Confronting ethical challenges and guideline deviations in neuro-oncological radiosurgery

Mustafa Mushtaq Hussain[1], Amjad Ali Qureshi[2], Tahir Shahab[3], Jawad Ahmed[4], Rashid Jooma[5], Muhammad Shahzad Shamim[6]

Abstract

Stereotactic radiosurgery (SRS) has transformed neuro-oncological care through its precision, minimally invasive nature. SRS involves multiple, convergent beams of high energy gamma rays, X-rays, or protons at a precisely defined treatment area. As the use of SRS continues to grow in neuro-oncology, it has brought with it a range of ethical and clinical concerns. This narrative review examines how deviations from accepted clinical guidelines and inappropriate use of SRS—such as overuse in low-volume centers, financial motivations, poor compliance with protocols, and unsuitable patient selection—can lead to compromised patient care. These practices not only pose risks to patient safety and outcomes but also threaten to undermine trust in the medical system. By reviewing real-world examples, this review highlights the necessity of stronger multidisciplinary decision-making, improved oversight and training of the clinical teams involved in delivering SRS. Addressing these issues is essential to ensure that radiosurgery remains a safe, effective, and ethically sound treatment option in the neuro-oncology practice.

Keywords: Steriotactic Radiosurgery, Radiation Therapy, Brain Tumour, Brain Metastases.

DOI: https://doi.org/10.47391/JPMA.25-48

Introduction

Stereotactic radiosurgery (SRS) was developed by the Lars Leksell, a Swedish neurosurgeon in 1950s, and involves the delivery of a "single, high dose of ionizing radiation to a small and critically located intracranial volume through the intact skull."[1] It offers targetted cell death with ultra-fine precision and is widely used in neuro-oncology for the management of primary brain tumours and brain metastases.[2] It can be delivered as a single dose, as in stereotactic radiosurgery (SRS), or as fractionated stereotactic radiotherapy, where multiple doses (2–5) are given over a span of 2–4 weeks.[3] While SRS has revolutionized the treatment of various intracranial conditions, its increasing use raises important ethical concerns regarding its application. There are growing apprehensions about the instances of inaccurate implementation, leading to suboptimal treatment outcomes and even patient harm. This narrative review aims to systematically examine and address these critical concerns.

[1-4]Department of Neurosurgery and Gamma Knife Radiosurgery, Pir Abdul Qadir Shah Jeelani (PAQSJ) Institute of Medical Sciences, Gambat, [5,6]Department of Neurosurgery, Aga Khan University Hospital, Karachi, Sindh, Pakistan.

Correspondence: Muhammad Shahzad Shamim.

Email: shahzad.shamim@aku.edu

ORCID ID: 0000-0001-8305-8854

Review of Evidence

The main components to maintain quality and safety in radiosurgery is learning of incidence and reporting, to establish patient safety culture.[4] In the domain of radiation therapy, there is ample evidence that treatment of head and neck cancer patients at high volume facility centers have better outcome rates, owing to better expertise and are better equipped to manage complications.[5,6] The employment of radiosurgery in settings where the volume of cases does not justify its use, raise concerns about practitioner expertise and patient safety. As low volume centers are less likely to adhere to clinical guidelines and with less resources and lack of robust multidisciplinary teams, these centers may not be well equipped to manage treatment related complications.[7] In above context, it may be reasonable to speculate that patient care may be compromised if radiosurgery is not performed in high-volume specialized centers, unless the low-volume centers can exhibit a multidisciplinary team oversight, regular audits and robust data showing consistency in adhering to guidelines, achieving desired patient outcomes and managing complication.

Patients undergoing radiation therapy for brain lesions are already under significant financial burden.[8] A study analyzing Medicare data found that neurosurgeons received significantly higher reimbursement per SRS session than radiation oncologists. While this reimbursement was still 23.4% to 34.1% less than for open resection, the trend indicates that some neurosurgeons stand to benefit as SRS becomes more prevalent. Additionally, with neurosurgeons reimbursed per lesion,

the growing number of lesions treated per SRS session could eventually make SRS and open resection financially comparable.[9] The financial incentives associated with radiosurgery have also been identified as a factor contributing to its inappropriate use. In certain private centers, the reimbursement structure for radiotherapy tends to favour treatment plans with more radiation sessions, often persuading the adoption of shorter, hypofractionated regimens.[10] Co-ownership of medical imaging and radiotherapy facilities can lead to profitable self-referral practices within some clinics, further incentivizing the increased use of these services.

The application of radiosurgery in neuro-oncology is guided by established clinical protocols and guidelines designed to optimize patient outcomes and minimize risks.[11] However, some centres do not have policies governing SRS rules, and adherence to these guidelines can be inconsistent, leading to the inappropriate use of radiosurgery. A recent National Cancer Institute (NCI) designated cancer centres survey in the USA data show that 17.5% of physicians use SRS for more than 10 lesions without whole-brain radiation therapy (WBRT). This deviation from established practices reflects a shift. Most respondents reported increasing their use of SRS over the past five years. The survey did not address the impact of insurance on physician decisions, but private insurance generally supports SRS for multiple brain metastases.[12] Another survey revealed that 98% of British and Irish neurosurgeons do not recommend adjuvant radiotherapy for grade I meningiomas, regardless of resection status. For grade II meningiomas, 80% do not advocate radiotherapy if the tumour is completely resected, while 59% recommend it for subtotal resections, underscoring the need for guideline compliance.[13] This shows the wide variations in practice. In one of the largest studies on brain metastases involving nearly 90,000 US patients, disparities in SRS treatment patterns were identified. Adjusted analyses revealed that SRS was less likely to be utilized among patients of Hispanic ethnicity, those with lower income and educational attainment, individuals without private insurance, and patients treated at community centers. These findings also indicate the need to improve access to SRS for these underserved populations.[14] Moreover, the management of lesions with a V12 Gy >8.5 cm^3, which are associated with a radionecrosis risk exceeding 10%, often lacks adequate guideline compliance.[15] These cases should ideally be approached with hypofractionated stereotactic radiotherapy, particularly when the lesions are situated in or near eloquent areas. Historically, single-session SRS has been commonly used for large unresectable meningiomas, despite emerging evidence indicating that this approach can lead to higher complication rates and increased risk of radiation- induced toxicity. The recent data supports the growing consensus that single-session GKS for large inoperative meningiomas adjacent to eloquent areas should be avoided and appropriate fractionated regimen should be adapted for good tumour control and lower complications rates compared with single- session SRS ($P = 0.017$).[16] Deviations from established guidelines may result in severe complications, including radiation necrosis which can occur in up to 50% of patients and is associated with neurological complications in up to 30% of affected individuals including cognitive decline, and exacerbation of previous neurologic deficits.[17]

SRS is a highly conformal treatment method with minimum risk to surrounded neural tissue. However, ethical dilemmas often arise from the selection of patients where expected benefit may be minimal. A key ethical consideration involves salvage SRS in cases of metastases with poor prognosis of less than 3 months, uncontrolled extracranial disease, poor functional status and lack of initial response to radiotherapy in which salvage SRS may not be beneficial.[18] SRS related radionecrosis is an important cause of neurological toxicity with some centres reported 24% after initial radiosurgery alone.[15] For large brain metastases, SRS can lead to significant neurotoxicity, therefore, reducing the marginal dose is recommended to mitigate these risks.[19] Despite advancements in SRS, its use in patients with short expected survival, remains controversial.

Solutions and Way Forward

The integration of interdisciplinary tumour boards in decision-making is crucial in evaluating eligibility for surgical resection and SRS. No patient should be subjected to any form of oncological treatment without an MDT discussion, and SRS should not be an exception. To ensure alignment with latest research and best practices, regional guidelines need to be developed with consensus, and periodically updated. Adherence to these guidelines will be a key to improving patient outcomes and preventing harm. Institutions should also adhere to minimum case volume thresholds to ensure that practitioners maintain a high level of expertise and skill.[20] Good training programmes and continuous professional development are vital and mentorship programmes that pair less experienced practitioners with seasoned professionals can also enhance clinical competencies.

There is a need to develop and implement robust national accrediting and monitoring systems to track how radiosurgery is used, similar to the frameworks

established by ASTRO (American Society for Radiation Oncology) and ESTRO (European Society for Radiotherapy & Oncology). The strict adherence to safety checklist for SRS procedure promotes a zero-tolerance attitude for errors.[21] This should include setting up accountability measures such as peer reviews and outcome reporting. Jackson et al.[22] stress the importance of sharing treatment and outcome data across institutions in the radiosurgical community.

Conclusion

The inappropriate use of radiosurgery in oncological practice presents significant ethical and clinical challenges. Evidence indicates that misuse, often driven by financial incentives or a lack of adherence to guidelines, can lead to suboptimal patient outcomes and ethical violations. Addressing these issues requires a multifaceted approach, including strengthening clinical guidelines, enhancing patient communication, and implementing oversight mechanisms.

Disclaimer: None.

Conflict of Interest: None.

Source of Funding: None.

References

1. Leksell L. The stereotaxic method and radiosurgery of the brain. Acta chir scand. 1951;102:316-9.
2. Deora H, Tripathi M, Tewari MK, Ahuja CK, Kumar N, Kaur A, et al. Role of gamma knife radiosurgery in the management of intracranial gliomas. Neurol India. 2020;68:290-8.
3. Elaimy AL, Mackay AR, Lamoreaux WT, Demakas JJ, Fairbanks RK, Cooke BS, et al. Clinical outcomes of gamma knife radiosurgery in the salvage treatment of patients with recurrent high-grade glioma. World Neurosurg. 2013;80:872-8.
4. Pawlicki T, Coffey M, Milosevic M. Incident learning systems for radiation oncology: development and value at the local, national and international level. Clin Oncol. 2017;29:562-7.
5. David JM, Ho AS, Luu M, Yoshida EJ, Kim S, Mita AC, et al. Treatment at high-volume facilities and academic centers is independently associated with improved survival in patients with locally advanced head and neck cancer. Cancer. 2017;123:3933-42.
6. Naghavi AO, Echevarria MI, Strom TJ, Abuodeh YA, Venkat PS, Ahmed KA, et al. Patient choice for high-volume center radiation impacts head and neck cancer outcome. Cancer Med. 2018;7:4964- 79.
7. Tchelebi LT, Shen B, Wang M, Gusani NJ, Walter V, Abrams R, et al. Impact of radiation therapy facility volume on survival in patients with cancer. Cancer. 2021;127:4081-90.
8. Kazda T, Polachova K. Financial toxicity of radiotherapy for multiple brain metastases: Will it get worse or better? : Oxford University Press US; 2023. p. 318-9.
9. Lad M, Gupta R, Raman A, Parikh N, Gupta R, Chandra A, et al. Trends in physician reimbursements and procedural volumes for radiosurgery versus open surgery in brain tumor care: an analysis of Medicare data from 2009 to 2018. J Neurosurg. 2021;136(1):97-108.
10. Konski A, Yu JB, Freedman G, Harrison LB, Johnstone PA. Radiation oncology practice: Adjusting to a new reimbursement model. J Oncol Prac. 2016;12:e576-e83.
11. Seung SK, Larson DA, Galvin JM, Mehta MP, Potters L, Schultz CJ, et al. American College of Radiology (ACR) and American Society for Radiation Oncology (ASTRO) practice guideline for the performance of stereotactic radiosurgery (SRS). Am.J. clin. Oncol. 2013;36:310-5.
12. Blomain ES, Kim H, Garg S, Bhamidipati D, Guo J, Kalchman I, et al. Stereotactic radiosurgery practice patterns for brain metastases in the United States: a national survey. J.Radiat.Oncol. 2018;7:241-6.
13. Marcus H, Price S, Wilby M, Santarius T, Kirollos R. Radiotherapy as an adjuvant in the management of intracranial meningiomas: are we practising evidence-based medicine? Br. J. Neurosurg. 2008;22:520-8.
14. Shih J, Jain B, Patel MI, Taparra KA. Stereotactic radiosurgery practice patterns for treatment of brain metastases: A large national cancer database study. American Society of Clinical Oncology ASCO; 2024.
15. Minniti G, Clarke E, Lanzetta G, Osti MF, Trasimeni G, Bozzao A, et al. Stereotactic radiosurgery for brain metastases: analysis of outcome and risk of brain radionecrosis. Radiat.Oncol. 2011;6:1-9.
16. Han M-S, Jang W-Y, Moon K-S, Lim S-H, Kim I-Y, Jung T-Y, et al. Is fractionated gamma knife radiosurgery a safe and effective treatment approach for large-volume (> 10 cm3) intracranial meningiomas? World Neurosurg. 2017;99:477-83.
17. Barisano G, Bergamaschi S, Acharya J, Rajamohan A, Gibbs W, Kim P, et al. Complications of Radiotherapy and Radiosurgery in the Brain and Spine. Neurographics. 2018;8:167-87.
18. Kurtz G, Zadeh G, Gingras-Hill G, Millar B-A, Laperriere NJ, Bernstein M, et al. Salvage radiosurgery for brain metastases: prognostic factors to consider in patient selection. Int. J. Radiat. Oncol.* Biology* Physics. 2014;88:137-42.
19. Miyakawa A, Shibamoto Y, Takemoto S, Serizawa T, Otsuka S, Hirai T. Fractionated stereotactic radiotherapy for metastatic brain tumors that recurred after gamma knife radiosurgery results in acceptable toxicity and favorable local control. Int.J.Clin. Oncol. 2017;22:250-6.
20. Peters LJ, O'Sullivan B, Giralt J, Fitzgerald TJ, Trotti A, Bernier J, et al. Critical impact of radiotherapy protocol compliance and quality in the treatment of advanced head and neck cancer: results from TROG 02.02. J. Clin.Oncol. 2010;28:2996-3001.
21. Tuleasca C, Zeverino M, Patin D, Marguet M, Lopes NR, Vallet V, et al. Lausanne checklist for safe stereotactic radiosurgery. Acta neurochirurgica. 2019;161:721-7.
22. Jackson A, Marks LB, Bentzen SM, Eisbruch A, Yorke ED, Ten Haken RK, et al. The lessons of QUANTEC: recommendations for reporting and gathering data on dose–volume dependencies of treatment outcome. Int. J. Radiat. Oncol.* Biology* Physics. 2010;76:S155-S60.