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FULL PAPER

Focus on the expected quality of reporting in SBRT/radiosurgery prospective studies: how far have we come in 30 years?

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Objectives: We aimed at describing and assessing the quality of reporting in all published prospective trials about radiosurgery (SRS) and stereotactic body radiotherapy (SBRT).
Methods: The Medline database was searched for. The reporting of study design, patients' and radiotherapy characteristics, previous and concurrent cancer treatments, acute and late toxicities and assessment of quality of life were collected.
Results: 114 articles – published between 1989 and 2019 - were analysed. 21 trials were randomised (18.4%). Randomisation information was unavailable in 59.6% of the publications. Data about randomisation, ITT analysis and whether the study was multicentre or not, had been significantly less reported during the 2010–2019 publication period than before (respectively 29.4% *vs* 57.4% ($p < 0.001$), 20.6% *vs* 57.4% ($p < 0.001$), 48.5% *vs* 68.1% ($p < 0.001$). 89.5% of the articles reported the number of included patients. Information about radiation total dose was available in 86% of cases and dose *per* fraction in 78.1%. Regarding the method of dose prescription, the prescription isodose was the most reported information (58.8%). The reporting of radiotherapy characteristics did not improve during the 2010 s-2019s. Acute and late high-grade toxicity was reported in 37.7 and 30.7%, respectively. Their reporting decreased in recent period, especially for all-grade late toxicities ($p = 0.044$).
Conclusion: It seems necessary to meet stricter specifications to improve the quality of reporting.
Advances in knowledge: Our work results in one of the rare analyses of radiosurgery and SBRT publications. Literature must include necessary information to first, ensure treatments can be compared and reproduced and secondly, to permit to decide on new standards of care.

INTRODUCTION

Prospective trials are the cornerstone of evidence-based oncology. Phase III studies should theoretically demonstrate the benefit of innovative radiotherapy techniques. However, modern techniques such as volumetric modulated arc therapy often became commonplace without a proper evaluation of their therapeutic index. Efficacy and toxicity outcomes were only assessed in early phase trials or prospective observational cohorts.

Thanks to the technological advances, the total dose can now be delivered in many locations either in a few fractions (hypofractionated stereotactic body radiotherapy (SBRT) or in just one [radiosurgery (SRS)] in order to maximise the biological effects of hypofractionation.[1] However, such high doses *per* fraction require a specific management of the inter- and intrafractional movements of the target, immobilisation devices, planning treatment and dosimetry techniques, dose prescription, goals of target coverage according to the International Commission on Radiation Unit and Measurements (ICRU) 2017 report. Moreover, mathematical models for the calculation of the equivalent to the total dose when delivered in 2 Gy *per* fraction (EQD2) are uncertain.[2] Although these techniques offer curative possibilities in patients who were previously treated with palliative intent only, we still have no evidence about their radiobiology. Therefore, toxicities and efficacy remain difficult to predict. Hence, the importance of prospective publications about SBRT and SRS. Only their results can determine the risk–benefit ratio of such techniques. The identifications of

main trials' biases are necessary conditions to be able to criticise their methodology and respect their limits.[3,4] Lacks in the quality of reporting in radiation oncology trials were noticed in the past few years.[5,6] Yet, prospective literature about SBRT/SRS has been rarely specifically analysed.[7] Our review of literature about the prospective trials about SRS and SBRT aimed at describing and assessing the quality of reporting of all the publications.

METHODS AND MATERIALS

The trials about SRS and SBRT were identified thanks to PubMed/Medline, Current Contents, Embase, Oncoline, Elsevier Biobase and Scopus databases. The key words (stereotactic radiosurgery [Title/Abstract]) OR (stereotatic radiation [Title/Abstract]) were first used. Publications were eligible whatever the language. Then, a second selection based on the whole article was made by the first two authors (Inter-reader agreement was good, both authors worked together to gather data.) Reviewing list of reported trials from large cooperative radiotherapy groups were analysed to ensure major studies have not been omitted. References were crossed with clinicaltrials.gov to identify publications that could not be identified in Medline. The latest update was performed in June 2019. In order to be eligible for the present final analysis, trials had to be either Phase I, II or III clinical or prospective observational studies (randomised, non-randomised comparative or quasi-randomised studies) only dedicated to cancer patients, whatever the tumour type and the stage of cancer.

Data collection

To date, there are no guidelines or the existing guidelines do not precisely describe the necessary reporting criteria. Thus, we arbitrarily chose to use the criteria we previously published in Phase II and III studies analyses reported by our team[6]: and.[7] A Supplementary Material 1 was added to give information about data extraction form. Quality of reporting can be considered to the highest number of selected criteria to be found in most articles.

The selected criteria corresponding to those references for quality reporting are listed in Table 1, they are the characteristics assessed in all the 114 studies. For each selected trial, general information (first author's name, title of the journal, title and year of publication, phase); study design (number of arm, objective, randomisation, intention-to-treat (ITT) analysis, multicentred or not), patients characteristics (number of patients, median age); tumour characteristics (location), radiotherapy characteristics (SBRT or SRS, total dose, dose per fraction, number of fraction, fractionation, biological equivalent to a 2 Gy per fraction dose (EQD2), isodose covering PTV, prescription isodose, dose to isocentre, type of machine, use of immobilisation devices, guiding imaging, treatment planning technique, assessment of tumour motion during treatment; information about combined treatments [neoadjuvant surgery, previous radiotherapy treatments, concurrent systemic treatment (chemotherapy, targeted therapy, immune therapy)], description of acute and late toxicities (all grades, or high-grades only), assessment of quality of life.

Statistical analysis

The 23.0 version of SPS software was used for the statistical analysis. A descriptive analysis of the results was performed. The

Table 1. Characteristics of prospective studies testing stereotactic body radiotherapy or radiosurgery (n = 114 studies)

Study characteristics	Number of studies (%)
Journal	
International Journal of Radiation Oncology-Biology-Physics	32 (28.1)
Journal of Neuro-Oncology	7 (6.1)
Stereotactic and functional neurosurgery	6 (5.3)
BMC cancer	5 (4.4)
Radiation oncology	5 (4.4)
Neuro Oncology	4 (3.5)
Lancet Oncology	3 (2.6)
American Journal of Neuro-radiology	2 (1.8)
Annals of Oncology	2 (1.8)
Archives of neurology	2 (1.8)
Cancer	2 (1.8)
Journal of Clinical Endocrinology and Metabolism	2 (1.8)
Journal of Radiation Research	2 (1.8)
Journal of the American Medical Association	2 (1.8)
Lung Cancer	2 (1.8)
Neuro surgery	2 (1.8)
Practical Radiation Oncology	2 (1.8)
Journal of Clinical Oncology	1 (0.8)
Other	31 (27.2)
Year of publication	
2010–2019	68 (59.6)
2000–2009	26 (22.8)
1989–1999	20 (17.5)
Design	
Observational prospective study	50 (43.9)
Phase 1	24 (21.1)
Phase 2	24 (21.1)
Phase 1/2	3 (2.6)
Phase 3	13 (11.4)
Randomisation	
Yes	21 (18.4)
Not	25 (21.9)
Not reported	68 (59.6)
Intent-to-treat analysis	
Yes	9 (7.9)
Not	32 (28.1)
Not reported	73 (64)

(Continued)

Table 1. (Continued)

Study characteristics	Number of studies (%)
Number of treatment arms	
1	56 (49.1)
2	30 (26.3)
>2	18 (15.8)
Not reported	10 (8.8)
Number of participating centres	
Single centre	39 (34.2)
Multicentre	25 (21.9)
Not reported	50 (43.9)
Primary end point	
Reported	97 (85.1)
Not reported	17 (14.9)

Pearson's χ^2 test was used to compare percentages of independent dataset. The threshold for significance of the *p*-value was set to 0.05.

RESULTS

Publication selection

Initial searches resulted in 6250 records. After a first selection on title and abstract, 276 articles were identified. Retrospective studies and publications without available full text were excluded. As a result, 114 articles – published between 1989 and June 2019 – were analysed (Figure 1 aiming to describe the flowchart for the final selected 114 publications and Supplementary Material 2 listing and referencing all these 114 papers).

Studies characteristics

Most studies were published in the *International Journal of Radiation Oncology-Biology-Physics* (28.1%). Most publications were from the last decade as 59.6% of the articles were published after 2010. Publications mainly resulted from prospective observational studies (43.9%). Only 13 Phase III trials (11.4%) were identified. 21 trials were randomised (18.4%) but such information was not given in more than half of the publications (59.6%). ITT analysis was performed in nine trials. The information about ITT analysis was not available in more than 60% of the publications (64%). One treatment arm was performed in 49.1%. 34.2% were single participating centre; in 43.5% this information was not reported. Finally, the primary end point was not described in 14.9% of publications.

Studies characteristics were compared regarding the period of publication. Data about randomisation, ITT analysis and whether the study was multicentre or not, had been significantly less reported during the 2010–2019 publication period than during the period before 2010 (respectively 29.4% *vs* 57.4% ($p < 0.001$), 20.6% *vs* 57.4% ($p < 0.001$), 48.5% *vs* 68.1% ($p < 0.001$).

Patients' characteristics

The number of included patients was reported in 89.5% of the articles. The median age was given in 59.6% of the cases. The treated location was available in 95.6% of articles. Brain tumours – whether benign, malignant and primary or secondary – were the most studied locations (76.4%). Brain metastases represented one-third of treated tumours (32.7%). The other irradiated

Figure 1. Flow chart about selection of trials for the analysis. Initial screening was performed with PubMed/Medline and then, closed with Current Contents, Embase, Oncoline, Elsevier Biobase and Scopus databases and, finally, selected references were crossed with clinicaltrials.gov.

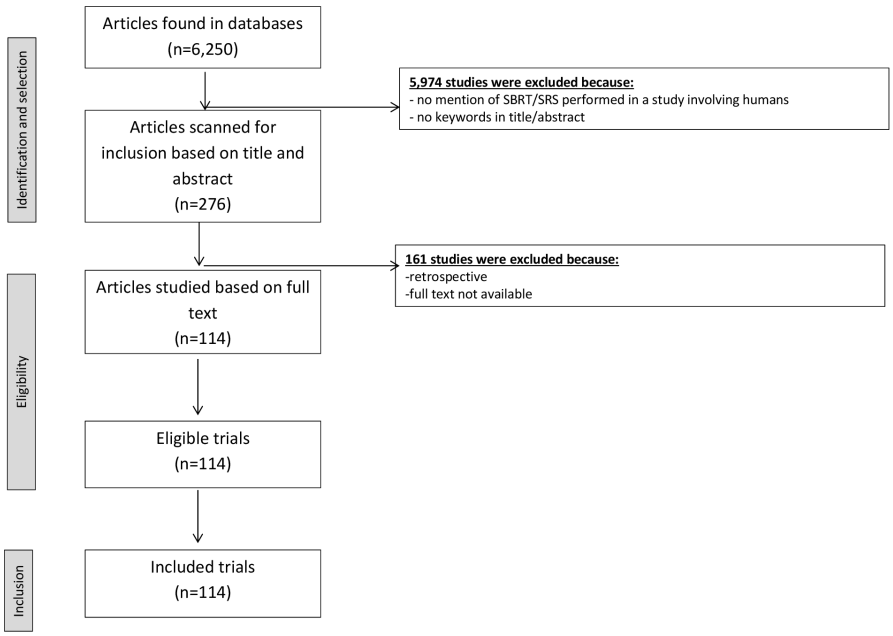

Table 2. Patient characteristics (*n* = 114 studies)

Patient characteristics	Number of studies (%)
Number of patients	
Reported	102 (89.5)
Not reported	12 (10.5)
Median age	
Reported	68 (59.6)
Not reported	46 (39.4)
Tumour location	
Brain	
Benign brain tumours	22 (19.3)
Primary malignant brain tumours	23 (20.2)
Secondary malignant brain tumours	37 (32.5)
Epilepsy	5 (4.4)
Lung	
Primary and secondary malignant lung tumours	5 (4.4)
Bone	
Secondary malignant bone tumours	7 (6.1)
Digestive	
Malignant digestive tumours	4 (3.5)
Urinary	
Malignant urinary system tumours	3 (2.6)
Head and Neck	
Malignant head and neck tumours	3 (2.6)
Not reported	5 (4.4)

Table 3. Previous/concurrent treatment characteristics (*n* = 114 studies)

Information about previous/ concurrent treatment	Number of studies (%)
Previous surgery	
Yes	50 (43.9)
No	30 (26.3)
Not reported	34 (29.8)
Previous radiotherapy	
Yes	29 (25.4)
No	41 (36)
Not reported	44 (38.6)
Concurrent systemic cancer therapy	
Yes	23 (20.2)
No	39 (34.2)
Not reported	52 (45.6)

locations were lung, bone, digestive, urinary, head and neck, and brain (epilepsy). There was no significant difference between the different locations dealt with in publications whatever the publication period. For instance, brain locations represented 75% of the tumours treated in articles after 2010 *vs* 78.7% before 2010 ($p = 0.643$). (Table 2)

Information about previous and combined treatments

Data about previous treatments – neoadjuvant surgery or any previous radiotherapy – on the treated location was missing in respectively 29.8 and 38.6% of cases. Information about concurrent systemic cancer treatments was unavailable in 45.6% of publications.

The reporting of previous radiotherapy treatments or any concurrent systemic treatment significantly decreased in the studies published after 2010 by respectively 50 *vs* 78.7% ($p < 0.001$) and 45.6 *vs* 68.1% ($p = 0.005$). Similarly, indications about previous surgery were less given after 2010 (63.2% *vs* 80.9%, $p = 0.126$), even if the difference remained non-significant. (Table 3)

Characteristics of radiotherapy treatments

Most publications (71.9%) were about SRS. Few trials compared or combined SRS with SBRT (7%). Information about radiation total dose was available in 86% of cases and dose per fraction in 78.1%. Regarding the method of dose prescription, the prescription isodose was the most reported information (58.8%).

As far as treatment delivering was concerned, the type of machine and the immobilisation devices were reported in half of the publications (respectively 57.9 and 46.5%). Guiding imaging and treatment planning technique were reported in one-third of the articles (respectively 35.1 and 31.6%). The energy of photon-beam and the methods to assess tumour motion were hardly reported (respectively 19.3 and 20%).

When compared to the previous periods, the description of treatment characteristics during the 2010–2019 period did not improve. As a matter of fact, dose to isocentre was significantly less often reported in the most recent period (2.9% *vs* 36.2% before 2010, $p < 0.001$). The same trend was to be noticed – though not significantly – for the total dose (82.4% *vs* 91.5%, $p = 0.164$), the type of machine (50% *vs* 68.1%, $p = 0.054$), the use of immobilisation devices (42.6% *vs* 51.1%, $p = 0.373$), the type of energy (16.2% *vs* 23.4%, $p = 0.333$) and the way tumour motion was managed (14.7% *vs* 27.7%, $p = 0.088$). The description of the prescription isodose was also less reported after 2010 (51.5% *vs* 68.1%, $p = 0.076$).

Conversely, the dose per fraction (83.8% *vs* 70.2%, $p = 0.082$), number of fractions (83.8% *versus.* 70.2%, $p = 0.082$), overall treatment time (64.7% *vs* 61.7%, $p = 0.742$), EQD2 (5.9% *vs* 0.0%, $p = 0.091$) and isodose covering PTV (27.9% *vs* 12.8%, $p = 0.052$) tended to be reported more often after 2010, even if the difference remained non-significant. (Table 4)

Table 4. Radiation characteristics (n = 114 studies)

Radiation characteristics	Number of studies (%)
Technique	
SRS	82 (71.9)
SBRT	22 (19.3)
SRS *plus* or *vs* SBRT	8 (7)
Not reported	2 (1.8)
Total dose	
Reported	98 (86)
Not reported	16 (14)
Dose per fraction	
Reported	89 (78.1)
Not reported	25 (21.9)
Number of fractions	
Reported	89 (78.3)
Not reported	25 (21.7)
Overall treatment time	
Reported	72 (63.2)
Not reported	42 (36.8)
Equivalent dose in 2 Gy fractions (EQD2)	
Reported	4 (3.5)
Not reported	110 (96.5)
Prescription isodose	
Reported	67 (58.8)
Not reported	47 (41.2)
Isodose covering PTV	
Reported	25 (21.9)
Not reported	89 (78.1)
Dose to the isocentre	
Reported	19 (16.7)
Not reported	95 (83.3)
Planning treatment technique	
Reported	36 (31.6)
Not reported	78 (68.4)
Energy	
Reported	22 (19.3)
Not reported	92 (80.7)
Type of machine	
Reported	66 (57.9)
Not reported	48 (42.1)
Use of immobilisation devices	
Reported	53 (46.5)
Not reported	61 (53.5)
Guiding imaging	
Reported	40 (35.1)
Not reported	74 (64.9)
Methods to assess tumour motion	
Reported	23 (20)
Not reported	91 (79.8)

Description of acute and late toxicities and assessment of the quality of life

Information about acute toxicities (all grades) was available in nearly half of the trials (47.4%), whereas late toxicities (all grades) were indicated in 39.4% of the cases. There was little difference as far as high-grade only toxicities were concerned. Acute and late data were reported in 37.7 and 30.7% of publications, respectively. Besides, only 25.4% of the studies reported on the impact of treatment on the quality of life.

The analysis of the period of publication showed a decrease in the reporting in the most recent trials but the difference remained unsignificant (but for all grades late toxicities). All grades acute toxicities were described in 41.2% in after 2010 trials *vs* 55.3% in those before 2010 (p = 0.135). As to late toxicities (all grades), they were reported in 32.4% after 2010 *vs* 51.1% before 2010 (p = 0.044). The assessment of the quality of life was reported in 22.1% of the recent publications *vs* 29.8% in the studies published before 2010 (p = 0.348). (Table 5)

Table 5. Description of acute and late toxicities and assessment of quality of life (n = 114 studies)

Results	Number of studies (%)
Acute toxicities (all grades)	
Reported	54 (47.4)
Not reported	60 (52.6)
Acute toxicities (high grades)	
Reported	43 (37.7)
Not reported	71 (62.3)
Late toxicities (all grades)	
Reported	46 (39.4)
Not reported	68 (59.6)
Late toxicities (high grades)	
Reported	35 (30.7)
Not reported	79 (69.3)
Quality of life	
Reported	29 (25.4)
Not reported	85 (74.6)

DISCUSSION

Our work results in one of the rare analyses of SRS and SBRT publications as far as reporting is concerned. The development of such innovating techniques has entailed an increasing number of articles. Yet, literature must include necessary information in order to first, ensure treatments can be compared and reproduced and secondly, to permit to decide on new standards of care.[8,9]

Thus, we studied criteria corresponding to major general characteristics including the study design, tumour location, patients' and treatment characteristics, combined anticancer therapies and data about toxicities and quality of life. Apart from the data about total dose and patients' characteristics, the results showed a poor reporting of most criteria especially those about the study design (randomisation, ITT analysis). Besides, although information about the preparation and achievement of radiotherapy is essential, they were rarely reported. Thus, the energy used and the isodose covering PTV were only indicated in about 20% of the publications.

A previous analysis of similar criteria in 458 concurrent chemoradiation Phase II trials had come to the same results. Indeed, there was no information about the type of radiotherapy (IMRT *vs* 3D-CRT *vs* 2D) in 20% of cases. Moreover, toxicities –especially late toxicities – were reported in less than 45% of trials.[5] The same authors analysed radiotherapy Phase III trials and came to the same conclusions. Acute toxicities were reported in 49.6% and late toxicities in 31% of studies. Moreover, the type of radiotherapy was unavailable in nearly 40% of treatment arms.[6] Such results corroborated other publications highlighting that many CONSORT elements were rarely reported in radiation oncology publications.[10–15] As a result, the reliable analysis of their results and, *in fine,* the implementation of new standards of treatment is made impossible because of such a lack.[16] In addition, the quality of the design and reporting was lower in radiotherapy trials than in medical oncology trials.[17,18]

The present analysis reveals that although the number of publications has increased over the years, reporting practices have not improved. The quality of reporting of some crucial characteristics for trials to be reproducible (total dose, prescription isodose, type of machine…) even tended to decrease over the decades. Thus, although health professionals are more and more encouraged to publish, our results tend to show that the reporting of necessary elements in radiotherapy is not enough. Yet, the results of our work should be moderated. Indeed, even if the quality of reporting was generally poor it does not mean that all radiosurgery and SRS trials were poorly designed or misconducted.[19] Our review of literature points out the necessity for each publication to meet stricter specifications including common elements but also adaptations to disciplines and treatment techniques. This would be a major step in the improvement strategy we call for.[20,21] As a matter of fact, the ICRU 29 (1978), ICRU50 (1993), ICRU62 (1999), ICRU 91 (2017) reports represent the evolution in prescribing, reporting, recording, of radiation treatments as a function of technological evolution. Therefore, it would be useful to impose the compliance of the reporting criteria with respect to the ICRU recommendations of the time.

CONCLUSION

In order to conclude, the present study points out a lack of reported data in most clinical trials and this could be explained by many reasons. There are no guidelines or the existing guidelines do not clearly describe the reporting criteria. As authors want to publish trials as soon as possible, initial drafting of trial designs remain superficial. Moreover, Research Ethics Committees members are usually defined as having no specific qualification with respect to biomedical research, medicine, or health care. Similarly, peer-review process by reviewers are not appropriately qualified. Finally, the increasing number of low impact factor journals and "predator" journals could be detrimental to the highest quality of the scientific, medical and technical messages.[22–25]

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