The Oncologist®

Gastrointestinal Cancer

Medical Oncologists' Perspectives on How the Results of the IDEA Collaboration Impact the Adjuvant Treatment of Stage III Colon Cancer

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Abstract

Background. The International Duration Evaluation of Adjuvant Chemotherapy (IDEA) collaboration aimed to evaluate whether 3 months of adjuvant chemotherapy are noninferior to 6 months. Our study objectives were to characterize medical oncologists' perspectives toward the results of the IDEA collaboration and to evaluate how IDEA impacted prescribing patterns of adjuvant FOLFOX and CAPOX in colon cancer.

Materials and Methods. A list of questions developed by four medical oncologists regarding IDEA results were formulated and distributed online to gastrointestinal medical oncologists globally. Descriptive statistics and chi-square tests were used to summarize information.

Results. Of 174 responses, 145 were complete and analyzed. Responses were obtained globally from South America (53%); the U.S. and Canada (28%); Europe, Australia, and New Zealand (12%); and Asia (7%). Most clinicians (98%) were aware of the IDEA study. Prior to IDEA, clinicians preferred FOLFOX over CAPOX (81% vs. 19%). Subsequent to IDEA, 55% of clinicians preferred CAPOX over FOLFOX (odds ratio, 5.0; 95% confidence interval, 3.0–8.5; $p < .01$ compared with pre-IDEA). Two thirds (68%) of responders tailored duration of adjuvant therapy based on risk stratification. Most oncologists (76%) were more willing to discontinue oxaliplatin early if toxicities develop after the results of IDEA. Half of responders (50%) found that IDEA increased their confidence in decision making for adjuvant treatment; 36% were unchanged, and 15% indicated decreased confidence. Less than half (48%) were comfortable communicating the study results and the concept of a noninferiority trial with patients.

Conclusion. IDEA appears to have shifted clinician preference from FOLFOX to CAPOX for adjuvant therapy, and most clinicians now use a risk-stratified approach in determining duration of adjuvant therapy. Patient education resources may facilitate better communication of IDEA results to patients. ***The Oncologist*** 2020;25:229–234

Implications for Practice: This global survey illustrates that most gastrointestinal medical oncologists now use a risk-stratified approach for determining the duration of adjuvant chemotherapy for stage III colon cancer. Clinicians are five times more likely to choose CAPOX over FOLFOX after the International Duration Evaluation of Adjuvant Chemotherapy (IDEA) collaboration results.

Introduction

For more than a decade, the standard of care for adjuvant treatment of stage III colon cancer has been 6 months of a fluoropyrimidine combined with oxaliplatin [1–3], which improves both disease-free and overall survival. However, the delivery of oxaliplatin is often limited by neurotoxicity, which can negatively impact patients long after their treatment is completed [4]. The ideal therapy would balance maximal benefit, without compromising quality of life or causing harm.

The International Duration Evaluation of Adjuvant Chemotherapy (IDEA) collaboration involved six multicenter,

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1. Are you a medical oncologist who treats colon cancer as part of your practice?
2. What is your geographic region?
3. What is your gender?
4. What is your practice setting?
5. How long have you been in practice?
6. Regarding the data presented during the plenary section of the 2017 ASCO Annual Meeting: Prospective pooled analysis of six phase III trials investigating duration of adjuvant oxaliplatin-based therapy (3 vs 6 months) for patients with stage III colon cancer: The IDEA (International Duration Evaluation of Adjuvant chemotherapy) collaboration. Are you aware of the results of the study?
7. Has your practice changed as a result of the study?
8. Do you believe the study supports reducing the duration of adjuvant chemotherapy from 6 months to 3 months for some patients with colon cancer?
9. Do you offer 3 months as your standard treatment option or do you discuss the options of 3 vs 6 months with your patient?
10. Before the study was presented my preferred regimen was: (CAPOX, FOLFOX)
11. Since the study was presented, my preferred regimen is: (CAPOX, FOLFOX)
12. Do you believe the study supports the conclusion that CAPOX is a more active regimen than FOLFOX for some patients with colon cancer?
13. Since the study was presented, has it changed how likely you are to suggest a patient stop adjuvant chemotherapy early?
14. Since the study was presented, which of the following statements best describes your approach to stopping oxaliplatin?
15. Since the study was presented, how has your confidence changed regarding decision making for adjuvant therapy in stage III colon cancer?
16. The IDEA collaboration followed a non-inferiority trial design. How comfortable are you communicating the final results and meaning of a non-inferiority design to patients?

Figure 1. List of questions distributed via REDCap
Abbreviations: ASCO, American Society of Clinical Oncology; IDEA, International Duration Evaluation of Adjuvant Chemotherapy.

randomized phase III clinical trials in 12 countries. Its primary outcome was to evaluate the 3-year disease-free survival between 3 versus 6 months of adjuvant chemotherapy in the treatment of stage III colon cancer [5]. It was designed as a noninferiority study; 3 months would be noninferior to 6 months if the upper limit of the two-sided 95% confidence interval (CI) of the hazard ratio (HR) did not exceed 1.12. Although it did not meet its primary endpoint of noninferiority for the whole population [6], it did have intriguing findings in its subgroups. In a preplanned analysis, for those who were treated with CAPOX, 3 months was noninferior to 6 months with 3-year disease-free survival rates of 75.9% versus 74.8% (HR, 0.95; 95% CI, 0.85–1.06). In an exploratory analysis, in patients classified as low risk (pathological stage T1–3 N1), 3 months was also noninferior to 6 months with an HR of 1.01 (95% CI, 0.90–1.12), with the upper limit of the 95% confidence interval below the predefined 1.12 cutoff. This was not reflected in the higher risk category (T4 or N2), which carried an HR of 1.12 (95% CI, 1.03–1.23).

The authors of the IDEA collaboration concluded that for those who receive CAPOX, 3 months was as effective as 6 months, particularly in lower-risk patients with smaller tumors and N1 status. The data provide a framework for discussion between clinicians and patients, with regard to selecting FOLFOX versus CAPOX and the duration of therapy, as endorsed in the recent American Society of Clinical Oncology (ASCO) guidelines for adjuvant treatment of stage III colon cancer [7]. The adoption of these data in clinical practice is unclear. We hypothesize that there has been significant change in practice patterns, as there is an opportunity for de-escalating treatment to prevent unnecessary toxicities while maintaining the benefit in reducing the risk of recurrence. Our study objectives are to characterize medical oncologists' perspectives on the results of the IDEA collaboration and to assess the real-world uptake of these data.

Materials and Methods

A list of 16 questions developed by four medical oncologists regarding the views of physicians who treat gastrointestinal cancers toward the results of the IDEA collaboration were formulated and distributed using an online survey via REDCap (Fig. 1). Physicians were recruited using e-mail lists from the Canadian Cancer Trials Group, the Australasian Gastro-Intestinal Trials Group, the New Zealand Society for Oncology, the GI Cancers Alliance (U.S.), the Brazilian Society of Clinical Oncology, the Brazilian Gastrointestinal Tumors Group, and the Thai Society of Clinical Oncology. The survey had an initial screening question to include those clinicians who treat colon cancer as a part of their practice. Responses were divided geographically by similar groupings involved in the IDEA collaboration trials. Europe, Australia, and New Zealand were combined; Canada and U.S. were combined; and South America and Asia were

Table 1. Baseline characteristics of survey responders

Characteristics	Number of responders (n = 145), n (%)
Geography	
U.S., Canada	40 (27.6)
Europe, Australia, New Zealand	18 (12.4)
South America	77 (53.1)
Asia	10 (6.9)
Gender	
Male	89 (61.4)
Female	53 (36.6)
N/A	3 (2.1)
Practice setting	
Academic	51 (35.2)
Community	43 (29.7)
Both	51 (35.2)
Duration of practice	
Less than 10 years	61 (42.1)
More than 10 years	84 (57.9)

Abbreviation: N/A, other/decline to answer.

analyzed as separate cohorts. Survey answers were collected from December 2017 to November 2018. Descriptive statistics and chi-square tests were used to summarize information with IBM SPSS (version 25).

Results

Characteristics of Medical Oncologists

Of 174 responses, 145 were complete and included for analysis. Table 1 reports the responders' characteristics. All responders were oncologists who treated colon cancer. Of those, 89 (61.4%) were male. Responses were submitted globally, including from South America (53.1%); the U.S. and Canada (27.6%); Europe, Australia, and New Zealand (12.4%); and Asia (6.9%). In terms of practice settings, 51 (35.2%) practiced in an academic setting, 43 (29.7%) worked in a community setting, and 51 (35.2%) practiced in both. Sixty-one (42.1%) had been in practice for less than 10 years, whereas 84 (57.9%) had worked for more than 10 years.

Overall Interpretation and Impact of the IDEA Collaboration Data

Table 2 reports the survey responders' perspectives on the IDEA collaboration. The majority of responders (97.9%) were aware of the results of the IDEA collaboration presented at the 2017 ASCO Annual Meeting, and 103 (71.0%) physicians indicated the study had changed their practice. With respect to the primary endpoint of the study, 109 (75.2%) believed that the study supports 3 months of adjuvant therapy for some patients, compared with 19 (13.1%) who did not believe that it supports 3 months; 17 (11.7%) were undecided. Equal proportions of responders supported and refuted that CAPOX is a more active regimen compared with FOLFOX for some patients (35.9% in each group); 41 (28.2%) responders were undecided. After the IDEA collaboration, the majority of responders (75.9%) had a lower threshold to discontinue oxaliplatin early, and the remainder (24.1%) had the same threshold.

Table 2. Survey responders' perspectives on IDEA collaboration

Perspectives	Number of responders (n = 145), n (%)
Awareness of the IDEA collaboration from ASCO Annual Meeting 2017	
Yes	142 (97.9)
No	3 (2.1)
IDEA collaboration changed [their] practice	
Yes	103 (71.0)
No	42 (29.0)
IDEA collaboration supports 3 months of adjuvant therapy for some patients	
Yes	109 (75.2)
No	19 (13.1)
Undecided	17 (11.7)
CAPOX is more active than FOLFOX for some patients	
Yes	52 (35.9)
No	52 (35.9)
Undecided	41 (28.2)
Best description of approach for discontinuation of oxaliplatin early	
Lower threshold	110 (75.9)
Threshold unchanged	35 (24.1)
Confidence in decision making for adjuvant therapy in stage III colon cancer	
Less confident	21 (14.5)
More confident	72 (49.7)
Unchanged	52 (35.9)
Comfort level in communicating IDEA results and the meaning of a noninferiority trial to patients	
Comfortable	69 (47.6)
Somewhat comfortable	44 (30.3)
Challenging	32 (22.1)

Abbreviations: ASCO, American Society of Clinical Oncology; IDEA, International Duration Evaluation of Adjuvant Chemotherapy.

When equipped with the results of the study, half (49.7%) of physicians indicated that they were more confident in making recommendations for the adjuvant treatment of stage III colon cancer, whereas 21 (14.5%) were less confident, and 52 (35.9%) were unchanged. Overall, 69 (47.6%) physicians were comfortable communicating the results of the trial and explaining the concept of a noninferiority design to patients; 44 (30.3%) indicated that they felt somewhat comfortable, and 32 (22.1%) found it challenging.

Duration of Chemotherapy: 3 versus 6 Months

Participants were asked whether they would consider discontinuing adjuvant chemotherapy earlier based on

Table 3. Survey responders' recommended duration of adjuvant therapy post–International Duration Evaluation of Adjuvant Chemotherapy collaboration

Overall responses	6 months for all patients (*n* = 43), *n* (%)	3 months for all patients (*n* = 4), *n* (%)	3 months for T1–3 N1, 6 months for T4 or N2 (*n* = 98), *n* (%)	*p* value
Geography				
U.S., Canada	10 (25.0)	0 (0)	30 (75.0)	.22
Europe, Australia, New Zealand	2 (11.1)	1 (5.6)	15 (83.3)	
South America	26 (33.8)	3 (3.9)	48 (62.3)	
Asia	5 (50.0)	0 (0)	5 (50.0)	
Gender				
Male	25 (28.1)	1 (1.1)	63 (70.8)	.30
Female	18 (34.0)	3 (5.7)	32 (60.4)	
N/A	0 (0)	0 (0)	3 (100)	
Practice setting				
Academic	15 (29.4)	3 (5.9)	33 (64.7)	.31
Community	10 (23.3)	1 (2.3)	32 (74.4)	
Both	18 (35.3)	0 (0)	33 (64.7)	
Duration of practice				
Less than 10 years	21 (34.4)	2 (3.3)	38 (62.3)	.51
More than 10 years	22 (26.2)	2 (2.4)	60 (71.4)	

Abbreviation: N/A, other/decline to answer.

patients' risk profile as described in the IDEA collaboration, that is, low risk with T1–3 N1 disease versus high risk with T4 and/or N2 disease. Two thirds (67.6%) of responders tailored their duration of adjuvant therapy based on risk stratification, whereas 43 (29.7%) believed the standard of care should remain at 6 months, and 4 (2.8%) indicated that 3 months was the new standard for care for every patient with stage III colon cancer (Table 3). This was not influenced by geography, prescriber gender, practice setting, or duration of practice.

Chemotherapy Regimen: CAPOX Versus FOLFOX

Supplemental online Table 1 reports the survey responders' recommended adjuvant therapy before and after the IDEA collaboration. Prior to the IDEA collaboration, 28 (19.3%) responders preferred CAPOX, compared with 117 (80.7%) who preferred FOLFOX as the standard adjuvant therapy. The majority of oncologists from South America (92.2%); the U.S. and Canada (77.5%); and Europe, Australia, and New Zealand (61.1%) preferred FOLFOX. In contrast, 40% of clinicians in Asia chose FOLFOX ($p < .01$). There were no differences in prior preference for CAPOX versus FOLFOX when responses were stratified by responders' gender, practice setting, or duration of practice.

Subsequent to the IDEA study, there was a shift in preference favoring CAPOX with 79 responses (54.5%), an increase of 35.2%. Those in Europe, Australia, and New Zealand (88.9%); Asia (70.0%); and the U.S. and Canada (55.0%) had a higher proportion of clinicians supporting CAPOX, compared with South America (44.2%; $p < .01$). The proportion of physicians choosing CAPOX increased across all domains, regardless of stratification by gender, practice setting, or duration of setting. Overall, responders were five times more likely to choose CAPOX compared with FOLFOX post-IDEA collaboration (odds ratio, 5.0; 95% CI, 3.0–8.5; $p < .01$).

Discussion

The IDEA collaboration findings were first presented at the ASCO 2017 Annual Meeting, and ASCO has recently published guidelines on the duration of oxaliplatin-containing adjuvant therapy for stage III colon cancer to reflect these data [7]. Despite much discussion of the results, their interpretation remains varied. There are multiple aspects of treatment impacted as illustrated in our survey, including the choice between 3 versus 6 months of adjuvant therapy, FOLFOX versus CAPOX, and the threshold for early discontinuation of oxaliplatin. A previous case-based survey was conducted by Meyerhardt; the majority of responders were from Japan but also included the U.S., U.K., other European countries, and Australia and New Zealand [8]. Notably, 29% of those from the U.S. chose 3 months of FOLFOX for T3N1 disease; 37% chose 3 months of CAPOX. Our survey used a different approach to explore prescribing patterns of adjuvant therapy by asking about duration and regimen preferences separately.

In the IDEA study, 3 months of adjuvant therapy did not meet the study's primary endpoint for the modified intention-to-treat population, with the upper limit of the 95% confidence interval above the prespecified noninferiority margin of 1.12; however, it should be noted that 3 months of CAPOX was shown to be noninferior regardless of risk with an HR of 0.95 (95% CI, 0.85–1.06). In our study, two thirds of participants (67.6%) now take an approach of discussing 3 versus 6 months of adjuvant therapy with patients. Four (2.8%) indicated that they would offer 3 months as standard therapy to

all patients. Although the IDEA results do not statistically support universal adoption of 3 months of adjuvant therapy for all subgroups, a small proportion of survey responders are offering it routinely in all cases. With the decrease in duration of therapy by half, this may have implications from a systems perspective for resources in addition to decreased neurotoxicity to the patient. However, the majority of practicing oncologists are taking a risk-stratified approach for considering reduced duration, congruent with the current ASCO guidelines.

The majority of oncologists (80.7%) who treat colon cancer had previously preferred FOLFOX to CAPOX. This is also reflected in the IDEA collaboration with 60.5% of patients receiving FOLFOX based on prescribers' choice, although the North American cohort did not allow for the use of CAPOX in the CALGB/SWOG 80702 trial and reimbursement for intravenous infusions complicates interpretation of preferences. There is a shift of preference globally toward CAPOX after IDEA, with 54.5% of clinicians selecting CAPOX in our survey, an increase of 35.2%. Equal proportions of physicians (35.9% in each group) believed and refuted that CAPOX is a more active regimen than FOLFOX. It should be highlighted that in the IDEA collaboration study, the choice between CAPOX and FOLFOX was not based on secondary randomization, and firm conclusions cannot be drawn. However, it is a hypothesis-generating finding that appears to have increased the use of CAPOX, as demonstrated in our survey. Hypotheses to explain the potential difference include variations in fluoropyrimidine exposure and oxaliplatin dosing between the two regimens, but there were no significant differences in the trial to support this.

Although the IDEA collaboration was informative in multiple aspects, only half of the participants (49.7%) felt more confident in their decision-making abilities for recommending adjuvant treatment for stage III colon cancer. Furthermore, 52.4% of clinicians found it challenging or were only somewhat comfortable in communicating the evidence and study design to their patients. The concept of noninferiority trials is important to understand and communicate to patients, as the number of noninferiority trials has increased by 6-fold in the last decade [9]. This underscores the need to develop patient-directed resources to aid in decision making, to support both oncologists and patients.

There are several limitations to our study because of the nature of an online survey. No reward incentives were offered for completion of the survey, and only 145 responses were obtained. The denominator of the number of oncologists who received the survey is unknown, as the survey was disseminated through e-mail lists, social media, and word of mouth. Ideally, we would obtain more equal proportions of responses globally, as certain areas are underrepresented in our study, such as Asia and Europe, Australia, and New Zealand. However, the proportions of physicians in different practice settings and duration of practice were relatively well balanced. Furthermore, not all answers were complete and included, likely secondary to survey fatigue.

Conclusion

The IDEA collaboration has a global impact on the treatment of adjuvant stage III colon cancers, providing information for forming a framework for discussion with patients. There has been an increase in the prescribing pattern of CAPOX compared with FOLFOX, and most clinicians now use a risk-stratified approach in determining 3 versus 6 months of adjuvant therapy.

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Disclosures

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See http://www.TheOncologist.com for supplemental material available online.

For Further Reading:
Nina C.A. Vermeer, Yvette H.M. Claassen, Marloes G.M. Derks et al. Treatment and Survival of Patients with Colon Cancer Aged 80 Years and Older: A EURECCA International Comparison. ***The Oncologist*** 2018;23:982–990.

Implications for Practice:
With the increasing growth of the older population, clinicians will be treating an increasing number of older patients diagnosed with colon cancer. In this study of treatment patterns of 50,761 patients aged 80 and older, no clear linear pattern between adjuvant chemotherapy and better adjusted relative survival was observed. Future studies should also include data on surgical quality.