HEALTH SERVICES RESEARCH

Evaluating Quality Indicators of Glioblastoma Care: Audit Results From an Indian Tertiary Care Cancer Center

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PURPOSE There are limited reports of quality metrics in glioblastoma. We audited our adherence to quality indicators as proposed in the PRIME Quality Improvement study.

METHODS This is a retrospective audit of patients treated between 2017 and 2020. After postsurgical integrated diagnosis, patients received radiotherapy (RT) with concurrent and adjuvant temozolomide (TMZ). Multiparametric magnetic resonance imaging at predefined times guided management. Numbers with proportions for indices were calculated. Survival was estimated using the Kaplan-Meier method.

RESULTS One hundred six patients were consecutively treated. The median age was 55 years (interquartile range of 47-61 years) with a male preponderance (68%). Ninety-six (90.6%) patients underwent subtotal resection, and 10 (9.4%) biopsy alone. Isocitrate dehydrogenase was wild-type in 96 (91%), and O^6-methylguanine-DNA methyltransferase was unmethylated in 70 (66.0%) patients. Telomerase reverse transcriptase promoter was mutated in 64 (60.4%), and TP53 was mutated in 22 (20.8%). Concurrent radiation and TMZ were planned for 104 (98.1%), and radiation alone for 2 (1.9%). The median time to concurrent RT-TMZ was 36 days (interquartile range 30-44 days). All patients planned for RT-TMZ completed treatment, but only 81 (76%) completed adjuvant TMZ. Sixty-three (59%) completed six cycles, 18 (17%) received less than six cycles, and 25 (24%) did not receive adjuvant TMZ. At a median follow-up of 24 months (range 21-31 months), the median (95% CI) progression-free survival and overall survival were 11 (95% CI, 9.4 to 13.0) and 20.0 (95% CI, 15 to 26) months, respectively.

CONCLUSION Our patients met quality indices in most domains; outcomes are comparable with global results. Metrics will be periodically evaluated to include new standards and assess continuous service appropriateness.

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INTRODUCTION

Despite an increasing focus on quality of health care in oncology, there is only sporadic information in selected malignancies to identify key measures to report quality of care provided in health care systems.[1,2] Even if management decisions are evidence-based and in accordance with contemporary guidelines, the treatment outcome of any disease depends on how successfully intended decisions are implemented. Surgery followed by adjuvant radiation therapy with concurrent and adjuvant temozolomide (TMZ) remains the standard of care in newly diagnosed glioblastoma.[3,4] Interdisciplinary evidence-based care is integral to its management. Adding to the complexity of associative care, recent understanding of molecular pathogenesis of glioblastoma has led to a rapidly changing diagnostic landscape.[5-8] The WHO updated the classification of CNS tumors in 2016 to include molecular biomarkers that are now central to a correct diagnosis. This assumes considerable clinical importance as certain hitherto morphologically lower-grade adult diffuse gliomas are now recast as glioblastoma on the basis of their molecular expression, and the recent c-IMPACT recommendations have reshaped the current WHO classification 2021.[6,9] This necessitates that measures to evaluate diagnostic processes become important quality indicators (QIs) for glioblastomas in addition to evaluating compliance to standard treatment.

Indicators to assess the quality of glioblastoma treatment environments have not been identified globally, and little is reported about practice-level care quality.[10,11] There is an emerging movement toward oncology care models and provision of high quality care with limited health care resources.[12] Such models have the potential to structure objective multilevel treatment reporting standards, especially in malignancies with poor outcomes like glioblastoma that

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CONTEXT

Key Objective

Does evidence-based treatment decision in glioblastoma always meet quality indices of health care structure, process, and outcomes? We determined the degree to which glioblastoma care in an Indian tertiary care cancer center complied with selected quality measures of the PRIME Quality Improvement study.

Knowledge Generated

We achieved 100% compliance in establishing postoperative integrated molecular diagnosis, postoperative magnetic resonance imaging, and timely completion of adjuvant radiation with concurrent temozolomide; 76% of patients completed adjuvant temozolomide. We failed to meet the early postoperative magnetic resonance imaging metric, and no patient was enrolled in a clinical trial. Our clinical outcomes compare favorably with published data.

Relevance

This audit demonstrates that evaluation of quality indicators of glioblastoma care is an important tool to improve care. The process is achievable in diverse settings with limited resources and without budget access.

have a deep psychosocial impact on patients and their caregivers. QIs and their reporting can facilitate global comparison of demographic, molecular, treatment, and outcomes data on glioblastoma, identify challenges across economies, and help define common denominators of essential care. In the recent past, findings from a PRIME Quality Improvement–guided study on glioblastoma care helped identify quality improvement indices and implement action plans.[10] We aimed to audit our adherence to selected QIs proposed in the PRIME Quality Improvement study.

METHODS

This is a retrospective audit of quality indices for patients with newly diagnosed glioblastoma treated consecutively in our organization between 2017 and 2020. After safe maximal resection for adult diffuse astrocytoma, integrated molecular diagnosis was established with an initial immunohistochemistry panel consisting of antibodies against isocitrate dehydrogenase (IDH)1(R132H), α thalassemia/mental retardation syndrome X-linked gene (ATRX), and Ki-67 followed by combined gene sequencing for IDH 1 and 2 when indicated, as our institutional policy. Evaluation of O^6-methylguanine-DNA methyltransferase (MGMT) promoter methylation, TP53, and telomerase reverse transcriptase (TERT) promoter mutation status is integral to our diagnostic algorithm. All patients were offered and planned to be treated according to our Disease Management Group protocol of focal conformal radiotherapy (RT) with concurrent and adjuvant TMZ. Multiparametric magnetic resonance imaging (MRI) at predefined time points of pre- and postradiation, interim and end of adjuvant TMZ, and the Eastern Cooperative Oncology Group performance status (ECOG PS) governed glioblastoma management. Our radiation therapy planning methodology has been reported earlier in the context of evaluating neural stem-cell compartment dosimetry and its association with survival outcomes.[13] The RT prescription was 60 Gy at 2.0 Gy per fraction over 6 weeks or 40 Gy at 2.66 Gy per fraction over 3 weeks for patients with an ECOG PS of 0-2 or more than 2, respectively. As a policy, corticosteroids are not prescribed electively during treatment.

Demographic, clinical, pathologic, molecular, imaging, therapy, and outcomes data were abstracted from the hospital information system (HIS). The HIS and oncology information system (ARIA; Varian Medical System, Palo Alto, CA) was queried to obtain information on patient characteristics and treatment delivery patterns. We assessed the electronic medical records to evaluate demography, performance status, extent of resection on the basis of surgical notes and postoperative MRI, availability and timing of postoperative imaging, molecular test results, compliance to planned treatment, and use of corticosteroids during adjuvant treatment. All imaging data were reviewed on our picture archiving and communication system. Audit data were collected from HIS and managed using research electronic data capture instruments.[14,15] Frequency tables and descriptive analysis were used to evaluate demography, tumor, and treatment characteristics as direct measurements of quality metrics. Numbers with proportions for various indices were calculated. An event was described as progression and/or death. Progression was defined using MRI, and clinical features using the Response Assessment in Neuro-Oncology criteria. The duration of progression-free survival and overall survival, in months, was calculated from the date of surgery. Patients with progressive disease, whose performance status was considered optimal, were considered for salvage bevacizumab and irinotecan as our institutional policy. Quality indices for salvage chemotherapy are not a part of the current audit. Survival was estimated using the Kaplan-Meier method. RStudio was used for statistical analysis.[16]

This audit, as a part of an ongoing radiomics study in glioblastoma, received a waiver of consent after a detailed discussion from the institutional review board (2019/TMC/162/IRB33).

RESULTS

Demography, Tumors, and Treatment Characteristics

From January 2017 to December 2020, the HIS query returned 106 patients with glioblastoma who were consecutively treated in our organization. Table 1 shows patient, tumor, and treatment characteristics. The median age was 55 years (interquartile range [IQR] of 47-61 years) with a male preponderance (68%). The ECOG PS was 0-1 in 47 (44%), 2 in 43 (41%), and 3-4 in 16 (15%) patients. Ninety-six (90.6%) patients underwent a subtotal resection and 10 (9.4%) patients underwent biopsy alone, as the sole surgical approach because of the tumor location. IDH was wild-type in 96 (91%) and mutated in 10 (9.4%) patients. MGMT was unmethylated in 70 (66.0%) and methylated in 23 (22%), and the test failed after two attempts in 13 (12%) patients because of failure of RNA retrieval in poorly fixed samples. TERT promoter was mutated in 64 (60.4%), wild in 32 (30%), and failed after two attempts in 10 (9.6%) patients. Eighty-four (79.2%) patients had retained ATRX status, and TP53 was mutated on sequencing in 22 (20.8%) patients, wild in 84 (79.2%) patients, and failed in 1 (0.9%) patient.

All patients were planned for adjuvant treatment. Concurrent radiation and TMZ with prophylaxis against pneumocystis jirovecii were planned for 104 (98.1%) patients, and radiation alone was planned for 2 (1.9%) patients. Eighty (75%) patients received 60 Gy at 2.0 Gy per fraction over 6 weeks, and 26 (25%) patients received 40 Gy at 2.66 Gy per fraction over 3 weeks. Corticosteroid use was documented in 62 (58.5%) patients; 44 (41.5%) patients did not need steroids during treatment. With a median follow-up of 24 months (range 21-31 months), the median (95% CI) progression-free survival and overall survival were 11 (95% CI, 9.4 to 13.0) and 20.0 (95% CI, 15 to 26) months, respectively.

Quality Indices for Glioblastoma Care Processes

Table 2 shows the selected quality indices for glioblastoma care processes at the service level. All patients underwent a postoperative multiparametric MRI to assess the extent of resection. The median time for the postoperative scan was 21 days (IQR of 15-28 days). All patients had a histopathology confirmation. Integrated molecular diagnosis was attempted on all 106 formalin-fixed paraffin embedded tissue specimens by a combination of immunohistochemistry and sequencing studies. An integrated molecular diagnosis could be established in 92 (87%) patients, and the molecular test (any molecular parameter) in a total of 14 (13%) patients. One patient, treated with radiation alone, was a deviation from the institutional policy. In this patient, adjuvant TMZ was used upfront in the immediate postoperative period and focal radiation was delivered after completion of six cycles of adjuvant TMZ. This was a tumor board decision, on the basis of the patient's postoperative neurologic condition, young age, and MGMT-methylated

TABLE 1. Demography, Tumor, and Treatment Characteristics

Characteristic	No. (%)
Sex	
Male	72 (68)
Female	34 (32)
Median age (IQR), years	55 (47-61)
Conventional fractionation	54 (45-60)
Hypofractionation	60 (50-67)
ECOG score	
0-1	47 (44)
2	43 (41)
3-4	16 (15)
Extent of resection	
Subtotal resection	96 (91)
Biopsy	10 (9.4)
ATRX	
Retained	84 (79)
Lost	20 (19)
Test failed	1 (1.9)
IDH mutation status	
IDH wild-type	96 (91)
IDH-mutant	10 (9.4)
MGMT	
Unmethylated	70 (66)
Methylated	23 (22)
Test failed	13 (12)
TERT promoter mutation	
Mutated	64 (60.4)
Wild-type	32 (30)
Test failed	10 (9.6)
TP53 mutation status	
Mutated	22 (21)
Wild	83 (78)
Test failed	1 (0.9)
RT prescription dose	
60.0 Gy/30 fractions/6 weeks	80 (75)
40.0 Gy/15 fractions/3 weeks	26 (25)
Concurrent TMZ	
Yes	104 (98.1)
No	2 (1.9)
Steroid use	62 (58)
OS, median (95% CI), months	20 (15.0 to 26.0)
PFS, median (95% CI), months	11 (9.4 to 13.0)

Abbreviations: ATRX, alpha thalassemia/mental retardation syndrome X-linked; ECOG, Eastern Cooperative Oncology Group; IDH, isocitrate dehydrogenase; IQR, interquartile range; MGMT, O^6-methylguanine methyltransferase; OS, overall survival; PFS, progression-free survival; RT, radiotherapy; TERT, telomerase reverse transcriptase, TMZ, temozolomide.

TABLE 2. Quality Indices for the Glioblastoma Care Process

Metric	No. (%)
Surgery	106 (100)
Postoperative MRI	106 (100)
Postoperative MRI within 72 hours of surgery	0 (0)
Histopathology report	106 (100)
Molecular test	106 (100)
Molecular test report	92 (87)
Molecular test failed	14 (13)
N-O DMG treatment policy followed	105 (99)
Deviation from policy	1 (1)
Clinical trial considered	0 (0)
Median (IQR) from surgery to RT-TMZ, days	36 (30-44)
Compliance to concurrent RT-TMZ	104 (100)
Compliance to adjuvant TMZ	81 (76)
Adjuvant TMZ details	
Completed as planned	63 (59)
Incomplete	18 (17)
Not started	25 (24)

Abbreviations: IQR, interquartile range; MRI, magnetic resonance imaging; N-O DMG, Neuro-Oncology Disease Management Group; RT-TMZ, radiotherapy-temozolomide.

status. The median time to start postoperative concurrent RT-TMZ was 36 days (IQR 30-44 days). All patients (104) planned for RT-TMZ were able to complete the planned treatment, but only 81 (76%) patients could complete the planned adjuvant TMZ. Sixty-three (59%) patients completed six cycles, 18 (17%) patients received less than six cycles (noncompliance or progression), and 25 (24%) patients did not receive adjuvant TMZ (noncompliance or progression). No patient was considered for referral to any center that had an ongoing clinical trial.

DISCUSSION

Continuous development of understanding of glioma biology necessitating rapid refinements in the diagnostics landscape and lack of uniform QIs of multidisciplinary care pose unique challenges in glioblastoma.[8,11] To date, no existing QI set is globally applicable for glioblastoma. Our set of prioritized QIs were chosen from the PRIME Quality Improvement study to reflect key content areas (structure, process, and outcomes) and the feasibility of data collection. Our results give us an insight into patient demography and tumor characteristics and illustrate the quality of glioblastoma care within a tertiary care cancer center framework and challenges inherent to our system.

The Central Brain Tumor Registry of the United States (CBTRUS) recently published the population-based data on primary brain tumors.[17] Akin to CBTRUS, our glioblastoma data revealed a male preponderance (68%). By contrast, our patients with a median age at diagnosis of 55 years (IQR of 47-61 years) are a decade younger than the median age of 65 years reported for glioblastoma in the CBTRUS but similar to published data from India.[18] Population-based cancer registry data from India and the Global Burden of Disease study do not show any difference in the age-adjusted incidence rate of primary brain tumors in India, and therefore, the low median age most likely represents the relatively younger and fitter patients who can travel to tertiary care centers for treatment rather than a true difference in epidemiology.[19-21] Our population has a higher proportion (9.6%) of IDH-mutant glioblastomas compared with a much lower proportion (2%) reported in CBTRUS. This is similar to two earlier series from India that have reported IDH 1 mutation in glioblastoma to be 12.8 and 12.5%.[22,23] Our frequency of ATRX loss and TP53 and TERT promoter mutations is comparable with data reported from the east in the recent past.[22,24,25] Our results on prognostic stratification of glioblastoma into subgroups on the basis of individual or a combination of biomarkers are beyond the scope of this quality measures audit.

Our patients met quality indices in all but one selected domains. All (100%) patients underwent surgery. We were successful in processing biomarker tests on all 106 (100%) formalin-fixed paraffin embedded tissue specimens compared with the recently reported percentage of biomarker tests, namely, IDH1/2, MGMT, and TERT of 80%, 61%, and 5%, respectively, reported on 100 patients with glioblastoma from two academic tertiary care neuro-oncology centers from the United States.[10] Of 106 patients, an integrated molecular diagnosis could be established in 92 (87%) patients and the molecular test (any molecular parameter) failed in a total of 14 (13%) patients because of poor tissue fixation in blocks (12 patients) that were received from referral laboratories and failure of internal control in two cases. Postoperative MRI was available in all cases. We failed to meet the early (within 72 hours of surgery) imaging metric because of the referral intervals from community and academic neurosurgical centers with varying practices. The median time to initiate concurrent RT-TMZ at 36 days (IQR 30-44 days) was a week later than a mean of 29.3 days recently reported but aligned with the Stupp protocol to start postsurgical adjuvant treatment within 6 weeks of surgery.[4,10,11] The comparative delay of a week in our population can possibly be attributed to families who need to address logistics of caregiver(s) identification and out-of-home stays to get treated in our organization. Interdisciplinary care coordination was possible in all patients compared with 92% reported by Ahluwalia et al. There was deviation from the standard protocol in a 53-year-old lady with IDH wild-type, MGMT-methylated glioblastoma with no comorbidities, who developed postoperative wound complications that needed surgical interventions and prolonged rehabilitation that excluded the use of radiation within a reasonable postoperative window. After a tumor board discussion, she was treated

with six cycles of adjuvant TMZ followed by concurrent RT-TMZ. Despite an individualized, symptom-prompted, nonelective, steroid use policy, more than half (58%) of our patients needed corticosteroid support at any point during postoperative adjuvant treatment. This compares with contemporary information from a recent meta-analysis of steroid use in 55% of patients with glioblastoma, treated with various regimens across prospective and retrospective trials.[26]

Notwithstanding evidence-based Disease Management Group decisions to offer and treat all patients with RT and TMZ, we achieved variable adherence to planned therapy. Concurrent RT-TMZ could be delivered to 98.1% of cases; two patients with unmethylated MGMT were treated with RT alone because of their borderline performance status. A quarter of our patients were treated with hypofractionated RT with concurrent and adjuvant TMZ; this decision was a function of either an overall poor performance status or the motor deficit profile that needed active assistance for daily hospital visits that led to the use of hypofractionation. Our results reveal that 81 (76%) patients received some adjuvant TMZ. Sixty-three (59%) patients received all cycles of adjuvant TMZ planned. Interim radiologic progression in 7 (6%) patients prompted switch of therapy, and 11 patients discontinued treatment for various reasons, including inability to visit the hospital during the COVID19 pandemic although we had a planned priority-level–based approach that allowed treatment to be delivered to the patients most in need.[27] Of 25 patients who could not be started on adjuvant TMZ, four patients had deterioration of performance status with stable disease, two patients died of lower respiratory tract infection, and the remainder were switched to salvage chemotherapy because of progressive disease. In contrast to the CBTRUS radiation information completeness of 69.5%, we had information of all patients since all patients were offered some treatment.[28] Going forward, we intend to carefully analyze treatment decisions taken for patients with a borderline performance status in the future to eliminate any undue treatment where supportive care would be proper.

This audit has several limitations and highlights certain challenges inherent to our glioblastoma care structure. First, we did not evaluate the actual turnaround time for molecular test results. To date, apart from variable prognostic outcomes, the recommendation to start postoperative concurrent RT-TMZ remains independent of the final integrated diagnosis. Nonetheless, with emerging therapeutic development in gliomas, we intend to evaluate this metric in the near future.[29] Second, no patient was considered for clinical trial registration nor referral because of unavailability of clinical trials. Patients treated between 2018 and 2019 gave additional informed consent for image banking within our ongoing image banking and radiomics research across selected malignancies including high-grade gliomas.[30,31] Imaging research was not considered to be a clinical trial for the purposes of this service-level care quality audit. Chakraborty et al recently reported a stark disparity in geographical distribution of clinical trials' access in India. Therapeutic interventional studies are available for patients with brain tumor in only two states in the country.[32] Our findings reiterate the need to address this national gap with appropriate multicentric initiatives. Finally, we did not audit the compliance to salvage treatments that would have provided further insight and future refinements in clinical decision making at progression to balance cost, morbidity, and expected improvements in quality of life with any salvage therapy.

In conclusion, our results show that the comprehensive, yet simple QIs proposed in the PRIME Quality Improvement study to assess key content areas for selected cancers (breast and colorectal) can be assuredly adopted with malignancy-specific metrics, glioblastoma in the present study, and meaningfully assessed in any treatment environment. Our audit provides information that despite the application of contemporary evidence for glioblastoma treatment in a multidisciplinary, tertiary care cancer center, nonadherence to therapy because of reasons inherent and likely specific to care delivery habitat is a reality. On the basis of these preliminary results, we intend to design initiatives to explore the acceptability of these indicators among stakeholders across other tertiary care and community-based cancer centers. This will help to determine the importance and validity of this set of indicators. We will periodically evaluate and update these metrics to include newer standards when applicable. This will optimize our accountability to glioblastoma care and ensure continuous improvement in our service.

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AUTHORS' DISCLOSURES OF POTENTIAL CONFLICTS OF INTEREST

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