PROTECTING THE PEE-PEE: A COMPARISON OF ROBOTIC ASSISTED LAPAROSCOPIC PROSTATECTOMY AND EXTERNAL BEAM RADIATION THERAPY FOR URINARY AND SEXUAL FUNCTION IN MEN TREATED FOR PROSTATE CANCER

by

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A THESIS

Presented to the Department of Human Physiology
and the Robert D. Clark Honors College
in partial fulfillment of the requirements for the degree of
Bachelor of Science

June 2017

An Abstract of the Thesis of

Julia Fischer for the degree of Bachelor of Science
in the Department of Human Physiology to be taken June 2017

Title: Protecting the Pee-pee: A Comparison of Robotic Assisted Laparoscopic Prostatectomy and External Beam Radiation Therapy for Urinary and Sexual Function in Men Treated for Prostate Cancer.

Approved: _____

Dr. Carrie McCurdy

INTRODUCTION: Prostate cancer is the second most commonly diagnosed cancer in men. Robot Assisted Laparoscopic Prostatectomy (RALP) and External Beam Radiation Therapy (EBRT) are standard treatments for clinically localized prostate cancer, but both of these treatments have negative consequences for urinary and sexual function in patients.

PURPOSE: To compare changes in urinary and sexual function for men treated with RALP and EBRT.

HYPOTHESIS: It was hypothesized that patients treated with EBRT would have better recovery of sexual function, and patients treated with RALP would have better recovery of urinary function.

METHODS: Urinary and sexual function for patients treated for prostate cancer was examined using EPIC questionnaires. These questionnaires were completed before treatment and two years after initial treatment in 32 men treated with EBRT, and 104 men treated with RALP. The difference between initial treatment scores and 2-year

scores were analyzed with a GLM procedure to assess the quality of life outcomes for EBRT and RALP.

RESULTS: No significant difference was found for change in urinary function for either treatment group ($p = 0.41$). EBRT was found to significantly increase recovery sexual function compared to RALP ($p = 0.04$).

CONCLUSION: EBRT is a better treatment for preserving sexual function in men with prostate cancer, and urinary function will be largely similar with either treatment.

Acknowledgements

There are many wonderful people who helped me through this rewarding process, and I appreciate the opportunity to formally thank them now. I would like to thank Dr. Carrie McCurdy for agreeing to be my Primary Thesis Advisor. Thank you for your guidance that allowed me to find the most incredible resources that were invaluable to the development of this project. Thank you to Dr. David DiMarco for helping me navigate the nuances of clinical research for prostate cancer. I appreciate your expertise in this field. Thank you to Dr. Kelly Sutherland for being a wonderful CHC advisor, and for agreeing to be on my Thesis Committee. I have greatly valued your guidance in my time here at the University of Oregon. I am so grateful to Gerald Rouleau, a former OUI intern and a wonderful statistical analyst, who saved my sanity by agreeing to help me with the statistical analysis. The analysis you conducted was invaluable to the validity and importance of this project. Thank you Jon Runyeon, for kindly offering to let me do an abdominal prosection on a cadaver in the anatomy lab so I could understand the prostate anatomy on a more in-depth level. The experience helped me understand the significance of the abdominal anatomy in this project. Perhaps I am most appreciative to Stephanie Kerns and Renee Podesta, who must have decided that I was sassy enough to get along with and chose to give me the opportunity of being an intern at OUI. You have both been so helpful and encouraging as I have worked to pull this project together, and I am so grateful. Thank you to Martin Allums, who created the fabulous illustrations that made this project look much more professional than I could have ever imagined. I look forward to the day when every medical textbook I open is bursting with your illustrations. Finally, I would like to thank

my parents Liz and Doug Fischer. Your support and never-ending encouragement has always allowed me to do way more than I ever should, and kept me sane while I muddled through it. In the end I know that I am Julia Pauline Fischer, and I am loved very much. Thank you for being my parents, I love you.

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Background: An Overview of Prostate Cancer

Anatomy and Physiology of the Prostate

The prostate is a male specific organ that encircles the urethra and borders the inferior aspect of the bladder. The prostate contains the ejaculatory duct, which is the end of the spermatic tube that extends all the way down from the testes. Sperm travel through this tube to get to the urethra during ejaculation. Nerves that supply the urethra and penis run posterior-laterally along the prostate and are contained in the neurovascular bundles. The function of the prostate is to create and secrete certain components found in semen. One of these components is prostate specific antigen (PSA), which is a protein that helps maintain a low viscosity in semen to allow the sperm to swim freely (LEE et al., 1989).

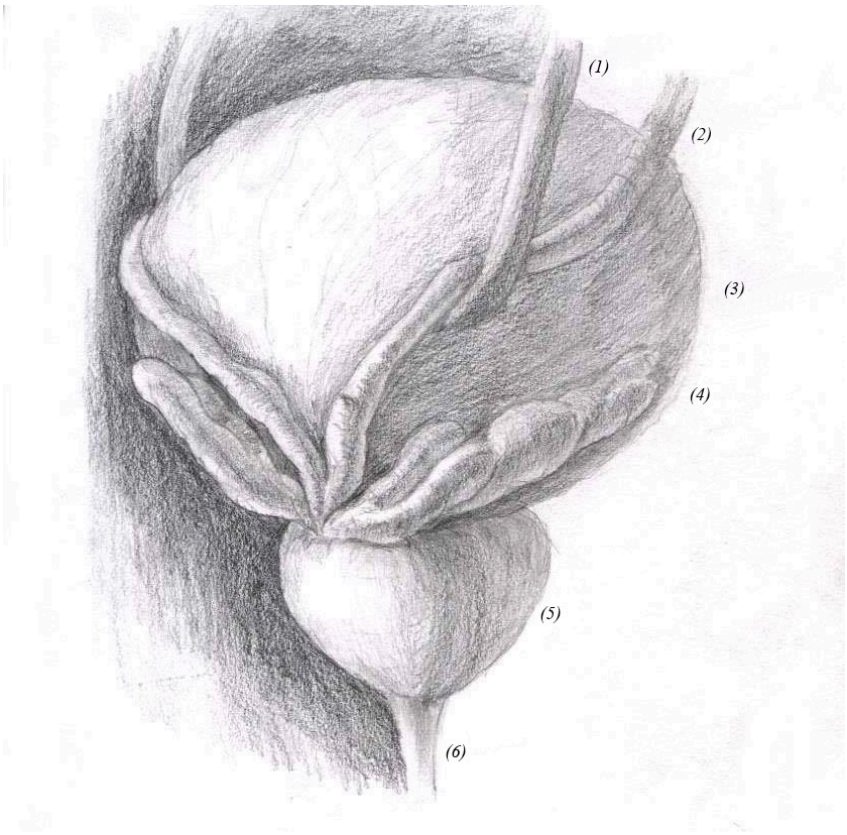


Illustration 1: Anatomy of the Prostate

(1) Ureter, (2) Vas Deferens, (3) Bladder, (4) Seminal Vesicle (5) Prostate (6) Urethra. Illustration by Martin Allums.

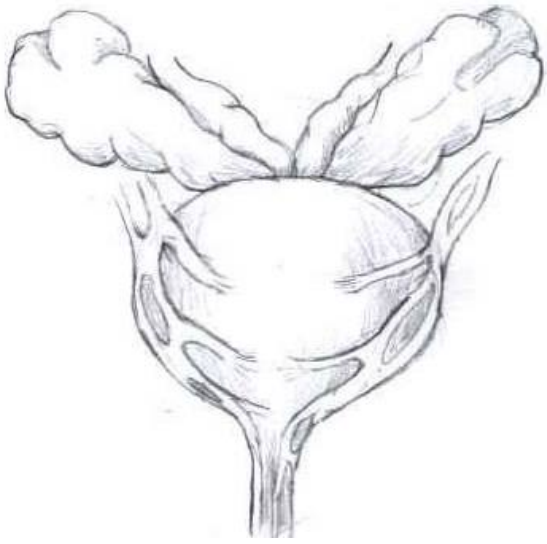


Illustration 2: Neurovascular Bundles of the Prostate

Illustration by Martin Allums

Prostate Cancer

Prostate cancer is the second most frequently diagnosed cancer in the United States, falling only behind skin cancer (Haas et al., 2008). In a healthy functioning prostate the PSA that is produced is almost entirely secreted into the urethra during ejaculation, with only small levels leaking into blood stream circulation (Stenman et al., 1999). When prostate cells become cancerous they rapidly proliferate and create an excess amount of PSA. This is more PSA than can be secreted into the urethra during ejaculation, and the excess is leaked into circulation and that be detected by a blood tests and indicate abnormal prostatic tissue growth (Smith et al., 2009). Thus, PSA screenings are conducted by physicians in men over 50 to look for sharp increases in PSA that could indicate prostate cancer (Smith et al., 2009).

While elevated PSA levels may indicate a cancer, there are other conditions that can cause PSA levels to rise. Benign Prostatic Hyperplasia (BPH) is a common condition among men over the age of 50, and also results in elevated levels of PSA (Stenman et al., 1999). BPH is a condition where the prostate grows larger without evidence of malignancy (Stenman et al., 1999). This additional growth of prostate cells will also produce an excess of PSA, which will be detected in a blood test. Other conditions such as a bladder or prostate infection can also cause the PSA to spike. If no inflammation or infection is clinically apparent, then further evaluation of elevated PSA often includes Transrectal Ultrasound (TRUS) guided biopsy of the prostate to deduce if prostate cells have become cancerous (Heidenreich et al., 2008).

A Transrectal Ultrasound (TRUS) guided biopsy takes up to 12 samples of prostatic tissue in each region of the prostate to test for malignancy. The samples taken

from the TRUS biopsy are examined and given a Gleason Score. This measures the histological appearance and number of cancerous prostate cells in the sample, and assigns them a grade from 1 to 5 (Humphrey, 2004). A grade of 1 represents cells that are packed closely together but are still separated with a uniform appearance and well differentiated growth patterns. A grade of 5 represents the most altered appearance of the cells with large, observable, different shaped masses (Humphrey, 2004). The grades 2-4 represent the range of appearances of the cancer cells between the grades 1 and 5 (Humphrey, 2004). The Gleason Score is calculated by summing the two largest grades assigned to the histological sample of the prostate tissue, generating a value of 2-10 (Humphrey, 2004). Patients with a Gleason Score of 2-6 are candidates for active surveillance, which is essentially just close surveillance of PSA progression without definitive treatment to avoid over-treatment (Shah, 2009). Patients with a Gleason Score of 7 or greater are in need of definitive therapy (Shah, 2009).

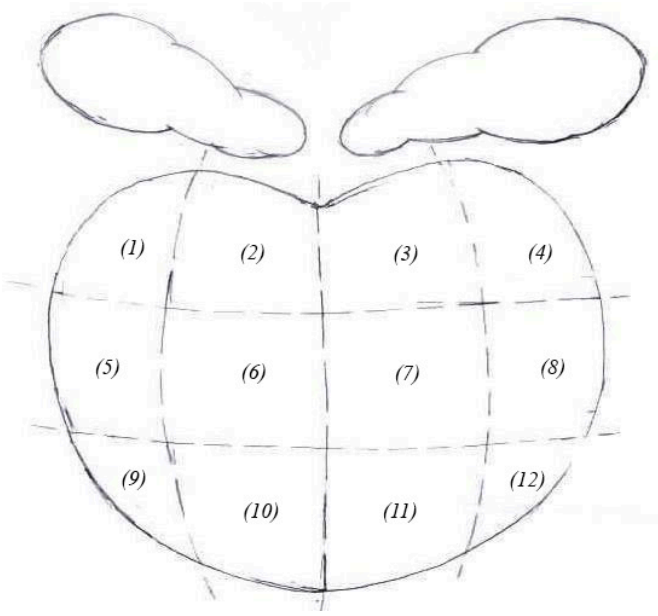


Illustration 3: Transrectal Ultrasound Guided Biopsy Specimen Sites

Illustration by Martin Allums

Another tool used to assess the extent of the cancer is the Tumor-Node-Metastasis (TNM) staging system. The TNM cancer staging system is used to assign a stage to cancerous prostatic samples (Edge & Compton, 2010). The TNM outlines the location of the cancer in relation to the prostate gland and the rest of the body. The letter T in the TNM score denotes that there is a tumor in the prostate. The letter N in the TNM score signifies a tumor in a lymph node, and the letter M indicates metastasis in other locations in the body. A common score is T2a, which indicates a tumor involving one half a prostatic lobe or less. The TNM staging can be diagnosed from a TRUS biopsy, or by palpation of the prostate via rectal exam (Edge & Compton, 2010).

Treatment of Prostate Cancer

Definitive Treatment Options

Surgical removal of the prostate is a common procedure used to treat prostate cancer. The surgical techniques of prostatectomies have evolved in the last two decades from the traditional Radical Retropubic Prostatectomy (RRP) which was considered the gold standard treatment for prostate cancer (Coelho et al., 2010). A RRP is an invasive procedure which involves a large open incision in the abdomen and surgical dissection of the prostate (Barré, 2007). New surgical techniques have developed such that laparoscopic dissection (a minimally invasive procedure with a few small incisions) of the prostate can be achieved with the assistance of a da Vinci Robotic Surgical System. This new technology allows surgeons to perform a Robot Assisted Laparoscopic Prostatectomy (RALP) with minimal invasion compared to the open incision of the RRP. RALP operations can be performed as Nerve Sparing (NS) procedures, where the neurovascular bundles are dissected away from the prostate in an attempt to preserve the urinary and sexual function of the patient (Coelho et al., 2010). As there is a neurovascular bundle that runs on both sides of the prostate, a NS procedure can be bilateral where both neurovascular bundles are dissected away, or unilateral if only one is dissected away. The type of NS procedure depends on the girth and location of the tumor, if the tumor extends into the regions of these neurovascular bundles they will not be dissected away in an attempt to remove all cancerous cells (Talcott et al., 1997).

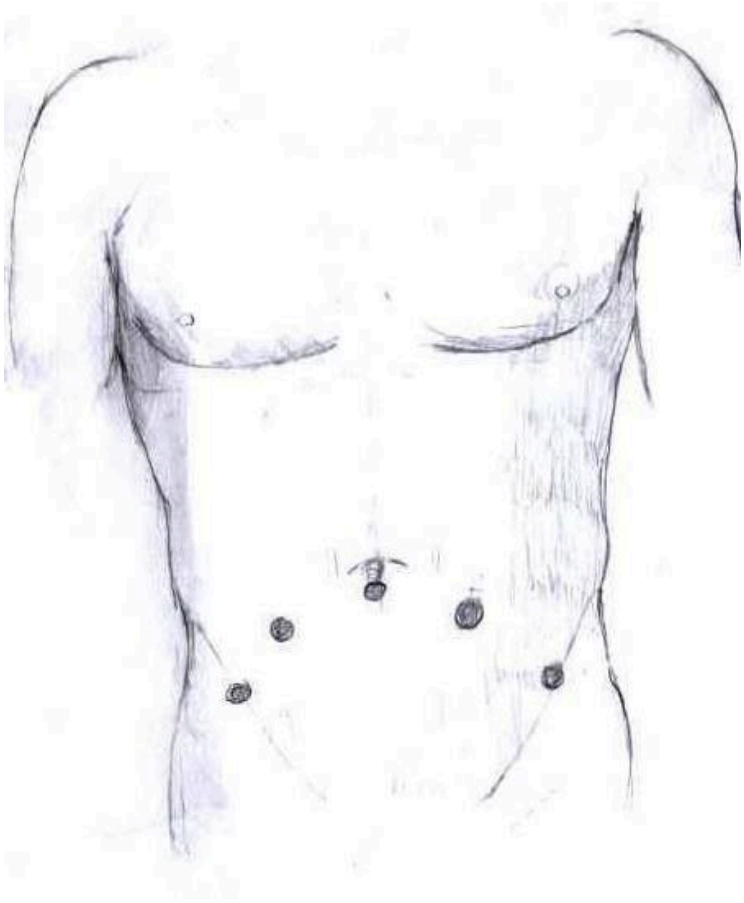


Illustration 4: Surgical Incision Sites for RALP

Illustration by Martin Allums

External Beam Radiation Therapy is another common treatment for prostate cancer. EBRT is radiation delivered from an external source directed at the prostate from different angles to preserve the tissue around the prostate (Heidenreich et al., 2008). If a patient has received a prostatectomy as initial treatment and there is reoccurrence of prostate cancer, they can go on to receive EBRT (Heidenreich et al., 2008). However, once a patient receives EBRT for their initial treatment, they have received a lifetime dose of radiation to that area and are not able to undergo any more radiation treatment for their prostate cancer (Heidenreich et al., 2008).

Another treatment for prostate cancer is Androgen Deprivation Therapy (also referred to as hormone therapy). The growth of most prostate cancer cells is dependent on androgens (sex hormones), most often testosterone or dihydrotestosterone (Miyamoto et al., 2004). To treat prostate cancer, hormone deprivation therapy aims to stop the production of testosterone. This is achieved by either pharmaceutically or surgically castrating the patient, or stopping the body's natural production of androgens (Miyamoto et al., 2004). Androgen deprivation therapy is not a curative treatment, it is used to slow the disease progression and extend patient life (Miyamoto et al., 2004). This therapy is often given to patients who have failed initial treatment of RALP or EBRT who's disease has spread to other areas of the body (Heidenreich et al., 2008).

Descriptions of Specific Treatment

Robotic Assisted Laparoscopic Prostatectomy Procedure

When a RALP is performed, the patient is brought into the operating room that houses the da Vinci robot. The patient is prepped for surgery and sterilized before the procedure begins (Tewari *et al.*, 2002). A small incision is made just above the bellybutton and a tube-like instrument called a port is inserted into the incision (Tewari *et al.*, 2002). Carbon dioxide is pumped into the abdomen through this port to inflate it, giving the surgeon more room to maneuver the surgical tools and a better field of vision (Tewari *et al.*, 2002). Up to six more incisions are made in the abdomen for additional ports—two for the rest of the surgical tools and the rest for the surgical assistant's tools (Tewari *et al.*, 2002). From there, the order of the steps vary, but the structures surrounding the bladder and prostate such as the vas deferens, neurovascular bundles,

and rectum are dissected away from the prostate so that it can be removed (Tewari *et al.*, 2002). The urethra above and below the prostate are severed to free the prostate so it can be removed (Tewari *et al.*, 2002). The severed ends of the urethra are connected with stitches to the bladder to bridge the gap of the now removed prostate (Tewari *et al.*, 2002). The prostate is removed from the abdomen in a small baggie, and the skin and fascia are sutured closed to complete the procedure (Tewari *et al.*, 2002).

External Beam Radiation Therapy

EBRT is produced via a machine that delivers radiation to a specific location in the body. For EBRT, placement of the radiation is essential to make sure both the cancer cells are all killed, and that the non-cancerous organs (such as the bladder) are spared as much radiation damage possible (Zaorsky *et al.*, 1996). OUI uses Image-Guided Radiotherapy Therapy (IGRT) to help maintain the specific location of radiation (Zaorsky *et al.*, 1996). Prior to EBRT, OUI patients have 2 gold fiducial makers placed in their prostate. Visualizing these markers with imaging helps create and maintain a consistent specific location for radiation to be delivered during each treatment session (Zaorsky *et al.*, 1996). The entire radiation treatment is delivered in doses, usually lasting about 15 minutes per day for about 8-9 weeks (Zaorsky *et al.*, 1996). The treatment course is long because only a small amount of radiation can be safely tolerated every day.

Oregon Urology Institute

Oregon Urology Institute (OUI) is the largest and most advanced urologic center in the Northwest. In 2006, the local hospital McKenzie Willamette purchased a da Vinci

robot, which was fairly new technology and on the verge of becoming much more prevalent in the medical field. With the procurement of this machine OUI hired Dr. David DiMarco, who is a surgeon trained on the use of this robot, to perform RALPs. As this was fairly new technology and the RALP was less prevalent, the procedure was more expensive and there were issues with insurance covering the cost for patients. To determine whether surgeries performed with the da Vinci robot lead to better surgical outcomes than conventional methods, OUI developed a Prostate Cancer database.

Originally, data was collected comparing RRP to RALP in terms of blood loss and other direct surgical comparisons to measure whether the RALP had significantly better surgical outcomes. Later, Health-Related Quality of Life (HRQOL) questionnaires were added to the database to track HRQOL in patients with RRP and RALP after treatment. EPIC questionnaires were used to assess urinary, bowel, sexual, and hormonal function as well as patient satisfaction. In 2008, this HRQOL protocol was extended to radiation patients. OUI has tracked HRQOL data for 11 years for prostatectomy patients, and 9 years for EBRT patients.

Introduction

Treating prostate cancer while attempting to maintain a high quality of life in terms of urinary and sexual function is difficult, as nerves that supply the urethra and penis are contained in neurovascular bundles that run posterior-laterally along the prostate (Walsh et al., 1983). Surgical removal or radiation of the prostate can damage these nerves and have a severe impact on urinary and sexual function of patients after treatment, which can lead to a lower quality of life (Walsh et al., 1983). Quality of life for patients being treated for prostate cancer is a major factor in the decision of which treatment to use. Poorer quality of life due to incontinence and erectile dysfunction can lead to depression, poorer quality of sleep, and lower levels of overall of health (Coyne et al., 2008). Thus, assessing which treatment leads to the best quality of life is an important factor in the deciding how to treat prostate cancer.

For cancer that is localized to the prostate, both Robot Assisted Laparoscopic Prostatectomy (RALP) and External Beam Radiation Therapy (EBRT) are considered acceptable treatments (Schreiber *et al.*, 2015). Patient input is essential in the treatment decision, thus randomized-control studies are difficult to perform to determine which treatment has better quality of life outcomes. Researchers have heavily relied on retrospective studies to assess the benefits of one treatment versus another, but these studies often yield no clear distinction. EBRT and RALP are both associated with a decline in Health Related Quality of Life (HRQOL) directly after treatment, but thus far there is no clear indication as to which is the better treatments in terms of the recovery of urinary and sexual function (Miller et al., 2005) (Frank et al., 2007). Many studies that investigate this were performed before 2006 when RALP surgical techniques

became more widespread, and have only compared Radical Retropubic Prostatectomy to EBRT. This study compares recovery of urinary and sexual function using information from the Prostate Cancer HRQOL database in patients that were treated with RALP or EBRT.

Purpose

The purpose of this study was to determine if EBRT results in better sexual and/or urinary function recovery in patients two years after initial treatment compared to RALP.

Hypothesis

I hypothesized that the changes in sexual function EPIC scores would indicate better sexual function recovery for patients treated with EBRT than RALP. I hypothesized that changes in urinary function EPIC scores would indicate better recovery of urinary function in patients treated with RALP than EBRT.

Methods

Patient Selection

This study compared EBRT to RALP, so patients selected for this study were good candidates for both EBRT and RALP at the time of their initial treatment. Almost all patients are good candidates for EBRT, but not all qualify for RALP. Therefore, only EBRT patients that were specifically noted to also qualify for RALP were selected for this study.

Candidacy Criteria for EBRT Patients

Surgical guidelines denote that patients should live long enough to benefit from lack of malignancy. As RALP is an invasive procedure, a patient should have a life expectancy of 10 years or more to receive treatment (Lepor, 2000). Although the probability that a man 70 years old will live 10 more years after prostatectomy is about 58% (Lepor, 2000), Oregon Urology Institute physicians do not discriminate treatment based on age and will select RALP if a patient has an estimated 10 year life expectancy. Thus, patients were selected for this study if it specified in their chart that they are good surgical candidates at the time of their initial treatment consultation. Patients selected had a Gleason Score of 6-8 indicating that they needed initial treatment. Patients with a Gleason score of 9-10 are very high risk and most often receive multiple treatment types such as surgery or radiation with hormone(Fowler, Jr *et al.*, 2000). This possibility of multiple treatments would confound the study results, so these patients were not included. Selected patients had a TNM score in the range of T1a-T3a indicating they

still had organ confined prostate cancer in order to be eligible for prostatectomy (Lepor, 2000).

Candidacy Criteria for RALP Patients

Patients selected had a Gleason Score of 6-8 indicating they needed initial treatment. Selected patients had a TNM score in the range of T1a-T3a indicating they still have organ confined prostate cancer in order to be eligible for prostatectomy (Lepor, 2000). Patients who were selected had a form of a nerve sparing procedure (Bilateral, Right, Split, etc.) to control for poor erectile function.

Data Collection

Sexual and Urinary Function Data

This study examines differences in sexual and urinary function for EBRT and RALP through Oregon Urology Institute's (OUI) Prostate Cancer Database. Measurements for Sexual and Urinary function have been acquired through the Expanded Prostate Index Composite (EPIC). EPIC questionnaires inquire about the patient's urinary, bowel, hormonal, and sexual bother and reflects their urinary, bowel, hormonal, and sexual function respectively (Wei *et al.*, 2000). The EPIC questionnaires relates the scores for each question in a section that are ranked on a 1-5 or 1-4 basis into a percentage that gives a summary of the function for that section. Thus if the top score is selected by the patient for each question in a section such as urinary function, that patient would receive 100 for that section when their EPIC score is calculated. Higher scores represent less bother and better function. The scores recorded for sexual and urinary function were used in this study, and all other information was omitted. A

packet with this questionnaire is sent out to patients willing to participate in the Prostate Cancer Database before their treatment, quarterly for the first year, and then annually. The 2-year time point was chosen to assess recovery of urinary and sexual function as improvement in both generally does not occur past 24 months (Penson *et al.*, 2008) (Donovan *et al.*, 2016).

Treatment Related Information

Many co-variants were included in this study. Smoking status was determined based off of smoking status at time of treatment. Co-morbidities were recorded from conditions recorded in patients' chart at time of treatment. Race was recorded on patient reported race in their chart. Use of hormone therapy was determined from listed medications on the patient's chart. Erectile aid use before and at the two year time point was determined based off medication lists and notes made in the patient's chart. Other information regarding Gleason Score and other biopsy information was recorded from the biopsy pathology report, and the TRUS surgical report. Surgery related information, such as procedures performed and diagnostics, were recorded from the prostatectomy pathology report and the surgical notes.

Data De-identification

Patients were assigned a random three-digit number generated by a random series generator. This number allowed for the data of an individual to stay associated with an individual outcome. No personal health information or identifiers (such as name, birthdate, or surgery dates) were included in the data used for this study. The key that connected this three-digit number to the patients was kept secure.

Statistical Analysis

The patients' clinical presentations were analyzed with Welch's t-test (two tailed t-test with unequal variance). Demographic information, which was included as possible confounding variables, was analyzed with Fisher's exact test. A Wilcoxon rank-sum test was used to compare baseline BMI of patients in each treatment group, as there were not normal distributions. General Linear Models (GLM) were used to assess significant differences between treatment groups, and identify if any variables were confounding the relationship between treatment groups and EPIC scores for Urinary and Sexual function.

Results

Table 1 shows the clinical presentations of each treatment group. The patients in both treatment groups were largely similar. One statistically significant difference was the TNM Stage between the two treatment groups. The RALP treatment group had a slightly higher average TNM staging of T2b than the EBRT group's T2a.

Patient Demographics

	EBRT		RALP	
	Average	Mode	Average	Mode
Age at start of tx (yr)	66 SD: 7	59	64 SD: 6.8	68
PSA Level (ng/mL)	5.7 SD: 3	5.5	6.1 SD: 4.3	5.5
Prostate Size (mL)	43 SD: 15.8	-	39.8 SD: 20.2	33
Gleason Score	6.4 SD: 0.5	6	6.6 SD: 0.7	6
1st Grade	3.1 SD: 0.3	3	3.2 SD: 0.4	3
2nd Grade	3.3 SD: 0.5	3	3.4 SD: 0.5	3
Biopsies (% of positive samples)	35.6 SD: 22.4	25	35 SD: 20.4	33
Highest % of Cores	49 SD: 28.7	80	46 SD: 29.9	80
Clinical TNM Stage*	t2a	t1c	t2b	t2c
BMI	29.1 SD: 4.4	-	27.9 SD: 3.9	25.9

Table 1: Comparison of Clinical Presentations for EBRT and RALP Patients

*Statistically significant with Welch's T-test $p < .05$.

Fisher's exact test revealed significant differences in the amount of cardiac disease between treatment groups. The EBRT group had more instances of cardiac disease, with 41% of the patients with cardiac disease. This prevalence of a disease, which influences the patient's overall health, denotes that the EBRT patient group was generally less healthy than the RALP group. Fisher's exact test revealed statistically significant differences in the number of patients treated with hormone therapy between groups during the time interval this study analyzed. The EBRT group had more patients (16% vs. 1%) treated with hormone therapy within the two-year interval post initial treatment. As there is decreased libido as well as other symptoms related to the use of hormone therapy, the patient's sexual function EPIC scores could be affected by this treatment. The demographic categories of race and use of erectile aid were not included in the GLM analysis due to an unacceptable amount of missing data.

	Number of Patients (%)	
	EBRT	RALP
Patients Included		
Total number of patients	32	104
Lost to follow up	0 (0%)	7 (6.7%)
Deceased	0 (0%)	2 (2%)
Radiation after initial tx	0 (0%)	10 (10%)
Pt w/ family history of prostate cancer	11 (34%)	32 (31%)
Comorbidities**		
No comorbidities	12 (38%)	94 (90%)
Cardiac disease**	13 (41%)	2 (2%)
Hypertension	1 (3%)	5 (5%)
Arterial disease	0 (0%)	1 (1%)
Smoking Status*		
Pt never smoked	12 (38%)	58 (56%)
Pt current smoker	2 (6%)	1 (1%)
Pt former smoker	18 (56%)	39 (38%)
Race°		
Alaskan native	1 (3%)	0 (0%)
White	23 (72%)	65 (63%)
Race not reported	8 (25%)	39 (37%)
Erectile Aid Use°		
No Erectile aid use before tx	6 (19%)	92 (88%)
Erectile aid use before tx	26 (81%)	11 (11%)
Erectile aid use not reported before tx	0 (0%)	1 (.01%)
No Erectile aid after tx	22 (69%)	32 (30%)
Erectile aid use after tx	9 (28%)	50 (48%)
Erectile aid use not reported after tx	1 (3%)	22 (21%)
Hormone Therapy*		
Received hormone therapy	5 (16%)	1 (1%)
No hormone therapy	27 (84%)	103 (99%)

Table 2: Comparison of Covariates in Treatment Patient Population

*Indicates statistically significant differences between the treatment groups $p < .05$

** Indicates statistical significant differences between treatment groups $p < .001$

° Indicates variable not included in analysis due to missing data

Statistical Tests

Figure 1 shows the distribution of urinary change scores for EBRT and RALP. The unadjusted GLM model illustrated in Table 3 had an overall F value of 0.52. This F value is not less than 0.05, suggesting that this model is not a successful fit so an adjusted model was run.

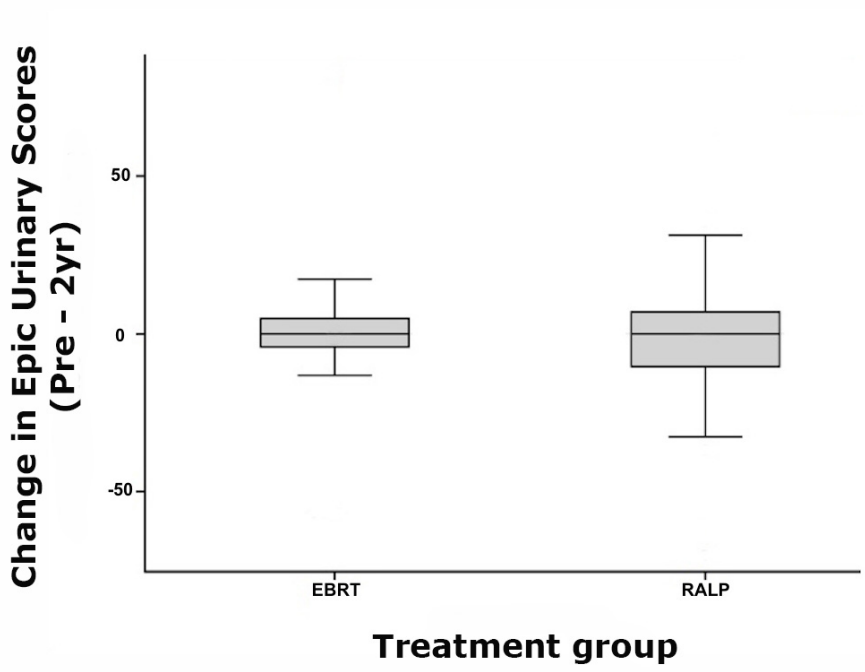


Figure 1: Distribution of Urinary EPIC Score Change

In this figure, 0 denotes baseline. As 2yr scores were subtracted from pre-treatment scores, negative scores indicate improvement from initial urinary function and positive scores represent a worsening from initial urinary function.

	Unadjusted GLM Model	
Mean	**R^2**	**Pr > F**
-1.22	0.003	0.52
	Estimate	**Pr > |t|**
Intercept	-1.79	0.35
EBRT	2.71	0.52
RALP	0.00	

Table 3: Reported Values from the Urinary Function Unadjusted GLM Model

Table 4 shows the reported values of the fully adjusted GLM model that included possible confounding variables. The variables that were found to confound the association (to have an effect on change in urinary EPIC score independent of treatment group) of study variables were cardiac disease, arterial disease, age, BMI, smoking, hypertension, and hormone treatment. None of these variables were found to modify the association (act in association with treatment group to affect urinary EPIC score) of study variables. The F-value for the fully adjusted GLM model was 0.0076 indicating a good fitting model. The R^2 value generated by this analysis was 0.18. This indicates that the treatment groups and all of the confounding variables explain 18% of the variation in urinary change for all the patients included in this analysis. EBRT had 4.45 greater increase in urinary change score than RALP, indicating a worsening in urinary function from baseline (as positive values represent a worsening in function). This association is not statistically significant with a p-value of 0.40. Thus, no statistically significant change was detected between urinary score change for EBRT and RALP. The mean of all patients included in the GLM procedure was -0.81. As this value is negative, it

shows that there was a general improvement of urinary function in men treated for prostate cancer with either treatment.

	Adjusted GLM Model	
Mean	**R^2**	**Pr > F**
-0.81	0.18	0.0076
	Estimate	**Pr > |t|**
Intercept	10.19	0.61
EBRT	4.45	0.41
RALP	0.00	

Table 4: Reported Values from the Urinary Function Fully Adjusted GLM Model

Figure 2 shows the unadjusted GLM model of change in sexual function from pre-treatment to 2 years post treatment. The F-value reported in Table 5 for this model was 0.012 indicating the model was a good fit. The R^2 value is 0.05 indicating, 5% of the variation in change sexual function from pre-treatment to 2 years is explained by type of treatment. The difference in change for patients undergoing EBRT was -11.9, which was statistically different ($p = 0.01$). As negative numbers represent an improvement in sexual function from baseline, this indicates that EBRT patients had better sexual function than RALP patients.

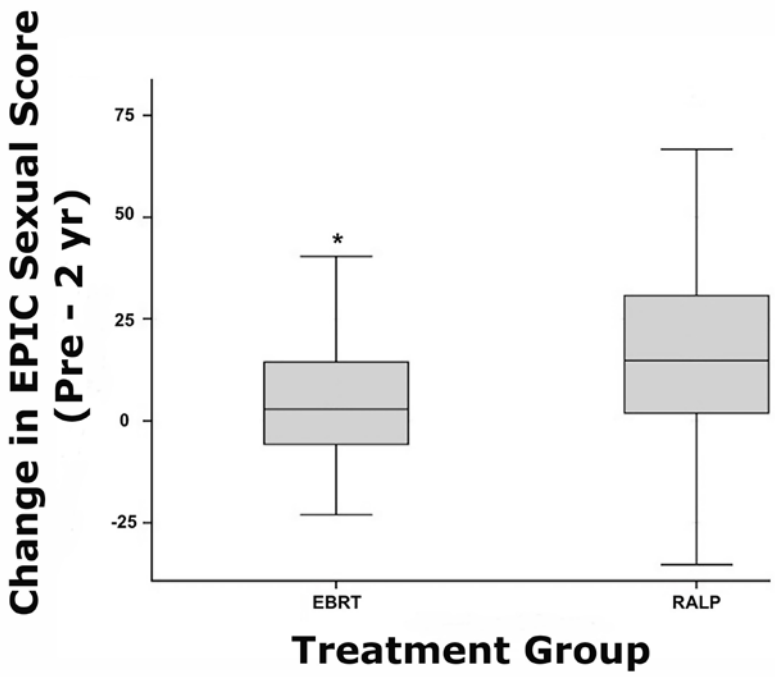


Figure 2: Distribution of Sexual EPIC Score Change

In this figure, 0 denotes baseline. As 2yr scores were subtracted from pre-treatment scores, negative scores indicate improvement from initial urinary function and positive scores represent a worsening from initial urinary function. *Indicates a statistically significant difference ($p < 0.05$)

	Unadjusted GLM Model	
Mean	**R^2**	**Pr > F**
15.94	0.052	0.012
	Estimate	**Pr > |t|**
Intercept	18.34	<.0001
EBRT	-11.88	0.012
RALP	0.00	

Table 5: Reported Values from Sexual Function GLM Unadjusted Model

The fully adjusted GLM procedure was performed which included hormone treatment in the analysis, as it was found to confound the relationship between treatment group and change in EPIC sexual function score. It was found that hormone treatment did not modify the association (act in conjunction with type of treatment) to affect change in EPIC score. The F value for the fully adjusted GLM model shown in Table 6 was 0.028, demonstrating a model of good fit. The R^2 value was 0.06, which indicates that treatment group can explain 6% of the variation in change in sexual function from baseline to 2 years. The difference in change between the EBRT patients and the RALP patients was -10.4, which is a statistically significant difference ($p = 0.04$). As negative numbers represent an increase in function, EBRT patients have better sexual function than RALP patients.

	Adjusted GLM Model	
Mean	**R^2**	**Pr > F**
15.94	0.06	0.028
	Estimate	**Pr > |t|**
Intercept	18.43	<.0001
EBRT	-10.42	0.036
RALP	0.00	

Table 6: Reported Values from Sexual Function Fully Adjusted GLM Model

Discussion

This study compared RALP to EBRT in terms of urinary and sexual function change from pre-treatment. The purpose of this comparison was to determine if either treatment provided better outcomes for patients. It was hypothesized that RALP patients would have better improvement urinary function, and EBRT would have better improvement sexual function.

No significant difference was identified between the treatments for change in urinary function at the two-year time point. This indicates that neither is superior at preserving urinary function. The mean of all of the patients included in the analysis of urinary function was negative. This indicates that in general, all patients who undergo treatment for prostate cancer have improved urinary function from before their initial treatment. This study's finding of no significant difference between urinary change and treatment groups does not coincide with a study performed by Chien in 2017. This study found that urinary function was significantly worse in RALP patients compared to other treatments such as EBRT (Chien *et al.*, 2017). As there are still few studies that compare RALP to EBRT these conflicting findings cannot be reconciled.

This study also uncovered an interesting finding that could help explain variation in urinary change scores for patients treated for prostate cancer. The analysis of urinary function found that arterial disease is significantly associated with a greater urinary change score compared to no artery disease ($p = 0.001$). This suggests that artery disease may be a better predictor of loss of urinary function after prostate cancer treatment than treatment type. Further investigation into this relationship between urinary function and arterial disease is warranted to distinguish if arterial disease should

be taken into account in the treatment decisions for patients when attempting to preserve urinary function.

A significant difference was found in the change in sexual function scores between treatment groups. The EBRT patients had a difference in change of -10.4 from the RALP patients. As negative numbers indicate an improvement in function, EBRT patients' sexual function improved when compared to RALP patients ($p = 0.04$). This indicates that EBRT is the superior treatment in the preservation sexual function. These findings agree with Chein's 2017 study that found EBRT patients had better sexual function when compared to RALP patients.

This study has limitations that affect the conclusions that are drawn. As this study was performed with self-report EPIC questionnaires, there is the chance that the answers the subjects provided are not an accurate representation of their urinary or sexual function. This study also contained a much smaller sample size of EBRT patients compared to RALP patients. This was due to extensive missing data in pre-treatment scores for patients treated with EBRT. This missing data likely results from differences in EPIC packet distribution practices at the location where patients receive EBRT. This study also relied heavily on data in patient charts for assessment of cofounding variables. If these charts were not updated or did not contain the information gathered by this study, the affect of these cofounding variables determined in this study could be inaccurate. As was mentioned, there was extensive missing data in erectile aid use and race. A study that was designed to collect this information in a more reliable way, rather than relying on information included in a patient's chart, would be able to assess cofounding variables to a more accurate degree. The diversity of patients is also a

limitation in this study because the demographic was largely white men. A study that included a larger representation of the diversity or the populations would be able to draw more extensive conclusions.

This is one of the first studies that compare RALP to other treatments. More studies that compare RALP to other treatments are needed to assess which treatment will best suit patient needs. As use of erectile aids was not able to be included in this analysis due to extensive missing data, studies that analyze the role of erectile aid use in sexual function change after prostate cancer treatment should be conducted to evaluate how they affect the change in sexual function in relation to treatment type.

This study will add to the growing field of knowledge of the benefits of different prostate cancer treatments. It supports that EBRT is a better therapy for preserving sexual function, and informs that either treatment will preserve urinary function to a similar degree.

Conclusion

Health related quality of life in terms of urinary and sexual function varies by treatment. EBRT was a better treatment for preserving sexual function, but neither treatment is better for preserving urinary function in this study. This study adds to the information about different prostate cancer treatments, and allows for the possibility that treatments can be specified to a patient's needs to create the best quality of life after surgery that can be achieved.

Appendix A: Statistical Analysis Report

The FREQ Procedure

treatment

treatment	Frequency	Percent	Cumulative Frequency	Cumulative Percent
RALP	104	76.47	104	76.47
EBRT	32	23.53	136	100.00

smoking0

smoking0	Frequency	Percent	Cumulative Frequency	Cumulative Percent
Non-smoker	70	54.26	70	54.26
Current Smoker	3	2.33	73	56.59
Former smoker	56	43.41	129	100.00

Frequency Missing = 7

race

race	Frequency	Percent	Cumulative Frequency	Cumulative Percent
white	88	98.88	88	98.88
Native American	1	1.12	89	100.00

Frequency Missing = 47

hormoneTx

hormoneTx	Frequency	Percent	Cumulative Frequency	Cumulative Percent
no	130	95.59	130	95.59
yes	6	4.41	136	100.00

EDaid0

EDaid0	Frequency	Percent	Cumulative Frequency	Cumulative Percent
no	118	87.41	118	87.41
yes	17	12.59	135	100.00

Frequency Missing = 1

EDaid2

EDaid2	Frequency	Percent	Cumulative Frequency	Cumulative Percent
no	52	46.02	52	46.02
yes	61	53.98	113	100.00

Frequency Missing = 23

The FREQ Procedure

cardiacDx	Frequency	Percent	Cumulative Frequency	Cumulative Percent
no	112	86.15	112	86.15
yes	18	13.85	130	100.00
Frequency Missing = 6				

hypertension	Frequency	Percent	Cumulative Frequency	Cumulative Percent
no	122	93.85	122	93.85
yes	8	6.15	130	100.00
Frequency Missing = 6				

arterialDx	Frequency	Percent	Cumulative Frequency	Cumulative Percent
no	129	99.23	129	99.23
yes	1	0.77	130	100.00
Frequency Missing = 6				

The FREQ Procedure

Frequency Expected Percent Row Pct Col Pct	Table of treatment by race		
		race(race)	
treatment(treatment)	white	Native American	Total
RALP	65	0	65
	64.27	0.7303	
	73.03	0.00	73.03
	100.00	0.00	
	73.86	0.00	
EBRT	23	1	24
	23.73	0.2697	
	25.84	1.12	26.97
	95.83	4.17	
	26.14	100.00	
Total	88	1	89
	98.88	1.12	100.00

Frequency Missing = 47

Statistics for Table of treatment by race

Statistic	DF	Value	Prob
Chi-Square	1	2.7391	0.0979
Likelihood Ratio Chi-Square	1	2.6521	0.1034
Continuity Adj. Chi-Square	1	0.2725	0.6017
Mantel-Haenszel Chi-Square	1	2.7083	0.0998
Phi Coefficient		0.1754	
Contingency Coefficient		0.1728	
Cramer's V		0.1754	

WARNING: 50% of the cells have expected counts less than 5. Chi-Square may not be a valid test.

Fisher's Exact Test	
Cell (1,1) Frequency (F)	65
Left-sided Pr <= F	1.0000
Right-sided Pr >= F	0.2697
Table Probability (P)	0.2697
Two-sided Pr <= P	0.2697

Effective Sample Size = 89
Frequency Missing = 47

WARNING: 35% of the data are missing.

The FREQ Procedure

Frequency Expected Percent Row Pct Col Pct	Table of treatment by hormoneTx		
		hormoneTx(hormoneTx)	
treatment(treatment)	no	yes	Total
RALP	103	1	104
	99.412	4.5882	
	75.74	0.74	76.47
	99.04	0.96	
	79.23	16.67	
EBRT	27	5	32
	30.588	1.4118	
	19.85	3.68	23.53
	84.38	15.63	
	20.77	83.33	
Total	130	6	136
	95.59	4.41	100.00

Statistics for Table of treatment by hormoneTx

Statistic	DF	Value	Prob
Chi-Square	1	12.4767	0.0004
Likelihood Ratio Chi-Square	1	10.1654	0.0014
Continuity Adj. Chi-Square	1	9.2419	0.0024
Mantel-Haenszel Chi-Square	1	12.3850	0.0004
Phi Coefficient		0.3029	
Contingency Coefficient		0.2899	
Cramer's V		0.3029	

WARNING: 50% of the cells have expected counts less than 5. Chi-Square may not be a valid test.

Fisher's Exact Test	
Cell (1,1) Frequency (F)	103
Left-sided Pr <= F	0.9999
Right-sided Pr >= F	0.0028
Table Probability (P)	0.0027
Two-sided Pr <= P	0.0028

Sample Size = 136

The FREQ Procedure

Frequency Expected Percent Row Pct Col Pct	Table of treatment by EDaid0		
		EDaid0(EDaid0)	
treatment(treatment)	no	yes	Total
RALP	92 90.03 68.15 89.32 77.97	11 12.97 8.15 10.68 64.71	103 76.30
EBRT	26 27.97 19.26 81.25 22.03	6 4.0296 4.44 18.75 35.29	32 23.70
Total	118 87.41	17 12.59	135 100.00

Frequency Missing = 1

Statistics for Table of treatment by EDaid0

Statistic	DF	Value	Prob
Chi-Square	1	1.4447	0.2294
Likelihood Ratio Chi-Square	1	1.3370	0.2476
Continuity Adj. Chi-Square	1	0.8045	0.3697
Mantel-Haenszel Chi-Square	1	1.4340	0.2311
Phi Coefficient		0.1034	
Contingency Coefficient		0.1029	
Cramer's V		0.1034	

WARNING: 25% of the cells have expected counts less than 5. Chi-Square may not be a valid test.

Fisher's Exact Test	
Cell (1,1) Frequency (F)	92
Left-sided Pr <= F	0.9294
Right-sided Pr >= F	0.1825
Table Probability (P)	0.1119
Two-sided Pr <= P	0.2341

Effective Sample Size = 135
Frequency Missing = 1

The FREQ Procedure

Frequency Expected Percent Row Pct Col Pct	Table of treatment by EDaid2		
		EDaid2(EDaid2)	
treatment(treatment)	no	yes	Total
RALP	30 37.735 26.55 36.59 57.69	52 44.265 46.02 63.41 85.25	82 72.57
EBRT	22 14.265 19.47 70.97 42.31	9 16.735 7.96 29.03 14.75	31 27.43
Total	52 46.02	61 53.98	113 100.00

Frequency Missing = 23

Statistics for Table of treatment by EDaid2

Statistic	DF	Value	Prob
Chi-Square	1	10.7051	0.0011
Likelihood Ratio Chi-Square	1	10.8816	0.0010
Continuity Adj. Chi-Square	1	9.3658	0.0022
Mantel-Haenszel Chi-Square	1	10.6104	0.0011
Phi Coefficient		-0.3078	
Contingency Coefficient		0.2942	
Cramer's V		-0.3078	

Fisher's Exact Test	
Cell (1,1) Frequency (F)	30
Left-sided Pr <= F	0.0010
Right-sided Pr >= F	0.9998
Table Probability (P)	0.0008
Two-sided Pr <= P	0.0014

Effective Sample Size = 113
Frequency Missing = 23

WARNING: 17% of the data are missing.

The FREQ Procedure

Frequency Expected Percent Row Pct Col Pct	Table of treatment by cardiacDx		
		cardiacDx	
treatment(treatment)	no	yes	Total
RALP	99 89.6 76.15 95.19 88.39	5 14.4 3.85 4.81 27.78	104 80.00
EBRT	13 22.4 10.00 50.00 11.61	13 3.6 10.00 50.00 72.22	26 20.00
Total	112 86.15	18 13.85	130 100.00
Frequency Missing = 6			

Statistics for Table of treatment by cardiacDx

Statistic	DF	Value	Prob
Chi-Square	1	35.6114	<.0001
Likelihood Ratio Chi-Square	1	28.4130	<.0001
Continuity Adj. Chi-Square	1	31.9237	<.0001
Mantel-Haenszel Chi-Square	1	35.3374	<.0001
Phi Coefficient		0.5234	
Contingency Coefficient		0.4637	
Cramer's V		0.5234	

WARNING: 25% of the cells have expected counts less than 5. Chi-Square may not be a valid test.

Fisher's Exact Test	
Cell (1,1) Frequency (F)	99
Left-sided Pr <= F	1.0000
Right-sided Pr >= F	<.0001
Table Probability (P)	<.0001
Two-sided Pr <= P	<.0001

Effective Sample Size = 130
Frequency Missing = 6

The FREQ Procedure

Frequency
Expected
Percent
Row Pct
Col Pct

Table of treatment by hypertension

treatment(treatment)	hypertension no	hypertension yes	Total
RALP	97	7	104
	97.6	6.4	
	74.62	5.38	80.00
	93.27	6.73	
	79.51	87.50	
EBRT	25	1	26
	24.4	1.6	
	19.23	0.77	20.00
	96.15	3.85	
	20.49	12.50	
Total	122	8	130
	93.85	6.15	100.00

Frequency Missing = 6

Statistics for Table of treatment by hypertension

Statistic	DF	Value	Prob
Chi-Square	1	0.2997	0.5841
Likelihood Ratio Chi-Square	1	0.3329	0.5640
Continuity Adj. Chi-Square	1	0.0083	0.9273
Mantel-Haenszel Chi-Square	1	0.2974	0.5855
Phi Coefficient		-0.0480	
Contingency Coefficient		0.0480	
Cramer's V		-0.0480	

WARNING: 25% of the cells have expected counts less than 5. Chi-Square may not be a valid test.

Fisher's Exact Test	
Cell (1,1) Frequency (F)	97
Left-sided Pr <= F	0.4987
Right-sided Pr >= F	0.8414
Table Probability (P)	0.3401
Two-sided Pr <= P	1.0000

Effective Sample Size = 130
Frequency Missing = 6

The FREQ Procedure

Frequency
Expected
Percent
Row Pct
Col Pct

Table of treatment by arterialDx

treatment(treatment)	arterialDx: no	arterialDx: yes	Total
RALP	103	1	104
	103.2	0.8	
	79.23	0.77	80.00
	99.04	0.96	
	79.84	100.00	
EBRT	26	0	26
	25.8	0.2	
	20.00	0.00	20.00
	100.00	0.00	
	20.16	0.00	
Total	129	1	130
	99.23	0.77	100.00

Frequency Missing = 6

Statistics for Table of treatment by arterialDx

Statistic	DF	Value	Prob
Chi-Square	1	0.2519	0.6157
Likelihood Ratio Chi-Square	1	0.4482	0.5032
Continuity Adj. Chi-Square	1	0.0000	1.0000
Mantel-Haenszel Chi-Square	1	0.2500	0.6171
Phi Coefficient		-0.0440	
Contingency Coefficient		0.0440	
Cramer's V		-0.0440	

WARNING: 50% of the cells have expected counts less than 5. Chi-Square may not be a valid test.

Fisher's Exact Test	
Cell (1,1) Frequency (F)	103
Left-sided Pr <= F	0.8000
Right-sided Pr >= F	1.0000
Table Probability (P)	0.8000
Two-sided Pr <= P	1.0000

Effective Sample Size = 130
Frequency Missing = 6

The MEANS Procedure

Variable	Label	N	N Miss
id	id	136	0
treatment	treatment	136	0
age0	age0	136	0
smoking0	smoking0	129	7
race	race	89	47
hormoneTx	hormoneTx	136	0
bmi	bmi	133	3
EDaid0	EDaid0	135	1
EDaid2	EDaid2	113	23
urinaryChange_0_2	urinaryChange_0_2	134	2
sexualChange_0_2	sexualChange_0_2	133	3
cardiacDx		130	6
hypertension		130	6
arterialDx		130	6

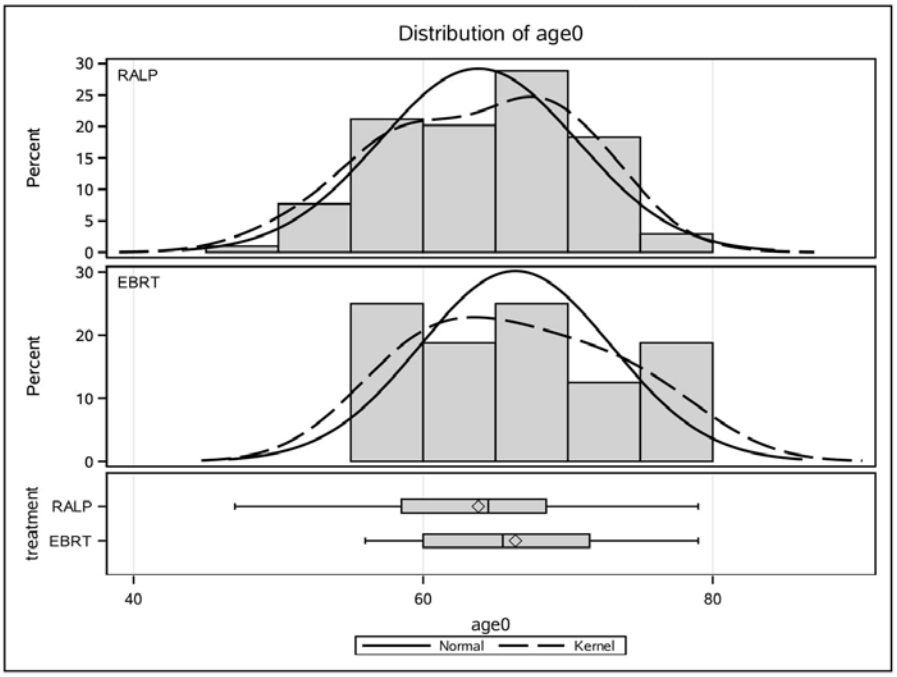
The TTEST Procedure

Variable: age0 (age0)

treatment	N	Mean	Std Dev	Std Err	Minimum	Maximum
RALP	104	63.8077	6.8281	0.6695	47.0000	79.0000
EBRT	32	66.3750	6.6077	1.1681	56.0000	79.0000
Diff (1-2)		-2.5673	6.7777	1.3701		

treatment	Method	Mean	95% CL Mean		Std Dev	95% CL Std Dev	
RALP		63.8077	62.4798	65.1356	6.8281	6.0094	7.9070
EBRT		66.3750	63.9927	68.7573	6.6077	5.2974	8.7848
Diff (1-2)	Pooled	-2.5673	-5.2772	0.1426	6.7777	6.0543	7.6991
Diff (1-2)	Satterthwaite	-2.5673	-5.2678	0.1332			

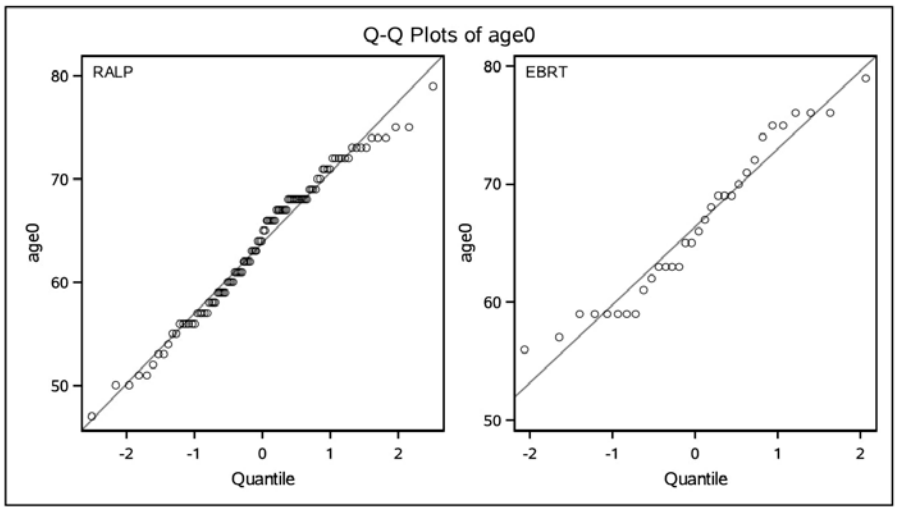
Method	Variances	DF	t Value	Pr > |t|
Pooled	Equal	134	-1.87	0.0631
Satterthwaite	Unequal	52.996	-1.91	0.0620



Equality of Variances				
Method	Num DF	Den DF	F Value	Pr > F
Folded F	103	31	1.07	0.8633

The TTEST Procedure

Variable: age0 (age0)



The NPAR1WAY Procedure

Wilcoxon Scores (Rank Sums) for Variable bmi Classified by Variable treatment

treatment	N	Sum of Scores	Expected Under H0	Std Dev Under H0	Mean Score
EBRT	30	2203.0	2010.0	185.747872	73.433333
RALP	103	6708.0	6901.0	185.747872	65.126214

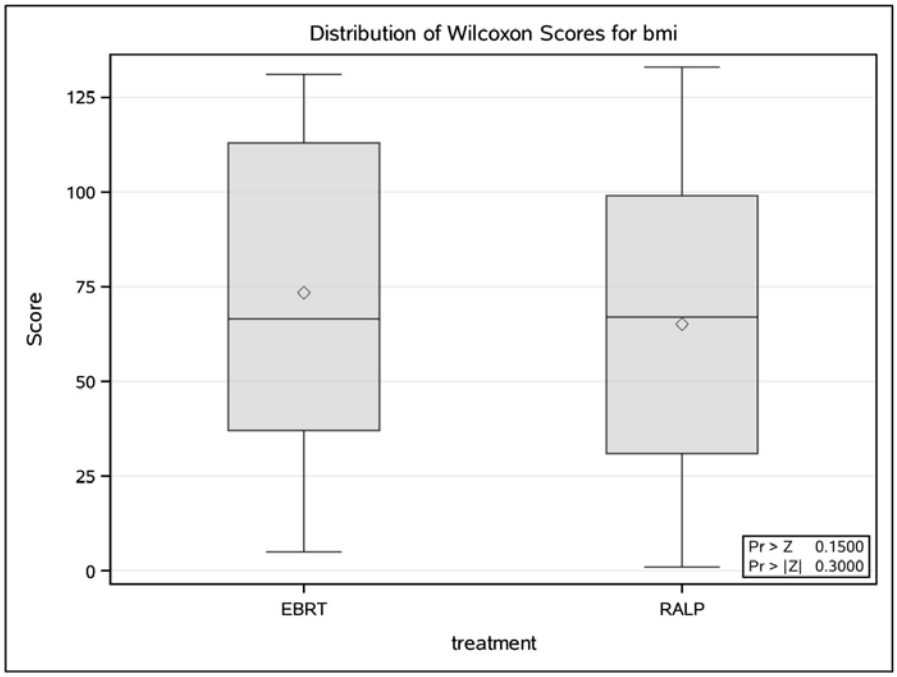
Average scores were used for ties.

Wilcoxon Two-Sample Test	
Statistic	2203.0000
Normal Approximation	
Z	1.0364
One-Sided Pr > Z	0.1500
Two-Sided Pr > |Z|	0.3000
t Approximation	
One-Sided Pr > Z	0.1510
Two-Sided Pr > |Z|	0.3019

Z includes a continuity correction of 0.5.

Kruskal-Wallis Test	
Chi-Square	1.0796
DF	1
Pr > Chi-Square	0.2988

The NPAR1WAY Procedure



UN-ADJUSTED MODEL

The GLM Procedure

Class Level Information

Class	Levels	Values
treatment	2	EBRT RALP
smoking0	3	Current Smoker Former smoker Non-smoker
hormoneTx	2	yes no
cardiacDx	2	yes no
hypertension	2	yes no
arterialDx	2	yes no

Number of Observations Read	136
Number of Observations Used	121

UN-ADJUSTED MODEL

The GLM Procedure

Dependent Variable: urinaryChange_0_2 urinaryChange_0_2

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	1	145.83791	145.83791	0.42	0.5201
Error	119	41694.01213	350.36985		
Corrected Total	120	41839.85004			

R-Square	Coeff Var	Root MSE	urinaryChange_0_2 Mean
0.003486	-1526.261	18.71817	-1.226407

Source	DF	Type I SS	Mean Square	F Value	Pr > F
treatment	1	145.8379102	145.8379102	0.42	0.5201

Source	DF	Type II SS	Mean Square	F Value	Pr > F
treatment	1	145.8379102	145.8379102	0.42	0.5201

Source	DF	Type III SS	Mean Square	F Value	Pr > F
treatment	1	145.8379102	145.8379102	0.42	0.5201

Source	DF	Type IV SS	Mean Square	F Value	Pr > F
treatment	1	145.8379102	145.8379102	0.42	0.5201

Parameter	Estimate		Standard Error	t Value	Pr > |t|
Intercept	-1.786650546	B	1.91041512	-0.94	0.3516
treatment EBRT	2.711579117	B	4.20291327	0.65	0.5201
treatment RALP	0.000000000	B	.	.	.

Note: The X'X matrix has been found to be singular, and a generalized inverse was used to solve the normal equations. Terms whose estimates are followed by the letter 'B' are not uniquely estimable.

UN-ADJUSTED MODEL

The GLM Procedure

Observation		Observed	Predicted	Residual	95% Confidence Limits for Mean Predicted Value	
1		0.00000000	0.92492857	-0.92492857	-6.48784024	8.33769739
2		-11.08333333	0.92492857	-12.00826190	-6.48784024	8.33769739
3		-56.25000000	0.92492857	-57.17492857	-6.48784024	8.33769739
4		4.16666667	0.92492857	3.24173810	-6.48784024	8.33769739
5	*					
6	*					
7		6.91666667	0.92492857	5.99173810	-6.48784024	8.33769739
8		17.33333333	0.92492857	16.40840476	-6.48784024	8.33769739
9		6.25000000	0.92492857	5.32507143	-6.48784024	8.33769739
10		6.25000000	0.92492857	5.32507143	-6.48784024	8.33769739
11	*					
12	*					
13		0.00000000	0.92492857	-0.92492857	-6.48784024	8.33769739
14		0.00000000	0.92492857	-0.92492857	-6.48784024	8.33769739
15		2.08333333	0.92492857	1.15840476	-6.48784024	8.33769739
16		-4.16666667	0.92492857	-5.09159524	-6.48784024	8.33769739
17	*					
18		6.25000000	0.92492857	5.32507143	-6.48784024	8.33769739
19		-4.16666667	0.92492857	-5.09159524	-6.48784024	8.33769739
20		-6.91666667	0.92492857	-7.84159524	-6.48784024	8.33769739
21		-2.08333333	0.92492857	-3.00826190	-6.48784024	8.33769739
22	*	.	0.92492857	.	-6.48784024	8.33769739
23		4.83333333	0.92492857	3.90840476	-6.48784024	8.33769739
24		-4.83333333	0.92492857	-5.75826190	-6.48784024	8.33769739
25		-2.08333333	0.92492857	-3.00826190	-6.48784024	8.33769739
26		0.00000000	0.92492857	-0.92492857	-6.48784024	8.33769739
27		-5.58333333	0.92492857	-6.50826190	-6.48784024	8.33769739
28		-13.16666667	0.92492857	-14.09159524	-6.48784024	8.33769739
29	*					
30		83.50000000	0.92492857	82.57507143	-6.48784024	8.33769739
31		-3.53154762	0.92492857	-4.45647619	-6.48784024	8.33769739
32		-0.59523810	0.92492857	-1.52016667	-6.48784024	8.33769739
33		-18.75000000	-1.78665055	-16.96334945	-5.56946329	1.99616220
34		2.75000000	-1.78665055	4.53665055	-5.56946329	1.99616220
35		24.25000000	-1.78665055	26.03665055	-5.56946329	1.99616220
36		-20.16666667	-1.78665055	-18.38001612	-5.56946329	1.99616220
37		-13.91666667	-1.78665055	-12.13001612	-5.56946329	1.99616220
38	*					
39		11.08333333	-1.78665055	12.86998388	-5.56946329	1.99616220
40		-9.00000000	-1.78665055	-7.21334945	-5.56946329	1.99616220
41		5.58333333	-1.78665055	7.36998388	-5.56946329	1.99616220

UN-ADJUSTED MODEL

The GLM Procedure

Observation		Observed	Predicted	Residual	95% Confidence Limits for Mean Predicted Value	
42		4.83333333	-1.78665055	6.61998388	-5.56946329	1.99616220
43		-42.33333333	-1.78665055	-40.54668279	-5.56946329	1.99616220
44		1.41666667	-1.78665055	3.20331721	-5.56946329	1.99616220
45		16.66666667	-1.78665055	18.45331721	-5.56946329	1.99616220
46	*					
47		20.16666667	-1.78665055	21.95331721	-5.56946329	1.99616220
48	*					
49		-12.50000000	-1.78665055	-10.71334945	-5.56946329	1.99616220
50		17.50000000	-1.78665055	19.28665055	-5.56946329	1.99616220
51		2.75000000	-1.78665055	4.53665055	-5.56946329	1.99616220
52	*					
53		9.00000000	-1.78665055	10.78665055	-5.56946329	1.99616220
54		11.08333333	-1.78665055	12.86998388	-5.56946329	1.99616220
55	*					
56		-6.91666667	-1.78665055	-5.13001612	-5.56946329	1.99616220
57		9.00000000	-1.78665055	10.78665055	-5.56946329	1.99616220
58		-1.41666667	-1.78665055	0.36998388	-5.56946329	1.99616220
59		6.25000000	-1.78665055	8.03665055	-5.56946329	1.99616220
60		-8.33333333	-1.78665055	-6.54668279	-5.56946329	1.99616220
61		-2.08333333	-1.78665055	-0.29668279	-5.56946329	1.99616220
62	*					
63		-22.16666667	-1.78665055	-20.38001612	-5.56946329	1.99616220
64		-8.33333333	-1.78665055	-6.54668279	-5.56946329	1.99616220
65	*					
66		18.00000000	-1.78665055	19.78665055	-5.56946329	1.99616220
67		-32.66666667	-1.78665055	-30.88001612	-5.56946329	1.99616220
68		-7.66666667	-1.78665055	-5.88001612	-5.56946329	1.99616220
69		0.66666667	-1.78665055	2.45331721	-5.56946329	1.99616220
70		-8.33333333	-1.78665055	-6.54668279	-5.56946329	1.99616220
71		-4.16666667	-1.78665055	-2.38001612	-5.56946329	1.99616220
72		-2.08333333	-1.78665055	-0.29668279	-5.56946329	1.99616220
73		22.16666667	-1.78665055	23.95331721	-5.56946329	1.99616220
74		22.16666667	-1.78665055	23.95331721	-5.56946329	1.99616220
75		2.75000000	-1.78665055	4.53665055	-5.56946329	1.99616220
76		35.41666667	-1.78665055	37.20331721	-5.56946329	1.99616220
77		27.52916667	-1.78665055	29.31581721	-5.56946329	1.99616220
78		15.25000000	-1.78665055	17.03665055	-5.56946329	1.99616220
79		-54.91666667	-1.78665055	-53.13001612	-5.56946329	1.99616220
80		6.91666667	-1.78665055	8.70331721	-5.56946329	1.99616220
81		-7.66666667	-1.78665055	-5.88001612	-5.56946329	1.99616220
82		-4.16666667	-1.78665055	-2.38001612	-5.56946329	1.99616220

UN-ADJUSTED MODEL

The GLM Procedure

Observation	Observed	Predicted	Residual	95% Confidence Limits for Mean Predicted Value	
83	0.66666667	-1.78665055	2.45331721	-5.56946329	1.99616220
84	6.91666667	-1.78665055	8.70331721	-5.56946329	1.99616220
85	9.00000000	-1.78665055	10.78665055	-5.56946329	1.99616220
86	-5.58333333	-1.78665055	-3.79668279	-5.56946329	1.99616220
87	6.25000000	-1.78665055	8.03665055	-5.56946329	1.99616220
88	-1.41666667	-1.78665055	0.36998388	-5.56946329	1.99616220
89	6.91666667	-1.78665055	8.70331721	-5.56946329	1.99616220
90	6.91666667	-1.78665055	8.70331721	-5.56946329	1.99616220
91	6.25000000	-1.78665055	8.03665055	-5.56946329	1.99616220
92	-14.58333333	-1.78665055	-12.79668279	-5.56946329	1.99616220
93	2.08333333	-1.78665055	3.86998388	-5.56946329	1.99616220
94	0.03333333	-1.78665055	1.81998388	-5.56946329	1.99616220
95	-18.75000000	-1.78665055	-16.96334945	-5.56946329	1.99616220
96	2.08333333	-1.78665055	3.86998388	-5.56946329	1.99616220
97	4.16666667	-1.78665055	5.95331721	-5.56946329	1.99616220
98	0.66666667	-1.78665055	2.45331721	-5.56946329	1.99616220
99	-19.41666667	-1.78665055	-17.63001612	-5.56946329	1.99616220
100	2.08333333	-1.78665055	3.86998388	-5.56946329	1.99616220
101	2.08333333	-1.78665055	3.86998388	-5.56946329	1.99616220
102	-25.00000000	-1.78665055	-23.21334945	-5.56946329	1.99616220
103	-9.00000000	-1.78665055	-7.21334945	-5.56946329	1.99616220
104	-6.25000000	-1.78665055	-4.46334945	-5.56946329	1.99616220
105	-2.08333333	-1.78665055	-0.29668279	-5.56946329	1.99616220
106	0.00000000	-1.78665055	1.78665055	-5.56946329	1.99616220
107	11.16666667	-1.78665055	12.95331721	-5.56946329	1.99616220
108	31.25000000	-1.78665055	33.03665055	-5.56946329	1.99616220
109	18.83333333	-1.78665055	20.61998388	-5.56946329	1.99616220
110	9.66666667	-1.78665055	11.45331721	-5.56946329	1.99616220
111	-4.16428571	-1.78665055	-2.37763517	-5.56946329	1.99616220
112	-70.16666667	-1.78665055	-68.38001612	-5.56946329	1.99616220
113	-25.00000000	-1.78665055	-23.21334945	-5.56946329	1.99616220
114	-9.75000000	-1.78665055	-7.96334945	-5.56946329	1.99616220
115	-14.58333333	-1.78665055	-12.79668279	-5.56946329	1.99616220
116	-36.83333333	-1.78665055	-35.04668279	-5.56946329	1.99616220
117	-11.08333333	-1.78665055	-9.29668279	-5.56946329	1.99616220
118	-10.41666667	-1.78665055	-8.63001612	-5.56946329	1.99616220
119	4.83333333	-1.78665055	6.61998388	-5.56946329	1.99616220
120	6.91666667	-1.78665055	8.70331721	-5.56946329	1.99616220
121	-12.50000000	-1.78665055	-10.71334945	-5.56946329	1.99616220
122	-11.83333333	-1.78665055	-10.04668279	-5.56946329	1.99616220
123	-3.50000000	-1.78665055	-1.71334945	-5.56946329	1.99616220

UN-ADJUSTED MODEL

The GLM Procedure

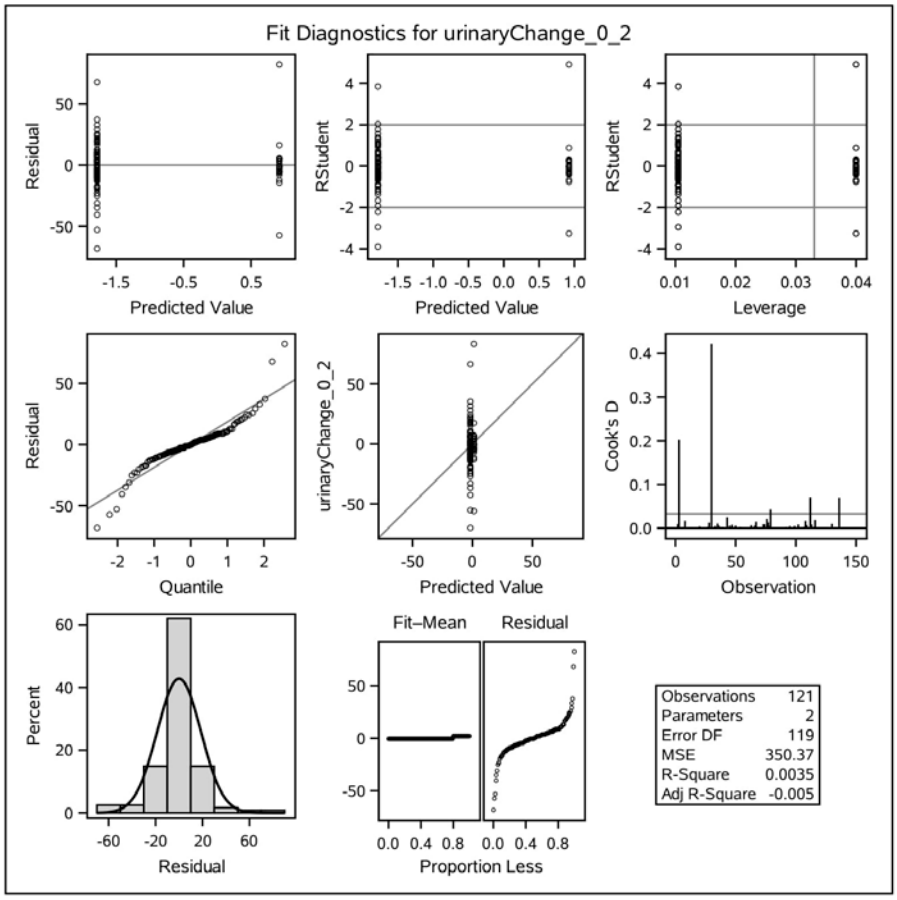
Observation		Observed	Predicted	Residual	95% Confidence Limits for Mean Predicted Value	
124		4.83333333	-1.78665055	6.61998388	-5.56946329	1.99616220
125		-10.41666667	-1.78665055	-8.63001612	-5.56946329	1.99616220
126		2.08333333	-1.78665055	3.86998388	-5.56946329	1.99616220
127	*	.	-1.78665055	.	-5.56946329	1.99616220
128		-4.16666667	-1.78665055	-2.38001612	-5.56946329	1.99616220
129		0.00000000	-1.78665055	1.78665055	-5.56946329	1.99616220
130		-27.08333333	-1.78665055	-25.29668279	-5.56946329	1.99616220
131		-13.16666667	-1.78665055	-11.38001612	-5.56946329	1.99616220
132		-11.08333333	-1.78665055	-9.29668279	-5.56946329	1.99616220
133		-6.25000000	-1.78665055	-4.46334945	-5.56946329	1.99616220
134		6.91666667	-1.78665055	8.70331721	-5.56946329	1.99616220
135		-11.83333333	-1.78665055	-10.04668279	-5.56946329	1.99616220
136		66.16666667	-1.78665055	67.95331721	-5.56946329	1.99616220

*** Observation was not used in this analysis**

Sum of Residuals	0.00000
Sum of Squared Residuals	41694.01213
Sum of Squared Residuals - Error SS	0.00000
PRESS Statistic	43284.49617
First Order Autocorrelation	0.07005
Durbin-Watson D	1.74913

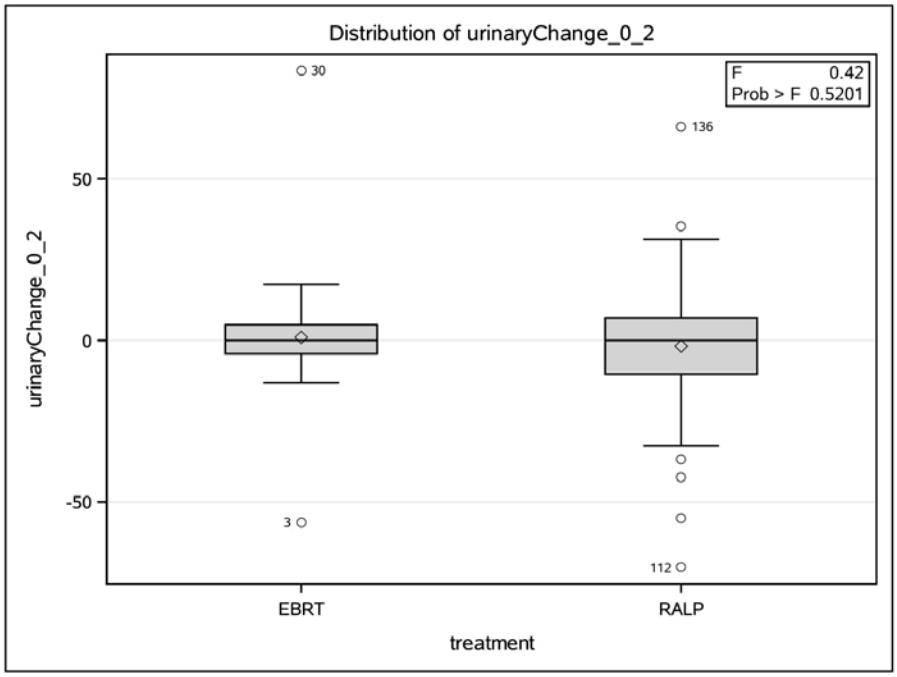
UN-ADJUSTED MODEL

The GLM Procedure



UN-ADJUSTED MODEL

The GLM Procedure



FULLY-ADJUSTED MODEL

The GLM Procedure

Class Level Information

Class	Levels	Values
treatment	2	EBRT RALP
smoking0	3	Current Smoker Former smoker Non-smoker
hormoneTx	2	yes no
cardiacDx	2	yes no
hypertension	2	yes no
arterialDx	2	yes no

Number of Observations Read	136
Number of Observations Used	119

FULLY-ADJUSTED MODEL

The GLM Procedure

Dependent Variable: urinaryChange_0_2 urinaryChange_0_2

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	9	7014.16338	779.35149	2.68	0.0076
Error	109	31748.30655	291.26887		
Corrected Total	118	38762.46994			

R-Square	Coeff Var	Root MSE	urinaryChange_0_2 Mean
0.180952	-2108.696	17.06660	-0.809344

Source	DF	Type I SS	Mean Square	F Value	Pr > F
treatment	1	474.408222	474.408222	1.63	0.2046
cardiacDx	1	2259.699214	2259.699214	7.76	0.0063
arterialDx	1	3230.230972	3230.230972	11.09	0.0012
age0	1	571.658477	571.658477	1.96	0.1641
bmi	1	52.979889	52.979889	0.18	0.6706
smoking0	2	258.179818	129.089909	0.44	0.6431
hypertension	1	133.919271	133.919271	0.46	0.4992
hormoneTx	1	33.087520	33.087520	0.11	0.7367

Source	DF	Type II SS	Mean Square	F Value	Pr > F
treatment	1	200.232543	200.232543	0.69	0.4088
cardiacDx	1	417.015906	417.015906	1.43	0.2341
arterialDx	1	3547.695117	3547.695117	12.18	0.0007
age0	1	402.922978	402.922978	1.38	0.2421
bmi	1	95.886957	95.886957	0.33	0.5673
smoking0	2	262.735067	131.367534	0.45	0.6382
hypertension	1	164.672126	164.672126	0.57	0.4537
hormoneTx	1	33.087520	33.087520	0.11	0.7367

Source	DF	Type III SS	Mean Square	F Value	Pr > F
treatment	1	200.232543	200.232543	0.69	0.4088
cardiacDx	1	417.015906	417.015906	1.43	0.2341
arterialDx	1	3547.695117	3547.695117	12.18	0.0007
age0	1	402.922978	402.922978	1.38	0.2421
bmi	1	95.886957	95.886957	0.33	0.5673
smoking0	2	262.735067	131.367534	0.45	0.6382
hypertension	1	164.672126	164.672126	0.57	0.4537
hormoneTx	1	33.087520	33.087520	0.11	0.7367

FULLY-ADJUSTED MODEL

The GLM Procedure

Dependent Variable: urinaryChange_0_2 urinaryChange_0_2

Source	DF	Type IV SS	Mean Square	F Value	Pr > F
treatment	1	200.232543	200.232543	0.69	0.4088
cardiacDx	1	417.015906	417.015906	1.43	0.2341
arterialDx	1	3547.695117	3547.695117	12.18	0.0007
age0	1	402.922978	402.922978	1.38	0.2421
bmi	1	95.886957	95.886957	0.33	0.5673
smoking0	2	262.735067	131.367534	0.45	0.6382
hypertension	1	164.672126	164.672126	0.57	0.4537
hormoneTx	1	33.087520	33.087520	0.11	0.7367

Parameter		Estimate		Standard Error	t Value	Pr > |t|
Intercept		10.19061656	B	20.07968954	0.51	0.6128
treatment	EBRT	4.45141659	B	5.36880885	0.83	0.4088
treatment	RALP	0.00000000	B	.	.	.
cardiacDx	yes	6.98616407	B	5.83861050	1.20	0.2341
cardiacDx	no	0.00000000	B	.	.	.
arterialDx	yes	64.23058696	B	18.40415064	3.49	0.0007
arterialDx	no	0.00000000	B	.	.	.
age0		-0.29151253		0.24785246	-1.18	0.2421
bmi		0.23595026		0.41123279	0.57	0.5673
smoking0	Current Smoker	-0.90374821	B	17.23296719	-0.05	0.9583
smoking0	Former smoker	-3.21920282	B	3.38950615	-0.95	0.3443
smoking0	Non-smoker	0.00000000	B	.	.	.
hypertension	yes	5.08785063	B	6.76661301	0.75	0.4537
hypertension	no	0.00000000	B	.	.	.
hormoneTx	yes	-3.02192546	B	8.96599869	-0.34	0.7367
hormoneTx	no	0.00000000	B	.	.	.

Note: The X'X matrix has been found to be singular, and a generalized inverse was used to solve the normal equations. Terms whose estimates are followed by the letter 'B' are not uniquely estimable.

FULLY-ADJUSTED MODEL

The GLM Procedure

Observation		Observed	Predicted	Residual	95% Confidence Limits for Mean Predicted Value	
1		0.00000000	-0.58283164	0.58283164	-12.02526396	10.85960068
2		-11.08333333	9.62222352	-20.70555686	-2.15198704	21.39643409
3	*					
4	*					
5	*					
6	*					
7		6.91666667	-2.43261133	9.34927800	-13.85350996	8.98828729
8		17.33333333	6.47761319	10.85572014	-2.94845688	15.90368326
9		6.25000000	-4.44640658	10.69640658	-15.47581133	6.58299817
10		6.25000000	-7.52602591	13.77602591	-24.07928189	9.02723007
11	*					
12	*					
13		0.00000000	9.73935744	-9.73935744	-1.03636407	20.51507895
14		0.00000000	4.88601471	-4.88601471	-5.11126817	14.88329759
15		2.08333333	8.91840804	-6.83507471	-1.14446648	18.98128256
16		-4.16666667	-1.44534381	-2.72132286	-13.12376440	10.23307679
17	*					
18		6.25000000	4.94263019	1.30736981	-14.06274965	23.94801003
19		-4.16666667	-1.96489019	-2.20177648	-14.48722958	10.55744921
20		-6.91666667	2.71049069	-9.62715736	-15.83150789	21.25248927
21		-2.08333333	-3.41591393	1.33258060	-14.20603670	7.37420883
22	*	.	4.28299230	.	-7.11231916	15.67830376
23		4.83333333	-4.68235685	9.51569018	-15.82474546	6.46003177
24		-4.83333333	8.98819770	-13.82153103	-1.84318841	19.81958380
25		-2.08333333	4.93898957	-7.02232290	-4.75743692	14.63541606
26		0.00000000	3.22745340	-3.22745340	-10.37156420	16.82647099
27		-5.58333333	8.85172865	-14.43506198	-1.91109356	19.61455085
28		-13.16666667	11.36437438	-24.53104104	1.01210644	21.71664231
29	*					
30		83.50000000	10.50939652	72.99060348	-0.02934148	21.04813452
31		-3.53154762	-2.30208375	-1.22946387	-19.30370324	14.69953574
32		-0.59523810	8.82813362	-9.42337172	-1.89685929	19.55312653
33		-18.75000000	-8.79484296	-9.95515704	-16.47628611	-1.11339981
34		2.75000000	7.71505486	-4.96505486	-7.11934195	22.54945166
35		24.25000000	-2.90955967	27.15955967	-14.19388171	8.37476236
36		-20.16666667	1.27528514	-21.44195180	-12.45382682	15.00439710
37		-13.91666667	-2.98948117	-10.92718549	-11.72845801	5.74949566
38	*					
39		11.08333333	-1.58800698	12.67134032	-6.01762721	2.84161325
40		-9.00000000	-0.91379923	-8.08620077	-7.10086274	5.27326428
41		5.58333333	0.48774534	5.09558799	-5.03596937	6.01146005

FULLY-ADJUSTED MODEL

The GLM Procedure

Observation		Observed	Predicted	Residual	95% Confidence Limits for Mean Predicted Value	
42		4.83333333	-0.11887474	4.95220807	-5.19394734	4.95619786
43		-42.33333333	-3.28989208	-39.04344125	-8.32179564	1.74201147
44		1.41666667	-5.81776063	7.23442730	-11.37887047	-0.25665079
45		16.66666667	-3.36067716	20.02734383	-8.39196629	1.67061197
46	*					
47		20.16666667	-2.39845588	22.56512255	-12.08222432	7.28531255
48	*					
49		-12.50000000	-7.83520908	-4.66479092	-17.97014813	2.29972997
50		17.50000000	-3.68538025	21.18538025	-9.94504543	2.57428494
51		2.75000000	-2.97759983	5.72759983	-10.30743371	4.35223405
52	*					
53		9.00000000	0.02269542	8.97730458	-5.22950847	5.27489931
54		11.08333333	-1.47581666	12.55914999	-6.07666856	3.12503524
55	*					
56		-6.91666667	-3.97780105	-2.93886561	-9.39576804	1.44016594
57		9.00000000	-1.13514000	10.13514000	-9.50667200	7.23639201
58		-1.41666667	-5.46619474	4.04952807	-11.35054391	0.41815444
59		6.25000000	-7.08245405	13.33245405	-13.56380513	-0.60110296
60		-8.33333333	1.00105111	-9.33438445	-5.03847096	7.04057319
61		-2.08333333	2.39018817	-4.47352150	-5.17668269	9.95705902
62	*					
63		-22.16666667	-1.59942239	-20.56724428	-10.39145406	7.19260928
64		-8.33333333	-1.85957768	-6.47375565	-6.36504122	2.64588585
65	*					
66		18.00000000	-6.04046216	24.04046216	-13.79662749	1.71570317
67		-32.66666667	-5.68669428	-26.97997238	-11.09221569	-0.28117288
68		-7.66666667	0.82796952	-8.49463618	-5.89424402	7.55018305
69		0.66666667	-0.77481647	1.44148314	-5.62484432	4.07521138
70		-8.33333333	0.96634227	-9.29967560	-7.77502282	9.70770736
71		-4.16666667	-3.80319786	-0.36346881	-9.12135078	1.51495507
72		-2.08333333	-4.40403313	2.32069979	-10.64600418	1.83793793
73		22.16666667	10.68481594	11.48185073	-5.09688961	26.46652149
74		22.16666667	-0.29370583	22.46037250	-5.77209453	5.18468286
75		2.75000000	-3.85336073	6.60336073	-12.41751584	4.71079438
76		35.41666667	-1.34261871	36.75928537	-5.79686385	3.11162643
77		27.52916667	5.59985653	21.92931013	-10.28700754	21.48672060
78		15.25000000	-0.01825403	15.26825403	-5.70984406	5.67333600
79		-54.91666667	-5.42478949	-49.49187718	-10.95762725	0.10804827
80		6.91666667	-4.23560016	11.15226683	-11.82021886	3.34901855
81		-7.66666667	-1.20942076	-6.45724591	-6.06337967	3.64453816
82		-4.16666667	-6.15258211	1.98591544	-11.99394085	-0.31122336

FULLY-ADJUSTED MODEL

The GLM Procedure

Observation	Observed	Predicted	Residual	95% Confidence Limits for Mean Predicted Value	
83	0.66666667	-6.39949198	7.06615865	-12.01512067	-0.78386329
84	6.91666667	-4.51889468	11.43556135	-12.76971301	3.73192365
85	9.00000000	-0.11544943	9.11544943	-5.47013676	5.23923789
86	-5.58333333	-8.49625193	2.91291859	-15.96673052	-1.02577333
87	6.25000000	-3.83745422	10.08745422	-9.63023466	1.95532623
88	-1.41666667	-0.21432065	-1.20234602	-5.24653363	4.81789234
89	6.91666667	-0.44075698	7.35742365	-13.87969873	12.99818477
90	6.91666667	0.57999384	6.33667283	-5.30331789	6.46330557
91	6.25000000	-1.18080845	7.43080845	-9.37710527	7.01548837
92	-14.58333333	-0.95847557	-13.62485776	-8.60690202	6.68995087
93	2.08333333	-0.93632845	3.01966179	-6.44296086	4.57030395
94	0.03333333	-1.29436285	1.32769619	-6.03098032	3.44225462
95	-18.75000000	0.02421702	-18.77421702	-5.63875250	5.68718653
96	2.08333333	-1.65559466	3.73892799	-6.86714124	3.55595193
97	4.16666667	-0.22695606	4.39362273	-6.80780417	6.35389204
98	0.66666667	-3.10326348	3.76993014	-7.92154225	1.71501530
99	-19.41666667	-0.37842003	-19.03824664	-5.24102510	4.48418505
100	2.08333333	2.59097933	-0.50764600	-10.79017449	15.97213314
101	2.08333333	-1.99125403	4.07458737	-7.97541321	3.99290514
102	-25.00000000	-3.52112334	-21.47887666	-8.59483492	1.55258823
103	-9.00000000	-3.53999936	-5.46000064	-8.62265338	1.54265465
104	-6.25000000	0.51971257	-6.76971257	-5.08908124	6.12850639
105	-2.08333333	-2.08333333	0.00000000	-35.90878155	31.74211488
106	0.00000000	-0.69352758	0.69352758	-5.37548744	3.98843227
107	11.16666667	-4.79777179	15.96443846	-10.70990391	1.11436032
108	31.25000000	-4.13132625	35.38132625	-9.80911645	1.54646396
109	18.83333333	-0.25207269	19.08540602	-5.27963258	4.77548720
110	9.66666667	2.73656442	6.93010225	-10.52892761	16.00205644
111	-4.16428571	-2.20535877	-1.95892694	-6.76525809	2.35454055
112	-70.16666667	-6.53055833	-63.63610834	-12.34163398	-0.71948267
113	-25.00000000	-5.28923204	-19.71076796	-11.42142792	0.84296384
114	-9.75000000	-5.54732611	-4.20267389	-12.55158905	1.45693684
115	-14.58333333	-4.93986813	-9.64346521	-11.92948279	2.04974654
116	-36.83333333	-6.88235212	-29.95098121	-13.27228267	-0.49242157
117	-11.08333333	-6.85655884	-4.22677449	-25.48441774	11.77130006
118	-10.41666667	3.07254023	-13.48920689	-5.90012918	12.04520964
119	4.83333333	-4.72995622	9.56328955	-14.38745616	4.92754372
120	6.91666667	-7.30340939	14.22007606	-13.38533812	-1.22148066
121	-12.50000000	-3.04382011	-9.45617989	-9.96305523	3.87541500
122	-11.83333333	-1.64570085	-10.18763249	-6.40357613	3.11217444
123	-3.50000000	-5.15542077	1.65542077	-11.83384893	1.52300739

FULLY-ADJUSTED MODEL

The GLM Procedure

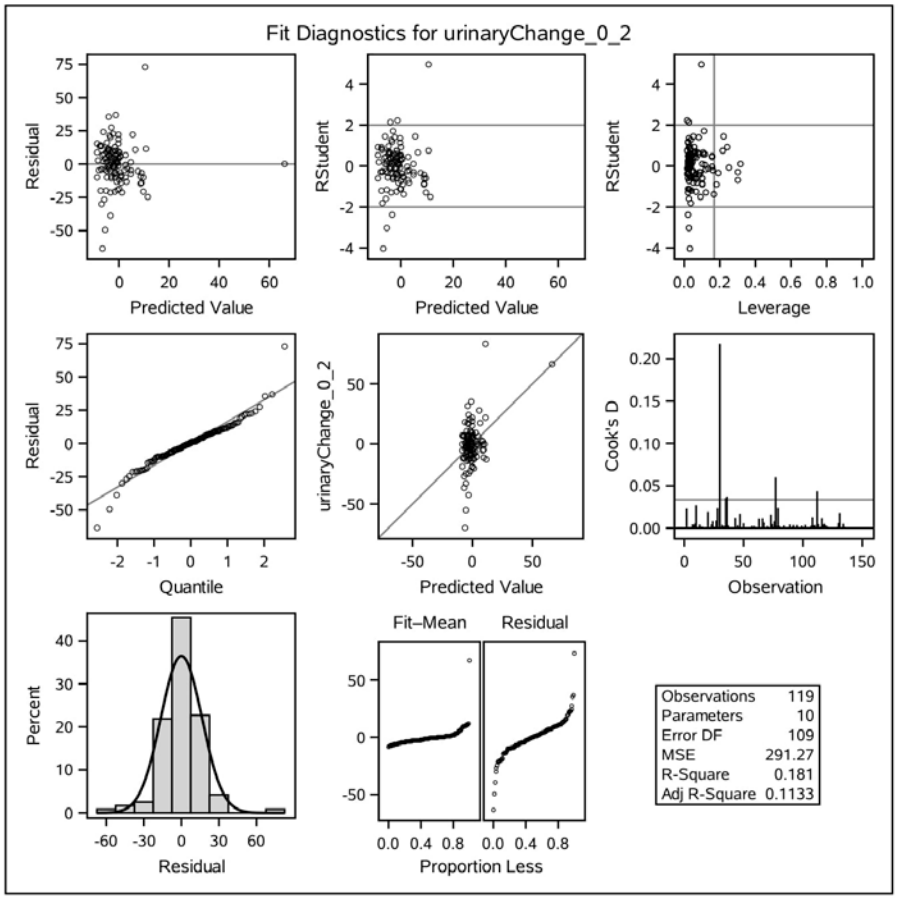
Observation		Observed	Predicted	Residual	95% Confidence Limits for Mean Predicted Value	
124		4.83333333	-3.31561871	8.14895205	-8.38466813	1.75343070
125		-10.41666667	-4.89002029	-5.52664637	-10.28394734	0.50390676
126		2.08333333	-4.00048780	6.08382113	-10.16602312	2.16504752
127	*	.	-4.58525903	.	-11.22868097	2.05816290
128		-4.16666667	-3.86896565	-0.29770101	-10.34216072	2.60422942
129		0.00000000	-8.58850043	8.58850043	-15.76155610	-1.41544476
130		-27.08333333	-7.24525973	-19.83807360	-14.04288109	-0.44763836
131		-13.16666667	0.92895749	-14.09562416	-13.38259084	15.24050583
132		-11.08333333	-6.95953201	-4.12380132	-14.37276738	0.45370336
133		-6.25000000	-4.31863524	-1.93136476	-10.40053303	1.76326256
134		6.91666667	-8.71804518	15.63471184	-16.63792380	-0.79816655
135		-11.83333333	0.20825823	-12.04159156	-5.37371622	5.79023268
136		66.16666667	66.16666667	0.00000000	32.34121845	99.99211488

*** Observation was not used in this analysis**

Sum of Residuals	0.00000
Sum of Squared Residuals	31748.30655
Sum of Squared Residuals - Error SS	-0.00000
PRESS Statistic	36178.79093
First Order Autocorrelation	0.04964
Durbin-Watson D	1.90072

FULLY-ADJUSTED MODEL

The GLM Procedure



UN-ADJUSTED MODEL

The GLM Procedure

Class Level Information

Class	Levels	Values
treatment	2	EBRT RALP
smoking0	3	Current Smoker Former smoker Non-smoker
hormoneTx	2	yes no
EDaid0	2	yes no
cardiacDx	2	yes no
hypertension	2	yes no
arterialDx	2	yes no

Number of Observations Read	136
Number of Observations Used	119

UN-ADJUSTED MODEL

The GLM Procedure

Dependent Variable: sexualChange_0_2 sexualChange_0_2

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	1	2703.42421	2703.42421	6.48	0.0122
Error	117	48792.49206	417.02985		
Corrected Total	118	51495.91626			

R-Square	Coeff Var	Root MSE	sexualChange_0_2 Mean
0.052498	128.0782	20.42131	15.94441

Source	DF	Type I SS	Mean Square	F Value	Pr > F
treatment	1	2703.424206	2703.424206	6.48	0.0122

Source	DF	Type II SS	Mean Square	F Value	Pr > F
treatment	1	2703.424206	2703.424206	6.48	0.0122

Source	DF	Type III SS	Mean Square	F Value	Pr > F
treatment	1	2703.424206	2703.424206	6.48	0.0122

Source	DF	Type IV SS	Mean Square	F Value	Pr > F
treatment	1	2703.424206	2703.424206	6.48	0.0122

Parameter	Estimate		Standard Error	t Value	Pr > |t|
Intercept	18.34008097	B	2.09518206	8.75	<.0001
treatment EBRT	-11.87854251	B	4.66540796	-2.55	0.0122
treatment RALP	0.00000000	B	.	.	.

Note: The X'X matrix has been found to be singular, and a generalized inverse was used to solve the normal equations. Terms whose estimates are followed by the letter 'B' are not uniquely estimable.

UN-ADJUSTED MODEL

The GLM Procedure

Observation		Observed	Predicted	Residual	95% Confidence Limits for Mean Predicted Value	
1		9.61538462	6.46153846	3.15384615	-1.79392204	14.71699897
2		-1.92307692	6.46153846	-8.38461538	-1.79392204	14.71699897
3		40.38461538	6.46153846	33.92307692	-1.79392204	14.71699897
4		-23.07692308	6.46153846	-29.53846154	-1.79392204	14.71699897
5	*					
6	*					
7		-5.76923077	6.46153846	-12.23076923	-1.79392204	14.71699897
8		35.23076923	6.46153846	28.76923077	-1.79392204	14.71699897
9	*	.	6.46153846	.	-1.79392204	14.71699897
10		13.46153846	6.46153846	7.00000000	-1.79392204	14.71699897
11	*					
12	*					
13		0.00000000	6.46153846	-6.46153846	-1.79392204	14.71699897
14		5.76923077	6.46153846	-0.69230769	-1.79392204	14.71699897
15		-1.92307692	6.46153846	-8.38461538	-1.79392204	14.71699897
16		-5.76923077	6.46153846	-12.23076923	-1.79392204	14.71699897
17	*					
18		-19.23076923	6.46153846	-25.69230769	-1.79392204	14.71699897
19		28.23076923	6.46153846	21.76923077	-1.79392204	14.71699897
20		11.53846154	6.46153846	5.07692308	-1.79392204	14.71699897
21		-5.76923077	6.46153846	-12.23076923	-1.79392204	14.71699897
22		9.61538462	6.46153846	3.15384615	-1.79392204	14.71699897
23		-9.61538462	6.46153846	-16.07692308	-1.79392204	14.71699897
24		23.69230769	6.46153846	17.23076923	-1.79392204	14.71699897
25		44.84615385	6.46153846	38.38461538	-1.79392204	14.71699897
26		1.92307692	6.46153846	-4.53846154	-1.79392204	14.71699897
27	*	.	6.46153846	.	-1.79392204	14.71699897
28		3.84615385	6.46153846	-2.61538462	-1.79392204	14.71699897
29	*					
30		15.38461538	6.46153846	8.92307692	-1.79392204	14.71699897
31		-15.38461538	6.46153846	-21.84615385	-1.79392204	14.71699897
32		0.00000000	6.46153846	-6.46153846	-1.79392204	14.71699897
33		0.00000000	18.34008097	-18.34008097	14.19068269	22.48947925
34		15.38461538	18.34008097	-2.95546559	14.19068269	22.48947925
35		13.46153846	18.34008097	-4.87854251	14.19068269	22.48947925
36		51.92307692	18.34008097	33.58299595	14.19068269	22.48947925
37		3.84615385	18.34008097	-14.49392713	14.19068269	22.48947925
38	*					
39		46.15384615	18.34008097	27.81376518	14.19068269	22.48947925
40		5.76923077	18.34008097	-12.57085020	14.19068269	22.48947925
41		13.46153846	18.34008097	-4.87854251	14.19068269	22.48947925

UN-ADJUSTED MODEL

The GLM Procedure

Observation		Observed	Predicted	Residual	95% Confidence Limits for Mean Predicted Value	
42		-18.00000000	18.34008097	-36.34008097	14.19068269	22.48947925
43		12.84615385	18.34008097	-5.49392713	14.19068269	22.48947925
44		-1.30769231	18.34008097	-19.64777328	14.19068269	22.48947925
45		3.84615385	18.34008097	-14.49392713	14.19068269	22.48947925
46	*					
47		65.38461538	18.34008097	47.04453441	14.19068269	22.48947925
48	*					
49		-7.69230769	18.34008097	-26.03238866	14.19068269	22.48947925
50		0.00000000	18.34008097	-18.34008097	14.19068269	22.48947925
51		19.23076923	18.34008097	0.89068826	14.19068269	22.48947925
52	*					
53		11.53846154	18.34008097	-6.80161943	14.19068269	22.48947925
54		26.92307692	18.34008097	8.58299595	14.19068269	22.48947925
55	*					
56		39.76923077	18.34008097	21.42914980	14.19068269	22.48947925
57		11.53846154	18.34008097	-6.80161943	14.19068269	22.48947925
58		32.69230769	18.34008097	14.35222672	14.19068269	22.48947925
59		32.69230769	18.34008097	14.35222672	14.19068269	22.48947925
60		-3.84615385	18.34008097	-22.18623482	14.19068269	22.48947925
61		0.00000000	18.34008097	-18.34008097	14.19068269	22.48947925
62	*					
63		-35.30769231	18.34008097	-53.64777328	14.19068269	22.48947925
64		37.15384615	18.34008097	18.81376518	14.19068269	22.48947925
65	*					
66		66.69230769	18.34008097	48.35222672	14.19068269	22.48947925
67		31.38461538	18.34008097	13.04453441	14.19068269	22.48947925
68		1.92307692	18.34008097	-16.41700405	14.19068269	22.48947925
69		-11.53846154	18.34008097	-29.87854251	14.19068269	22.48947925
70		62.15384615	18.34008097	43.81376518	14.19068269	22.48947925
71		1.92307692	18.34008097	-16.41700405	14.19068269	22.48947925
72		-5.76923077	18.34008097	-24.10931174	14.19068269	22.48947925
73		-1.92307692	18.34008097	-20.26315789	14.19068269	22.48947925
74		29.46153846	18.34008097	11.12145749	14.19068269	22.48947925
75		80.15384615	18.34008097	61.81376518	14.19068269	22.48947925
76		19.84615385	18.34008097	1.50607287	14.19068269	22.48947925
77		12.15384615	18.34008097	-6.18623482	14.19068269	22.48947925
78	*	.	18.34008097	.	14.19068269	22.48947925
79		0.00000000	18.34008097	-18.34008097	14.19068269	22.48947925
80		20.53846154	18.34008097	2.19838057	14.19068269	22.48947925
81		16.07692308	18.34008097	-2.26315789	14.19068269	22.48947925
82		11.53846154	18.34008097	-6.80161943	14.19068269	22.48947925

UN-ADJUSTED MODEL

The GLM Procedure

Observation	Observed	Predicted	Residual	95% Confidence Limits for Mean Predicted Value	
83	15.38461538	18.34008097	-2.95546559	14.19068269	22.48947925
84	23.07692308	18.34008097	4.73684211	14.19068269	22.48947925
85	26.30769231	18.34008097	7.96761134	14.19068269	22.48947925
86	1.92307692	18.34008097	-16.41700405	14.19068269	22.48947925
87	27.53846154	18.34008097	9.19838057	14.19068269	22.48947925
88	22.46153846	18.34008097	4.12145749	14.19068269	22.48947925
89	10.92307692	18.34008097	-7.41700405	14.19068269	22.48947925
90	0.00000000	18.34008097	-18.34008097	14.19068269	22.48947925
91	50.61538462	18.34008097	32.27530364	14.19068269	22.48947925
92	10.92307692	18.34008097	-7.41700405	14.19068269	22.48947925
93	44.84615385	18.34008097	26.50607287	14.19068269	22.48947925
94	65.38461538	18.34008097	47.04453441	14.19068269	22.48947925
95	13.46153846	18.34008097	-4.87854251	14.19068269	22.48947925
96	32.07692308	18.34008097	13.73684211	14.19068269	22.48947925
97	25.00000000	18.34008097	6.65991903	14.19068269	22.48947925
98	49.38461538	18.34008097	31.04453441	14.19068269	22.48947925
99	1.92307692	18.34008097	-16.41700405	14.19068269	22.48947925
100	41.00000000	18.34008097	22.65991903	14.19068269	22.48947925
101	10.23076923	18.34008097	-8.10931174	14.19068269	22.48947925
102	18.61538462	18.34008097	0.27530364	14.19068269	22.48947925
103	27.53846154	18.34008097	9.19838057	14.19068269	22.48947925
104	41.00000000	18.34008097	22.65991903	14.19068269	22.48947925
105	19.23076923	18.34008097	0.89068826	14.19068269	22.48947925
106	16.69230769	18.34008097	-1.64777328	14.19068269	22.48947925
107	18.61538462	18.34008097	0.27530364	14.19068269	22.48947925
108	-3.84615385	18.34008097	-22.18623482	14.19068269	22.48947925
109	65.38461538	18.34008097	47.04453441	14.19068269	22.48947925
110	21.15384615	18.34008097	2.81376518	14.19068269	22.48947925
111	34.61538462	18.34008097	16.27530364	14.19068269	22.48947925
112	16.00000000	18.34008097	-2.34008097	14.19068269	22.48947925
113	1.92307692	18.34008097	-16.41700405	14.19068269	22.48947925
114	19.23076923	18.34008097	0.89068826	14.19068269	22.48947925
115	-8.30769231	18.34008097	-26.64777328	14.19068269	22.48947925
116	3.84615385	18.34008097	-14.49392713	14.19068269	22.48947925
117	13.46153846	18.34008097	-4.87854251	14.19068269	22.48947925
118	-7.69230769	18.34008097	-26.03238866	14.19068269	22.48947925
119	30.76923077	18.34008097	12.42914980	14.19068269	22.48947925
120	11.53846154	18.34008097	-6.80161943	14.19068269	22.48947925
121	5.15384615	18.34008097	-13.18623482	14.19068269	22.48947925
122	23.69230769	18.34008097	5.35222672	14.19068269	22.48947925
123	14.76923077	18.34008097	-3.57085020	14.19068269	22.48947925

UN-ADJUSTED MODEL

The GLM Procedure

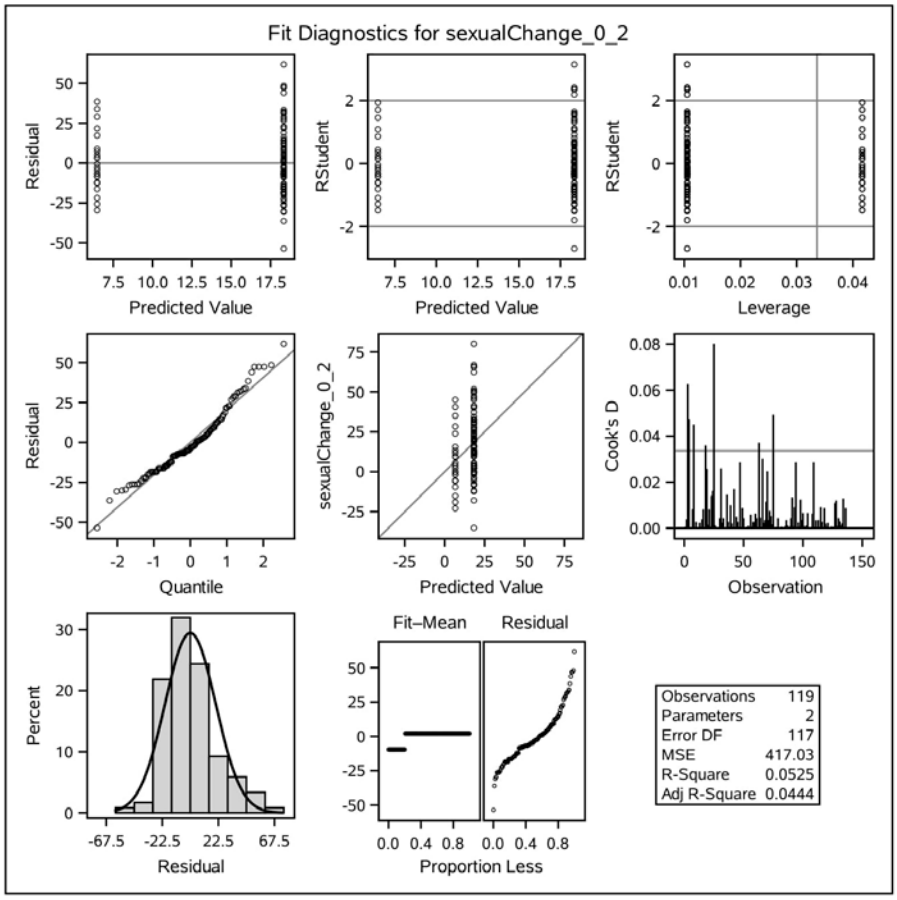
Observation		Observed	Predicted	Residual	95% Confidence Limits for Mean Predicted Value	
124		10.92307692	18.34008097	-7.41700405	14.19068269	22.48947925
125		20.53846154	18.34008097	2.19838057	14.19068269	22.48947925
126		11.53846154	18.34008097	-6.80161943	14.19068269	22.48947925
127		47.46153846	18.34008097	29.12145749	14.19068269	22.48947925
128		-12.23076923	18.34008097	-30.57085020	14.19068269	22.48947925
129		10.23076923	18.34008097	-8.10931174	14.19068269	22.48947925
130		0.00000000	18.34008097	-18.34008097	14.19068269	22.48947925
131		3.23076923	18.34008097	-15.10931174	14.19068269	22.48947925
132		9.61538462	18.34008097	-8.72469636	14.19068269	22.48947925
133		30.76923077	18.34008097	12.42914980	14.19068269	22.48947925
134		50.00000000	18.34008097	31.65991903	14.19068269	22.48947925
135	*					
136		-7.69230769	18.34008097	-26.03238866	14.19068269	22.48947925

**** Observation was not used in this analysis***

Sum of Residuals	-0.00000
Sum of Squared Residuals	48792.49206
Sum of Squared Residuals - Error SS	-0.00000
PRESS Statistic	50333.04448
First Order Autocorrelation	-0.07853
Durbin-Watson D	2.14297

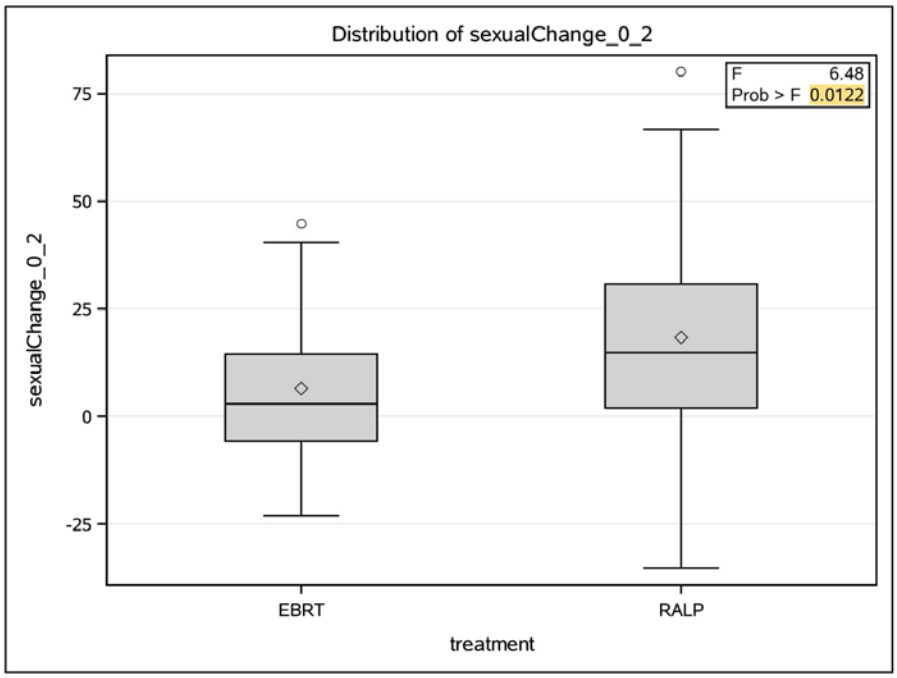
UN-ADJUSTED MODEL

The GLM Procedure



UN-ADJUSTED MODEL

The GLM Procedure



FULLY-ADJUSTED MODEL

The GLM Procedure

Class Level Information

Class	Levels	Values
treatment	2	EBRT RALP
smoking0	3	Current Smoker Former smoker Non-smoker
hormoneTx	2	yes no
EDaid0	2	yes no
cardiacDx	2	yes no
hypertension	2	yes no
arterialDx	2	yes no

Number of Observations Read	136
Number of Observations Used	119

FULLY-ADJUSTED MODEL

The GLM Procedure

Dependent Variable: sexualChange_0_2 sexualChange_0_2

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	2	3079.87454	1539.93727	3.69	0.0280
Error	116	48416.04173	417.37967		
Corrected Total	118	51495.91626			

R-Square	Coeff Var	Root MSE	sexualChange_0_2 Mean
0.059808	128.1319	20.42987	15.94441

Source	DF	Type I SS	Mean Square	F Value	Pr > F
treatment	1	2703.424206	2703.424206	6.48	0.0122
hormoneTx	1	376.450331	376.450331	0.90	0.3442

Source	DF	Type II SS	Mean Square	F Value	Pr > F
treatment	1	1877.943116	1877.943116	4.50	0.0360
hormoneTx	1	376.450331	376.450331	0.90	0.3442

Source	DF	Type III SS	Mean Square	F Value	Pr > F
treatment	1	1877.943116	1877.943116	4.50	0.0360
hormoneTx	1	376.450331	376.450331	0.90	0.3442

Source	DF	Type IV SS	Mean Square	F Value	Pr > F
treatment	1	1877.943116	1877.943116	4.50	0.0360
hormoneTx	1	376.450331	376.450331	0.90	0.3442

Parameter	Estimate		Standard Error	t Value	Pr > |t|
Intercept	18.43831169	B	2.09861111	8.79	<.0001
treatment EBRT	-10.42145355	B	4.91306745	-2.12	0.0360
treatment RALP	0.00000000	B	.	.	.
hormoneTx yes	-9.33191808	B	9.82613489	-0.95	0.3442
hormoneTx no	0.00000000	B	.	.	.

Note: The X'X matrix has been found to be singular, and a generalized inverse was used to solve the normal equations. Terms whose estimates are followed by the letter 'B' are not uniquely estimable.

FULLY-ADJUSTED MODEL

The GLM Procedure

Observation		Observed	Predicted	Residual	95% Confidence Limits for Mean Predicted Value	
1		9.61538462	8.01685814	1.59852647	-0.85688688	16.89060316
2		-1.92307692	8.01685814	-9.93993506	-0.85688688	16.89060316
3		40.38461538	8.01685814	32.36775724	-0.85688688	16.89060316
4		-23.07692308	8.01685814	-31.09378122	-0.85688688	16.89060316
5	*					
6	*					
7		-5.76923077	8.01685814	-13.78608891	-0.85688688	16.89060316
8		35.23076923	8.01685814	27.21391109	-0.85688688	16.89060316
9	*	.	8.01685814	.	-0.85688688	16.89060316
10		13.46153846	-1.31505994	14.77659840	-19.51543558	16.88531570
11	*					
12	*					
13		0.00000000	8.01685814	-8.01685814	-0.85688688	16.89060316
14		5.76923077	8.01685814	-2.24762737	-0.85688688	16.89060316
15		-1.92307692	8.01685814	-9.93993506	-0.85688688	16.89060316
16		-5.76923077	8.01685814	-13.78608891	-0.85688688	16.89060316
17	*					
18		-19.23076923	-1.31505994	-17.91570929	-19.51543558	16.88531570
19		28.23076923	8.01685814	20.21391109	-0.85688688	16.89060316
20		11.53846154	-1.31505994	12.85352148	-19.51543558	16.88531570
21		-5.76923077	8.01685814	-13.78608891	-0.85688688	16.89060316
22		9.61538462	8.01685814	1.59852647	-0.85688688	16.89060316
23		-9.61538462	8.01685814	-17.63224276	-0.85688688	16.89060316
24		23.69230769	8.01685814	15.67544955	-0.85688688	16.89060316
25		44.84615385	8.01685814	36.82929570	-0.85688688	16.89060316
26		1.92307692	8.01685814	-6.09378122	-0.85688688	16.89060316
27	*	.	8.01685814	.	-0.85688688	16.89060316
28		3.84615385	8.01685814	-4.17070430	-0.85688688	16.89060316
29	*					
30		15.38461538	8.01685814	7.36775724	-0.85688688	16.89060316
31		-15.38461538	-1.31505994	-14.06955544	-19.51543558	16.88531570
32		0.00000000	8.01685814	-8.01685814	-0.85688688	16.89060316
33		0.00000000	18.43831169	-18.43831169	14.28174795	22.59487542
34		15.38461538	18.43831169	-3.05369630	14.28174795	22.59487542
35		13.46153846	18.43831169	-4.97677323	14.28174795	22.59487542
36		51.92307692	18.43831169	33.48476523	14.28174795	22.59487542
37		3.84615385	18.43831169	-14.59215784	14.28174795	22.59487542
38	*					
39		46.15384615	18.43831169	27.71553447	14.28174795	22.59487542
40		5.76923077	18.43831169	-12.66908092	14.28174795	22.59487542
41		13.46153846	18.43831169	-4.97677323	14.28174795	22.59487542

FULLY-ADJUSTED MODEL

The GLM Procedure

Observation		Observed	Predicted	Residual	95% Confidence Limits for Mean Predicted Value	
42		-18.00000000	18.43831169	-36.43831169	14.28174795	22.59487542
43		12.84615385	18.43831169	-5.59215784	14.28174795	22.59487542
44		-1.30769231	18.43831169	-19.74600400	14.28174795	22.59487542
45		3.84615385	18.43831169	-14.59215784	14.28174795	22.59487542
46	*					
47		65.38461538	18.43831169	46.94630370	14.28174795	22.59487542
48	*					
49		-7.69230769	18.43831169	-26.13061938	14.28174795	22.59487542
50		0.00000000	18.43831169	-18.43831169	14.28174795	22.59487542
51		19.23076923	18.43831169	0.79245754	14.28174795	22.59487542
52	*					
53		11.53846154	18.43831169	-6.89985015	14.28174795	22.59487542
54		26.92307692	18.43831169	8.48476523	14.28174795	22.59487542
55	*					
56		39.76923077	18.43831169	21.33091908	14.28174795	22.59487542
57		11.53846154	18.43831169	-6.89985015	14.28174795	22.59487542
58		32.69230769	18.43831169	14.25399600	14.28174795	22.59487542
59		32.69230769	18.43831169	14.25399600	14.28174795	22.59487542
60		-3.84615385	18.43831169	-22.28446553	14.28174795	22.59487542
61		0.00000000	18.43831169	-18.43831169	14.28174795	22.59487542
62	*					
63		-35.30769231	18.43831169	-53.74600400	14.28174795	22.59487542
64		37.15384615	18.43831169	18.71553447	14.28174795	22.59487542
65	*					
66		66.69230769	18.43831169	48.25399600	14.28174795	22.59487542
67		31.38461538	18.43831169	12.94630370	14.28174795	22.59487542
68		1.92307692	18.43831169	-16.51523477	14.28174795	22.59487542
69		-11.53846154	18.43831169	-29.97677323	14.28174795	22.59487542
70		62.15384615	18.43831169	43.71553447	14.28174795	22.59487542
71		1.92307692	18.43831169	-16.51523477	14.28174795	22.59487542
72		-5.76923077	18.43831169	-24.20754246	14.28174795	22.59487542
73		-1.92307692	18.43831169	-20.36138861	14.28174795	22.59487542
74		29.46153846	18.43831169	11.02322677	14.28174795	22.59487542
75		80.15384615	18.43831169	61.71553447	14.28174795	22.59487542
76		19.84615385	18.43831169	1.40784216	14.28174795	22.59487542
77		12.15384615	18.43831169	-6.28446553	14.28174795	22.59487542
78	*	.	18.43831169	.	14.28174795	22.59487542
79		0.00000000	18.43831169	-18.43831169	14.28174795	22.59487542
80		20.53846154	18.43831169	2.10014985	14.28174795	22.59487542
81		16.07692308	18.43831169	-2.36138861	14.28174795	22.59487542
82		11.53846154	18.43831169	-6.89985015	14.28174795	22.59487542

FULLY-ADJUSTED MODEL

The GLM Procedure

Observation	Observed	Predicted	Residual	95% Confidence Limits for Mean Predicted Value	
83	15.38461538	18.43831169	-3.05369630	14.28174795	22.59487542
84	23.07692308	18.43831169	4.63861139	14.28174795	22.59487542
85	26.30769231	18.43831169	7.86938062	14.28174795	22.59487542
86	1.92307692	18.43831169	-16.51523477	14.28174795	22.59487542
87	27.53846154	18.43831169	9.10014985	14.28174795	22.59487542
88	22.46153846	18.43831169	4.02322677	14.28174795	22.59487542
89	10.92307692	18.43831169	-7.51523477	14.28174795	22.59487542
90	0.00000000	18.43831169	-18.43831169	14.28174795	22.59487542
91	50.61538462	18.43831169	32.17707293	14.28174795	22.59487542
92	10.92307692	18.43831169	-7.51523477	14.28174795	22.59487542
93	44.84615385	18.43831169	26.40784216	14.28174795	22.59487542
94	65.38461538	18.43831169	46.94630370	14.28174795	22.59487542
95	13.46153846	18.43831169	-4.97677323	14.28174795	22.59487542
96	32.07692308	18.43831169	13.63861139	14.28174795	22.59487542
97	25.00000000	18.43831169	6.56168831	14.28174795	22.59487542
98	49.38461538	18.43831169	30.94630370	14.28174795	22.59487542
99	1.92307692	18.43831169	-16.51523477	14.28174795	22.59487542
100	41.00000000	18.43831169	22.56168831	14.28174795	22.59487542
101	10.23076923	18.43831169	-8.20754246	14.28174795	22.59487542
102	18.61538462	18.43831169	0.17707293	14.28174795	22.59487542
103	27.53846154	18.43831169	9.10014985	14.28174795	22.59487542
104	41.00000000	18.43831169	22.56168831	14.28174795	22.59487542
105	19.23076923	18.43831169	0.79245754	14.28174795	22.59487542
106	16.69230769	18.43831169	-1.74600400	14.28174795	22.59487542
107	18.61538462	18.43831169	0.17707293	14.28174795	22.59487542
108	-3.84615385	18.43831169	-22.28446553	14.28174795	22.59487542
109	65.38461538	18.43831169	46.94630370	14.28174795	22.59487542
110	21.15384615	18.43831169	2.71553447	14.28174795	22.59487542
111	34.61538462	18.43831169	16.17707293	14.28174795	22.59487542
112	16.00000000	18.43831169	-2.43831169	14.28174795	22.59487542
113	1.92307692	18.43831169	-16.51523477	14.28174795	22.59487542
114	19.23076923	18.43831169	0.79245754	14.28174795	22.59487542
115	-8.30769231	18.43831169	-26.74600400	14.28174795	22.59487542
116	3.84615385	18.43831169	-14.59215784	14.28174795	22.59487542
117	13.46153846	9.10639361	4.35514486	-10.59306060	28.80584782
118	-7.69230769	18.43831169	-26.13061938	14.28174795	22.59487542
119	30.76923077	18.43831169	12.33091908	14.28174795	22.59487542
120	11.53846154	18.43831169	-6.89985015	14.28174795	22.59487542
121	5.15384615	18.43831169	-13.28446553	14.28174795	22.59487542
122	23.69230769	18.43831169	5.25399600	14.28174795	22.59487542
123	14.76923077	18.43831169	-3.66908092	14.28174795	22.59487542

FULLY-ADJUSTED MODEL

The GLM Procedure

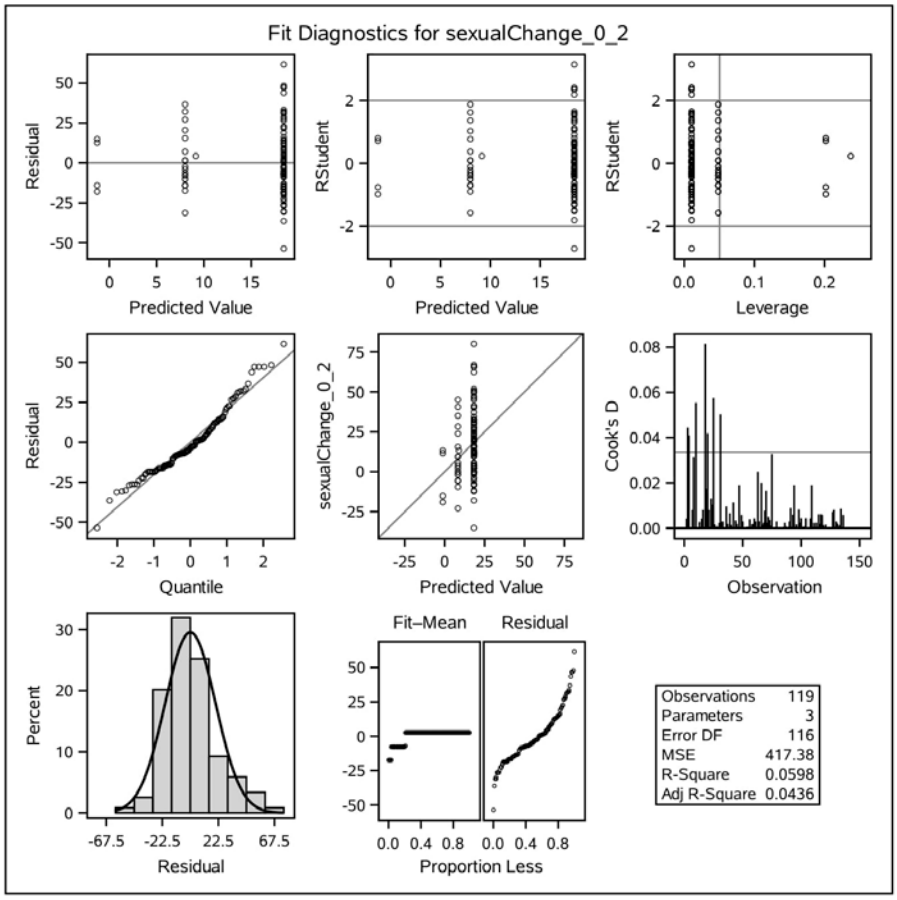
Observation		Observed	Predicted	Residual	95% Confidence Limits for Mean Predicted Value	
124		10.92307692	18.43831169	-7.51523477	14.28174795	22.59487542
125		20.53846154	18.43831169	2.10014985	14.28174795	22.59487542
126		11.53846154	18.43831169	-6.89985015	14.28174795	22.59487542
127		47.46153846	18.43831169	29.02322677	14.28174795	22.59487542
128		-12.23076923	18.43831169	-30.66908092	14.28174795	22.59487542
129		10.23076923	18.43831169	-8.20754246	14.28174795	22.59487542
130		0.00000000	18.43831169	-18.43831169	14.28174795	22.59487542
131		3.23076923	18.43831169	-15.20754246	14.28174795	22.59487542
132		9.61538462	18.43831169	-8.82292707	14.28174795	22.59487542
133		30.76923077	18.43831169	12.33091908	14.28174795	22.59487542
134		50.00000000	18.43831169	31.56168831	14.28174795	22.59487542
135	*					
136		-7.69230769	18.43831169	-26.13061938	14.28174795	22.59487542

*** Observation was not used in this analysis**

Sum of Residuals	-0.00000
Sum of Squared Residuals	48416.04173
Sum of Squared Residuals - Error SS	-0.00000
PRESS Statistic	50464.39068
First Order Autocorrelation	-0.07936
Durbin-Watson D	2.14456

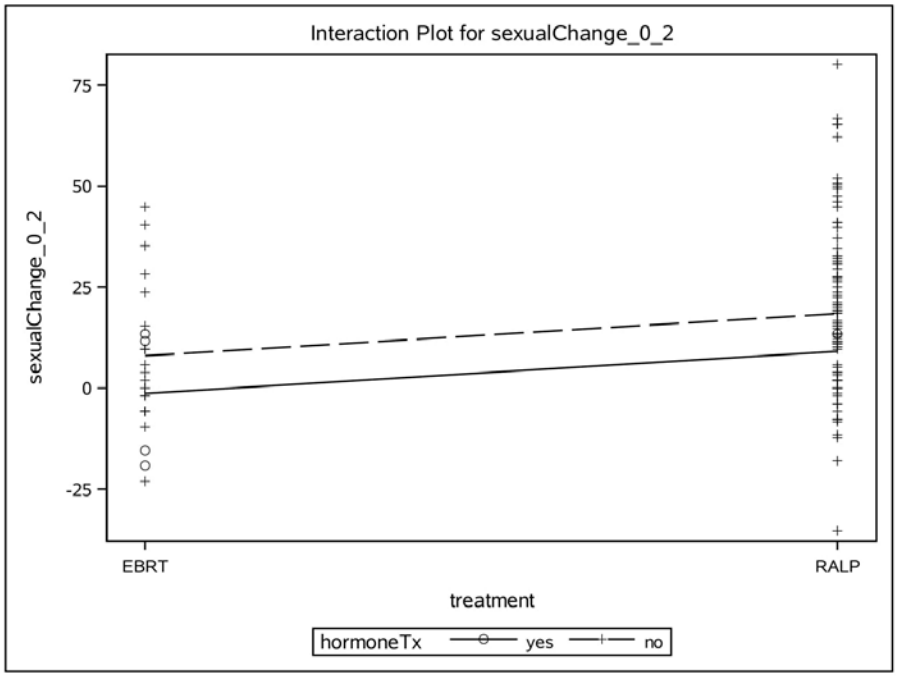
FULLY-ADJUSTED MODEL

The GLM Procedure



FULLY-ADJUSTED MODEL

The GLM Procedure



Appendix B: EPIC Questionnaire

OREGON UROLOGY INSTITUTE

Dear Patient,

Quality assurance and scientific advancement are very important in the treatment of prostate cancer. In an effort to improve patient outcomes and clinical care, we are enclosing 3 questionnaires related to your health and quality of life after treatment. You should have received a similar document at the time your treatment was scheduled.

We will mail you new copies of the enclosed forms to fill out every three months for the first year and then annually thereafter.

All data returned to us is kept separate from your medical record. If you wish for us to submit this questionnaire to your doctor, please note this on the forms you return. Please understand that it is your responsibility to pursue follow up contact if you would like something on these questionnaires to be addressed.

Every patient has the right to not participate. Your care will not be affected by whether you choose to participate or not.

We have included a self-addressed and stamped envelope in this packet to return the questionnaires. If you have any questions please call our Community Outreach Department at 541-284-5508

Sincerely,

Oregon Urology Institute

Prostate Cancer Support Groups

Meets first Wednesday of every month at our Radiation Center

1457 G Street, Springfield, OR

5:30 pm – 7:00 pm

For more information, please visit our website at

www.oregonurology.com

2400 Hartman Lane, Springfield, Oregon 97477 **Phone** 541.334.3350 **Toll Free** 1.800.246.9925 oregonurology.com

EPIC

The Expanded Prostate Cancer Index Composite

This questionnaire is designed to measure Quality of Life issues in patients with Prostate cancer. To help us get the most accurate measurement, it is important that you answer all questions honestly and completely.

Remember, as with all medical records, information contained within this survey will remain strictly confidential.

Today's Date (please enter date when survey completed): Month _____ Day _____ Year _____

Name (optional): _____

Date of Birth (optional): Month _____ Day _____ Year _____

Printed with permission from Dr. David Woods, University of Michigan, March, 2007.

cod EPIC 07/15

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URINARY FUNCTION

This section is about your urinary habits. Please consider **ONLY THE LAST 4 WEEKS.**

1. Over the **past 4 weeks**, how often have you leaked urine?

   More than once a day.....1
   About once a day.....2
   More than once a week .....3 (Circle one number) 23/
   About once a week.....4
   Rarely or never.....5

2. Over the **past 4 weeks**, how often have you urinated blood?

   More than once a day.....1
   About once a day.....2
   More than once a week .....3 (Circle one number) 24/
   About once a week.....4
   Rarely or never.....5

3. Over the **past 4 weeks**, how often have you had pain or burning with urination?

   More than once a day.....1
   About once a day.....2
   More than once a week .....3 (Circle one number) 25/
   About once a week.....4
   Rarely or never.....5

4. Which of the following best describes your urinary control **during the last 4 weeks**?

   No urinary control whatsoever..... 1
   Frequent dribbling..... 2 (Circle one number) 26/
   Occasional dribbling..... 3
   Total control..... 4

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5. How many pads or adult diapers per day did you usually use to control leakage **during the last 4 weeks**?

None 0
1 pad per day 1
2 pads per day ..... 2 (Circle one number)
3 or more pads per day 3 27/

6. How big a problem, if any, has each of the following been for you **during the last 4 weeks**? (Circle one number on each line)

	No Problem	Very Small Problem	Small Problem	Moderate Problem	Big Problem	
a. Dripping or leaking urine	0	1	2	3	4	28/
b. Pain or burning on urination	0	1	2	3	4	29/
c. Bleeding with urination	0	1	2	3	4	30/
d. Weak urine stream or incomplete emptying	0	1	2	3	4	31/
e. Waking up to urinate	0	1	2	3	4	32/
f. Need to urinate frequently during the day	0	1	2	3	4	33/

7. Overall, how big a problem has your urinary function been for you **during the last 4 weeks**?

No problem 1
Very small problem 2
Small problem ..... 3 (Circle one number) 34/
Moderate problem 4
Big problem 5

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BOWEL HABITS

The next section is about your bowel habits and abdominal pain.
Please consider **ONLY THE LAST 4 WEEKS.**

8. How often have you had rectal urgency (felt like I had to pass stool, but did not) **during the last 4 weeks**?

More than once a day.....1
About once a day.....2
More than once a week.....3 (Circle one number) 42/
About once a week.....4
Rarely or never.....5

9. How often have you had uncontrolled leakage of stool or feces?

More than once a day.....1
About once a day.....2
More than once a week.....3 (Circle one number) 43/
About once a week.....4
Rarely or never.....5

10. How often have you had stools (bowel movements) that were loose or liquid (no form, watery, mushy) **during the past 4 weeks**?

Never.....1
Rarely.....2
About half the time.....3 (Circle one number) 44/
Usually.....4
Always.....5

11. How often have you had bloody stools **during the past 4 weeks**?

Never.....1
Rarely.....2
About half the time.....3 (Circle one number) 45/
Usually.....4
Always.....5

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12. How often have your bowel movements been painful **during the past 4 weeks**?

Never 1
Rarely.....2
About half the time .....3 (Circle one number) 46/
Usually 4
Always.....5

13. How many bowel movements have you had on a typical day **during the past 4 weeks**?

Two or less.....1
Three to four .....2 (Circle one number) 47/
Five or more.....3

14. How often have you had crampy pain in your abdomen, pelvis or rectum **during the past 4 weeks**?

More than once a day.....1
About once a day.....2
More than once a week .....3 (Circle one number) 48/
About once a week.....4
Rarely or never.....5

15. How big a problem, if any, has each of the following been for you? (Circle one number on each line)

	No Problem	Very Small Problem	Small Problem	Moderate Problem	Big Problem	
a. Urgency to have a bowel movement.....	0	1	2	3	4	49/
b. Increased frequency of bowel movements.....	0	1	2	3	4	50/
c. Watery bowel movements.....	0	1	2	3	4	51/
d. Losing control of your stools.....	0	1	2	3	4	52/
e. Bloody stools	0	1	2	3	4	53/
f. Abdominal/Pelvic/Rectal pain	0	1	2	3	4	54/

16. Overall, how big a problem have your bowel habits been for you **during the last 4 weeks**?

No problem.....1
Very small problem 2
Small problem.....3 (Circle one number) 55/
Moderate problem 4
Big problem 5

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SEXUAL FUNCTION
The next section is about your **current** sexual function and sexual satisfaction. Many of the questions are very personal, but they will help us understand the important issues that you face every day. Remember, THIS SURVEY INFORMATION IS COMPLETELY **CONFIDENTIAL**. Please answer honestly about **THE LAST 4 WEEKS ONLY.**

17. How would you rate each of the following during the last 4 weeks? (Circle one number on each line)

	Very Poor to None	Poor	Fair	Good	Very Good	
a. Your level of sexual desire?	1	2	3	4	5	56/
b. Your ability to have an erection?	1	2	3	4	5	57/
c. Your ability to reach orgasm (climax)?	1	2	3	4	5	58/

18. How would you describe the usual QUALITY of your erections **during the last 4 weeks**?

None at all.....1
Not firm enough for any sexual activity.....2
Firm enough for masturbation and foreplay only.....3 (Circle one number) 59/
Firm enough for intercourse.....4

19. How would you describe the FREQUENCY of your erections **during the last 4 weeks**?

I NEVER had an erection when I wanted one.....1
I had an erection LESS THAN HALF the time I wanted one.....2
I had an erection ABOUT HALF the time I wanted one.....3 (Circle one number) 60/
I had an erection MORE THAN HALF the time I wanted one.....4
I had an erection WHENEVER I wanted one.....5

20. How often have you awakened in the morning or night with an erection **during the last 4 weeks**?

Never.....1
Less than once a week.....2
About once a week.....3 (Circle one number) 61/
Several times a week.....4
Daily.....5

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21. **During the last 4 weeks**, how often did you have any sexual activity?

Not at all	1	
Less than once a week	2	
About once a week	3	(Circle one number) 62/
Several times a week	4	
Daily	5	

22. **During the last 4 weeks**, how often did you have sexual intercourse?

Not at all	1	
Less than once a week	2	
About once a week	3	(Circle one number) 63/
Several times a week	4	
Daily	5	

23. Overall, how would you rate your ability to function sexually **during the last 4 weeks**?

Very poor	1	
Poor	2	
Fair	3	(Circle one number) 64/
Good	4	
Very good	5	

24. How big a problem, **during the last 4 weeks**, if any, has each of the following been for you? (Circle one number on each line)

	No Problem	Very Small Problem	Small Problem	Moderate Problem	Big Problem	
a. Your level of sexual desire	0	1	2	3	4	65/
b. Your ability to have an erection	0	1	2	3	4	66/
c. Your ability to reach an orgasm	0	1	2	3	4	67/

25. Overall, how big a problem has your sexual function or lack of sexual function been for you **during the last 4 weeks**?

No problem	1	
Very small problem	2	
Small problem	3	(Circle one number) 68/
Moderate problem	4	
Big problem	5	

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HORMONAL FUNCTION

The next section is about your hormonal function. Please consider **ONLY THE LAST 4 WEEKS.**

26. **Over the last 4 weeks**, how often have you experienced hot flashes?

More than once a day.....1
About once a day.....2
More than once a week.....3 (Circle one number) 69/
About once a week.....4
Rarely or never.....5

27. How often have you had breast tenderness **during the last 4 weeks**?

More than once a day.....1
About once a day.....2
More than once a week.....3 (Circle one number) 70/
About once a week.....4
Rarely or never.....5

28. **During the last 4 weeks**, how often have you felt depressed?

More than once a day.....1
About once a day.....2
More than once a week.....3 (Circle one number) 71/
About once a week.....4
Rarely or never.....5

29. **During the last 4 weeks**, how often have you felt a lack of energy?

More than once a day.....1
About once a day.....2
More than once a week.....3 (Circle one number) 72/
About once a week.....4
Rarely or never.....5

30. How much change in your weight have you experienced **during the last 4 weeks**, if any?

Gained 10 pounds or more.....1
Gained less than 10 pounds.....2
No change in weight.....3 (Circle one number) 73/
Lost less than 10 pounds.....4
Lost 10 pounds or more.....5

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31. How big a problem, **during the last 4 weeks**, if any, has each of the following been for you? (Circle one number on each line)

	No Problem	Very Small Problem	Small Problem	Moderate Problem	Big Problem	
a. Hot flashes	0	1	2	3	4	74/
b. Breast tenderness/enlargement	0	1	2	3	4	75/
c. Loss of body hair	0	1	2	3	4	76/
d. Feeling depressed	0	1	2	3	4	77/
e. Lack of energy	0	1	2	3	4	78/
f. Change in body weight	0	1	2	3	4	79/

OVERALL SATISFACTION

32. Overall, how satisfied are you with the treatment you received for your prostate cancer?

Extremely dissatisfied.....1
Dissatisfied 2
Uncertain .....3 (Circle one number) 80/
Satisfied 4
Extremely satisfied.....5

THANK YOU VERY MUCH!!

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Appendix C: IRB Exemption

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DATE: March 03, 2017 **IRB Protocol Number: 02222017.026**

TO: Julia Fischer, Principal Investigator

RE: Protocol entitled, "Protecting the P"

Notice of Review and Determination-Not Human Subject Research as per Title 45 CFR Part 46.102 (d-f)

Research Compliance Services has reviewed the proposed project identified above. Based on the project description and materials provided, the study activities do not meet the definition of research with human subjects according to Title 45 CFR 46.102 (d-f).

You may conduct your activities as described without further IRB review. However, should the nature of your interactions with individuals or the nature of your project aims be modified, you will need to contact Research Compliance Services to determine if further review and approval is required by the University of Oregon Institutional Review Board (IRB).

Should you have any questions regarding this determination, please contact Research Compliance Services at ResearchCompliance@uoregon.edu or (541)346-2510.

Sincerely,

Carolyn J. Craig, PhD, CIP
Senior Research Compliance Administrator

Research Compliance Services
University of Oregon

CC: Carrie McCurdy, Faculty Advisor

COMMITTEE FOR THE PROTECTION OF HUMAN SUBJECTS • RESEARCH COMPLIANCE SERVICES
677 E. 12th Ave., Suite 500, 5237 University of Oregon, Eugene OR 97401-5237
T 541-346-2510 F 541-346-5138 http://rcs.uoregon.edu

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Human Subjects Research Determination Worksheet

Purpose: It is against federal regulations to conduct research involving human subjects without prior Institutional Review Board (IRB) approval. The purpose of this worksheet is to help you determine and record whether or not your project constitutes research involving human subjects, according to regulatory definitions of these terms.

Special Considerations:

- If your study involves human biological or genetic material, or repositories, please contact Research Compliance Services (RCS) for specific instructions (the information provided in this worksheet may not apply to your research).
- In general, activities undertaken for the fulfillment of a single course requirement and not the development of or contribution to generalizable knowledge (e.g., public presentation or publication) do not require IRB review.

Instructions: Complete this worksheet to determine whether or not your research is human subjects research and therefore requires review and approval by (RCS) and the IRB.

If your answers reveal that your project **is** human subjects research, you must complete and submit an IRB application (available on the RCS website) prior to commencing any interaction with human subjects.

If your answers reveal that your project **is not** human subjects research, you do not need to submit an IRB application to RCS, but you should keep this worksheet with your records. If you would like a formal letter from RCS documenting that your project is not human subjects research, complete the supplemental information requested on the last page and submit it with your answers to RCS.

If you have any questions, please contact RCS at 541-346-2510 or ResearchCompliance@uoregon.edu. Before proceeding, save this form to your computer.

Part I: Determination of *research*. (45 CFR 46.102)

- Human subjects research regulations apply only to activities that meet the federal definition of ***research***, defined as "a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge." Answer questions 1 and 2 below to determine whether or not your project meets this definition of research.

1. Is the study a ***systematic*** investigation? ***Systematic*** means having or involving a system, method, or plan.
   Examples of studies that are systematic include, but are not limited to, those which:
   - Gather data for the purpose of hypothesis building or testing.
   - Ask individuals the same sets of questions, or obtain the same kind of information from them.
   - Apply the same measures in gathering the data – whether through interaction, observation, or experiment.
   - Utilize data collection methods that can be replicated.

   ☒ Yes ☐ No

   Explain your answer: The study uses data that was collected with methods that can be replicated.

Human Subjects Research Determination Worksheet

Part I: Determination of *research*. (45 CFR 46.102)

2. Is the study designed to contribute to ***generalizable knowledge***?
   - Your study contributes to generalizable knowledge if you intend for findings from it to be applicable to a larger population, or otherwise make the findings of it available for the development of knowledge beyond the scope of the study.
   - If the study activities involving people are conducted solely for the purpose of fulfilling a course requirement, they are not considered research because they are not designed to contribute to general knowledge. However, activities involving people that are conducted in conjunction with the requirements of a thesis or dissertation generally are research because the purpose of the thesis or dissertation is by definition to make a contribution to general knowledge.

☒ Yes ☐ No

Explain your answer: It will contribute to general knowledge about prostate cancer treatments.

✓ If you answered "No" to ***either*** question 1 ***or*** 2, STOP - you do not need to complete the rest of this form. Your study is not considered research.

✓ If you answered "Yes" to questions 1 ***and*** 2, continue to Part II.

Part II: Determination of *human subjects*. (45 CFR 46.102)

➢ Human subjects protection regulations apply only to research involving ***human subjects***, defined as "living individuals **about whom** an investigator (whether professional or student) conducting research obtains: (1) data through intervention or interaction with the individual; or (2) identifiable private information." Answer the questions below to determine if your research involves human subjects.

3. Does the research involve information about or from living individuals?
   Information involving or about an individual includes, but is not limited to, the following:
   - Ideas, attitudes, opinions, feelings, experiences, thoughts, beliefs, assessments, reflections, etc., reported by an individual, even when the individual provides the information while working in a professional capacity.
   - Data about living individuals that was gathered by another researcher or source.
   - Data about living individuals gathered through the use, analysis or harvesting of cell lines, tissue, or the products of labor and delivery.

☒ Yes ☐ No

Explain your answer: Data is collected from patients treated for prostate cancer.

Human Subjects Research Determination Worksheet

Part II: Determination of *human subjects*. (45 CFR 46.102)

✓ If you answered "No" to question 3, STOP - you do not need to complete the rest of this form. Your project is not considered research involving human subjects.

✓ If you answered "Yes," continue to questions 4 ***and*** 5 below.

4. Does the research involve obtaining data through ***intervention*** or ***interaction*** with individuals? ***Intervention*** or ***interaction*** includes the following:
   - Physical procedures by which data are gathered (e.g., drawing blood from subjects, timing subjects running laps, recording brain activity during sleep, etc.).
   - Manipulations of the subject or the subject's environment that are performed for research purposes.
   - Communication or interpersonal contact between investigator and subject (e.g., a street interview, an online survey, recording posts on a blog or listserv, a mailed questionnaire, etc.).

☒ Yes ☐ No

Explain your answer: Study involves quesstionairres

5. Will you obtain ***private information*** about any subjects? ***Private information*** is explained as follows:
   - Information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place.
   - Information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (e.g., a medical record, emails, certain listserv communications, class papers and exams, etc.).
   - Private information must be individually identifiable, meaning:
     - the identity of the subject is or may readily be ascertained by the investigator, ***or***
     - the identity of the subject is or can be associated with the information directly or through links to identifiable information.

☐ Yes ☒ No

Explain your answer: Identity of the subject will not be able to be obtained.

✓ If you answered "No" to questions 4 ***and*** 5, STOP - you do not need to complete the rest of this form.

✓ If you answered "Yes" to ***either*** question 4 ***or*** 5, your project **does** involve human subjects and you must complete an IRB application (available on the RCS website).

Part III: What's Next?

- ✓ If your answers indicate that your project does involve human subjects research, you must complete and submit an IRB application. IRB approval is required before any research activities – including recruitment – with human subjects may begin. Complete and submit an application according to instructions provided on the application.
- ✓ If your answers reveal that your project is not human subjects research, keep a copy of this worksheet with your records.
- ✓ If you would like a formal letter from RCS documenting that your project is not human subjects research, please provide the supplemental information requested on the next page and submit it with your answers above to RCS.
- ✓ If you are not sure if your project is human subjects research or if you have any questions, contact RCS at 541-346-2510 or ResearchCompliance@uoregon.edu.

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Human Subjects Research Determination Worksheet

Instructions: Complete the following and submit to researchcompliance@uoregon.edu if you would like a formal letter from RCS documenting that your project is not human subjects research. If your answers above indicate that your project involves human subjects, please fill out an application for IRB review.

Principal Investigator (PI)	Julia Fischer	**PI Email**	jfischer@uoregon.edu
Department or Institution	Oregon Urology Institution	**Are You?** (choose one)	Choose an Item
Faculty Advisor (required for students)	Dr. Carrie McCurdy	**Faculty Advisor Email**	cmccurd5@uoregon.edu
Study Title	Protecting the P		

1. **Briefly describe the project, and what you expect to do with your findings:**

   This study looks at different treatments for prostate cancer and how they affect quality of life related outcomes. It specifically looks at urninary and erectile function and whether treatment External Beam Radiation Therapy or Robot Assisted Laparoscopic Prostatectomy provides better outcomes for patients. This study may provide information about which treatment would be better to preserve urinary and sexual function for men treated with prostate cancer. The findings will be used to create my Honors College Thesis.

2. **Briefly describe the study population or subject of the research:**

   The study population is patients treated for prostate cancer at Oregon Urology Institute who have filled out questionairres asking about their quality of life. In general, the demographics of the subjects are white males ages 60-70.

3. **Briefly describe the data collection methods to be used:**

   EPIC Quesstionaires that ask about quality of life are sent out to patients before their treatment and at different time periods after their treatment. Their answers are recorded in a database along with information about their treatment. The information used for this study was provided from that database with no pieces of personal health information (such as names of any dates) included. It is essentially just a table of numbers. The only way the data is connected to an individual patient is by a number randomly assigned to them to keep track of which information belongs with which value. I will not have access to the key that connects these numbers to the individual so the information in this study cannot be linked back to the individual. Essentially, the data used is just a bunch of values that relate to a quality of life outcome from an unidenfitifed individual.

From:	Julia Fischer
To:	Research Compliance Services
Subject:	Fwd: RCS 02222017.026 Additional Information
Date:	Thursday, March 02, 2017 12:28:00 PM
Attachments:	image001.jpg ATT00001.htm OUI EPIC signed Policy.pdf ATT00002.htm

---

This is the additional information and official letter from the appropriate person of authority at OUI that you requested. Name of individual signing off on this protocol: Stephanie Kerns. Position: Research Manager. Contact information: stephanie@oregonurology.com (541) 284-5508.

Best,
Julia Fischer

Begin forwarded message:

From: "Kerns, Stephanie" <Stephanie@oregonurology.com>
Subject: FW: Request for letter documenting non-human research
Date: March 2, 2017 at 11:22:15 AM PST
To: "jfischer@uoregon.edu" <jfischer@uoregon.edu>
Cc: "Podesta, Renee" <rpodesta@oregonurology.com>

Julia,

Attached is our finalized 'Policy'. As for the clarification below, yes as you know, we do have safeguards in place identifiable information isn't release to you or anyone else, even our physicians.

If you need anything else let me know,
Stephanie

Stephanie Kerns
Research Manager

2400 Hartman Lane
Springfield, OR 97477
p) 541.284.5508 f) 541.284.5509
stephanie@oregonurology.com

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POLICY

Date: February 27, 2017

From: Oregon Urology Institute, Executive Council

Re: EPIC Database (Expanded Prostate Cancer Index Composite)

In regards to OUI's EPIC Database, please see the following internal review/determination as to the data already collected.

We have concluded that this project was/is a quality improvement project. As such it does not meet the definition of human research as per 45 CFR 46.102(d)[i].

For example the OHRP Guidance we reviewed in our determination:

Question 2: Do the HHS regulations for the protection of human subjects in research (45 CFR part 46) apply to quality improvement activities conducted by one or more institutions whose purposes are limited to: (a) implementing a practice to improve the quality of patient care, and (b) collecting patient or provider data regarding the implementation of the practice for clinical, practical, or administrative purposes?

Answer: No. Such activities do not satisfy the definition of "research" under 45 CFR 46.102(d), which is "…a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge…" Therefore the HHS regulations for the protection of human subjects do not apply to such quality improvement activities, and there is no requirement under these regulations for such activities to undergo review by an IRB, or for these activities to be conducted with provider or patient informed consent.

To further assure confidentiality of the EPIC data base the following is in place:

1. No Oregon Urology Institute Provider will have access to the full database.
2. Database will be overseen by the Director of Community Outreach.
3. Director of Community Outreach will not use data from database for any reason (i.e. presentation/publication, etc).
4. Database will be password protected.
5. Limited number of staff/interns will have secure access granted by the Director of CO.
6. Any changes in staffing, the password will be changed.

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7. Database will be kept on a secure server with limited access as aforementioned.
8. Information collected via paper EPIC forms will not have patient name, DOB. A unique identifier will be on form so that staff/interns who are given secure access will be able to assure data is entered into correct timeline (ex. pre-surgery, post-radiation, 3 year post treatment).
9. Any data shared with a Provider will be double checked by two staff assuring that no identifiers or PHI are included.
10. Any data shared from the database will not contain PHI that could be directly traced to a patient who shared their quality of life information.
11. This policy will not require re-review unless changes are made/needed.

[i] https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/

Unanimously agreed upon by the Oregon Urology Institute, Executive Council;

Brady Walker, MD — Date: 2/28/17

Bryan Mehlhaff, MD — Date: 2/28/2017

David Esrig, MD, FACS — Date: 2/28/17

Douglas Hoff, MD — Date: 2/28/2017

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