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Quality Assurance in Stereotactic Radiosurgery and Stereotactic Body Radiotherapy

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Authors' contributions

This work was carried out in collaboration among all authors. Authors YS, YB, US and ET designed the study, performed the statistical analysis, wrote the protocol and wrote the first draft of the manuscript. Authors AIA, FK, AK and BP managed the literature searches and analyses of the study. All authors read and approved the final manuscript.

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ABSTRACT

Stereotactic radiosurgery (SRS) and stereotactic body radiotherapy (SBRT) have settled down in the center of modern palliative and recently curative intent treatments in the last two decades. Being special, technology-driven, direct knowledge and experience based clinical procedures, both SRS and SBRT require high precision, accuracy and reproducibility to be safely and effectively delivered, which delineates the importance of quality assurance (QA) procedures from head to toe. In this review, we focused on summary of the comprehensive QA program covering clinical, technical and patient-specific treatment aspects, which need to be individualized per department based on several current recommendation guidelines.

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1. INTRODUCTION

Stereotactic radiosurgery (SRS) and stereotactic body radiation therapy (SBRT) remain the two commonly and efficiently used treatment options for the triumphant management of various primary and secondary malignancies [1]. The ultimate intention of the SRS/SBRT may be either curative or palliative typically depending on the nature of the tumor (benignant versus malignant and local versus widespread metastatic) and the extent of the disease spread (oligometastatic versus widespread metastatic), respectively. Following the first productive utilization, the SRS [Gamma Knife (GK) unit] for unrespectable intracranial benignant lesions by the Swedish neurosurgeon Lars Leksell in 1969, the SRS procedure gained soaring popularity and has been used for more than 50 years in the successful management of brain metastases (BM) and various other intracranial tumors and functional disorders, which yielded high local control rates and better survival times and/or better quality of life measures in some settings [2,3]. Recently GK system, known to be a single fraction device, has been upgraded to its latest version ICON, which supports frameless multi fraction SRS with the installation of cone-beam CT (CBCT) for reproducible stereotactic coordinate definition and daily positioning (Fig. 1). The use of SRS succeeded radically and continuously increased further acceptance by the radiation oncology society with the development of Linear accelerator-based SRS systems (LINAC) in the early 1980s [4,5]. Technological advances increased the capability of LINACs over the years, allowing SRS and SBRT applications with high accuracy (Fig. 2). The apparent prosperity of cranial SRS as a robust way of local tumor treatment has likewise generated an increased curiosity in the implementation of similar strategies of high-dose per fraction radiotherapy in the treatment of extracranial disease.

SRS/SBRT is fundamentally different from the conventional radiotherapy because of its ablative dose range that defeats the self-defense capacities of a target consisting of any cell type, including the cancer cells. The term SRS principally defines the single fraction high-dose radiotherapy applications for intracranial tumors, whereas, SBRT is a radiotherapy technique that provides high-doses of radiation to the intended target by using a single high-dose or a limited number of fractions of moderately higher doses of radiation with extraordinary sensitivity in the extracranial sites. The unique ability to deliver a single or a few fractions (usually ≤ 5 fractions) of high doses of ionizing radiation with high targeting accuracy and rapid dose fall-off gradients encompassing tumors within a patient provides the factual basis for the development of SRS and SBRT techniques [6]. Naturally, SRS/SBRT describes an aggressive treatment approach that strikingly resembles the conventional surgical procedures by prescribing locally ablative doses delivered per SRS/SBRT fractions. Consequently, even any minor deviations in defining the target volume or dose delivery can lead to critical errors with drastic clinical outcomes. To depreciate such potential errors to as low as reasonable levels, the SRS quality assurance (QA) should be more sensitive and comprehensive than the conventional radiotherapy applications.

Considering the high geometric accuracy and precision for isocenter localization and dose calculation are the chief goals of the SRS/SBRT, modern geometric localization techniques with image guidance and dose calculation algorithms have been faithfully implemented to the routine QA practice of any SRS or SBRT applications [7-11]. In this respect, several guidance documents became available to be of use to practitioners in the commencement and maintenance of the QA programs to eliminate or reduce errors [9,12,13]. Organizations such as The American Association of Physicists in Medicine (AAPM), American Society for Radiation Oncology (ASTRO), The American College of Radiology (ACR), The European Society for Radiotherapy and Oncology (ESTRO), and The International Atomic Energy Agency (IAEA) have published various QA guideline reports to rule out possible errors [13-20]. The first official report from AAPM for SRS-specific QA was published as Task Group 42 (TG-42) in 1995 [21] and revised reports adapted for advanced technology became available accordingly with the latest published one being the TG-142 [13]. Additionally, The Radiation Therapy Oncology Group (RTOG) has also published QA for SRS/SBRT guidelines [22]. The clinical recommendations including the standard protocols, necessary equipment, and QA procedures have been explained in detail in the

AAPM TG-101 report [9]. The most notable features of SRS/SBRT adapted from AAPM TG-101 are outlined in Table 1.

Typically resembling the conventional radiotherapy QA, the QA of SRS/SBRT consolidates many steps from the initial patient immobilization step to imaging, treatment planning, treatment delivery, and the final daily and periodical machine and planning system check steps. Self-evident lack of an institutional peculiar and comprehensive QA policy may lead to resolute treatment failures via redundant over dosage of the neighboring healthy normal tissues and/or under dosage of the intended target volume, which may inadvertently lead to severe toxic events and lessened local control success rates. Although the standard SRS/SBRT procedure is unquestionably teamwork, yet the medical physicists naturally represent the primarily responsible members for the physical and technical aspects of the SRS QA procedure. Radiation physicists should initially perform the specified machine and accessory acceptance tests to fitly establish the fundamental standards for more sustained SRS/SBRT applications. In like manner, the SRS equipment should undergo thorough requisite checks after any major renovation procedure to ensure compliance with the acceptance test specifications in use.

2. ACCEPTANCE AND COMMISSIONING

Regardless of the treatment technique, the initial calibration and commissioning of all SRS/SBRT equipment comprise the next critical step and is typically time-consuming. Acceptance testing and commissioning must be carried out precisely and comprehensively, and all measurements should be carefully documented in considerable detail before the integration of the treatment and planning systems to the routine SRS/SBRT practice [13,15,16,19-22]. Acceptance testing should be perpetually done according to discrete parameters and specific limits for each system, to ensure the equipment operates properly within the particularized specifications and per legal obligations. As SRS/SBRT demands remarkable precision for the target volume and dose localization, the operational capabilities of the LINAC, GK, and Cyber Knife (CK) units must be guaranteed to be matching the SRS/SBRT prerequisites.

Following the completion of the acceptance tests, still, extra data has to be procured before the clinical use of devices, namely the commissioning process. Principally, the first step of the commissioning task is the measurement of the radiation characteristics of the machine. Acquisition of beam data, although different for each SRS/SBRT device, is a traditional task routinely performed by medical physicists. For GK with Cobalt-60, beam data is limited to the activity and output measurements of the radioactive sources, while it is a much more long span and sensitive procedure in LINACs. Obtaining beam data for SRS/SBRT in LINAC can be extraordinarily challenging because of the small size of the areas practiced, and the necessity for suitably manufactured small detectors for such measurements. Small volume detector should be used that has minimum energy, dose and dose rate dependence. As described in Dosimetry of Small Static Fields Used in External Beam Radiotherapy of Technical Reports Series on IAEA, definition of small field at least one of the following three physical conditions will be fulfilled for an external photon beam to be designated small:

(i) There is a loss of lateral charged particle equilibrium (LCPE) on the beam axis;
(ii) There is partial occlusion of the primary photon source by the collimating devices on the beam axis;
(iii) The size of the detector is similar or large compared to the beam dimensions.

The first two characteristics are beam related, while the third one is detector related for a given field size. All three of these conditions result in overlap between the field penumbrae and the detector volume. Micro-ion chambers are best suited for small field dosimetry; however, signal to noise should be evaluated. Stereotactic diode with micron size detector could be suitable for radiosurgery beam as recommended in the AAPM TG-106 [23]. An example of ≤ 0.01cc volume ion chambers used for small area in LINAC based SRS SBRT is shown in Fig. 3.

After the measurement of beam data and stuffed into the treatment planning system as per the protocol, the physicist has to confirm the commissioned LINAC along with its treatment planning system using the AAPM TG-119 end-to-end test. End-to-end test validation is necessary because of the check on all processes from the start of treatment to deliver on the treatment machine before preparing the devices for patient treatment. As expected, the most comprehensive commissioning recommendations AAPM TG-106 have been specified for LINAC-based SRS/SBRT applications [23].

Table 1. General comparison of conventional (3D/IMRT) to stereotactic (SRS/SBRT) radio surgery (9)

Parameter	3D-CRT/IMRT/IGRT	SRS/SBRT
Dose/fraction	1.8 - 3 Gy	5–30 Gy
Fractions	10 - 30	1 (SRS) 1 < SBRT ≤ 10
Target definition	CTV/PTV (Gross disease + subclinical extent). Tumor may not have sharp boundary	GTV/CTV/ITV/PTV well-defined tumors: GTV=CTV Margins GTV › CTV none Margins CTV › PTV ~ 0.2–1.0 cm depend with IGRT and immobilization
Prescription Isodose line	~90 - 95%	~50–80 % (SRS) ~60–95 % (SBRT)
Dose gradient outside PTV	Moderate falloff	Very steep falloff
Margin	~Centimeter	Millimeters
Beam arrangement	Typically coplanar beams	Typically non-coplanar beams
Physics/dosimetry	Indirect	Direct
Primary imaging modality	Multi-modality: CT/MR/PET	Multi-modality: CT/MRI/PET
Redundancy in geometric verification	No	Yes, imaging prior to each treatment, and possibly during the treatment
Maintenance of target accuracy throughout treatment	Moderate patient positioning control and monitoring	High; strict immobilization and high frequency position monitoring
Need for respiratory motion management	Potentially	Necessary in sites with potential for respiratory motion
Staff training requirements	High	High + additional SBRT training
Technology implementation	Highest	Highest
Radiobiological understanding	Moderately well understood	Poorly understood

Abbreviations: 3D-RT: 3-dimensional conformal radiotherapy; IMRT: Intensity-modulated radiotherapy; IGRT: Image-guided radiotherapy; SRS: Stereotactic radiosurgery; SBRT: Stereotactic body radiotherapy; Gy: Gray; GTV: Gross tumor volume; CTV: Clinical target volume; PTV: Planning target volume; ITV: Internal target volume; CT: Computerized tomography; MRI: Magnetic resonance Imaging; PET; Positron emission tomography

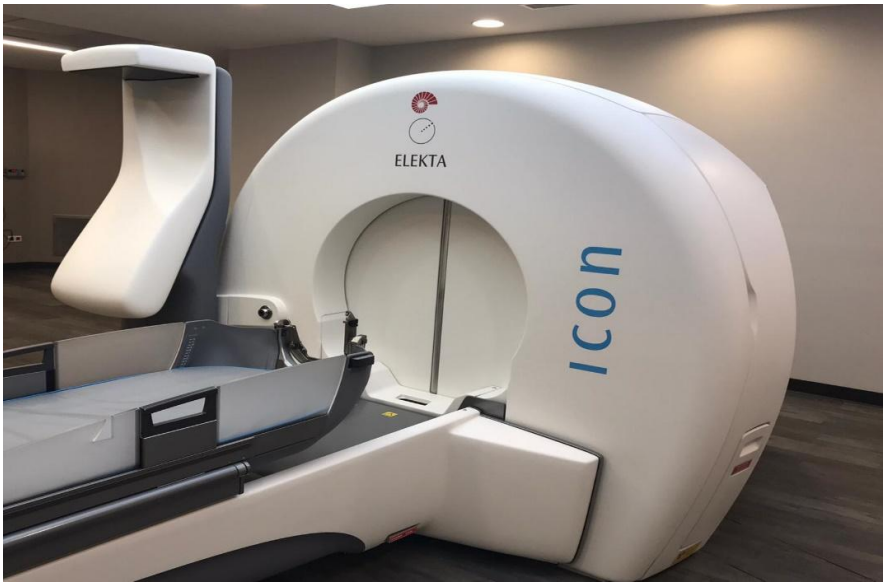

Fig. 1. ICON, Gamma Knife Elekta®

Table 2. Summary of all SRS/SBRT tests in AAPM TG-142 (13)

Tests	Daily	Monthly	Annual
Mechanical and dosimetric			
Laser localization	< 1-mm		
[a]Distance indicator	< 2-mm		
[b]Collimator size	Indicator < 1-mm		
Stereotactic interlocks testing for accessories	Functional	2% at SRS dose rate, MU < 1-mm/0.5°	Monitor units and gantry arc set vs delivered: 1.0 MU / 1.0° or 2% Gantry arc set vs. delivered 1◦ or 2%
[c,d]Typical dose rate output constancy.			
Treatment couch position indicators			
SRS arc rotation mode (range 0.5 - 10 MU/deg)			
X-ray MU linearity (output constancy)			
Coincidence of radiation and mechanical isocenters			5% (2-4 MU), 2% 5 MU
Stereotactic accessories, lockouts, etc.			1-mm from baseline
[e]End-to-end localization assessment/dosimetric evaluation using SRS frame or IGRT system			< 1-mm, < 2%
MV and KV imaging			
[f]Positioning/repositioning	< 1-mm		
[g] Spatial linearity1 (x and y) (single gantry angle)		< 1-mm	< 1 mm
Imaging and treatment coordinate coincidence (4 cardinal angles)		< 1-mm	< 1 mm
Cone-beam CT (kV and MV)			
[f]Positioning/repositioning	< 1-mm		
Imaging and treatment coordinate coincidence (single gantry angle)	< 1-mm		< 1-mm
Geometric distortion			< 1 mm

[a]Optical distance indicator check with a pointer compared lasers and source skin distance.
[b]Tolerance is summation of total for each width or length and Asymmetric jaws should be checked at settings of 0.0 and 10.0, [c]Dose monitoring as a function of dose rat; [d]Lateral, longitudinal, and rotational
[e]All tests must cover; 1) geometric accuracy, 2) dosimetric accuracy, and 3) treatment reproducibility.
[f]kV imaging refers to both 2-dimensional fluoroscopic and radiographic imaging.
[g]Scaling measured at SSD (source-to-skin distance) typically used for imaging.
Abbreviations: SRS: Stereotactic radiosurgery; MU: Monitor units: IGRT: Image-guided radiotherapy

3. PERIODICAL QUALITY ASSURANCE OF SRS AND SBRT

Periodical QA check steps should be carried out after the settlement of the treatment machine into clinical usage, as recommended by international protocols or guideline reports. Several guiding QA of SRS/SBRT reports are readily accessible for different devices. Medical physicists can easily achieve numerous protocols open for specialized procedures and equipment, such as a) AAPM TG-24, Physical aspect of quality assurance in radiotherapy (1984), b) World Health Organization (WHO) quality assurance in radiotherapy (1988), c) AAPM TG-40, Comprehensive QA for radiation oncology (1994), d) IAEA, Setting up a radiotherapy program (2008), e) AAPM TG-142, Quality assurance of medical accelerators (2009), f) AAPM, Guidance document on delivery, treatment planning, and clinical implementation of IMRT, g) AAPM TG-42, Stereotactic radiosurgery, h) AAPM TG-101, Stereotactic body radiation therapy and i) AAPM TG-135, Quality assurance for robotic surgery, j) AAPM TG-148, Quality assurance for helical tomotherapy, respectively. The AAPM TG-142 remains to be the most broadly adopted protocol to assess the performance of LINAC machines [2,6]. Nevertheless, it is of utmost significance to acknowledge that the SRS/SBRT measures outlined and recommended in all reports embody just a unique component of a more ubiquitous QA process that holds the periodic review of errors, incidents, and near misses. Hence, their proper use in fitting QA steps may serve further profitable in the fulfillment of a guaranteed entire QA procedure.

Fig. 2. Versa HD, linear accelerator elekta®

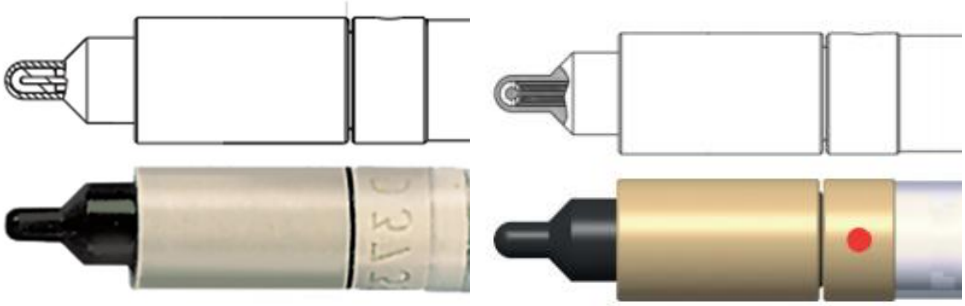

Fig. 3. Micro ion chambers < 0.01 cc for measuring small areas in SRS/SBRT

The broadly appreciated QA recommendations for the global performance of the entire SRS equipment typically consist of two periodically administered steps; namely the general QA (daily, monthly, and annually) and the patient-specific or specific QA (pretreatment calibration and preparation).

a) **General QA:** Periodically authorized general QA tests are demanded to accurately ascertain the entire wellbeing and the performance status of the equipment, which at least includes but not limited to the target localization QA, basic dosimeter QA, and treatment planning QA, and output calibration and delivery QA. A comprehensive QA program following the international recommendations ought to be meticulously prepared and the solicited frequency of any test ought to be prudently defined according to the possible hazards for failures, their relative frequencies, and the potential for catastrophic consequences related to the failure type. Accordingly, any item with high failure rates and/or catastrophic consequences should undergo compulsory frequent checks. The cardinal goal of the periodically performed general check procedure is to ensure that the whole treatment planning and treatment delivery systems are continuously operating in excellent accordance with the initial performance obtained on the acceptance and commissioning tests. Rigorously excluding the exceptional conditions, like serious mechanical or electronic failures

requiring repair procedures, the frequency of each QA program should follow the recommended check frequencies by the international reports on the issue: usual recommendation is daily, monthly and annual testing. Of note, all tests should ultimately aim to accurately identify key performance losses compared to the initial acceptance and commissioning tests.

Currently practiced QA policies and standard procedures per various AAPM TG reports for LINAC-based SRS/SBRT are outlined in Table 2. In brief, though the AAPM TG-142 remains the most fundamental report, other tests or shorter test intervals are also highlighted in several publications, simply depending on the treatment machine type and the technologies in use [2,24, 25]. Customarily the target localization is counseled to be tested using a specific or handmade phantom with a geometrically familiar target. The urged maximum sensitivity in AAPM reports appeared to be 1- mm or less. The dosimetric and non-dosimetric states of treatment planning systems should be carefully checked per the AAPM TG-53 report [16] and the absolute outputs should be properly calibrated as per TG-51 during the annual QA procedures [17], with all secondary QA dosimeters being instantly cross-checked against such calibrations.

Dosimetric procedures for QA are specific to the delivery systems like the GK and LINAC units. The recommended periodical tests for the global endorsement of the GK units incorporate the dose rate at the center of a 16-cm diameter tissue-equivalent sphere; shutter error; frame connections, collimator helmets, sliding couch; and leakage tests on collimator helmets. In like manner, periodical dosimetric and non-dosimetric tests are recommended to assure the general status of the LINAC systems. Dosimetric tests include however not limited to daily output control and periodic flatness-symmetry checks. It should be recalled that small-field dosimetry or modeling errors may, regrettably, lead to severe and irreversible consequences, especially in the SRS applications. Irrespective of the type of the SRS system utilized, the intersection of the lasers on the isocenter must be meticulously verified for the precision of the patient alignment.

The precise arrangement of the mechanical accuracy of the nominal isocenter represents the most vital component of the standard QA procedure, where the mechanical isocenter is defined as the intersection point obtained independently from the rotational gantry movement, collimators, and the treatment table. It is strictly recommended to carefully keep the nominal isocenter in a sphere with < 1-mm diameter around the isocenter [5,26]. Though the agreement between the mechanical and radiation isocenters are of indispensable significance additionally for other advanced radiotherapy techniques, yet, it is undeniably considerably more significant for SRS/SBRT applications concerning the ablative nature of them. Besides, the irradiation of volumetrically small targets via using flattening-filter-free energies create high dose prominences in the center of the intended targets and sharpens the field edges, those favored for SRS/SBRT applications. Therefore, it is of utmost vitality to confirm that the radiation isocenter is compatible with the mechanical isocenter [< 1 mm with the Winston-Lutz (Ball-bearing) test] during the installation process of the SRS unit [27]. Since the radiation isocenter of each energy level may vary significantly, it is worthwhile to carry out these tests for each of them separately.

The greater part of the likely errors in radiation oncology is not brought about by malfunctions in the treatment device, assistive equipment, and software; rather, they in common are workflow and process failures. Therefore, the radiation therapy chain needs to be controlled methodically. End-to-end tests are habitually used to determine the general exactness of the radiation treatment chain, aside from the patient-specific error factors. The end-to-end testing represents one of the most convenient strategies in deciding any dosimetric or mechanical issues which guarantee the global success of SRS/SBRT. Even though the end-to-end tests are not free of error, yet the process-related cumulative total of trivial errors can be precisely determined through the use of phantoms as recommended by AAPM TG-142 [13]. Besides, ASTRO and ACR suggest the check of the whole framework by comprehensive “end-to-end” testing at pre-specified interims [12], while different reports further prompt that each test must mimic the genuine treatment conditions by utilization of all treatment equipment [6,12-14, 24]. A guiding summary of the tests used in AAPM TG-142 is as illustrated in Table 2.

b) Specific QA: The last step of a standard QA procedure is specific QA or patient-specific pre-treatment QA, like the IMRT or VMAT QA, which aims to accurately ascertain that the whole treatment and

assistive devices and the treatment parameters are set correctly including the calibration procedure just before and during the treatment process (Figs. 4 and 5).

For GK SRS, specific to the facility and the GK unit, a thorough pre-SRS check of the mechanical parts such as frame and table position is strongly recommended [28]. Because the GK unit is a specific device developed exclusively for intracranial SRS, the specific QA for conventional GK units is relatively less intense with only a few safety checks [29]. However, pre-treatment or daily machine and image guidance checks with using special phantoms are imperative for accurate GK SRS applications in the novel GK Icon System, as fractionated SRS is conceivable with this sophisticated system. In this particular manner, several researchers specified different tolerance limits for the image guidance system consisting of a cone-beam CT and a sofa-mounted infrared camera, which may labor usefully in daily GK Icon System practice [30,31].

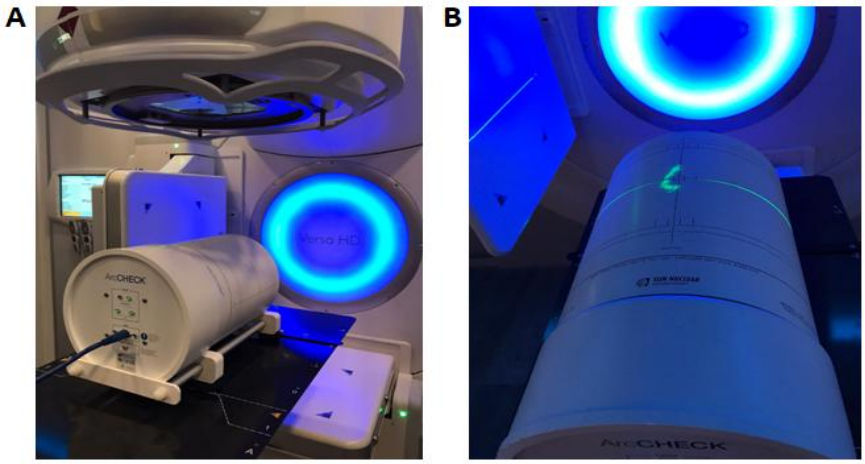

Fig. 4. Arc check with show of imaging patient-specific QA on carbon fiber couch of elekta versa HD® Linear accelerator

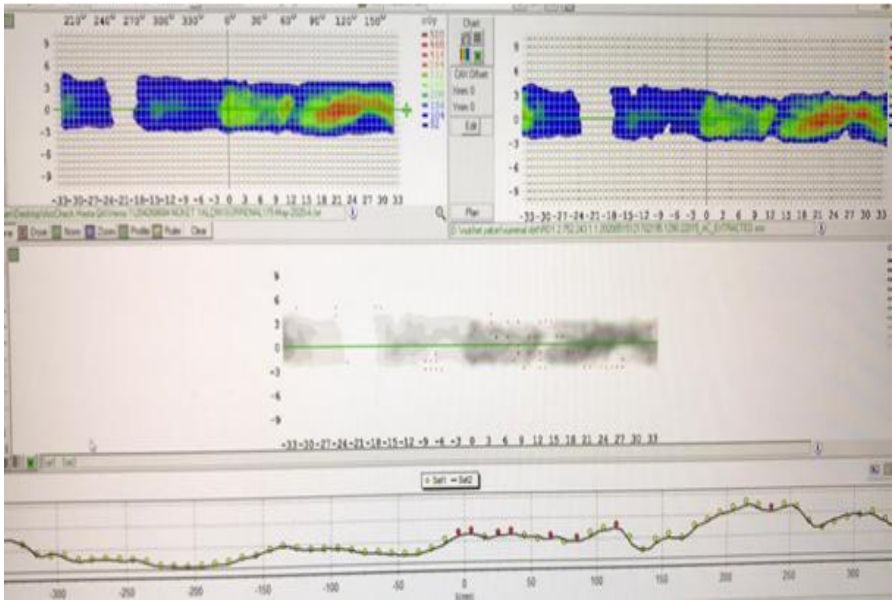

Fig. 5. Sample QA result image of VMAT technique with ArcCheck system

Table 3. The american association of physicists in medicine (AAPM) task group reports for quality assurance

Report No	Heading	Aim
TG-13	Physical aspects of quality assurance in radiation therapy	This report addressed only the physical tests and procedures essential to assure that a radiation therapy facility can precisely and reproducibly deliver the prescribed dose to the target volume with minimal dose to normal tissue. Additionally, the problems of optimal design and operation of a facility with regard to radiation, mechanical, and electrical safety were also discussed.
TG-40	Comprehensive QA for radiation oncology	The frequencies and tolerance limits of the desired QA tests are comprehensively listed in this old report, where AAPM Report 13 was updated due to the advances in radiation oncology in the previous decade.
TG-142	Quality assurance of medical accelerators	This report updated the TG-40's QA recommendations and offered new QA advices for asymmetric jaws, multileaf collimation, and dynamic/virtual wedges, as well as for imaging devices that are part of the standard LINACs.
TG-104	The Role of in-room kV X-ray imaging for patient setup and target localization	This report intended to review the accessible kV x-ray systems used in the radiation treatment room, including system configurations, specifications, operation principles, and functionality; to discuss the available methods that could be used to improve the accuracy of the treatment and their limitations; to discuss issues related to routine clinical procedures for effective implementation; and finally to discuss issues related to acceptance testing and QA.
TG-179	Quality assurance for image-guided radiation therapy utilizing CT-based technologies	This report provided a comprehensive list of general QA testing and frequency of tests for kV CBCT and MV CBCT, and CT-on-rails units.
TG-147	Quality Assurance for non-radiographic localization and positioning systems	This report reviewed concepts, clinical applications, and quality assurance for patient positioning, localization, and motion compensation that use non-radiographic sophisticated technologies like video and infrared cameras, surface texture map imaging, and radiofrequency tracking systems.
TG- 135	Quality assurance for robotic radiosurgery	This report aimed to define standards for an institutional QA protocol for robotic radiosurgery, and intended to give guidelines on setting up a comprehensive QA program for robotic radiosurgery systems to complement the vendor guidelines.

Abbreviations: TG: task group; QA: Quality assurance; LINAC: Linear accelerator; Kv: kilo volts; CT: Computerized tomography; MV: Million volts; CBCT: Cone-beam CT

For LINACs, the specific QA does not only aim to measure the precision of the delivery of the prescribed dose per treatment fraction, but it also aims to properly calibrate the device for treatment considering that the dose difference per fraction is very high in SRS/SBRT applications. It is heavily advised to check patient-specific treatment plans before each treatment by using special or homemade phantoms, particularly focusing on the point doses and overall dose distributions on the plan. The dose delivered from the LINAC can be measured and objectively compared with the dose calculated in the treatment planning system by utilizing various methods like ion chamber or film dosimetry, though the currently accessible guidelines have no strong recommendation favoring a particular method for the accuracy of complex treatment plans [32-34]. Patient-specific plan checks assure the trustworthiness of the whole system from the treatment planning to the dose delivery systems, by building up distinct treatment plans for each patient, transferring the plan over the data network, checking the imaging

systems, and auxiliary applicators or immobilization devices. Of particular importance, it is counseled to create facility-specific teamwork checklists for each test: patient QA, equipment calibration and control, and decent documentation of the measurements in tissue equivalent phantoms, like dose calibration, percent depth doses, relative dose exit factors, and cross-beam profiles [15,16]. Enthusiastically supporting this key guidance, AAPM TG-101 particularly emphasized that a radiation oncologist and medical physicist should invariably be involved in the QA procedure from the initiation to the completion of the first fraction of the treatment and should additionally check the image guidance results before each treatment fraction, with specific QA schemes and checks being prudently implemented to all systems to precisely align the patient [9].

4. CONCLUSION

SRS/SBRT has established efficiency in the prosperous management of various primary malignant tumors or their metastatic extensions, with significant potential for further gains soon. Either of the SRS/SBRT is a technology-driven clinical procedure that depends upon admirable precision for safe and effective administration. The SRS/SBRT applications can be typically accomplished with high accuracy if the readily accessible references concentrating on specific guidance strictly obeyed. To guarantee the secure and competent delivery of SRS/SBRT, a comprehensive QA program embracing all clinical, technical, and patient-specific treatment features should be collaboratively developed and obeyed, which is easily comprehensible, simple to apply, and facility-specific. Although the accessible task group reports may serve useful (Table 3), yet, for successful QA results, an explicit commitment to work in close association for the development and routine administration of the facility-specific QA program should be convincingly paraded among the professional regulatory organizations, vendors, and end-users, namely the radiation oncologists and radiation physicists.

DISCLAIMER

The products used for this research are commonly and predominantly use products in our area of research and country. There is absolutely no conflict of interest between the authors and producers of the products because we do not intend to use these products as an avenue for any litigation but for the advancement of knowledge. Also, the research was not funded by the producing company rather it was funded by personal efforts of the authors.

COMPETING INTERESTS

Authors have declared that no competing interests exist.

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