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HOW TO USE THIS MONOGRAPH

This is a CME activity that contains both audio and print components. To receive credit, the participant should listen to the CD or tape, review the monograph and complete the post-test and evaluation form on pages 22-24 or on our website. This monograph contains edited comments, clinical trial schemas, graphics and references that supplement the audio program and the website, **ProstateCancerUpdate.net**, where you will find an easy-to-use interactive version of this monograph with links to relevant full-text articles, abstracts, trial information and other web resources indicated here in **red underlined text**.

Prostate Cancer Update: A CME Audio Series and Activity

STATEMENT OF NEED/TARGET AUDIENCE

Prostate cancer is one of the most rapidly evolving fields in urology. Published results from clinical trials lead to the emergence of new surgical and radiation therapy techniques and therapeutic agents, along with changes in the indications for existing treatments. In order to offer optimal patient care — including the option of clinical trial participation — the practicing urologist and radiation oncologist must be well-informed of these advances. To bridge the gap between research and patient care, Prostate Cancer Update utilizes one-on-one discussions with leading urologic oncology investigators. By providing access to the latest research developments and expert perspectives, this CME program assists urologists and radiation oncologists in the formulation of up-to-date clinical management strategies.

GLOBAL LEARNING OBJECTIVES

Upon completion of this activity, participants should be able to:

- Critically evaluate the clinical implications of emerging clinical trial data in prostate cancer treatment.
- Inform patients about the specific risks and benefits of local and systemic therapies.
- Provide individualized counseling to patients regarding the choice and timing of endocrine therapy.
- Offer patients information regarding their prognosis with and without various therapeutic options.

Issue 4, 2003, of Prostate Cancer Update consists of discussions with three research leaders on a variety of important issues, including timing and duration of total androgen blockade, prostate-specific antigen (PSA) relapse, brachytherapy and several interesting case discussions.

SPECIFIC LEARNING OBJECTIVES FOR ISSUE 4

Upon completion of this activity, participants should be able to:

- Counsel prostate cancer patients about the results of the RTOG-9413 trial of whole-pelvic radiation therapy and neoadjuvant combined androgen suppression.
- Define the risk subsets for patients who are candidates for long-term hormone therapy after initial therapy with radiation.
- Review clinical trial data and research leaders' perspectives about early versus delayed hormonal therapy in order to counsel patients with postprostatectomy biochemical failure.
- Describe ongoing clinical trials evaluating adjuvant chemotherapy in order to counsel patients with high-risk prostate cancer about participation.
- Counsel patients about the sexual outcomes associated with the various treatment alternatives for localized prostate cancer and the success and treatment adherence rates for the therapeutic options for erectile dysfunction.

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Mack Roach III, MD	**Grants/Research Support:** Berlex Laboratories Inc, Amgen Inc **Consultant and Honoraria:** TAP Pharmaceutical Products Inc, Cytogen Corporation, NexCura Inc, Myriad Pharmaceuticals Inc, Calypso, Sanofi-Synthelabo Inc **Other Support:** Siemens **Speakers' Bureau:** TAP Pharmaceutical Products Inc, AstraZeneca Pharmaceuticals LP
Robert Dreicer, MD, FACP	**Grants/Research Support, Consultant:** Aventis Pharmaceuticals Inc, Millennium Pharmaceuticals Inc, Celgene Corporation **Speakers' Bureau:** Aventis Pharmaceuticals Inc, Eli Lilly and Company
Leslie R Schover, PhD	**Grants/Research Support:** American Cancer Society National Grant Principal Investigator

Pharmaceutical agents discussed in this program

GENERIC	TRADE	MANUFACTURER
bicalutamide	Casodex®	AstraZeneca Pharmaceuticals LP
bortezomib	Velcade®	Millennium Pharmaceuticals Inc
docetaxel	Taxotere®	Aventis Pharmaceuticals Inc
estramustine phosphate	Emcyt®	Pharmacia & Upjohn SpA
etoposide	VP-16, VePesid®	Bristol-Myers Squibb Company
goserelin acetate implant	Zoladex®	AstraZeneca Pharmaceuticals LP
mitoxantrone	Novantrone®	Immunex Corporation
paclitaxel	Taxol®	Bristol-Myers Squibb Company
prednisone	Various	Various
sildenafil citrate	Viagra®	Pfizer Inc [generics by many others]

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Editor's Note

The guy who takes out the trash

While audio is an effective, time-conserving media for continuing medical education, there are situations when it fails to communicate all that occurs during a one-on-one interview. For example, in this issue, medical oncologist Dr Robert Dreicer presents a case demonstrating the palliative benefits of chemotherapy in a patient with metastatic prostate cancer. Frequently, the researchers we interview present patients with unusual clinical courses or responses to treatment, but the details of this case were not particularly remarkable, and I wondered why this specific patient was being presented.

Then, I began to notice Dr Dreicer's eyes and facial expression as he talked about the man, and it became obvious that there was a great deal of caring between this doctor and his patient. When I asked him about this, his voice broke and his eyes swelled with tears. "He was one of those people that you just like — a 'salt of the earth kind of man.' I've been an oncologist for a long time, and I don't develop relationships with every patient. But there are certain people that you just connect with, in terms of how they approach the world and go about their daily business. He was one of those people I cared for a lot."

Providing medical care to people with cancer is not a simple occupation. For Dr Dreicer, the rewards of treating patients with incurable cancers come from effective palliation. However, with the benefits also come downsides, and Dr Dreicer notes that he is not immune to the emotional toll of his work. For years, he has struggled to find methods to cope with the tragedy that is a daily part of oncology practice. "As I've gotten a little older, I've spent a lot more time talking with my wife and trying to do things to overcome some of the negative impact of oncology. I don't have a magical solution, but I try to not bring work home with me. I'm still just the guy who has to take out the trash and do all the other things, and I think that's worked pretty well for me. Some people do it by taking three months of vacation a year; others by mountain biking. I don't know what the right answer is, but you do have to think about it."

Another facial expression our listeners missed related to the frustration expressed by Dr Leslie Schover, who believes that many men are "sold a false bill of goods" in pretreatment discussions about what to expect in terms of sexual function after surgery and radiation therapy for prostate cancer. Her informal clinical observations over many years of counseling men have been that the rates of sexual dysfunction after primary local therapy are far greater

than the rates reported in medical literature. In this program, Dr Schover reviews two groundbreaking papers she reported in *Cancer* from a consecutive series of men treated at the Cleveland Clinic.

With this center's outstanding staff of urologists and radiation oncologists, the incidence of post-therapy erectile dysfunction was far greater than those documented in other series. Dr Schover also notes that many prior studies with better results used suboptimal methods to assess outcomes. In addition to providing more accurate information to patients, she believes in a more structured approach to post-therapy rehabilitation.

Dr Mack Roach was also visually expressive during our meeting, particularly when he described a patient with locally advanced disease he treated with conformal external-beam radiation therapy and neoadjuvant and long-term androgen deprivation. A somewhat bemused and perhaps triumphant smile crept across his face when he described the "ups and downs" of a post-radiation therapy PSA rise that initially suggested possible disease recurrence.

When an eight-core biopsy failed to demonstrate tumor recurrence, Dr Roach patiently held off on any therapeutic intervention, and the PSA has now remained stable for years. The patient is cancer-free with normal erectile function, and it is easy to see that his follow-up visits provide a great sense of satisfaction for both the patient and physician.

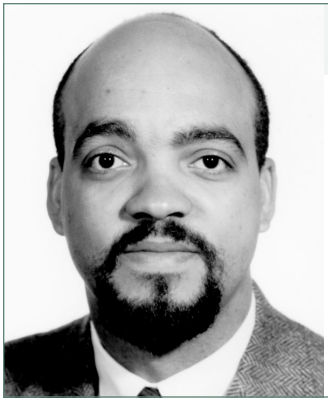
One consistent observation I have made through many years of face-to-face interviews with cancer researchers is that an aura of humility seems to pervade these people's personalities. And more often than not, it seems that the most humble researchers are those who have made the greatest contributions. Perhaps, it is important for all of us to remember that we are still "the guys who take out the trash" and that state-of-the-art cancer medicine is only part of the complex, biopsychosocial formula required to care for patients with this challenging disease.

— Neil Love, MD

ERRATUM:

In *Prostate Cancer Update*, Volume 2, Issue 2, in reference to the "Bolla" study*, an interviewee stated that LHRH agonist treatment was started on the last day of irradiation. Dr Warren Wilkins, InterCommunity Cancer Center, Illinois, contacted us and pointed out that, in fact, patients in the combined treatment group received goserelin every four weeks *starting on the first day of irradiation* and continuing for three years.

***Bolla M et al.** Improved survival in patients with locally advanced prostate cancer treated with radiotherapy and goserelin. *N Engl J Med* 1997;337(5):295-300.



Mack Roach III, MD

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Edited comments by Dr Roach

RTOG-9413: Benefits from whole-pelvic radiation therapy and neoadjuvant combined androgen suppression

We conducted a four-arm randomized trial in 1,300 patients, with more than 300 patients in each arm. The eligibility criteria included an estimated risk of lymph node involvement of greater than 15 percent.

Half of the patients received hormone therapy for two months before and two months during radiation therapy, and the other half received hormone therapy for four months after they finished radiation therapy.

Hence, everyone was treated with four months of hormone therapy. Additionally, half of the patients received radiation therapy to the pelvic region, including the lymph nodes, while the other half only received radiation therapy to the prostate. The group that received hormone therapy two months before and two months during whole-pelvic radiation therapy had the best outcome.

Phase III Randomized Trial Comparing Whole-Pelvic Versus Prostate-Only Radiotherapy and Neoadjuvant Versus Adjuvant Combined Androgen Suppression. Closed Protocol

Protocol ID: RTOG-9413
Actual Accrual: 1,323 patients

Eligibility: Localized prostate cancer with a ≥15% estimated risk of lymph node involvement

ARM 1: Whole-pelvic radiation therapy + neoadjuvant and concurrent hormone therapy
ARM 2: Prostate-only radiation therapy + neoadjuvant and concurrent hormone therapy
ARM 3: Whole-pelvic radiation therapy + adjuvant hormone therapy
ARM 4: Prostate-only radiation therapy + adjuvant hormone therapy

SOURCE: Roach III M et al. **Phase III trial comparing whole-pelvic versus prostate-only radiotherapy and neoadjuvant versus adjuvant combined androgen suppression: Radiation Therapy Oncology Group 9413.** *J Clin Oncol* 2003;21:1904-11. Abstract

RTOG 9413: Phase III Randomized Trial Comparing Whole-Pelvic Versus Prostate-Only Radiotherapy and Neoadjuvant Versus Adjuvant Combined Androgen Suppression

Treatment arm	N	Four-year progression-free survival	Four-year biochemical failure
Whole-pelvic radiation therapy + neoadjuvant and concurrent hormone therapy	319	59.6%	30.3%
Prostate-only radiation therapy + neoadjuvant and concurrent hormone therapy	316	44.3%	42.8%
Whole-pelvic radiation therapy + adjuvant hormone therapy	322	48.9%	36.7%
Prostate-only radiation therapy + adjuvant hormone therapy	322	49.8%	36.5%
P value		0.008	0.048

Roach III M et al. **Phase III trial comparing whole-pelvic versus prostate-only radiotherapy and neoadjuvant versus adjuvant combined androgen suppression: Radiation Therapy Oncology Group 9413.** *J Clin Oncol* 2003;21:1904-11. **Abstract**

Clinical implications of RTOG-9413

The clinical implications of RTOG-9413 are huge. These results explain why trials of radical prostatectomy plus hormone therapy were negative, while the radiation therapy studies were positive. If one is going to give patients hormone therapy with radiation, they should give it before and during radiation therapy.

There are three different groups of patients — those who don't need hormone therapy, those who need therapy to improve local-regional control and those who need long-term hormone therapy to suppress microscopic disease. In a patient with intermediate risk, the purpose of hormone therapy is to help control the lymph nodes.

Synergy between hormone therapy and radiation therapy

There aren't any preclinical or biologic clues about which type of hormonal therapy might be most synergistic with radiation therapy. In RTOG-9413, we used a combined approach with an LHRH and an antiandrogen. Another question that has not been studied is: What about an LHRH or an antiandrogen alone? We have a trial (RTOG-9601) in postoperative patients randomized to bicalutamide monotherapy with radiation therapy or radiation therapy alone. The question becomes: What if we had given bicalutamide before the radiation therapy, and what if we had treated the lymph nodes? If RTOG-9601 has negative results, we still won't know the answers to these questions.

Phase III Randomized Study of Radiotherapy with or without Bicalutamide in Patients with PSA Elevation following Radical Prostatectomy for Carcinoma of the Prostate **Closed Protocol**

Protocol IDs: RTOG-9601, SWOG-R9601, CTSU, RTOG-R9601
Projected Accrual: 810 patients

Eligibility: Stage T3 N0 or pT2 pN0 with positive inked margin, postradical prostatectomy and pelvic lymphadenectomy for prostate cancer with PSA 0.2-4.0 ng/mL at study entry

Arm 1: Radiotherapy + (bicalutamide x 2 yrs)
Arm 2: Radiotherapy + (placebo x 2 yrs)

Recommended treatment for increasing PSA and bone metastases consists of maximal androgen blockage. Patients are followed every 3 months for 2 years, every 6 months for 3 years and annually thereafter.

SOURCE: NCI Physician Data Query, July 2003.

Case Study: 42-year-old man with Gleason 3+4, T3c prostate cancer

History

In 1997, this man had a PSA of 29.2 ng/mL and was diagnosed with Gleason 3+3, T2b prostate cancer. He was potent and otherwise healthy with the exception of hepatitis B. A digital rectal exam revealed a bulky lesion, mid-gland to the base.

I reviewed his pathology report, and his cancer was upgraded to a Gleason 3+4. An MRI demonstrated a large volume lesion with extension to the right seminal vesicle. Using the 1992 staging system, his tumor was staged as a T3c lesion. He underwent a lymph node dissection, which was negative.

The patient decided he didn't want surgery, and I supported his decision. This was in 1997, so I recommended hormone therapy and radiation therapy.

We treated him with neoadjuvant hormone therapy for two months before and two months during radiation therapy. He also received 3D-conformal radiation therapy (7,700 cGy) followed by two years of the adjuvant hormonal therapy, both were well-tolerated. During the time he was on hormone therapy, his PSA was undetectable.

He finished his hormone therapy in 2000. His PSA in February 2000 was 0.2 ng/mL, and in May 2000 it was 0.9 ng/mL. We repeated his PSA in June of 2000, and it was 1.0 ng/mL. The endorectal MRI and MRS indicated possible abnormal voxels. In July of 2000, he had an eight-core biopsy, which only revealed radiation effects.

Following the biopsy, his PSAs have remained stable. It's been nearly three years since the elevated PSA of 0.9 ng/mL. In March 2002 and March 2003, his PSA was 0.7 ng/mL, and a repeat MRI in July 2002 was negative. It has been six years since he began therapy, and the patient is potent, continent and very happy.

Discussion

This patient was believed to have a T2b lesion, but I was very concerned that he really had a T3 lesion. It didn't appear to be a transition zone tumor, which is one of the things I would have considered. There are patients with very high PSAs who have transition zone tumors, and their disease is confined — I would consider that type of patient, an ideal candidate for a radical prostatectomy.

Some urologists probably would not have done an MRI and would have done a radical prostatectomy. After the MRI, some urologists would still have prefered a radical prostatectomy. They would cite the data from the Mayo Clinic or the Messing study indicating that they could give adjuvant hormone therapy for node-positive disease. However, if there were a type of patient in which urologists would favor hormone therapy and radiation therapy, this would be the typical patient, because this is consistent with the Bolla study.

Based on the RTOG meta-analysis, we concluded that patients with Gleason 7, T3 prostate cancer require long-term hormone therapy to have the best chance of surviving prostate cancer. This is consistent with the results from the Bolla study and a newer study, RTOG-9202.

According to the RTOG meta-analysis, the eight-year disease-specific survival in patients treated this way, but with a lower radiation dose, was 88 percent. Because we were giving this man a higher dose of radiotherapy and 3D-conformal radiation therapy, our results would be better. I would have estimated his eight-year survival to be over 88 percent and his ten-year survival to be closer to 90 percent.

We just published a study in *Urology* demonstrating that patients with pretreatment PSAs greater than 20 ng/mL have a higher overall mortality from prostate cancer. However, in that study, all patients were treated with just radiotherapy. In the RTOG meta-analysis, we did not see a relationship between the pretreatment PSA and death due to prostate cancer in patients treated with radiation therapy and hormone therapy. Therefore, hormone therapy will alter the natural history of prostate cancer.

I have other patients, similar to this man, who have also done well. I think the use of hormone therapy and radiation therapy is partially responsible for the decline in prostate cancer mortality in the United States. I believe that the decline in mortality is a reflection of the diagnosis and the appropriate aggressive management of patients with high-risk disease who would have almost been guaranteed to fail with the conventional therapy of lower-dose radiation alone.

This man would have had a greater than 75 percent chance of recurrence within five years if he had been treated with low-dose radiation therapy alone. Now, six years from initial diagnosis, his PSA and MRI spectroscopy look great and he's potent.

Eight-Year, Disease-Specific Survival from a Meta-Analysis of Five Phase III RTOG Prostate Cancer Trials

Risk group	Radiation therapy alone	Radiation plus hormone therapy	*P* value
T3Nx, GS = 7; or N+, GS = 7, or T1-2Nx, GS = 8-10	70%	88%	0.004
T3Nx, GS = 8-10, or N+, GS = 8-10	42%	69%	0.001

Roach III M et al. **Predicting long-term survival, and the need for hormonal therapy: A meta-analysis of RTOG prostate cancer trials.** *Int J Radiat Oncol Biol Phys* 2000;47(3):617-27. **Abstract**

Today this patient would have been a candidate for RTOG-9902, comparing long-term hormone therapy and radiation therapy with or without paclitaxel, estramustine phosphate and etoposide. If we were going to use implants in such a patient, we would probably favor high-dose-rate brachytherapy because of the flexibility of getting needles outside the prostate.

Select publications

Publications discussed by Dr Roach

Bolla M et al. **Long-term results with immediate androgen suppression and external irradiation in patients with locally advanced prostate cancer (an EORTC study): A phase III randomised trial.** *Lancet* 2002;360(9327):103-6. **Abstract**

Hanks GE et al. **RTOG protocol 92-02: A phase III trial of the use of long term total androgen suppression following neoadjuvant hormonal cytoreduction and radiotherapy in locally advanced carcinoma of the prostate.** *Int J Radiat Oncol Biol Phys* 2000;48(3 Suppl A-4):112. **Abstract**

Lerner SE et al. **Analysis of risk factors for progression in patients with pathologically confined prostate cancers after radical retropubic prostatectomy.** *J Urol* 1996 Jul;156(1):137-43. **Abstract**

Messing EM et al. **Immediate hormonal therapy compared with observation after radical prostatectomy and pelvic lymphadenectomy in men with node-positive prostate cancer.** *N Engl J Med* 1999;341(24):1781-8. **Abstract**

Noguchi M et al. **An analysis of 148 consecutive transition zone cancers: Clinical and histological characteristics.** *J Urol* 2000;163(6):1751-5. **Abstract**

Pound CR et a. **Natural history of progression after PSA elevation following radical prostatectomy.** *JAMA* 1999;281(17):1591-7. **Abstract**

Roach III M et al. **Phase III trial comparing whole-pelvic versus prostate-only radiotherapy and neoadjuvant versus adjuvant combined androgen suppression: Radiation Therapy Oncology Group 9413.** *J Clin Oncol* 2003;21:1904-11. **Abstract**

Roach III M et al. **Predicting long-term survival, and the need for hormonal therapy: A meta-analysis of RTOG prostate cancer trials.** *Int J Radiat Oncol Biol Phys* 2000;47(3):617-27. **Abstract**

Roach III M et al. **Serum prostate-specific antigen and survival after external beam radiotherapy for carcinoma of the prostate.** *Urology* 2003;61(4):730-5. **Abstract**

Shariat SF et al. **Detection of clinically significant, occult prostate cancer metastases in lymph nodes using a splice variant-specific RT-PCR assay for human glandular kallikrein.** *J Clin Oncol* 21:1223-31. **Abstract**

Robert Dreicer, MD, FACP

Director, Genitourinary Medical Oncology

Associate Director, Experimental Therapeutics
Taussig Cancer Center

Cleveland Clinic Foundation

Edited comments by Dr Dreicer

Case study: Biochemical recurrence postprostatectomy

History

This patient had a screening PSA of 4.5 ng/mL when he was in his mid-50s, and he was referred to a urologist who diagnosed clinical T1c, Gleason 3+4 prostate cancer. When he underwent radical prostatectomy, he was found to have pathologically organ-confined disease. He did well for a couple of years. About one year ago, he had evidence of biochemical failure and a PSA of 0.2 ng/mL. A month later, a repeat PSA was 0.3 ng/mL.

Follow-up

The patient's postsurgical sexual functioning was normal; occasionally he used sildenafil. Ultimately, he opted to go to another institution for a second opinion, where he was started on 50 mg of bicalutamide as monotherapy. There was some decrease in erectile function associated with the bicalutamide; he used a little more sildenafil and was able to function. He also had some gynecomastia, which was uncomfortable. Other than that, he was a bit more fatigued, but he wasn't sure whether the fatigue was related to the therapy or the anxiety associated with the relapse.

He responded to bicalutamide 50 mg for a few months, but then his PSA began to rise. He was referred back to me, and we discontinued the bicalutamide hoping that he might manifest an antiandrogen withdrawal response.

Six weeks later, we repeated his PSA and it was rising. Because of his exposure to bicalutamide, he was not a candidate for our available clinical trials. We were left with the options of hormonal therapy with an LHRH agonist or expectant management. His PSA doubling time was now about four months. Ultimately, he decided to initiate LHRH therapy. Despite making three appointments to receive his LHRH, he has not yet shown up.

Case discussion

This patient's postprostatectomy risk of biochemical recurrence was probably about 30 percent. There is emerging evidence that a Gleason 3+4 lesion is a different entity than a Gleason 4+3 cancer. The newer Partin tables are beginning to take that into account. If he had a Gleason 4+3 cancer, I suspect his risk of biochemical recurrence would have been five or ten percent higher.

When he initially came to see me, we discussed the natural history of the disease and reviewed the Pound data from Hopkins about time to failure and death. We also talked about therapeutic options. At the time, we were between studies and didn't have an open clinical trial.

I reviewed the controversies over early versus delayed hormonal therapy, and we discussed the role of salvage radiation therapy. I recommended radiation therapy, even though it had been about a year and a half since his surgery. It was still reasonable to consider radiation therapy in this setting, but the patient opted not to pursue this therapy. He obtained a second opinion and was again counseled to consider radiation therapy.

I told him if he was not going to have radiation therapy, the issue of early versus delayed hormonal therapy was controversial, and my standard practice was not to utilize early hormonal therapy. If his PSA doubling time were to shorten, I would certainly consider early hormonal therapy for him; however, I would have discussed primary therapy with an LHRH as a more favorable option. The physician from whom he obtained a second opinion offered similar information, but that individual was more willing to use alternative forms of hormonal therapy, and the patient was started on bicalutamide 50 mg.

Because I care for a large number of patients on hormonal therapy, I look at the debate over early versus delayed hormonal therapy with great respect for the side-effect profile of androgen deprivation. I discuss the litany of major side effects that a subset of patients will complain about, including cognitive dysfunction, weight gain, fatigue, sexual dysfunction, hot flashes and osteoporosis.

Early versus delayed hormonal therapy in patients with biochemical relapse

The debate over early versus delayed hormonal therapy comes down to perspective. No advocate on either side of the argument can point to the literature with absolute certainty. It's difficult to apply the information in the literature to a subset of patients with a different stage of disease.

Additionally, the therapy has very significant ramifications for the patients; these are not benign therapies. I tend to approach medicine as a therapeutic nihilist. I cannot, in good conscience, recommend a therapy that may cause significant quality-of-life alterations, in the absence of definitive evidence that it will prolong life expectancy.

No study of hormonal therapy has been completed in patients with biochemical relapse. We are extrapolating the findings from the Bolla, ECOG and MRC trials, which included patients with locally advanced or metastatic disease. That may ultimately be a rational thing to do, but in medicine, we have learned that it doesn't always turn out the way we think it will.

It is not absolutely clear whether we change clinical progression with early hormonal therapy. There are multiple criticisms of the MRC trial, including Pat Walsh's criticism that the hormonal therapy administration in the delayed group of the MRC trial has no correlation to the practice in the United States. These patients were not treated until they had overt, clinical evidence of metastatic disease and in some cases, not even then.

Clearly, in the United States, hormonal therapy is not delayed until patients have extremely advanced disease. If you opt to follow a patient with early biochemical failure expectantly, you must watch them carefully.

If their PSA doubling time goes from 14 months to four months, they are more likely to be treated at that juncture than to wait until they have spinal cord compression. Hence, early versus delayed is a continuum.

Ongoing adjuvant chemotherapy trials

All of us understand that there are subsets of patients who are at risk and that we need to address systemic failure. Several ongoing trials, including an Intergroup adjuvant trial, the SWOG trial and an industry-sponsored Phase II trial, are evaluating adjuvant chemotherapy.

Some of the adjuvant trials have hormonal therapy as the control arm. The SWOG trial has two treatment arms. We wanted to compare adjuvant therapy to no treatment, but we also recognized that doing trials like that in the United States is not practical in this era. Therefore, patients are randomized to two years of combined androgen ablation with or without six cycles of mitoxantrone and prednisone.

Unfortunately, that trial is having difficulty accruing patients, in part because the protocol was designed to evaluate the best chemotherapy regimen at that time. Most medical oncologists feel that it's not as active as some other therapies now available.

Another trial currently being conducted at selected sites around the country is evaluating single-agent docetaxel in patients with a 50 percent risk of failure at three years. The trial has been accruing relatively well at six or seven sites.

Phase III Randomized Study of Adjuvant Androgen Deprivation Therapy with or without Mitoxantrone and Prednisone After Radical Prostatectomy in Patients with High-Risk Adenocarcinoma of the Prostate **Open Protocol**

Protocol IDs: SWOG-S9921, CLB-99904, CTSU

Projected Accrual: 1,360 patients

Eligibility: Clinical T1-T2 prostate cancer treated by radical prostatectomy and at least one of the following pathologic criteria: Gleason sum ≥8; pT3b (seminal vesicle) or pT4 or N1; Gleason sum of 7 and positive margin; preoperative PSA > 15 ng/mL or biopsy Gleason score > 7, or PSA > 10 ng/mL and biopsy Gleason score > 6.

ARM 1: [Goserelin + bicalutamide] x 2 years

ARM 2: ([Goserelin + bicalutamide] x 2 years) + ([mitoxantrone + prednisone] every 3 weeks x 6)

Patients are followed every 6 months for 2 years and then annually for up to 13 years.

Study Contacts:

Southwest Oncology Group
Michael Glode, MD
Protocol Chair
Tel: 303-315-4757, 800-473-2288

Cancer and Leukemia Group B
Nancy Ann Dawson, MD
Protocol Chair
Tel: 410-328-2565

SOURCE: NCI Physician Data Query, July 2003.

Phase II Study of Adjuvant Docetaxel in Patients with Adenocarcinoma of the Prostate at High Risk of Relapse After Prostatectomy **Open Protocol**

Protocol IDs: RPCI-DS-0212, AVENTIS-XRP6976J/2501

Projected Accrual: 75 patients

Eligibility: M0 prostate cancer, treated by radical prostatectomy, with a high risk of disease progression (weighted risk of recurrence greater than 2.84)

ARM 1: Docetaxel on days 1, 8 and 15 every 28 days x 6

Patients are followed every 3 months for 3 years.

Study Contact:

Roswell Park Cancer Institute
Donald L Trump, MD
Protocol Chair
Tel: 716-845-3499, 800-767-9355

SOURCE: NCI Physician Data Query, July 2003.

Adjuvant androgen deprivation in patients with positive nodes

The Eastern Cooperative Oncology Group (ECOG) trial demonstrated a survival advantage for adjuvant androgen deprivation and an unpublished, ongoing European trial, using a similar trial design has not yet been reported. One can argue about the results of the ECOG trial, but it was a Phase III trial. I believe a patient with positive nodes represents a somewhat different dynamic on the continuum than a patient who is three years postprostatectomy, and has

biochemical failure. Over the last two years, approximately one-half of my patients with positive nodes have opted to initiate adjuvant hormonal therapy.

Case study: 74-year-old man with spinal cord compression

History

This man had a radical prostatectomy for a Gleason 7 tumor at another institution about three years prior to his presentation. His PSA was undetectable after surgery, and he had not obtained any follow-up for approximately 18 months.

He presented with severe back pain and had a T8 cord compression on MRI. He was hospitalized, started on steroids and underwent radiation therapy. After the radiation therapy, a bone scan showed only one metastatic site, and his PSA was about 300 ng/mL. He was started on hormonal therapy and his PSA declined.

Follow-up and discussion

It is uncommon, but not rare, for metastatic disease to present so quickly after a successful prostatectomy. In retrospect, the patient probably had a Stage C, Gleason 7 tumor.

He received hormonal therapy over the next 18 months, and then developed a second spinal cord compression. He also developed nodal and pulmonary metastases. At that juncture, he received radiation therapy again for the second spinal cord lesion. He did remarkably well in terms of function, however, he required opiates to control pain and he lost 25 pounds.

He enrolled in a clinical trial evaluating docetaxel and an investigational agent, PS-341 (Velcade™ [bortezomib]) and he had a very dramatic response. Bortezomib is the first in a novel class of agents called proteasome inhibitors. This patient was part of an investigational trial that was based on evidence that bortezomib has single-agent activity. Bortezomib is in development and the trial is ongoing.

This patient responded clinically after about three weeks. His appetite improved and his pain and opiate requirements decreased. He was receiving an active chemotherapy drug, and I don't know whether the investigational drug added anything. This is the kind of response that a subset of patients with symptomatic advanced prostate cancer receives from chemotherapy.

He had a window of three and a half to four months in which his quality of life dramatically improved, and he actually became opioid-free with only mild discomfort in the site of the original cord compression. Unfortunately, his disease progressed and he faired poorly. I did not treat him with systemic agents again. His performance status declined, and I converted our approach to a supportive care mode — opiates, additional radiation therapy and hospice. He passed away a short time ago.

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Leslie R Schover, PhD

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Edited comments by Dr Schover

Problems with studies of erectile dysfunction after local therapy for prostate cancer

I believe that the literature sells these men a "false bill of goods." They receive overestimates of the likelihood of recovering erectile function after prostate cancer treatment — whether it's surgery or radiation therapy.

Part of the problem with the literature is the way erectile function had been measured. Many of the published studies were conducted at academic medical centers where relatively healthy men with early stage disease often seek out a particular physician. These men are less likely to have erectile dysfunction before their prostate cancer and may be more likely to recover no matter what they do.

Secondly, in some of these studies, recovery was defined by the ability to have intercourse after treatment, and we know that most men can have intercourse occasionally or without a very rigid erection, but they are not satisfied with their level of recovery. Many men in that category were classified as recovered, while they were likely to be using treatments for their erectile dysfunction.

Another problem with the literature is that partners are often not included in the assessments, and I believe this is an important factor in recovery. The literature suggests that most men do not continue treatment because it is a hassle, they don't know how to troubleshoot when it stops working or their partner doesn't like it. Ultimately, only about one-third of the men being treated are satisfied and continue to use the treatment long-term.

Sexual outcomes after treatment for localized prostate cancer

In our study, erectile function was assessed for the month prior to the survey, so we were able to assess not just whether a man had intercourse once since the treatment, but whether he had intercourse during the last month. We also evaluated whether he was consistently able to have an erection when he wanted to and to maintain it for satisfying intercourse.

The most salient finding was that the rates of recovery for erectile function were much lower than had been previously reported. At least 75 percent of men did not have satisfying erections after their prostate cancer treatment. No group had more than a 20 percent rate of recovery of functional erections.

Bilateral nerve-sparing prostatectomy yielded better recovery rates than unilateral or non-nerve-sparing prostatectomy. In the radiation therapy group, men treated with brachytherapy had better recovery rates, followed by those treated with conformal-3D or intensity-modulated radiation therapy. Men treated with standard external beam radiation had the worst results in this group.

Influence of age on recovery of sexual function

We found that men under the age of 62 had the best chance for recovery of totally normal sexual function. A man in his mid-50s, with normal sexual function and libido prior to treatment, would have a one in three chance of recovering good erectile function after a bilateral nerve-sparing prostatectomy. He would probably have another 20 percent chance of achieving good erectile function with medical interventions. The chances of recovery with brachytherapy in a younger man are similar to those with bilateral, nerve-sparing prostatectomy, and the chances are less with radiation therapy.

Percentage of men with erectile dysfunction after local therapy for prostate cancer and benefit of medical therapy for erectile dysfunction

	Men with ED after local therapy (n=939)	Men achieving erectile function after medical treatment for ED (n=89)
Bilateral Nerve-Sparing RP (n=240)	82%	15%
Unilateral Nerve-Sparing RP (n=90)	87%	6%
Non-Nerve-Sparing RP (n=239)	95%	6%
Brachytherapy (n=138)	81%	7%
Conformal or Intensity-Modulated RT (n=231)	85%	6%
External Beam RT (n=143)	93%	6%
Overall (n=1,081)	**87%**	**8%**

ED = erectile dysfunction; RP = radical prostatectomy; RT = radiation therapy

"Only 13% of men reported recovering or retaining functional erections after treatment, and another 8% of men achieved a normal level of sexual function by using medical treatments for ED."

SOURCE: Schover LR et al. **Defining sexual outcomes after treatment for localized prostate carcinoma.** *Cancer* 2002;95(8):1773-85. **Abstract**

Sexual function after prostatectomy versus radiation therapy

After radical prostatectomy, sexual function is as bad as it's going to get and often improves over the next one to two years. Radiation therapy has the

opposite effect. Often, men still have good erectile function right after radiation therapy, but over the next one to three years, sexual function gradually deteriorates.

Most prior studies demonstrating that radiation therapy has less of an effect on sexual function than surgery, have had a very short follow-up — one or two years. The average length of follow up in our study was four and one-half years, which provides a more fair comparison. I think our follow-up is long enough to show that there is no "free lunch" when it comes to prostate cancer treatment. A man can have surgery and have immediate dysfunction or he can have radiation therapy and end up with just as many problems — it just takes longer to develop.

Rates of seeking treatment for erectile dysfunction among prostate cancer survivors

The National Health and Social Life Survey published in *JAMA* a few years ago found that only 10 percent of men with sexual problems ever seek professional help. I wondered how this pattern compared to patients treated for prostate cancer.

When we analyzed the data from our survey, many more men sought help than we originally expected. We found that seeking medical treatment for erectile dysfunction was more of a process than an event. Many of these men sought help more than once, and the men who ended up with a successful outcome had tried, on average, at least two treatments.

Types of treatment for erectile dysfunction

Men in our study preferred noninvasive treatments. While more than one-half of men who attempted treatment had tried sildenafil, only a small fraction reported that it greatly improved their sex lives and were still using it. Unfortunately, this agent doesn't work very well after prostate cancer treatment.

Sildenafil provided some extra firmness for men who could achieve partial erections that were almost firm enough for intercourse; therefore, it tended to work best for men who had bilateral, nerve-sparing prostatectomy or brachytherapy.

We found that the more invasive methods were more effective, but fewer men used them. With regard to penile injection, many couples find that the pain, eventual complications like penile fibrosis, and the lack of spontaneity with injection therapy are difficult to deal with. The couples who do well with the vacuum device tend to be older (in their late 60s or 70s), have been married for a long time, don't expect perfection in their sex life and are willing to deal with the hassle.

I think the penile prosthesis is underutilized. In general, urologists guide men away from the prosthesis because it's irreversible. First, they try sildenafil injections and then a vacuum device. While this is a reasonable approach, many

couples become so fatigued and frustrated after trying all those things, they don't consider surgical placement of a prosthesis. It's also difficult for the men who have had radical prostatectomy to consider surgery again, however, I think penile prostheses are much more reliable, and the erections are much closer to natural erections. It's a treatment that results in a higher satisfaction rate than anything else.

Treatment options attempted for erectile dysfunction, success rates and treatment adherence in 1,188 men treated for prostate cancer

	Men who tried option	Men who tried option and greatly improved	Men who tried option and are still using the treatment
Sexual Counseling	14%	7%	29%
Sildenafil	52%	16%	39%
Vacuum Device	19%	19%	41%
Intraurethral Prostaglandin	10%	6%	21%
Penile Injections	18%	29%	34%

SOURCE: Schover LR et al. **The use of treatments for erectile dysfunction among survivors of prostate carcinoma.** *Cancer* 2002;95(11):2397-407. **Abstract**

Role of counseling in sexual rehabilitation

While counseling will not restore erections in a man who has organic erectile dysfunction, it enhances sexual communication and helps couples integrate the medical treatments for erectile dysfunction into their sex lives.

Very often, partners are left out of the treatment decision and are apprehensive about how these treatments will affect their partner's health — I see this quite often with older couples. This can result in the patient's partner being unresponsive when they try to initiate sex because they are afraid it will be harmful to their partner's health. Therefore, it's very important that the partner is included in the decision and understands the treatments available.

At each follow-up visit, couples should be asked: What's going on with your sexual activity? Are you still showing affection to each other? Have you tried any sexual touching?

Even without an erection, with the right kind of penile caressing, men may experience an orgasm; however, it will be a dry orgasm. We focus so much on the erection that we forget to reassure couples about things like sexual desire and the ability to reach orgasm. Men and women need to understand that erections, interest in sex and penile sensation are all very separate parts of the sexual response.

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Post-test: Prostate Cancer Update, Issue 4, 2003

Conversations with Urologic Oncology Leaders

Bridging the Gap between Research and Patient Care

QUESTIONS (PLEASE CIRCLE ANSWER):

1. In RTOG-9413, which of the following treatment regimens was superior?
   a. Whole-pelvic radiation therapy + neoadjuvant and concurrent hormone therapy
   b. Prostate-only radiation therapy + neoadjuvant and concurrent hormone therapy
   c. Whole-pelvic radiation therapy + adjuvant hormone therapy
   d. Prostate-only radiation therapy + adjuvant hormone therapy

2. Which hormone therapy regimen was evaluated in RTOG-9413?
   a. LHRH + antiandrogen
   b. LHRH alone
   c. Antiandrogen alone

3. According to the RTOG meta-analysis of prostate cancer trials, patients with Gleason 7 or higher, T3 prostate cancer require long-term hormone therapy to have the best prostate cancer survival.
   a. True
   b. False

4. There is emerging evidence that a Gleason 3+4 tumor has a worse prognosis than a Gleason 4+3 tumor.
   a. True
   b. False

5. Velcade™ (bortezomib) is the first in a novel class of agents called proteasome inhibitors.
   a. True
   b. False

6. Ongoing adjuvant trials in men with prostate cancer are evaluating which of the following chemotherapy agents?
   a. Mitoxantrone
   b. Docetaxel
   c. Both of the above
   d. None of the above

7. A Phase III ECOG trial demonstrated a survival advantage for adjuvant androgen deprivation in patients with positive nodes.
   a. True
   b. False

8. The majority of men have satisfying erections after receiving treatment for localized prostate cancer.
   a. True
   b. False

9. In Dr Schover's study, men who received external beam radiation therapy had lower rates of sexual recovery than those who underwent either bilateral nerve-sparing prostatectomy or brachytherapy.
   a. True
   b. False

10. According to Dr Schover, which treatment for erectile dysfunction is underutilized in patients with prostate cancer?
    a. Sildenafil
    b. Penile prosthesis
    c. Penile injections
    d. Vacuum devices

Answer key: 1a, 2a, 3a, 4b, 5a, 6c, 7a, 8b, 9a, 10b

Evaluation Form: Prostate Cancer Update, Issue 4, 2003

NL Communications respects and appreciates your opinions. To assist us in evaluating the effectiveness of this activity and to make recommendations for future educational offerings, please complete this evaluation form. A certificate of completion is issued upon receipt of your completed evaluation form.

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5 = *Outstanding* 4 = *Good* 3 = *Satisfactory* 2 = *Fair* 1 = *Poor*

GLOBAL LEARNING OBJECTIVES

Upon completion of this activity, participants should be able to:

- Critically evaluate the clinical implications of emerging clinical trial data in prostate cancer treatment 5 4 3 2 1
- Inform patients about the specific risks and benefits of local and systemic therapies 5 4 3 2 1
- Provide individualized counseling to patients regarding the choice and timing of endocrine therapy 5 4 3 2 1
- Offer patients information regarding their prognosis with and without various therapeutic options 5 4 3 2 1

SPECIFIC LEARNING OBJECTIVES FOR ISSUE 4

Upon completion of this activity, participants should be able to:

- Counsel prostate cancer patients about the results of RTOG-9413 trial of whole-pelvic radiation therapy and neoadjuvant combined androgen suppression 5 4 3 2 1
- Define the risk subsets for patients who are candidates for long-term hormone therapy after initial therapy with radiation 5 4 3 2 1
- Review clinical trial data and research leaders' perspectives about early versus delayed hormonal therapy in order to counsel patients with postprostatectomy biochemical failure 5 4 3 2 1
- Describe ongoing clinical trials evaluating adjuvant chemotherapy in order to counsel patients with high-risk prostate cancer about participation 5 4 3 2 1
- Counsel patients about the sexual outcomes associated with the various treatment alternatives for localized prostate cancer and the success and treatment adherence rates for the therapeutic options for erectile dysfunction 5 4 3 2 1

EFFECTIVENESS OF THE INDIVIDUAL FACULTY MEMBERS

Faculty	Knowledge of Subject Matter	Effectiveness as an Educator
Mack Roach III, MD	5 4 3 2 1	5 4 3 2 1
Robert Dreicer, MD, FACP	5 4 3 2 1	5 4 3 2 1
Leslie R Schover, PhD	5 4 3 2 1	5 4 3 2 1

OVERALL EFFECTIVENESS OF THE ACTIVITY

Objectives were related to overall purpose/goal(s) of activity 5 4 3 2 1
Related to my practice needs 5 4 3 2 1
Will influence how I practice 5 4 3 2 1
Will help me improve patient care 5 4 3 2 1
Stimulated my intellectual curiosity 5 4 3 2 1
Overall quality of material 5 4 3 2 1
Overall, the activity met my expectations 5 4 3 2 1
Avoided commercial bias or influence 5 4 3 2 1

Evaluation Form: Prostate Cancer Update, Issue 4, 2003

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What other faculty would you like to hear interviewed in future educational programs?

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Degree:

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To obtain a certificate of completion and receive credit for this activity, please complete the post-test, fill out the evaluation form and mail or fax both to: NL Communications Inc, 400 SE Second Avenue, Suite 401, Miami, FL 33131-2117, FAX 305-377-9998. You may also complete the Post-test and Evaluation online at www.ProstateCancerUpdate.net.