DIAGNOSTIC ULTRASOUND OF THE PROSTATE

Diagnostic Ultrasound of the Prostate

Proceedings of the First International Workshop on Diagnostic Ultrasound of the Prostate, held October 22 through 23, 1988, in Washington, D.C.

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PREFACE

In July, 1979, an International Workshop on Diagnostic Ultrasound in Urology and Nephrology was held in Kyoto, Japan. Recognized investigators from over ten countries contributed to this very successful and informative meeting, the proceedings of which were published in 1981 in a monograph entitled, "Diagnostic Ultrasound in Urology and Nephrology" and edited by Hiroki Watanabe, Joseph H. Holms, Hans H. Holm and Berry B. Goldberg. Technical and clinical aspects of the field have continued to evolve over the past eight years and because of the rapid changes related to the clinical applications of ultrasonography, and particularly prostatic ultrasonography, it was believed that a meeting devoted specifically to this latter topic would be timely and of great value.

The First International Workshop on Diagnostic Ultrasound of the Prostate was held on October 22-23, 1988, and the organizers coordinated the meeting with the 1988 World Federation for Ultrasound in Medicine and Biology which met the week before in Washington, DC. Participants of the workshop included distinguished investigators from Europe, Japan and the United States who represented various disciplines including urology, radiology and pathology.

Because of the rapid changes and developments in transrectal ultrasonography three major categories were reviewed. These were the role of prostate ultrasonography in early diagnosis and screening for carcinoma of the prostate, the value of transrectal ultrasonography in tumor staging, and the use of transrectal ultrasonography in monitoring response to therapy. In addition to multiple presentations related specifically to transrectal prostatic ultrasonography, much discussion was also devoted to the value of other imaging (computerized tomography, magnetic resonance imaging) and laboratory (prostatic specific antigen, prostatic acid phosphatase) studies. Fruitful discussions were held following these presentations and all have been included in this monograph.

The editors would like to express their appreciation to the many investigators who contributed to the success of the meeting and this monograph. Additionally, the support of sponsoring organizations (National Science Foundation, Organ Systems Coordinating Center of the National Cancer Institute's Organ Systems Program, and the Japanese Society for the Promotion of Sciences) is highly valued and without their active involvement this meeting would not have been possible. This undertaking which has involved so many individuals from different countries and of different backgrounds, has truly been a cooperative effort. For those attending the meeting and those reading the monograph, the importance of this interaction is evident.

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ORGAN SYSTEMS PROGRAM STAGING CLASSIFICATION FOR PROSTATE CANCER*

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Panelists: William J. Catalona, John T. Grayhack, Gerald Hanks, Paul C. Peters,

William U. Shipley, and Patrick C. Walsh

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PREAMBLE

Although a staging classification ideally should have qualities of permanence that obviate the problems associated with revisions, it is inevitable that advances in knowledge will justify future changes. The rationale to treatment and prognosis of some of the stage subdivisions in this classification is presumptive but whereas it would be impossible to make such subdivisions retrospectively, it will be simple to combine unnecessary subdivisions if future experience so dictates. The conscientious use of the proposed prostatic diagram will provide one basis for prospective collection of relevant information in the latter regard and will help resolve existing uncertainties regarding the importance of tumor location, absolute tumor size and relative tumor size to treatment and to prognosis. Furthermore, a diagram offers the potential for retrospective reassignment of T category if classification changes.

It is appreciated that existing and developing techniques of tumor assessment will improve the <u>accuracy</u> of clinical staging but the availability and perceived utility of such methods are not uniform. The specified minimal requirements do not exclude the concomitant use of whatever supplemental staging procedures may be elected but assure a minimal common denominator in staging.

It is recommended that this staging classification be utilized in conjunction with whatever other staging classification is employed.

OBJECTIVE

The objective is to provide a simple and reproducible clinical staging classification for primary adenocarcinoma of the prostate which has prognostic and/or therapeutic relevance.

RULES FOR CLASSIFICATION

(Minimal requirements) This classification is for use in histologically verified primary adenocarcinoma of the prostate. Digital rectal examination is the basis for T categorization. N categorization is variously based upon such clinical (C) imaging procedures as lymphangiography, computerized tomography, magnetic resonance imaging and urography, and/or upon histologic (H) confirmation of lymph node metastasis by aspiration biopsy, lymph node sampling or formal lymph node dissection. M categorization is based upon a minimum of chest x-ray, radionuclide bone scan, and at least two serum acid phosphatase determinations.

^{*}Published with permission of Plenum Publishing Corporation. (Coffey, D.S., Resnick, M.I., Door, F.A., Karr, J.P. (eds.). In: <u>A Multidisciplinary Analysis of Controversies in the Management of Prostate Cancer</u>, pp. 295-297, 1988.)

For purposes of prospective studies, preparation of a two-dimensional diagram indicating the estimated actual size in centimeters and shape of the prostate, and the size, shape, location and degree of induration [10 degree or equivocal (20 one crosshatch); 20 degree or moderate (50 two crosshatches); 30 degree or stony hard (50 three crosshatches)] of the tumor is recommended. The diagram should include a transverse sectional view(s), at a specified level(s) of the prostate, to characterize any asymmetry of the rectal surface of the gland. The diagram provides information regarding estimated absolute and relative (to the prostate) two-dimensional tumor size and location that supplements the specific T categorization and is intended to indicate the perceived actual size, shape and induration of the prostate and the tumor. As imaging techniques permitting objective measurements of prostatic size and/or tumor size evolve and are utilized, they will serve to supplement the prostatic diagram.

PRIMARY TUMOR (T)

T Category Definitions

- T_x Anatomical relationships undefinable e.g. prior total prostatectomy; prior abdominoperineal resection of rectum.
- T_A <u>Digitally unrecognizible neoplasm</u>, proved histologically.*
- T_{A1} An estimated 5 recreent or less of the total surgical specimen and of low or medium grade.
- T_{A2} More than an estimated 5 percent of the total surgical specimen and/or of high grade.
- T_{Ax} Implies T_A but stratification into A₁ or A₂ category is not possible (for whatever reason).
- *Tumor volume may be assessed by estimating at low power the proportion of the total specimen involved by tumor. Examination of the entire specimen is necessary for validation of the T_{A1} category.
- T_B Palpable tumor, not beyond the prostatic capsule. (This does not preclude palpable deformity of the margins of the gland provided such is judged to be within the capsule).
- T_{B1} No more than one-half of one lobe in size, regardless of location.
- T_{B2} Tumor more than one-half of one lobe but no more than one lobe in size, regardless of location.
- T_{B3} Tumor greater than one lobe in size, or more than one palpable tumor.
- T_{Bx} Palpable tumor within prostatic capsule but not otherwise characterized.
- TBTC Palpable tumor extending beyond the prostatic capsule. The categorization of an extracapsular tumor involves specification both of the extent of apparent intracapsular involvement according to the TB category definitions indicated in the previous section and of the extent of extracapsular involvement according to the following TC category definitions:
- TC, Extension beyond margin of gland unilaterally.

TC, Extension beyond margin of gland bilaterally.

TC₃ Extension beyond margin of gland with involvement of base of bladder and/or rectum and/or levator muscle(s) and/or pelvic side wall(s).

TC_x Extension beyond prostatic capsule but not otherwise characterized.

LYMPH NODE STATUS (N)

N Category Definitions

Metastasis to the regional lymph nodes of the pelvis below the level of the aortic bifurcation may be clinically suspected from imaging studies (C), and/or histologically verified (H). The clinical imaging modality(s) should be specified.

No regional lymph node metastasis.

N_{1 (H)} Microscopic regional lymph node metastasis. Histologic or cytologic

confirmation is required.

N_{2 (C and/or H)} Gross regional lymph node metastasis.

N_{3 (C and/or H)} Extra regional lymph node metastasis. (This may include inguinal, periaortic,

supraclavicular, axillary nodes, etc.)

N_x Minimal requirements have not been met.

DISTANT METASTASIS STATUS (M)

M Category Definitions

Distant metastases (excluding lymph nodes).

M₀ No evidence of metastasis.

M₁ Elevated acid phosphatase only (repeated at least 2x; i.e. total of 3

elevations)*

M_{2 (V and/or B)} Visceral (V) and/or bone (B) metastasis.

M. Minimal requirements have not been met.

^{*}It is recognized that an elevated acid phosphatase determination may result from a still "localized" prostatic cancer.

THE JAPANESE STAGING SYSTEM

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Two major systems have been widely used for staging prostatic cancer (PC). One of them is the so called "American system", modified by the National Prostatic Cancer Project (NPCP), and the other is the TNM classification. Both systems are essentially similar to the classical clinical staging proposed by Whitmore in 1956, as rectal examination (RE) is employed as the only means of assessing stage.

However, in many cases diagnosed by RE as being an early stage, one can frequently detect invasion beyond the capsule in specimens of the prostate after radical surgery. For that reason, it is generally said that staging by RE has a tendency to underestimate the stage.

Transrectal sonography (TRS) has been credited as being the most reliable technique for imaging the prostate. Among the various diagnostic capabilities of sonography, its suitability for staging PC was noticed even in its very early period of development [1] and it is highly praised without objection at present. It is, however, being performed in various institutions based upon different criteria, making it necessary to standardize the criteria in order to be able to compare and assess results. Thus, we have proposed a staging system for PC by TRS and have evaluated its efficacy in clinical cases belonging to various stages, and have compared it with RE and histological findings.

PROCEDURE

A cooperative research group for imaging modalities in urology, supported by a grant for scientific research from the Ministry of Education, Japan, was organized for 3 years, starting in 1981. The group consisted of 14 urologists in different academic institutions and was moderated by Dr. Hiroki Watanabe. The main objective of the group was the establishment of diagnostic criteria, including a staging system, for ultrasound and CT of the kidney, bladder, prostate and retroperitoneal lymph nodes. The completed list of criteria was authorized by the Japanese Urological Association and the Japan Society of Ultrasonics in Medicine and was published in a special report [2], a guideline for prostatic cancer [3], and the Japanese Journal of Medical Ultrasonics [4].

The staging system for PC by TRS, according to the authorized criteria, is herein described. Judgement is made on the following three items.

- deformity of prostatic section: DF
- interruption of capsular echoes: CA
- invasion into adjacent organs, such as the seminal vesicles or the bladder: NI

There are six staging steps, from UTO to UT4, as given in Table 1. The steps are first independently determined in each item, and then the highest step among the determinations for each item is indicated as the final stage of PC for the patient.

Table 1. UT Staging System

UT steps	Deformity	Interruption	Invasion	TNM	NPCP
UT0	DF ₀	CA ₀	NI _o	Т0	A ₁₋₂
UT1	DF_0a	CA ₀	NI _o	T1	$\mathbf{B_{i}}$
UT2	DF ₁	CA ₀	NI ₀	T2	B ₂
UT3a	DF ₂	CA ₁	NI _o	T2	B_3 - C_1
UT3b	DF ₂	CA ₂	NI,	Т3	C_2
UT4	$\mathrm{DF_2}$	CA ₃	NI ₂	T4	D_i

Deformity; DF

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DF₀: Deformity (-)

DF₀a: Hypoechoic lesion

DF₁: Asymmetry only DF₂: Deformity (+)

CA₀: Interruption (-)

Capsular interruption; CA

CA,: One portion <1/4 circumference

CA; 2 or more portions or >1/4 circumference

CA₃: 2 or more portions or >1/4 circumference + invasion to pelvic bone

Invasion; NI

NI_o: Invasion (-)

NI₁: Invasion to seminal vesicle NI₂: Invasion to other organ

The first item, deformity of prostatic section (DF), includes findings of asymmetry, abnormal prolongation on the antero-posterior diameter, protrusion towards the rectum and less similarity among sections at different scanning levels. The finding of hypoechoic lesions, which suggests the existence of small cancer nodules, is also included in this item. There are four classes of deformity:

- DF_o: No deformity

- DF_{0a}: Hypoechoic lesion without deformity

- DF,: Asymmetry only

- DF,: Remarkable deformity

The second item, interruption of capsular echoes (CA), should be determined very carefully, because the capsular echoes become dim, giving a false invasive sign, when the tangential line of the capsule coincides with the beam line of the projected ultrasound. This item is also comprised of 4 classes: