consent form. Prior to the psychosocial interview at each time point, the MMSE was administered to assess for cognitive impairment (Folstein, Folstein, & McHugh, 1975). The MMSE is a test that assessed several areas of cognitive functioning, such as orientation, recall, and calculation. The MMSE yields a maximum score of 30. The



proposed study followed a procedure where a score of 22 or less is likely indicative that the participant may be experiencing cognitive difficulties, but is not sufficient evidence for exclusion. A participant that scored a 22 or below was only excluded if he was not oriented to person, place, and time and was unable to comprehend the study questionnaires. The previous procedure was used as the current sample was ethnically diverse and previous studies have shown that ethnic minorities score significantly lower on the MMSE than non-Hispanic Whites suggesting the measure may be problematic when used on minority populations (e.g., Wood, Giuliano, Bignell, & Pritham, 2006). A score of 19 or below was a definite cut-off value for exclusion. Because the MMSE was administered after initiation into the study (post-informed consent), participants who were excluded due to a score below the cut-off value were compensated the full monetary amount for the visit for their time and effort.

Assessments

A clinical health psychology graduate student or research associate conducted the psychosocial assessments, which lasted approximately 2.5 hours. The psychosocial assessments measured various psychosocial processes and functioning domains, such as coping strategies, quality of life, social support, and mood. Blood samples were also collected at each visit to assess immune functioning and PSA levels, but were not be analyzed in the current study. Additionally, participants were asked to complete a takehome psychosocial questionnaire prior to each study visit along with saliva samples to assess stress levels for the two days prior to each face-to-face assessment. The take-home materials were mailed to the participants at the time they were scheduled for their next visit. Participants were compensated \$50.00 for each face-to-face assessment, for a total



of \$250.00 for full participation in the larger study. Participants in the current study received \$50.00 for the baseline assessment.

The proposed study utilized psychosocial data collected at the baseline time point of the study. Analyses focused only on men who were undergoing AS for the clinical management of PC.



Chapter 4: Statistical Analyses

Preliminary Analyses

Normality, Internal Consistency, and Descriptive Statistics

Variables included in the study were tested for normality by examining the skewness and kurtosis of each variable. Variables were considered to have non-normal distributions when the absolute value of the skew index was greater than 3.0 and the absolute value of the kurtosis index was greater than 8.0 (Kline, 2005). The descriptive statistics for each variable were also screened (e.g., appropriate maximum and minimum values for each variable and means within range of possible values).

Once testing for normality was completed, the internal consistency of the items was evaluated. Coefficient alpha was used as a measure of internal consistency in the current study. Before the reliability coefficients were interpreted, a few modifications were made to the PSA Anxiety Scale and the PC Knowledge Scale. The four quantitative items in the PSA Anxiety Scale were transformed to standard scores, as the items did not have the same metric. The z-scores for the quantitative items were summed to create an overall PSA Anxiety score (Green & Salkind, 2008). In addition, items were reverse-coded on the PC Knowledge Scale so that a response of "0" indicated an incorrect response and a score of "1" indicated a correct response. All responses with a value of "3" were transformed to a score of "0", as this value indicated the participant did not know the correct answer. Internal consistency was first calculated for English and Spanish measures combined. To determine whether the Spanish measures were as reliable as the English measures, internal consistency analyses were conducted for Spanish measures only.



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Analysis of Covariates

Correlation analyses were conducted to test possible significant relationships between all continuous control variables (i.e., age, comorbid medical conditions, PC knowledge, time since diagnosis, and PSA level within six months of the assessment) and all outcome measures. The statistical rule used to determine whether variables were significantly related was: p<.10 or $r\ge.30$. Descriptive statistics for categorical demographic, medical, and psychosocial variables were also evaluated. Several one-way analysis of variance (ANOVA) tests were conducted with ethnicity, education, total combined family income, and partner status entered separately as the factor in the analyses. The purpose of conducting the ANOVAs was to determine whether the psychosocial variables in the proposed model varied by ethnic background, socioeconomic status, and relationship status. Factors that did not result in significant differences among psychosocial variables were not included in the primary analyses.

Analysis of Study Variables by Language

Several analyses were conducted in order to determine whether the nine Spanish speakers included in the study varied in any way from the rest of the sample in covariates, demographics, and study measures. Independent t-tests were used to compare the means of all continuous variables of English-speaking participants to those of monolingual Spanish-speaking participants. In addition, two-way contingency table analyses were conducted to evaluate whether education, total combined family income, and partner status varied by language. The purpose of these analyses was descriptive in nature.



Calculation of Cortisol AUCG

Cortisol AUC_G was calculated by taking the sum of area under the curve with respect to baseline (AUC_B) and area under the curve with respect to increase (AUC_D, where AUC_G = AUC_B + AUC₁ (Fekedulegn et al., 2007). Calculations included four time points that corresponded to each sample collected on Day 2, where time equaled number of minutes from baseline (waking). Time 1 was always equal to zero (i.e., zero minutes from waking) and Times 2, 3, and 4 were derived from number of minutes from waking. Cortisol AUC_G was not calculated for any participant with Day 2 missing data, as all time points were required for the calculation. Before cortisol AUC_G calculations were made, individual cortisol values were evaluated to ensure they were within the reportable range of $0.005 - 4.000 \mu g/dL$. Out of the 34 participants with complete Day 2 data, one participant had cortisol values that were out of range. Only the 33 participants with valid Day 2 salivary cortisol values were included in the arousal analyses.

Primary Analyses

Specific Aim 1

Hypothesis 1a: Greater perceived stress management skills are significantly associated with less anxiety.

Hypothesis 1b: Greater perceived stress management skills are significantly associated with less cortisol AUC_G .

Multiple linear regression analyses were conducted to determine whether greater levels of perceived stress management skills are significantly associated with lower levels of anxiety/arousal. Demographic, psychosocial, and medical control variables were



entered in the first block, followed by perceived stress management skills in the second block. Significance was determined by a p level <.05 for the Beta coefficient of perceived stress management skills, after controlling for relevant control variables. Separate multiple regression analyses were conducted for each measure of anxiety/arousal. Specifically, regression models were run with total anxiety as measured by the IES-R, PSA Anxiety as measured by four items from the PSA Anxiety Scale, and cortisol AUC_G as outcome measures.

Specific Aim 2

Hypothesis 2: Greater perceived stress management skills are significantly associated with fewer PC psychosocial concerns.

Multiple linear regression analyses were conducted to determine whether greater levels of perceived stress management skills are significantly associated with fewer PC psychosocial concerns. Demographic, psychosocial, and medical control variables were entered in the first block, followed by perceived stress management skills in the second block. A significant relationship was determined by a p level <.05 for the Beta coefficient of perceived stress management skills, after controlling for covariates.

Specific Aim 3

Hypothesis 3a: Fewer PC psychosocial concerns are significantly associated with less anxiety.

Hypothesis 3b: Fewer PC psychosocial concerns are significantly associated with less cortisol AUC_G .

Multiple linear regression analyses were conducted to determine whether fewer PC psychosocial concerns are associated with lower levels of anxiety/arousal.



Demographic, psychosocial, and medical control variables were entered in the first block, followed by PC psychosocial concerns in the second block. Significant relationships were determined by p levels <.05 for the Beta coefficient of PC psychosocial concerns, after controlling for relevant control variables. Three separate multiple regression analyses were conducted with the two anxiety measures and one arousal measure as dependent variables.

Specific Aim 4

Hypothesis 4a: PC psychosocial concerns meditate the relationship between perceived stress management skills and anxiety.

Hypothesis 4b: PC psychosocial concerns meditate the relationship between perceived stress management skills and cortisol AUC_G .

Hierarchical multiple regression analyses were conducted to determine whether PC psychosocial concerns mediate the relationship between perceived stress management skills and anxiety/arousal. Baron and Kenny's (1986) methodology for testing mediation was used. The criteria include: 1) significant regression of anxiety/arousal on perceived stress management skills, 2) significant regression of PC psychosocial concerns on perceived stress management skills, 3) significant regression of anxiety/arousal on PC psychosocial concerns, and 4) the addition of PC psychosocial concerns to the regression of anxiety/arousal on perceived stress management skills results in a non-significant relationship between the predictor and outcome measures. The fourth criterion was examined by regressing anxiety/arousal measures on both perceived stress management skills and PC psychosocial concerns. In all analyses, the first block of predictors included relevant psychosocial and medical control variables. The second block included



perceived stress management skills. The third block included the PC psychosocial concerns composite score. The outcome measures were anxiety/arousal, each analyzed separately (see Figure 3 for overall mediation model that was tested).

Full mediation is established if all four criteria are met. When PC psychosocial concerns are added to the regression of anxiety/arousal on PSMS, the relationship between PC psychosocial concerns and anxiety/arousal is significant and the relationship between perceived stress management skills and anxiety/arousal drops to zero (Dudley & Benuzillo, 2004). If the fourth condition is not met, a Sobel test assesses whether PC concerns partially mediate the relationship between perceived stress management skills and anxiety/arousal (Sobel, 1982). Two analyses are required to conduct the test: the regression of the mediator on the independent variable and the regression of the dependent variable on the independent and mediator variables. The two regression analyses provide unstandardized regression coefficients for each relationship along with their corresponding standard errors. The Sobel test was used to calculate a Z statistic using the computed four values (Preacher & Leonardelli, 2010).



Chapter 5: Results

Preliminary Analyses

Normality and Internal Consistency

Normality testing revealed normal distributions for all study variables, except for cortisol AUC_G, which was positively skewed (skew index= 4.26; kurtosis= 21.27). The log transformation of cortisol AUC_G was calculated and used in the primary analyses. Internal consistency analyses conducted on the entire sample demonstrated adequate psychometric properties and internal reliability for all measures used in the current study (i.e., Cronbach's alpha= .79, .91, .92, .92, and .92 for PC Knowledge Scale, MOCS-A, PCPC, IES-R, and PSA Anxiety Scale, respectively). Similar results were found when internal consistency analyses were conducted only on Spanish measures (i.e., Cronbach's alpha= .50, .92, .92, and .94 for PC Knowledge Scale, MOCS-A, PCPC, and PSA Anxiety Scale, respectively). Caution should be used when interpreting the Spanish internal consistency results as only nine participants in the current study completed the measures in Spanish. Reliability analyses excluded items from Spanish measures that had zero variance. Because many items from the Spanish IES-R had zero variance, a reliability coefficient was not computed.

Sample Description

Analyses were conducted with a sample of 71 men undergoing AS for the clinical management of prostate cancer. Participants were an average age of 65.40 years (*SD*= 7.85). Their ethnic distribution was 52% non-Hispanic White, 31% Hispanic, and 17% African American/Black. The majority of participants completed the assessment in English, with only 13% of assessments completed in Spanish. The participants were well



educated, with 55% of the sample having at least a 2-year college degree. The total combined family income of half of the sample was \leq \$49,999 per year, while the remaining 50% of the sample's was \geq \$50,000 per year. Approximately 60% of participants were married or in equivalent relationships. Participants had an average of 2.16 (*SD*= 2.30) medical comorbidities and approximately 78% reported access to healthcare. The mean number of months from PC diagnosis to the assessment date was 16.52 months (*SD*=23.04) and average PSA level within six months of the assessment was 5.76 ng/mL (*SD*= 5.77). See Table 1 for a complete list of descriptive statistics for sociodemographic, medical, and psychosocial variables.

Analysis of Covariates

Conceptually relevant control variables were tested to determine whether they were significantly related to the current study's outcome variables. Results indicated that PC knowledge was negatively associated with PSA Anxiety, r=-.23, p<.06. Although this was the only significant relationship between control and outcome variables, the current study included a conceptually relevant list of covariates based on the literature (i.e., age, medical comorbidities, time since diagnosis, access to healthcare, and PSA level within six months of the assessment). ANOVAs were conducted to determine whether psychosocial variables in the current study varied by ethnic group membership, partner status, education, and income. The results of the multiple ANOVAs indicated that mean levels of perceived stress management skills, PC-related psychosocial concerns, anxiety, and arousal did not vary as a function of ethnicity, relationship status, education, or income. Therefore, these variables were not included as control variables in subsequent analyses.



Analysis of Study Variables by Language

Various independent samples t-tests were conducted to evaluate whether the means of all continuous study variables of English-speaking participants significantly differed from those of monolingual Spanish-speaking participants. The results indicated that there were no differences between the two groups on any of the variables that were tested: Age t(68)=.34, p=.73; PSA level t(61)=1.09, p=.28; Time since diagnosis t(69)=1.77, p=.08; Medical comorbidities t(68)=.70, p=.48; PC knowledge t(68)=1.36, p=.18; Perceived stress management skills t(65)=.66, p=.51; PC psychosocial concerns t(58)=.94, p=.35; IES-R anxiety t(69)=.22, p=.83; PSA anxiety t(68)=.62, p=.54; Cortisol AUC_G t(6.14)=1.08, p=.32. Both groups exhibited comparable levels among all variables tested.

Multiple two-way contingency table analyses were conducted to test whether education, total combined family income, and partner status varied by primary language spoken (English or Spanish). Education was not found to significantly differ between English and non-English speakers, Pearson $\chi^2(4, N=71)=6.26, p=.18$, Cramér's V=.30. Partner status was also not found to significantly differ between English and non-English speakers, Pearson $\chi^2(3, N=70)=3.66, p=.30$, Cramér's V=.23. However, a significant relationship was found between income and language, Pearson $\chi^2(3, N=66)=8.19, p<$. .05, Cramér's V=.35. One hundred percent of monolingual-Spanish speakers earned a total combined family income of \leq \$49,999 compared to only 47% of English-speakers who earned \leq \$49,999. These findings suggest that the two groups had comparable levels of education and similar partner statues; however, were significantly different based on income.



Primary Analyses

All statistical analyses were run using the most current SPSS software (PASW Statistics 18.0).Significance was determined by a *p* level <.05 for the Beta coefficients of interest. All continuous covariates were included in all primary analyses regardless of whether they were significantly related to outcome variables or not. Control variables included in all analyses were: age, access to healthcare, medical comorbidities, time since diagnosis, PSA level within six months of the assessment, and PC knowledge. Mean substitution was used for missing values of all continuous variables (with the exception of cortisol AUC_G), as the percentage of missing values in each measure ranged from 1-7%. Specifically, the percent of missing values for all measures were: Charlson Comorbidities Index (1.4%), PC Knowledge Scale (2.8%), MOCS Part A (5.6%), PCPC (7.0%), IES-R (4.2%), and PSA Anxiety Scale (1.4%).

Specific Aim 1

Hypothesis 1a: Greater perceived stress management skills are significantly associated with less anxiety.

Hypothesis 1b: Greater perceived stress management skills are significantly associated with less cortisol AUC_G .

The first set of multiple linear regression analyses assessed whether greater levels of perceived stress management skills were associated with lower levels of anxiety/arousal. After controlling for relevant demographic, psychosocial, and medical variables, results indicated that perceived stress management skills were significantly associated with anxiety as measured by the IES-R (β = -.28, p< .04). However, perceived stress management skills were not significantly associated with PSA Anxiety (β = -.18, p>



.05) and cortisol AUC_G (β = .11, p> .05). The results suggest that greater perceived stress management skills are significantly related to lower anxiety as measured by the IES-R (see Table 2).

Specific Aim 2

Hypothesis 2: Greater perceived stress management skills are significantly associated with fewer PC psychosocial concerns.

The second set of statistical analyses evaluated whether greater levels of perceived stress management skills were associated with fewer PC psychosocial concerns. After controlling for relevant demographic, psychosocial, and medical variables, results indicated that perceived stress management skills were not significantly associated with PC-related concerns (β = -.02, p> .05). PC-related concerns, as measured by the PCPC, were not related to perceived stress management skills (see Table 3).

Specific Aim 3

Hypothesis 3a: Fewer PC psychosocial concerns are significantly associated with less anxiety.

Hypothesis 3b: Fewer PC psychosocial concerns are significantly associated with less cortisol AUC_G .

The third set of analyses examined whether fewer PC psychosocial concerns were significantly associated with less anxiety/arousal. After controlling for relevant demographic, psychosocial, and medical variables, results indicated that PC-related concerns were significantly associated with anxiety as measured by the IES-R (β = .61, p< .01) and PSA Anxiety Scale (β = .42, p< .01). However, PC-related concerns were not significantly associated with cortisol AUC_G (β = .28, p> .05). The results suggest that



fewer PC psychosocial concerns are significantly related to lower anxiety as measured by the IES-R and PSA Anxiety Scale (see Table 4).

Specific Aim 4

Hypothesis 4a: PC psychosocial concerns meditate the relationship between perceived stress management skills and anxiety.

Hypothesis 4b: PC psychosocial concerns meditate the relationship between perceived stress management skills and cortisol AUC_G .

The final analysis was conducted to test the hypothesis that PC psychosocial concerns mediated the relationship between perceived stress management skills and anxiety/arousal. Because the criteria for mediation were not met (i.e., the path between the predictor and mediator was not significant indicating a violation of criterion #2 in Baron and Kenny's mediation methodology), a mediation model was not tested.

Secondary Analyses

Test of Incremental Variance

Because a mediation model could not be tested due to the non-significant relationship between perceived stress management skills and PC concerns, an alternative model was evaluated. A hierarchical regression model was used to test incremental variance in the relationship between perceived stress management skills and IES-R with the inclusion of PC concerns. Incremental variance testing was only conducted for the relationship between perceived stress management skills and anxiety as measured by the IES-R as perceived stress management skills were not significantly associated with PSA anxiety or arousal. Results indicated that the inclusion of PC concerns (β = .60, p< .01) in



the model resulted in an additional 34% of the variance of IES-R anxiety explained, above and beyond control variables and perceived stress management skills, R^2 *change*= .34, F(1,62)= 39.24, p<.01 (see Table 5 and Figure 4).

Analysis of Specific Aims 1 and 3 using IES-R subscales

Perceived stress management skills and PC psychosocial concerns were both significantly associated with total IES-R anxiety. Exploratory analyses were conducted to examine whether these variables were significantly associated with specific IES-R subscales (i.e., Avoidance, Hyperarousal, and Intrusion). Greater perceived stress management skills were significantly associated with lower Hyperarousal (β = -.28, p<.03) and less Intrusion (β = -.27, p<.04). However, perceived stress management skills were not associated with Avoidance (β = -.16, p>.05). PC concerns were significantly associated to more Avoidance (β = .52, p<.01), Hyperarousal (β = .48, p<.01), and Intrusion (β = .54, p<.01). These findings suggest that perceived stress management skills and PC concerns are significantly related to various domains of IES-R anxiety.

Analysis of PC Psychosocial Concerns as a Moderator of the Relationship Between Perceived Stress Management Skills and Anxiety

Due to the non-significant relationship between perceived stress management skills and PC concerns, PC concern was tested as a moderator of the relationship between perceived stress management skills and anxiety/arousal instead of as a mediator. The outcomes that were included in the analyses were: IES-R Total anxiety, IES-R Avoidance, IES-R Hyperarousal, IES-R Intrusion, PSA Anxiety, and cortisol AUC_G). All of the analyses were conducted separately for the anxiety outcomes and the arousal



outcome as they consisted of different sample sizes (i.e., anxiety analyses had 71 participants and arousal analyses had 33 participants). In order to test the moderation effect of PC concerns on these relationships, separate hierarchical regression models were conducted for each outcome measure. Several steps were taken before conducting the regression analyses. The continuous predictor (perceived stress management skills) and continuous moderator (PC concerns) were centered at the mean to reduce collinearity. After perceived stress management skills and PC concerns were centered, an interaction term was created by multiplying the centered perceived stress management skills variable by the centered PC concerns variable. The variables were entered into separate hierarchical regression models (one for each dependent variable) in the following order: covariates in the first block, centered perceived stress management skills and centered PC concerns in the second block, and the interaction term in the third block.

The results of the hierarchical regression models indicated that PC concerns did not moderate the relationship between perceived stress management skills and IES-R Total anxiety (β = -.16, p> .05), IES-R Avoidance (β = .03, p> .05), IES-R Hyperarousal (β = -.13, p> .05), or PSA Anxiety (β = -.05, p> .05). The results were significant for IES-R Intrusion and cortisol AUC_G, indicating that PC concerns significantly moderated the relationship between perceived stress management skills and IES-R Intrusion and cortisol AUC_G. Specifically, the main effects and interaction accounted for approximately 47% of the variance in IES-R Intrusion, R^2 = .466. The interaction effect of perceived stress management skills and PC concerns was significant when controlling for the main effects, R^2 change= .08, F(1, 61)= 9.20, p< .01. In addition, the main effects and interaction accounted for approximately 39% of the variance in cortisol AUC_G, R^2 = .389.



The interaction effect of perceived stress management skills and PC concerns was significant when controlling for the main effects, R^2 change= .20, F(1, 23)= 7.63, p< .02. Post-hoc testing was conducted to test the significant moderation effects.

All post-hoc probing analyses were conducted separately for the IES-R Intrusion and cortisol AUC_G analyses. Procedures recommended by Holmbeck (2002) were used to conduct the following analyses. The first step in the post-hoc analyses was to compute a conditional moderator by creating two new scores: PC concerns one standard deviation above (+1SD) and below (-1SD) the mean. The second step was to create two new interaction terms, where +1SD PC concerns and -1SD PC concerns were each multiplied by the centered perceived stress management skills variable. The final step was to conduct separate hierarchical regression analyses for +1SD PC concerns (i.e., high PC concerns) and -1SD PC concerns (i.e., low PC concerns). Each regression analysis contained covariates and centered perceived stress management skills in the first block, +1SD (or-1SD) PC concerns, and the interaction between +1SD (or -1SD) PC concerns and centered perceived stress management skills in the second block.

Simple slope analyses revealed that when PC concerns were low (-1SD below the mean), perceived stress management skills did not predict IES-R Intrusion, β = -.05, t(70)= -.35, p>.05. When PC concerns were high (+1SD above the mean), perceived stress management skills were significantly negatively related to IES-R Intrusion, β = -.70, t(70)= -4.14, p< .01. Additionally, simple slope analyses indicated that when PC concerns were low (-1SD below the mean), perceived stress management skills did not predict cortisol AUC_G, β = -.34, t(32)= -1.35, p>.05. When PC concerns were high (+1SD below the mean), perceived stress management skills did not predict cortisol AUC_G, β = -.34, t(32)= -1.35, p>.05. When PC concerns were high (+1SD below the mean), perceived stress management skills did not predict cortisol AUC_G, β = -.34, t(32)= -1.35, p>.05. When PC concerns were high (+1SD below the mean) and predict cortisol AUC_G, β = -.34, t(32)= -1.35, p>.05. When PC concerns were high (+1SD below the mean) and predict cortisol AUC_G, β = -.34, t(32)= -1.35, p>.05. When PC concerns were high (+1SD below the mean) and predict cortisol AUC_G.



above the mean), however, perceived stress management skills were significantly positively related to cortisol AUC_G, β = .69, t(32)= 2.62, p< .02.

Exploratory Factor Analysis of PCPC

Follow-up analyses were conducted to assess whether items from the PCPC clustered into different factors. An exploratory factor analysis was used to determine whether there is a single dimension or multiple dimensions underlying the 25 PCPC items. The exploratory factor analysis was conducted using baseline data for all participants (N= 166) in the parent study (i.e., not limited to AS sample as in the current study).

The most current SPSS software version (PASW Statistics 18.0) was used to run the analyses. Principal Components Analysis was the extraction method used to determine the number of components (factors) underlying the measured variables (Green & Salkind, 2008). The factors were extracted in order from greatest amount of variability to least amount of variability among the items. The minimum eigenvalue, which refers to the variability of a factor, was set at a value of "1". All factors that had eigenvalues greater than "1" were retained. A total of five factors were extracted, accounting for approximately 69% of the variance. Next, the factors were rotated. An oblique rotation method was used in order to allow correlations among factors. The purpose of the rotation was to increase the interpretability of the factors.

The items that made up the five factors were evaluated to determine whether items loaded onto more than one factor. Three factors consisted of items that loaded exclusively to one factor (i.e., there were no second loadings for any of the items). However, two factors contained items that loaded onto more than one factor. To ensure



maximum interpretability, the factor analysis procedures were repeated while excluding items with multiple loadings to produce a final model where each item loaded onto only one of the factors. The final model resulted in the extraction of four factors, accounting for approximately 70% of the variance. The items in the four factors were examined to determine whether they made conceptual sense to load together. The final analyses omitted items 6, 8, 17, and 24 (see Table 6).

Factor 1 (Treatment Side Effect Concerns) tapped into issues regarding potential urinary and sexual dysfunction, as well as a sense of compromised masculinity (e.g., "That the treatment makes you less responsive sexually").Factor 2 (Social Rejection Concerns) was comprised of items related to possible isolation from family and friends (e.g., "That your friends will withdraw from you").Items that loaded on Factor 3 (Life and Premature Closure Concerns) were associated with premature death, fear of recurrence, and the inability to do the things one would like to do ("That you won't be able to go to places you want to go or do things you want to do"). Factor 4 (Financial Concerns) was made up of two items regarding job-related concerns (e.g., "That you won't be given the raises you deserve because of your illness"). None of the factors were significantly correlated with each other. The PCPC items, along with the results of the exploratory factor analysis, are listed in Table 6.

Analysis of Specific Aims 2 and 3 using PCPC Factors

Given that perceived stress management skills were not related to the PCPC composite score, follow-up analyses were conducted to test whether perceived stress management skills were associated with the PCPC factors. Further analyses were conducted to evaluate whether specific dimensions of the PCPC, in addition to the PCPC



composite score, were also associated with anxiety and arousal. The same procedures used to run the primary analyses were used to conduct the secondary analyses. The following analyses controlled for age, PSA level within 6 months of the assessment, time since diagnosis, medical comorbidities, access to healthcare, and PC knowledge.

Similar to the results of Specific Aim 2, post-hoc results indicated that perceived stress management skills were not significantly associated with Treatment Side Effect Concerns ($\beta = .07, p > .05$), Social Rejection Concerns ($\beta = .01, p > .05$), Life and Premature Closure Concerns(β = -.19, p> .05), or Financial Concerns (β = .05, p> .05; see Table 7). In addition, consistent with the results of Specific Aim 3, all four PCPC subscales were significantly associated with anxiety. Specifically, Treatment Side Effect Concerns were significantly associated with anxiety as measured by the IES-R (β = .53, p< .01) and the PSA Anxiety Scale (β =.35, p<.01; See Table 8). Social Rejection Concerns were significantly associated with IES-R anxiety (β = .39, p< .01) and PSA Anxiety (β = .30, p < .02; see Table 9). Additionally, Life and Premature Closure Concerns were significantly related to anxiety as measured by the IES-R (β = .54, p< .01) and by the PSA Anxiety Scale (β = .38, p< .01; see Table 10). Financial concerns were only significantly associated with IES-R anxiety (β = .40, p< .01) and were not related to PSA anxiety (β = .22, p > .05; see Table 11). However, none of the PCPC subscales were significantly related to arousal (Treatment Side Effect Concerns: β = .20, p> .05; Social Rejection Concerns: $\beta = .14$, p > .05; Life and Premature Closure Concerns: $\beta = -.01$, p > .05; Financial Concerns: $\beta = .19$, p > .05). Results from the post-hoc analyses indicate that perceived stress management skills were not significantly related to any of the PCPC



subscales, that all four PCPC subscales were significantly associated with anxiety, and that none of the PCPC subscales were significantly related to arousal.

Anxiety Levels: AS versus Active PC Treatment

Anxiety levels of men in the current study were compared to those of men from the larger NIH-funded study that had undergone active PC treatment (e.g., had received surgery or radiation therapy). An independent samples t-test was conducted to determine whether mean levels of IES-R total anxiety and PSA anxiety were significantly different among men undergoing AS (N=71) and those who had received active treatment (N=72). The results indicated that IES-R total anxiety was not significantly different between men on AS (M= 9.46, SD= 11.03) and treated men (M= 8.08, SD= 9.65), t(140)= 0.79, p=.21. PSA anxiety was also not significantly different between men on AS (M= 2.40, SD= 3.46) and treated men (M= 1.86, SD= 2.74), t(140)= 1.03, p=.30.

Self-report Anxiety versus Cortisol AUC_G Arousal

Additional analyses were conducted to further examine anxiety levels in the current study's sample. Results of the primary analyses indicated that perceived stress management skills and PC concerns were significantly associated with anxiety as measured by self-report psychosocial measures. However, none of those variables were associated with arousal as measured by cortisol <u>AUC_G</u>. Independent samples t-tests were conducted to compare the IES-R total anxiety and PSA anxiety levels of men who collected complete Day 2 saliva (N=34) to men who did not collect complete Day 2 saliva (N=37). The results indicated that men who collected saliva reported significantly higher IES-R total anxiety (M= 13.50, SD= 12.19) than men who did not collect saliva (M= 5.96, SD= 8.62), t(56)= 2.97, p<.01. However, there was no significant difference in



PSA anxiety between men who collected saliva (M= 0.19, SD= 3.14) and men who did not collect saliva (M= .17, SD= 3.97), t(69)= 0.41, p>.05.

Chapter 6: Discussion

The purpose of the current study was to examine psychosocial correlates of anxiety in men undergoing AS for the treatment of PC. The availability of PC screening techniques has led to an increase in the diagnosis of low-risk PC in younger men. Various effective treatment options are available for low-risk PC (e.g., radical prostatectomy and radiation therapy). However, they are all associated with compromises in disease-specific quality of life (e.g., urinary, bowel, and sexual dysfunction). Although men diagnosed with low-risk PC are candidates for these active treatments, surgery and radiation may not be appropriate for the risk these tumors pose. Schroeder et al. (2009) found that 1,410 men would need to be screened for PC and an additional 48 men would need to receive active treatment in order to prevent a single death. Due to the controversy associated with the overtreatment of PC, AS is becoming a more viable option for men with low-risk PC. AS serves as an alternative to immediate active treatment and is beneficial in that it delays the undesirable side effects of treatment until there is clinical evidence of progression. AS is also advantageous because it prevents men without clinical progression from ever receiving active treatment. AS is an aggressive type of clinical management with a curative intent that involves attending multiple doctor's appointments for PSA testing, DREs, and biopsies every year. The intensive, ongoing monitoring can be a stressful experience and may ultimately lead to greater psychological distress.

Living with active cancer has been associated with greater overall psychological distress, anxiety, fear of progression, and uncertainty (Barocas et al., 2008; Roemeling et al., 2006; Pickles et al., 2007). Specifically, PC screening, biopsy, follow-up PSA testing, and rising PSA levels have been associated with greater anxiety and elevated cortisol



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levels (Bisson et al, 2002; Dale et al., 2005; Kunkel et al., 2000). Although the purpose of AS is to delay treatment until there is clinical evidence of progression, one study found that approximately 25% of men undergoing AS received active treatment without evidence of disease progression when greater anxiety was reported (Patel et al., 2004).

The current literature provides support for medical correlates of increased distress and arousal (e.g., screening and biopsy procedures, PSA testing, and rising PSA levels; Bisson et al., 2002; Dale et al., 2005; Kunkel et al., 2000). However, a gap remains in understanding the psychosocial correlates of distress in this population. The current study aimed to contribute to the developing literature on the AS experience by examining potential correlates of anxiety/arousal that may promote better adjustment. The PC literature has supported the importance of stress management skills in survivors, as they have been associated with improved quality of life and mood, lower anxiety and depression, and have served as a buffer against the effects of stress (Faul et al., 2009; Penedo et al., 2003; Penedo et al., 2006). To this date, no study has examined the function of perceived stress management skills on the AS experience.

Based on Mishel's Uncertainty in Illness model, the current study proposed that men undergoing AS are exposed to elevated levels of illness-related uncertainty, which can lead to compromises in adjustment depending on how well one is able to manage the uncertainty and how one appraises the uncertainty (Mishel, 1988). The current study conceptualized ability to manage uncertainty as perceived stress management skills, appraisal of uncertainty as PC-related Concerns, and adjustment as anxiety/arousal. Previous studies have shown that men who undergo AS report several PC-related concerns, suggesting that there are multiple stressors associated with the AS experience



(van den Bergh, Essink-Bot, et al., 2009; Pickles et al., 2007). Some commonly reported areas of concern are fear of disease progression and potential future treatment side effects (Oliffe et al., 2009). The impact of perceived stress management skills and PC-related concerns on anxiety/arousal was examined in addition to the appraisal of PC-related concerns as a mediator of the relationship between perceived stress management skills and anxiety/arousal. The current study addressed several gaps in the literature by examining psychosocial correlates of anxiety/arousal in the understudied group of men undergoing AS, including an ethnically diverse sample, and using a quantitative (versus qualitative) measure of PC-related concerns.

Preliminary Analyses Findings

The first step involved conducting preliminary analyses to evaluate the extent to which anxiety/arousal measures varied as a function of ethnicity, education, income, and partner status. Preliminary analyses revealed that the psychosocial measures did not vary as a function of these sociodemographic variables and were not included in primary analyses. A possible explanation for the lack of significant differences in the sociodemographic and psychosocial variables is that in order to be a candidate for AS, men must be diagnosed with low-risk PC. Ethnic minorities tend to have higher rates of advanced stage disease at diagnosis compared to non-Hispanic White men (ACS, 2010). However, the ethnic minorities in the present study were all diagnosed with low-risk PC, distinguishing this sample from the typical population of ethnic minority PC survivors. In previous studies, research has shown that low-risk disease is associated with increased education, greater income, and better access to healthcare as men with a higher socioeconomic status are more likely to engage in screening procedures. This was



supported by the findings of the current sample. Approximately 50% of the sample earned greater than or equal to the median household income in the United States (i.e., \$49,777), 93% had greater than or equal to a high school education, and 78% had access to healthcare (DeNavas-Walt, Proctor, & Smith, 2010). Although the sample was ethnically diverse, there was limited variability among sociodemographic factors that may have contributed to a lack of significant differences among psychosocial variables.

Test of Study Hypotheses

The current study consisted of three aims. The first aim examined the relationship between perceived stress management skills and anxiety/arousal in men undergoing AS. The first hypothesis of the first aim (greater perceived stress management skills are significantly associated with less anxiety) was confirmed when anxiety was measured by the IES-R, but not when measured by the PSA Anxiety scale. The second hypothesis of the first aim (perceived stress management skills are significantly associated with arousal) was also not supported. This significant finding in the relationship between perceived stress management skills and IES-R anxiety suggests that one's perceived ability to manage challenging situations is related to fewer symptoms of intrusion, avoidance, and hypervigilance when faced with a stressful situation such as the AS experience. This finding is supported by previous studies that have reported on the beneficial effects of perceived stress management skills and provides an extension of prior work in PC literature by including men undergoing AS. The effects of perceived stress management skills have been examined in PC survivors who had previously received or were scheduled for active PC treatment, but no previous study has explored



their influence on PC survivors undergoing AS (Faul et al., 2009; Penedo et al., 2003; Penedo et al., 2006).

The second aim of the study was to examine the relationship between perceived stress management skills and PC psychosocial concerns in men undergoing AS. The hypothesis, which stated greater perceived stress management skills would be associated with fewer PC psychosocial concerns, was not supported. However, the direction of the non-significant relationship between the variables was in the expected (negative) direction. The lack of support for the hypothesis suggests that one's ability to manage stress and the appraisal of PC concerns are independent processes that may not influence each other. A possible explanation for the independent influences perceived stress management skills and PC concerns have on anxiety is that having confidence in dealing with difficult situations does not necessarily mean that concerns will not arise. It is possible for one to have tools to cope (e.g., have the ability to use muscle relaxation techniques and seek support when in need) and simultaneously experience concerns related to PC. Given that the ability to perceived ability to manage stress is not associated with concerns, other variables should be explored as protective factors against PC concerns.

The third study aim was to examine the relationship between PC psychosocial concerns and anxiety/arousal in men undergoing AS. The first hypothesis of the third aim was supported, where fewer PC psychosocial concerns were significantly associated with less anxiety as measured by the IES-R and the PSA Anxiety Scale. However, the relationship between PC concerns and arousal was not statistically significant. The results suggest that the more negative perceptions men have about issues related to a PC


diagnosis, the greater psychological distress that they will experience. These results expanded on the findings of a previous study, where results suggested that negative illness perceptions were associated with poorer emotional well-being in PC cancer survivors who had undergone radical prostatectomy or radiation therapy (Traeger et al., 2009). That study used the revised Illness Perception Questionnaire (IPQ-R) as a measure of PC perceptions (Moss-Morris et al., 2002). Although similar to the PCPC used in the current study, one of the differences is that the IPQ-R is comprised of global items related to illness, whereas as the PCPC contains items specific to PC. The current study extended those findings by using a more salient measure of the kinds of concerns a man diagnosed with PC experiences. Furthermore, the present study showed that illness-related concerns impact emotional well-being even before initiating active treatment.

The fourth aim of the study was to examine whether PC psychosocial concerns mediated the relationship between perceived stress management skills and anxiety/arousal in men undergoing AS. However, this hypothesis was not supported as mediation criteria were not met. Secondary analyses were conducted as alternatives to the mediation model (i.e., test of incremental variance and moderation test).

Secondary Analyses

Test of Incremental Variance

Since the relationship between perceived stress management skills and PC concerns was not statistically significant, a mediation analysis was not conducted. Instead, a hierarchical regression model was run to test whether PC concerns, in addition to perceived stress management skills, contributed a significant amount of variance of IES-R anxiety. The test of incremental variance was only conducted using IES-R anxiety



as an outcome, as perceived stress management skills were not related to either PSA anxiety or cortisol AUC_G. The results of the incremental variance analysis revealed that PC psychosocial concerns contributed a significant amount of the variance of IES-R anxiety, above and beyond control variables and perceived stress management skills. As expected, greater perceived stress management skills and fewer PC concerns were associated with that lower anxiety. Because perceived stress management skills remained a significant correlate of IES-R anxiety, the finding suggests that confidence in being able to manage stress and degree of PC-related concern are both related to lower psychological disturbance. However, degree of PC psychosocial concerns is not the mechanism by which greater self-efficacy in managing stress is promoting lower anxiety, but rather a measure that independently contributes to anxiety. The finding also implies that although perceived stress management skills did not play a significant role in their relationship with PC concerns, neither psychosocial factor should be ignored as both accounted for variance in anxiety levels.

IES-R Subscales

Follow-up analyses were conducted in order to assess whether specific domains of IES-R total anxiety were related to perceived stress management skills and PC concerns. Greater perceived stress management skills were significantly related to lower Hyperarousal and Intrusion. However, they were not significantly associated with avoidance. The findings suggest that one's ability to manage stress is more greatly associated with lower physiological arousal and fewer intrusive thoughts. In addition, PC concerns were positively associated with IES-R subscales where greater concerns were related to more avoidance, hyperarousal, and intrusive thoughts. The finding expands on



the significant relationship between PC concerns and IES-R total anxiety by indicating that each domain of IES-R is affected by how concerned one is.

It is important to note that although perceived stress management skills and PC concerns were significantly associated with various IES-R subscales, mean levels of Avoidance, Intrusion, and Hyperarousal were much lower compared to those found in a study conducted among men newly diagnosed with PC (Bisson et al., 2002). Mean levels of IES-R Avoidance, Intrusion, and Hyperarousal in the current study were .67 (SD= .79), .41 (SD= .61), and .27 (SD= .47), respectively, compared to 8.66 (SD= 7.67), 8.64 (SD= 6.87), and 3.80 (SD= 4.89) in the localized PC study. However, the current study's IES-R subscale scores were comparable to a sample of post-treatment rectal cancer survivors whose mean IES-R subscale scores ranged from 0.35 to 0.5 (Ristvedt & Trinkaus, 2009).

Test of Moderation

The aim of the current study was to examine whether PC concerns mediated the relationship between stress management skills and anxiety/arousal. However, the model was not supported and PC concerns were tested as a moderator instead of as a mediator. The significant interaction between perceived stress management skills and PC concerns provided a better explanation for how perceived stress management skills and anxiety/arousal were related to one another. The relationship between perceived stress management skills and anxiety/arousal were related to one another. The relationship between perceived stress management skills and anxiety/arousal were related to a function of the level of PC concerns. Specifically, the results indicated that at high levels of PC concern (+1SD), greater perceived stress management skills were significantly related to less intrusion and greater Cortisol AUC_G. At low levels of PC concerns (-1SD), the relationships between



perceived stress management skills and IES-R Intrusion/ cortisol AUC_G were nonsignificant.

The findings imply that only when men report greater PC-related concerns do perceived stress management skills aid in the minimization of intrusive thoughts about PC. However, the effect stress management skills on arousal were in the opposite expected direction, where greater confidence in one's ability to manage stress resulted in greater levels of arousal. The finding is inconsistent with results of previous studies, where participation in a CBSM intervention (that promotes perceived stress management skills) have been associated with less arousal (Antoni et al., 2009; Cruess et al., 2000; Phillips et al., 2008). The inconsistencies in the findings may be a result of the analyses being conducted with different samples. The IES-R Intrusion analyses consisted of the full AS sample, while cortisol AUC_G analyses consisted only of the participants that collected saliva, which translated to approximately half of the full sample.

Test of Study aims using PCPC Factors

Post-hoc analyses were conducted using the four factors derived from an exploratory factor analysis on the PCPC (i.e., Treatment Side Effect Concerns, Social Rejection Concerns, Life and Premature Closure Concerns, and Financial Concerns). The addition of the PCPC subscales to the analyses allowed for the examination of whether perceived stress management skills influenced specific areas of concern rather than a global concern score. The rationale for assessing the relationship between the variables was that appraisal of a situation is influenced by the coping resources one has to deal with the situation. In other words, the more confident one feels about handling a difficult situation, the fewer negative appraisals one will make.



The MOCS scale is comprised of a list of various stress management skills that that people may have and these skills were hypothesized to directly influence PCPC factors. For example, assertiveness skills (as measured by MOCS) may be particularly relevant as the ability to express one's needs to loved ones may reduce concerns in the PCPC Social Rejection concerns domain. Also, relaxation techniques and awareness of tension may be skills that lead to a reduction in number of Life and Premature Closure concerns as these concerns are most effectively relieved by using emotion-focused coping techniques such as progressive muscle relaxation or mental imagery. However, the post-hoc analyses that examined the relationship between perceived stress management skills and the four PCPC subscales resulted in null findings. These findings suggest that even when analyzing specific concerns, the construct of self-efficacy in stress management is not significantly related to any PC concern domain. These findings contrast those of a previous study that found lower levels of self-efficacy predicted greater negative illness appraisals and poorer quality of life at follow-up (Kershaw et al., 2008). The investigators of the longitudinal study used a self-efficacy measure that directly assessed how well PC survivors were able to manage cancer-related stress as opposed to the current study, which is not specific to cancer and refers to managing general stressful events. The current study may not have captured a direct link between perceived ability to manage stress and PC concerns as participants may have interpreted their ability to manage stress to a global extent (e.g., handling financial or work-related stress unrelated to PC). This implies that whereas PC survivors may feel confident about handling difficult situations, it does not necessarily mean that PC concerns are not evident.



The four derived PCPC subscales were also analyzed for their relationship with anxiety/arousal outcomes. Parallel to findings between the composite PCPC score and anxiety/arousal, all of the PCPC subscales, with the exception of Financial Concerns, were related to anxiety as measured by the IES-R and PSA Anxiety Scale. PCPC Financial Concerns were only significantly positively related to IES-R total anxiety. None of the PCPC factors were significantly associated with arousal. These findings provide further support for the relationship between concerns and anxiety, as greater concerns in all domains were indicative of greater intrusion, avoidance, and hyper reactivity as well as greater nervousness surrounding PSA testing. This finding suggests that men who are reporting greater anxiety may be at risk for heightened distress. Not all men may report concerns in every domain and these findings indicate that reporting greater concerns in at least one domain may lead to greater levels of distress in men undergoing AS. The findings of the current study provide clinical implications for the importance of the assessment of concerns that patients have about PC. Health care providers can pay a key role in addressing concerns that are associated with adjustment.

Anxiety Levels: AS versus Active Treatment

The anxiety levels of men undergoing AS in the current study were compared to those of men in the parent study who had received active treatment (e.g., radical prostatectomy or radiation therapy). Although there were no statistically significant differences in IES-R and PSA anxiety between the AS versus active treatment groups, the AS group reported marginally higher levels of anxiety. In a review examining the role of anxiety in men diagnosed and treated for cancer, Dale et al. (2005) reported that a score between eight and 19 on the IES-R indicated medium distress and a score above 35



indicated a high level of distress. The participants in the current study endorsed a medium level of overall anxiety, as the average IES-R total anxiety score was 9.46 (*SD*= 11.03). The current study replicated the findings of a previous study, which reported no statistically significant differences in the levels of psychological distress of men undergoing watchful waiting and those who underwent radical prostatectomy (Steineck et al., 2002). Steineck et al.'s study was conducted during a time period where watchful waiting was used interchangeably with AS. All participants undergoing watchful waiting were diagnosed with low-risk PC and would benefit from curative treatment if deemed necessary.

Self-Report Anxiety versus Cortisol AUC_G

Because different samples were used to conduct anxiety and arousal analyses, the IES-R total anxiety and PSA anxiety levels of men who collected saliva were compared to those of men who did not collect saliva to test whether anxiety levels were different among the two groups. The results indicated that the group that collected saliva reported significantly greater IES-R total anxiety than the group that did not collect saliva. This finding suggests that men with the highest levels of anxiety were the ones that collected saliva. Although anxiety levels were statistically different between the two samples, mean levels of anxiety within each group remained in the medium distress group (in the 8-19 range; Dale et al., 2005).

Implications

The results of the current study suggest that there is a role for stress management as it relates to anxiety in the AS experience. However, the proposed mechanism of PC



concerns explaining the relationship between perceived stress management skills and anxiety was not supported as perceived stress management skills were not associated with PC concerns. Instead, the current study found that PC concerns functioned as a moderator of the relationship between perceived stress management and anxiety/arousal. At high levels of PC concerns, greater confidence in one's ability to manage stress was related to less intrusion and greater arousal. This finding suggests that interventions aimed at improving perceived stress management skills in men undergoing AS should target men who report a high number of concerns as anxiety (in the form of intrusion) may be reduced in this group.

The study also provided evidence for significant positive relationships between PC psychosocial concerns and anxiety, indicating that men who had fewer concerns were less anxious. Levels of perceived stress management skills in the current study were comparable to those of men who participated in a CBSM intervention and underwent radical prostatectomy or radiation therapy for Stage I or II PC, where the mean MOCS score was 69.75 (SD= 14.73) for men in the current study and 63.02 to 63.6 (SD= 13.04 and 12.3, respectively) for men who underwent treatment (Penedo et al., 2004; Penedo et al., 2003). Furthermore, there were some similarities and differences that resulted from the PCPC factor analysis conducted in the current study compared to the PCBC factor analysis of the PCBC conducted by Spencer et al. (1999). Specifically, the factor analysis of the PCBC conducted for 67% of the variance, whereas the PCPC yielded four factors and accounted for 70% of the variance. Prostate cancer survivors in the current sample reported concerns about their sense of masculinity and sexual functioning as the largest area of



concern. In contrast, breast cancer survivors reported greatest concern about issues related to premature death and loss of independence. Both groups indicated social rejection concerns as moderately important.

Although longitudinal designs are needed to test the prospective association among the variables, the significant relationships between PC concerns (composite score and subscales) and anxiety as measured by the IES-R and PSA Anxiety Scale have several implications. The findings suggest that having fewer concerns about PC are associated with fewer intrusive thoughts, hypervigilance, and avoidance. Having control over concerns may protect men undergoing AS from becoming overly worried about any physical changes they may experience. For example, someone who is overly concerned about disease progression and life being cut short may be more likely to misinterpret changes in urinary or sexual functioning as a result of PC worsening compared to men who are in a different state of mind (Bailey et al., 2007). Being overly concerned about a particular issue can take a toll on emotional well-being as demonstrated in the current study.

Similar to the finding between PC concerns and IES-R anxiety, the directionality of the relationship between PC concerns (composite score and subscales) and PSA anxiety, can only be determined by conducting a longitudinal design. However, one argument in favor of concerns predicting PSA anxiety is that the more PC-related concerns one has, the more salient the PSA testing becomes. PSA testing is a major part of the AS experience, as men typically undergo testing every three months for the first two years post-diagnosis and every six months after that (AUA 2007; Soloway et al., 2007). Perhaps men who are highly concerned about PC are most likely to experience



anxiety surrounding the PSA test since the testing may confirm their concerns. In a scenario where a man is overly concerned about potential side effects of treatment and how he will be able to cope with quality of life decrements should he need active treatment, PSA testing may bring about a heightened anxiety level because of the implications it has for him. In a different scenario, a man who is not overly concerned about his illness may interpret PSA testing simply as information. In the first scenario, the concerns may serve as triggers to anxiety, whereas in the second scenario, the triggers are absent. Whether PC concerns are related to potential treatment side effects, social rejection, or general life issues, upcoming PSA tests may result in greater anxiety in specific areas (Ercole et al., 2008; Carlsson et al., 2007).

Limitations

As with all cross-sectional studies, caution should be taken when interpreting results as causal relationships cannot be determined. Future studies should examine the relationship between perceived stress management skills, PC psychosocial concerns, and anxiety/arousal using longitudinal designs in order to verify the directionality of the relationship among these variables. A further source of caution in interpreting the results of the current study is the use of mean substitution for missing data. Although the percentage of missing data for each variable was low (ranged from 0% to 7% missing), mean substitution of missing data may alter the value of correlations by decreasing the variability of scores (Kline, 2005).

Although the study contributed some information about the psychosocial experience of men undergoing AS, there were several limitations that should be



addressed. One of the limitations in the current study was that no information was collected regarding the treatment decision process. Specifically, whether the decision was made by the doctor or by the patient is undetermined and the treatment options that were offered to the patients were also unknown. Gaining a broader perspective of the treatment decision process is helpful as it may provide insight into individual factors that may lead some PC survivors to undergo AS, while others choose to undergo immediate active treatment. Another limitation was that no information was collected regarding the time since the participants' last PSA test, time to upcoming PSA test, and number of PSA tests prior to entering the study. According to the AUA, men undergoing AS are recommended to undergo PSA testing every three months for the first two years post-diagnosis and every six months thereafter. Future studies should examine treatment compliance in men undergoing AS in the context of anxiety to determine whether men who report greatest levels of anxiety are the same men that do not adhere to treatment recommendations, as it may be possible that greater number of PSA tests leads to less anxiety. However, the current study did account for time since diagnosis, as men undergoing AS and other cancer survivors have reported higher levels of anxiety with greater time since diagnosis (e.g., Burnet et al., 2007; Lintz et al., 2003; Parker et al., 2003). In the current study, time since diagnosis was not significantly related to anxiety/arousal. A possible explanation for the null finding is that the majority of the participants in the current study were diagnosed within six months compared to other studies that have examined elevated anxiety levels in cancer survivors greater than one year post-diagnosis (Burnet et al., 2007; Lintz et al., 2003).



Despite the ethnically diverse sample used in the current study, which included monolingual English, monolingual Spanish, and bilingual participants, the sample size of monolingual Spanish speakers was very small, making it difficult to draw conclusions about this group. Future studies should examine the psychosocial correlates of anxiety as they apply to members of this group. The current study lacked information about the number of monolingual Spanish speakers who chose AS versus the number of monolingual Spanish speakers who were offered AS as a treatment. The vast majority of the sample was English speaking, suggesting that there may be a barrier to choosing AS in monolingual Spanish speakers. One of the factors that may have contributed to the low number of monolingual Spanish speakers undergoing AS is a language barrier created by having a monolingual English speaking urologist. The vast majority of the urologists from whose clinics participants were recruited from were monolingual English speakers. The inability to express concerns, ask questions, and have them answered in detail may deter some patients from choosing AS.

Additionally, the current study's findings on the relationship between perceived stress management skills, PC concerns, and anxiety/arousal are limited to men who are undergoing AS. The generalizability of the findings to men who have received active treatment is unknown as none of the participants in the current study had ever received active treatment. Men who receive active PC treatment are also subjected to follow-up PSA testing and biopsies, which may cause anxiety about the possibility of recurrence (Dale et al., 2005). However, the psychological experiences of actively treated survivors versus those that are undergoing AS are very different. PC survivors that undergo curative, active treatment are left with the burden of disease-specific quality of life



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decrements, while men who undergo AS have the burden of an impending treatment that may affect various areas of functioning (Penson et al., 2008; Roth et al., 2008; Steineck et al., 2002). Whereas treated men are aware of PC treatment-related consequences, men who undergo AS suffer with the uncertainty of what is to come. Managing anxiety is essential in the AS experience in order to maximize the benefits of this type of clinical management. Elevated levels of anxiety in men undergoing AS may place them at greater risk for engaging in maladaptive coping strategies such as skipping appointments and ultimately lead to the receipt of unnecessary treatment (Latini et al., 2007). Given the major issue in the AS experience of receiving unnecessary treatment, a further limitation in the current study is that it did not account for anxiety as a predictor of unnecessary treatment. The limitation was due to the cross-sectional design of the study, which did not allow for the evaluation of whether increased anxiety was predictive of treatment without evidence of clinical progression.

Limitations of Measures

The current study used Mishel's Uncertainty in Illness model as a framework to test the relationship between perceived stress management skills, PC psychosocial concerns, and anxiety/arousal. The Uncertainty in Illness model proposes that uncertainty occurs when patients lack sufficient information to draw conclusions about their illness (Mishel, 1998). There are two primary sources of uncertainty for PC survivors who undergo AS (Oliffe et al., 2009; Bailey et al., 2011). The first source of uncertainty results from the asymptomatic nature of low-risk PC, where men are living with an active cancer for which they do not experiences any symptoms. Men who undergo AS are diagnosed with low-risk tumors that are most often are not accompanied by symptoms



commonly found in more advanced stages (e.g., urinary or sexual dysfunction; ACS, 2010). The second major source of uncertainty in men undergoing AS results from the monitoring strategies (i.e., PSA tests and DREs) physicians use to detect disease progression, which lack information about tumor aggressiveness (ACS, 2010). The uncertainty associated with the AS experience is offset by the immediate benefits of delaying active treatment-related impairments in quality of life. The current study lacked an accurate measure of uncertainty, which is a central component to the Uncertainty in Illness model. The incongruence between the measure commonly used to assess illness uncertainty (i.e., Mishel Uncertainty in Illness Scale; MUIS-C; Mishel, 1981) and the measure used in the current study (i.e., PCPC) may have led to the lack of support for the proposed mediation model.

PCPC

The PCPC, conceptualized as a measure of illness uncertainty, did not accurately assess uncertainty as described by Mishel. Specifically, the PCPC assessed how concerned men were about future threats, such as compromises in sexual functioning and social/family well-being instead of assessing current uncertainty as measured by the MUIS-C (Mishel, 1981). The MUIS-C is comprised of 23 items that tap into present ambiguity and unpredictability of AS. Sample items from the MUIS-C include: "Because of the treatment, what I can do and cannot to keeps changing", "I have a lot of questions without answers", and "I am unsure if my illness is getting better or worse". The PCPC did include these types of uncertainties and instead focused on future-oriented issues. In addition, the Uncertainty in Illness model also proposes that uncertainty can be appraised as an opportunity or as a danger and the PCPC did not assess for any opportunity



appraisals such as, flexibility in future treatment options and low-perceived cancer threat (Bailey et al., 2007).

MOCS-A

The current study used a composite score of the MOCS- A to measure perceived stress management skills. The MOCS-A has four subscales (i.e., relaxation, awareness of tension, assertiveness about needs, and confidence in using adaptive coping strategies), which were not examined in the current study. Although specific MOCS-A subscales may have been more closely related to certain domains of the PCPC (e.g., assertiveness about needs associated with Social Rejection Concerns), the high internal consistency of the MOCS-A items revealed that the measure was most likely one-dimensional. The various PC concerns require different sets of skills in order to manage them effectively. Therefore, the perceived stress management skills were conceptualized as one construct. The MOCS-A composite score has been shown to be significantly associated with increased quality of life, benefit finding, and positive mood in men treated for PC (Penedo et al., 2006; Penedo et al., 2004; Penedo et al., 2003).

PSA Anxiety Scale

There were a few limitations regarding the measure used to assess PSA anxiety in the current study. The PSA Anxiety Scale was comprised of a total of four items that may not represent an accurate assessment of PSA-related anxiety. Two items in the scale contained wording that may lead men not to endorse the item. For example, one item states "I get a sort of frightened feeling like butterflies in the stomach when I think of my PSA test". Although many men experience symptoms of anxiety prior to PSA testing, they may be unlikely to describe their feelings in that manner. The PSA Anxiety scale



was derived from the Anxiety subscale of the HADS measure. However, results from the current study are not comparable to results from studies using the HADS to assess anxiety as the current study only used four out of the seven items. Therefore, the PSA anxiety levels reported in the current study cannot be compared to any published study as the PSA Anxiety Scale used in the current study has never been used in the past. The scale that has traditionally been used is the Memorial Anxiety Scale for Prostate Cancer (MAX-PC; Roth et al., 2003). The MAX-PC is comprised of 3 subscales assessing general PC anxiety, PSA anxiety, and fear of recurrence. Future studies should explore psychosocial correlates of anxiety using this scale as it may be a more accurate measure of PSA anxiety.

Cortisol

There were also several limitations in saliva collection, which affected the arousal measure by limiting analyses to a very small sample size. Ideally, cortisol AUC_G would have been calculated for Day 1 and Day 2 separately and the two results would have been correlated to determine whether the results of Day 1 were significantly associated with Day 2 results. A significant correlation between both days would have provided support for a reliable measure of arousal and the average cortisol AUC_G would have been calculated to use in the current study. Some examples of the saliva collection limitations that prevented using an average measure of cortisol AUC_G were that participants forgot to collect saliva on the first day, skipped time points during each day, and used incorrect methods to collect samples (e.g., did not use the provided cotton swab to collect saliva). For these reasons, more than half of the participants in the current study were excluded from the cortisol AUC_G analyses. The small sample size may explain the null arousal



results in the study since there may not have been enough power to detect an effect. Another reason for the null results may be that arousal in the current study was assessed irrespective of upcoming PSA tests, DREs, and biopsies, which have been found to be associated with elevated levels of arousal. Interestingly, one study found that participants' serum cortisol levels returned to baseline after receiving their results, regardless of the whether their biopsy results were positive or negative (Gustafson et al., 1995). Future studies should examine salivary cortisol levels in men receiving AS immediately before an upcoming PSA test, DRE, or biopsy or before receiving results in order to determine whether the previous findings can be replicated in this type of sample. Future studies should also consider exploring additional indices of cortisol, other than cortisol AUC_G, that may play a role in the stress response. Some examples of alternative indices of cortisol include: area under the curve with respect to increase (AUC₁), area under the curve with respect to baseline (AUC_B), peak cortisol, and slope from baseline to peak (Fekedulegn et al., 2007).

Future Directions

Future research should use the findings of the current study as a foundation to continue to explore the psychosocial experience of men undergoing AS. A couple of areas that remain to be explored in this population are treatment adherence and coping style. Treatment adherence is an important measure to consider as anxiety may prevent proper care (i.e., attending appointments regularly). AS is only effective when men adhere to the recommended screening schedule to monitor disease progression so that active treatment may be initiated at an appropriate time (if necessary). Similarly, men's



choice of coping strategies are also important factors in understanding the outcomes of PC since flexible use of coping techniques may lead to more positive psychosocial functioning. Due to the nature of AS, men who choose to undergo this type of treatment have various demands that require a broad range coping techniques. For example, adhering to treatment recommendations may require more problem-focused strategies, such as coming up with a plan about what to do. On the other hand, dealing with the uncertainty associated with living with an active cancer may best be dealt with by using emotion-focused techniques, such as relaxation exercises. The better the match between the demand a person experiences and the coping techniques one uses, the better the outcome.

Ultimately, the purpose of the present study was to determine the correlates of anxiety, as anxiety is often a predictor of unnecessary treatment. Although the current study provided novel information on the AS psychosocial experience, future studies should include time to active treatment as an outcome measure. With the increase in screening procedures and over diagnosis of indolent disease, it is beneficial for men to remain on AS for as long as clinically indicated. Researchers should conduct follow-up studies using a longitudinal design to determine whether greater perceived stress management skills at baseline result in lower anxiety/arousal and a significant reduction in unnecessary treatment at follow-up. Such a study would provide support for an intervention aimed at improving stress management skills in men who choose to undergo AS and promote optimal well-being.



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Appendix

Prostate Cancer Knowledge Scale

Directions: Please indicate whether the statements below are *true*, *false*, or if you *do not know* the answer.

1. Prostate cancer is the most common cancer, excluding skin cancer, in men living in the U.S.

2. White men are more likely to have prostate cancer than are African-American men.

3. Prostate cancer is the eighth leading cause of cancer death in U.S. men

4. One in six men will be diagnosed with prostate cancer.

5. African-American men are twice as likely to die of prostate cancer compared to white Men.

6. Prostate cancer is more common in Asia than in North America or Europe.

7. The prostate gland produces sperm.

8. In healthy men, the normal range for Prostate-specific antigen (PSA) is 0.0 to 4.0.

9. A Gleason score indicates how large a prostate cancer tumor is.

10. "Active Surveillance" refers to waiting for the lab to send your PSA results.

11. More than 70% of all prostate cancers are diagnosed in men over the age of 65.

12. After prostate cancer treatment, men are unable to have a sexual orgasm (climax).

13. Having a father or brother with prostate cancer doubles a man's risk of developing prostate cancer.

14. African American men should begin screening for prostate cancer at age 65.

15. Your PSA level can only be taken from a sample of blood.

16. Men who have a history of a prostate infection are more likely to develop prostate cancer than men who have never had an infection.

17. It is possible to have prostate cancer even if a man does not have any symptoms.

18. Prostate cancer is more common in 50-year-old men than in 70-year-old men.

19. Radiation treatment for prostate cancer causes a man's head hair to fall out.

20. Doctors are sure that screening will prevent men from dying of prostate cancer.

21. If a man weighs 180 pounds about 30% percent of his food calories should be from fat.

22. Rectal examination and a PSA test is the best method for detecting prostate cancer.

23. For a man with early stage prostate cancer, active surveillance may be equal to surgery or radiation treatment.

24. Compared to prostate cancers detected without screening, the prostate cancers detected by screening are more likely to be curable.

25. Normal erections may return in some men with prostate cancer who undergo surgery to remove the prostate.



26. Eating red meat is more likely to increase a man's risk of developing prostate cancer than eating chicken.

27. Eating tomatoes may help prevent the development of prostate cancer.



Measure of Current Status (MOCS)—Part A

Directions: People have different levels of various skills for responding to the challenges and demands of everyday life. The following items list several things that people are able to do—to a greater or lesser degree—to deal with daily stresses. For each item, indicate how well you *currently can do what it describes*. Please don't tell us what you think you *should* be able to do, or what you *wish* you could do. Be as accurate as you can in reporting your degree of confidence about being able to do each of these things. Choose from the following responses:

I = I cannot do this at all; 2 = I can do this just a little bit; 3 = I can do this a medium amount; 4 = I can do this pretty well; 5 = I can do this extremely well

- 1. I am able to use muscle relaxation techniques to reduce any tension I experience.
- 2. I am able to use mental imagery to reduce any tension I experience.
- 3. I become aware of any tightness in my body as soon as it develops.
- 4. I can easily recognize situations that make me feel stressed or upset.
- 5. I notice right away whenever my body is becoming tense.
- 6. I am aware of the stream of thoughts that pass through my mind as events occur.
- 7. Whenever I get negative, I re-examine my thoughts to gain a new perspective.
- 8. I can keep my thoughts positive even during negative times.
- 9. I can express my anger in a balanced and reasonable manner.
- 10. If I get angry, I can express it openly without overdoing it.
- 11. When problems arise I know how to cope with them.
- 12. It's easy for me to decide how to cope with whatever problems arise.
- 13. I am confident about being able to choose the best coping responses for hard situations.
- 14. It's easy for me to go to people in my life for help or support when I need it.
- 15. I can ask people in my life for support and assistance whenever I need it.
- 16. I can clearly express my needs to other people who are important to me.
- 17. I can go to a safe place in my mind where I feel at peace.
- 18. I can change from day-to-day worries to having a sense of quiet, when I want to.
- 19. I can quiet my mind when I want to.
- 20. I am able to concentrate fully.



Profile of Concerns About Prostate Cancer (PCPC)

Directions: When a serious illness strikes, there are many sorts of things that go through a person's mind, many concerns that arise. I want to ask you about a long list of concerns that sometimes go through people's minds when they're being treated for the problem that you are being treated for. For each of these issues, I want you to tell me how concerned you are about this issue. How much does this issue bother you when you think about it? Answer for how you feel right now, not at the moment you found out you had the disease, but today, and for the last few days. Choose from the following responses:

l = *Not at all concerned; 2*= *Somewhat concerned; 3*= *Neutral*—*neither concerned or not concerned; 4*= *Mostly concerned; 5*= *Very concerned*

- 1. That you may die soon.
- 2. That you won't be able to go places you want to go and things you want to do.
- 3. That you will always feel physically damaged from this disease.
- 4. That your life with your partner will be cut short.
- 5. That the cancer may come back.
- 6. That you won't be able to have children.
- 7. That you won't see your children or grandchildren grow up.

8. That your partner (or a potential new partner) will reject you because of the cancer or your treatment.

- 9. That your children will become more distant from you.
- 10. That your family will become angry with you.
- 11. That you will argue more with partner.
- 12. That your friends will withdraw from you.
- 13. That people at work won't want to interact with you.
- 14. That your friends will act as though your disease is contagious.

15. That you won't be able to get a better job (or be promoted) if they know you had cancer.

- 16. That you won't be given the raises you deserve because of your illness.
- 17. That the bills from the treatment will be overwhelming.
- 18. That your treatment will make you sick.
- 19. That your treatment will damage your body in some way.
- 20. That the treatment will cause you to leak urine.
- 21. That the treatment will make you feel less masculine.
- 22. That the treatment will make you less desirable sexually to your partner.
- 23. That the treatment makes you less responsive sexually.
- 24. That you won't be able to support your family as well as you have up until now.

25. That you won't be able to satisfy your sexual partner as well as you have up until now.



Impact of Event Scale-Revised (IES-R)

Directions: Below is a list of difficulties made by people after stressful life events. Please check each item, indicating how frequently these comments were true <u>during the past</u> seven days with respect to your prostate cancer. How much were you distressed or bothered by these difficulties. If they did not occur, please mark "not at all". Choose from the following responses:

0 = Not at all; 1 = A little bit; 2 = Moderately; 3 = Quite a bit; 4 = Extremely

- 1. Any reminder brought feelings about it.
- 2. I had trouble staying asleep.
- 3. Other things may make me think about it.
- 4. I felt irritable and angry.
- 5. I avoided letting myself get upset when I thought about it or was reminded of it.
- 6. I thought about it when I didn't mean to.
- 7. I felt as if it hadn't happened or wasn't real.
- 8. I stayed away from reminders about it.
- 9. Pictures about it popped into my mind.
- 10. I was jumpy and easily startled.
- 11. I tried not to think about it.
- 12. I was aware that I still had a lot of feelings about it, but I didn't deal with them.
- 13. My feelings about it were kind of numb.
- 14. I found myself acting as though I were back at that time.
- 15. I had trouble falling asleep.
- 16. I had waves of strong feelings about it.
- 17. I tried to remove it from my memory.
- 18. I had trouble concentrating.
- 19. Reminders of it caused me to have physical reactions (sweating, trouble breathing, nausea, or a pounding heart).
- 20. I had dreams about it.
- 21. I felt watchful and on-guard.
- 22. I tried not to talk about it.



PSA Anxiety Scale

Directions: This questionnaire is designed to help us know how you feel. Read each item and place a firm tick in the box opposite the reply, which comes closest to how you have been feeling in the past week.

- Have you had your PSA tested in the past week?
 0 = No
 1 = Yes
- 2) When was the date of your last PSA test?
- 3) What was your PSA value the last time your PSA level was tested?
- 4) I feel tense or wound up about my PSA test:
 - 0 = Not at all
 - 1 = Time to time, occasionally
 - 2 = A lot of the time
 - 3 = Most of the time
- 5) I get a sort of frightened feeling as if something awful is about to happen when my PSA level is tested:
 - 0 = Not at all
 - 1 = A little, but it doesn't worry me
 - 2 =Yes, but not too badly
 - 3 = Very definitely and quite badly
- 6) Worrying thoughts go through my mind about PSA tests:
 - 0 = Not at all
 - 1 = Only occasionally
 - 2 = From time to time, but not too often
 - 3 = A lot of the time
 - 4 = A great deal of the time
- 7) I get a sort of frightened feeling like "butterflies" in the stomach when I think of my PSA test:
 - 0 = Not at all
 - 1 = Occasionally
 - 2 =Quite often
 - 3 =Very often



Table 1

Descriptive Statistics for Sociodemographic, Medical, and Psychosocial Variables

Total Sample (N=7)	71) Mean	SD
Age (years)	65 40	(7.85)
Time since diagnosis (months)	16.52	(23.04)
PSA level at baseline (ng/mL)	5 76	(5.77)
Medical co-morbidity	2.16	(2.32)
PC Knowledge	14.24	(4.81)
MOCS-A Perceived Stress Management Skills	69.75	(14.73)
PCPC PC psychosocial concerns	41 27	(15.93)
IES-R Total Anxiety	9.46	(11.35)
Cortisol AUC _G (μ g/dL; <i>N</i> =33)	2.53	(0.26)
Ethnicity	N	Dorcontago
Non-Hispanic White	27	52 10%
Hispanic	22	31.00%
A frican American/Black	12	16.90%
Antan Antician/ Diack	12	10.9070
Primary Language		
English	62	87.32%
Spanish	9	12.68%
Partner status		
Single, never married	10	14.08%
Married/equivalent relationship	42	59.15%
Separated/Divorced	12	16.90%
Widowed	6	8.45%
(Missing)	(1)	(1.41%)
Education (highest degree earned)		
Less than high school	5	7.00%
High school diploma or equivalent	27	38.00%
Associate degree or 2-year technical degree	12	16.90%
Bachelor's degree	19	26.80%
Graduate degree	8	11.30%
Total combined family income		
\leq \$24,999	19	26.76%
\$25,000 - \$49,999	16	22.53%
\$50,000 - \$99,999	16	22.53%
\geq \$100,000	15	21.13%
(Missing)	(5)	(7.04%)
Access to healthcare		
Yes	50	70.42%
No	14	19.72%
(Missing)	(7)	(9.86%)



الم للاستشارات	Table 2 Hierar	2 vchical Regression Analysis of the Relationship Betwee	en Percei	ved Stress	s Management S	kills and IES-R Anx	iety		
iKI	Step	Factor	\mathbb{R}^2	$\mathrm{R}^{2}\Delta$	F for $\mathbb{R}^2\Delta$	Significance F\Delta	β	<i>p</i> value	N=71
		Age PSA level Time since diagnosis Medical Comorbidities	.06	90.	.73	.63	24 .17 05	00 19 85 85 85 85	
	7	Access to Healthcare PC Knowledge Perceived Stress Management Skills	.13	.07	4.86	.03	10 10 28	.42 .41 .03	
	Hierar	rchical Regression Analysis of the Relationship Betwee	en Percei	ved Stress	s Management S	kills and PSA Anxie	ty		
		Age PSA level Time since diagnosis	.37	.13	1.66	.14	31 .24 .05	.03 .06 .70	
	7	Medical Comorbidities Access to Healthcare PC Knowledge Perceived Stress Management Skills	.40	.03	2.07	.16	.04 04 18 18	.71 .74 .02 .15	

Table 2 (continued)

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Hierarchical Regression Analysis of the Relationship Between Perceived Stress Management Skills and Cortisol AUC_G

Step	Factor	\mathbb{R}^2	${ m R}^2\Delta$	F for $\mathbb{R}^2\Delta$	Significance F\Delta	β	<i>p</i> value	N=33
-	Age PSA level Time since diagnosis Medical Comorbidities	.11	.11	.53	.78	.10 25 .02 09		
7	Access to Healthcare PC Knowledge Perceived Stress Management Skills	.12	.01	.29	.59	10 .24 .11	.64 .31 .59	
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	Hieraı	rchical Regression Analysis of the Relationship Between	n Percei	ved Stres.	s Management Si	cills and PC Psycho	social C	oncerns	
ikl	Step	Factor	\mathbb{R}^2	${ m R}^2\Delta$	F for $\mathbb{R}^2\Delta$	Significance FA	β	<i>p</i> value	N=71
	-	Age	.27	.07	.85	.54	20	.16	
		PSA level					.12	.38	
		Time since diagnosis					.19	.17	
		Medical Comorbidities					.10	.44	
		Access to Healthcare					.02	.85	
		PC Knowledge					16	.22	
	7	Perceived Stress Management Skills	.27	00 [.]	.03	.86	02	.86	

Hieran	chical Regression Analysis of the Relationship Betweer	i PC Psy	vchosocia	il Concerns and II	ES-R Anxiety			
Step	Factor	\mathbb{R}^2	${ m R}^2\Delta$	F for $\mathbb{R}^2\Delta$	Significance FA	β	<i>p</i> value	N=71
-	Age PSA level Time since diagnosis Medical Comorbidities	.06	.06	.73	.63	04 .08 13 06	.70 .48 .53 .53	
7	Access to Healthcare PC Knowledge PC Psychosocial Concerns	.41	.34	36.48	00	15 02 .61	.15 .82 .00	
Hieran	chical Regression Analysis of the Relationship Between	PC Psy	chosocie	ul Concerns and P	SA Anxiety			
Ц	Age PSA level Time since diagnosis	.13	.13	1.66	.14	18 .18 01	.15 .12 .94	
7	Medical Comorbidities Access to Healthcare PC Knowledge PC Psychosocial Concerns	.29	.16	14.22	00	.02 07 23 .18	.89 .52 .00	

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Table 4 (continued)

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Hierarchical Regression Analysis of the Relationship Between PC Psychosocial Concerns and Cortisol AUC_G

Step	Factor	\mathbb{R}^2	${ m R}^2\Delta$	F for $\mathbb{R}^2\Delta$	Significance F\Delta	β	<i>p</i> value	N=33
-	Age PSA level Time since diagnosis Medical Comorbidities Access to Healthcare	.11	.11	.53	.78	.13 30 .03 21	.55 .16 .31 .31	
5	PC Knowledge PC Psychosocial Concerns	.18	.07	2.00	.17	.25	.17	

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Hierarchical Regression Test of Incremental Variance in the Relationship Between Perceived Stress Management Skills, PC Psychosocial Concerns, and IES-R Anxiety

Step	Factor	\mathbb{R}^2	$\mathrm{R}^2\Delta$	F for $\mathbb{R}^2\Delta$	Significance FA	β	<i>p</i> value	N=71
-	Age	90.	90.	.73	.63	11	.31	
	PSA level					.10	.33	
	Time since diagnosis					16	.11	
	Medical Comorbidities					08	.40	
	Access to Healthcare					11	.24	
	PC Knowledge					01	.93	
2	Perceived Stress Management Skills	.13	.07	4.86	.03	26	.01	
ŝ	PC Psychosocial Concerns	.47	.34	39.24	00 [.]	.60	00 [.]	

Item		Factor Loading
Factor 1: Treatment Side Effect Con	cerns	
23. That the treatment makes you less responsive sexually.	.890	
21. That the treatment will make you feel less masculine.		.878
20. That the treatment will cause you to leak urine.		.836
25. That you won't be able to satisfy your sexual partner as well as you have up until now.		.814
19. That your treatment will damage your body in some way.	.808	
22. That the treatment will make you less desirable sexually to your partner.	.741	
18. That your treatment will make you sick.		.628
Factor 2: Social Rejection Concer	rns	
13. That people at work won't want to interact with you.		.907
10. That your family will become angry with you.		.873
14. That your friends will act as though your disease is contagious.		.848
12. That your friends will withdraw from you.		.840
9. That your children will become more distant from you.		.803
11. That you will argue more with partner.		.745



Item	Factor Loadings
Factor 3: Life and Premature Closure Concerns	
2. That you won't be able to go places you want to go and do things you want to do.	759
4. That your life with your partner will be cut short.	758
1. That you may die soon.	724
7. That you won't see your children or grandchildren grow up.	673
3. That you will always feel physically damaged from this disease.	656
5. That the cancer may come back.	643
Factor 4: Financial Concerns	
15. That you won't be able to get a better job (or be promoted) if they know you had cancer.	.829
16. That you won't be given the raises you deserve because of .790 your illness.	

Hierar	chical Regression Analysis of the Relationship Between	Perceiv	ed Stress	Management Skil	ls and Treatment	Side Effe	ect Concerns	
Step	Factor	\mathbb{R}^2	${ m R}^2\Delta$	F for $\mathbb{R}^2\Delta$	Significance F∆	β	<i>p</i> value	N=71
_	Age PSA level Time since diagnosis Medical Comorbidities	.07	.07	.86	.53	-24 .13 .11 .10	. 10 . 10 . 10 . 10 . 10 . 10 . 10 . 10	
7	Access to Healthcare PC Knowledge Perceived Stress Management Skills	80.	00.	.30	.59	.13 10 .07	.51 .41 .59	
Hierar	chical Regression Analysis of the Relationship Between	Perceiv	ed Stress	Management Skil	ls and Social Rej	ection Co	ncerns	
	Age PSA level Time since diagnosis	90.	90.	.73	.62	.03 .01 .01	.53 .92 97	
2	Access to Healthcare PC Knowledge Perceived Stress Management Skills	90.	00.	00.	96.	-00- -04 01 01	.78 10 96	

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Hierar	chical Regression Analysis of the Relationship Between	Perceiv	ved Stress	. Management Ski	lls and Life/Prem	ature Clo	sure Concerns	
Step	Factor	\mathbb{R}^2	$\mathbb{R}^{2}\Delta$	F for $\mathbb{R}^2\Delta$	Significance FA	β	<i>p</i> value	N=71
-	Age PSA level Time since diagnosis Medical Comorbidities	.15	.15	1.87	.10	35 .07 .18 .17	.01 .56 .15 .16 .7	
7	PC Knowledge Preceived Stress Management Skills	.18	.03	2.56	.11	12 12 19	.11	
Hierar	chical Regression Analysis of the Relationship Between	Perceiv	ved Stress	. Management Ski	lls and Financial	Concern.	s	
_	Age PSA level Timo level	.12	.12	1.51	61.	16 .33	.25 .01 .02	
0	nume surce duagnosis Medical Comorbidities Access to Healthcare PC Knowledge Perceived Stress Management Skills	.13	00.	.17	89.	.00 .11 .02 .05	.02 .39 .12 .68	

Table 7 (continued)

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Hierar	chical Regression Analysis of the Relationship Between	Treatm	tent Side	Effect Concerns a	ind IES-R Anxiety			
Step	Factor	\mathbb{R}^2	${ m R}^2\Delta$	F for $\mathbb{R}^2\Delta$	Signifícance FA	β	<i>p</i> value	N=71
_	Age PSA level Time since diagnosis Medical Comorbidities	90.	.06	.73	.63	03 .07 05	8. 53 63 63	
0	Access to Healthcare PC Knowledge Treatment Side Effect Concerns	.32	.26	23.67	00.	21 06 53	.06 .54 .00	
Hierar	chical Regression Analysis of the Relationship Between	Treatm	ent Side	Effect Concerns a	ind PSA Anxiety			
1	Age PSA level Time since diagnosis	.13	.13	1.66	.14	17 .18 .04	.18 .14 .77	
0	Medical Comorbidities Access to Healthcare PC Knowledge Treatment Side Effect Concerns	.25	11.	9.55	00	.02 11 26 .35	.83 .34 .03	

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Hierarchical Regression Analysis of the Relationship Between Treatment Side Effect Concerns and Cortisol AUC_G

Step	Factor	\mathbb{R}^2	$\mathrm{R}^2\Delta$	F for $\mathbb{R}^2 \Delta$	Significance FA	β	<i>p</i> value	N=33
	Age	90.	.06	.71	.64	.12	.41	
	PSA level					.22	.10	
	Time since diagnosis					.08	.56	
	Medical Comorbidities					10	.42	
	Access to Healthcare					10	.43	
	PC Knowledge					.19	.14	
7	Treatment Side Effect Concerns	.10	.04	2.56	.11	.20	11.	

Hiera	chical Regression Analysis of the Relationship Betweer	Social	Rejection	1 Concerns and II	ES-R Anxiety			
Step	Factor	\mathbb{R}^2	${ m R}^2\Delta$	F for $\mathbb{R}^2\Delta$	Significance FΔ	β	<i>p</i> value	N=71
	Age PSA level Time since diagnosis Medical Comorbidities	90.	90.	.73	.63	20 .16 .02	. 13 13 13 13 13 13 13 13 13 13 13 13 13 1	
0	Access to Healthcare PC Knowledge Social Rejection Concerns	.21	.14	11.26	00.	15 03 .39	.21 .77 .00	
Hieran	chical Regression Analysis of the Relationship Between	Social .	Rejection	1 Concerns and P	SA Anxiety			
1	Age PSA level	.13	.13	1.66	.14	29 .24	.03 .05	
2	1 ime since diagnosis Medical Comorbidities Access to Healthcare PC Knowledge Social Rejection Concerns	.22	.08	6.82	.01	.07 .06 07 .23 .30	ęc. 19. <u>6</u> . 8. 8. 90. 10. 10.	

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Hierarchical Regression Analysis of the Relationship Between Social Rejection Concerns and Cortisol AUC_G

Step Factor Step Factor 1 Age PSA level Time since diag Medical Comor Access to Health PC Knowledge	gnosis thidities thcare	·	.06 R ²	.06 R ² ∆ .06	F for R ² Δ .71	Significance F Δ .64	β 19 08 08 08 08	<i>p</i> value 71 .71 .48 .52 .52 .13	N=33
2 Social Rejection	n Concerns		80.	.02	1.29	.76	.14	.26	

Hieran	chical Regression Analysis of the Relationship Betweer	Life/Pru	emature	Closure Concerns	and IES-R Anxiet	ý		
Step	Factor	\mathbb{R}^2	${ m R}^2\Delta$	F for $\mathbb{R}^2\Delta$	Significance F∆	β	<i>p</i> value	N=71
-	Age PSA level Time since diagnosis Medical Comorbidities	.06	.06	.73	.63	01 .12 13 10	.97 .31 .27 .36	
7	Access to Healthcare PC Knowledge Life/Premature Closure Concerns	.31	.25	22.49	00.	04 05 54	.71 .67 .00	
Hieran	chical Regression Analysis of the Relationship Betweer	Life/Pr	emature	Closure Concerns	and PSA Anxiety			
1	Age PSA level Time since diagnosis	.13	.13	1.66	.14	15 .21 01	.25 .08 .01	
7	Access to Healthcare PC Knowledge Life/Premature Closure Concerns	.26	.13	10.69	00	01 24 .38	.00 .00	

Table 10 (continued)

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Hierarchical Regression Analysis of the Relationship Between Life/Premature Closure Concerns and Cortisol AUC_G

Step	Factor	\mathbb{R}^2	${ m R}^2\Delta$	F for $\mathbb{R}^2\Delta$	Significance F ∆	β	<i>p</i> value	N=33
	Age PSA level Time since diagnosis Medical Comorbidities Access to Healthcare PC Knowledge	90.	.06	.71		.06 19 .10 08 .17		
0	Life/Premature Closure Concerns	90.	00 [.]	00 [.]	.95	01	.95	

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ik	Step	Factor	R ²	$\mathbb{R}^2\Delta$	F for R ² ∆	Significance FA	В	<i>p</i> value	N=71
	-	Age PSA level Time since diagnosis Medical Comorbidities	90.	90.	.73	.63	10 .01 04	.47 .93 .72	
	6	Access to Healthcare PC Knowledge Financial Concerns	.20	.14	10.81	00.	15 04 .40	.22 .72 .00	
	Hiera	rchical Regression Analysis of the Relationship Between	n Financ	cial Conce	erns and PSA An	xiety			
	1	Age PSA level Time since diagnosis	.13	.13	1.66	.14	22 .15 .06	.10 .24 .65	
	0	Medical Comorbidities Access to Healthcare PC Knowledge Financial Concerns	.18	.04	3.26	80.	.03 07 25 :22	.77 .57 .08	

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Hierarchical Regression Analysis of the Relationship Between Financial Concerns and Cortisol AUC_{G}

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Step	Factor	\mathbb{R}^2	${ m R}^2\Delta$	F for $\mathbb{R}^2\Delta$	Signifīcance F ∆	β	<i>p</i> value	N=33
_	Age PSA level Time since diagnosis Medical Comorbidities Access to Healthcare PC Knowledge	.00	90.	17.	.64	.10 26 08 08		
7	Financial Concerns	.10	.03	2.29	.13	.19	.35	



Figure 1. The diagram illustrates the overall conceptual model that guided the research plan in the present study. The conceptual model suggests that men undergoing AS will experience illness uncertainty. Using Mishel's Reconceptualized Uncertainty in Illness Model as a framework, which states that adjustment depends on the appraisal of the uncertainty, as well as the ability to manage the uncertainty, the proposed study examined whether men who have greater ability to manage stress experienced decreased psychological distress and arousal due to their appraisal of cancer-related concerns as less threatening.





Figure 2. Depiction of how the final sample in the current study was achieved.





Figure 3. The overall mediation model that was evaluated in the current study. The model suggests that greater perceived stress management skills are associated with decreased anxiety/arousal and this relationship is mediated by fewer prostate cancer psychosocial concerns.





*p<.05 **p<.01 ^{NS}Not Significant

Figure 4. The final model suggests that greater perceived stress management skills are significantly associated with less anxiety as measured by the IES-R, fewer psychosocial concerns are associated with less anxiety as measured by the IES-R, and the addition of PC psychosocial concerns to the regression of IES-R anxiety on perceived stress management skills results in an increase of IES-R anxiety variance explained.

