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Radiotherapy for Gastric MALT Lymphoma: Low Doses, Local Control and Toxicity - A Narrative Review

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Abstract **Review Article**

Radiotherapy (RT) is the reference treatment for localized gastric mucosa-associated lymphoid tissue (MALT) lymphoma that is *Helicobacter pylori*-negative or persists after eradication. Because the disease is indolent and patients often survive for decades, dose de-escalation has become a central question. This review examines how far the dose can be lowered without losing local control, and what the toxicity gain actually amounts to. Narrative review of prospective trials, large retrospective series and guidelines, with priority given to prospective data and to studies reporting endoscopic, biopsy-based response and graded toxicity. Doses of 24-30 Gy deliver complete response and local control rates that are consistently above 90%. Prospective data in 62 patients (24-25.5 Gy) and a retrospective series of 202 patients (24 vs 30 Gy) suggest that 24 Gy is at least as effective as 30 Gy, with less grade 2 acute toxicity. A single-centre pilot trial of response-adapted 4 Gy in 24 patients reported an 83% complete response rate at one year and 96% three-year local control after selective 20 Gy completion, without grade 3 or higher events. Acute toxicity is mostly mild nausea and dyspepsia. Late risks (cardiac, pancreatic, splenic, renal, second cancers) are dose-dependent in principle but poorly quantified in this specific setting, and follow-up of de-escalated regimens is short. A 24 Gy prescription to the stomach is currently the best-supported standard. Ultra-low-dose 4 Gy with response-adapted completion is promising but remains investigational. Larger, longer, ideally randomized studies with patient-reported outcomes are needed.

Keywords: Gastric MALT lymphoma; extranodal marginal zone lymphoma; radiotherapy; dose de-escalation; local control; toxicity.

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INTRODUCTION

Extranodal marginal zone lymphoma of MALT type most often arises in the stomach, where it is closely tied to chronic *Helicobacter pylori* infection. When infection is present, eradication therapy is the first step and induces durable remission in a large proportion of patients [1-4]. A substantial minority, however, are *H. pylori*-negative at diagnosis, relapse, or keep residual lymphoma after successful eradication. Some of these tumours carry the t(11;18) translocation, which is enriched in *H. pylori*-negative disease and is associated with resistance to antibiotics [7]. Empirical antibiotics can still produce responses in *H. pylori*-negative cases, with complete responses reported in up to 57% in some series [6], but responses are slow and the evidence is limited.

For localized disease that is not controlled by antibiotics, RT of the whole stomach is the preferred curative option in European and international recommendations [1,2,8]. It replaced gastrectomy and extended-field irradiation decades ago, and large series now report local control in the 90-100% range [9-11]. Systemic options are less attractive in stage I-II disease: single-agent rituximab has shown clinical activity in antibiotic-resistant cases [34], but local control appears inferior to RT, and chemotherapy adds toxicity [21].

The good prognosis is exactly what makes treatment intensity contentious. A patient treated at 60 may live another 25 years with a stomach, heart, pancreas and kidneys that were partly irradiated. If 24 Gy, or even 4 Gy, achieves the same disease control as 30 Gy, the case for lowering the dose is strong. If it does not, one risks trading a small reduction in toxicity for

more relapses and more endoscopies. This review asks three questions: (i) what dose is needed for durable local control, (ii) what toxicity is attached to each dose level, and (iii) how reliable is the evidence on which current practice stands.

METHODS

This is a narrative review. The literature on gastric MALT lymphoma RT consists of a handful of prospective studies and many single-institution retrospective series, with heterogeneous endpoints, which rules out formal meta-analysis. Sources were identified through targeted searches of the published and indexed literature and conference abstracts, and through the reference lists of key papers. Prospective data, studies with biopsy-confirmed endoscopic response, and studies reporting graded toxicity were given the most weight. Extranodal MALT lymphomas at other sites are discussed only where they inform dose questions. Numerical results are reported as given by the original authors.

Rationale and clinical context

Where RT fits

The decision sequence is now fairly standard. After staging by endoscopy with multiple biopsies, cross-sectional imaging (with FDG-PET/CT or MRI at the clinician's discretion) and *H. pylori* testing, positive patients receive eradication therapy. RT is considered for *H. pylori*-negative stage I-II disease, for persistent or progressive disease after eradication, and for relapse [1,2,8]. In practice this population is small, which explains why high-level evidence is scarce.

Why the whole stomach is treated

Gastric MALT lymphoma is frequently multifocal and often endoscopically subtle, so the clinical target volume encompasses the entire stomach, with involved perigastric nodes or proximal duodenum added when suspected [8,21]. This is the main reason why "low-dose" and "small-field" are different questions: the volume cannot be reduced much, but the dose can.

Dose and local control

Conventional doses: 30 Gy and above

The 26-year Memorial Sloan Kettering experience in 178 *H. pylori*-independent cases (86% stage I; median dose 30 Gy in 20 fractions) found a local failure rate of 9.6% and distant disease in 11.8% over a median follow-up of 6.2 years, with 5- and 10-year overall survival of 94% and 79% [9]. A prospective trial of RT at 24-39.6 Gy for localized MALT lymphoma at several sites, 34 of whose 75 patients had gastric disease, confirmed excellent relapse-free survival over a median follow-up of 9.8 years [11]. Earlier moderate-dose series reported local control of 97% (60 of 62 irradiated patients, stomach and other organs; median dose 30 Gy) [33], and a Japanese series addressed outcomes beyond 10 years [12]. Teckie and colleagues showed that most relapses after curative RT in early-stage extranodal marginal zone lymphoma were distant rather than local [10], a point which matters when interpreting dose-response claims: relapse outside the field is not a failure of the prescription.

Moderate reduction: 24-25.5 Gy

Several lines of evidence support 24 Gy to 25.5 Gy (Table 1).

- A randomized phase II comparison (HELYX II) of 25.2 Gy versus 36 Gy for refractory or *H. pylori*-negative stage IE-II1E disease reported stable complete remission in all analysed patients irrespective of dose, but only 29 were randomized, 7 dropped out, and the trial was not powered to show equivalence [5].
- Pinnix et al., using IMRT in 32 patients, found that 11 treated with 24 Gy did as well as those given 30-36 Gy: all patients achieved a pathologic complete response, and 2-year freedom from local failure was 100% [13].
- Saifi *et al.,*compared 23.5-27 Gy (n=16) with 30-36 Gy (n=26) in 42 patients and reported comparable complete response with minimal toxicity [14].
- The Korean KROG 16-18 multicentre prospective study treated 62 patients with stage IE disease and no evidence of infection with 24-25.5 Gy. Six-month complete remission was 96.7%, and 5-year local failure-free and progression-free survival were 92.0% and 90.4%. No patient had acute toxicity of grade 3 or more, and 17 (27.4%) had grade 2 [15].
- A retrospective comparison of 202 stage IE patients (74 at 24 Gy, 128 at 30 Gy) reported similar disease control and significantly less grade 2 acute toxicity with 24 Gy (39.2% vs 60.9%; p=0.003) [16].

The indirect precedent is the randomized trial of Lowry *et al.,* in indolent lymphomas, where 24 Gy gave similar responses to 40-45 Gy, although only about 17% of the patients had marginal zone histology [17].

Table 1: Key studies on dose and outcome in gastric (or predominantly gastric) MALT lymphoma

Study	Design, n	Dose	Main efficacy results	Toxicity
Yahalom 2021 [9]	Retrospective, 178	Median 30 Gy/20 fx	Local failure 9.6% at median 6.2 y; 5-y OS 94%	Low; see source

Fang 2021 [11]	Prospective, 75 (34 gastric, mixed sites)	24-39.6 Gy	Excellent long-term RFS (median FU 9.8 y)	Acute 92% (grade 1-2, one grade 3); late 30% (one grade 3)
Schmelz 2019 (HELYX II) [5]	Randomized phase II, 29 randomized	25.2 vs 36 Gy	Stable CR in all analysed pts regardless of dose	Not the main focus
Pinnix 2019 [13]	Retrospective, 32 (IMRT)	24 Gy (n=11) vs 30-36 Gy	CR in all; 2-y FFLTF 100%	Minimal
Saifi 2021 [14]	Retrospective, 42	23.5-27 vs 30-36 Gy	Comparable CR	Minimal
Jeon 2025, KROG 16-18 [15]	Prospective, 62, stage IE	24-25.5 Gy	6-mo CR 96.7%; 5-y LFFS 92.0%	No grade ≥3; grade 2 in 27.4%
Baek 2025 [16]	Retrospective, 202, stage IE	24 Gy (n=74) vs 30 Gy (n=128)	Comparable control	Grade 2 acute: 39.2% vs 60.9%
Gunther 2024 [21]	Prospective pilot, 24, stage I-IV	4 Gy, then 20 Gy if not CR	CR to 4 Gy at 1 y 83%; 3-y LC 96%	No grade ≥3

CR, complete response; FFLTF, freedom from local treatment failure; FU, follow-up; LC, local control; LFFS, local failure-free survival; OS, overall survival; RFS, relapse-free survival.

Ultra-low dose: 4 Gy

The 4 Gy in 2 fractions schedule was built on experience in indolent lymphomas at other sites [20]. The randomized FoRT trial, which included follicular and marginal zone lymphomas at any site, found 4 Gy inferior to 24 Gy for local control overall; for the marginal zone subgroup, however, the 5-year local progression-free rate was 88% with 4 Gy versus 100% with 24 Gy, and the authors did not regard the superiority of 24 Gy as established in that subgroup [18,19,21]. These data are not gastric-specific.

Gunther *et al.,* then designed a response-adapted strategy: 4 Gy in two fractions, endoscopic and imaging re-evaluation at 3-4 months, observation for complete responders, re-evaluation at 6-9 months for partial responders, and a further 20 Gy for stable or progressive disease or residual lymphoma at 9-13 months [21]. In 24 patients (median age 67; 83% stage I; median follow-up 36 months), 20 (83%; 95% CI 63-95%) had a complete response to 4 Gy alone, 16 at the first evaluation and 4 later. The four who needed completion with 20 Gy all reached complete response. Three-year local control was 96% (95% CI 88-100%). One local relapse occurred at 14 months in a patient whose flat, unbiopsied scar was the site of the later positive biopsy; it was salvaged with 20 Gy. One stage IV patient developed distant relapse as DLBCL [21].

These are encouraging figures, but they come from 24 patients treated at one centre, in a trial designed without a formal hypothesis or sample size. They justify the question; they do not answer it.

What "local control" means here

Published local control figures are not interchangeable. Definitions vary: relapse or refractory disease in the stomach, transformation to DLBCL counted as local failure in some series [9], biopsy-confirmed versus clinical response, and variable numbers of endoscopic biopsies (12-16 recommended in the 4 Gy trial [21]). Imaging response is usually scored with the Lugano criteria [32], but complete response here is defined histologically. Response after RT can be slow, so a "no complete response" at 3 months is not failure. In the 4 Gy pilot, two of four patients treated with an additional 20 Gy were not in complete response at their first reassessment and converted with time [21]. This matters for protocol design: a response-adapted strategy that re-treats too early would give away the benefit of dose reduction.

Toxicity

Acute effects

Acute toxicity after gastric RT is chiefly nausea, dyspepsia, abdominal pain and fatigue. In the 4 Gy trial, nausea was grade 1 in 9 patients and grade 2 in 1, pain was grade 2 in 2 patients (both with pre-existing pain unchanged by treatment), and no grade 3 or higher event occurred [21]. In KROG 16-18 (24-25.5 Gy), grade 2 acute events affected 27.4% and none were grade 3 or worse [15]. In the comparison of 24 and 30 Gy, grade 2 acute toxicity was reported in 39.2% and 60.9%, respectively [16]. Across the mixed-site prospective trial (24-39.6 Gy), 92% had acute toxicity, nearly all grade 1-2 [11]. Because many patients are symptomatic before RT (75% in the 4 Gy trial), baseline symptoms need to be recorded, or toxicity will be over-attributed; interestingly, gastrointestinal symptoms improved or resolved in all 18 symptomatic patients in that trial after treatment [21].

Late effects and organs at risk

The heart, pancreas, spleen, kidneys and liver all receive some dose with stomach-directed fields, and

the risk of late harm is dose-dependent in principle. The available data are suggestive rather than definitive.

- **Heart.** Stomach plans often include the inferior heart, including part of the left ventricle [21]. A population analysis of early-stage gastric MALT lymphoma found improved survival with RT without an increase in cardiac death [23], but cardiac events take many years to emerge and follow-up of contemporary regimens is shorter than that.
- **Pancreas and diabetes.** In a cohort treated at a median 30 Gy, 5-year cumulative incidence of diabetes was 9.6% after RT versus 1.6% in non-irradiated patients (p=0.008), and mean pancreatic dose independently predicted diabetes [22]. This is one of the few quantitative late-effect signals specific to this disease, and it provides the strongest argument for dose reduction.
- **Spleen and lymphopenia.** Higher splenic doses have been linked to lymphopenia and late infection-related mortality in other settings [28].
- **Second malignancies.** Patients with gastric MALT lymphoma have an elevated baseline risk of gastric adenocarcinoma (reported as 6-10 times that of the general population), which is why surveillance endoscopy for intestinal metaplasia and dysplasia is recommended regardless of treatment [3]. Prior RT is a dose-dependent risk factor for gastric cancer in Hodgkin lymphoma survivors [27], but these patients received higher doses and different chemotherapy, so extrapolation to 24-30 Gy for MALT lymphoma is uncertain.

What is not known

No study has compared late toxicity prospectively between 24 and 30 Gy, or between 4 Gy and 24 Gy, in gastric MALT lymphoma. The 4 Gy trial did not collect patient-reported outcomes or quality of life [21]. Late-effects data in the lower-dose cohorts are, by construction, immature. Dose reduction is therefore a well-founded expectation of benefit, not a demonstrated one.

Technical considerations that influence toxicity

Treatment planning has changed as much as dose. Involved-site RT replaced extended-field irradiation [8,31]. Simulation and treatment with an empty stomach limit variation in organ volume. Deep inspiration breath hold reduces heart dose in stomach lymphoma IMRT [24] and was feasible in a prospective phase 2 study [25]. Daily CT-based image guidance improves target coverage [26]. In the 4 Gy trial, 3D conformal technique with a 1-2 cm expansion of the internal target volume was used for the initial 4 Gy and IMRT for the 20 Gy completion [21]. Whatever the dose, comparisons between series should account for technique: a patient treated in 1995 with anteroposterior fields was exposed to something quite different from a contemporary DIBH-IMRT plan.

Response assessment is as important as the beam. Complete response is defined histologically, imaging is frequently normal, and subtle scars can hide residual disease: the single local relapse in the 4 Gy trial arose at an unbiopsied scar [21]. De-escalated strategies depend on endoscopists as much as on radiation oncologists, and lifelong follow-up is warranted because late relapses occur [29,30].

Critical appraisal of the evidence

Several limitations apply to the whole field.

- **No gastric-specific randomized dose comparison with adequate power.** HELYX II randomized 29 patients [5]; FoRT is not gastric-specific [18,19].
- **Small prospective cohorts and short follow-up** for the lowest doses, given the indolent history of the disease and the long interval before relapses and late effects appear.
- **Selection.** Reduced-dose series tend to include patients with stage I disease, without bulky or large-cell components, who are followed with rigorous endoscopy. Results may not extend to transformed or bulky disease, or to centres with less endoscopic expertise.
- **Heterogeneous endpoints.** Local control, freedom from treatment failure and progression-free survival are defined differently across studies [9,15,21].
- **Historical comparisons.** Most “comparable to standard dose” claims rest on indirect comparison with historical series, with the usual risks of confounding by era, technique and patient mix [15].
- **Weak toxicity measurement.** Toxicity is graded retrospectively in many series, symptom attribution is difficult, patient-reported outcomes are absent, and late events are rarely recorded systematically.
- **Publication and single-centre effects**, in which the best-performing institutions report the lowest doses.

These limitations do not undermine the consistent message that 24 Gy is sufficient for most patients. They do limit confidence in claims that 4 Gy can replace it.

Practical implications

The following reflects the evidence summarized above, rather than a formal guideline.

- **Dose.** 24 Gy (24-25.5 Gy) to the whole stomach is supported by prospective and large retrospective evidence and should be considered the default for stage I-II disease where RT is indicated. 30 Gy no longer seems necessary for most patients.
- **Ultra-low dose.** Response-adapted 4 Gy followed by 20 Gy only if needed is a

reasonable option within a protocol or in carefully counselled patients in whom radiation risk is high (for example, comorbidity or prior abdominal RT) or who decline longer treatment, with the understanding that follow-up is short.

- **Patient selection.** Prefer stage I disease without bulky or large-cell components. t(11;18) positivity should prompt closer follow-up rather than exclusion, as 2 of 4 such patients in the 4 Gy trial responded completely to 4 Gy alone [21].
- **Technique.** Use involved-site targeting, empty stomach, DIBH where available, and image guidance.
- **Response assessment.** Use systematic gastric biopsies (including normal-appearing antrum and body), allow time for response (up to 12 months), and avoid re-treating asymptomatic patients early.
- **Surveillance.** Lifelong follow-up, including surveillance for gastric adenocarcinoma [3,29].

Research priorities

The priorities are clear. A randomized non-inferiority trial of 24 Gy versus a response-adapted ultra-low-dose strategy in gastric MALT lymphoma would settle the dose question, provided its primary endpoint is durable local control with a pre-specified margin. It should record patient-reported outcomes, standardized baseline symptoms, dosimetric data on heart, pancreas, spleen and kidneys, and long-term endocrine and cardiac events. Biomarkers (t(11;18), prior antibiotic exposure) should be reported to predict who needs the completion dose. A larger study of the response-adapted approach in marginal zone lymphoma at several sites (NCT05929612) is ongoing, and a lower completion dose of 12 Gy has been proposed [21]. International registries would help given the rarity of the disease.

CONCLUSION

For localized gastric MALT lymphoma that is not controlled by antibiotics, RT remains a highly effective, organ-preserving treatment. The evidence supports 24 Gy as the best-supported dose, with local control above 90% and less acute toxicity than 30 Gy. Four gray, delivered as the first step of a response-adapted program, is a promising approach that could spare many patients further irradiation, but it rests on 24 patients and three years of follow-up. Until larger trials are available, it should be used within protocols or after careful counselling. Dose reduction should be pursued, but measured on both axes: local control and the late effects that justify it.

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