

A nighttime photograph of a cityscape featuring a large body of water in the foreground. In the background, a tall, illuminated building stands prominently. The scene is lit with warm, golden lights from street lamps and buildings, creating a starburst effect. A fountain is visible on the right side of the water. In the foreground, there are several park benches and trees.

BE THE LIGHT OF
HOPE OR THE
MIRROR THAT
REFLECTS IT.

WATSON CLINIC^{LLP}
Cancer & Research Center

 MOFFITT ONCOLOGY NETWORK MEMBER

2017 ANNUAL REPORT



Shining Bright

OUR LOCAL EFFORTS REFLECT THE GLOBAL FIGHT AGAINST CANCER

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The Watson Clinic Cancer & Research Center is fully accredited by the American College of Surgeons Commission on Cancer, Florida’s sole recipient of that organization’s Outstanding Achievement Award for both 2013 and 2016, and the only local member of the Moffitt Oncology Network. These accolades reflect our commitment to serving the physical and emotional needs of our patients, and to advancing the battle against cancer through research, technology and community outreach.

We’re proud of the legacy we’ve worked to build over our 14 year history.

It’s a legacy defined by each member of our multi-disciplinary team who possess expertise in a number of disciplines, including oncology-hematology, radiation oncology, surgical oncology, and gynecologic and urologic oncology. They’re supported by Watson Clinic’s extended family of over 200 board-certified specialists in fields as diverse as gastroenterology, plastic

& reconstructive surgery and primary care. Social workers, nurse navigators and other support staff facilitate a smooth transition of care between specialists, and remain at the ready to answer any question and assuage any concern.

The technologies they employ include the TrueBeam linear accelerator, the Trilogy linear accelerator, open-bore 3-Tesla MRI, PET/CT scan systems and 3D mammography. Our cancer center is frequently the first facility in the area to offer many of these cancer-fighting tools.

Our partnership with Moffitt Cancer Center offers patients access to the most progressive and promising clinical trials. Meanwhile, our outreach efforts elevate the consciousness of cancer risk in our community, and vigorously promote the benefits of early detection.

The following report summarizes the imprint we’ve had in the global fight against cancer, and our hopes for contributing to a future free from the disease.



A MESSAGE FROM

Shalini Mulaparthi, MD

CANCER
COMMITTEE CHAIR

I am pleased to invite you to get a glimpse of the outstanding clinical, research and community-based values that encompass the Commission on Cancer designated Watson Clinic Cancer & Research Center.

The physicians and staff at the cancer center are dedicated to providing the most sophisticated treatments available in a caring environment built on multidisciplinary teams that bring together experts in radiation, medical and surgical oncology, pathology, and diagnostic radiology. This team approach is critical to fulfilling our mission of providing the highest quality care and customized treatment plans for all patients who seek treatment at our facility.

Our ability to dissect an individual's cancer down to the very gene alterations that caused it to develop and grow makes our team unique in Polk County. Precision medicine is the key to reducing cancer mortality in the future and Watson Clinic is poised to be a leader in the new approach to cancer prevention, diagnosis and treatment.

Annually, Watson Clinic Cancer & Research Center clinicians diagnose and treat more than 1,700 new cancer cases. Patients also benefit from access to several clinical trials, many of them featuring therapeutic regimens, as well as studies to help understand the incidence and progression of cancer, and to improve quality of life. Our enrollment this year was exceptional. We continue to provide ground breaking trials for our community.

This is the time of the year when we, at Watson Clinic take time to be thankful for the opportunity to provide care to our patients during the past year safeguarding our patients and families from Hurricane Irma and at the same time review our commitment to serve in the year to come. Our resolve is strong and our hope for the future is bright.

Wherever you are and whatever you celebrate as the year draws to a close I wish you and your loved ones health, safety, peace and above all hope.



A MESSAGE FROM

Galina Vugman, MD

CANCER LIAISON
PHYSICIAN

It has been my privilege to serve as the Cancer Liaison Physician over the past year. Cancer is a disease which has touched many people whether it is a personal diagnosis or that of a loved one or friend. Through research and clinical trials, there continue to be strides in developing new treatments. So far in 2017, the FDA has approved numerous new therapies for hematologic and solid tumors. In the new year we will welcome the 8th edition of the American Joint Committee on Cancer (AJCC) staging manual which has begun to incorporate molecular markers in guiding the way we stage and treat cancers.

At Watson Clinic we take a multidisciplinary approach to treatment including non-physician and physician practitioners. We continue to be

the only freestanding cancer center in Florida to hold the Outstanding Achievement Award from the Committee on Cancer (CoC). We participate in any research in which we are able that may benefit our community and all patients battling cancer. We also request patients join registries so that our patients, as well as others across our nation, can have their progress followed over time.

I thank you for the trust you put in us on a daily basis. We understand how life changing a diagnosis of cancer can be and we do our best to treat you with compassion, understanding and inclusion of the whole family. We strive on a daily basis to help every one of our patients live a rich and fulfilling life.

Outreach & Events

The Watson Clinic Foundation, Watson Clinic LLP and the Watson Clinic Cancer & Research Center share a close-knit partnership that has reaped many healthy rewards for residents in our community and beyond.

We have worked together to enhance public awareness of early detection, share educational materials on a variety of cancer-related concerns, and provide a number of potentially life-saving screenings free of charge.

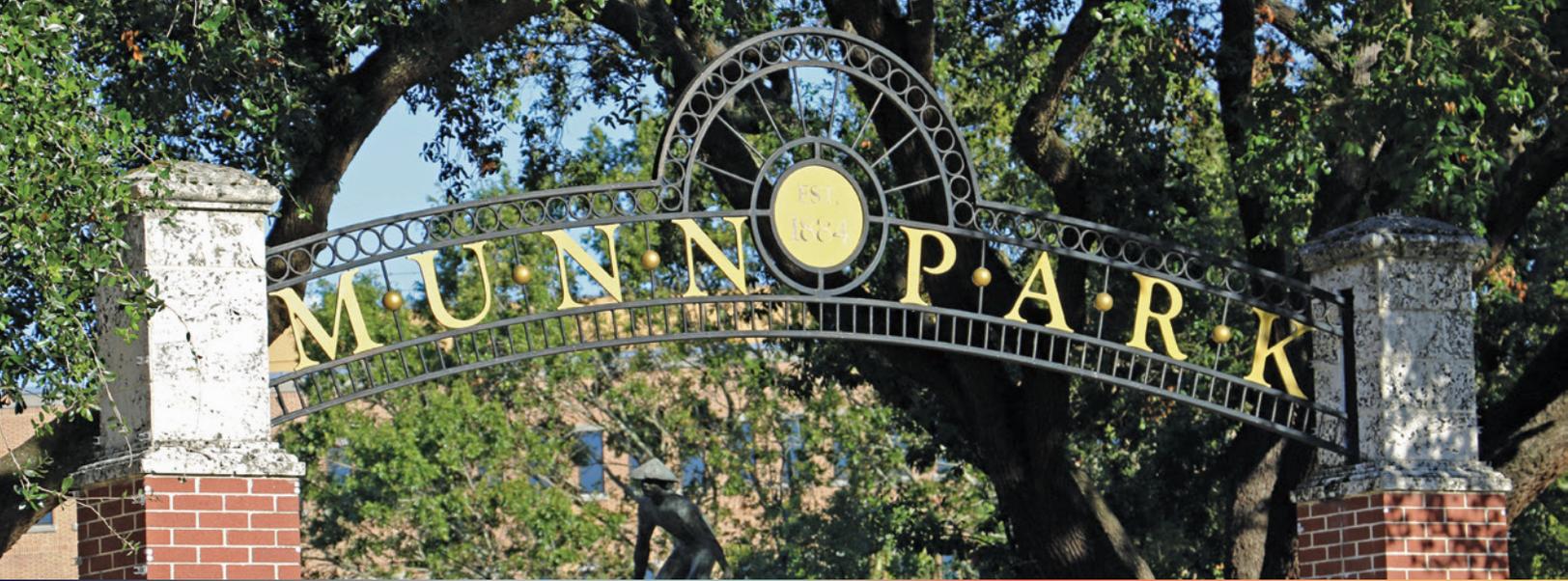
Additionally, we have offered our time, talent and financial support to a host of local and national organizations, including the American Cancer Society's Making Strides Against Breast Cancer and Relay for Life events, the Young Survival Coalition Tour de Pink charity ride, and the Ovarian Cancer Society Support Group of Polk County.

Additional outreach efforts spearheaded by the Foundation include:

- The distribution of colon cancer awareness posters throughout multiple clinic locations in an effort to educate visitors about the importance of regular screening.
- An educational booth at a Detroit Tigers Spring Training Game to engage in conversation with attendees and promote colon cancer awareness.
- Free skin cancer screenings at clinic locations across Polk and Hillsborough counties.
- Monthly Smoking Cessation programs to assist smokers who have a desire to quit.
- A Speaker's Bureau program, which provides local businesses and organizations with medical professionals who educate on a variety of topics related to cancer.
- A community education program focused on breast cancer and a variety of related health concerns.

Collectively, our partnership has set the groundwork for a healthier and vital community, and continues to shape the future of cancer survivorship.





Center for Research

Clinical trials are the cornerstone of gleaning knowledge to build the evidence that helps us treat cancer patients at the Watson Clinic Cancer & Research Center. Every day our oncology patients are screened to determine if they may be eligible for an open clinical trial. Our focus is to improve the clinical treatment options and therefore overall survival of our patients. Many patients choose to volunteer to enroll in a clinical trial to gain access to new medicines that will combat their cancer diagnosis.

The Watson Clinic Cancer & Research Center is conducting trials that treat patients diagnosed with breast, colon, lung, leukemia, lymphoma, melanoma, renal, pancreatic and prostate cancer. We actively recruit patients for the National Cancer Institute, pharmaceutical industry and medical universities.

Our research team strives to be on the cutting edge of cancer treatment. Our research team conducts clinical trials that treat patients with new or advanced disease. Its members include investigators from medical, surgical, radiology, radiation, and pathology disciplines. The goal is to choose trials that will best fit the patients seen daily in our practice.

Our investigators implement the evidence-based research into their clinical practice. This year we have studied cancer prognostic and predictive biomarkers of tissue, blood and imaging. The trials have explored imaging technologies and blood-based tests as tools for predicting response and risk of recurrence. Our team of investigators are enrolling in a multicenter trial to explore new surgical techniques that may result in reduction of additional surgeries for positive margins and possibly reduce the chance of local recurrence.

Our research efforts are frequently focused on the quality of life and survivorship experience of our cancer patients. We open trials that help our patients manage the challenges of dealing with their disease. During treatment, the patients are taught to foster good behaviors of quitting smoking, adding exercise and healthy eating. These trials are designed to provide patients with the tools to make lasting changes in their lifestyle that can last past the acute phase of the illness.

The Watson Clinic Cancer & Research Center's experienced researchers have a common goal to prevent and cure cancer in our community. Clinical trial evidence is the core part of achieving this goal.

Cancer Committee Members 2017

PHYSICIAN MEMBERS

Dr. John Barrett, Radiation Oncology
Dr. Elisabeth Dupont, Breast Surgery
Dr. Luis Franco, Medical Oncology-Hematology
Dr. Edward Garcia, Pathology
Dr. Howard Gorell, Radiology
Dr. Thomas Moskal, Surgical Oncology
Dr. Shalini Mulaparathi, Medical Oncology-Hematology, Cancer Committee Chair
Dr. Sandra Sha, Radiation Oncology
Dr. Galina Vugman, Medical Oncology-Hematology, Cancer Liaison Physician

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Dr. Richard Cardosi, Gynecologic Oncology
Dr. Tim Dickason, Pathology
Dr. Randy Heysek, Radiation Oncology
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Cancer Conferences

WATSON CLINIC CANCER & RESEARCH CENTER – 2016 AND 2017

Cancer conferences not only serve as a forum for prospective review of cancer cases involving a multidisciplinary team in the patient care process, but also offers education for the physicians and care team. Our multidisciplinary team includes physicians in the departments of medical oncology-hematology, radiation oncology, surgical oncology, pathology, diagnostic radiology, and other specialties, as well as allied health professionals from research, nursing, social services, cancer registry and administration. They attend cancer conferences three times a week for collaborative discussions of diagnosis, stage, prognostic factors, and national treatment guidelines pertaining to the cases presented and cancer related educational activities.

CANCER CONFERENCES YEAR END 2016

Total # of Cancer Conferences:

93

Total # of Cancer Related Educational Activities:

17

Total # of Cases Presented:

769

85% of Analytic Caseload

Total # of Cases Presented Prospectively:

764

99% of Cases Presented

CANCER CONFERENCES JANUARY 1, 2017 – JULY 31, 2017

Total # of Cancer Conferences:

80

Total # of Cancer Related Educational Activities:

19

Total # of Cases Presented:

661

73% of Analytic Caseload

Total # of Cases Presented Prospectively:

654

99% of Cases Presented





Patterns of Lung Cancer Treatment at Watson Clinic

NANCY WIDICK AND GALINA VUGMAN, MD

INTRODUCTION

Lung cancer, consisting of mainly Non-Small Cell Lung Cancer (NSCLC), is the leading cause of cancer related death worldwide, but improvements in chemotherapy, radiation therapy and surgical procedures have prolonged the lives of patients diagnosed by providing new treatment options. Studies involving targeted drug therapies have shown clinical benefit in the survival of patients who received them over those who were given routine chemotherapy (Zhou, C. et.al, 2011). Epidermal Growth and Factor Receptor (EGFR) and Anaplastic Large-cell Lymphoma Kinase (ALK) have become routine biomarkers to check in determining whether a patient should receive a targeted drug therapy such as Erlotinib (Tarceva), Afatinib (Gilotrif), Gefitinib (Iressa), Crizotinib (Xalkori), Ceritinib (Zykadia), or Alectinib (Alecensa) (Targeted Therapy, 2017). 17% of NSCLCs express the EGFR rearrangement, a mutation in the epidermal membrane receptor that causes cell proliferation, an increased number of cells; while only around 5% of all NSCLCs express the ALK mutation, this rearrangement results in the

activation of cell growth and proliferation (Lovly, 2015). EGFR and ALK biomarkers are key in being able to tailor treatments towards an individual patient in hopes of improving their survival. The main objective of this study is to see if patients diagnosed with NSCLC at Watson Clinic have the same benefits from the targeted oral drug therapies as the patients in the clinical trials.

METHODOLOGY

A list of patients that were diagnosed with NSCLC between January 1, 2014 and August 31, 2016 that have undergone treatment was provided by the Watson Clinic Cancer & Research Center – Cancer Registry. Watson Clinic’s medical records were examined for data abstraction as well as Lakeland Regional’s CERNER hospital records. A chart review including 150 patients was conducted by searching through the doctor’s notes, pathology findings, chemotherapy notes, as well as radiation therapy notes and summaries. Upon exploration of the patient chart the following data was recorded: pathology results, cancer stage, EGFR and ALK test results or reason they weren’t tested, ECOG,



chemotherapy, radiation therapy, targeted therapy and surgery record.

The patients were then narrowed down to all stage IV NSCLC and Stage III's who did not receive radiation therapy, 60 patients, for the first part of the study. These 60 patients were split further into Stage IV adenocarcinomas versus squamous cell carcinomas leaving 40 patients. Out of the 40 patients 7 EGFR or ALK positive patients were separated from the 33 EGFR or ALK negative patients, leaving the two study populations for the overall survival portion of the study. The original 60 patients were looked at to see what percent of patients were tested for EGFR and ALK mutations, the 33 stage IV adenocarcinomas and the 7 EGFR, ALK positive patients were observed to see if the targeted therapies had the intended affect on the patients' survival.

RESULTS

As noted in the methodology there are two parts to this study, what percent of patients were tested for the EGFR and ALK mutations or why they weren't tested and the overall survival of the patients that were EGFR, ALK negative versus those that were EGFR, ALK positive and received targeted therapies.

When looking at the first part of this study it was found that there are 60 patients out of the original

150 qualified by having stage IV NSCLC and stage III's that were not treated with radiation therapy. Out of these 60 patients 38 were tested for EGFR which is 63% but only 58% were tested for ALK, 35 patients, leaving the remaining 37% of patients without being tested for the EGFR mutation, 22 patients, and 42% without being tested for the ALK rearrangement, 25 patients.

Overall Survival for patients in the second part of this study was measured in days from date of diagnosis with NSCLC to the date of death. During the calculation of the overall survival it was found that 9 of the 33 EGFR or ALK negative patients are currently living, these 9 patients were not considered in the average survival for this group. The remaining 24 deceased patients' overall survival was calculated then the average found to be 285 days survived after date of diagnosis. The EGFR, ALK positive patients were separated into 2 groups, 5 were Stage IV adenocarcinomas and 2 were stage IIIB adenocarcinomas. None of the EGFR or ALK positive patients are currently living. The 5 stage IV EGFR or ALK positive patients had an average survival of 359 days after date of diagnosis, but the 2 stage EGFR or ALK positive patients had a lower average at just 183 days. When the two groups of EGFR or ALK positive patients were calculated together, all 7 patients, the average survival was 309 days.

PATIENTS THAT WERE TESTED FOR EGFR MUTATION

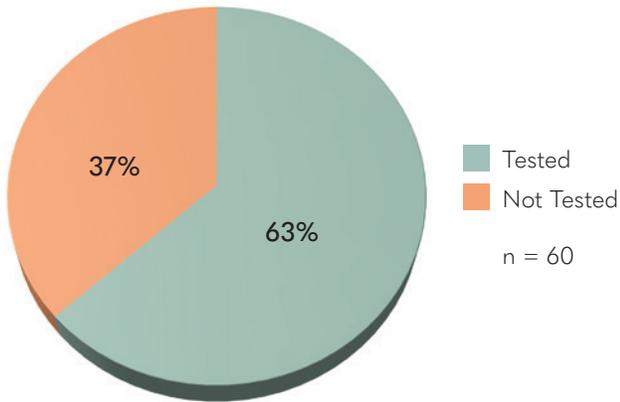


Figure 1: Percent of patients that were tested for EGFR. 63% or 38 patients were tested for the EGFR mutation.

REASONS EGFR WAS NOT TESTED

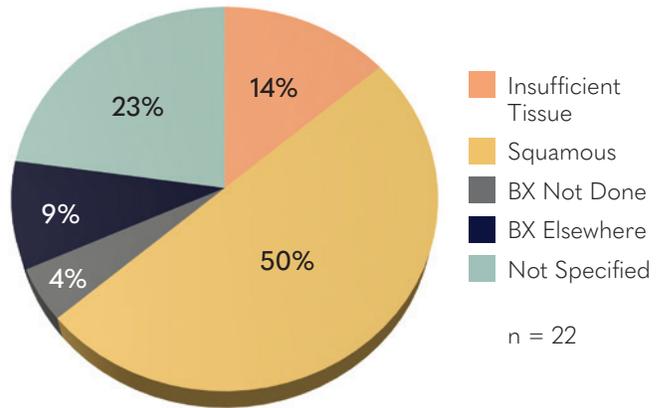


Figure 2: Reason EGFR mutation test was not run. 50% of the patients had squamous cell carcinoma 14% the quantity of the tissue was insufficient for the test to be run.

PATIENTS THAT WERE TESTED FOR ALK MUTATION

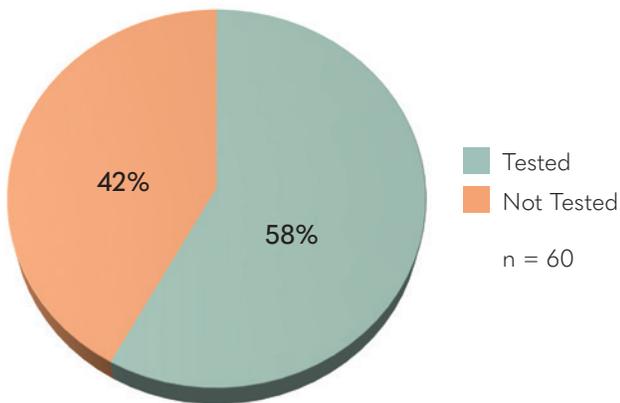


Figure 3: Percent of patients that had an ALK mutation test run. 58% or 35 patients were tested for an ALK mutation.

REASONS ALK WAS NOT TESTED

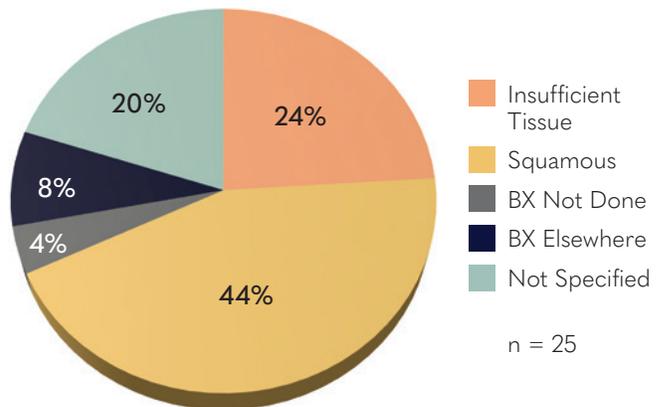


Figure 4: Reasons the ALK mutation wasn't tested. 44% or 11 patients had a squamous cell carcinoma and 25% or 6 patients didn't have enough tissue for the test to be preformed.



DISCUSSION

There is growing evidence based support in favor of targeted drug therapies for EGFR or ALK positive patients' showing targeted therapy is superior to routine chemotherapy yet not all patients are being tested for these mutations. In this study it was found that more than half of the patients were tested for EGFR and ALK, but out of the ones that weren't tested the most common reason to not get tested is that the patient had squamous cell carcinoma in which EGFR and ALK rearrangements are not commonly found. This raised the question of why the rest of the patients weren't tested for this mutation if they were an adenocarcinoma. In some cases though there wasn't enough tissue to run both of the tests or the biopsy wasn't ever performed so there was no tissue to test. In five cases the patients had an adenocarcinoma where the mutations are most commonly found, but they weren't tested for any specific reason. If the targeted therapies are as useful as they are proving to be it should be a priority to test for the EGFR and ALK mutations. When looking at the patients with that proved to be EGFR or ALK positive patients it was noted that five out of the seven patients received a targeted drug therapy. These patients on average lived longer than those who received routine chemotherapy. If you only include the EGFR or ALK positive patients that received a targeted therapy their average survival was 385 days whereas the EGFR or ALK positives that received routine chemotherapy lived on average 117 days and the patients that were EGFR or ALK negative lived 285 days. This shows that targeted drug therapies in fact do increase the survival of the patients who receive them.

EGFR AND ALK NEGATIVE PATIENTS CURRENTLY LIVING

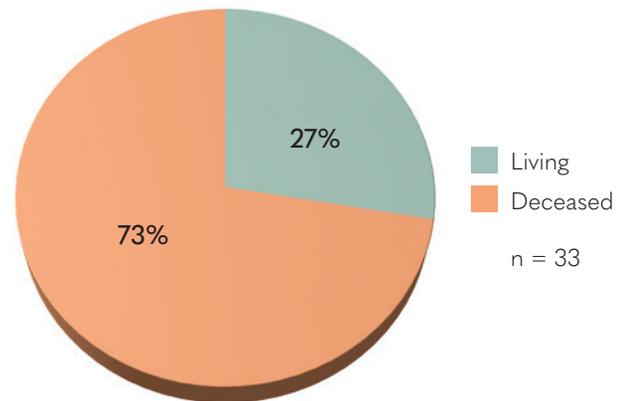


Figure 5: EGFR and ALK patients that are living as of July 7, 2017. 27% or 9 of the EGFR and ALK negative patients are living at the time of the study.

OVERALL SURVIVAL FROM DATE OF DIAGNOSIS TO DATE OF DEATH

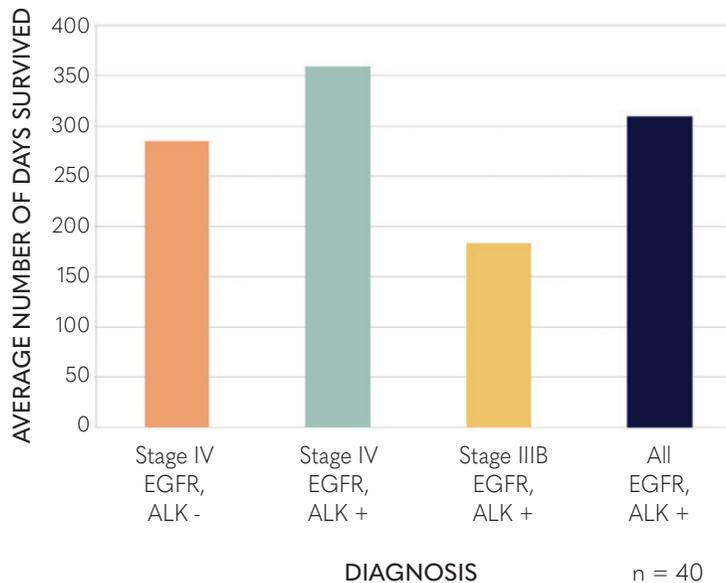


Figure 6: Overall survival of patients with adenocarcinomas. The patients that survived the longest from date of diagnosis to date of death were the stage IV EGFR or ALK positive patients with an average of 359.4 days. The lowest was stage III B EGFR and ALK positive patients averaging 183 days.

OVERALL SURVIVAL FROM DATE OF DIAGNOSIS TO DATE OF DEATH FOR EGFR OR ALK POSITIVE PATIENTS

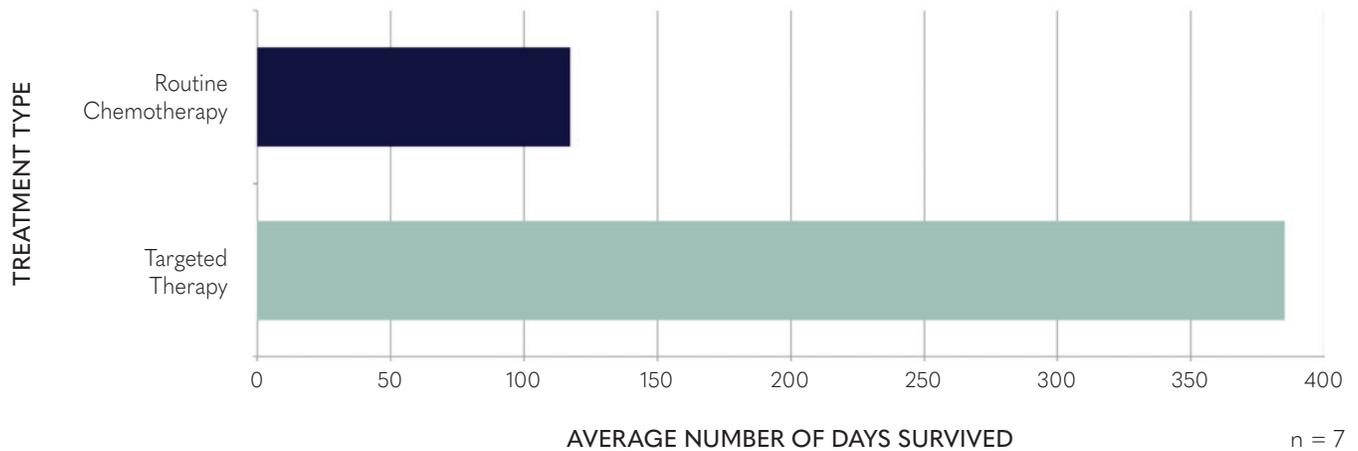


Figure 7: Overall survival of EGFR or ALK patients who received different forms of treatment. Patients who received targeted therapy survived an average of 385 days.

CONCLUSION

The trial conducted at Watson Clinic has shown that the patients at the Watson Clinic Cancer & Research Center had the intended affects of the targeted therapy. Overall survival was significantly increased in those patients on targeted therapy as would be expected according to trials. No reason

has been stated for the two patients that had the appropriate mutations, but were not given targeted therapy. 12% of patients did not undergo EGFR or ALK tests; no reason for this was able to be discerned in chart records. More vigilant efforts should be taken in making sure relevant tests are done because it significantly alters the survival of patients able to receive targeted therapy.

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Prostate Cancer Active Surveillance Outcome Study at Watson Clinic

MICHELLE MOSKAL AND JOHN T. BARRETT, MD, PH.D.

PURPOSE

We assessed the outcome of an active surveillance protocol with selective delayed intervention by using clinical prostate-specific antigen (PSA), or histologic progression as treatment indications for clinically localized prostate cancer at the Watson Clinic Cancer & Research Center.

PATIENTS AND METHODS

This was a retrospective, single-arm, cohort study. Patients were managed with an initial expectant approach and followed by Urology, Radiation Oncology or both. Reasons for definitive intervention were searched for, such as patients with a PSA doubling time of less than three years, Gleason score progression (to 3+4 or greater), or unequivocal clinical progression by digital rectal

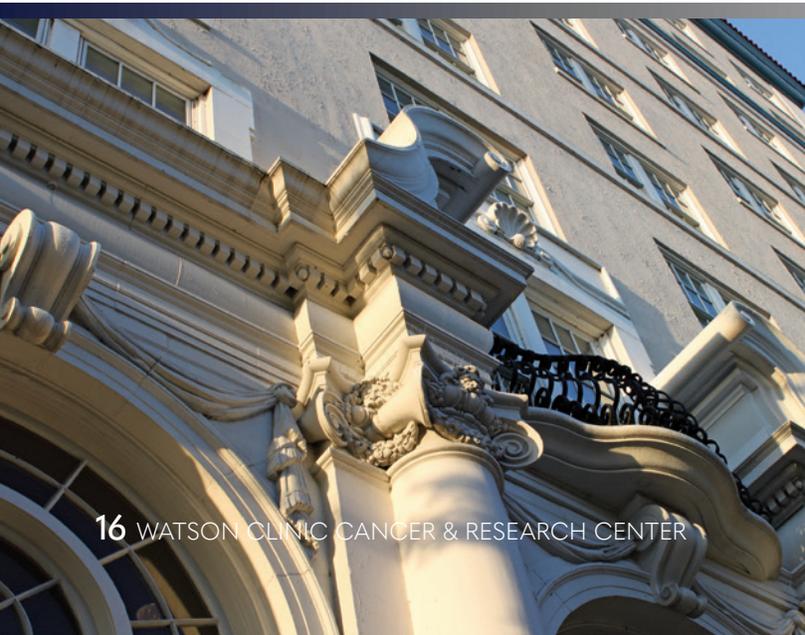
exam (DRE). Some patients without evidence of progression by these criteria elected to pursue definitive treatment.

RESULTS

A total of 97 patients have been observed with active surveillance. Median follow-up was six years. Overall survival was 91%. The 10-year prostate cancer actuarial survival was 100%. Overall, 46% of patients have been reclassified as higher risk during the course of active surveillance, but 42% of those patients did not pursue treatment and remained on active surveillance or were lost to follow-up.

CONCLUSION

We observed no prostate cancer mortality among this small cohort of mostly low risk prostate cancer



patients who initially pursued active surveillance. Other-cause mortality accounted for all of the deaths. As demonstrated by many prospective active surveillance trials of low risk prostate cancer, our small retrospective study confirms the safety of the active surveillance strategy. A uniform protocol for active surveillance, in terms of eligibility, interval surveillance procedures and criteria for recommending treatment should be developed for the institution. Advances to improve the identification of patients who harbor more aggressive disease despite favorable clinical parameters at diagnosis, and alternatives to routine surveillance prostate biopsy are discussed.

INTRODUCTION

Active surveillance for favorable-risk, localized prostate cancer may reduce the risk of overtreatment of clinically insignificant prostate cancer while retaining the option of definitive therapy for those patients who are reclassified over time as higher risk. Estimates in autopsy studies indicate that 50% of men older than 50 years of age have prostate cancer. In the United States and Canada, the likelihood of being diagnosed is approximately 18%. The estimated lifetime probability of dying as a result of prostate cancer is 2.8%. The incidence-to-mortality ratio is 6.4. The most common cause of death in men diagnosed

with prostate cancer is cardiovascular disease. The European Randomized Study of Screening demonstrated a 20% reduction in prostate cancer mortality in the screened arm. The number needed to treat for each death avoided was 48. These data emphasize that, although screening and early detection offer benefits in terms of reduced mortality, there is a significant risk of over-treatment. This dilemma is the rationale for a selective approach to treatment, especially in very low and low risk individuals:

Very low-risk: Characteristics of a man considered to be at very low risk for progression of his prostate tumor would include a low prostate specific antigen density indicating that his PSA is appropriate for the volume of the prostate, a Gleason score of less than seven, less than three cores of tissue from the biopsy showing cancer, and unilateral cancer (cancer found on only one side of the prostate either right or left). Surveillance would be the preferred option for these men if life expectancy is less than 20 years, which would include most men over age 65 years.

Low-risk: Characteristics of a man considered to be at low risk for progression of his prostate tumor would include a Gleason score of less than seven, a PSA measurement of less than 10, and stage T1c or T2a disease. Surveillance would be the preferred





option for men with low risk prostate cancer that have less than a 10 year life expectancy; and should be considered for men over age 65 years.

We performed a retrospective clinical trial to evaluate active surveillance as practiced at the Watson Clinic, in which the decision to intervene was determined by prostate-specific antigen (PSA) kinetics and/or histological progression and/or clinical progression on DRE. This strategy offers the attraction of individualizing therapy according to the biologic behavior of cancer. Patients with a slowly growing malignancy would be spared the adverse effects of radical treatment, whereas those with more rapidly progressive cancer would still potentially benefit from curative therapy.

METHODS

A retrospective study was initiated to assess the prevalence, adherence, and outcome of observation protocols for low risk prostate cancer with selective, delayed intervention by using PSA kinetics and/or histologic or clinical progression as triggers for intervention. We retrospectively reviewed the medical records of all patients treated during the study period with the biopsy-proven diagnosis of prostate cancer. Demographics and ECOG performance scores of newly diagnosed prostate cancer patients who elected active surveillance were recorded, along with the initial

PSA, Gleason's score and number of biopsy cores involved.

For favorable-risk patients that were offered an initial surveillance approach, intervals at which PSA measurements, DRE's and repeat prostate biopsies were recorded. Patients that were reclassified as higher risk and offered radical intervention were identified.

RESULTS

PATIENT DEMOGRAPHICS: AGE (AT DIAGNOSIS)

Mean	71.6
Median	72
Range	56 – 84
Age < 70	34/97 (35%)
Age ≥ 70	63/97 (65%)
History of BPH/Prostatitis	
Total	38/97 (39%)
Patient Update	
# of Deceased Patients	9/97 (9%)

Figure 1: At follow-up, 91% of patients are still alive and none of the causes of death appeared to be related to prostate cancer.

PERCENTAGE DISTRIBUTION OF ECOG SCORES DURING ACTIVE SURVEILLANCE/TREATMENT

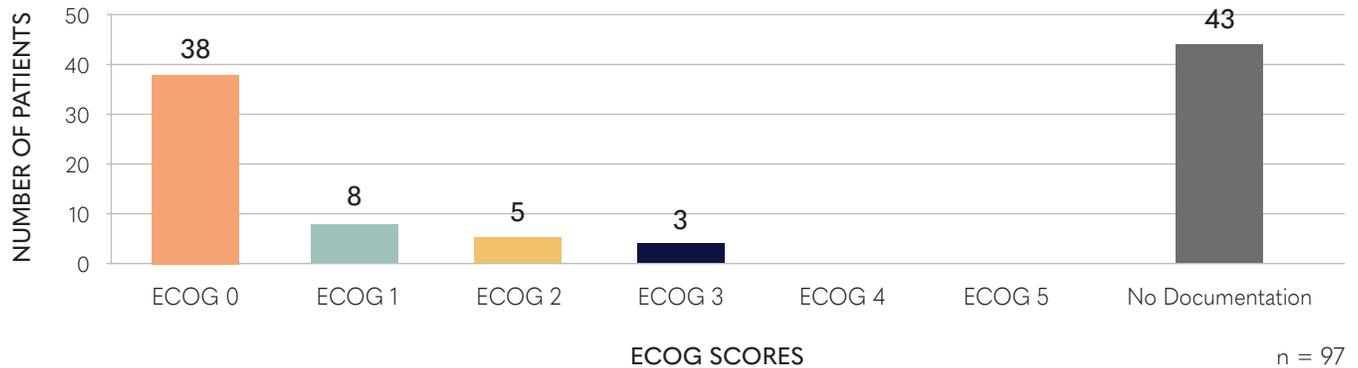


Figure 2: Distribution of ECOG performance scores at time of diagnosis. 85% of the patients for which performance status was recorded were ECOG 0 or 1.

GLEASON SCORES

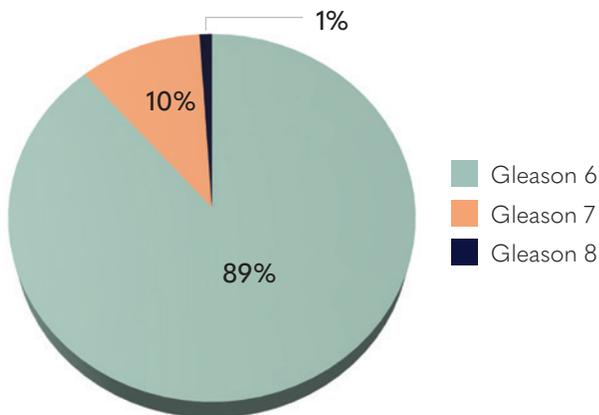


Figure 3: Distribution of Gleason Scores at Diagnosis. 89% were low risk with scores of 3+3=6 and PSA<10.

AVERAGE NUMBER OF POSITIVE BIOPSY CORES

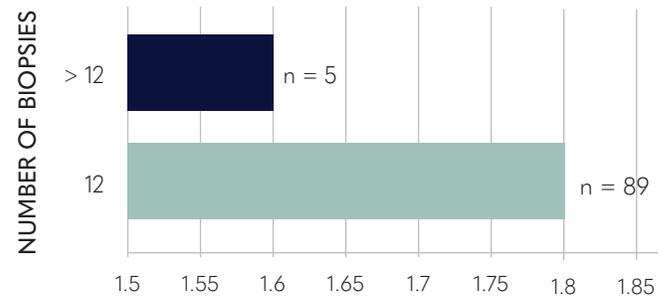


Figure 4: Five patients had “saturation biopsies” after prior negative prostate biopsies and the remainder had 12 cores obtained. On average, 2/12 cores were involved. Pathology reports could not be located on the remaining three patients on surveillance.

PATIENTS WITH DRE FOLLOW-UP

# of Patients with Six Month Follow-up	45/97 (46%)
# of Patients with Annual Follow-up	17/97 (18%)
# of Patients with One Inconsistent Follow-up	13/97 (13%)
# of Patients with Only Consult DRE	17/97 (18%)
# of Patients with No Data	5/97 (5%)

Figure 5: Number of patients who had follow-up DRE on a six month basis vs. greater intervals or no consistent DRE follow-up. 22% of patients showed evidence of progression on DRE (formation or enlargement of nodularity or induration).

AVERAGE PERCENTAGE CHANGE IN PSA

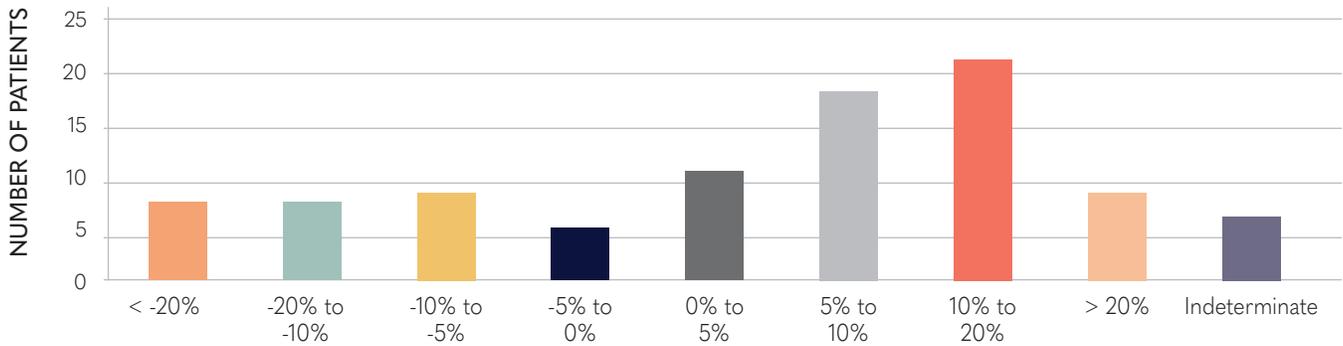


Figure 6: Although PSA generally increased with time in the majority of patients on surveillance, a significant proportion remained relatively stable or decreased.

PATIENTS WITH REPEAT BIOPSY

One Follow-up Biopsy	28/32 (88%)
> One Follow-up Biopsy	4/32 (12%)
Patient Total	32/97 (33%)

Figure 7: Number of Surveillance patients who had one or more repeat biopsies either for routine surveillance or because of change in PSA velocity and/or DRE. Only 33% of all surveillance patients had a follow-up prostate biopsy and of this group, only 12% had more than one follow-up biopsy. 17% of those patients with follow-up biopsies showed progression in their Gleason score, usually from 6 to 7.

PATIENTS WITH PROGRESSION VS. THOSE WITHOUT

Patients	Received Treatment	Did Not Receive Treatment	Total
Patients With Progression	26	19	45
Patients Without Progression	4	48	52
Total	30	67	97

Figure 8: Treatment Decisions of those who met criteria for "progression of disease" vs. those who did not. 31% of the cohort received treatment and 69% did not. 42% of the 45 patients who met criteria for progression declined treatment and elected to continue active surveillance and 8% of the 52 patients who did not progress elected to receive treatment.

TYPES OF TREATMENTS

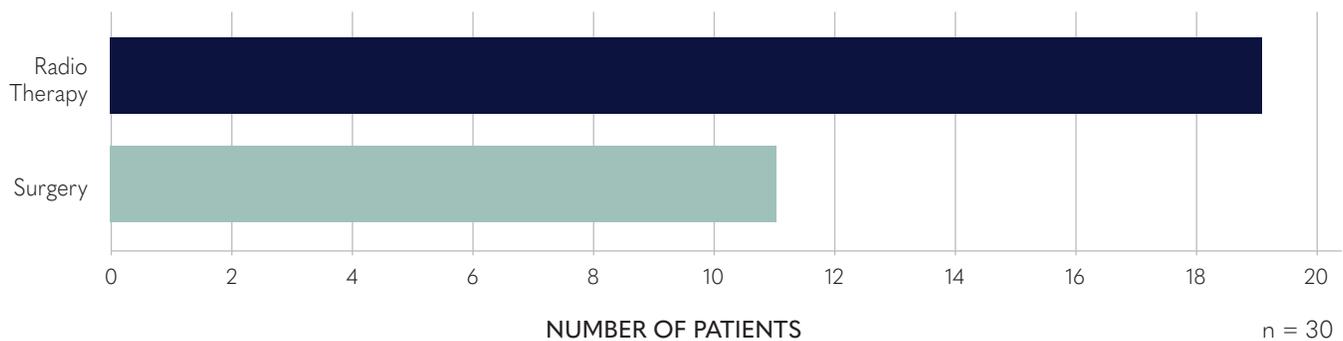


Figure 9: Types of definitive therapy received by patients who elected or were advised to undergo treatment. Radiotherapy included brachytherapy, IMRT, or a combination of the two.

DISCUSSION

This study of the Watson Clinic experience with active surveillance of very low to low risk prostate cancer is similar to many large published trials which have established the relative safety of this approach. Candidates may also include those with intermediate risk disease and limited life expectancy, or those with intermediate risk disease that have a strong preference for avoiding treatment. The latter two groups may be enrolled provided they understand there is a higher risk of harm without treatment when compared to men with very low to low risk. Recommendations for active surveillance can be made with greater certainty when the initial biopsy is guided by MRI/TRUS fusion. 3-dimensional rendering of the prostate as imaged by MRI and ultrasound to be aligned or fused. This provides the physician with the ability to target areas of the prostate suspicious on MRI using live ultrasound. As compared to non-targeted biopsies that sample the prostate systematically under ultrasound guidance alone, targeted biopsies are more likely to uncover high grade cancers.

Several tissue-based molecular assays (e.g. Prolaris) have been developed in an effort to improve decision-making in newly diagnosed men considering active surveillance. Uncertainty about

risk of disease progression can be reduced if such molecular assays can provide accurate and reproducible prognostic information beyond the NCCN risk group assignment, life expectancy tables and nomograms.

We recommend clinic-wide adoption of the NCCN guidelines for active surveillance of very low and low risk prostate cancer. This includes PSA check every six months, DRE yearly unless greater frequency is clinically indicated, and repeat prostate biopsy no more often than yearly unless clinically indicated. Repeat biopsies on this schedule are difficult to maintain due to patient reluctance and concern about the morbidity of infectious complications due to transrectal prostate biopsies, such as prostatitis and urosepsis. Multiparametric MRI can reduce the frequency of monitoring biopsies in those men that have no suspicion of transition to high grade cancer on MRI. The three parameters used to estimate the likelihood of cancer in the gland are signal intensity on T2-weighted images, restriction on diffusion weighted images, and the extent to which contrast material is taken up by tissues and washes out of tissues (DCE). The PI-RADS grading system from 1-5 corresponds to the suspicion that cancer is present: grade 1-2 (low suspicion), grade 3 (indeterminate), and grade 4-5 (high suspicion).



RESOURCES & INFORMATION ON CANCER

A Place For Her

727-447-1146 • www.aplaceforher.com

American Cancer Society (ACS)

800-227-2345 • www.cancer.org

American College of Surgeons (ACoS)

800-621-4111 • www.facs.org

American Institute for Cancer Research (AICR)

800-843-8114 • www.aicr.org

American Lung Association

www.lungassociation.org

CancerCare

800-813-HOPE • www.cancercare.org

Centers for Disease Control and Prevention (CDC)

www.cdc.gov

Central Florida Health Care Center

866-234-8534 • www.cfhconline.org

Chronic Disease Fund

877-968-7233 • www.cdfund.org

Citrus Connection Handy Bus

www.ridecitrus.com

Comfort Keepers

866-225-0320 • comfortkeepers.com

Commission on Cancer (CoC)

312-202-5009 • www.facs.org/cancer

Compassionate Care Hospice

877-494-3219 • www.cchnet.net

Cornerstone Hospice

866-742-6655 • web.cshospice.org

Department of Children and Families

407-317-7000 • www.myflfamilies.com

Florida Cancer Data System (FCDS)

305-243-4600 • www.fcds.med.miami.edu

Florida Department of Health (FDH)

www.doh.state.fl.us

Good Shepherd Hospice

800-544-3280 • www.chaptershealth.org

Healthwell Foundation

800-675-8416 • www.healthwellfoundation.org

Lakeland Volunteers in Medicine

863-688-5846 • www.lvim.net

Leukemia & Lymphoma Society

800-955-4572 • www.leukemia-lymphoma.org

Lighthouse Ministries

863-687-4076 • www.lighthousemin.org

National Cancer Institute (NCI)

800-4CANCER • www.cancer.gov

Nurses Helping Hands Assisted Living

www.nurseshelpinghandsalf.com

Patient Access Network

866-316-7263 • www.panfoundation.org

Patient Advocate Foundation

800-532-5274 • www.patientadvocate.org

Patient Services, Inc.

800-366-7741 • www.patientservicesinc.org

Polk County Elderly Services

863-534-5320 • www.polk-county.net

Polk County Transport

www.polk-county.net

Social Security Administration

www.ssa.gov

Susan G. Komen

800-468-9273 • www.komen.org

Talbot House

863-687-8475 • www.talbothouse.org

United Way

2-1-1 or 863-648-1515 • www.uwcf.org

VITAS Hospice

863-583-7100 • www.vitas.com

Volunteers In Service to the Elderly

863-284-0828 • www.viste.org

We Care of Polk County

863-662-4227 • www.wecarecentralflorida.org



A Special Thank You

At the Watson Clinic Cancer & Research Center, our patients and the medical professionals who care for them are a close-knit family.

This year, we bid a fond farewell to two highly respected and beloved members of that family: oncologist-hematologist Dr. Luis Franco (above left) and radiation oncologist Dr. John Barrett (above right). Both of these specialists are moving on to enjoy the next phase of their lives and careers.

Dr. Franco joined Watson Clinic in 2002, and transferred to the cancer center upon its opening the following year. In 2008, he was the recipient of the Cancer Physician Liaison Outstanding Performance Award from the American College of Surgeons Commission on Cancer. He also served honorably as our Cancer Committee Chair.

Dr. Barrett started with the cancer center in 2007. With an emphasis on Intensity Modulated Radiation Therapy (IMRT) and brachytherapy, he led the way in employing cutting-edge technologies with personalized care.

Both of these cancer warriors fought for their patients with great tenacity and compassion. They have played a significant role in motivating the spirit of survivorship in each community they served, and in shaping the legacy of excellence for which our center has become known.

**WE WISH THEM BOTH THE VERY BEST
IN ALL THEIR FUTURE ENDEAVORS.**



WATSON CLINIC^{LLP}
Cancer & Research Center

 MOFFITT ONCOLOGY NETWORK MEMBER