American College of Radiology
ACR Appropriateness Criteria®

Clinical Condition: **Staging of Testicular Malignancy**

Variant 1: **Testis tumor (diagnosed by orchiectomy).**

Radiologic Procedure	Rating	Comments	RRL*
CT abdomen and pelvis with contrast	9		High
X-ray chest	8		Min
CT chest with contrast	7	If ordered alone (ie, not with the CT abdomen and pelvis examination), without contrast preferred.	Med
MRI abdomen and pelvis with or without contrast	6	Alternative method of imaging nodes if CT is indeterminate or technically unsatisfactory. See statement regarding contrast in text under "Anticipated Exceptions."	None
FDG-PET whole body	4	Possibly indicated for follow-up of residual or recurrent disease, or for differentiating residual nonseminomatous tumor from mature teratoma. No clear benefit in initial staging over CT.	High
Tc-99m bone scan whole body	3		Med
US abdomen and retroperitoneum	3	In patients with lean or average body habitus it is worth trying to visualize the retroperitoneum.	None
Lymphangiography abdomen and pelvis bipedal	2		NS
US scrotum	2	Essential for initial diagnosis, usually not useful for staging. If questionable for opposite testis.	None
X-ray abdomen	1		Med
X-ray intravenous urography	1		Med
Rating Scale: 1=Least appropriate, 9=Most appropriate			***Relative Radiation Level**

STAGING OF TESTICULAR MALIGNANCY

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Summary of Literature Review

Although carcinoma of the testicle is relatively uncommon, representing only 1% of all malignancies occurring in men, it is the most frequent malignancy in men between the ages of 20 and 35 and accounts for 11%-14% of all deaths due to cancer in the 25-34-year age group [1]. The National Cancer Institute estimates that there will be about 8,400 new case of testicular cancer in the U.S. and about 380 deaths from the disease in 2009 [2].

Over 90% of testicular tumors are of germ cell origin and are malignant. Of these, 40% are seminoma. The nonseminomatous tumors include embryonal cell carcinoma (15%-20%), teratoma (5%-10%), and choriocarcinoma (less than 1%) [3,4]. Non-germ-cell tumors are typically benign and have their origin from the Leydig and Sertoli cells or from connective tissue stroma.

Various systems have been used for staging patients with testicular cancer, but most commonly the American Joint Commission on Cancer's staging and end-results reporting are used (Appendix 1).

Testicular tumors spread or metastasize by either the hematogenous or lymphatic route. Most follow the regional lymphatic chain alongside the spermatic vessels. Typically, the first order of metastases is the "sentinel" lymph node, which on the left is located at the renal hilar region and on the right in the paracaval region below the renal artery and vein. Left-sided tumors typically spread to the periaortic nodes and preaortic nodes, and right-sided tumors most commonly involve interaortocaval, precaval, and preaortic nodes. Crossover is not uncommon, but typically is from the right to the left [5]. Further drainage is through the thoracic duct, resulting in more widespread metastases.

Tumor Markers

Tumor markers such as lactate dehydrogenase (LDH), alpha-fetoprotein (AFP), and beta-human chorionic gonadotropin (β-hCG) are helpful not only in diagnosing patients with testicular tumors but in staging them as well. Approximately 90% of patients with advanced nonseminomatous tumors will have elevated levels of one or more of these markers (Appendix 1).

AFP is elevated in approximately 50%-70% of those with embryonal cell carcinoma, yolk sac carcinoma, or tumors of mixed composition [4,6]. β-hCG is elevated in 40%-60% of patients with testicular cancer, including all those with choriocarcinoma, 80% of those with embryonal cell carcinoma, and 10%-25% of those with histologically pure seminoma [7,8]. An elevated AFP is never found in pure seminomas or choriocarcinomas.

Obtaining tumor markers before and after orchiectomy is also very helpful in determining whether any residual disease is present and in planning further therapy. Additionally, tumor markers are essential in the follow-up evaluation to assess both the need for and response to therapy (eg, chemotherapy). Some patients may exhibit an elevation in serum markers at any time despite normal clinical findings and imaging studies. If causes for false-positive marker elevation are ruled out, these patients need to be treated for active disease [9]. Significant marker elevation at presentation often contributes to a worse prognosis for the patient.

A number of patients with nonseminomatous tumors post-treatment may develop retroperitoneal masses of relatively low attenuation, which represent mature teratoma (differentiated teratoma in the British literature) rather than lymphadenopathy, new or residual. This process is benign; however, the tumors continue to grow over time and may result in significant morbidity due to their bulk. Mature teratoma is treated by surgical resection. Differentiation between mature teratoma and residual or recurrent lymphadenopathy may be possible by measuring serum marker levels. Treatment options may differ depending on the histology of the mass(es). CT and, often MRI cannot reliably separate the two entities, which may sometimes coexist.

Imaging Studies

Many imaging studies have been used in assessing patients with testicular tumors. In years past, intravenous urography was commonly used for staging purposes; however, with the development of newer techniques the use of this imaging study is of historical interest for this purpose. Studies used today to assess the retroperitoneum include abdominal ultrasonography (US), computed tomography (CT), magnetic resonance imaging (MRI),

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and pedal lymphangiography. Studies used to assess pulmonary disease include chest radiograph and chest CT. US continues to be used preferentially for assessing the primary tumors.

Ultrasonography

Scrotal US is frequently used, and should always be the initial imaging modality, in assessing patients with scrotal masses. This study can often differentiate fluid-filled spermatoceles and hydroceles from solid intratesticular tumors [10]. Oftentimes the diagnosis is apparent by clinical evaluation, and US can be used for confirmation and for local staging [11]. The finding of testicular microlithiasis should increase the suspicion of testicular malignancy, and if none is found periodic follow-up is recommended [12].

With the development of newer imaging studies, (eg, CT) staging with US has found little application in the assessment of patients with some metastatic testicular tumors to the retroperitoneum [13,14]. Unfortunately, US is operator-dependent, making the uniformity and the reproducibility of the study less than would be desirable. Additionally, because of the interference of overlying intestinal gas and obesity, this study is nondiagnostic in approximately 15%-17% of patients [3].

Computed Tomography

CT is the most common study used for assessing the retroperitoneum for the presence of metastatic testicular malignancy. This study is noninvasive and reproducible and provides excellent imaging of the periaortic and pericaval regions [15-17]**.** Difficulties with CT are that many young men have little retroperitoneal fat, which tends to be an impediment to the study, and that CT cannot detect metastatic disease in lymph nodes of normal size. Additionally, inflammatory lymph nodes cannot be differentiated from those that are enlarged secondary to malignant disease [18,19].

CT interpretation is aided by understanding the lymphatic drainage of the testicles. Node involvement is usually limited to the side of the primary tumor, and crossover is usually present only in the presence of advanced disease. Various benign conditions have also been found to mimic metastases from testicular tumors [20]. Lymph nodes >1 cm are suspicious for metastatic disease, particularly if they are located in the hilar regions of the kidney or in the periaortic or caval areas. Various studies have established the accuracy of CT in detecting metastatic retroperitoneal lymph nodes, which ranges from 73%-97%. Sensitivity ranges from 65%-96% and specificity from 81%-100% [3,21-26]. Experience also indicates that accuracy declines in patients with limited disease (stage N1 and stage N2) and also if the upper limit of normal lymph node size is lowered to 4 mm [17,21,25]**.**

Lymphangiography

Lymphangiography is now rarely used because of its disadvantages, which include its invasiveness, its inability to opacify the sentinel lymph node, and its inability to demonstrate the upper limits of involvement in patients with extensive disease. The accuracy of bipedal lymphangiography has been shown to be comparable to that of CT and varies from 62%-89%. Sensitivity ranges from 54%-90% and specificity from 67%-100% [3,26-34]. Studies have also indicated that a combination of lymphangiography and CT improves accuracy, but there is evidence that this approach is not cost-effective [3,22,24,35]. Magnetic resonance lymphangiography appears to have potential in the future, but experience is still too limited, and the agent, ferumoxytran, has not yet been approved by the Food and Drug Administration (FDA) for clinical use [36].

Magnetic Resonance Imaging

MRI has also been used in the staging of testicular tumors [35,37,38]; evidence indicates that it is comparable to CT [35,38]. MRI does offer an advantage, allowing for the differentiation of blood vessels from lymph nodes, and it may also have a potential for distinguishing residual tumor from fibrosis [37,38].

Chest Radiography

Many studies have addressed the value of chest radiography in assessing pulmonary metastases [39-41]. These studies indicate that chest radiograph alone is satisfactory in the initial staging in patients with testicular malignancies. Chest CT offers little in these patients; however, it may offer benefit in those with more advanced disease. More recent studies have suggested that initial and recurrent disease in the chest can be detected on chest CT [42,43] and that routine chest radiographs have a very low yield for early disease and are not considered useful for initial staging or for follow-up after therapy [44].

Radionuclide Imaging

Radionuclide studies have limited value for detecting retroperitoneal metastases. Radioimmunoassays for β-hCG and AFP labeled antibodies to these markers show promise, but further experience with them is needed [45-47]. Gallium scintigraphy has also been used to detect metastatic disease, but clinical experience is limited [48,49]. Positron emission tomography (PET) imaging with fluorine-18-2-fluoro-2-deoxy-D-glucose (FDG) has been used in assessing patients with testicular cancers, but its true value in staging patients has yet to be defined. In initial staging PET may be only slightly more sensitive than CT [50-54]. Its use in follow-up for residual masses is controversial, with some authors recommending it to distinguish mature teratoma from residual disease [55,56] and others seeing no benefit in assessing residual masses [57].

Furthermore, a recent trial by the National Cancer Research Institute's Testis Cancer Clinical Studies Group using FDG-PET in an effort to predict relapse in patients with high-risk stage I nonseminomatous germ cell tumors was terminated early due to unacceptable relapse rates among PET-negative patients [58].

Bone scans can be useful in assessing early bone lesions before they are detectable by CT [59], although one study

suggests that FDG-PET scans are more sensitive and can substitute for conventional bone scans [60].

Summary

- In most instances, the diagnosis of testicular tumors is established with a carefully performed physical examination and scrotal US.
- Tumor markers are useful for determining the presence of residual disease.
- Cross-sectional imaging studies (CT, MRI) are useful in determining the location of metastases.
- FDG-PET scans have a slightly higher sensitivity than CT, but their role in staging testicular cancer has not been determined in a large study.
- Bone scans are useful in the absence of FDG-PET scans and should be used when bone metastases are suspected.

Anticipated Exceptions

Nephrogenic systemic fibrosis (NSF) is a disorder with a scleroderma-like presentation and a spectrum of manifestations that can range from limited clinical sequelae to fatality. It appears to be related to both underlying severe renal dysfunction and the administration of gadolinium-based contrast agents. It has occurred primarily in patients on dialysis, rarely in patients with very limited glomerular filtration rate (GFR) (ie, <30 mL/min/1.73m^2), and almost never in other patients. There is growing literature regarding NSF. Although some controversy and lack of clarity remain, there is a consensus that it is advisable to avoid all gadolinium-based contrast agents in dialysis-dependent patients unless the possible benefits clearly outweigh the risk, and to limit the type and amount in patients with estimated GFR rates <30 mL/min/1.73m^2. For more information, please see the ACR *Manual on Contrast Media* [61].

Relative Radiation Level Information

Potential adverse health effects associated with radiation exposure are an important factor to consider when selecting the appropriate imaging procedure. Because there is a wide range of radiation exposures associated with different diagnostic procedures, a relative radiation level (RRL) indication has been included for each imaging examination. The RRLs are based on effective dose, which is a radiation dose quantity that is used to estimate population total radiation risk associated with an imaging procedure. Additional information regarding radiation dose assessment for imaging examinations can be found in the ACR Appropriateness Criteria® Radiation Dose Assessment Introduction document.

Relative Radiation Level Designations	
Relative Radiation Level*	**Effective Dose Estimate Range**
None	0
Minimal	< 0.1 mSv
Low	0.1-1 mSv
Medium	1-10 mSv
High	10-100 mSv

*The RRL assignments for some of the examinations cannot be made, because the actual patient doses in these procedures vary as a function of a number of factors (eg, the region of the body exposed to ionizing radiation, the imaging guidance that is used, etc). The RRLs for these examinations are designated as NS (not specified).

Supporting Document(s)

- ACR Appropriateness Criteria® Overview
- Evidence table under review

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The ACR Committee on Appropriateness Criteria and its expert panels have developed criteria for determining appropriate imaging examinations for diagnosis and treatment of specified medical condition(s). These criteria are intended to guide radiologists, radiation oncologists and referring physicians in making decisions regarding radiologic imaging and treatment. Generally, the complexity and severity of a patient's clinical condition should dictate the selection of appropriate imaging procedures or treatments. Only those examinations generally used for evaluation of the patient's condition are ranked. Other imaging studies necessary to evaluate other co-existent diseases or other medical consequences of this condition are not considered in this document. The availability of equipment or personnel may influence the selection of appropriate imaging procedures or treatments. Imaging techniques classified as investigational by the FDA have not been considered in developing these criteria; however, study of new equipment and applications should be encouraged. The ultimate decision regarding the appropriateness of any specific radiologic examination or treatment must be made by the referring physician and radiologist in light of all the circumstances presented in an individual examination.

Appendix 1. Staging of Testicular Tumors [62]

Primary tumor (T)

Stage	Definition
TX	Primary tumor cannot be assessed. (In the absence of radical orchiectomy, TX is used).
T0	Histologic scar or no evidence of primary tumor.
Tis	Intratubular tumor: preinvasive cancer.
T1	Tumor limited to testis, including rete testis.
T2	Tumor invades beyond tunica albuginea or into epididymis.
T3	Tumor invades spermatic cord.
T4	Tumor invades scrotum.

Regional lymph nodes (N)

Stage	Definition
NX	Regional lymph nodes cannot be assessed.
N0	No regional lymph node metastasis.
N1	Metastasis in a single lymph node, 2 cm or less in greatest dimension.
N2	Metastasis in a single lymph node, more than 2 cm but not more than 5 cm in greatest dimension, or multiple lymph nodes, none more than 5 cm in greatest dimension.
N3	Metastasis in a lymph node more than 5 cm in greatest dimension.

Distant metastasis (M)

Stage	Definition
MX	Presence of distant metastasis cannot be assessed.
M0	No distant metastasis.
M1	Distant metastasis.

Serum tumor markers (S)

Marker	Definition
SX	Tumor marker studies not available or not performed.
S0	Tumor marker levels within normal limits.
S1	LDH < 1.5 X Normal and HCG (mIu/ml) < 5,000 and AFP (ng/ml) < 1,000.
S2	LDH 1.5-10 X Normal or HCG (mIu/ml) 5,000-50,000 or AFP (ng/ml) 1,000-10,000.
S3	LDH > 10 X Normal or HCG (mIu/ml) > 50,000 or AFP (ng/ml) > 10,000.