W5B-SPGI: Discordance rates on primary tumor assessment between Blinded Independent Central Review (BICR) readers in advanced or metastatic esophageal cancer applying RECIST 1.1 criteria

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INTRODUCTION

Esophageal cancer is the eighth most common type of cancer worldwide and the sixth leading cause of cancer-related mortality, with poor overall 5-year survival rate, ranging from 15% to 25%[1,2]. Poor outcome is related to diagnosis at locally advanced and metastatic stages[1].

The RECIST 1.1 criteria are widely applied for the response assessment to anti-cancer treatments in late-stage solid tumors. However, it is also known to have certain limitations with the digestive organ tumors, including esophageal cancer, because:

- **Primary lesions could infiltrate the cavity organ and appear with unclear margins**
- **The presence of scar tissue due to the prior local treatment may cause ambiguity**
- **Certain examines such as the use of barium meal and endoscopy are omitted from the RECIST1.1 evaluation**
- **Independent central readers are often blinded to patient clinical symptoms and outcomes**

Due to the above reasons, primary lesions at baseline are often classified as non-measurable, which may lead to the discrepancies in RECIST response assessment.

[1]. Pennathur, A et al. Oesophageal carcinoma. The Lancet 381, 400–412 (2013).
[2]. Arnal, M. J. D. Esophageal cancer: Risk factors, screening and endoscopic treatment in Western and Eastern countries. World J. Gastroenterol. 21, 7933 (2015).

OBJECTIVES

- **To assess the inter-reader variability between paired readers in the baseline lesion selection on esophagus**
- **To evaluate its impact on the response evaluation applying RECIST 1.1**

METHODS

- We included **426 esophageal cancer subjects** with **1506 timepoints** included in the BICR process and assessed by **8 independent radiologists**.
- We investigated Target Lesion (TL) **distribution** in different organs at baseline.
- Subsequently, we analyzed the **discordance rates of baseline assessment** of esophagus, categorized as no lesion, target lesion, and non-target lesion (NTL) and its **impact** on the overall response discordance.

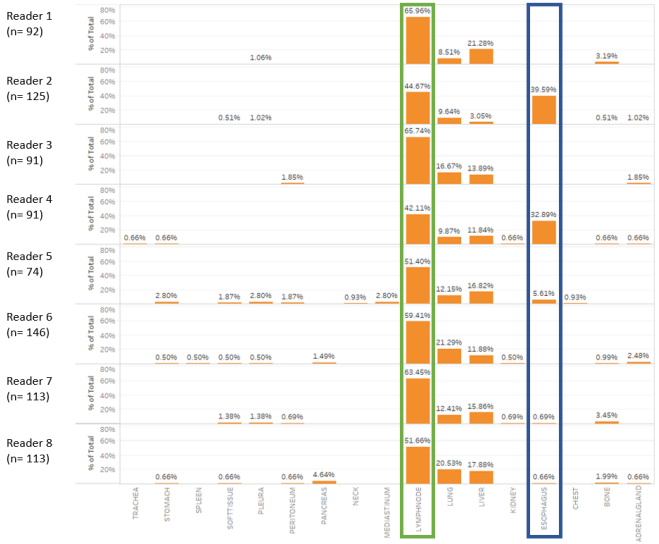

Fig. 1 The target lesion distribution in different organs is listed. The most common site of target lesion was lymph node (green), and two readers considered esophageal lesions as target lesion regularly (blue).

RESULTS

- **Two hundred forty-nine (58.5%) subjects had evidence of disease**, with either TL or NTL selected on esophagus by at least one reader at baseline.
- When both readers considered evidence of disease on esophagus (n=125), **the discordance of TL vs NTL selection was 46.4%.**
- The baseline TL distribution in different organs is listed in **Fig 1.** The **most common site of TL** selected by the readers was **lymph nodes**. Two readers considered esophageal lesions as TLs regularly. Discrepancy was detected to differentiate between **primary esophageal mass and lymph node** (an example shown in **Fig 2**)
- Considering overall response assessment, 13 subjects with **baseline esophageal NTL had progressive disease (PD)** due to the progression of the specified esophageal lesions by at least one reader (an example showed in **Fig 3**), while both readers assigned PD on 6 subjects.

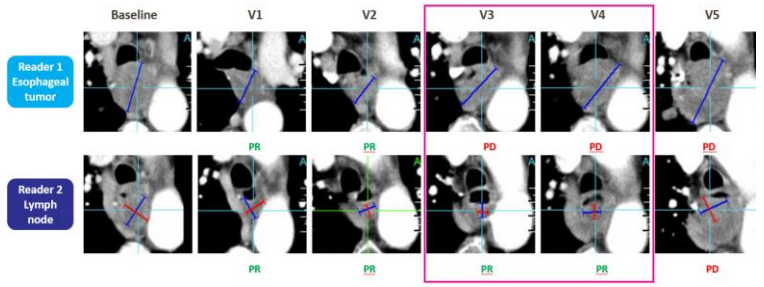

Fig. 2 The same lesion was selected as target lesion by both readers, while reader 1 considered it as primary esophageal tumor (measured the longest dimension) and reader 2 considered it as lymph node (measured on the short axis). The baseline discrepancy led to RECIST 1.1 overall response discordance between two readers due to target lesion selection and measurement.

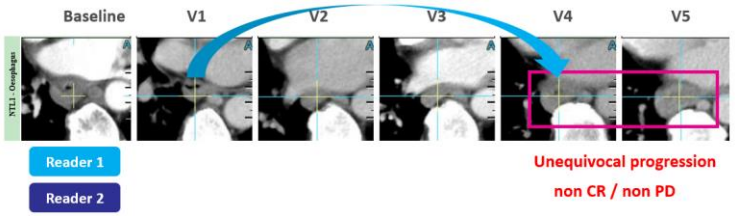

Fig. 3 The esophageal tumor was selected as non target lesion at baseline by both readers. Reader 1 assigned PD at V4, while reader 2 considered no progression. The discordance was due to non target lesion assessment.

CONCLUSIONS

- **This study demonstrated high discrepancies on assessing presence or measurability of primary esophageal tumor selection applying RECIST 1.1 with potential impact on local progression discrepancy.**
- **Therefore, reader training at the study initiation could be helpful to reach more consensus among readers through the group discussion on challenging cases.**

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