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Original Article

Efficacy and Safety of Tislelizumab in Combination with Chemotherapy versus Placebo Plus Chemotherapy in Patients with Advanced Gastric Cancer or Gastroesophageal Junction Cancer: A Systematic Review of Randomized Controlled Trials

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ABSTRACT

Introduction Advanced gastric cancer or gastroesophageal junction cancer (GC/GEJC) is an aggressive malignancy often having a poor prognosis. Despite current systemic therapies, GC/GEJC remains the third most common cause of cancer-related deaths worldwide. Tislelizumab, an anti-PD1 antibody, has shown promising results in treating various cancers. Therefore, this systematic review investigated the efficacy and safety of tislelizumab plus chemotherapy for patients with GC/GEJC.
Methods: Five databases were systematically searched until July 10, 2024. Articles identified in the screening process included two RCTs based on predefined inclusion criteria. We performed data extraction sheets and quality assessments using the Cochrane ROB2 tool.
Results: Out of the two randomized controlled trials (RCTs), 1646 patients were included in our systematic review. In Rational-306, efficacy outcomes improved, overall survival (OS) significantly improved from 10.6 months (95% CI 9.3–12.1) to 17.2 months (95% CI 15.8–20.1), and progression-free survival (PFS) from 5.6 months (4.9–6.0) to 7.3 months (6.9–8.3). Rational-305 also notably significantly improved.
Outcomes: Improved OS from 12.9 months (12.1-14.1) to 15 months (13.6-16.5), and PFS from 6.2 months (5.6 to 6.9) to 6.9 months (5.7 to 7.2). The proportion of patients with any grade 3 or worse treatment-related adverse events was similar between treatment groups.
Conclusion: Compared with chemotherapy and placebo, Tislelizumab plus chemotherapy demonstrates superior efficacy with a similar safety profile in the two groups, encouraging the use of the tislelizumab group in patients with GC/GEJC.

1. Introduction

Gastrointestinal (GI) cancers account for more than 25% of newly diagnosed cancers worldwide, with incidence reaching up to more than 4 million cases per year [1]. In 2020, Gastroesophageal junction cancers (GEJCs) ranked 7th globally in incidence and 6th in mortality rate [2]. Although GEJCs are rare [3], their diagnosis is still poor until metastasized [4, 5]. GEJC poses significant therapeutic challenges due to its complex location where the stomach and esophagus meet and its tendency to present at advanced stages [6]. Surgical intervention remains the only definite treatment, even though high recurrence may occur in poorly differentiated tumors [7], with 5-year survival rates averaging around 30% with surgery alone [8]. Therefore, there is a revolution of immunotherapy use as a potential treatment in a neoadjuvant setting before the surgery, hoping to minimize surgery and tumor recurrence. Immune evasion occurs when PD-1 binds to its ligand, programmed death-ligand 1 (PD-L1), in turn inhibiting T-cell activity and establishing an immunosuppressive environment. [9, 10]. Targeting the PD-1/PD-L1 pathway has shown good antitumor activity and safety in gastroesophageal junction cancer [11, 12]. Tislelizumab (BGB-A317), a humanized immunoglobulin G4 variant, is an anti-PD-1 monoclonal antibody [13]. It shows superior clinical efficacy in multiple types of cancer, including non-small cell lung cancer (NSCLC) [14], nasopharyngeal carcinoma (NPC) [15], unresectable hepatocellular carcinoma (uHCC) [16], and upper tract urothelial carcinoma (UC) [17]. In March 2024, the FDA approved Tislelizumab in esophageal squamous cell carcinoma (ESCC) compared to chemotherapy based on the RATIONALE-302 trial as a second-line setting for patients who have not previously received any PD-1/PD-L1 inhibitors. Also, in December 2024, the FDA approved Tislelizumab in combination with chemotherapy as a first-line setting for advanced gastric cancer and gastroesophageal junction cancer (GC/GEJC) based on the RATIONALE-305, which

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is included in our systematic review. This systematic review investigated the efficacy and safety of tislelizumab plus chemotherapy compared to placebo and chemotherapy in GC/GEJC, trying to shed light on this combination as a first-line setting for GC/GEJC patients.

2. Methods

We established this systematic review with the standards of the Cochrane Handbook for Systematic Reviews of Interventions 2019 and the preferred reporting items for systematic reviews and meta-analysis 2020. Our protocol is registered on Prospero with the ID number CRD42024616507.

2.1. Literature Search

We performed a comprehensive literature search on five databases: PubMed, Cochrane Library, Scopus, Ovid, and Embase, to identify the relevant studies for our systematic review. The retrieval cutoff date was July 10, 2024. Our strategy was based on Medical Subject Headings (MeSH terms), other medical synonyms, and search strategies in advanced gastric cancer or gastroesophageal junction adenocarcinoma (GC/GEJC). A part of our literature search is ("Tislelizumab") OR ("BGB-A317") AND ("Chemotherapy") AND ("Gastroesophageal Junction Adenocarcinoma").

2.2. PICO and Eligibility Criteria

Our specific PICO represents patients with advanced gastric cancer or gastroesophageal junction cancer (GC/GEJC) aged 18 years or more without restrictions to tumor grade. They were randomized to receive either tislelizumab, an intravenous PD-1-targeted inhibitor, combined with chemotherapy or chemotherapy plus placebo, measuring overall survival (OS) as the primary outcome, and progression-free survival (PFS), objective response rate (ORR), time to progression, duration of response (DoR), and adverse events (AEs) as the secondary outcomes. We determined specific inclusion criteria as follows: (a) included all randomized controlled clinical trials (RCTs) that assessed the efficacy and safety of tislelizumab plus chemotherapy versus placebo plus chemotherapy in patients with advanced gastric cancer or gastroesophageal junction cancer (GC/GEJC). (b) We only included RCTs written in English. Exclusion Criteria: (a) Excluded all study designs rather than RCTs (literature reviews, case reports, and cohorts). (b) Excluded other combinations, either with tislelizumab or chemotherapy in patients with advanced gastric cancer or gastroesophageal junction cancer (GC/GEJC). (c) Excluded chemotherapy combined with tislelizumab in patients with other types of cancer. (d) Excluded animal studies or preclinical studies.

2.3. Data Extraction

We created a spreadsheet to extract data from the included RCTs. Two independent reviewers extracted the following data from each study: study characteristics, including study ID, authors' names, year of publication, country of the study, and study design; patients' demographic characteristics, including the number of patients in intervention and control groups, age, gender distribution, race, number of metastases, PDL expression, TAP score, interventions, dosage of the combined interventions, and duration of the treatment; and outcome characteristics including Overall survival (OS), Progression-free survival (PFS), objective response rate (ORR), disease control rate (DCR), and adverse events (AES).

2.4. Quality Assessment

To assess the risk of bias (RoB) in included RCTs and minimize the potential of bias, two independent authors used the Cochrane Risk of Bias (RoB2) version. They evaluated the five domains in the ROB2 tool: randomization process, deviations from intended interventions, missing outcome data, measurement of the outcome, and selection of the reported result. The overall RoB for each study was determined based on the judgments made for each of the five domains. Each domain is assessed for RoB 2 as either low, with some concerns, or high. The two authors followed the guidelines provided by the Cochrane Handbook for Systematic Reviews of Interventions to assess the RoB 2 in included RCTs. More details about ROB2 results are provided in **(Figure 1)**.

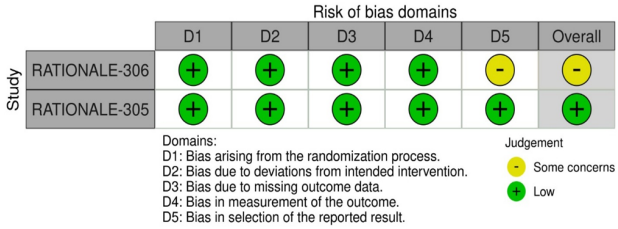


Figure 1: Risk of Bias Assessment of Included Trials

3. Results

3.1. Study Selection

The initial search identified 1,880 studies. After removing 558 duplicates, 1,322 unique records were screened by title and abstract. Of these, 1,303 records were excluded for not meeting the inclusion criteria, leaving 19 full-text articles for detailed evaluation. Among these, five were excluded as protocol-only publications, nine as abstracts, one as an editorial, and two as single-arm. Ultimately, only two studies met the eligibility criteria and were included in this systematic review. The PRISMA flow diagram **(Figure 2)** details the study selection process.

3.2. Study Characteristics

The included studies were large-scale randomized controlled trials published between 2023 and 2024, investigating the efficacy and safety of Tislelizumab, a monoclonal antibody targeting programmed cell death-1 (PD-1), in combination with chemotherapy versus placebo and chemotherapy for patients with locally advanced or metastatic esophageal squamous cell carcinoma (ESCC) and gastric or gastroesophageal junction (G/GEJ) adenocarcinoma. The trials, conducted globally, enrolled HER2-negative patients aged 18 or older with advanced or unresectable disease. Key exclusion criteria included HER2-positive tumors, active leptomeningeal disease, uncontrolled brain metastasis, and prior anti-PD-1/PD-L1 therapy. In all trials, patients were randomized to receive 200 mg of Tislelizumab or a matching placebo every three weeks, along with chemotherapy regimens tailored to each study. Frequently used agents included capecitabine, oxaliplatin, and cisplatin, administered as initial cycles or maintenance therapy until disease progression or unacceptable toxicity. Baseline characteristics and demographics were balanced across treatment groups. Specific endpoints included survival outcomes, progression metrics, and objective response rates **(Table 1)**.

3.3. Efficacy outcomes

3.3.1. Overall Survival (OS)

The study by Qiu et al. (2024) found that Tislelizumab-treated patients had a median OS of 15.0 months (range: 13.6–16.5)

Table 1: Baseline Characteristics of Included Randomized Controlled Trials

Study ID	Country	Study Design	Year	No. of Patients	Age, median (range), years	No. Male
Miao-Zhen Qiu, 2024 (Rational-305)	China	RCT (randomized, double-blind, phase 3 trial)	2024	997	60.0 (53.0–66.0)	692
Jianming Xu, 2023 (Rational-306)	China	RCT (randomized, double-blind, phase 3 trial)	2023	649	64.0 (59.0–69.0)	563

Table 2: Efficacy Outcomes of Included Randomized Controlled Trials

Study ID	Median Overall Survival (months, CI)	Median Progression-free Survival (months, CI)	Median Objective Response Rate (CI)	Median Disease Control Rate (CI)
Miao-Zhen Qiu, 2024 (Rational-305)	15.0 (13.6–16.5) vs 12.9 (12.1–14.1)	6.9 (5.7–7.2) vs 6.2 (5.6–6.9)	90 (87–92) vs 83 (80–86)	48 (43–52) vs 41 (36–45)
Jianming Xu, 2023 (Rational-306)	17.2 (15.8–20.1) vs 10.6 (9.3–12.1)	7.3 (6.9–8.3) vs 5.6 (4.9–6)	89% (85–92) vs 80% (75–84)	63% (58–69) vs 42% (37–48)

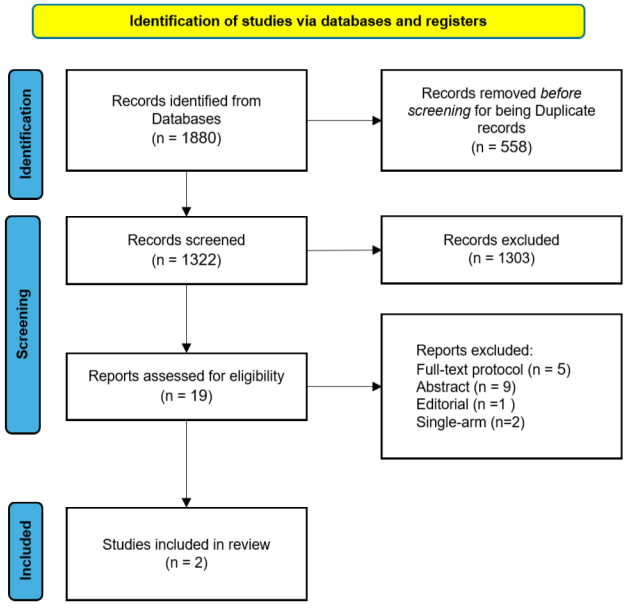


Figure 2: PRISMA Flow Diagram of Study Selection

compared to 12.9 months (range: 12.1–14.1) in the control group. In the study by Xu et al. (2023), Tislelizumab-treated patients had a median OS of 17.2 months (range: 15.8–20.1), which was significantly longer than the 10.6 months (range: 9.3–12.1) in the control group. Both studies showed a clear survival benefit with Tislelizumab **(Table 2)**.

CI, confidence interval; OS, overall survival; PFS, progression-free survival; ORR, objective response rate; DCR, disease control rate.

3.3.2. Progression-Free Survival (PFS)

Qiu et al. (2024) reported a median PFS of 6.9 months (range: 5.7–7.2) for Tislelizumab-treated patients compared to 6.2 months (range: 5.6–6.9) in the control group. The study by Xu et al. (2023) showed a median PFS of 7.3 months (range: 6.9–8.3) for Tislelizumab-treated patients, compared to 5.6 months (range: 4.9–6.0) in the control group. In both studies, Tislelizumab demonstrated a benefit in PFS **(Table 2)**.

3.3.3. Disease Control Rate (DCR)

In the study by Qiu et al. (2024), Tislelizumab-treated patients achieved a DCR of 90% (range: 87–92%) compared to 83% (range: 80–86%) in the control group. Xu et al. (2023) reported a DCR of 89% (range: 85–92%) for Tislelizumab-treated patients versus 80% (range: 75–84%) in the control group. Both studies showed a higher DCR in the Tislelizumab-treated group **(Table 2)**.

3.3.4. Objective Response Rate (ORR)

The study by Qiu et al. (2024) found that 48% of Tislelizumab-treated patients achieved an ORR (range: 43–52%), compared to 41% (range: 36–45%) in the control group. In the study by Xu et al. (2023), Tislelizumab-treated patients showed a higher ORR of 63% (range: 58–69%) compared to 42% (range: 37–48%) in the control group **(Table 2)**.

3.3.5. Adverse Events (AEs)

Across both RATIONALE-306 and RATIONALE-305, nearly all treatment-emergent adverse events were low grade: most adverse events were Grade 1–2, and no Grade 5 events occurred in either arm. This implies that adding Tislelizumab to chemotherapy has meaningful safety besides its high efficacy compared to a placebo with chemotherapy. For instance, Grade 1–2 rates for decreased appetite were 33.53% vs. 34.07% in Tislelizumab and placebo groups, respectively in RATIONLE 306 and 32.82% vs 33.44% in RATIONALE-305. Nausea, vomiting, fatigue, hypoesthesia, asthenia, and a few hematologic events (e.g., anemia, decreased WBC, peripheral sensory neuropathy) showed only mild differences in the two groups Tislelizumab and placebo groups. The sole notable imbalance was hypothyroidism, which was modestly higher with Tislelizumab (10.78% vs 2.42% in RATIONALE-306 and 9.51% vs 4.33% in RATIONALE-305).

4. Discussion

In this systematic review, we found that the combination therapy of Tislelizumab and chemotherapy was superior to placebo with chemotherapy in all efficacy measurements: overall survival (OS), progression-free survival (PFS), objective response rate (ORR), and disease control rate (DCR), in turn, it represents a potent

targeted therapy for GC/GEJC. Importantly, this combination therapy maintained an acceptable and manageable profile of adverse effects that was consistent with the adverse events associated with the usage of anti-PD-1 drugs. Multiple studies have investigated the safety and efficacy of tislelizumab alone or combined for the treatment of gastroesophageal junction cancer: adenocarcinoma and ESCC. A phase I study by Desai et al. has demonstrated an acceptable safety profile for tislelizumab in the treatment of advanced solid tumors, including esophageal cancer (EC) and gastric cancer (GC) [18]. A phase II study by Xu et al. has shown that tislelizumab plus chemotherapy had durable responses and a manageable safety profile in patients with advanced GEJ adenocarcinoma [19]. In the RATIONALE-302 phase III study, Ajani et al. found that tislelizumab monotherapy had better overall survival rates and safety profile than mono-chemotherapy [20]. Another study by Kim et al. found that Asian patients with ESCC who received tislelizumab monotherapy had better health-related quality of life and ESCC symptoms compared to patients who received chemotherapy alone [21]. However, and to the best of our knowledge, no RCTs have directly compared tislelizumab monotherapy to combination therapy of tislelizumab plus chemotherapy. In the TD-NICE phase II study, Yan et al. found that the combination therapy of tislelizumab plus chemotherapy demonstrated a promising antitumor activity [22]. Moreover, Xu et al. found that adding tislelizumab to chemotherapy could be a new first-line treatment for advanced ESCC and GEJ adenocarcinoma [23]. Tislelizumab plus chemotherapy has shown superiority to pembrolizumab plus chemotherapy in KEYNOTE-059, KEYNOTE-061, and KEYNOTE-062 [24]. In addition, Tislelizumab plus chemotherapy is superior to other combinations such as Nivolumab plus chemotherapy in ATTRACTION-4 [23] and Sintilimab plus chemotherapy in ORIENT-16 [25]. Our results from RATIONALE-305, and RATONALE-306 imply that Tislelizumab may yield better results for patients with higher PD-L1 TAP scores. However, due to the limited amount of RCTs and the challenges associated with multiple PD-L1 scoring methods across different studies, future studies should further investigate the relationship between PD-L1 TAP score status and their ability to predict treatment efficacy with PD-L1 inhibitors such as tislelizumab for patients with ESCC or GEJ adenocarcinoma.

In addition to its novelty, a notable strength of this paper is that both RCTs included in our review were conducted globally, involving numerous medical centers across Asia, Europe, Oceania, and North America. However, the study has limitations, including two RCTs and the potential concerns regarding the risk of bias in one of the included RCTs. Despite the limitations, the results of our systematic review confirm the safety and efficacy of tislelizumab when used in conjunction with chemotherapy for treating gastroesophageal junction adenocarcinoma or esophageal squamous cell carcinoma. These findings also emphasize the need for further RCTs investigating this topic.

More randomized clinical trials are necessary to compare tislelizumab plus chemotherapy and placebo plus chemotherapy in GC/GEJC. In addition, we need clinical trials to compare tislelizumab plus chemotherapy versus tislelizumab as monotherapy in GC/GEJC since this approach has not yet been studied. Tislelizumab plus chemotherapy has shown promising results in GEJC and NSCLC; in turn, it should be investigated in new solid tumors treated with PD-1 inhibitors like breast cancer and colorectal. In addition, Tislelizumab plus chemotherapy should be more investigated in GC/GEJC, HCC, NSCLC, and nasopharyngeal carcinoma, as there are still few trials about this combination, which requires more trials to be clearly understood.

5. Conclusion

Compared with chemotherapy and placebo, Tislelizumab plus chemotherapy demonstrates superior efficacy with a similar safety profile in the two groups, encouraging the use of the tislelizumab group in patients with GC/GEJC. More clinical is necessary to compare tislelizumab plus chemotherapy to chemotherapy and placebo and to use tislelizumab with chemotherapy in more solid tumors, which are now treated with PD-1 inhibitors as first or second lines.

Conflicts of Interest

The authors declare that they have no competing interests that could have influenced the objectivity or outcome of this investigation.

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Institutional Review Board (IRB) approval

None

Large Language Model Statement

None

Authors Contribution Statement

ARB conceptualized the study; ARB and AMH developed the methodology; ARB, MA, and MW conducted literature screening; MA and AMS performed quality assessment; MA and ARB handled data extraction; ARB, MA, MW, and AMS wrote the manuscript; ARB and AMS reviewed and edited; All authors reviewed and approved the final manuscript and ensured its accuracy and integrity.

Data Availability Statement

This review article does not contain any new primary data. All information discussed is derived from previously published sources and publicly available databases, as cited in the manuscript.

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