

Assessment of Seasonal Variation in the Performance of Fecal Immunochemical Testing for Colorectal Cancer Screening

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Background

- Colorectal cancer (CRC) is a heavy burden worldwide, and CRC screening has been implemented nationally in developed countries.
- The guaiac fecal occult blood test (gFOBT) has been the primary screening modality for CRC screening, but it has recently been replaced with fecal immunochemical testing (FIT).

Colorectal cancer screening in Japan

- CRC screening was incorporated into the national program in 1992. The method employed is FIT, with a screening interval of one year. Since its introduction, the two-sample method has been maintained.
- The participation rate, including both community-based and workplace screening, has remained below 50% over the past decade.
- Individuals who undergo FIT are required to bring their samples to clinics or hospitals directly. Mailing FIT has generally been prohibited, but some municipalities have implemented it, excluding this option only in the summer.

Objective

- While FIT is generally well accepted due to the lack of dietary or medication restrictions, test results may be unstable during the summer because of hemoglobin degradation. However, recent advances in FIT technology have improved its reliability across all seasons.
- Mailing FIT has become common due to its convenience, and increased participation has been reported.
- We assessed the seasonal variation in FIT performance using large-scale data of community-based screening in Japan.

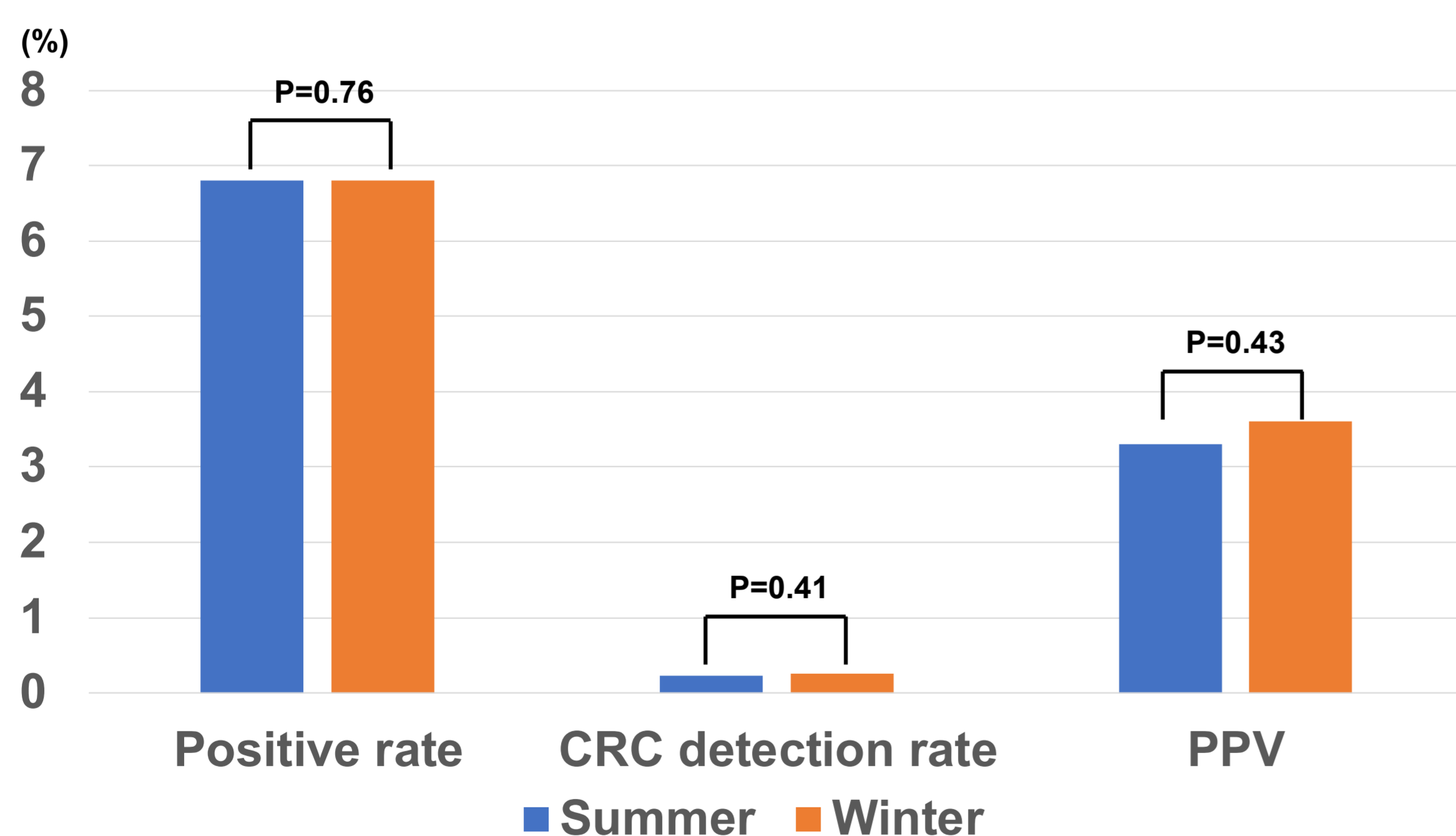
Methods

- A total of 383,793 individuals participated in community-based screening in Ibaraki Prefecture from April 2021 to March 2023.
- Participants whose eligibility was confirmed on the testing day were included in the analysis.
- The four seasons were defined according to the criteria of the Japan Meteorological Agency.
- The positive rate, CRC detection rate, positive predictive value (PPV), and number needed to scope (NNS) were calculated for each season. The chi-square test was used to compare these indicators in each season.

Table. Test performance of FIT among the four seasons

	Spring March to May	Summer June to August	Autum September to November	Winter December to February	All season
Number of participants	37,087	130,824	144,247	58,261	370,419
Number of positive results	2,796	8862	9,342	3,969	24,969
(%)	(7.5)	(6.8)	(6.5)	(6.8)	(6.7)
Number of detected cancers	80	295	345	143	863
(%)	(0.22)	(0.23)	(0.24)	(0.25)	(0.23)
Positive predictive value (%)	2.9	3.3	3.7	3.6	3.5
Number needed to scope	35	30	27	28	29

Figure. Comparison of the test performance of FIT between summer and winter



Results

- The subjects were divided by season as follows; 37,087 in spring, 130,824 in summer, 144,247 in autumn, and 58,261 in winter.
- The average of the performance indicators was 6.7% for the positive rate, 0.23% for the CRC detection rate, and 3.5% for the PPV.
- The positive rate in spring (7.5%) was higher than in other seasons, while the CRC detection rate in winter (0.25%) was higher than in other seasons.
- There are no statistically significant differences in test performance indicators between summer and winter; positive rates were 6.8% vs. 6.8%, CRC detection rates were 0.23% vs. 0.25%, and PPVs were 3.3% vs. 3.6%.

Discussion

- Throughout the year, participation in summer is relatively high as well as in autumn. Although low test performance was reported in summer in some previous studies, this study suggested that comparative performance could be maintained between summer and winter.
- In Japan, mailing FIT was not recommended due to the high summer temperatures; however, advanced devices are used during summer.
- If the test performance of FIT screening is reliable throughout all seasons, mailing FIT may be a feasible approach to improve the participation rate in Japan.

Conclusion

- There is no significant difference in the seasonal variations of test performance indicators in FIT screening.
- Stable results can be obtained throughout all seasons, and it is unnecessary to avoid the summer.
- Mailing FIT may be considered as an option for CRC screening to improve flexibility.