



# Current Status of “Watch-and-Wait” Rectal Cancer Treatment in Asia-Pacific Countries

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**Purpose:** Current acceptance of the watch-and-wait (W&W) approach by surgeons in Asia-Pacific countries is unknown. An international survey was performed to determine status of the W&W approach on behalf of the Asia-Pacific Federation of Coloproctology (APFCP).

**Methods:** Surgeons in the APFCP completed an Institutional Review Board-approved anonymous e-survey and/or printed letters (for China) containing 19 questions regarding nonsurgical close observation in patients who achieved clinical complete response (cCR) to neoadjuvant chemoradiotherapy (nCRT).

**Results:** Of the 417 responses, 80.8% (n = 337) supported the W&W approach and 65.5% (n = 273) treated patients who achieved cCR after nCRT. Importantly, 78% of participants (n = 326) preferred a selective W&W approach in patients with old age and medical comorbidities who achieved cCR. In regard to restaging methods after nCRT, the majority of respondents based their decision to use W&W on a combination of magnetic resonance imaging results (94.5%, n = 394) with other test results. For interval between nCRT completion and tumor response assessment, most participants used 8 weeks (n = 154, 36.9%), followed by 6 weeks (n = 127, 30.5%) and 4 weeks (n = 102, 24.5%). In response to the question of how often responders followed-up after W&W, the predominant period was every 3 months (209 participants, 50.1%) followed by every 2 months (75 participants, 18.0%). If local regrowth was found during follow-up, most participants (79.9%, n = 333) recommended radical surgery as an initial management.

**Conclusion:** The W&W approach is supported by 80% of Asia-Pacific surgeons and is practiced at 65%, although heterogeneous hospital or society protocols are also observed. These results inform oncologists of future clinical study participation.

**Keywords:** Rectal neoplasms; Neoadjuvant chemoradiotherapy; Watch and wait

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## INTRODUCTION

The standard management for patients with locally advanced rectal cancer is neoadjuvant chemoradiotherapy (nCRT) followed by total mesorectal excision, which can produce good local control and long-term survival [1, 2]. However, radical surgical resection can be associated with postoperative morbidities, including sexual, urinary, and sphincteric dysfunction, in addition to permanent stoma formation [3, 4]. A watch-and-wait (W&W) approach for select patients with rectal cancer may also allow for the achievement of a complete clinical response (cCR) to CRT [5-7].

Evidence supporting this organ-preserving W&W paradigm has been recently reported; however, a lack of evidence from randomized clinical trials may be a hurdle for the adoption of this

approach in routine clinical practice.

Current attitudes toward W&W among colorectal surgeons in Asia-Pacific countries are unknown. An international survey was performed to determine the current status of W&W paradigm use on behalf of the Asia-Pacific Federation of Coloproctology (APFCP).

## METHODS

This study was approved by the Samsung Medical Center Institutional Review Board (IRB No. 2019-08-036-001). We designed an online survey using a google survey (<https://forms.gle/zuFtV-jATomWz4oim9>) (Appendix). The survey consisted of 19 questions pertaining to respondent characteristics, general recognition of the W&W policy, detailed methods for CRT, and follow-up after W&W. The survey was sent anonymously to APFCP members (except for those in China) from August 31, 2019 to November 16, 2019. Printed letters were sent to the participants in China (mostly Beijing area). The IBM SPSS Statistics ver. 25.0 (IBM Co., Armonk, NY, USA) was used for descriptive statistical analysis. Comparison between groups was tested using the chi-square or Fisher exact test as appropriate. A P-value  $\leq 0.05$  was considered statistically significant.

## RESULTS

A total of 417 participants (13.3%) responded to the survey that was sent to a total of 3,125 email or mail addresses within 3 months from initial contact. Distribution of the responders according to participating country, age, specialty, and affiliation are listed in Table 1. Twenty-three responders (5.5%) were from Australia, 79 (18.9%) from Japan, 81 (19.4%) from Korea, 202 (48.4%) from China, and the remaining responders were from Bangladesh, England, India, Malaysia, Myanmar, New Zealand, Philippines, Singapore, Thailand, and Vietnam. The majority of responders (407 responders, 97.6%) were colorectal surgeons, and 379 responders (90.9%) were staff of a university or tertiary hospital.

### General recognition

Of the 417 responders, 80.8% (n = 337) supported the W&W approach, and 65.5% (n = 273) practiced this approach in patients with cCR after nCRT (Fig. 1). Seventy-eight percent of surgeons (n = 323) explained the W&W option to patients showing cCR after nCRT. Importantly, 78% of responders (n = 326) preferred a selective W&W approach in patients with old age and medical comorbidities who achieved cCR, whereas 13% (n = 54) performed radical surgery regardless of clinical response, and 9% (n = 37) always recommended W&W.

Responders were able to select multiple responses to questions # 5 and #7; thus, percentages do not sum to 100%. Lack of experience with this policy (n = 144, 34.5%) was mainly due to inaccuracy of current evaluation methods (n = 93), followed by lack of

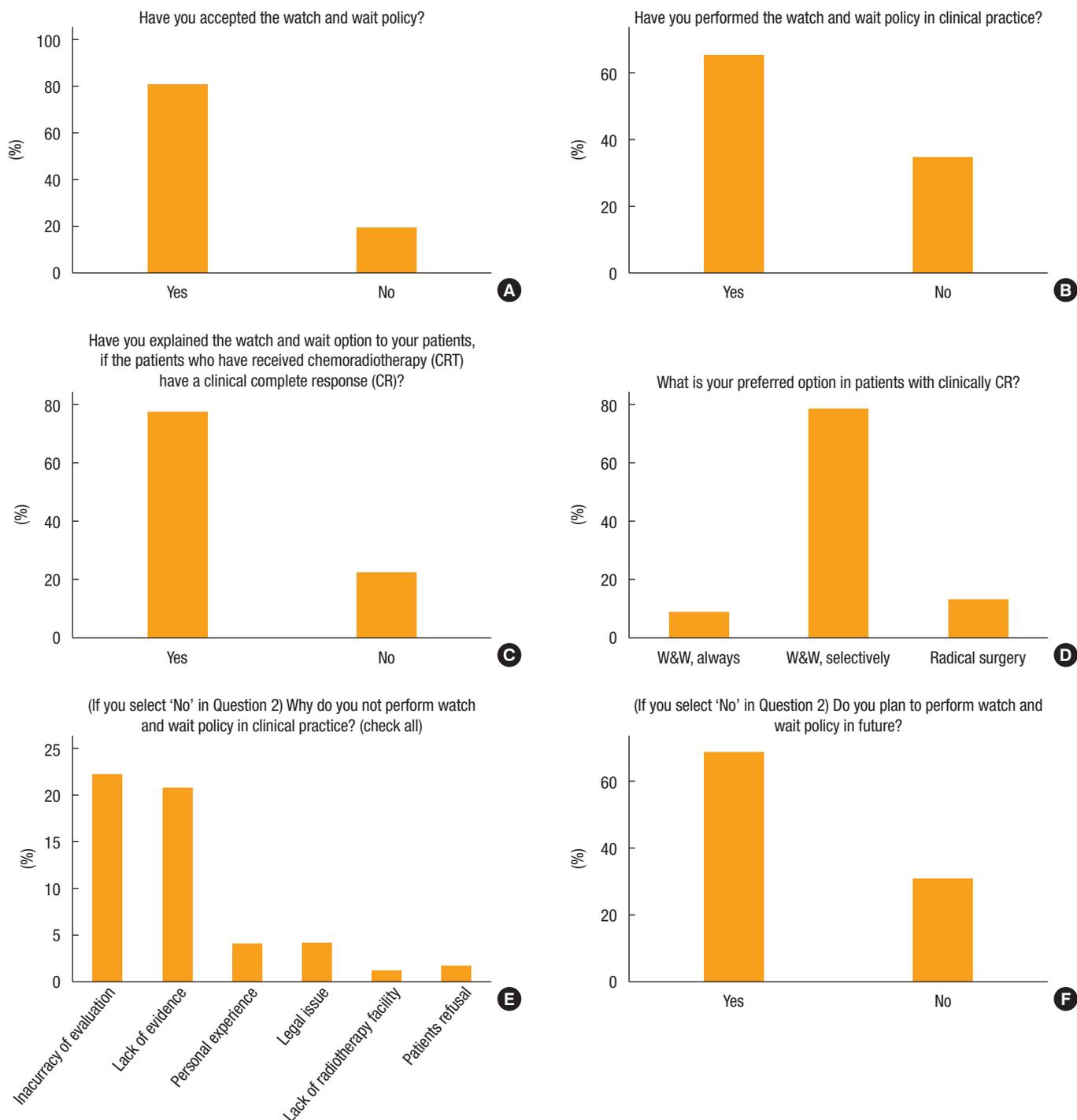
**Table 1.** General characteristics (N = 417)

Characteristic	No. (%)
Participating country (n = 14)	
Australia	23 (5.5)
Bangladesh	1 (0.2)
China	202 (48.4)
England	1 (0.2)
India	4 (1.0)
Japan	79 (18.9)
Korea	81 (19.4)
Malaysia	9 (2.2)
Myanmar	1 (0.2)
New Zealand	2 (0.5)
Philippines	7 (1.7)
Singapore	2 (0.5)
Thailand	2 (0.5)
Vietnam	1 (0.2)
Not available	2 (0.5)
Age (yr)	
30–39	90 (21.6)
40–49	179 (42.9)
50–59	114 (27.3)
60–69	33 (7.9)
70–71	1 (0.2)
Colorectal surgeon	
Yes	407 (97.6)
No	10 (2.4)
Affiliation	
University or tertiary hospital	379 (90.9)
Others	38 (9.1)
Department of Radiation Oncology	
Yes	370 (88.7)
No	47 (11.3)

evidence supporting W&W (n = 87), personal memory of treatment failure (n = 17), legal issues (n = 17), failure of patient informed consent (n = 7), and lack of a radiation facility (n = 5). However, 69% of participants (71 of 103) who had not recommended W&W were willing to do so in the near future (Fig. 1).

### Methods for CRT

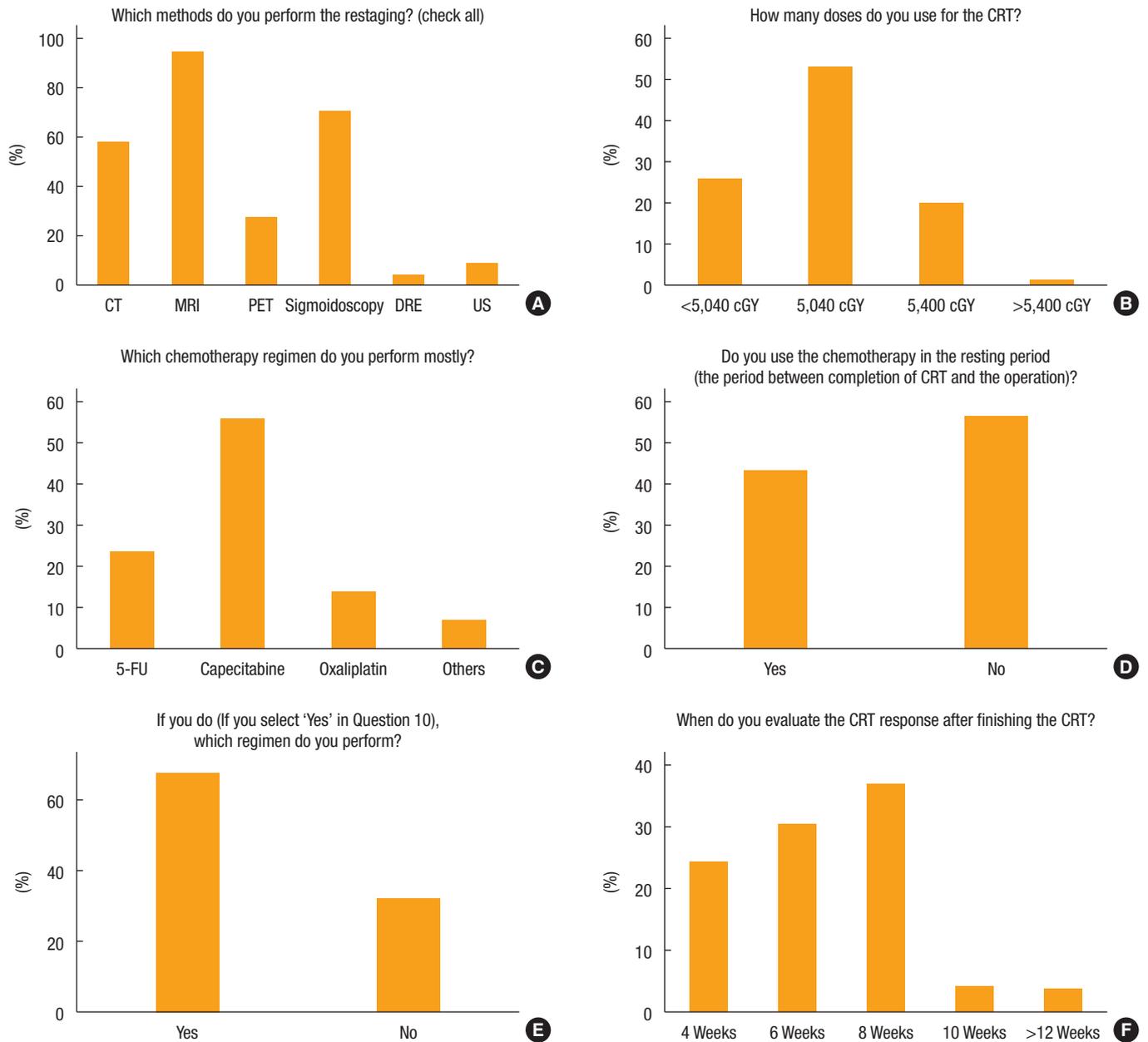
In regard to restaging methods after nCRT, the majority based their decision to use W&W on a combination of magnetic resonance imaging (MRI) (94.5%, n = 394), sigmoidoscopy with biopsy (70.3%, n = 293), computed tomography (CT) (57.8%, n =



**Fig. 1.** Questions regarding general recognition for the watch-and-wait (W&W) policy: (A) acceptance of W&W, (B) experience with W&W, (C) choice in patients with clinical complete response (cCR), (D) option for cCR, (E) reasons for not performing W&W, and (F) future plans for W&W.

241), positron emission tomography (PET)-CT (27.3%,  $n = 114$ ), endo-rectal ultrasound (9.1%,  $n = 38$ ), and digital rectal examination (4.6%,  $n = 19$ ) (Fig. 2). The predominant combination reported in this study was CT and/or PET and MRI with sigmoid-

oscopy and biopsy (213 responders, 51.1%), followed by CT and/or MRI (109 responders, 26.1%), CT and/or MRI with sigmoidoscopy and biopsy (77 responders, 18.5%), CT and/or PET-CT and MRI (14 responders, 3.4%), and sigmoidoscopy only (4 re-



**Fig. 2.** Methods for chemoradiotherapy: (A) restaging method, (B) radiation dose, (C) chemotherapy regimen, (D) chemotherapy during resting period, (E) chemotherapy regimen during resting period, and (F) evaluation time. CT, computed tomography; MRI, magnetic resonance imaging; PET, positron emission tomography; DRE, digital rectal examination; US, ultrasound; CRT, chemoradiotherapy; 5-FU, 5-fluorouracil.

sponders, 1%).

Of all respondents, 53.2% (222 people) preferred a radiation dose of 5,040 cGy and 55.6% (232 people) favored capecitabine as a chemotherapy regimen. In addition, 43.4% (n = 181) maintained chemotherapy during the resting period, and 67.9% (127 of 187) repeated the same chemotherapeutic regimen if indicated. For interval between nCRT completion and tumor response assessment, most participants used 8 weeks (n = 154, 36.9%), fol-

lowed by 6 weeks (n = 127, 30.5%), and 4 weeks (n = 102, 24.5%) (Fig. 2).

#### Follow-up after W&W

In response to the question of how often the responders followed-up after W&W, the predominant period was every 3 months (209 responders, 50.1%), followed by every 2 months (75 responders, 18.0%) and every month (74 responders, 17.7%) (Fig. 3). If local

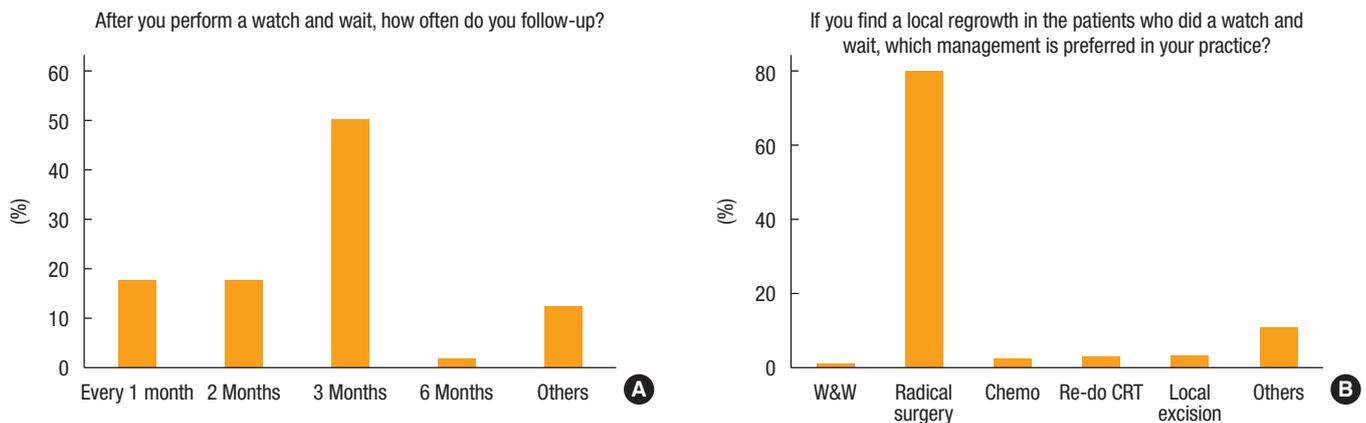


Fig. 3. Follow-up after W&W: (A) follow-up interval and (B) treatment for local regrowth. CRT, chemoradiotherapy.

regrowth was found during follow-up, most responders (79.9%,  $n = 333$ ) recommended radical surgery as an initial management (Fig. 3).

#### Comparison between countries

Current adoption of the W&W approach between countries is compared in Table 2. Age, affiliation, acceptance of W&W, experience in clinical practice, informed consent in the case of cCR, reasons for refusal, future plans, restaging methods, radiation dose, chemotherapy regimen, interval between nCRT and evaluation, regular follow-up periods, and management of local regrowth were significantly different between countries. Participants in China favored the W&W policy in clinical practice compared to all other countries. The preferred treatment option for local regrowth was radical surgery by most surgeons from South Korea.

## DISCUSSION

Management of rectal cancer has evolved substantially over the past 2 decades. Neoadjuvant CRT followed by radical surgery remains the gold standard for locally advanced rectal cancer but is potentially associated with perioperative morbidity and mortality, sexual and urinary dysfunction, and bowel dysfunction as well as risk of permanent stoma [3, 4, 8]. The organ-preserving strategies including close observation following cCR to nCRT have gained attention and are supported by growing evidence [6, 7, 9, 10]. In 2014, Habr-Gama et al. [7] reported that 31% of patients experienced local regrowth by 60 months, of whom 93% were amenable to salvage (90 of 183 patients). They reported 5-year cancer-specific overall survival and disease-free survival of 91% and 68%, respectively. Appelt et al. [6] demonstrated that 75% of patients achieved cCR, and 15% showed regrowth at 1 year after high-dose CRT for 6 weeks (60 Gy in 30 fractions) in 2015. Of note, all patients were salvageable with overall survival and disease-free survival at 2 years. In 2016, the OnCoRe project compared sur-

vival between cCR and W&W ( $n = 109$ ) and surgical resection ( $n = 109$ ) after CRT in a propensity-score matched cohort [10]. Local regrowth rate was 34% with a median of 33 months follow-up; 88% of patients with nonmetastatic local regrowth were salvageable. That study found no differences in 3-year nonregrowth disease-free survival and 3-year overall survival between the 2 groups. In addition, colostomy-free survival was better in the observational group (74% vs. 47%).

Despite such findings, use of the W&W protocol is undefined and uncertain. Currently, no universal guidelines on findings or methods that accurately predict cCR following nCRT are established. In addition, no randomized control trials evaluating close observation after CRT are available, probably due to logistical obstacles. Most of the published data available on W&W are from retrospective analyses with heterogeneous populations, highlighting the importance of our international survey of surgical oncologists. Habr-Gama et al. [11] performed a national survey in Brazil regarding rectal cancer management in 2011. They reported that the W&W approach in patients with cCR after nCRT was preferred by almost one-third of all participants, and surgeons showed a more favorable opinion than medical oncologists (44.7% vs. 14.2%). In 2010, a national survey in Great Britain and Ireland showed that 58% of surgeons would never consider W&W in patients with cCR, and 69% of participants would not discuss the option of nonoperative management in rectal cancer patients [12]. The 2019 UK National Institute for Health and Care Excellence guidelines recommend W&W in patients who achieved cCR after nCRT in view of a clinical trial or national registry [13]. In 2018, the American Society of Colon and Rectal Surgeons (ASCRS) conducted an international survey for global practices of W&W with members of American, European, Australian/New Zealand, and Brazilian colorectal societies [14]. They reported that 41% of ASCRS respondents trusted the W&W paradigm compared to 75% of non-ASCRS respondents. They also concluded that W&W seemed to be widely practiced throughout the world, despite the lack of a standard protocol in most institutions

**Table 2.** Comparison according to country

Variable	China	Japan	Korea	Others	P-value
Age (yr)					<0.001
30–39	63 (31.2)	0 (0)	19 (23.5)	8 (14.5)	
40–49	98 (48.5)	26 (32.9)	33 (40.7)	22 (40.0)	
50–59	37 (18.3)	40 (50.6)	21 (25.9)	16 (29.1)	
60–69	4 (2.0)	13 (16.5)	8 (9.9)	8 (14.5)	
70–71	0 (0)	0 (0)	0 (0)	1 (1.8)	
Colorectal surgeon					0.830
Yes	195 (96.5)	79 (100)	81 (100)	52 (94.5)	
No	7 (3.5)	0 (0)	0 (0)	3 (5.5)	
Affiliation					0.046
University or tertiary hospital	189 (93.6)	70 (88.6)	75 (92.6)	45 (81.8)	
Others	13 (6.4)	9 (11.4)	6 (7.4)	10 (18.2)	
Department of Radiation Oncology					0.073
Yes	185 (91.6)	66 (83.5)	74 (91.4)	45 (81.8)	
No	17 (8.4)	13 (16.5)	7 (8.6)	10 (18.2)	
Acceptance of W&W					<0.001
Yes	178 (88.1)	67 (84.8)	54 (66.7)	38 (69.1)	
No	24 (11.9)	12 (15.2)	27 (33.3)	17 (30.9)	
Experience with W&W in clinical practice					<0.001
Yes	160 (79.2)	34 (43.0)	40 (49.4)	39 (70.9)	
No	42 (20.8)	45 (57.0)	41 (50.6)	16 (29.1)	
Informed consent in case of clinical CR					<0.001
Yes	174 (86.1)	48 (60.8)	55 (67.9)	46 (83.6)	
No	28 (13.9)	31 (39.2)	26 (32.1)	9 (16.4)	
Preferred option in clinical CR					0.531
W&W, always	16 (7.9)	5 (6.3)	6 (7.4)	10 (18.2)	
W&W, selectively	163 (80.7)	62 (78.5)	63 (77.8)	38 (69.1)	
Radical surgery	23 (11.4)	12 (15.2)	12 (14.8)	7 (12.7)	
Reasons for refusal of W&W (multiple)					
Inaccuracy of imaging	167 (82.7)	57 (72.2)	55 (67.9)	45 (81.8)	0.025
Lack of evidence	182 (90.1)	49 (62.0)	54 (66.7)	45 (81.8)	<0.001
Personal experience	7 (3.5)	3 (3.8)	5 (6.2)	2 (3.6)	0.581
Legal issue	7 (3.5)	1 (1.3)	9 (11.1)	0 (0)	0.580
Lack of radiotherapy facility	2 (1.0)	3 (3.8)	0 (0)	0 (0)	0.445
Patient refusal	3 (1.5)	1 (1.3)	0 (0)	3 (5.5)	0.269
Plan for W&W in the future					<0.001
Yes	1 (0.5)	38 (48.1)	24 (39.4)	8 (14.5)	
No	2 (1.0)	7 (8.9)	17 (21.0)	6 (10.9)	
NA	199 (98.5)	34 (43.0)	40 (49.4)	41 (74.5)	
Restaging methods (multiple)					
CT	69 (34.2)	72 (91.1)	67 (82.7)	33 (60.0)	<0.001
MRI	196 (97.0)	70 (88.6)	76 (93.8)	52 (94.5)	0.274
Sigmoidoscopy	122 (60.4)	68 (86.1)	65 (80.2)	38 (69.1)	<0.001
PET-CT	41 (20.3)	43 (54.4)	5 (6.2)	25 (45.5)	0.089
Ultrasound	12 (5.9)	7 (8.9)	13 (16.0)	6 (9.1)	0.061
Digital rectal examination	9 (4.5)	2 (2.5)	4 (4.9)	4 (7.3)	0.455

(Continued to the next page)

Table 2. Continued

Variable	China	Japan	Korea	Others	P-value
Doses for radiation					0.003
<5,040 cGy	67 (33.2)	32 (40.5)	3 (3.7)	5 (9.1)	
5,040 cGy	89 (44.1)	32 (40.5)	68 (84.0)	33 (60.0)	
5,400 cGy	42 (20.8)	14 (17.7)	10 (12.3)	17 (30.9)	
>5,040 cGy	4 (2.0)	1 (1.3)	0 (0)	0 (0)	
Chemotherapy regimen					<0.001
5-Fluorouracil	25 (12.4)	14 (17.7)	30 (37.0)	29 (52.7)	
Capecitabine	137 (67.8)	33 (41.8)	43 (53.1)	19 (34.5)	
Oxaliplatin	36 (17.8)	10 (12.7)	8 (9.9)	5 (9.1)	
Others	4 (2.0)	22 (27.8)	0 (0)	2 (3.6)	
Chemotherapy during the resting period					<0.001
Same regimen of CRT	90 (44.6)	19 (24.1)	11 (13.6)	7 (12.7)	
Different regimen of CRT	36 (17.8)	7 (8.9)	10 (12.3)	7 (12.7)	
None	76 (37.6)	53 (67.1)	60 (74.1)	41 (74.5)	
Interval between CRT and evaluation					0.009
4 Weeks	42 (30.7)	17 (21.5)	15 (18.5)	8 (14.5)	
6 Weeks	59 (29.2)	17 (21.5)	37 (45.7)	14 (25.5)	
8 Weeks	74 (36.6)	40 (50.6)	28 (34.6)	30 (54.5)	
10 Weeks	5 (2.5)	5 (6.3)	1 (1.2)	3 (5.5)	
12 Weeks	2 (1.0)	0 (0)	0 (0)	0 (0)	
>12 Weeks	0 (0)	0 (0)	0 (0)	0 (0)	
Follow-up					0.031
Every month	60 (29.7)	4 (5.1)	8 (9.9)	2 (3.6)	
Every 2 months	39 (19.3)	16 (20.3)	14 (17.3)	6 (10.9)	
Every 3 months	62 (30.7)	56 (70.9)	49 (60.5)	42 (76.4)	
Every 6 months	0 (0)	1 (1.3)	4 (4.9)	2 (3.6)	
Others	41 (20.3)	2 (2.5)	6 (7.4)	3 (5.5)	
Management for local regrowth					<0.001
Wait and follow-up	3 (1.5)	0 (0)	0 (0)	0 (0)	
Radical surgery	146 (72.3)	64 (81.0)	74 (91.4)	49 (89.1)	
Chemotherapy	2 (1.0)	5 (6.3)	1 (1.2)	1 (1.8)	
Repeat CRT	9 (4.5)	0 (0)	0 (0)	2 (3.6)	
Proton therapy	0 (0)	0 (0)	0 (0)	0 (0)	
Local excision	0 (0)	8 (10.1)	4 (4.9)	2 (3.6)	
Others	42 (20.8)	2 (2.5)	2 (2.5)	1 (1.8)	

Values are presented as number (%).

W&W, watch-and-wait; CRT, chemoradiotherapy; CR, complete response; CT, computed tomography; MRI, magnetic resonance imaging; PET-CT, positron emission tomography-computed tomography; NA, not applicable.

(ASCRS: 55% vs. non-ASCRS: 83%).

Here, we present results of an international survey about W&W in patients who achieved cCR after nCRT in Asia-Pacific countries. We found high support for the W&W approach among surgeons in the APFCP. Eighty percent of responders supported the W&W strategy, and 65.5% of responders used such a strategy for cCR after nCRT. This is the first international survey on contemporary views of the W&W approach in Asia-Pacific countries. The low response rate is the major limitation to our study. Re-

sponse bias, as well as the unequal distribution of participants with up to 48% of replies from China, could have potentially influenced our results. However, we received over 400 replies, over 97% of which were from colorectal surgeons and over 90% were from a university or tertiary hospital. This critical mass indicates the validity of the results and provides a general overview about the use of the W&W strategy in clinical practice in Asia-Pacific countries and also presents opinions regarding several critical issues.

In conclusion, our survey provides current views of a W&W ap-

proach for patients who achieved clinical complete response after nCRT among specialized surgeons in Asia-Pacific countries. Our analysis suggests high support for the W&W strategy in clinical practice in our area. These results will be useful for designing future prospective clinical trials in Asia-Pacific countries.

### CONFLICT OF INTEREST

No potential conflict of interest relevant to this article was reported.

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**Appendix.** Questionnaire (Current Status of Watch-and-Wait Policy for Irradiated Rectal Cancer in Asia-Pacific Countries 2019 by APFCP)

Nationality: \_\_\_\_\_

Age:  30-39  40-49  50-59  60-69  >70Colorectal Surgeon:  Yes  NoAffiliation:  University or Tertiary Hospital  OthersHospital has a Department of Radiation Oncology:  Yes  No

Please tick each statement that you agree with:

1. Have you accepted the watch-and-wait policy?  
 Yes  No
2. Have you performed the watch-and-wait policy in clinical practice?  
 Yes  No
3. Have you explained the watch-and-wait option to your patient, if the patients who have received preoperative chemoradiotherapy (CRT) have a clinical complete response (CR)?  
 Yes  No
4. What is your preferred option in patients with clinically CR?  
 Watch-and-wait, always  
 Watch-and-wait, selectively (old age, poor general condition, etc.)  
 Radical surgery
5. (If you select 'No' in Question. 2) Why do you not perform the watch-and-wait policy in current practice? (check all)  
 Inaccuracy of the evaluation method (imaging study)  
 Lack of the evidence supporting the policy  
 Personal memory of failure the treatment  
 Legal issue  
 Lack of radiotherapy facility  
 Others: \_\_\_\_\_
6. (If you select 'No' in Question. 2) Do you plan to perform the watch-and-wait in future?  
 Yes  No
7. Which methods do you perform for restaging? (check all)  
 CT  
 MRI  
 Ultrasound  
 Sigmoidoscopy (with biopsy)  
 PET-CT  
 Others: \_\_\_\_\_
8. How many doses do you use for the CRT?  
 Less than 5,040 cGy  
 5,040 cGy  
 5,400 cGy  
 More than 5,400 cGy

9. Which chemotherapy regimen do you perform mostly?
- 5-FU
  - Capecitabine
  - Oxaliplatin
  - Others: \_\_\_\_\_
10. Do you use the chemotherapy in the resting period (the period between completion of CRT and the operation)?
- Yes  No
11. If you do (If you select 'Yes' in Question. 10), which regimen do you perform?
- Same regimen of CRT
  - Different regimen of CRT
  - Others: \_\_\_\_\_
12. When do you evaluate the CRT response after finishing the CRT?
- 4 Weeks
  - 6 Weeks
  - 8 Weeks
  - 10 Weeks
  - 12 Weeks
  - More than 12 weeks
13. After you perform a watch-and-wait, how often do you follow up?
- Every 1 months
  - Every 2 months
  - Every 3 months
  - Every 6 months
  - Others: \_\_\_\_\_
14. If you find a local regrowth in the patient who did a watch-and-wait, which management is preferred in your practice?
- Just wait and follow-up
  - Radical surgery
  - Chemotherapy
  - Re-do CRT
  - Proton therapy
  - Local excision
  - Others: \_\_\_\_\_