Early MRI response and documented acute toxicity in patients receiving an intensified multimodality protocol incorporating pembrolizumab

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Running title

Early MRI response and documented acute toxicity

Keywords

brachytherapy; cervical cancer; chemoradiotherapy; locally advanced cervical cancer; magnetic resonance imaging; pembrolizumab

Synopsis

This descriptive observational cohort documents early MRI response and recorded acute toxicity in patients receiving an intensified multimodality protocol incorporating pembrolizumab.

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Author contributions

Conceptualization: Shahrzad Sheikh Hasani, Afsane Maddah Safaei, Mohadese Rezaei, and Zeinab Sinaeifar; Data curation: Zeinab Sinaeifar, Narges Zamani, Shakiba Sheykholeslamy, Leila Nazeri, Amirmohammad Heydari Dehnoodasht, and Elahe Rezayof; Formal analysis: Zeinab Sinaeifar and Mohadese Rezaei; Investigation: Zeinab Sinaeifar, Narges Zamani, Shakiba Sheykholeslamy, Leila Nazeri, Amirmohammad Heydari Dehnoodasht, and Elahe Rezayof; Writing – original draft: Zeinab Sinaeifar; Writing – review & editing: Shahrzad Sheikh Hasani, Afsane Maddah Safaei, Mohadese Rezaei, Zeinab Sinaeifar, Setare Akhavan, Azamsadat Mousavi, Narges Zamani, Shakiba Sheykholeslamy, Leila Nazeri,

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Conflict of interest

The authors declare no conflicts of interest.

Data availability statement

The data that support the findings of this study are available from the corresponding author upon reasonable request, subject to institutional and ethical restrictions.

Declaration of generative AI and AI-assisted technologies

OpenAI ChatGPT, GPT-5.6 Thinking (OpenAI, San Francisco, CA, USA; accessed July 2026), was used solely for English-language editing, stylistic refinement, and reference-formatting assistance during manuscript revision. The tool was not used to generate or analyze study data, perform statistical analyses, or make scientific decisions. All AI-assisted text was reviewed and verified by the authors, who take full responsibility for the accuracy, originality, and integrity of the manuscript.

Abstract

Background: To describe early imaging response and documented acute toxicity in patients with high-risk locally advanced cervical cancer treated with an intensified multimodality regimen incorporating induction chemotherapy, definitive chemoradiotherapy, brachytherapy, and pembrolizumab in routine clinical practice.

Methods: This observational single-center cohort study included 28 treated patients with non-surgical, high-risk locally advanced cervical cancer. Patients were managed with induction weekly paclitaxel/carboplatin, definitive cisplatin-based chemoradiotherapy, brachytherapy, and pembrolizumab followed by maintenance therapy when feasible. Pelvic magnetic resonance imaging (MRI) was performed before treatment and at approximately 3 and 6 months after completion of chemoradiotherapy. The main imaging endpoint was MRI-based clinical complete response (cCR), defined as absence of residual primary tumor and

radiologically active nodal disease. Acute adverse events were retrospectively abstracted from routine clinical documentation; therefore, toxicity findings were treated as descriptive secondary observations rather than systematic estimates of treatment-related toxicity.

Results: Mean age was 49.8 ± 10.3 years. At 3 months, 27/28 patients (96.4%; 95% CI, 82.3–99.4) were tumor-negative and 25/28 (89.3%; 95% CI, 72.8–96.3) achieved MRI-based cCR. At 6 months, all 28 patients had tumor- and node-negative pelvic MRI findings (100%; 95% CI, 87.9–100). Because this finding derives from an uncontrolled cohort of only 28 patients, with an imprecise confidence interval and no long-term progression-free or overall survival data, it should be considered descriptive only and not interpreted as evidence of durable disease control or survival benefit. Adverse-event documentation was present in 12/28 patients (42.8%; 95% CI, 26.5–60.9). CTCAE grade was explicitly recorded in 6/12 patients with documented adverse events, with grade 3 toxicity documented in two patients. One patient developed distant pulmonary metastasis and died of progressive disease.

Conclusion: The intensified multimodality protocol was deliverable in this small real-world cohort, and favorable early MRI findings were documented. These observations are descriptive and hypothesis-generating; they do not establish treatment effect, durable disease control, or survival benefit. Larger prospective studies with standardized response assessment, complete adverse-event capture, and longer follow-up are needed to determine whether early imaging response translates into durable progression-free and overall survival benefit.

Keywords: brachytherapy; cervical cancer; chemoradiotherapy; locally advanced cervical cancer; magnetic resonance imaging; pembrolizumab

Introduction

Cervical cancer remains a major global health problem despite being largely preventable. In 2022, it was responsible for approximately 660,000 new cases and 350,000 deaths worldwide, with the highest incidence and mortality in low- and middle-income countries. The World Health Organization (WHO) has therefore prioritized elimination efforts through its 90–70–90 targets, which address human papillomavirus vaccination, screening, and treatment coverage[1]. For patients who present with locally advanced cervical cancer (LACC), definitive radiotherapy combined with concurrent chemotherapy and brachytherapy is the backbone of curative treatment. Concurrent chemoradiotherapy (CCRT) improves survival compared with radiotherapy alone, and brachytherapy is an essential component for delivering a curative tumor dose[2,3]. However, outcomes remain suboptimal, with relapse reported in approximately

30–50% of patients after CCRT in contemporary series, highlighting the need for more effective systemic intensification strategies[4].

Radiotherapy can enhance antitumor immune responses through increased antigen release and immune priming, providing a biologic rationale for combining immune checkpoint inhibitors with CCRT. Programmed cell death-1/programmed death ligand-1 blockade has shown clinically meaningful activity across multiple tumor types, and preclinical and early clinical evidence supports potential synergy when these agents are integrated with radiotherapy[5].

In cervical cancer, pembrolizumab has demonstrated antitumor activity in previously treated advanced disease (KEYNOTE-158) and improved survival when added to first-line platinum-based chemotherapy, with or without bevacizumab, for persistent, recurrent, or metastatic disease (KEYNOTE-826)[6,7]. These findings established immunotherapy as an important component of systemic treatment for advanced-stage cervical cancer.

More recently, immunotherapy has been tested in the curative-intent setting for LACC. The phase 3 CALLA trial, which evaluated durvalumab with and after CCRT, did not significantly improve progression-free survival in an unselected population[8]. In contrast, the phase 3 ENGOT-cx11/GOG-3047/KEYNOTE-A18 trial showed that pembrolizumab added to CCRT, followed by pembrolizumab maintenance, improved progression-free and overall survival in high-risk LACC[9,15]. Regulatory approvals have followed in some regions, including U.S. Food and Drug Administration approval of pembrolizumab with chemoradiotherapy for FIGO 2014 stage III–IVA cervical cancer[10].

Although radiologic regression after standard chemoradiotherapy can be delayed, recent treatment-intensification trials have shown improved outcomes in selected settings. KEYNOTE-A18 supports concurrent and maintenance pembrolizumab with chemoradiotherapy, whereas INTERLACE supports short-course induction carboplatin/paclitaxel before standard chemoradiotherapy[9,13,15]. These data provide the rationale for evaluating intensified real-world strategies that combine systemic treatment, definitive local therapy, and immunotherapy.

Clinical trial populations and documentation practices may differ from routine care. Real-world data can therefore complement trial evidence by characterizing baseline features, early post-treatment imaging response patterns, treatment delivery, and the completeness of acute toxicity documentation in everyday clinical settings. Accordingly, this study describes patient and disease characteristics, summarizes early MRI-based response at 3 and 6 months, reports treatment delivery using available records, and presents documented acute adverse events as descriptive secondary observations.

Methods

Study design

This was an observational cohort study conducted at a tertiary oncology center. Analyses were based on variables available in a prospectively assembled institutional dataset and on information retrospectively abstracted from routine medical records, treatment charts, and imaging reports. Medical records from November 2023 to November 2025 were reviewed.

Participants

Eligible patients were adults (≥18 years) with histologically confirmed cervical cancer, including squamous cell carcinoma, adenocarcinoma, or adenosquamous carcinoma, who were not candidates for primary surgery and were planned for definitive chemoradiotherapy. Eligibility criteria were aligned with the KEYNOTE-A18 (ENGOT-cx11/GOG-3047) high-risk population and included FIGO 2018 stage IB2–IIB with lymph-node positivity or stage III–IVA, with ECOG performance status ≤1. Patients were excluded if they had distant metastasis at diagnosis, prior treatment for cervical cancer, major deficiencies in documentation precluding outcome ascertainment, early discontinuation for non-medical reasons, or active autoimmune disease.

Staging classification and interpretability

Disease stage was recorded according to FIGO 2018. Most patients were classified as FIGO 2018 stage IIIC1 or IIIC2 because of nodal involvement. Because FIGO 2014 did not assign stage IIIC based on nodal status, these patients would not necessarily correspond to FIGO 2014 stage III solely on the basis of nodal disease; instead, they would be classified according to local anatomic tumor extent, with nodal positivity reported separately. Therefore, direct comparison with KEYNOTE-A18 eligibility criteria and regulatory language based on FIGO 2014 stage III–IVA should be interpreted cautiously. Patient-level conversion to FIGO 2014 categories was not performed because the original local-anatomic stage before nodal upstaging was incompletely available for all patients.

Treatment approach

Patients were treated according to an institutional protocol modeled on contemporary pembrolizumab-based chemoradiation strategies for locally advanced, non-surgical cervical cancer. The protocol incorporated induction chemotherapy, definitive CCRT followed by brachytherapy, and continuation (maintenance) pembrolizumab when clinically feasible.

Induction chemotherapy consisted of weekly paclitaxel 80 mg/m² intravenously plus carboplatin at an area under the curve (AUC) of 2, administered weekly for 6 weeks. Pembrolizumab was incorporated according to the institutional protocol.

Definitive CCRT consisted of pelvic external-beam radiotherapy to 45–50.4 Gy delivered in 20–28 fractions, with concurrent weekly cisplatin 40 mg/m² for 5–6 weeks.

Brachytherapy was delivered after external-beam radiotherapy to complete definitive dose delivery, with the goal of achieving a cumulative EQD2 within the definitive range according to the institutional target of 78–86 Gy, when applicable.

All patients received an Iranian pembrolizumab product (Zakaria, Iran). Pembrolizumab was administered during CCRT and then continued as post-CCRT therapy according to the institutional regimen: 200 mg intravenously every 3 weeks for 5 cycles during CCRT, followed by 400 mg intravenously every 6 weeks for up to 15 cycles, or until disease progression or unacceptable toxicity.

Imaging schedule and response assessment

Pelvic MRI was used for response assessment. MRI was performed before treatment initiation and at routine post-treatment follow-up. For this study, imaging outcomes were abstracted from routine radiology reports at two planned time points: approximately 3 months after completion of CCRT (operationally, about 12 ± 4 weeks) and approximately 6 months after completion of CCRT (operationally, about 24 ± 4 weeks).

Both primary tumor and nodal findings were considered in response categorization. Standardized RECIST measurements were not systematically available, and imaging was not centrally reviewed. Response assessment was therefore based on routine pelvic MRI reports rather than independent blinded central radiology review. No pathologic confirmation of complete response was required; consequently, cCR in this manuscript refers specifically to MRI-based clinical complete response.

Data collection and variables

Data extracted from the medical records included demographic and baseline clinical characteristics, tumor and pathology features, FIGO 2018 stage, nodal status as reported in imaging studies, treatment delivery variables available in treatment charts, and clinical events documented during the treatment course. Acute adverse events were abstracted from free-text clinical documentation. Severity grading was recorded only when explicitly documented using CTCAE v5.0 terminology.

Outcomes and operational definitions

The main imaging endpoint was MRI-based cCR at 3 and 6 months after completion of CCRT. MRI-based cCR was defined as absence of residual primary tumor and absence of radiologically active nodal disease on pelvic MRI. Additional imaging outcomes included primary tumor status, nodal status, and composite response categories reflecting combinations of tumor and nodal findings.

Safety outcomes were prespecified as descriptive secondary observations. Safety variables included the presence of any adverse-event documentation, whether a CTCAE grade was explicitly reported, the maximum recorded grade, and adverse-event categories derived from free-text notes. Because adverse events were retrospectively abstracted from routine clinical documentation, toxicity findings should be interpreted as descriptive observations rather than systematic estimates of treatment-related toxicity. Absence of an adverse-event note was not interpreted as confirmed absence of toxicity.

Statistical analysis

Analyses were primarily descriptive. Continuous variables were summarized as mean ± standard deviation or median [interquartile range], as appropriate. Categorical variables were summarized as counts and percentages. Imaging response proportions were reported among patients with imaging available at each assessment time point. Exact hypothesis testing was not planned. To improve interpretability in this small cohort, 95% confidence intervals (CIs) for key binomial proportions were calculated using the Wilson method.

Ethics

The study protocol was reviewed and approved by the institutional ethics committee (approval details withheld for double-blind peer review). Patient data were handled confidentially and analyzed in de-identified form. Written informed consent was obtained when required by the ethics committee.

Results

Patient flow

A total of 29 patients were screened. One patient was excluded before treatment initiation because of a mood disorder. Therefore, 28 treated patients were included in the final analysis. Pelvic MRI assessment was available for all 28 patients at the 3-month and 6-month follow-up time points. Patient flow is shown in Figure 1.

Baseline characteristics

Baseline patient and disease characteristics are summarized in Table 1. The cohort included 28 patients with a mean age of 49.8 ± 10.3 years and a median baseline tumor size of 5.4 cm (IQR, 4.7–6.8). The population was predominantly composed of advanced-stage and node-positive disease, most commonly FIGO 2018 stage IIIC1. Squamous cell carcinoma was the most common histology, and adenocarcinoma represented a smaller subset. One patient with FIGO 2018 stage IIA disease had radiologically documented nodal involvement and therefore met the study eligibility criteria.

Treatment delivery and feasibility

Treatment delivery variables abstractable from the available records are summarized in Table 2. The table explicitly includes the treatment-delivery items requested for feasibility assessment, including induction chemotherapy, planned chemoradiotherapy, brachytherapy, maintenance pembrolizumab, and documented discontinuation or interruption reasons. Cycle-level completion data for induction chemotherapy, concurrent cisplatin, and maintenance pembrolizumab were not completely extractable for every patient from the current abstracted dataset; therefore, these variables are reported descriptively rather than as definitive completion rates. Documentation showed that one patient was unable to proceed with the planned course because of disease progression with pulmonary metastasis and respiratory symptoms before brachytherapy initiation. Temporary treatment hold or delay related to toxicity or a procedure-related event was documented in four patients. No permanent discontinuation due to toxicity was documented in the available records.

Imaging response

At 3 months, tumor absence on pelvic MRI was documented in 27/28 patients (96.4%; 95% CI, 82.3–99.4). MRI-based cCR, defined as tumor-negative and node-negative status, was documented in 25/28 patients (89.3%; 95% CI, 72.8–96.3). Two patients remained non-cCR because of residual nodal abnormality, although both showed interval nodal size reduction on the 3-month MRI, and one patient had persistent residual tumor. MRI-based response outcomes are summarized in Table 3.

At 6 months, pelvic MRI was available for all 28 patients and showed no residual primary cervical tumor or radiologically active pelvic nodal disease (28/28; 100%; 95% CI, 87.9–100). The observed 100% proportion derives from only 28 patients and remains statistically imprecise; in the absence of a control group and long-term progression-free or overall survival data, it should not be interpreted as evidence of durable local control or survival benefit. This

later imaging time point is reported separately because post-chemoradiotherapy regression can continue beyond the 3-month assessment and may be more clinically meaningful for interpreting complete radiologic response. Despite tumor- and node-negative pelvic MRI findings at 6 months, one patient developed distant pulmonary metastasis and died of progressive disease, underscoring that early pelvic imaging response does not substitute for progression-free or overall survival follow-up.

Documented acute adverse events

Acute adverse-event notes were documented for 12/28 patients (42.8%; 95% CI, 26.5–60.9). Among patients with adverse-event documentation, CTCAE grade was explicitly recorded in 6/12 (50.0%; 95% CI, 25.4–74.6). The maximum recorded adverse-event grade was grade 2 in six patients and grade 3 in two patients. One severe vaginal bleeding event during brachytherapy required hospitalization and embolization but did not have a recorded CTCAE grade. Documented adverse-event categories are summarized in Table 4.

The most frequently documented adverse-event categories were hematologic and gastrointestinal events, followed by neuropathy. Other single events included dermatologic toxicity, endocrine toxicity, procedure-related bleeding, and musculoskeletal fracture. A concurrent primary spinal tumor and one case of pulmonary metastasis with death due to progressive disease were documented as clinical events during the treatment course but were not interpreted as treatment-related toxicity. Because adverse-event capture was retrospective and documentation-based, these data should not be interpreted as reliable incidence estimates.

Discussion

In this single-center real-world cohort of 28 patients with predominantly high-risk locally advanced cervical cancer treated with induction chemotherapy, definitive chemoradiotherapy, brachytherapy, and pembrolizumab, early pelvic MRI response patterns were documented. MRI-based cCR was documented in 89.3% of patients at 3 months, and tumor- and node-negative pelvic MRI findings were observed in all 28 patients at 6 months. The 6-month finding is descriptive only and should be interpreted cautiously because it arose from a small uncontrolled cohort, the lower bound of the 95% CI was 87.9%, and long-term progression-free and overall survival outcomes were unavailable. Accordingly, it cannot establish treatment effect, durable disease control, or survival benefit.

The results are directionally consistent with the KEYNOTE-A18 program, in which pembrolizumab added to chemoradiotherapy followed by maintenance improved progression-free and overall survival in high-risk locally advanced cervical cancer[9,15]. However, direct

comparison with KEYNOTE-A18 should be made cautiously. KEYNOTE-A18 was a randomized trial powered for time-to-event outcomes, whereas the present study describes early MRI-based response in routine practice. In addition, our cohort received induction paclitaxel/carboplatin before definitive chemoradiotherapy, which differs from the KEYNOTE-A18 regimen and affects comparability.

Because all patients received a complex multimodality protocol, the contribution of any individual treatment component cannot be isolated. The favorable imaging outcomes observed here cannot be attributed specifically to pembrolizumab. They may reflect the combined effects of induction chemotherapy, concurrent chemoradiotherapy, brachytherapy, pembrolizumab, patient selection, and routine-care treatment delivery. This distinction is important because INTERLACE showed benefit from induction carboplatin/paclitaxel before standard chemoradiotherapy, whereas OUTBACK did not show survival benefit from adjuvant chemotherapy after chemoradiotherapy and was associated with increased short-term toxicity[13,17]. These trials suggest that timing and structure of treatment intensification matter.

The timing of response assessment is also important. Post-treatment MRI abnormalities after chemoradiotherapy do not necessarily indicate persistent viable tumor because edema, fibrosis, necrosis, and delayed regression can persist for several months after treatment[11,12,14]. The tumor- and node-negative pelvic MRI findings at 6 months may reflect delayed radiologic regression beyond the 3-month assessment; however, the observed 100% proportion is unstable in a cohort of 28 patients and cannot establish durable disease control or survival benefit. Moreover, one patient developed distant pulmonary metastasis and died of progressive disease, emphasizing that early pelvic MRI response does not replace progression-free or overall survival follow-up.

Toxicity findings must be interpreted with particular caution. The pattern of documented adverse events was broadly similar to prior pembrolizumab-chemoradiotherapy studies, with hematologic and gastrointestinal toxicities being the most frequently recorded events. However, comparisons of toxicity frequency should be interpreted cautiously because adverse-event capture was retrospective and incomplete. In routine care, toxicities may be recorded in free-text notes, graded inconsistently, or omitted if mild or managed outside the treating oncology documentation pathway. Therefore, the lower apparent frequency of documented adverse events in this cohort should not be interpreted as evidence of lower toxicity than clinical trials.

This study has several limitations. First, the sample size was small, and the single-center, non-comparative design prevents causal inference. Second, because all patients received induction

chemotherapy, chemoradiotherapy, brachytherapy, and pembrolizumab, the contribution of any individual treatment component to treatment response cannot be determined. Third, cCR was based on routine MRI reports without pathologic confirmation, standardized RECIST assessment, or central radiology review. Fourth, adverse events were retrospectively abstracted from routine documentation, and CTCAE grading was available for only a subset of patients; toxicity findings are therefore descriptive and not reliable for incidence estimation. Fifth, cycle-level treatment completion and full maintenance pembrolizumab completion were not fully mature or not completely extractable for all patients in the current dataset. Finally, progression-free survival and overall survival data were not available, which is a major limitation because early imaging response does not necessarily correlate with durable clinical benefit.

Despite these limitations, this study provides pragmatic real-world evidence from a population enriched for advanced and node-positive disease. The findings support the feasibility of delivering an intensified protocol incorporating induction chemotherapy, definitive chemoradiotherapy, brachytherapy, and pembrolizumab in routine practice. Future prospective studies should include standardized imaging criteria, central radiology review when feasible, complete CTCAE-based toxicity capture, detailed treatment-delivery reporting, and longer follow-up for progression-free and overall survival.

Conclusion

In this small, single-center observational cohort, an intensified multimodality protocol incorporating induction chemotherapy, chemoradiotherapy, brachytherapy, and pembrolizumab was deliverable, and favorable early MRI findings were documented. These findings do not demonstrate treatment effect because the study was uncontrolled and non-comparative, response was imaging-based without pathologic confirmation, toxicity capture was retrospective and incomplete, and long-term progression-free and overall survival outcomes were unavailable. Larger prospective studies with standardized radiologic response assessment, comprehensive adverse-event reporting, detailed treatment-completion data, and longer follow-up are required.

Declarations

Ethics approval and consent to participate

The study protocol was reviewed and approved by the institutional ethics committee (approval details withheld for double-blind peer review). Patient data were handled confidentially and analyzed in de-identified form. Written informed consent was obtained when required by the ethics committee.

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The authors received no specific funding for this work.

Competing interests

The authors declare no conflicts of interest.

Data availability

The data that support the findings of this study are available from the corresponding author upon reasonable request, subject to institutional and ethical restrictions.

Author contributions (CRediT)

The CRediT author-contribution statement is provided in the separate title-page file and has been withheld from this manuscript to preserve double-blind peer review.

Declaration of generative AI and AI-assisted technologies in the writing process

OpenAI ChatGPT, GPT-5.6 Thinking (OpenAI, San Francisco, CA, USA; accessed July 2026), was used solely for English-language editing, stylistic refinement, and reference-formatting assistance during manuscript revision. The tool was not used to generate or analyze study data, perform statistical analyses, or make scientific decisions. All AI-assisted text was reviewed and verified by the authors, who take full responsibility for the accuracy, originality, and integrity of the manuscript.

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Tables

Table 1. Baseline patient and disease characteristics

Characteristic	Overall (N = 28)
Age, years, mean ± SD	49.8 ± 10.3
Baseline tumor size, cm, median [IQR]	5.4 [4.7–6.8]
FIGO 2018 stage	
IIIC1	17 (60.7%)
IIB	6 (21.4%)
IIIC2	3 (10.7%)
IIA	1 (3.6%)
IVA	1 (3.6%)
Histology	

Characteristic	Overall (N = 28)
Squamous cell carcinoma	23 (82.1%)
Adenocarcinoma	5 (17.9%)

Note: The patient with FIGO 2018 stage IIA disease had radiologically documented nodal involvement and therefore met the study eligibility criteria. FIGO, International Federation of Gynecology and Obstetrics; IQR, interquartile range; SD, standard deviation.

Table 2. Patient flow and treatment delivery variables available from routine records

Treatment delivery variable	Available result
Patients screened	29
Excluded before treatment initiation	1 (mood disorder)
Treated and included in analysis	28
Completion of induction chemotherapy	Cycle-level completion not fully extractable for all patients from the current abstracted dataset
Completion of planned concurrent chemoradiotherapy	Cycle-level concurrent cisplatin completion not fully extractable for all patients; temporary chemotherapy delay was documented in two patients
Completion of brachytherapy	One patient was unable to proceed before brachytherapy initiation because of progression/respiratory deterioration; no other non-completion was documented in the abstracted records
Completion of maintenance pembrolizumab	Not mature/not fully extractable for all patients at the time of analysis
3-month MRI assessment available	28/28 (100%)
6-month MRI assessment available	28/28 (100%)
Documented temporary anti-cancer treatment hold/delay due to toxicity or procedure-related event	4/28 (14.3%)
Permanent treatment discontinuation due to toxicity documented in available records	0/28 (0%)

Treatment delivery variable	Available result
Treatment discontinuation or inability to proceed because of progression	1/28 (3.6%)

Note: This table summarizes variables available from the current abstracted dataset and routine documentation. CCRT, concurrent chemoradiotherapy; MRI, magnetic resonance imaging.

Table 3. MRI-based response at 3 and 6 months

MRI outcome	3-month assessment	6-month assessment
Pelvic MRI available	28/28 (100%)	28/28 (100%)
Primary tumor absent	27/28 (96.4%; 95% CI, 82.3–99.4)	28/28 (100%; 95% CI, 87.9–100)
Node-negative/inactive nodal disease	25/28 (89.3%; 95% CI, 72.8–96.3)	28/28 (100%; 95% CI, 87.9–100)
MRI-based clinical complete response	25/28 (89.3%; 95% CI, 72.8–96.3)	28/28 (100%; 95% CI, 87.9–100)
Distant progression/death	0/28 at this assessment	1/28 developed pulmonary metastasis and died of progressive disease

CI, confidence interval; MRI, magnetic resonance imaging.

Table 4. Summary of documented adverse events and clinical events

Category or variable	Documented finding
Any adverse-event documentation	12/28 (42.8%; 95% CI, 26.5–60.9)
CTCAE grade documented among patients with AE notes	6/12 (50.0%; 95% CI, 25.4–74.6)
Maximum recorded AE grade	Grade 2 in 6 patients; grade 3 in 2 patients
Severe procedure-related bleeding without CTCAE grade	1 patient; hospitalization and embolization during brachytherapy
Most frequently documented AE categories	Hematologic and gastrointestinal events; neuropathy also recorded
Other documented AE/clinical categories	Endocrine, dermatologic, musculoskeletal, concurrent spinal tumor, pulmonary metastasis/progression

AE, adverse event; CTCAE, Common Terminology Criteria for Adverse Events. Because AE ascertainment was based on routine documentation, absence of an AE note was not considered evidence that toxicity was absent.

Legend for figures

Figure 1. Patient flow diagram. A total of 29 patients were screened; 1 patient was excluded before treatment initiation because of a mood disorder; 28 treated patients were included in the final analysis; and all 28 patients underwent pelvic MRI assessment at approximately 3 and 6 months.

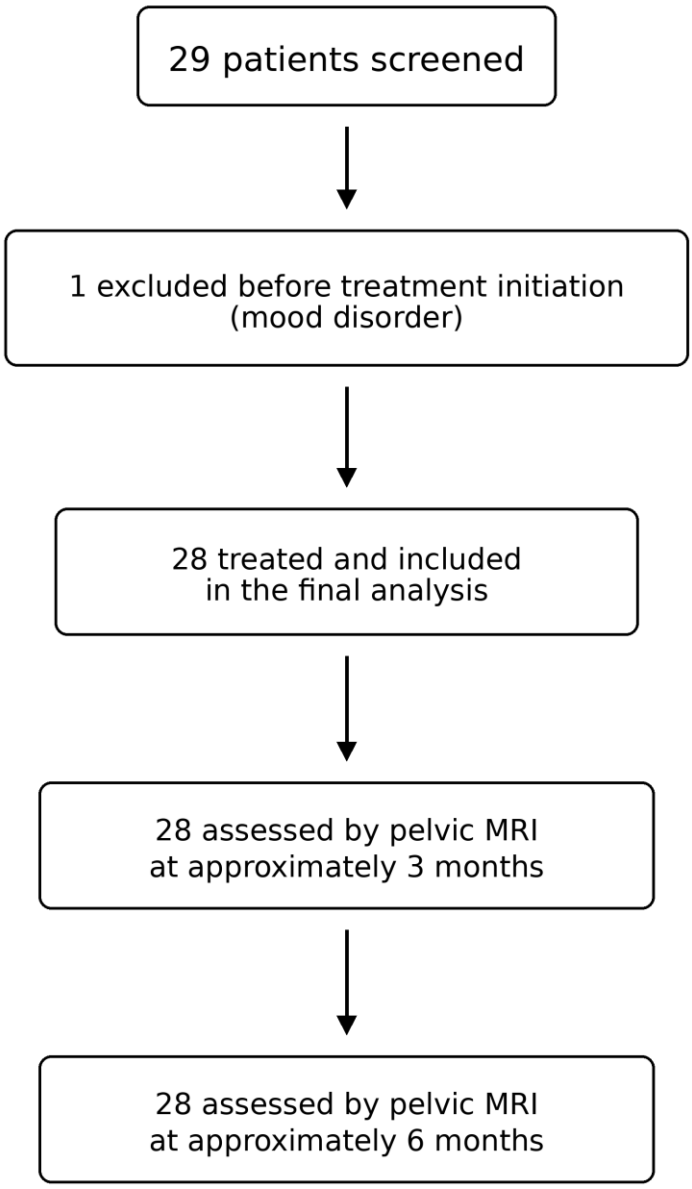

Figure 1. patient flow diagram (PNG/JPEG; also embedded in the manuscript for review).