Adjuvant treatment for elderly patients: how to address it

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ESMO Preceptorship Programme – Colorectal Cancer
Adjuvant Setting of Colorectal Cancer
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Disclosures

- Ad Boards: Roche, Novartis, Merck
- Speaker at sponsored meetings / satellite symposia: Roche, Amgen, Merck
- Financial support to attend conferences: Roche, Merck, MSD
Outline

• Background / epidemiology
• Stage III disease
• Stage II disease
• Current recommendations / conclusions
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• Background / epidemiology
• Stage III disease
• Stage II disease
• Current recommendations / conclusions
Background/epidemiology

- Fastest growing section of population in Western countries is that of over 65s

- Approximately half the incidence of colorectal cancer occurs in the over 70s
Population pyramid

2010
(16.6 million)

Born in 1946

Born in 1975

Men

Women

V. Lemmens Personal Communication
Population pyramid

2030
(17.7 million)

Born in 1946

Born in 1975

N (x 1000)

Men

Women

V Lemmens Personal Communication
Background

- Fastest growing section of population in Western countries is that of over 65s
- Approximately half the incidence of colorectal cancer occurs in the over 70s
Colorectal Cancer: A disease of the elderly

- Median age of patients in clinical trials ~ 60 years
- Median age at diagnosis of CRC ~ 70 years
  - 76% > age 65
  - 40% > age 75
  - 12% age > 85
- 40% of CRCs are stage III at diagnosis

Howlander, SEER Cancer Statistics Review, 2011
Older Patients with CRC: Key Issues

- Limited life expectancy
- Physiological heterogeneity
  - Chronologic age ≠ biologic age
- Reduced treatment tolerance (frailty)
- Different treatment goals (frailty)
- Limited evidence
  - Under-representation in clinical trials

The Clinical Trial Is Open. The Elderly Need Not Apply.
### US Cancer Demographics and Cancer Trial Enrollment

#### DEMOGRAPHICS

1996-2002 (N=75215)

<table>
<thead>
<tr>
<th></th>
<th>SEER Incident Cancer Cases %</th>
<th>Cancer Trial Participants %</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>RACE</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>White</td>
<td>83%</td>
<td>85.6%</td>
</tr>
<tr>
<td>Black</td>
<td>11%</td>
<td>9%</td>
</tr>
<tr>
<td>Hispanic</td>
<td>4%</td>
<td>3%</td>
</tr>
<tr>
<td><strong>AGE</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>30-64</td>
<td>38%</td>
<td>68%</td>
</tr>
<tr>
<td>65-74</td>
<td>31%</td>
<td>24%</td>
</tr>
<tr>
<td>≥75</td>
<td>31%</td>
<td>8%</td>
</tr>
</tbody>
</table>

#### ENROLLMENT

2000-2002

<table>
<thead>
<tr>
<th></th>
<th>Enrollment Fraction*</th>
<th>OR enrollment 95% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>RACE</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>White</td>
<td>1.7%</td>
<td>1</td>
</tr>
<tr>
<td>Black</td>
<td>1.3%</td>
<td>0.71, 0.68-0.74</td>
</tr>
<tr>
<td>Hispanic</td>
<td>1.3%</td>
<td>0.72, 0.68-0.77</td>
</tr>
<tr>
<td><strong>AGE</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>30-64</td>
<td>3%</td>
<td>1</td>
</tr>
<tr>
<td>65-74</td>
<td>1.3%</td>
<td>0.43, 0.42-0.44</td>
</tr>
<tr>
<td>≥75</td>
<td>0.5%</td>
<td>0.15, 0.15-0.16</td>
</tr>
</tbody>
</table>

*enrollment fraction:* number of trial enrollees divided by the estimated US cancer cases in each sub-group.

Murthy et al, JAMA 2004; 291: 2720
Life Expectancy

Women have a life expectancy of more than 20 years at 60, 15 years at 70 and 10 years at 80.

Men of 20 years at 60, 12 years at 70 and 8 years at 80.

Most recurrences of Stage III and high-risk Stage II colon cancer occur in the 3 years after surgery...Adjuvant chemotherapy should be considered.
Outline

• Background / epidemiology
• Stage III disease
• Stage II disease
• Current recommendations / conclusions
The Truth about adjuvant chemotherapy

Relapsing patients
No benefit

Rescued patients
Thanks to adjuvant chemo

« Cured » patients
Treated for nothing

No adjuvant
Adjuvant
### Adjuvant Setting: Initial Pooled Analysis: 5-FU/LV vs Control

<table>
<thead>
<tr>
<th>Study</th>
<th>Regimen</th>
<th>N</th>
</tr>
</thead>
<tbody>
<tr>
<td>NCCTG</td>
<td>5-FU/Lev</td>
<td>271</td>
</tr>
<tr>
<td>ECOG</td>
<td>5-FU/LV</td>
<td>415</td>
</tr>
<tr>
<td>SWOG</td>
<td>5-FU/Lev</td>
<td>936</td>
</tr>
<tr>
<td>NCIC</td>
<td>5-FU/LV</td>
<td>364</td>
</tr>
<tr>
<td>FFCD</td>
<td>5-FU/LV</td>
<td>259</td>
</tr>
<tr>
<td>Siena</td>
<td>5-FU/LV</td>
<td>239</td>
</tr>
<tr>
<td>GIVIO</td>
<td>5-FU/LV</td>
<td>867</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td></td>
<td><strong>3351</strong></td>
</tr>
</tbody>
</table>

*Sargent et al, NEJM 2001*
Deaths without cancer

- As patients aged, the probability of death without cancer increased.

<table>
<thead>
<tr>
<th>Age Group</th>
<th>N</th>
<th>Deaths w/o cancer</th>
</tr>
</thead>
<tbody>
<tr>
<td>≤ 50</td>
<td>564</td>
<td>1%</td>
</tr>
<tr>
<td>51-60</td>
<td>1012</td>
<td>4%</td>
</tr>
<tr>
<td>61-70</td>
<td>1269</td>
<td>7%</td>
</tr>
<tr>
<td>&gt; 70</td>
<td>506</td>
<td>13%</td>
</tr>
<tr>
<td>Overall</td>
<td>3351</td>
<td>6%</td>
</tr>
</tbody>
</table>

Sargent et al, NEJM 2001
Time to Recurrence

Age $\leq 70$

Age $> 70$

Sargent et al, NEJM 2001
Overall Survival

Age \leq 70

Age > 70

Sargent et al, NEJM 2001
### ACCENT: 7 trials

<table>
<thead>
<tr>
<th>Trial</th>
<th>Accrual Period</th>
<th># pts</th>
<th>% pts ≥70 yrs</th>
<th>Experimental treatment arm†</th>
<th>% stage III‡</th>
</tr>
</thead>
<tbody>
<tr>
<td>MOSAIC</td>
<td>1998-01</td>
<td>2246</td>
<td>14</td>
<td>FOLFOX4</td>
<td>60</td>
</tr>
<tr>
<td>NSABP C-07</td>
<td>2000-02</td>
<td>2434</td>
<td>16</td>
<td>FLOX</td>
<td>71</td>
</tr>
<tr>
<td>C89803</td>
<td>1999-01</td>
<td>1263</td>
<td>24</td>
<td>IFL</td>
<td>98</td>
</tr>
<tr>
<td>PETACC-3</td>
<td>2000-02</td>
<td>3186</td>
<td>13</td>
<td>FOLFIRI</td>
<td>71</td>
</tr>
<tr>
<td>NSABP C-06</td>
<td>1997-99</td>
<td>1557</td>
<td>23</td>
<td>Uracil/tegafur</td>
<td>53</td>
</tr>
<tr>
<td>X-ACT</td>
<td>1998-01</td>
<td>1983</td>
<td>20</td>
<td>Capecitabine</td>
<td>100</td>
</tr>
<tr>
<td>XELOXA</td>
<td>2003-4</td>
<td>1862</td>
<td>22</td>
<td>XELOX</td>
<td>100</td>
</tr>
</tbody>
</table>

† Compared to control arm of intravenous 5-flourouracil (IV 5-FU) and leucovorin (LV)
‡ Remaining patients were stage II or unknown

N Jackson-McLeary et al J Clin Oncol 2013
## Efficacy – All 7 trials

<table>
<thead>
<tr>
<th>Age</th>
<th>Endpoint HR (95% CI)</th>
<th>Deaths within 6 mo Exp v Control % (p-value)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Experimental v Control IV 5-FU/LV</td>
<td></td>
</tr>
<tr>
<td></td>
<td>DFS*</td>
<td>OS*</td>
</tr>
<tr>
<td>&lt;70</td>
<td></td>
<td></td>
</tr>
<tr>
<td>n = 11,953</td>
<td>0.85 (0.80-0.90)</td>
<td>0.87 (0.81-0.93)</td>
</tr>
<tr>
<td>≥ 70</td>
<td></td>
<td></td>
</tr>
<tr>
<td>n = 2575</td>
<td>1.05 (0.94,1.19)</td>
<td>1.08 (0.95,1.23)</td>
</tr>
</tbody>
</table>

Interaction of age by treatment p-value

<table>
<thead>
<tr>
<th>Interaction of age by treatment p-value</th>
<th>DFS*</th>
<th>OS*</th>
<th>TTR*</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>0.001</td>
<td>0.004</td>
<td>0.002</td>
</tr>
</tbody>
</table>

* Values < 1 favor experimental arm
# Efficacy – oxaliplatin-based therapy (3 Trials)

<table>
<thead>
<tr>
<th>Age</th>
<th>Experimental v Control IV 5-FU/LV</th>
<th>Endpoints HR (95% CI)</th>
<th>Deaths within 6 mo Exp v Control % (p-value)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>DFS*</td>
<td>OS*</td>
<td>TTR*</td>
</tr>
<tr>
<td>&lt;70 (n = 5,420)</td>
<td>0.78 (0.71, 0.86)</td>
<td>0.83 (0.74, 0.92)</td>
<td>0.77 (0.69, 0.85)</td>
</tr>
<tr>
<td>≥ 70 (n = 1,119)</td>
<td>0.94 (0.78, 1.13)</td>
<td>1.04 (0.85, 1.27)</td>
<td>0.86 (0.69, 1.06)</td>
</tr>
<tr>
<td>Interaction of age by treatment p-value</td>
<td>0.09</td>
<td>0.05</td>
<td>0.36</td>
</tr>
</tbody>
</table>

* Values < 1 favor experimental arm

*N Jackson-McLeary et al J Clin Oncol 2013*
Elderly patients ACCENT analysis stage II and III

Table 1. Adjuvant Colon Cancer Trials Included

<table>
<thead>
<tr>
<th>Trial</th>
<th>Accrual Period</th>
<th>No. of Patients</th>
<th>Patients Age ≥ 70 Years (%)</th>
<th>Experimental Treatment Arm*</th>
<th>Stage III (%)†</th>
</tr>
</thead>
<tbody>
<tr>
<td>Oxaliplatin</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>MOSAIC</td>
<td>1998 to 2001</td>
<td>2,246</td>
<td>14</td>
<td>FOLFOX4</td>
<td>60</td>
</tr>
<tr>
<td>NSABP-C07</td>
<td>2000 to 2002</td>
<td>2,434</td>
<td>16</td>
<td>FLOX</td>
<td>71</td>
</tr>
<tr>
<td>XELOXA</td>
<td>2003 to 2004</td>
<td>1,862</td>
<td>22</td>
<td>XELOX</td>
<td>100</td>
</tr>
<tr>
<td>Irinotecan</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>CALGB-89803</td>
<td>1999 to 2001</td>
<td>1,263</td>
<td>24</td>
<td>IFL</td>
<td>98</td>
</tr>
<tr>
<td>PETACC-3</td>
<td>2000 to 2002</td>
<td>3,186</td>
<td>13</td>
<td>FOLFIRI</td>
<td>71</td>
</tr>
<tr>
<td>Oral fluoropyrimidine</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>NSABP-C08</td>
<td>1997 to 1999</td>
<td>1,557</td>
<td>23</td>
<td>Uracil/tegafur</td>
<td>53</td>
</tr>
<tr>
<td>X-ACT</td>
<td>1998 to 2001</td>
<td>1,983</td>
<td>20</td>
<td>Capecitabine</td>
<td>100</td>
</tr>
</tbody>
</table>

Abbreviations: CALGB, Cancer and Leukemia Group B; FLOX, bolus intravenous fluorouracil, leucovorin, and oxaliplatin; FOLFIRI, infusional fluorouracil, leucovorin, and irinotecan; FOLFOX, infusional fluorouracil, leucovorin, and oxaliplatin; IFL, bolus intravenous fluorouracil, leucovorin, and irinotecan; MOSAIC, Multicenter International Study of Oxaliplatin/Fluorouracil/Leucovorin in the Adjuvant Treatment of Colon Cancer; NSABP, National Adjuvant Breast and Bowel Project; PETACC, Pan-European Trials in Adjuvant Colon Cancer; X-ACT, Xeloda in Adjuvant Colon Cancer Therapy; XELOX, Xeloda and oxaliplatin; XELOXX, Xeloda and Oxaliplatin in Adjuvant Colon Cancer Treatment.

*Compared with control arm of intravenous fluorouracil and leucovorin.
†Remaining patients had stage II disease or unknown stage.
Interpretation pitfalls

• No information for:
  - Toxicity data
  - Dose-intensity
  - Comorbidity

This may confound interaction between age & newer adjuvant chemotherapy regimens

  - Small population
  - Different FP regimens
Impact of age and medical comorbidity on adjuvant treatment outcomes for stage III colon cancer: a pooled analysis of individual patient data from four randomized, controlled trials


1Abramson Cancer Center at the University of Pennsylvania, Philadelphia; 2National Surgical Adjuvant Breast and Bowel Project (NSABP), Pittsburgh; 3Department of Oncology, Florida Cancer Affiliates, Ocala, USA; 4Leeds Institute of Cancer and Pathology and St James’s University Hospital, Leeds, UK; 5US Medical Affairs, Genentech, Inc., South San Francisco; 6University of Pittsburgh Cancer Institute, Pittsburgh; 7Tufts University School of Medicine, Boston; 8Biostatistical Center and University of Pittsburgh Graduate School of Public Health Department of Biostatistics, Pittsburgh, USA; 9University Clinic, Martin Luther University, Halle, Germany

Received 9 July 2014; revised 17 December 2014; accepted 18 December 2014

Background: Adjuvant oxaliplatin plus capcitabine or leucovorin/5-fluorouracil (LV/5-FU) (XELOX/FOLFOX) is the standard of care for stage III colon cancer (CC); however, there is disagreement regarding oxaliplatin benefit in patients aged $>70$. In most analyses, the impact of medical comorbidity (MC) has not been assessed. Efficacy and safety of adjuvant XELOX/FOLFOX versus LV/5-FU were compared with respect to age and MC using pooled data from four randomized, controlled trials, selected for access to patient-level MC data and including commonly endorsed and utilized regimens.

Patients and methods: Individual data from patients with stage III CC in NSABP C-08, XELOXA, X-ACT, and AVANT were pooled, excluding bevacizumab-treated patients. Patients were grouped by treatment, MC (low versus high), or age ($<70$ versus $\geq 70$), and compared for disease-free survival (DFS), overall survival (OS), and adverse events (AEs). Multivariable Cox proportional hazards regression controlled for gender, T stage, and N stage.

Results: DFS benefits were shown for XELOX/FOLFOX versus LV/5-FU regardless of age or MC, although benefits were modestly attenuated for patients aged $\geq 70$. Hazard ratios were $0.69$ ($P < 0.0001$) and $0.77$ ($P < 0.014$) for $<70$ and $\geq 70$ age groups; $0.69$ ($P < 0.0001$) and $0.59$ ($P < 0.0001$) for Charlson Comorbidity Index $\leq 1$ and $>1$ groups; and $0.70$ ($P < 0.0001$) and $0.58$ ($P < 0.0001$) for National Cancer Institute Combined Index $\leq 1$ and $>1$ groups. OS was also significantly improved in all groups. Grade 3/4 serious AEs rates were comparable across cohorts and MC scores and higher in patients aged $\geq 70$. Oxaliplatin-relevant grade 3/4 AEs, including neuropathy, were comparable across ages and MC scores.

Conclusions: Results further support consideration of XELOX or FOLFOX as standard treatment options for the adjuvant management of stage III CC in all age groups and in patients with comorbidities, consistent with those who were eligible for these clinical trials.

Key words: age groups, capcitabine, adjuvant chemotherapy, colon cancer, comorbidity, oxaliplatin
5 FU Increases Cure Rate in Stage III colon cancer patients
Evidence in 13,793 Patients with Stage III

Moertel et al NEJM 1990

Sargent D, J Clin Oncol 2009
MOSAIC Study  Survival: Stage III infusional 5-FU/FA vs. FOLFOX

Overall survival (months)

Probability

Data cut-off: January 2007

FOLFOX4 stage III
LV5FU2 stage III

HR [95% CI]

Stage III  0.80 [0.66–0.98]

p=0.029

4.4%

De Gramont et al. ASCO 2007
Adjuvant Trials and the Elderly?

“Your pulse may be too weak to be eligible for my study”
IDEA Clinical Consensus: Risk-based approach to adjuvant chemotherapy in stage III colon cancer

<table>
<thead>
<tr>
<th>Risk group</th>
<th>Recommended duration of adjuvant therapy</th>
</tr>
</thead>
<tbody>
<tr>
<td>T1-3 N1</td>
<td>3 months</td>
</tr>
<tr>
<td>(~60% of stage III)</td>
<td>6 months</td>
</tr>
<tr>
<td>T4 and/or N2</td>
<td>Duration of therapy determined by</td>
</tr>
<tr>
<td>(Or other high-risk factors)</td>
<td>- tolerability of therapy</td>
</tr>
<tr>
<td></td>
<td>- patient preference</td>
</tr>
<tr>
<td></td>
<td>- assessment of risk of recurrence</td>
</tr>
<tr>
<td></td>
<td>- Regimen (CAPOX vs FOLFOX)</td>
</tr>
</tbody>
</table>

Presented at: ASCO Annual Meeting '17 #ASCO17
Presented by: Qian Shi, PhD on behalf of IDEA collaborators
In the IDEA trial more than 3000 patients over 70 received oxaliplatin-based therapy either for 3 or 6 months; overall, their outcomes in terms of duration effect did not differ substantially from those patients under 70 years, although there were significant interactions by treatment and male sex by risk group when subsets were considered.
Outline

• Background / epidemiology
• Stage III disease
• Stage II disease
• Current recommendations / conclusions
Adjuvant chemotherapy for stage II older colon cancer patients with poor prognostic features

- 20,847 pts with stage II cancer (SEER database)
- Pts 66 and older, between 1992 and 2005
- 75% had at least one poor prognostic feature
- HR (1.02 vs 1.03, non-poor vs poor) for the benefit of chemotherapy

O’Connor E et al J Clin Oncol 2011;29:3381-3388
Quick, simple & reliable

'Uncertain indication'
for chemotherapy
(3239 patients '94 -'03)

Randomize

Observation (n=1617)

5-FU/LV ± Lev (n=1622)
In patients with (A, B) stage II and (C, D) stage III disease, (A, C) recurrence and (B, D) mortality rates by time since random assignment. Risk of recurrence was calculated as the number of recurrences within each of the 6-month windows divided by the number of patients at risk (recurrence free) at the start of each interval. Risk of mortality was calculated in the same fashion.

Should the Benefit of Adjuvant Chemotherapy in Colon Cancer Be Re-Evaluated?

Lars A. Pählman, Uppsala University, Uppsala, Sweden
Werner M. Hohenberger and Klaus Matzel, Universität'sklinikums Erlangen, Erlangen, Germany
Kenichi Sugihara, Tokyo Medical and Dental University, Tokyo, Japan
Philip Quirke, St James’s University Hospital, Leeds, United Kingdom
Bengt Glimelius, Uppsala University, Uppsala, Sweden

Because favorable effects on survival were seen in randomized trials conducted during the 1980s, adjuvant chemotherapy in colon cancer was established as routine therapy in stage III disease in the United States in 1990.¹ Follow-up trials in the United States, Asia, and Europe²,³ soon meant that it became recommended therapy worldwide, not only in stage III but in stage II disease as well, if risk factors for recurrence were present. Additional trials established the combination of a fluoropyrimidine and oxaliplatin as reference treatment for patients with stage II disease with risk factors who are fit for therapy and for those with stage III disease.⁴⁻⁶ The addition of oxaliplatin in the treatment of elderly patients has been questioned.⁷

Thorax and abdomen, completed with ultrasonography or magnetic resonance imaging with contrast agents in the case of equivocal liver lesions or positron emission tomography-computed tomography in the case of equivocal findings outside the liver, has also resulted in fewer recurrences in those undergoing surgery (ie, the target patients for adjuvant therapy). The scenario has changed from fewer metachronous to more synchronous metastases. Furthermore, although pathologists cannot reduce recurrence risks per se, better pathologic staging results in lower stage-specific recurrence rates, often referred to as stage migration.

The rectal cancer radiotherapy story illustrates the same kind
Adjuvant! Online Prediction for stage II colon cancer: Cancer and non-cancer related 5-year-Mortality

Improvement of cancer specific survival by 1.7% (FU) and 2.3% (FOLFOX)

Assumption of Gill model
Validity of Adjuvant! Online in older patients with stage III colon cancer based on 2967 patients from the ACCENT database

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the Adjuvant Colon Cancer Endpoints (ACCENT) Group

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⁹Abramson Cancer Center, University of Pennsylvania, Philadelphia, PA, United States

ABSTRACT

Background: Adjuvant! Online is a tool used for clinical decision making in patients with early stage colon cancer. As details of the tool’s construction are not published, the ability of Adjuvant! Online to accurately predict outcomes for older patients (age 70+) with node positive colon cancer receiving adjuvant chemotherapy is unclear.

Methods: Individual data from older patients with stage III colon cancer who enrolled into multiple trials within the ACCENT database were entered into the Adjuvant! Online program to obtain predicted probabilities of 5-year overall survival (OS) and recurrence-free survival (RFS). Median predictions were compared with known rates. As co-morbidities were not known for ACCENT patients, but required for calculator entry, patients were assumed to have either “minor” or “average for age” co-morbidities.

Results: 2967 older patients from 10 randomized studies were included. When “minor” co-morbidities were assumed, the median predicted 5-year OS rate of 64% nearly matched the actual rate of 65%; when “average for age” co-morbidities were assumed, the median prediction dropped to 58%, outside the CI for the actual rate. On the other hand, assuming
Figure 1. Proportion of patients receiving chemotherapy after surgery and adjusted RERs of death for patients 80 years and older diagnosed with stage II colon cancer (A), stage III colon cancer (B), and stage IV colon cancer (C), according to country (2001–2006).
Outline

- Background / epidemiology
- Stage III disease
- Stage II disease
- Current recommendations / conclusions
Conclusions: SIOG recommendations on adjuvant therapy

- XELOX and FOLFOX are considered to be standard treatment options for the adjuvant management of stage III colon cancer, but their use is of uncertain benefit in patients aged >70 years.

- In view of the potential for increased serious adverse events (AEs) associated with combination chemotherapy regimens, the choice of whether to treat older patients with oxaliplatin-containing combination therapy or fluoropyrimidine monotherapy should depend on the treating physician’s clinical judgment and the individual patient’s risk of recurrence. The gains from the addition of oxaliplatin are modest and most of the benefit is still conferred by the fluoropyrimidine.

- The use of fluoropyrimidine monotherapy, either 5-FU/LV or capecitabine, is an appropriate adjuvant treatment option for many patients ≥70 years.

- The benefit of adjuvant chemotherapy in the management of older stage II colon cancer patients remains controversial.

Thank you