Strål
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Swedish Radiation Safety Authority

Research

2014:03

Report from SSM's scientific council on ionizing radiation within oncology, 2012

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SSM perspective

Background

In 2009, the Swedish Radiation Safety Authority (Strålsäkerhetsmyndigheten, SSM) appointed a scientific council on ionizing radiation within oncology. The council consists of scientific experts in the fields of oncology and medical physics. Their task is to annually review and evaluate scientific developments in radiotherapy and to give SSM advice in issues where a scientific examination of different views is necessary. The council began its work in the autumn of 2009 and this is the third report presented.

The need to develop a protocol template regarding the radiotherapy section in health care programs and clinical study protocols was noted in the latest report. Such template could serve as guidance to create conformity in how protocols are written.

Objectives

The objective this year is to provide a radiotherapy protocol template for external beam radiotherapy accepted by the Swedish radiation oncology community, the Regional Cancer Centers, care program groups and other potential users.

Results

In this report, a finalized version of a radiotherapy protocol template for external beam radiotherapy is presented. The focus is on procedural aspects, while issues regarding clinical evaluation during and after treatment are not dealt with. The use of this radiotherapy template is encouraged for structured description of contemporary radiotherapy in care programs and clinical trial protocols.

The template is a living document that will be updated according to new experiences and new developments. Suggestions of additions, improvements and other comments are highly appreciated and may be sent to SSM (registrator@ssm.se)

Project information

Contact persons at SSM: Peter Björk and Catarina Danestig Sjögren
Reference: SSM 2012:20, SSM 2009/3757-22

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This report concerns a study which has been conducted for the Swedish Radiation Safety Authority, SSM. The conclusions and viewpoints presented in the report are those of the author/authors and do not necessarily coincide with those of the SSM.

Content

External beam radiotherapy protocol template

1. Background

In the 2011 report from the Swedish Radiation Safety Authority's (SSM) scientific council on ionising radiation within oncology (SSM report 2012:20) an analysis of the steps in the modern radiotherapy process was performed. It was observed that guidelines for modern radiotherapy were not up-to-date with advanced treatment techniques. It was concluded that new guidelines for writing protocols for contemporary radiotherapy are required, and that it would be desirable to develop a protocol template in order to provide guidance and conformity in writing the radiotherapy sections in health care programmes and clinical study protocols of different complexity, i.e. suitable for both standard and advanced treatments.

Following the SSM report 2012:20, a radiotherapy protocol template for external beam radiotherapy was proposed and actively distributed to the Swedish radiation oncology community, the Regional Cancer Centres, care programme groups and other potential users. Upon request, it was also distributed internationally. Professionals were encouraged to use it and report their experience to the SSM council before February 2013. The council received several comments from care programme groups and other groups or individuals with an interest in radiotherapy. Constructive critique was given, although the comments were mostly positive in a general way.

2. Result

In this report, a finalized version of a radiotherapy protocol template for external beam radiotherapy is presented, se Appendix. The special requirements for description of brachytherapy are not met in the current version. The framework for the template, regarding content and layout, is discussed in detail in the above-mentioned report. The focus is on procedural aspects, while issues regarding clinical evaluation during and after treatment (e.g. acute and late toxicity, quality of life assessment, unexpected adverse events) are not dealt with. These issues should be included in other parts of the study protocol/health care programme.
The template is written in a general format and has to be completed for the specific clinical situation and diagnosis. It should be incorporated into another document where all other relevant information should be detailed (e.g. inclusion and exclusion criteria if a trial, timing and relation to other treatments, unless given concomitantly, etc.). The items within square brackets in the template are meant as examples (not in any way exhaustive), and should be replaced appropriately. Additional items may be included, and irrelevant parts should be deleted. The final phrasing of the body text is of course at the protocol author's discretion.

It is the ambition of the council to publish an abbreviated version of the 2011 report together with the template in a peer-reviewed international oncology journal. It is also the intention to translate it into Swedish.

3. Concluding remarks

The use of this radiotherapy template is encouraged for structured description of contemporary radiotherapy in care programmes and clinical trial protocols. Suggestions of additions, improvements and other comments are highly appreciated and may be sent to SSM (registrator@ssm.se). Even if the present template has been practically used and found well-functioning, it must be a living document that can be modified according to new experiences and new developments.

4. The members of the scientific council

The members of the scientific council on ionizing radiation within oncology producing this report were as follows:

- Professor Klas Blomgren, paediatric oncologist
  Barncancercentrum, Drottning Silvias barn- och ungdomssjukhus, Göteborg

- Associate professor Crister Ceberg, medical physicist
  Avdelningen för Medicinsk Strålningsfysik, Lunds Universitet, Lund

- Associate professor Giovanna Gagliardi, medical physicist
  Avdelningen för sjukhusfysik, Karolinska Universitetssjukhuset, Stockholm

- Professor Bengt Glimelius, oncologist (chairman)
  Onkologiklinikerna, Akademiska sjukhuset, Uppsala och Karolinska Universitetssjukhuset, Stockholm

- PhD Mikael Johansson, oncologist (secretary)
  Cancercentrum Norrlands Universitetssjukhus Umeå

- Associate professor Elisabeth Kjellén, oncologist
  Skånes onkologiska klinik, Skånes Universitetssjukhus Lund

- Professor Per Nilsson, medical physicist
  Skånes Onkologiska klinik, Skånes Universitetssjukhus Lund

- Professor Sten Nilsson, oncologist
  Onkologkliniken, Karolinska Universitetssjukhuset, Stockholm

5. Reference

SSM Report from SSMs scientific council on ionizing radiation within oncology (SSM Report 2012:20).

Appendix: External beam radiotherapy protocol template

Radiotherapy protocol for [diagnosis, stage, etc.]

Patient pre-treatment preparation

- A [*thermoplastic mask-mould/breast board/vacuum bag/leg fix/body fix/SBRT frame/SRT frame/…*] immobilisation device shall be [*manufactured/individualized*] for [*supine/prone*] patient position.
- [*Dental spacers/additional accessories*] shall be prepared and fitted to the patient.
- The patient reference coordinate system is defined by using [*tattoos/implanted fiducial markers/…*], positioned [*x days/weeks*] before preparatory imaging.
- The patient shall have [*empty-full bladder/rectum/…*] during imaging and treatment.

Pre-treatment imaging

- For structure delineation, [*CT/MRI/PET/…*] imaging shall be performed with [*oral/IV contrast agent/tracer*] according to [*scanning protocol*].
- The [*CT/MRI*] scanning shall be performed from [*anatomical landmark*] to [*anatomical landmark*].
- Image sets from the different modalities shall be registered by using [*specified registration technique*].
- Time resolved imaging will be obtained using [*4D imaging technique*].
- Reference imaging for IGRT shall be made with well-defined origin according to external [*optical surface scanning/…*] or internal reference system [*fiducials/…*].
- Imaging for treatment planning calculations shall be performed with [*CT/MRI*] according to [*scanning protocol*].

Specification of treatment prescription

- Volume specification
    - The recommendations made by ICRU shall be followed.
    - The volumes shall be delineated with [*grey scale window centre and width*]. The smallest volume that is allowed is [*size*].
    - The Gross Tumour Volume(s) (GTV) shall include [*all visible tumour growth*] based on [*CT/MRI/CT-PET/…*]. Any boost GTV shall include […].
    - The Clinical Target Volume(s) (CTV) shall include [*structures, lymph node stations, GTV plus margin for microscopic extent of tumour, known (painful) skeletal lesions with a margin of x cm/anatomical structure/…*] based on [*clinical assessment/anatomical atlas/…*].
    - The Planning Target Volume(s) (PTV) shall include [*margins for set-up uncertainties/…*].
    - The [*optical chiasm/spinal cord/lung/kidney/rectum/…*] shall be delineated as Organ(s) at Risk (OAR) based on [*anatomical atlas/…*].
    - The Planning Organ-at-Risk Volume(s) (PRV) for the [*optical chiasm/spinal cord/…*] shall be delineated using [*x mm*] margins.
    - Target and organs-at-risk motion shall be taken into account by using [*margins/gating/tracking/…*].

- Absorbed dose prescription
    - The prescribed total absorbed dose is [D] Gy, specified as [*dose to a reference point/dose to the target volume(s)/dose-volume objectives*].
    - For treatment planning optimisation, [*physical/biological*] objectives and constraints shall be prioritised according to [*priority order/volume/endpoint/objective/constraint/…*].

Table: Example of prescription priority list

Priority	Volume	Constraints	Objectives	Endpoint
1	CTV	D_{min} ≥ 74 Gy		
2	PTV	V_{74Gy} ≥ 95%		
3	Rectum		V_{70Gy} ≤ 15%	Grade ≥ 2 late rectal toxicity < 15%
4	PTV		$D_{98\%}$ ≥ 70 Gy	
5	Rectum		V_{60Gy} ≤ 35%	Grade ≥ 2 late rectal toxicity < 15%
6	FemoralJoint		$D_{2\%}$ ≤ 55 Gy	Femoral head necrosis
7	Rectum		V_{50Gy} ≤ 45%	Grade ≥ 2 late rectal toxicity < 15%
8	External		D_{max} ≤ 82 Gy	

- Fractionation and treatment time
    - Radiotherapy is given [*daily/BID/every other weekday/…*], [*n days/week*] with [*N*] fractions of [*d*] Gy.
    - The minimum time between daily fractions is [*t hours*].
    - Boost is given [*sequential/concomitant/simultaneous*].
    - Minimum and maximum allowed treatment days are [*Nmin, Nmax*].
    - Unintended interruptions shall be compensated within the intended overall treatment time according to [*BED/EQD$_x$/modified fractionation schedule*].

Relation to other concomitant therapies

- Surgery
    - Radiotherapy is given [*pre-/post-*] operatively.
    - The intention with the pre-operative treatment is to reduce [*tumour size/risk of loco-regional recurrence/…*]
    - Radiotherapy should start [*n days/weeks/months*] [*before/after*] surgery.
    - Details about the surgical treatment are stated in chapter [*x*] in the treatment protocol.
- Drug therapy
    - Radiotherapy is given [*pre-/concomitant/ post-*] chemo-therapy.
    - Concomitant chemotherapy shall be given [*n hours before/after*] the radiotherapy fraction.
    - Details about the chemotherapy are stated in chapter [*x*] in the treatment protocol.

Treatment planning and delivery

- Treatment technique
    - The radiation treatment shall be given with [*radiation type/beam quality/dose rate*] and [*3DCRT/IMRT/VMAT/HT/…*] technique.
    - [*Machine dependent constraints, e.g. leaf travel, segment size, etc. shall be reported*].

- Dose computation
    - Reference dosimetry is carried out according to [*IAEA*], and verified through the [*dosimetry audit program/…*].
    - The absorbed dose in the patient geometry shall be calculated by using [*analytical algorithm/MC*], and presented as absorbed dose to [*water/tissue*].
    - The calculation grid shall be [*3D size and resolution*].

- Treatment plan evaluation
    - The choice of the final treatment plan shall be documented by [*dose/volume summary/fulfilment of objectives and constraints/…*].

- Image-guided and adaptive treatment delivery
    - The [*position/shape/size/response*] of the [*patient/target(s)/fiducials/OAR(s)*] shall be re-estimated based on [*CBCT/MRI/PET/…*].
    - The verification shall be performed [*before/during*] the treatment at [*frequency*], and a statistical analysis shall be performed after [*n/all*] treatments.
    - Based on the analysis, the treatment [*delivery/plan*] shall be [*guided/adapted*] according to [*protocol for corrective action/replanning criteria*].
    - The additional absorbed dose contribution due to imaging procedures is estimated to [*X Gy*].
    - The treatment delivery shall be adapted during the radiotherapy course according to [*tumour response/toxicity/…*] in order to [*maximise TCP/minimize NTCP/…*]. Evaluation of [*tumour/normal tissue*] response shall be based on [*CT/PET/MR/CBCT/…*] performed [*timing and frequency*] during the radiotherapy course in order to change [*treatment schedule/modality/…*].

- In-vivo dosimetry
    - The absorbed dose to the patient shall be estimated based on [*in vivo measurements/in vivo dose reconstruction/…*].
    - The verification shall be performed [*during/after completion of*] the treatment at [*frequency*] and a statistical analysis shall be performed after [*n/all*] treatments. Based on the analysis the treatment [*delivery/plan*] shall be adjusted according to [*protocol for corrective action*].

Quality Management

- Preparatory
    - Dummy run(s) will be performed before the [*start of study/commissioning of new treatment/…*].

- Pre-treatment patient specific dosimetry
    - The treatment for each new patient shall be independently verified with [*independent calculations/measurements*].
    - The delivery shall be compared to the plan, and analysed with [*absorbed dose difference/DTA/gamma*] using acceptance criteria of [*%/mm*] and the pass rate shall be better than [*%*].
    - In case a plan is not passing the acceptance criteria, the reasons shall be further analysed, and [*replanning/change of technique/….*] shall be considered.

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The Swedish Radiation Safety Authority has a comprehensive responsibility to ensure that society is safe from the effects of radiation. The Authority works to achieve radiation safety in a number of areas: nuclear power, medical care as well as commercial products and services. The Authority also works to achieve protection from natural radiation and to increase the level of radiation safety internationally.

The Swedish Radiation Safety Authority works proactively and preventively to protect people and the environment from the harmful effects of radiation, now and in the future. The Authority issues regulations and supervises compliance, while also supporting research, providing training and information, and issuing advice. Often, activities involving radiation require licences issued by the Authority. The Swedish Radiation Safety Authority maintains emergency preparedness around the clock with the aim of limiting the aftermath of radiation accidents and the unintentional spreading of radioactive substances. The Authority participates in international co-operation in order to promote radiation safety and finances projects aiming to raise the level of radiation safety in certain Eastern European countries.

The Authority reports to the Ministry of the Environment and has around 270 employees with competencies in the fields of engineering, natural and behavioural sciences, law, economics and communications. We have received quality, environmental and working environment certification.

Strålsäkerhetsmyndigheten
Swedish Radiation Safety Authority

SE-171 16 Stockholm
Solna strandväg 96

Tel: +46 8 799 40 00
Fax: +46 8 799 40 10

E-mail: registrator@ssm.se
Web: stralsakerhetsmyndigheten.se