A6651

ROLE OF RADIOLOGY IN THE PRETREATMENT EVALUATION OF INVASIVE CERVICAL CANCER

This is joint ACRIN/GOG protocol with ACRIN being the lead organization.

Study Investigators:
PI: Hedvig Hricak, M.D., Ph.D.
Larry Schwartz, M.D.
Elliot Fishman, M.D.

Statistician:
Constantine Gatsonis, Ph.D.

GOG Study Investigators:
PI: Dennis Chi, M.D.

Protocol Manager:
Bradley Snyder, M.S.

Data Managers:
Sophia Sabina, M.B.A., R.T. (R) (T)
Robert Sole, R.T.(R) (CT)
Chris Steward, B.S., R.T. (R) (CV)

Protocol Associate:
Tess Thompson, M. PHIL

Status:
Closed

Closed Date:
November 11, 2002

Schema

R

E

G

I

S Institutions will register eligible participants; planned imaging sequence will be specified by the institution at the time of registration: CT followed by MRI or MRI followed by CT

T

E

First imaging must be within 20 days of registration

R

Surgery will follow the first imaging study by ≤ 6 weeks

Follow-up information will be collected on each participant for a 2-year period.

Objectives

1. To compare the diagnostic performance of MRI and CT to each other and to clinical FIGO staging in the primary evaluation of invasive cancer of the cervix. In particular, a primary objective of the study is to examine the agreement of the stage determined by each cross sectional imaging modality to FIGO stage.
2. To compare the accuracy of MRI, CT and clinical FIGO staging in the evaluation of morphologic tumor prognostic factors in FIGO stage IB1 with clinically visible gross lesion, and stages IB2, II, IIA, IIB, III, IIIA, IIIB, IV, IVA, IVB participants. The factors to be evaluated include: tumor size (including AP, width and length), tumor volume, tumor location, depth of stromal invasion, parametrial invasion, presence of lower uterine segment and corpus uterus extension, invasion of the vagina, invasion of the urinary bladder and/or rectum, tumor extension outside the uterus and presence of lymph node metastasis.
3. To examine the value of imaging assessment of tumor prognostic factors, alone or in combination, as predictors of recurrence within two years after surgery**.**
4. To evaluate interobserver variability in the interpretation of MRI and CT.
5. To examine participant experience and preferences about their diagnostic work-up and to conduct a pilot data collection about quality of life in the 12 month period subsequent to staging and treatment in order to facilitate *post hoc* modeling of outcomes with respect to potential changes in the staging accuracy.
6. To estimate the impact on health care utilization, costs and net benefits when cross-sectional imaging is performed prior to surgery; and to compare health care utilization, costs and net benefits of staging using the cross sectional modalities and using clinical FIGO staging.

Participant Population

Inclusion criteria:

1. Biopsy-documented invasive cervical cancer including invasive squamous cell carcinoma, adenocarcinoma, or adenosquamous carcinoma.
2. Pathology slides *(tumor grade)* available for review at participating institution upon request.
3. Clinical FIGO stage IB1 with clinically visible gross lesion, or any of stages IB2, II, IIA, IIB, III, IIIA, IIIB, IV, IVA, IVB assigned before imaging. Participants will have FIGO clinical staging as the initial method of staging and will have CT and MRI examinations. Outside CT and MRI studies will be accepted, and the primary institution will make the decision if the CT/MRI is of diagnostic quality. Additional diagnostic tests may be performed as needed to complete the pretreatment work-up. (Cross-sectional imaging should be performed after clinical decision for surgery has been made. If the imaging study shows enlarged nodes or obvious parametrial invasion, therefore precluding participant from surgery, this participant will not be classified as ineligible and will not constitute a violation for GOG study accrual.)
4. Surgery intended at participating institution. Participant should be enrolled based on clinical eligibility for surgery. Types of surgery accepted include: hysterectomy (laparoscopic, transabdominal, or transvaginal), extrafascial TAH or trachelectomy.
5. The maximum interval between the first protocol imaging and surgery must not exceed 6 weeks.
6. Participants will sign a study-specific informed consent prior to study entry.
7. Participant must be available for follow-up.

Exclusion criteria:

1. Participant unwilling to undergo contrast-enhanced CT and MRI.
2. Participant with previous medical, surgical or radiation treatment for invasive cervical cancer.
3. Participant who because of age, general medical or psychiatric condition, or physiologic status unrelated to the presence of cervical cancer cannot give an informed medical consent.
4. Participant who because of age, general medical or psychiatric or physical status is not considered a surgical candidate.
5. Participant with contraindication to CT: history of allergic reaction to contrast medium.
6. Participant with contraindication to MR: participants with cardiac pacemakers or intracranial vascular clips.
7. Pregnant participants
8. Scheduled for LEEP procedure or cone biopsy only.

Summary of Study Design
Participating institutions will accrue eligible participants into the study. Once registered, participants will undergo both CT and MRI before surgery. The first imaging study will take place within 20 days of registration. Scheduled surgery will follow the first imaging study within 6 weeks. CT and MR images will be collected and reviewed for image quality. A reader study will assess variability across radiologists. Participant questionnaires will be administered one week after last imaging to assess quality of life. A Health Utilities will be administered at one and 12 months after surgery. Follow-up information will be collected on each participant for a 2-year period.

Per Case Reimbursement: $1500.00

Accrual Goals
465 participants are expected to be accrued.

Progress to Date
As of January 31, 2002, a total of 133 participants were enrolled into this study. All participants are female.
No adverse events have been reported. A formal interim analysis will be conducted in the summer 2002.

Registration by Institution
As of January 31, 2002

INSTITUTION	ACCRUAL
Mayo Clinic	17
Mem. Sloan-Kettering Cancer Ctr.	17
Univ. of Penn. Med. Ctr.	15
Univ. of Texas, MD Anderson	10
Thomas Jefferson Univ. Hospital	9
Wash. Univ./Mallinckrodt Rad.	8
Univ. of Miami	8
Rhode Island Hospital	7
Ohio State Univ.	7
Mt. Carmel Health System	7
Cooper Hospital Univ. Med. Ctr.	5
Clinical Radiologists, S.C.	4
Christiana Care Health Services, Inc.	4
Wake Forest	4
Tacoma General Hospital	3
Univ. of Washington	2
Georgetown Univ. Hospital	1
Sacred Heart/Tampa Bay Ca Consortium	1
UPMC - Magee Women's Hospital	1
Univ. of Alabama	1
St Elizabeth Health Center	1
John Hopkins	1
The Cleveland Clinic Foundation	0
	133

Participant Characteristics
Data as of January 31, 2002

	n = 133	
AGE		
Median	44	
Minimum	24	
Maximum	82	
RACE		
White	95	17 %
Hispanic/Latino	14	11 %
African-American	19	14 %
Asian	4	3 %
Other	1	1 %