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Clinical practice in stereotactic radiotherapy delivery at treatment unit: a practitioner survey and consensus-based recommendations for multidisciplinary professional development

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Abstract

Purpose Stereotactic radiation therapy (SRT) is on the rise around the world. We aimed to provide recommendations to streamline and assess medical practices in SRT delivery at treatment unit, while complying with legal obligations concerning safety.

Materials and methods We conducted an online closed practice survey for heads of radiotherapy departments both nationally in comprehensive cancer centers and university hospitals throughout France, and internationally. The aim was to obtain a better understanding of how the delivery of SRT at treatment unit was managed across different centers according to experience, and to the machines and repositioning techniques used. Radiation oncologists (ROs) were also asked to assess the difficulties of technical implementation in the department, and whether residents were involved in the validation and delivery of SRT. Differences among countries regarding legislation governing the validation of SRT sessions at treatment unit were also collected. A videoconference was then held to draw up proposals for regulatory changes based on the results obtained. Finally, recommendations were drawn up by the steering committee and approved by heads of radiotherapy departments in comprehensive cancer centers and university hospitals throughout France.

Results Thirty-five French centers and 15 centers from 14 foreign countries responded to the questionnaire. The most common stereotactic machines were Varian Truebeam STX® (45%) and Cyberknife® (39.2%). The departments had been performing SRT for more than 10 years in 60.5% of cases, and for less than 5 years in 10.1% of cases. A RO validated the SRT fractions at each session in 62.9% of French departments, while in countries outside France RO validation concerned the first fraction only for 35.3% or was performed only in the event of an issue for 23.5%. RO patient positioning validation of SRT fractions were considered as: time-consuming / task-interrupting (80%); having no added value with regards its systematic use (41.8%); and leading to a loss of machine time (33.1%). Most

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heads of departments would like to see an evolution towards systematic RO validation for the first session, then validation by a radiation therapist (RTT) for all subsequent sessions, leaving open the possibility of RO intervention when required in case of difficulty. We drew up a task delegation procedure to meet these requirements.

Conclusion Comparing the French practice to international ones confirmed the need to develop and harmonize recommendations in terms of patient positioning validation at treatment unit. Regulatory changes incorporating a competence transfer to RTTs, particularly after the empowerment process, is key. However, these changes need to be adapted to the experience of each Center and to that of each RTT, as assessed with clearly established criteria and learning curve.

Keywords Stereotactic radiotherapy, Radiation oncologist validation, Patient positioning verification, Legislation, Regulatory framework

Introduction

Stereotactic radiotherapy (SRT) indications are increasing in radiation oncology departments around the world. For example in France, this increase is observed in both intra (66% of centers in 2021 vs. 45% in 2017) and extra cranial SRT (60% of centers in 2021 vs. 45% in 2017) [1]. SRT relies on precise spatial localization and real-time tumor tracking, achieved through either frame-based or frameless systems, ensuring accurate alignment between the treatment unit and the patient's anatomy. This procedural precision enables dose escalation [2, 3]. Due to the high doses delivered per fraction with SRT, special attention to the quality assurance and safety aspects of SRT is required. Solberg et al. [4] summarized the quality and safety considerations for a robust and effective SRT program. The United Kingdom Stereotactic Ablative Body Radiation Therapy (SABR) Consortium report provides a detailed overview of recommendations for SRT programs, covering aspects of safety, quality assurance, and treatment protocols across various anatomical sites [5]. Several reports, guidelines, reviews, and textbooks have been published to provide a framework for the practice of SRT. In France, regulations require the validation of the radiation oncologist (RO) for all radiotherapy sessions with doses strictly exceeding 8 Grays (Gy), regardless of the radiotherapy technique. This decree thus establishes the threshold for the autonomy of radiation therapists (RTTs), beyond which, in hypofractionated radiotherapy, the RTT must be assisted by a RO or a medical physicist for the entire duration of the treatment [6]. The French recommendations are the only ones to set a threshold. In 2010, the American Association of Physicists in Medicine Task Group 101 (AAPM TG-101) published a report providing comprehensive guidance to SRT treatment delivery as well as recommendations on clinical implementation, quality assurance, quality improvement, and patient safety. The role of the various members of the treatment team (RO, medical physicist, RTT) is specified. Specifically, the RO was recommended to approve the result of the image guidance and verify the positioning images before every fraction [7]. This mission has been largely superseded by NRG recommendations and ASTRO/ACR Practice Guidelines for stereotactic radiosurgery (SRS) and stereotactic body radiation therapy (SBRT) [8–11]. According to ASTRO/ACR Practice Guidelines, RO oversees treatment, ensuring accurate patient positioning, image guidance, and motion review. They approve these aspects before delivery and are present at the start of each fraction, remaining available for any issues. The RTT performs image-guided radiation therapy (IGRT), assists in patient review, and operates the treatment unit after RO and physicist approval, ensuring precise treatment delivery. The medical physicist is present during the first fraction to oversee setup, image guidance, and motion review, working with the RO to ensure technical accuracy and addressing any issues during treatment [10]. More recently, AAPM published practice guidelines for SRT, describing the role of the medical physicist [12]. It is notified that a qualified medical physicist with relevant SRS/SBRT training must provide personal supervision during the entire first treatment session, particularly for patient setup to verify immobilization imaging, registration, gating, and set up correction. The physicist is responsible for the technical aspects required to validate the treatment, while the clinical aspects are managed by the RO. For subsequent sessions, direct supervision must be provided by either the medical physicist who was present during the first session or another qualified medical physicist. The Canadian Association of Radiation Oncology scope of practice guidelines seem to offer greater flexibility recommending that the RO validates at least the first session. Alternatively, a medical physicist may fill this role once appropriately trained in the image guidance specific to the site, but it is recommended that the RO be available to help in communicating the purposes of therapy and IGRT [13].

However, with the development of SRT in terms of technique and indications, these recommendations are deemed time-consuming and difficult to systematically implement into the daily routine. Indeed, in the absence

of data supporting the added value of RO validation compared to RTT validation for SRT fractions, questions are raised as to its usefulness. Moreover, technological advancements in SRT have coincided with increasing expertise of RTT teams. Validation by an RO may not therefore be necessary for all routine clinical situations, although there exist some higher-risk situations where RO presence is required, such as reirradiation and single fractions.

The aim of our manuscript is to provide relevant benchmarks, to harmonize practices governing the delivery of SRT fractions and to reduce unnecessary interruption of medical tasks while ensuring safe treatment delivery, informed by a practice survey conducted in France and abroad.

Materials and methods

Working group and review group

A group of ROs was created through the mailing list of the heads of radiation oncology departments in comprehensive cancer centers as well as university and regional hospitals throughout France. A medical physicist, a head of RTT and a head of quality officer were also involved to provide a multidisciplinary approach, enrich discussions, and ensure that all the recommendations made complied with the French legal framework.

Guidelines construction

The guidelines were developed in three steps:

(i) A closed and voluntary practice survey was developed comprising 13 multiple-choice questions to understand current practice in French oncology departments, the difficulties encountered in daily practice and what improvements could be made (see Appendix). The quality, usability, and technical functionality of the web-questionnaire were tested by the steering committee before fielding. Each question was followed by a free comment to give respondents the opportunity to expand on their answer. Respondents were able to review and change their answers until final dispatch of the questionnaire. The questionnaire was distributed by e-mail to 40 public radiotherapy centers in France using Google Form, with an automatic method for capturing responses. The survey was conducted from December 2022 to March 2023, requiring 4 reminders.

(ii) Results obtained in France were compared with those in other countries to optimize recommendations, using the same Google Form. Before releasing the form internationally, adaptations were made to specify the locations considered to have a higher risk of anatomical errors (e.g., risk of incorrect vertebral level) and requiring RO validation. Distribution was achieved individually by e-mail and more globally by Linked In. The survey was conducted from June 2023 to January 2024.

(iii) Guidelines were developed after several videoconferences before being reviewed and validated by the entire working group.

Legal aspects

The proposed guidelines adhere to all legislative frameworks published to date. All respondents gave their consent to participate in this survey.

Conflicts of interest

None of the members of the working group have any conflicts of interest related to this subject.

Results

French practice survey

Thirty-five of the 40 heads of French radiation oncology departments of comprehensive cancer centers or university hospitals answered the web-questionnaire, corresponding to a response rate of 87.5%. All questionnaires were fully completed.

Experience of SRT in France

France has extensive experience in SRT, with more than 10 years use for 57.1% of centers, 5 to 10 years for 28.6% and less than 5 years for just 14.3%. SRT is mostly performed on Varian Truebeam STX® (42.9%), Cyberknife® (31.4%) and Novalis STX® (28.6%). To a lesser degree, Elekta Versa HD® (17.1%) and MRI Linac MRIdian ViewRay® (11.4%) are also used.

SRT procedure in France

Validation of SRT fractions is done by the RO at each fraction in 62.9% of the departments, at first fraction only in 17.6%, only for fractions considered at risk (e.g., risk of incorrect vertebral level) in 5.7%, and depending on the technique and dose used for 14,3% (Fig. 1A). However, SBRT fractions ≤ 8 Gy are validated by ROs in 65.7% of cases, in proportions similar to conventional radiotherapy (51.4%). On a scale of 1 to 10, heads of radiation departments rated the difficulty of implementing the current recommendations in routine clinical practice as 5 (median score) [2–7], with a scale from 0 (no difficulties) to 10 (many difficulties). In this context, final year residents may sometimes (31.4%) be asked to validate positioning images but usually never (40%), while for 5.7% they are often or always asked. In the large majority of centers (80%) other more junior residents never validate positioning images.

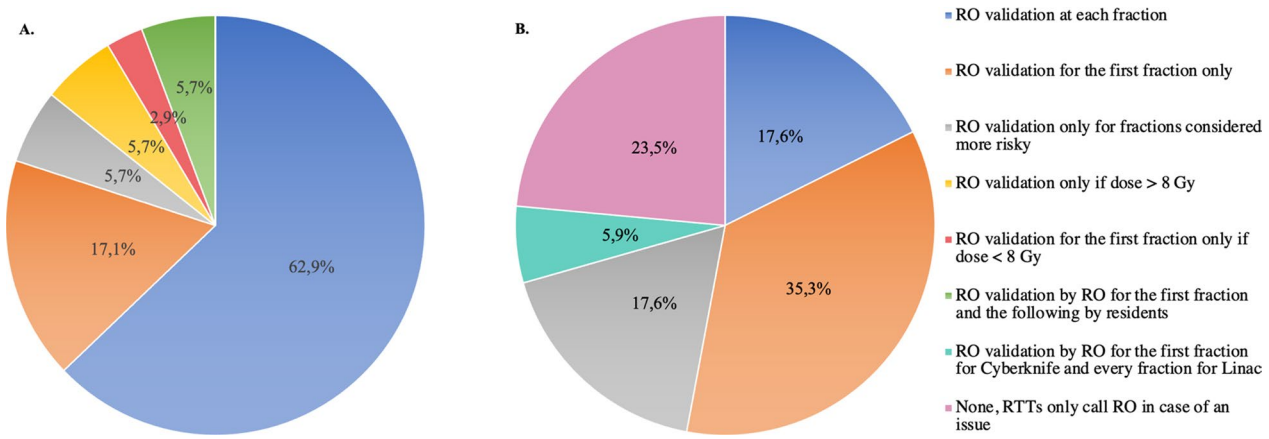

Fig. 1 Radiation oncologist validation of SBRT fractions in France (**A**) and other countries (**B**). *Footnotes*: SBRT: Stereotactic Body Radiation Therapy

Difficulties adhering to current recommendations concerning SRT fraction validation in France

According to responders, RO validation is time-consuming with task interruptions (85.7%) yet with no systematic added value (60%) and is responsible for wasted machine time (48.6%).

Desired changes to recommendations are mainly based on the validation by RO for the first fraction only, with subsequent fractions being validated by RTT with the option of calling a RO for assistance in case of difficulties (80%), then RO validation for single fraction (34.3%). To a lesser extent, changes to recommendations are considered warranted towards the need for RO uniquely: in the event of significant or high-risk modifications to default technical parameters (e.g., in CyberKnife®: the number of fiducials used for displacement calculation, adjustments to the limits of distance deviations between markers (rigid body), and contrast parameters for 6D-skull treatments) (31.4%); in case of problems (as for conventional radiotherapy) (28.7%); for re-irradiations (25.7%); for anatomical sites at higher risk of error (22.9%); for multiple target irradiation (17.1%); or for departments inexperienced in using SRT (17.1%). A small minority of departments desire no change (2.9%) (Fig. 2).

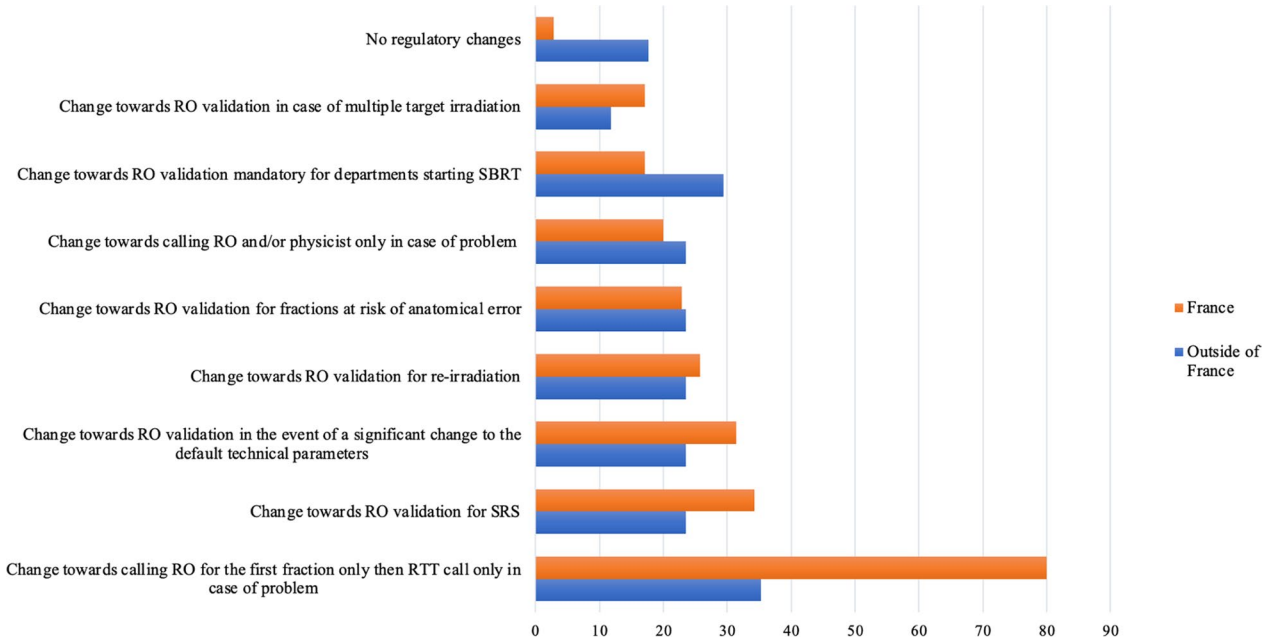

Fig. 2 Desired regulatory changes in France and other countries (% respondents). *Footnotes*: RO: Radiation Oncologist, SBRT: Stereotactic Body Radiation Therapy, SRS: Stereotactic RadioSurgery, RTT: RadiaTion Therapist

Foreign practice survey

Seventeen radiation oncology departments from 14 countries answered the web-questionnaire. They came from the USA, the United Kingdom, the Netherlands, Canada, Belgium, Denmark, Switzerland, Italy, India, Japan, Tunisia, and Australia, as well as 2 French-speaking countries: Luxembourg and Monaco.

SRT experience outside France

Most of the centers surveyed had many years of experience using SRT: 64.7% more than 10 years, 29.4% between 5 and 10 years and 5.9% less than 5 years. SRT is mostly performed on Varian Truebeam STX® (47.1%), followed by Cyberknife® (23.5%) and Elekta Versa HD® (23.5%). To a lesser degree, Gammaknife® (17.6%), MRI Linac MRIdian ViewRay® (17.6%), MRI Linac Elekta Unity® (11.8%) and Novalis STX® (11.8%) are also used.

SRT procedure outside France

The RO performs the validation of SRT fractions at first fraction only in most of the answering departments (35.3%), only in the event of an issue in 23.5% (e.g., in case of doubt or difficulties during registration by RTTs), for SRT fractions considered at risk for 17.6%, at each fraction for 17.6%, or when the dose exceeds 8 Gy in 5.9% (Fig. 1B). Last year residents may be asked to validate positioning images: always for 23.5% or sometimes for 17.6% but usually never (35.3%). Other more junior residents never validate positioning images in 52.9% of centers. SRT fractions ≤ 8 Gy are mainly validated by a RO (58.8%), in contrast to conventional radiotherapy fractions requiring RO validation in 35.3%. Centers consider it not difficult implementing recommendations into clinical routine use with a median difficulty score of 1/10 [0–10]. The collected SRT practice recommendations are summarized in Table 1.

Difficulties experienced implementing SRT fraction validation outside France

According to responders, RO validation is time-consuming due to task interruptions (64.7%), offers no systematic added value (23.5%) and is responsible for wasted machine time (17.6%). Departments in which the RO does not systematically perform the validation (35.3%) experienced no such problems.

Experts suggest a RO validation for only the first fraction with all subsequent fractions validated by the RTT with the possibility of calling the RO in the event of difficulties (35.3%); for departments new to SRT (29.4%); for single fraction SRT (23.5%); for re-irradiation (23.5%); in

Table 1 Specific SBRT practice recommendations for on-board imaging, based on the responses from the countries surveyed that addressed this question

Country		Recommendation
	USA	For each fraction: RO ensures patient positioning and field placement
	Canada	Minimum = attend the patient's initial SBRT session: To verify proper patient positioning To confirm that image registration is accurate
	Denmark	No specific recommendation for SRT: After approving the treatment plan, RO are not involved in the treatment process unless an issue arises
	Switzerland	No specific recommendation for SRT: Same
	Belgium	No specific recommendation for SRT: Same
	France	For each fraction > 8 Gy: RO ensures patient positioning and field placement
	Luxembourg	Based on French recommendations
	Monaco	Based on French recommendations

SBRT Stereotactic Body Radiation Therapy

cases where there is a risk of anatomical error (23.5%); in the event of significant or high-risk modifications to the default technical parameters (e.g., in CyberKnife®: the number of fiducials used for displacement calculation, adjustments to the limits of distance deviations between markers (rigid body), and contrast parameters for 6D-skull treatments) (23.5%); or only in the event of problems (as for conventional radiotherapy) (23.5%). To a lesser degree, they propose RO validation for only non-dedicated machines (17.6%), only in the absence of fiducials (17.6%). Some departments (17.6%) expressed no desire for change to regulations (Fig. 2).

Foreign practice with regards RO validation of SRT according to anatomic location

The anatomic location deemed as the most error-prone and thus requiring RO validation is the liver (35.3%). Experts are divided regarding the kidney and vertebrae, regardless of level, with 35.3% recommending systematic RO validation and an equal percentage opposing it. For other locations, most experts considered that no RO validation is required (lung (47.1%), brain (47.1%), head and neck (47.1%), bone other than vertebrae (41.2%), adrenal gland (41.2%), and prostate (35.3%)).

Discussion

There is a significant disparity between the regulations in and outside France regarding the RO validation of SRT sessions. All recommendations governing this practice are relatively outdated and have failed to keep up the pace with technological advancements and expanding indications. Regulations need updating, adapting and harmonizing to better meet these rapidly developing clinical needs, without compromising patient safety.

In France, the RO must be present at the treatment unit for all hypofractionated treatments as specified by the regulations. However, as the results of this survey show, the procedures in the departments are heterogeneous, reflecting variability in the interpretation of the decree. Indeed, in only 62.9% of centers is medical presence required during each session as mandated by regulations, while in 22.8% it is only required during the first session or for locations considered to be at higher risk. Consequently, under certain circumstances and following codified written procedures, the French Nuclear Safety Authority (ASN) may authorize the RO to validate only the first fraction but to remain available if needed for subsequent sessions. Indeed, RO presence at the treatment unit seems impracticable for routine clinical practice. In other countries, the experts who responded to the questionnaire grant more freedom to RTTs, with 58.8% of respondents only requiring validation of stereotactic radiotherapy sessions during the sessions themselves or in case of issues. These results are higher than those published in 2020 by Chetvertkov et al., [8] where 55.3% of institutions reported that patient positioning approval by the physician is required for each fraction, while 22% stated that physician approval is only required for patient setup for each treatment fraction, after which the physician must be immediately available in the clinical area. Therefore, it appears that radiotherapy departments are increasingly delegating tasks to RTTs as they gain more experience. Moreover, international recommendations published to date and governing the delivery of SRT sessions are not uniform [7, 8, 14]. The notion of RO presence varies across the different country-specific recommendations, although some do not insist on the presence of a RO at the treatment unit. Task interruptions and machine downtime can have a significant impact on the efficiency and smooth running of treatments. These interruptions not only increase the total time required to complete an individual treatment but can also reduce the overall efficiency of resource utilization and extend waiting times for other patients. Moreover, increased session duration negatively and significantly affects treatment precision [15]. Nevertheless, it should be noted that face-to-face validation enables an important link with RTTs thus strengthening team cohesion. It is also necessary to consider the RTTs' point of view in the event of greater empowerment: some feel comfortable and happy to be empowered, while others are anxious about the idea of greater autonomy. Delegating certain responsibilities to RTTs also imposes the acquisition of new skills, diversifies their professional activities, and meets their need for recognition. This competence transfer can only be achieved if robust training programs, competency frameworks, and educational courses are developed by the institution through a multidisciplinary team [16–18]. Therefore, the role of the RTTs appears to be evolving with the creation of advanced practice, which helps revitalize their training and diversify their profession [19–21]. Greater involvement of RTTs in the treatment process improves the workflow for patient management and potentially optimizes resource utilization [22]. However, this competence transfer must be accompanied by clear "stop procedures" that RTTs are required to know and rigorously apply to ensure maximum patient safety. This has been recognized during inspections of several French radiotherapy departments and presumes extensive training of the various professionals (RO, RTT and medical physicists) as well as a substantial volume of patients treated by SRT. Nevertheless, RO validation makes sense during the first treatment session when SRT or a new indication of SRT, based on

the published recommendations, is implemented in the department, or for more risky situations (re-irradiation, single fraction, in the event of significant modification of default technical parameters (e.g., in CyberKnife®: the number of fiducials used for displacement calculation, adjustments to the limits of distance deviations between markers (rigid body), and contrast parameters for 6D-skull treatments), if there is a risk of anatomical errors, or absence of fiducials). However, none of the questions on dedicated machines, length of time SRT in use within the department, or multiple target irradiation highlighted any particular need for improvement in corresponding regulations (only 15–25% of respondents desiring a change).

Data collected in countries outside France point to a difference in practices concerning the validation of SRT sessions. The national recommendations collected clearly show the absence of specific guidelines for the medical validation of SRT sessions, and especially the absence of notion of dose threshold outside French-speaking countries (Table 1). Indeed, more than half of the centers surveyed validate only the first SRT fraction (35.3%), or just in the event of an issue (23.5%) (e.g., in case of doubt or difficulties during registration by RTTs). This largely explains why, unlike in France, many radiotherapy departments experience little or no difficulty in implementing their national guidelines. Moreover, most experts agree that systematic RO validation is time-consuming and a waste of machine time. Transferring the validation task to a RTT is considered beneficial to their in-depth training, especially in Belgium and the Netherlands. Experts in both France and abroad are therefore converging upon such a change in practice, with a move towards RO validation during the first session only and for single fractions, and to a lesser extent during re-irradiations, significant or high-risk modifications of default technical parameters, for departments new to SRT, and in the event of risk of anatomical error. Anatomic locations considered to be at greater risk are mainly liver, spinal bone lesions (cervical, thoracic, and lumbosacral vertebrae) and kidney. The need for RO presence during SRT fractions can vary depending on several specific technical factors. The tracking technique used plays a crucial role: certain automated real-time tracking methods, such as respiratory tracking or fiducial markers, may more easily allow for delegation following appropriate training of RTTs. Additionally, the registration technique employed, whether it be surface guided radiation therapy (SGRT), cone-beam computed tomography (CBCT), or 2D radiography, also influences the requirement for RO presence. In case of technical or organizational difficulties with SBRT, other ablative radiotherapy techniques, such as liver brachytherapy, may be considered. These techniques offer a dosimetric advantage for OARs but are limited to highly specialized centers [23, 24].

However, all surveyed experts seemed to agree that SRT is as safe as normofractionated radiotherapy, provided it is in experienced hands, and that standardization of practice is necessary. SRT is associated with a low rate of severe toxicities (typically < 10%) due to its high precision and ability to spare surrounding healthy tissues [25–29]. RTT training with a mentoring program would allow a decrease in the need and number of RO interventions during treatment execution. Recommendations in countries outside France already give treatment centers greater flexibility in the way they supervise SRT sessions with no obvious negative impact on patient safety. Indeed, no data have been published to our knowledge, showing the positive influence of RO validation on reducing the number of adverse events. French radiotherapy departments therefore need to move towards more adapted and scalable validation whilst maintaining meticulous planning and the close monitoring of patients for the early detection and management of potential toxicity.

The limitations of the national survey include the lack of differentiation according to anatomic location as well as use of fiducials. This was corrected in the survey conducted outside France. In addition, the national survey contained no data on the use of Gammaknife®, which is increasingly restricted in France but used by neurosurgeons worldwide. In addition, all the centers surveyed both in and outside France were university centers, with no private clinics or non-university public hospitals. Another limitation is that, in the international survey, two of the countries were French-speaking, with the same regulations (Luxembourg and Monaco). Moreover, the issue of coordination and responsibility among teams in the case of neoadjuvant SRT was not addressed, but it depends on the lesion location, the comorbidity of procedures, and the intended objectives [30].

All respondents took an active part in the discussions that followed the questionnaire, which helped us draw up recommendations for the delivery of SRT fractions, based on each person's experience and in compliance with the law.

Recommendations

We propose the following recommendations for validation of SRT/SBRT sessions:

- Validation by senior RO for the first SRT session
- Validation by accredited RTT at the discretion of each radiotherapy department, except in certain situations (new indication or for more risky situations defined by the RO).

- Off-line validation seems reasonable without physical attendance at the treatment unit, although this is not possible with all accelerators.
- Appropriate initial training programs for all RO, medical physicist and RTTs must be completed. The skills acquired should be re-evaluated regularly throughout the professional career.
- The creation of anatomic location-specific IGRT procedures by a multidisciplinary team of physicians, medical physicist, RTT and quality officer is a mandatory prerequisite.

The working group proposes use of a typical framework for the accreditation of RTT and RO adaptable to each radiotherapy department depending on risk situations generally encountered. This approach offers the advantage of avoiding a rigid and non-scalable system while better accounting for technological advances in equipment and treatment indications, as well as the specific local context of each radiotherapy department.

- Theoretical (provided by manufacturers, e-learning and on-the-job training) and practical training, adapted to each position can be offered:

  General

  Organ specific with particular emphasis on discriminating markers and safety elements

  Adapted to the presence or not of fiducials

  Adapted to repositioning methods

  Adapted to the machines used in the radiation department

  Adapted to situations considered riskier specifically in the department (for example, re-irradiation, single session (SRS), multi-site concomitant irradiation…)

  Adapted to the number of patients treated and experience of the department

  Adapted to technical developments in the department

- Formalize through a skills assessment outlined in the service authorization system
- Frequent advanced courses

This move towards accreditation could be integrated into the paramedical cooperation protocol process, which in France consists of an advanced pre-practice for RTTs, with financial benefits and supervision by the health authorities.

Conclusion

With the development of stereotactic radiotherapy, practice changes regarding the systematic RO validation of fractions are necessary in order to fluidify therapeutic management at the treatment unit and limit interruptions to medical tasks. Any changes must however respect the legal framework and ensure the non-compromising of treatment quality. The results of this survey should enable clinicians to compare their practice, with regards the validation of SRT and SBRT fractions, with practices outside France. Our proposed recommendations for practice development and application in clinical routine should help optimize both RO and workstation time. The RO time freed up could be used to focus on other higher value-added medical tasks and to develop adaptive radiotherapy in radiation oncology departments.

Abbreviations

AAPM TG-101:	American association of physicists in medicine task group 101
ASN:	French nuclear safety authority
CBCT:	Cone-beam computed tomography
IGRT:	Image-guided radiation therapy
RO:	Radiation oncologist
RTT:	RadiaTion therapist
SBRT:	Stereotactic body radiation therapy
SGRT:	Surface guided radiation therapy
SRS:	Stereotactic RadioSurgery
SRT:	Stereotactic radiation therapy

Supplementary Information

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Supplementary material 1.

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Author contributions

Nicolas Martz, Jean-Christophe Faivre, Stéphane Supiot and Maximilien Rogé participated in the development of the web-questionnaire. Nicolas Martz

and Jean-Christophe Faivre wrote the manuscript text and created tables and figures. All authors reviewed and approved the manuscript.

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Competing interests
The authors declare no competing interests.

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