Annual Progress Report

William Beaumont Army Medical Center
DCI
El Paso, Texas

Fiscal Year 1993

DRE1.940922.008

DETAIL SUMMARY SHEET

DATE: 1 October 93 PROTOCOL #: 76/33 STATUS: Ongoing

TITLE: Diagnostic Adrenal Scanning with 131I (NP59)

START DATE: Mar 76 ESTIMATED COMPLETION DATE: Indefinite

PRINCIPAL INVESTIGATOR: LTC Albert J. Moreno

DEPARTMENT: Med FACILITY: William Beaumont Army Medical Center

ASSOCIATE INVESTIGATORS:

KEY WORDS: adrenal scanning

Study Objective: To determine the usefulness of ^{131}I-NP59 in scanning of the adrenal glands. This agent will be used (1) as a screening test for detection of primary aldosterone tumor, Cushing's disease, adrenal cortical adenoma, or pheochromocytoma; (2)to image adrenals in patients who require adrenal venography and are allergic to contrast media; (3) to detect unilateral adrenocortical hypofunction - calcification, metastatic carcinoma, post-venography infarction, etc.; (4) to detect functioning adrenal remnant after adrenalectomy for Cushing's syndrome; (5) to aid in assessment of adrenocortical function in patients who have been on adrenocortical steroid therapy.

Technical Approach: Patients with clinical evidence of adrenal disease will be thoroughly evaluated by an endocrinologist. Following intravenous administration of ^{131}I-NP59, adrenal scanning will be performed after 7-10 days. The material will be obtained from the Nuclear Pharmacy, University of Michigan. The WBAMC radiopharmacist will perform sterility and pyrogenicity tests on the radiochemical to ensure that radiopharmaceutical standards are met prior to injection

NOTE: Project was erroneously terminated in Oct 84. Project reactivated in Sep 92 and folder was reconstituted to include required documentation.

Progress: Fourteen patients have been studied since this protocol was approved. No adverse effects noted.

DETAIL SUMMARY SHEET

DATE: 1 October 93 PROTOCOL #: 93/36 STATUS: Ongoing

TITLE: The Effect of Meal Consumption Before Radionuclide Ventriculography (Monitor: LTC Algeo)

START DATE: Jul 93 ESTIMATED COMPLETION DATE: Jun 94

PRINCIPAL INVESTIGATOR: MAJ Elmer J Pacheco

DEPARTMENT: Med FACILITY: William Beaumont Army Medical Center

ASSOCIATE INVESTIGATORS: A Moreno, G Turnbull, M Brodbeck, D Hokanson

KEY WORDS: meal radionuclide ventriculography

Study Objective: To determine the effect of a standardized meal on the resting LVEF in patients with a normal LVEF.

Technical Approach: A retrospective and prospective study in which patients with a known normal LVEF derived through a MUGA performed at our institution and during a fasting state, will be asked to undergo a repeat study 45 min after the ingestion of a standardized meal totalling 700 cal, consisting of 50% carbohydrates, 30% fat, and 20% protein. This meal will consist of 4 oz orange juice, 8 oz 2% milk, 2 pieces of toast, 2 boiled eggs, 2 slices of bacon, 1 cup of coffee with sugar and non-dairy cream, and 1 banana.

Progress: Seven patients have completed protocol as per guidelines with deviations. No side effects have been reported. In patients who have completed both phases of the study (i.e., fasting and post-prandial MUGA), there seems toward increased LVEF post-prandially, although statistical analysis is pending.

DETAIL SUMMARY SHEET

DATE: 1 October 93 PROTOCOL #: 93/53 STATUS: Ongoing

TITLE: Phase II Study of Interferon-Modulated Indium-111-Labeled b72.3 Monoclonal Antibody (MoAb) Scintigraphy in the Staging and Follow-Up of Breast Cancer Patients of Poor Prognosis (Monitor: MAJ Cadiz)

START DATE: Nov 1993 ESTIMATED COMPLETION DATE: Oct 2000

PRINCIPAL INVESTIGATOR: MAJ Elmer J Pacheco

DEPARTMENT: Med FACILITY: William Beaumont Army Medical Center

ASSOCIATE INVESTIGATORS: A Moreno, W Sippo, S Hetz, TH Nguyen, ME Nash, GG Turnbull, G Morgan

KEY WORDS: breast cancer, scintigraphy

Study Objective: The use of human leukocyte interferon-alpha (HuIFN-α)in this study would attempt to enhance the expression of a tumor-associated antigen (TAG-72) in breast cancer patients of poor prognosis. The sensitivity and specificity of Indium-111-labeled B72.3 MoAb against TAG-72 in this subset of patients will be compared to conventional bone scintigraphy during their initial staging and follow-up. An analysis of the poor prognostic factors (i.e. Aneuploid DNA content, high S-phase, high Ki-67 growth fraction, negative ER/PR status, low pS2, high EGF, high HER-2neu, high Cathepsin D level, and low p53 expression) will be performed so as to document their importance in the prediction of survival in this set of patients, as well as discerning which combination of these factors will more accurately predict outcome.

The Modified Scarff-Bloom-Richardson system will be compared to nuclear grading, with and without mitotic count in the histopathological assessment of the obtained tissues. Their effectiveness in predicting relapse will be defined.

Technical Approach: Details are too lengthy to list here. Protocol is on file in Department of Clinical Investigation.

Progress: Approval of grant is pending.

DETAIL SUMMARY SHEET

DATE: 1 October 93 PROTOCOL #: 91/34 STATUS: Ongoing

TITLE: GOG #95/SWO6 #9047, Randomized Clinical Trial for the Treatment of Women with Selected Stage IC & II (A, B, C) and Selected Stage IA & IB Ovarian Cancer (Monitor: MAJ Nash)

START DATE: Oct 91 ESTIMATED COMPLETION DATE: Indefinite

PRINCIPAL INVESTIGATOR: LTC Andrew Soisson

DEPARTMENT: Obgyn FACILITY: William Beaumont Army Medical Center

ASSOCIATE INVESTIGATORS: C Hawley-Bowland

KEY WORDS: ovarian cancer

Study Objective: To determine if a short course of chemotherapy is more effective than intra-peritoneal radioisotope therapy in the treatment of early stage ovarian cancer and to determine the relative toxicity of each treatment.

Technical Approach: The details are lengthy and specified in the protocol. Duplicates are kept on file in the Department of Clinical Investigation and are available upon request.

Semiannual Review: Apr 93 - 1 patient enrolled. Patient randomized to P32 treatment arm and received therapy without complication.

Progress: Three patients are enrolled to date. No adverse reactions have been reported.

DETAIL SUMMARY SHEET

DATE: 1 October 93 PROTOCOL #: 92/04 STATUS: Ongoing

TITLE: Protocol GOG # 99, A Phase III Randomized Study of Surgery VS. Surgery Plus Adjunctive Radiation Therapy in Intermediate Risk Endometrial Adenocarcinoma (Monitor: MAJ Nash)

START DATE: Nov 91 ESTIMATED COMPLETION DATE: Indefinite

PRINCIPAL INVESTIGATOR: LTC Andrew Soisson

DEPARTMENT: Obgyn FACILITY: William Beaumont Army Medical Center

ASSOCIATE INVESTIGATORS: C Hawley-Bowland

KEY WORDS: endometrial adenocarcinoma

Study Objective: To determine if patients with intermediate risk endometrial adenocarcinoma, who have no spread of disease to their lymph nodes, benefit from postoperative pelvic radiotherapy. To evaluate how the addition of radiotherapy will alter the site and rate of cancer recurrence in those intermediate risk individuals.

Technical Approach: The details are lengthy and specified in the protocol. Duplicates are kept on file in the Department of Clinical Investigation and are available upon request.

Semiannual Review (Apr 93): No patients enrolled.

Progress: No patients enrolled.

DETAIL SUMMARY SHEET

DATE: 1 October 93 **PROTOCOL #:** 92/32 **STATUS:** Ongoing

TITLE: GOG #125, Extended Field Radiation Therapy with Concomitant 5-FU Infusion and Cisplatin Chemotherapy in Patients with Cervical Carcinoma Metastatic to Para-Aortic Lymph Nodes (Phase II) (Monitor: MAJ Sheffler)

START DATE: Apr 92 **ESTIMATED COMPLETION DATE:** Apr 97

PRINCIPAL INVESTIGATOR: LTC Andrew Soisson

DEPARTMENT: Obgyn **FACILITY:** William Beaumont Army Medical Center

ASSOCIATE INVESTIGATORS: C Hawley-Bowland

KEY WORDS: cervical carcinoma (metastatic)

Study Objective: In this study, patients with cervical cancer who have biopsy confirmed para-aortic lymph node metastases will receive combination chemotherapy consisting of cisplatin and 5-FU intravenous infusion concomitantly with pelvic and para-aortic extended field radiation therapy. The objectives of this study are to assess progression-free survival and overall survival; sites of initial failure; and morbidity of the treatment.

Technical Approach: The details are lengthy and specified in the protocol. Duplicates are kept on file in the Department of Clinical Investigation and are available upon request.

Semiannual Review (Apr 93): No patients enrolled to date.

Progress: No patients enrolled. MAJ Sheffler has replaced COL Lundy as medical monitor. COL Lundy has retired.

DETAIL SUMMARY SHEET

DATE: 1 October 93 **PROTOCOL #:** 92/34 **STATUS:** Ongoing

TITLE: GOG #109, A Randomized Comparison of 5-Fu Infusion and Bolus Cisplatin as an Adjunct to Radiation Therapy versus Radiation Therapy Alone in Selected Patients with Stages IA2, IB and IIA Carcinoma of the Cervix Following Radical Hysterectomy and Node Dissection (Monitor: MAJ Nash)

START DATE: Apr 92 **ESTIMATED COMPLETION DATE:** Apr 97

PRINCIPAL INVESTIGATOR: LTC Andrew Soisson

DEPARTMENT: Obgyn **FACILITY:** William Beaumont Army Medical Center

ASSOCIATE INVESTIGATORS: C Hawley-Bowland

KEY WORDS: cervical carcinoma

Study Objective: To determine whether the combination of 5-fluorouracil (%-FU) and cisplatin used as an adjunct to radiation therapy will improve survival rate or progression-free survival and decrease extra pelvic failure compared to radiation therapy alone in patients with positive pelvic lymph nodes, positive parametrial involvement or positive surgical margins following radical hysterectomy and lymph node dissection for stages IA2, IB, and IIA carcinoma of the cervix. To determine the increase in toxicities due to 5-FU and cisplatin as an adjunct to radiation therapy versus radiation therapy alone.

Technical Approach: The details are lengthy and specified in the protocol. Duplicates are kept on file in the Department of Clinical Investigation and are available upon request.

Semiannual Review (Apr 93): No patients enrolled to date.

Progress: No patients enrolled to date.

DETAIL SUMMARY SHEET

DATE: 1 October 93 PROTOCOL #: 93/27 STATUS: Completed FY93

TITLE: Patella Implant Size and Positioning: A Clinical Review and Radiographic Analysis

START DATE: Apr 93 ESTIMATED COMPLETION DATE: Sep 93

PRINCIPAL INVESTIGATOR: MAJ T. Scott McGee

DEPARTMENT: Surg FACILITY: William Beaumont Army Medical Center

ASSOCIATE INVESTIGATORS: R Bagg, MG Anderson, ME Reid, RA Espinosa, RB Gustilo, I Guloy

KEY WORDS: Patella Implant

Study Objective: To determine if (1) the smaller sized patella implant is correlated with fewer post-operative problems;(2) alignment is significantly improved (also assessing the indications for intraoperative lateral release); (3) pain is decreased, and/or (4) instability is lessened.

Technical Approach: A retrospective review of all TKA patients over the last 2-3 years (50 patients approximately will be followed up with a standardized knee society rating score and radiographic evaluation of patella positioning.

Progress: The most frequent complication of total knee joint prosthetic replacement is malfunction of the patella femoral mechanisms. The incidence of patella femoral malfunction may be related to the size of the prosthetic component chosen to resurface the patella. WE tested this hypothesis by examining the outcome achieved in 115 knees in 96 patients who had been followed for more than two years post operatively. All knees were evaluated by the Knee Society Scoring System and the Knee Society Function Score. the patients were also evaluated as to their ability to rise from a chair and to climb stairs. The knees were divided into three groups: Group I had extra small patellar components, Group II small and Group III medium patellar components. There were no significant differences in the groups except for the post operative stair climbing ability, which was more impaired in the extra small patella group.