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Revised 2011 (CSC/BOC)*

ACR–ASTRO PRACTICE GUIDELINE FOR THE PERFORMANCE OF TOTAL BODY IRRADIATION

PREAMBLE

These guidelines are an educational tool designed to assist practitioners in providing appropriate radiation oncology care for patients. They are not inflexible rules or requirements of practice and are not intended, nor should they be used, to establish a legal standard of care. For these reasons and those set forth below, the American College of Radiology cautions against the use of these guidelines in litigation in which the clinical decisions of a practitioner are called into question.

The ultimate judgment regarding the propriety of any specific procedure or course of action must be made by the physician or medical physicist in light of all the circumstances presented. Thus, an approach that differs from the guidelines, standing alone, does not necessarily imply that the approach was below the standard of care. To the contrary, a conscientious practitioner may responsibly adopt a course of action different from that set forth in the guidelines when, in the reasonable judgment of the practitioner, such course of action is indicated by the condition of the patient, limitations of available resources, or advances in knowledge or technology subsequent to publication of the guidelines. However, a practitioner who employs an approach substantially different from these guidelines is advised to document in the patient record information sufficient to explain the approach taken.

The practice of medicine involves not only the science, but also the art of dealing with the prevention, diagnosis, alleviation, and treatment of disease. The variety and complexity of human conditions make it impossible to always reach the most appropriate diagnosis or to predict with certainty a particular response to treatment.

Therefore, it should be recognized that adherence to these guidelines will not assure an accurate diagnosis or a successful outcome. All that should be expected is that the practitioner will follow a reasonable course of action based on current knowledge, available resources, and the needs of the patient to deliver effective and safe medical care. The sole purpose of these guidelines is to assist practitioners in achieving this objective.

I. INTRODUCTION

This guideline was revised collaboratively with the American College of Radiology (ACR) and the American Society for Radiation Oncology (ASTRO).

Total body irradiation (TBI) is a radiotherapy technique frequently used as a component of hematopoietic stem cell transplant (HSCT). TBI in conjunction with chemotherapeutic agents has proven useful for eradicating residual malignant or genetically disordered cells and for immunosuppression prior to HSCT. According to data summarized by the Center for International Blood and Marrow Transplant Research, in 2005 the diseases most commonly treated with HSCT were (in decreasing order of frequency): multiple myeloma, non-Hodgkin lymphoma, acute myelogenous leukemia, Hodgkin disease, acute lymphoid leukemia, myelodysplastic syndrome, chronic myelogenous leukemia, and additional malignant and nonmalignant diseases [1]. HSCT is considered autologous if native stem cells are reinfused and allogeneic if the hematopoietic graft is derived from someone other than the recipient. Allogeneic grafts can be from related or unrelated individuals, but “matching” of donor and recipient is performed. The graft may be in the form of bone marrow, peripheral stem cells, and umbilical cord blood [2].

Unique features of TBI that make it a valuable component of transplant preparative regimens include:

1. No sparing of “sanctuary” sites such as testes and the central nervous system.
2. Dose homogeneity to the whole body regardless of blood supply.
3. Less chance of cross-resistance with other antineoplastic agents (chemotherapy).
4. No problems with excretion or detoxification.
5. Ability to tailor the dose distribution by shielding specific organs or by “boosting” sites.

A wide variety of TBI dose and fractionation schedules have been studied. The optimal regimen depends on a range of clinical variables, including patient age, disease, and type of HSCT. With competing goals of disease eradication and avoidance of toxicity, the most commonly accepted total dose of TBI for myeloablative HSCT is 12 to 15 Gy delivered in 8 to 12 fractions over 4 days [3-4]. Numerous investigators have shown that efficacy is improved and a variety of important late toxicities are significantly decreased when TBI is fractionated in 2 to 3 treatments per day [5-6]. Relatively low dose-rates are also important for optimal outcome [7]. Many protocols require a dose rate of < 0.2 Gy per minute.

Low dose TBI, often in conjunction with chemotherapy, has recently emerged as an effective form of conditioning in reduced intensity HSCT for patients who may not be able to tolerate myeloablation because of poor performance status or comorbidity. Notable studies have included TBI doses of 2 to 8 Gy in 1 to 4 fractions [8-12].

It is essential that the complicated treatment and care of the patient receiving TBI be well coordinated among the various subspecialties (medical oncology, radiation oncology, etc.) and caregivers (physicians, nurses, physicists, psychologists, dietitians, etc). TBI presents a unique challenge because it results in potentially lethal myeloablation without intensive medical support and stem cell backup. Incorrectly delivered TBI may result in fatal toxicity. Anticipated immediate toxicity includes the following signs and symptoms: nausea, emesis, parotitis, xerostomia, headache, fatigue, mucositis, diarrhea, and loss of appetite [13]. Prophylactic interventions to manage these toxicities include intravenous hydration, antiemetics, and antimucositis agents [14]. Patients must be counseled regarding the risks of long-term sequelae of TBI, which vary in incidence depending on the clinical scenario and TBI regimen. These late risks may include pneumonopathy [15], veno-occlusive disease of the liver [16], kidney dysfunction [17], cataracts [7], hypothyroidism [18], infertility [19], and secondary malignancies [20]. Because of the significant risk associated with this treatment, the entire team must take great care to assure the best possible multidisciplinary care with attention to all facets of TBI.

Although the techniques of TBI vary widely from institution to institution, certain basic principles apply, such as the achievement of relative-dose homogeneity throughout the body, with the exception of intentionally shielded or boosted areas. Most centers use opposing anterior and posterior fields with the patient standing upright several meters from the source and the beam pointed horizontally. A beam spoiler placed upstream may be used to prevent skin sparing [21]. Alternatively, patients can be irradiated with lateral fields in a sitting or partly reclining position [22]. This approach is usually better tolerated by patients but presents additional dosimetric challenges that must be considered/addressed to improve dose uniformity. Very young children who require anesthesia may be treated lying on the floor with the gantry pointing downward and with the spoiler and blocks placed above the patient. Successful planning and delivery of TBI requires close interaction and coordination among the radiation oncologist, medical physicist, dosimetrists, nurses, and radiation therapists.

This guideline describes a quality assurance program for TBI and is supplementary to the [ACR Practice Guideline for Radiation Oncology](#) [23] and the [ACR Technical Standard for the Performance of Radiation Oncology Physics for External Beam Therapy](#) [24].

II. PROCESS OF TOTAL BODY IRRADIATION

The use of TBI is a complex process involving many trained personnel who carry out highly coordinated activities.

A. Clinical Evaluation

The initial evaluation should include a detailed history, including a review of issues that may impact on treatment tolerance (previous radiotherapy to sensitive organs, factors affecting pulmonary, renal or hepatic function, and exposure to infectious agents); physical examination; review of all pertinent diagnostic and laboratory tests; and communication with the referring physician and other physicians involved in the patient’s care in accordance with the [ACR Practice Guideline for Communication: Radiation Oncology](#) [25]. Careful review of the applicable treatment plan or clinical trial protocol for the particular disease being treated is essential since standardized institutional or cooperative group protocols are typically used for transplantation.

As with delivery of any chemotherapy or radiotherapy, policies and procedures should be in place to determine whether a female patient is pregnant before initiating any component of a transplant program, including TBI. If the patient is determined to be pregnant, other therapies should be considered in an effort to preserve the pregnancy. Alternatively, if the patient wishes to proceed

with transplant, the pregnancy may be electively terminated.

B. Informed Consent

Prior to simulation and treatment, informed consent must be obtained and documented and must be in compliance with applicable laws, regulations, or policies, in accordance with the [ACR Practice Guideline on Informed Consent: Radiation Oncology](#) [26]. This should include a detailed discussion of the benefits and potential tissue-specific acute and late toxicities of TBI, as well as the details of, rationale for, and alternatives to TBI.

C. Treatment Planning

Treatment planning for TBI requires detailed knowledge of the specific transplant program to be followed (either on or off of a clinical trial). Specific treatment parameters to be determined in advance of treatment include: field size, collimator rotation, treatment distance, dose per fraction, dose rate, total dose, number of fractions per day, interval between fractions, beam energy, geometry to achieve dose homogeneity, bolus or beam spoilers to increase skin dose, shielding and dose compensation requirements (e.g., lungs, kidneys), and boost specifications (e.g., testes, chest wall). Patient thickness measurements should be obtained at the prescription point (often at the level of the umbilicus) and at other points of interest for possible dose calculations and homogeneity determinations, such as head, neck, mid-mediastinum, mid-lung, pelvis, knee, ankle, etc. Patient height is recorded to determine the appropriate source-to-patient distance to fit the patient within the beam with sufficient margin around the patient (usually >5 cm). Special attention should be paid to the dramatic decrease in dose that can be seen in the field corners for many treatment units when the collimator is in the full open position.

D. Simulation of Treatment

For lung or other organ blocking, simulation or other treatment planning is generally done in the treatment position, i.e., if the patient is standing for TBI, the simulation should be done in the standing position if possible. As an alternative to CT-simulation in the supine position, lung blocks may be designed on megavoltage radiographs generated by a linear accelerator with the patient in an upright position. If the planning session is performed in another position, positional differences in organ location should be considered and the medical physicist should be consulted. Reference points for block placement at the time of treatment should be marked on the patient's body for reproducibility.

E. Calculations

Calculations are performed by the medical physicist or his or her designee to determine the beam-on time necessary to achieve the prescribed dose, dose homogeneity, and any other relevant dose points. Consideration should always be given to differences in the patient's separation in different body regions, with the resulting dose heterogeneities. For example adjustments should be considered for overweight patients who can experience severe head and neck mucositis when only umbilical separation is used for prescribing dose. A medical physicist or a dosimetrist who did not perform the initial computation should independently check the calculation before the first fraction is delivered. It is recommended here that in-vivo dosimetry be used to assess dose homogeneity. Every effort should be made to maintain dose inhomogeneity to within $\pm 10\%$.

F. Treatment Aids

Special TBI stands, treatment couches, or treatment tables are often used to aid in immobilization, placement of organ shields, and patient support and comfort.

G. Treatment Delivery

TBI containing myeloablative transplant programs typically use fractionated or hyperfractionated regimens (twice a day or three times a day) over several days in order to minimize both acute and chronic toxicities and to minimize overall treatment time. Prior to treatment, any shielding of normal organs should be checked with portal images. In the setting of low-dose TBI, where total doses are typically only 2 to 4 Gy, organ shielding is usually not used. Dosimetry should be checked against department protocols to verify dose delivery at the extended distances that are used for treatment. A medical physicist should be available during all treatments in case of questions regarding dosimetric details, equipment function, patient setup, etc. Treatments are carried out by the radiation therapist per the [ACR Practice Guideline for Radiation Oncology](#) [23].

A physician should be in close proximity to manage any problems related to treatment. Avoidance of medications that may cause orthostatic hypotension and the administration of IV fluids for hydration or transfusions for anemia may help to prevent syncope or near-syncope episodes if the patient is treated in the standing position.

III. QUALIFICATIONS AND RESPONSIBILITIES OF PERSONNEL

Application of this guideline should be in accordance with the [ACR Practice Guideline for Radiation Oncology](#) [23].

A. Radiation Oncologist

The radiation oncologist should have had training in TBI procedures prior to embarking on any of these regimens.

The responsibilities of the radiation oncologist include:

1. Consultation and decision-making regarding the course of treatment.
2. Coordination of the patient's care with the transplantation service and other physicians.
3. Participation in the treatment planning process (immobilization techniques, simulation, block design, prescription, dosimetric and physics review, etc).
4. Review of treatment verification images.
5. Clinical assessment of the patient's tolerance during the treatment course.

B. Qualified Medical Physicist

The responsibilities of the Qualified Medical Physicist include: (see references [21-22] for helpful details relating to this section)

1. Establish and manage the system of dosimetric measurements, calculating and shielding.
2. Establish the system for beam-spoiling designed to adjust the dose at the beam entry surface.
3. Initiate and maintain a quality assurance program for TBI performance.
4. Act as a technical resource for planning of immobilization devices, dosimetry techniques, shielding, dose compensation devices, and bolus methods.
5. Calibrate the external beam delivery system and the in-vivo measurement system.
6. Direct supervision of dosimetry measurements and calculations for TBI delivery.
7. Verify the calculations performed by the dosimetrist.

C. Dosimetrist

The responsibilities of the dosimetrist include:

1. Generation of the dose calculations for treatment.
2. Dosimetry measurements.

D. Radiation Therapist

The responsibilities of the radiation therapist include:

1. Setting up the patient in the treatment position, including using appropriate treatment devices.
2. Verifying that the prescribed and calculated treatment distances match the utilized treatment distances.

3. Performing and reviewing of imaging procedures to verify the setup and blocking, if any.
4. Treating the patient according to the prescription and plan provided.
5. Monitoring and evaluating the patient during the treatments.

E. Nurse

The responsibilities of the nurse may include:

1. Educating the patient and family about the procedures, acute/late side effects, and procedures taken to promote safe/comfortable treatment.
2. Monitoring the patient's tolerance of the procedure to promote adequate supportive care.
3. Communicating any special precautions to the rest of the team regarding the care of immunosuppressed patients.

IV. EQUIPMENT

High-energy photon beams in the range of 4 to 18 MV are preferred for TBI. Early investigations in the use of helical tomotherapy for total body or selective total marrow irradiation show promise and warrant further study [27-28]. Additional equipment may include a fluoroscopy or CT simulator, immobilization devices, equipment for the manufacture of shielding, computers for dose calculations, a beam spoiler, custom bolus, custom compensators, and dosimetry and calibration devices. A backup beam delivery system must be available in case of unanticipated machine failure.

V. PATIENT AND PERSONNEL SAFETY

A. Safety measures should be in accordance with the [ACR Practice Guideline for Radiation Oncology](#) [23].

B. Special Patient Protection Measures

1. Charting systems for prescription; delineation of treatment parameters of the setup, including any position settings of the TBI stand; and treatment delivery record, including time of delivery for multiple treatments in a day.
2. Physics program for calibrating the treatment machine, independent checking of dose calculations, and monitoring of dose delivery to the patient.
3. Visual and audio contact with the patient during treatment.

VI. DOCUMENTATION

Reporting should be in accordance with the [ACR Practice Guideline for Communication: Radiation Oncology](#) [25].

VII. EDUCATIONAL PROGRAM

Continuing medical education programs should include radiation oncologists, physicists, dosimetrists, nurses, and radiation therapists. The program should be in accordance with the [ACR Practice Guideline for Continuing Medical Education \(CME\)](#) [29].

VIII. QUALITY CONTROL AND IMPROVEMENT, SAFETY, INFECTION CONTROL, AND PATIENT EDUCATION

Policies and procedures related to quality, patient education, infection control, and safety should be developed and implemented in accordance with the ACR Policy on Quality Control and Improvement, Safety, Infection Control, and Patient Education appearing under the heading *Position Statement on QC & Improvement, Safety, Infection Control, and Patient Education* on the ACR web site (<http://www.acr.org/guidelines>).

The Medical Director of Radiation Oncology is responsible for the institution and ongoing supervision of the Continuing Quality Improvement (CQI) program as described in the [ACR Practice Guideline for Radiation Oncology](#). It is the responsibility of the director to identify problems, see that actions are taken, and evaluate the effectiveness of the actions.

ACKNOWLEDGEMENTS

This guideline was revised according to the process described under the heading *The Process for Developing ACR Practice Guidelines and Technical Standards* on the ACR web site (<http://www.acr.org/guidelines>) by the Guidelines and Standards Committee of the ACR Commission on Radiation Oncology in collaboration with the ASTRO.

SUMMARY

Total body irradiation (TBI) is a specialized radiation technique often used prior to hematopoietic stem cell transplant (HSCT). Delivery of TBI requires knowledge of the clinical indications, specialized treatment setup, as well as dosimetric and physics staff with training in the procedures. Safe and accurate delivery of TBI can be performed with attention to the special indications, specific morbidities, and specialized treatment delivery measurements and techniques required for this procedure.

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*As of May 2010, all radiation oncology collaborative guidelines are approved by the ACR Council Steering Committee and the ACR Board of Chancellors and will not go through the ACR Council (ACR Resolution 8, 2010). The effective date is displayed below:

Development Chronology for this Guideline

2001 (Resolution 19)

Revised 2006 (Resolution 23)

Revised 2011 (CSC/BOC) – Effective August 1, 2011