ABSTRACT

A fundamental problem in radiotherapy is the variation of organ at risk (OAR) volumes. Here we present our initial experience in engaging a large Radiation Oncology (RO) community to agree on national guidelines for OAR delineations. Our project builds on associated standardization initiatives and invites professionals from all radiotherapy departments nationwide. Presently, one guideline (rectum) has successfully been agreed on by a majority vote. Reaching out to all relevant parties in a timely manner and motivating funding agencies to support the work represented early challenges. Population-based data and a scalable methodological approach are major strengths of the proposed strategy.

1. Introduction

A fundamental problem in radiotherapy (RT) is the variation in volumes for organs at risk (OAR) [1,2]. OARs are ideally contoured based on consensus guidelines and published delineation atlases, but opinions about which anatomical landmarks to use as references still diverge across different studies, countries, and continents [3]. In reality, OAR delineations are often left to the judgement of treating healthcare professionals resulting in significant volume variations between practitioners. It is well recognized that the real-life quality of data regarding delivered doses to OARs, therefore, can be of variable quality. This makes it hard to relate and dose volume metrics to treatment outcomes both in clinical practice as well as in clinical studies [1,2,4] and can potentially even affect treatment decisions.

To date, multiple consensus guidelines for various body sites and OARs have been published [5–10]. There are also guidelines for the naming of OARs [11,12]. Educational efforts at larger international conferences, such as those offered by ESTRO and ASTRO, also take a large responsibility for teaching professionals how to contour and name OARs according to many of these, but the wider radiation oncology (RO) community lacks a strategy for how to implement such guidelines on a larger scale. Vaguely defined standard OAR delineation references and suboptimal compliance with these poses a particular problem for the growing number of “big data” efforts in RO. The lack of delineation standards for normal structures in this context was pointed out by several scientists at a recent workshop, where both the need for foundational work and large community efforts were acknowledged as means to counteract this [3,13].

This paper describes an approach to reach the agreement on OAR
delineation guidelines on a national scale and the early experiences with executing such an activity. Our aim was to find a strategy involving the whole RO community nationally to reduce variability in clinically-used OAR volumes. The present work has a developmental character with the overall project being based on a multi-step plan inviting clinically active professionals from all national RT departments.

2. Materials and methods

This project started as a national initiative by members of the Swedish RT-register steering committee in Sweden in 2016 and is referred to as STRÅNG (acronym for the project in English: STRONG).

2.1. Overall project outline

We devised a multi-step plan, where key decision makers and RO professionals were identified and approached for project approval purposes. Applications for funding and ethical approval were submitted to relevant agencies/authorities in 2017. The latter was created as a multi-centre application to allow participation from all RT departments (n = 17, including both University and County Hospitals; granted by the Regional Ethical Agency in Gothenburg, Ref no.: Dnr 641-17/ T1115-18).

The core of the plan evolves around clinical residents in RO being invited to execute sub-projects for a limited number of clinically-relevant OARs as part of a compulsory learning objective during their clinical rotation. This is to be followed by a national comment round involving a panel of RO experts from all RT departments to reach a decision of acceptance or rejection of the proposed guideline based on a majority vote. As a final step, contour variability between clinically-used OAR volumes and OAR volumes according to an accepted guideline will be quantified, as will potential effects on treatment decisions and associated toxicities. This last aspect includes ongoing work and will not be reported here.

2.2. Identifying OARs used in clinical practice

A survey was directed to all RT departments to collect baseline data and identify regularly-used OARs in clinical practise. The departments were asked to fill in a table listing example OAR names in different body sites (Breast, Central nervous system [CNS], gastrointestinal [GI], genitourinary [GU], Head and Neck [HN], and Other) and report to what extent and with what frequency these or other OARs were contoured. The pre-written number of entries was 65 with 12 structures listed for ≥2 body sites (Bladder, Bowel, BowelBag, BrainStem, BronchialPlexus, Esophagus, Eye, FemoralHead, Heart, Lens, Lung, and SpinalCord); possible answers were “always”, “sometimes”, and “never”.

2.3. Planning and executing sub-projects in detail

Each sub-project will include approximately five OARs within a certain body site and will be conducted in a preparatory phase (all OARs) and in an evaluating phase (OARs where contour variability can be evaluated; Fig. 1).

Anatomical landmarks for selected OARs (identified as described above) will be suggested based on a structured literature search by participating clinical residents in RO guided by their local supervisors. Publicly available imaging datasets (CT and MRI) for visualisation of examples will be used when possible, but we expect that additional data from a small number of patients may also need to be collected. After approval of written and visual examples by a radiologist with expertise within the body site of interest, proposed guidelines will be sent to RO experts within the relevant anatomical site. These are then to be returned with either a recommendation of acceptance or suggestions of amendments of identified limitations. Agreement will be established as ≥50% of experts approving both text and image example(s) for a given guideline. Guidelines for each structure by this majority vote will finally be made publically available through RO-specific organizations and communicated back to the RT departments through educational workshops/meetings.

2.4. Current state of project

To date, we have arranged local and national meetings with residents in training at multiple occasions and we have participated at national RO meetings to inform about project outline and recruit local project members. In addition, discussions with representatives from the Radiation Safety Authority and the Regional Cancer Centers, two key stakeholders in the Swedish RO community, are ongoing to discuss possibilities to present the results of this project to healthcare professionals on a larger scale and through their established infrastructures. Both are official bodies of the Swedish government and work to protect citizens from the harmful effects of radiation and to assist in providing cancer care on equal terms to all patients, respectively. A first sub-project with guidelines for rectum (anatomical landmarks for male pelvis as suggested by RTOG, ASTRO and ESTRO ACROP) [8,14] have been completed using CT and MRI data from the Gold-Atlas project [15].

3. Results

3.1. OARs used in clinical practice

The survey was conducted in fall 2018 with responses from all 17 RT departments and revealed large local differences in terms of OARs contoured in clinical practice. Of the initial 65 OAR listings, 16/10/13 entries was reported as “always”/“sometimes”/“never” contoured in clinical routine by a majority of departments (≥9/17). The results for OARs reported as “always” are summarized in Table 1.

3.2. First sub-project on male pelvis and rectum volumes

For a first comment round to agree on the proposed guidelines, written information about anatomical landmarks for rectum (in Swedish) were presented to GI/GU experts at all RT departments on December 14, 2018, together with accordingly delineated volumes on one non-surgically-treated prostate cancer case. Instructions of how to respond to our request were included. Within two months’ time, expert opinions from a first evaluation round resulted in a majority vote in favour of the proposed guideline (in total, 10 departments responded by April 9, 2019 when we decided to close the round). The expert evaluations revealed a substantial discrepancy primarily concerning length differences between the suggested guideline and the local clinical practice for delineation of rectum, with anatomical landmarks either being determined by the extent of the planning target volume or by referring to the whole anorectum.

4. Discussion

The importance of efforts aiming at standardization in RT including minimizing OAR volume variability cannot be overstated. Standardized delineation of treatment volumes and OARs is of highest importance to compare treatment planning, dosimetric results and, to some extent, clinical outcomes. To the best our knowledge, the STRÅNG initiative is first out to suggest a strategy of how to implement delineation guidelines exclusively dedicated to OARs at all treatment sites on a national scale. So far, we have established a multi-professional collaborative network and a strategy to involve one large RO community to reach national agreement on written- and visually-presented guidelines. Logistics for the proposed strategy has been tested successfully in a pilot...
project setting including male pelvis and rectum as a first OAR and the strategy is now being extended to involve RO residents in training.

When a RO community adheres to guidelines for the naming of OARs, the first step towards achieving findable, accessible, interoperable, and reusable (FAIR) RT data [16] is taken. However, if the underlying volumes are created without associated guidelines for the delineation of OARs, the use of such collected data will be limited by effects of inconsistently reported dose. Our proposed strategy aims to obtain agreement on both aspects in one large community using accepted OAR nomenclature and OAR delineation guidelines and has the potential to provide national references both for automated image segmentation [17] and large-scale imaging processing algorithms in the future. In an era of “big data” efforts and where transition into AI-based delineations of both target and OARs are becoming a reality, data harmonizing initiatives such as STRÅNG, to assure consistency and to provide benchmark datasets for validation and testing of these new technologies, are urgently needed. Another area of importance in this context is to agree on which OARs to be contoured for different disease sites. A recent publication by Wright et al. [18] summarizes recommendations for this and includes various resources that define tissue delineations. In contrast to our approach here, they neither present associated anatomical landmarks as such nor do they suggest how to implement their recommendations on a larger scale. In fact, a PubMed search on June 26, 2019, found no relevant publications on this subject using various combinations of the search terms (and equivalents thereof) “radiotherapy”, “standardization”, “normal tissue”, “guideline”, and “implementation strategy”.

Internationally, there are several examples of strategies to reduce contour variability of target volumes, most of them being focused on clinical target volume (CTV) standardization for one particular treatment site in a specific study protocol [19–22]. For instance, the Belgian initiative PROCARE [21] took a national approach to improve outcome in rectal cancer patients between 2003 and 2014, including the creation of a central review platform to reduce variability for CTV delineation. All 25 national centers were invited to participate, and the full operation was successfully established between 20 centers in 2011 leading to increased uniformity in CTV delineations between them. Keeping in mind that our work only concerns the identification of guidelines for OARs, it is still interesting to note that there is a similarity between our voluntary multidisciplinary strategies with respect to identifying guidelines by both a literature review and the use of visual examples. Otherwise, the two strategies are fundamentally different with PROCARE providing feedback on uploaded cases to clinicians and our strategy having more of an educational aspect for residents in training. Knowing that the use of digital platforms such as the Anatom-e and eContour have as well been shown to increase the consistency of delineation processes [19,20,23] we also aim to take the educational aspect of STRÅNG further and have ongoing discussions about how to integrate our guidelines into such RO educational tools.

The proposed approach of STRÅNG has several strengths. If RO residents in training can be made aware of the importance of standardized OAR volumes when being introduced into clinical RT work, they can be expected to comply to such guidelines in the future. Acceptance among senior colleagues is also more likely if they are invited to

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**Table 1**

OARs contoured in clinical practice by a majority of RT departments. Grouped by anatomical sites; number of originally listed OARs in national survey from 2018/total number or OARs including departmental additions in parentheses.

| OAR reported as “always” included in clinical routine | Breast (n = 16/19) | CNS (n = 13/16) | GI (n = 10/13) | GU (n = 6/11) | HN (n = 18/23) | Other (n = 2/2) |
|--------------------------------------------------|------------------|----------------|----------------|----------------|----------------|----------------|
| Bladder                                          |                  | 16 (94%)       |                |                |                |                |
| BrainStem                                        |                  | 14 (82%)       |                |                |                |                |
| Chiasm                                          | 13 (76%)         |                |                |                |                |                |
| Cochlea                                         | 10 (59%)         |                |                |                |                |                |
| Eye                                             | 11 (65%)         |                |                |                |                |                |
| External/Body                                    |                  |                |                |                | 17 (100%)      |                |
| FemoralHead                                     | 12 (71%)         |                |                |                | 9 (53%)        |                |
| Heart                                           |                  | 11 (65%)       |                |                |                |                |
| Lens                                            | 12 (71%)         |                |                |                |                |                |
| Lung                                            | 17 (100%)        |                |                |                |                |                |
| OpticNerve                                      | 12 (71%)         |                |                |                |                |                |
| Parotid                                         |                  |                |                | 12 (71%)       |                |                |
| Rectum                                          | 16 (94%)         |                |                |                | 14 (82%)       |                |

**Abbreviations:** CNS = central nervous system; GI = gastrointestinal; GU = genitourinary; HN = head and neck.

**Note:** Percentages are calculated based on originally listed OARs in survey.

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1 FemoralHead and Kidney were contoured in clinical practice at 8/17 departments (47%).
participate in the decision process of a proposed guideline. Furthermore, if expert groups in oncology can be convinced to integrate guidelines with other clinical recommendations on cancer diagnosis, treatment, and follow up, they can reach the wider RO community through already established infrastructures. In Sweden, the latter is partly coordinated by the Regional Cancer Centers. Challenges with the proposed strategy include difficulties to coordinate the number of parties involved and to reach out to all of them in a timely manner. The administrative efforts are in direct proportion to the scale of the project. It will take a lot of networking and coordination to build the multi-professional network needed to reach the goal. For our conditions, we have identified that a full-time national coordinator will be required to orchestrate this in the long-term. Educational initiatives can be expected to add to this through the need for planning, organizing, and executing national meetings/workshops/on-site visits.

The successful outcome of the project so far can partly be attributed to previous RT data standardization initiatives in Sweden where improvements on the national level have already been generally accepted by our community, the national naming convention [24] and the Medical Information Quality Archive (MIQA) [25]. The level of acceptance and commitment from the individuals and official bodies involved in the project was, therefore, high already from the beginning. How a similar strategy would fare in other countries will depend on their previous experience of data standardization initiatives and existing RO infrastructure. Finding financial support for infrastructural work can, however, be expected to be difficult in early stages of projects like these [3,13]; this is something we encountered here as well. Still, the advantage of having one unified approach to harmonize RT data per country is unquestionable if challenges of world-wide data sharing/integration to optimally tailor treatments according to patient’s needs are to be met.

In summary, we present the initial experiences with introducing national guidelines for CT- and MRI-based delineation of organs at risk in RT. The presented initiative aims to create a solid foundation for how to delineate OARs by taking a scientific approach when identifying and evaluating appropriate guidelines and by involving relevant parts of our RO community when searching for agreement and acceptance of them. National population-based data and scalable methodological approach including educational aspects for residents in RO are the major strengths of the project. Our hope is that this initiative will inspire more countries to devise strategies to obtain consistent OAR volumes in RT for reliable high-quality data in multicentre clinical trials, clinical follow up as well as quality assurance studies. Only when there is an agreement on which OARs to delineate, how to delineate them, and what to call them, each RO community has done their part in contributing towards FAIR RT data.

Conflict of interest statement

The authors of the manuscript have no conflict of interest to declare.

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