SASCRO Statement on Appropriate Clinical Indications for Intensity Modulated Radiation Therapy (IMRT) or Volumetric Modulated Arc Radiotherapy (VMAT) as part of Universal Health Care Coverage in South Africa

Contents

A. GENERAL INFORMATION

IMRT is considered a standard of care in the treatment of many types cancer in South Africa. It is widely available, and used regularly, in many radiation departments– be they in the private or public sector.

1. Definition of IMRT / VMAT:

- IMRT is a high precision, high resource radiation treatment modality.
- IMRT is a form of static field modulated conformal radiotherapy that allows radiation to be delivered to complex shaped tumours volumes while relatively sparing normal tissues close to the target area.
- IMRT has been used for more than 15 years in clinical practice in many parts of the world and in South Africa increasingly over the last 10 years.
- VMAT is a non-static form of IMRT technique. The intensity of the radiation beam is continuously modulated as the radiation machine arcs around the patient.

2. Benefits of IMRT / VMAT:

3-D conformal radiotherapy (3DCRT) is an acceptable form of therapy in many clinical situations. However, IMRT / VMAT is preferred for cancer patients where delivery of a high dose of radiation to tumours and the protection of normal tissues is relatively complex but also critical to a successful outcome.
IMRT / VMAT with contemporary technology also allows for a higher through put of patients.
Thus IMRT / VMAT for specific indications results in:

1. a higher (i.e. more effective) doses of radiation to be delivered to tumours, and
2. reduced dose to normal tissue or organs at risk (OARs)[1]

[1] OARs – organs that may be permanently damaged by certain doses of radiation, e.g. eyes, brain, spinal cord, kidneys, heart, lung, bowel.

3. an increase in the therapeutic index[2] of the radiotherapy delivered
   This results in:
- improved tumour response rates
- reduced acute and late radiation side effects/toxicity
- improved long term clinical outcomes
- improved quality of life for cancer survivors

4. VMAT allows for reduced delivery time compared with static field IMRT

3. Processes and Quality Assurance in IMRT VMAT:

- IMRT uses computer-based planning technology and specialised radiotherapy delivery equipment.
- A team of specialised medical personnel trained in this form of specialised radiotherapy is central to this form of treatment.
- Stringent standards of quality assurance are particularly important in when patients are treated with hypofractionation – that is a reduced number of fractions.

The team consist of:
- radiation oncologists,
- medical physicists,
- planning radiation therapists or dosimetrists,
- treatment radiation therapists

The team are involved in:
- detailed delineation of target volume,
- complex planning protocols to maximise the technical advantages of this treatment,
- stringent medical physics quality assurance programme to ensure accuracy of the planning and radiation dose distribution,
- careful treatment delivery protocols,
- verification procedures to ensure the required optimization of the delivery of the radiation treatment at each radiotherapy treatment session.

4. Appropriate Care:

Successful IMRT programs involve the integration of many processes:
- appropriate patient selection based on clinical evidence.
- integrated processes in the selection, planning and treatment phases of IMRT,

IMRT should be used for the correct clinical indications, using peer-reviewed, evidence-based treatment protocols and guidelines on the appropriate use of IMRT (see below).

IMRT should only be performed in radiotherapy units where there are stringent QA/QC protocols for careful patient positioning/immobilization, scanning protocols, target definition, treatment plan development, and accurate treatment delivery.
The support of experienced medical physicists, planning and treatment radiation therapists are mandatory.

Facilities without the above quality assurance and clinical and technical competencies should not offer this form of specialised treatment due to the risk of poorer outcomes for cancer patients.

[2] Therapeutic index – achieving the greatest benefit without unacceptable side effects; favourable trade-off between treatment benefit and morbidity (also called therapeutic ratio)

5. Evidence for IMRT:

There is high level evidence for the benefit of this form of radiation therapy for numerous different clinical indications and lower level evidence for many others. The results from ongoing trials in several disease entities are eagerly awaited.[3]

The American Society for Radiation Oncology (ASTRO) considers **IMRT reasonable in instances where sparing the surrounding normal tissue is of added clinical benefit to the patient** (ASTRO, 2013) (1).
Examples of when IMRT might be advantageous include the following:

- the target volume is in close proximity to one or more critical structures and a steep dose gradient outside the target must be achieved to avoid exceeding the tolerance dose to the critical structure(s).
- a decrease in the amount of dose inhomogeneity in a large treatment volume is required to avoid an excessive dose "hotspot" within the treated volume to avoid excessive early or late normal tissue toxicity.
- a non-IMRT technique would substantially increase the probability of clinically meaningful normal tissue toxicity.
- the same or an immediately adjacent area has been previously irradiated, and the dose distribution within the patient must be sculpted to avoid exceeding the cumulative tolerance dose of nearby normal tissue.

ASTRO believes that tumour location, size, adjacent organs and dosimetry define the appropriate role for IMRT. **They support an approach where the clinical circumstances in addition to specific diagnoses are the most important determinants for using IMRT**.

B. CLINICAL INDICATIONS FOR IMRT / VMAT:

- IMRT / VMAT is largely restricted to patients who are being treated with radiation therapy with curative intent.
- The role of IMRT / VMAT in non-curative treatment is limited to patients:
  - for retreatment of an area that has previously received a radical dose of radiotherapy
  - where certain constraints or limits in the treatment planning are required for safe patient outcomes.

IMRT / VMAT is recommended as appropriate therapy in Universal Health Care Coverage in South Africa for the following specific indications.

1. **Anal cancer**
   - used with chemotherapy as curative treatment for disease localised to the pelvis. This reduces the need for debilitating surgery and colostomy.

2. **Cervical cancer**
   - in patients who have had surgery
   - for primary definitive treatment when para-aortic nodes require treatment

[3] INPACT (penile cancer); SCOPE 2 (oesophageal cancer); SCALOP 2 (pancreatic cancer); INTERLACE (cervical cancer)

3. **Oesophageal cancer**
   - localised disease where radical radiotherapy with or without chemotherapy is used

4. **Head and Neck Cancers**, including the following areas: pharynx (nasopharynx, oropharynx and hypopharynx), larynx, salivary glands, oral cavity (includes the tongue), nasal cavity and paranasal sinuses, trachea.
   - adjuvant or definitive neck nodal regions I - VII

5. **Central Nervous System**
   - primary or benign tumours of the brain, brainstem and spinal cord that are not suitable for surgical excision or stereotactic radiosurgery.

6. **Prostate cancer**
   - for patients with high risk of pelvic nodal involvement.
   - post brachytherapy boost therapy in higher risk patients to minimize dose to the rectum and bladder.

7. **Mediastinal tumours**
   - certain instances for Hodgkin's and non-Hodgkin's Lymphoma

8. **Localised pancreatic cancers**
   - borderline resectable or small unresectable primary tumours

9. **Paediatric Oncology Radiotherapy**

The role of radiation treatment generally in the paediatric population is limited in modern oncology. Proliferating tissues can be permanently damaged by radiation and permanently affect normal development.

The issue of a secondary malignant neoplasm due to radiotherapy that may develop after a prolonged latent period is also of concern.

The Royal College of Radiologists, Society and College of Radiographers, Children's Cancer and Leukaemia Group Good practice guide for paediatric radiotherapy have statements regarding the use of IMRT in the paediatric population that need consideration:

- Children should have access to IMRT where a superior dose distribution can be obtained
- Ideally the technique should be evaluated in clinical trials
- If IMRT is used outside a trial setting, long-term follow-up is mandatory

IMRT has the advantage of allowing for adaptive radiotherapy to better tailor the target volume if there is shrinkage of a tumour during a course of treatment.

In general, IMRT should be reserved for cases where there is proximity to sensitive structures or organs.

IMRT may be considered an option in paediatric practice to improve dose distributions and reduce long-term toxicity.

The use of VMAT rather than static field IMRT may be preferable in paediatric oncology in certain clinical situations.

10. Other indications:

- IMRT may be considered for a diagnosis that is not listed above when at least one of the following conditions is present:
  - A non-IMRT technique would substantially increase the probability of clinically meaningful normal tissue radiation toxicity.
  - The same or an immediately adjacent area has been previously irradiated, and the dose distribution within the patient must be sculpted to avoid exceeding the cumulative tolerance dose of nearby normal tissue.

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