

A Report to Physicians OncoLog



The University of Texas M. D. Anderson Hospital and Tumor Institute at Houston • October-December 1985 • Volume 30, Number 4

Endocrine Therapy for Prostatic Cancer Can Replace Orchiectomy and Estrogens

By treating patients who have advanced prostate cancer with a drug that changes endocrine function, physicians in the UT MDAH Department of Urology have produced remissions and promoted well-being in patients who have traditionally had to face the radical side effects of surgical castration and estrogen therapy.

Since January 1983, Andrew C. von Eschenbach, M.D., department chairman, has led a study of the use of buserelin, a luteinizing hormone-releasing hormone (LHRH) agonist, in 22 men between the ages of 59 and 80. All had stage D prostate cancer that had metastasized.

Tests to establish tumor stage and identify metastasis included biopsy, hematologic and biochemical blood assays, urinalysis, radionuclide bone scan, bone radiographs, and lymphangiography or computed tomography (CT) scan, or both. The patients' general physical condition and endocrine function were evaluated at the beginning and during therapy. Clinical monitoring in collaboration with Naguib A. Samaan, M.D., Department of Endocrinology, and Herbert A. Fritsche, Ph.D., Department of Laboratory Medicine, continues for patients who are still taking buserelin, although entry into the formal study period has ended.

Buserelin has not yet been approved by the Food and Drug Administration for general clinical use, but a similar drug, luprolide (Lupron), is now on the market after being tested at other research centers. It is prescribed by MDAH physicians for some patients with prostate cancer who are not in the buserelin study.

During the first week of therapy, the patients received 1,500 µg of buserelin daily, administered subcutaneously in three doses of 500 µg each, after which the daily dose has been 200 µg.

In a recent interview, von Eschenbach described the results of the study. "Buserelin treatment resulted in a favorable response in all 22 patients," he said. "Nineteen patients had bone scans that were considered positive for metastatic disease, and 13 of these patients demonstrated improvement. Thirteen patients had lymph node metastases, which regressed in eight patients. Among 17 patients who showed abnormal prostatic acid phosphatase (PAP) secretion, 15 patients improved, and in 12 of these the PAP levels returned to normal."

Today, nine patients are still in the study. The others suffered relapses and are being treated with chemotherapy. Six patients have died, including two who died from causes other than prostate cancer.

Endocrine therapy, von Eschenbach said, is not curative, nor is any other therapy so far attempted for patients in advanced stages of the disease. But endocrine therapy promotes remissions. It usually alleviates the severe pain of disseminated prostatic cancer in the bones and may relieve problems of urination caused by urethral obstruction, thus improving the patients' performance status and emotional well-being.

The major advantage of this kind of endocrine therapy, von Eschenbach said, is that buserelin and similar drugs have made orchiectomy and estrogen therapy—which caused gynecomastia in most patients—no longer obligatory. The problems of loss of libido and impotence remain, because all endocrine treatments for prostate cancer exert their effects by withdrawing testosterone from these hormone-sensitive tumors (Fig. 1).

Most Prevalent Cancer in Men

The buserelin results have an importance beyond their numbers, von Eschenbach explained, because cancer of the prostate is an example of the diagnostic and treatment problems clinicians face in dealing with many other forms of neoplasia.

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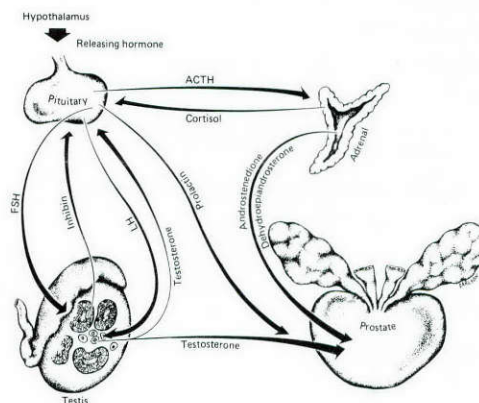


Fig. 1. Mechanisms of endocrine regulation. The prostate is directly affected by androgens produced principally by the testis. These various regulatory mechanisms provide numerous options for endocrine control strategies. ACTH, adrenocorticotrophic hormone; FSH, follicle-stimulating hormone; LH, luteinizing hormone. (Reproduced with permission from Smith, D. R.: *General Urology*, 11th Ed. Copyright 1984 by Lange Medical Publications, Los Altos, CA.)

Endocrine Therapy. . .

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Although it is a disease of aging and rarely occurs in men younger than 50, it is one of the most common cancers in men. About 75,000 cases of prostate cancer are expected to be diagnosed annually, and about 24,000 deaths occur yearly as a result of the disease.

Prostate cancers have differing biologic characteristics and malignant potential, ranging from the slow-growing, confined tumor to the type that grows rapidly and quickly develops aggressive metastasis. In the mid-range is the prostatic tumor that grows slowly for years and then suddenly develops sufficient numbers of cell clones to disseminate to the bones and lymphatic system.

The disease was once considered rare because it is so difficult to diagnose. Compared to the number of prostate cancers diagnosed, three to eight times more cases are not found until patients undergo a prostatectomy for benign disease or during autopsy examinations.

A comparable disease is breast cancer in women, but this occurs earlier in life and is perhaps easier to diagnose at earlier stages because of public and medical education about the disease. There are striking similarities between breast and prostate cancer; for example, both are adenocarcinomas for which hormonal treatments are used, von Eschenbach said.

A Report to Physicians **OncoLog**

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Because of the difficulties of diagnosing prostatic carcinoma and the heterogeneity of its expression, von Eschenbach and his colleagues have called for a new look at the incidence, development, diagnosis, therapeutic decisions, and evaluation of results—a new effort of which the buserelin study is a part.

Epidemiologic Factors

Epidemiologic studies have shown, he said, that genetic factors (Fig. 2) may play a role because cancer of the prostate is more common among American black men than white men, and because Oriental peoples in their home countries have a lower incidence of clinically diagnosed disease. The latter finding has also led to the suggestion that a diet low in fat and rich in vitamins A and D may play a part in modulating the incidence and virulence of malignant prostatic disease. Environmental factors may have an influence as well, since some studies have linked work in the rubber, textile, and fertilizer industries to higher rates of prostate cancer.

That hormones have a role is certain, although their exact mechanism of action is not known and the responsible endocrine factors have not been identified. The appearance of prostate cancer after age 50 suggests strongly, however, that development of the cancer is related to changes with age in the male endocrinologic environment, when serum testosterone declines and the ratio of estrogen to testosterone rises. The fact that prostatic carcinoma responds to androgen deprivation supports a direct relationship between the tumor and hormonal change.

Pathologic Features

As von Eschenbach explained, the formation of malignant tissue begins in the stem cells of the acinar prostatic epitheli-

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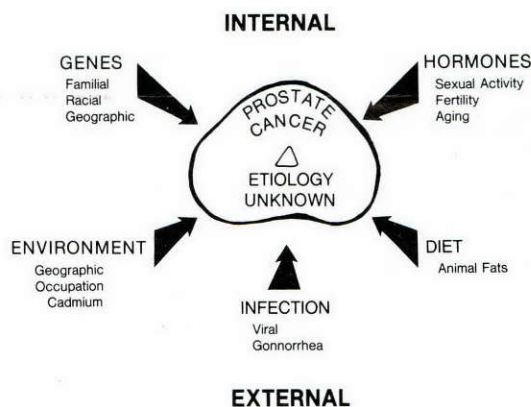
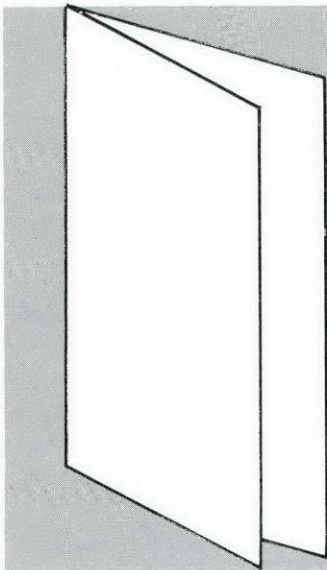


Fig. 2. Epidemiologic influences. Many factors may contribute to the development of cancer of the prostate and affect its biologic behavior. (Reproduced with permission from von Eschenbach, A. C.: Cancer of the prostate, in Hickey, R. C. et al., eds.: *Current Problems in Cancer*. Copyright 1981 by Year Book Medical Publishers, Chicago.)



Clinical Staff Directory

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Referral of Patients

To respond to the needs of referring physicians and their patients, this special section of the *OncoLog* contains a list, by specialty, of staff physicians at The University of Texas M. D. Anderson Hospital and Tumor Institute at Houston.

The list is printed as a pull-out section for the convenience of physicians in Texas and nearby states who may wish to consult a physician at this institute, seek a patient's examination for the purpose of a second opinion, or refer a patient for treatment. For each division or department, the first name listed is that of the head or chairperson, followed by the names of other staff members in alphabetical order. Physicians may call any staff member directly at the number listed (area code 713) for consultation.

"Care for all patients at our hospital begins with a referral from the patient's personal physician and ends with the patient's return to his or her physician's care," said Joseph T. Ainsworth, M.D., vice president for patient care. If a physician is not sure whom to call or has any questions, he or she may call Ainsworth directly at 713-792-7475.

A physician may also arrange a patient's referral by calling the New Patient Referral Office at the toll-free number for Texas, 1-800-392-1611, or from out of state at 713-792-6161. The office is open Monday-Friday from 8 a.m. to 5 p.m.

In addition, a referral may be made by writing the Vice President for Patient Care, M. D. Anderson Hospital and Tumor Institute, Houston, Texas 77030.

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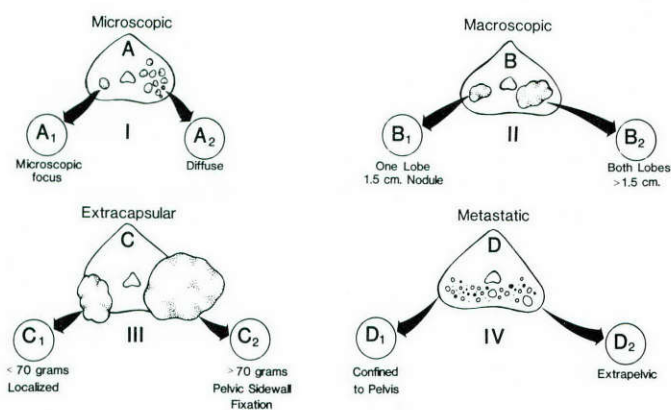


Fig. 3. Staging of prostate cancer. Based on extent of tumor, various modifications in the A, B, C, and D types of prostate cancer have been proposed and are currently in use, but the definition of these subdivisions is not uniform. (Reproduced with permission from von Eschenbach, A. C.: Cancer of the prostate, in Hickey, R. C. et al., eds.: *Current Problems in Cancer*. Copyright 1981 by Year Book Medical Publishers, Chicago.)

continued from page 2

um. The degree of abnormality varies, so that some tumors are difficult to distinguish from normal prostate tissue, except that the glands are small and crowded. In others the cellular structure will be strikingly altered, with the tissue forming a solid pattern in which the glands cannot be distinguished. Since structural differences may occur in parts of the same tumor, the grading of prostate cancer is often difficult and confusing.

Fig. 3 is a graphic interpretation of tumor stages. At this hospital, von Eschenbach explained, *stage* is based on extent of disease, and tumor *grade* is based on percentage of gland formation within the primary tumor.

Clinical Findings

The tumor has few warning signs because it does not progress in predictable fashion from microscopic disease to regional spread to distant metastasis. That is why, in many patients, symptoms of metastasis may occur before the disease is diagnosed in the prostate gland. Benign disease usually causes obstructive voiding symptoms in older men. Prostate cancer, however, originates in the periphery of the gland and impairs micturition only after the tumor has grown quite large. Most patients do not experience pain on ejaculation or have problems of sexual function but, according to von Eschenbach, hematospermia and hematuria, which may accompany benign hypertrophic hyperplasia, may lead to the detection of unsuspected cancer. The presence of these symptoms in patients older than 50 years should always alert physicians to do a careful assessment.

This is true also for elderly men who may complain of persistent bone pain, which may be multifocal or restricted to the

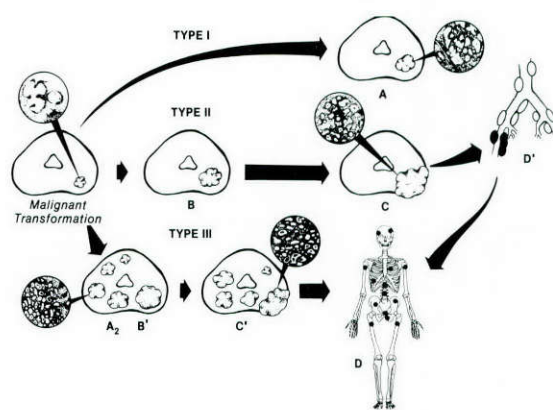


Fig. 4. Trilogy of the clinical manifestations of prostate cancer. (Reproduced with permission from Johnson, D. E., and von Eschenbach, A. C.: Prostatic carcinoma: A trilogy of clinical expressions. *Southern Medical Journal* 73(10):1304, 1980.)

spine or pelvis. A general feeling of illness, fatigue, and weight loss are nonspecific clinical indications of the disease. Fig. 4 represents the clinical manifestations, which von Eschenbach summarized as follows:

- Changes in the size, shape, or consistency of the prostate. A hard discrete nodule in the prostate of a man older than 50 has an about 50% chance of being a malignant tumor.
- Metastases to the bones manifested by areas of tenderness on palpation. Sometimes lymphadenopathy is detected by palpating the inguinal region, the pelvic side wall, or the supraclavicular fossa.

When a patient is suspected of having cancer of the prostate, von Eschenbach recommended these procedures:

- Biopsy of the gland with histologic examination of tissue obtained by needle biopsy of the prostate or, at times, by transurethral resection.
- Laboratory studies including complete blood count and serum biochemical profile. Determination of the serum level of acid phosphatase is most important because of the association of elevated levels of serum acid phosphatase and advanced prostatic cancer.
- Radiologic studies including chest radiography, radiographs of the lower spine and pelvis, and radionuclide bone scan.
- Lymphangiography for patients suspected of having nodal disease.
- CT complementary to lymphangiography. Although CT scans do not show intranodal architecture, they reveal enlarged nodes completely replaced by the tumor. Unfortunately, both CT scans and lymphangiograms tend to understage patients with nodal disease.

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