WCGC – ESMO GI
Barcelona, July 3, 2019

Is adjuvant or Neo-adjuvant Treatment for Resectable Pancreatic Cancer the Way to Go? Neo-adjuvant Chemotherapy

Thomas Seufferlein
Department of Internal Medicine I
Ulm University, Germany
Conflicts of Interest

- Honoraria: Amgen, Bayer, Merck, Sanofi, Celgene
- Advisory boards: Lilly, Amgen, Bayer, Celgene, Shire
- Research Support: Boehringer Ingelheim, Sanofi, Celgene, AMGEN
How many PDACs are clearly resectable?

Unresectable
- Distant metastases
- Arterial encasement (celiac trunk, superior mesenteric artery, or hepatic artery)
- Arterial involvement (celiac trunk, superior mesenteric artery, or hepatic artery)
- Venous encasement (portal or superior mesenteric vein)
- Venous involvement (portal or superior mesenteric vein)
- Attached to other organs
- No arterial or venous involvement

Resectable

Borderline-resectable

Pre-operative treatment

≈ 20%

Adjuvant treatment has substantially improved

FOLFIRINOX:
3-year-DFS rate almost doubled (39.7% vs. 21.4%)
- Advantage also in
  - tumors with unfavourable grading
  - Stage III
  - R1 resection
  - Grad 3/4 toxicity 46.8%!

But:
- Not all patientes qualify for FOLFIRINOX
- Up to 50% of patients receive no adjuvant treatment
  - Reasons:
    - Peri-/ postoperative complications
    - Reduced ECOG

Conroy, NEJM 2018
What shall neoadjuvant treatment achieve in (resectable) PDAC?

- Improve RO resection rate
- Treatment of early (micro-) metastasis
- Improve overall survival
Rationale for Neoadjuvants - Micrometastasis

- Even small tumors exhibit micrometastases at initial diagnosis

Computational Modeling of Pancreatic Cancer Reveals Kinetics of Metastasis Suggesting Optimum Treatment Strategies

Haeno, Cell 2012
Problems of neoadjuvant treatment: We need a definitive diagnosis before treatment!

- Tissue or cells
- In up to 30% of cases there is not enough material
  - neither for histology
  - nor for cytology
  - -> potential delay in treatment in case of neoadjuvant strategy
- Alternative means – e.g. liquid biopsies?!
### ctDNA Biological Plausibility

**Genotyping concordance studies**

<table>
<thead>
<tr>
<th>Cancer Type</th>
<th>Point mutations</th>
<th>N patients</th>
<th>Mutation rate plasma / serum</th>
<th>Mutation rate tumor</th>
<th>Concordance plasma / serum &amp; tumor</th>
</tr>
</thead>
<tbody>
<tr>
<td>NSCLC</td>
<td>EGFR (exon 19 deletions, ptL858R)</td>
<td>42</td>
<td>19 %</td>
<td>21 %</td>
<td>92 %</td>
</tr>
<tr>
<td></td>
<td></td>
<td>12</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td></td>
<td>KRAS</td>
<td>164</td>
<td>N/A</td>
<td>12 %</td>
<td>1 %</td>
</tr>
<tr>
<td></td>
<td></td>
<td>273</td>
<td>12 %</td>
<td>13 %</td>
<td></td>
</tr>
<tr>
<td>Melanoma</td>
<td>BRAF</td>
<td>96</td>
<td>26 %</td>
<td>6 %</td>
<td></td>
</tr>
<tr>
<td>Breast cancer</td>
<td>PIK3CA</td>
<td>41</td>
<td>19 %</td>
<td>29 %</td>
<td></td>
</tr>
<tr>
<td><strong>Pancreatic cancer</strong></td>
<td>KRAS</td>
<td>39</td>
<td>23 %</td>
<td>72 %</td>
<td>32 %</td>
</tr>
<tr>
<td></td>
<td>RAS</td>
<td>76</td>
<td>54 %</td>
<td>55.3 %</td>
<td>93.4%</td>
</tr>
<tr>
<td></td>
<td>RAS/BRAF</td>
<td>100</td>
<td>97 %</td>
<td>100 %</td>
<td>97%</td>
</tr>
<tr>
<td></td>
<td>KRAS/BRAF</td>
<td>95</td>
<td>44 %</td>
<td>42 %</td>
<td>96%</td>
</tr>
<tr>
<td></td>
<td>KRAS</td>
<td>206</td>
<td>33 %</td>
<td>38 %</td>
<td>95%</td>
</tr>
<tr>
<td></td>
<td>KRAS/PIK3CA</td>
<td>503 (1)</td>
<td>69% / 17%</td>
<td>3%</td>
<td>76% / 88%</td>
</tr>
<tr>
<td></td>
<td>BRF</td>
<td>236 (2)</td>
<td>3%</td>
<td>1%</td>
<td>97%</td>
</tr>
<tr>
<td><strong>CRC summary</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>76-97%</td>
</tr>
</tbody>
</table>

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ctDNA based KRAS mutation analysis as alternative to histology/cytology is not suitable to make a definitive diagnosis.

---

R. Salazar, ASCO 2016

1 Joensuu, et al. Annal of Oncology 2015
5 Tabernero, et al. Lancet Oncology 2015
Combining parameters in liquid biopsies

- N = 54 Patients, treatment-naïve
- Study cohort: 39 patients with PDAC UICC I-III, histopathologically confirmed
  - Recruited from NEONAX-trial; clinical trial identifier: NCT0204751
- Control cohort: 15 patients with side-branch IPMNs (no worrisome features), age-matched

Berger, A., ... Seufferlein, T. Theranostics, 2019
Combination of single marker (CA19-9, THBS2, cfDNA)

<table>
<thead>
<tr>
<th>Marker</th>
<th>Cut-off</th>
<th>Sensitivity (%)</th>
<th>Specificity (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>CA19-9 (≥ 55 U/ml)</td>
<td></td>
<td>56</td>
<td>100</td>
</tr>
<tr>
<td>THBS2 (≥ 42 ng/ml)</td>
<td></td>
<td>46</td>
<td>100</td>
</tr>
<tr>
<td>cfDNA (ng/ml)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>4 FP</td>
<td>&gt; 7.65</td>
<td>74</td>
<td>73</td>
</tr>
<tr>
<td>3 FP</td>
<td>&gt; 9.4</td>
<td>64</td>
<td>80</td>
</tr>
<tr>
<td>2 FP</td>
<td>&gt; 9.6</td>
<td>64</td>
<td>87</td>
</tr>
<tr>
<td>1 FP</td>
<td>&gt; 9.65</td>
<td>64</td>
<td>93</td>
</tr>
<tr>
<td>0 FP</td>
<td>&gt; 12.6</td>
<td>54</td>
<td>100</td>
</tr>
<tr>
<td>CA19-9 (≥ 55 U/ml) + THBS2 (≥ 42 ng/ml)</td>
<td></td>
<td>77</td>
<td>100</td>
</tr>
<tr>
<td>CA19-9 (≥ 55 U/ml) + THBS2 (≥ 42 ng/ml) + cfDNA (ng/ml)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>4 FP</td>
<td>&gt; 7.65</td>
<td>92</td>
<td>73</td>
</tr>
<tr>
<td>3 FP</td>
<td>&gt; 9.4</td>
<td>90</td>
<td>80</td>
</tr>
<tr>
<td>2 FP</td>
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<tr>
<td>1 FP</td>
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<td>93</td>
</tr>
<tr>
<td>0 FP</td>
<td>&gt; 12.6</td>
<td>90</td>
<td>100</td>
</tr>
</tbody>
</table>

- cfDNA threshold 12.6 ng/ml → 54% of PDACs
- Marker combination identifies 90% of PDACs

Berger, A, ... Seufferlein, T. Theranostics, 2019
Problems of neoadjuvant treatment – progress during treatment?

- Up to 25% of patients may have disease progress during neoadjuvant treatment
- \textit{\textup{\textnormal{window of opportunity}}} to get to know tumor biology

or:

- Disadvantage for patients when potentially curative resection is not possible any more?
First experience with nab-Paclitaxel + Gemcitabin as neoadjuvant treatment – NEONAX trial

No increase in complications and no obvious tumor progress during neoadjuvant treatment

<table>
<thead>
<tr>
<th>Surgery</th>
<th>Total n=48</th>
<th>Arm A (perioperative arm) n=25</th>
<th>Arm B (adjuvant arm) n=23</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pancreatic tumor resection, No. (%)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>41 (85.4%)</td>
<td>20 (80.0%)</td>
<td>21 (91.3%)</td>
</tr>
<tr>
<td>No</td>
<td>7 (14.6%)</td>
<td>5 (20.0%)</td>
<td>2 (8.7%)</td>
</tr>
<tr>
<td>Postoperative 60 day mortality, No. (%)</td>
<td>0 (0%)</td>
<td>0 (0%)</td>
<td>0 (0%)</td>
</tr>
<tr>
<td>Revision surgery</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Re-laparotomy due to abdominal abscess (1 patient, arm A)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Reasons for not undergoing pancreatic resection within the NEONAX trial</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>intraoperatively determined, small liver metastases (2 patients, arm A)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>withdrawal of informed consent (2 patients in each arm): resection outside the trial</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>uncontrolled cholestasis (1 patient, arm A): resection outside the trial</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Uhl, W; Seufferlein, T; ASCO 2019, #4128
Problems of neoadjuvant treatment: Postoperative complications? Systematic review, 30 trials

- Surgery only:
  - Delayed gastric emptying: 17-24%
  - Pancreatic fistula: 10-20%
  - Leaky anastomosis: 0-10%
  - Leaky anastomosis: 2-13%
  - Infections: 3-19%
  - Mortality: <5%

- Neoadjuvant treatment

Conclusion: No significant increase in complication rates by neoadjuvant chemotherapy

- Bleeding: 3-12%
- Infections: 3-7%
- Mortality: 0-4%

Potentially higher risk for venous thrombembolism (10%) during neoadjuvant treatment -> Anticoagulation

What does the statistics say?

- Markov model
- Literature search Pubmed 2000-2015
- 22/786 studies fulfilled the criteria
- Neoadjuvant:
  - Higher life expectancy
    - 32.2 vs. 26.7 mo
  - Higher quality adjusted life expectancy
    - 25.5 vs. 20.8 mo
  - Similar data in case series

<table>
<thead>
<tr>
<th>Strategy</th>
<th>Life expectancy (in months)</th>
<th>Gain in life expectancy</th>
<th>Quality adjusted life expectancy (in months)</th>
<th>Gain in quality adjusted life expectancy</th>
</tr>
</thead>
<tbody>
<tr>
<td>Neoadjuvant therapy</td>
<td>32.2</td>
<td>5.5</td>
<td>25.5</td>
<td>4.7</td>
</tr>
<tr>
<td>Upfront surgery</td>
<td>26.7</td>
<td>-</td>
<td>20.8</td>
<td>-</td>
</tr>
</tbody>
</table>

De Geus, EJSO, 2016; Christians, SURGERY 2016
Neoadjuvant Therapy Followed by Resection Versus Upfront Resection for Resectable Pancreatic Cancer: A Propensity Score Matched Analysis

- National Cancer Database
- 2006-2012
- N=15237 mit PDAC SI und II
- 2104 neoadjuvant, 12837 adjuvant
- 3:1 propensity score matching

Table 2. Comparison of Surgical and Early Postoperative Outcomes in the Matched Data Set

<table>
<thead>
<tr>
<th>Variable</th>
<th>UR (n=6,105)</th>
<th>NAT (n=2,005)</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pathologic T stage</td>
<td></td>
<td></td>
<td>&lt;.01</td>
</tr>
<tr>
<td>pT0/Tis</td>
<td>22 (6)</td>
<td>47 (2)</td>
<td></td>
</tr>
<tr>
<td>pT1</td>
<td>171 (3)</td>
<td>212 (11)</td>
<td></td>
</tr>
<tr>
<td>pT2</td>
<td>667 (11)</td>
<td>281 (15)</td>
<td></td>
</tr>
<tr>
<td>pT3</td>
<td>4,728 (79)</td>
<td>1,193 (60)</td>
<td></td>
</tr>
<tr>
<td>pT4</td>
<td>427 (7)</td>
<td>262 (13)</td>
<td></td>
</tr>
<tr>
<td>Positive lymph nodes</td>
<td>4,306 (73)</td>
<td>932 (48)</td>
<td>&lt;.01</td>
</tr>
<tr>
<td>Positive resection margin</td>
<td>1,417 (24)</td>
<td>335 (17)</td>
<td>&lt;.01</td>
</tr>
<tr>
<td>Length of stay, mean ± SD, days</td>
<td>11 ± 10</td>
<td>11 ± 10</td>
<td>.86</td>
</tr>
<tr>
<td>30-day unplanned readmission</td>
<td>502 (9)</td>
<td>147 (8)</td>
<td>17</td>
</tr>
<tr>
<td>30-day mortality</td>
<td>175 (3)</td>
<td>50 (3)</td>
<td>16</td>
</tr>
<tr>
<td>90-day mortality</td>
<td>343 (6)</td>
<td>125 (6)</td>
<td>22</td>
</tr>
</tbody>
</table>

NOTE: Data are given as No. (%) unless otherwise noted.
Abbreviations: NAT, neoadjuvant chemotherapy plus resection; SD, standard deviation; UR, upfront resection.

Neoadjuvant treatment: Effect on T stage, Lymph nodes and R status

Mokdad et al., JCO 2016
Predictors of mortality

<table>
<thead>
<tr>
<th>Variable</th>
<th>Adjusted HR*</th>
<th>95% CI</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Treatment group</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>UR</td>
<td>Reference</td>
<td></td>
<td></td>
</tr>
<tr>
<td>NAT</td>
<td>0.74</td>
<td>0.69 to 0.79</td>
<td>&lt;.01</td>
</tr>
<tr>
<td>Pathologic T stage</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>pT0/Tis</td>
<td>0.58</td>
<td>0.34 to 0.98</td>
<td>.04</td>
</tr>
<tr>
<td>pT1</td>
<td>Reference</td>
<td></td>
<td></td>
</tr>
<tr>
<td>pT2</td>
<td>1.52</td>
<td>1.26 to 1.84</td>
<td>&lt;.01</td>
</tr>
<tr>
<td>pT3</td>
<td>1.59</td>
<td>1.34 to 1.89</td>
<td>&lt;.01</td>
</tr>
<tr>
<td>pT4</td>
<td>1.22</td>
<td>0.99 to 1.50</td>
<td>.06</td>
</tr>
<tr>
<td>Lymph node</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Negative</td>
<td>Reference</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Positive</td>
<td>1.68</td>
<td>1.56 to 1.82</td>
<td>&lt;.01</td>
</tr>
<tr>
<td>Resection margin</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Negative</td>
<td>Reference</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Positive</td>
<td>1.59</td>
<td>1.48 to 1.71</td>
<td>&lt;.01</td>
</tr>
<tr>
<td>Adjuvant therapy</td>
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<tr>
<td>No</td>
<td>Reference</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>0.62</td>
<td>0.58 to 0.66</td>
<td>&lt;.01</td>
</tr>
</tbody>
</table>

Abbreviations: HR, hazard ratio; NAT, neoadjuvant chemotherapy plus resection; UR, upfront resection.
*Patient and facility variables were accounted for in this model.

Mokdad et al., JCO 2016
What does the statistics say?

Neoadjuvant Therapy Followed by Resection Versus Upfront Resection for Resectable Pancreatic Cancer: A Propensity Score Matched Analysis

HR 0.72

HR 0.83

Neoadjuvant treatment confers a significant survival advantage compared to upfront surgery.

Mokdad et al., JCO 2016
Neoadjuvant treatment — role of tumor response

Significance of Pathologic Response to Preoperative Therapy in Pancreatic Cancer

Proportion surviving

Major response: P < 0.001
Partial response: P = NS
Minor response

Overall survival (months)

Chun et al., Ann Surg Oncol 2011
**BACKGROUND AND RATIONALE**

- Survival following surgery and current standard adjuvant chemotherapy for resectable pancreatic cancer is 15-20% at 5 years, with median survival 20 months (Seltzer, JAMA 2007; Neoptolemos, NEJM 2004)
- FOLFIRINOX has significant activity in metastatic pancreatic cancer (Conroy, NEJM 2011)
- Preoperative chemotherapy (+/- radiation) is commonly practiced for borderline resectable pancreatic cancer (Katz, J Am Coll Surg 2008 and others)
- A regimen of perioperative therapy with FOLFIRINOX has not been previously reported in resectable pancreatic cancer
- The toxicity and efficacy of this novel approach has yet to be defined

**ENDPOINTS**

**Primary:**
- Evaluate the percentage of patients able to complete 4 cycles of pre-operative mFOLFIRINOX (no delay for 5-FU and addition of S-1) and undergo a resection.
- Early withdrawals due to toxicity, disease progression, or intercurrent illness are considered failures.

**Secondary:**
- Evaluate the percentage of patients able to complete the full course of therapy, including 4 cycles of preoperative mFOLFIRINOX, surgical resection, and 4 cycles of postoperative mFOLFIRINOX.
- Assess treatment-related toxicity and other adverse events (AES) during preoperative, operative and postoperative phases and safety of this approach.
- Assess the R0 resection rate.
- Assess disease-free survival and overall survival from the start of study treatment.

**METHODS**

**ERSE EVENTS**

<table>
<thead>
<tr>
<th>Event</th>
<th>Pre-op</th>
<th>Post-op</th>
</tr>
</thead>
<tbody>
<tr>
<td>5</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>13</td>
<td>4.5</td>
<td>0</td>
</tr>
<tr>
<td>25.5</td>
<td>4.5</td>
<td>0</td>
</tr>
<tr>
<td>35</td>
<td>4.5</td>
<td>52</td>
</tr>
<tr>
<td>52</td>
<td>4.5</td>
<td>52</td>
</tr>
<tr>
<td>71</td>
<td>4.5</td>
<td>35</td>
</tr>
</tbody>
</table>

**TREATMENT RESULTS**

**FOLFIRINOX:**

- ORR: 20%
- R0 Resection rate: 94%
- Only 17/21 resected
- ORR: 59%
- pCR: 6%
- Liver metastases during surgery: 15%
- mOS: 33.4 mo
- Grade 3/4 toxicity pre-op: 50%

**CONCLUSIONS**

- The majority of patients were able to complete pre-op FOLFIRINOX and undergo a resection; two-thirds of those who started completed all planned therapy
- 4 months of pre-postoperative FOLFIRINOX is feasible and tolerable in resectable PDAC
- Toxicity is predictable and manageable
- No patient progressed on preoperative chemotherapy
- There was a high rate of R0 resection and pathologic response
- The median OS of 33.4 months compares favorably with historical data in this population
- A follow-up study assesses a longer period of preoperative chemotherapy and examines predictive biomarkers and biologic correlations of behavior
Neoadjuvant Chemoradiation

Preoperative Radiochemotherapy Versus Immediate Surgery For (Borderline) Resectable Pancreatic Cancer: (PREOPANC)

R/BR PDAC

R

N = 244 Patients

Primary Endpoint: ITT Overall Survival

Presented at: 2018 ASCO Annual Meeting

Presented by: Colin D. Weekes, MD, PhD
## Neoadjuvant Chemoradiation

### Results

<table>
<thead>
<tr>
<th></th>
<th>Immediate surgery N=127</th>
<th>Preop. radiochemotherapy N=119</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Resection rate</td>
<td>91/127 (72%)</td>
<td>72/119 (60%)</td>
<td>.065</td>
</tr>
<tr>
<td>R0 resection rate PP</td>
<td>28/91 (31%)</td>
<td>45/72 (63%)</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>Serious Adverse Events</td>
<td>49 (39%)</td>
<td>55 (46%)</td>
<td>.28</td>
</tr>
</tbody>
</table>
Disease-Free Survival

Overall DFS (ITT)

- Exploratory laparotomy
- Radiochemotherapy followed by exploratory laparotomy

P-value stratified logrank test 0.0024

DFS: 7.9 vs 9.9 Months, HR 0.71; p = 0.023

Distant Metastasis Free Interval

- Exploratory laparotomy
- Radiochemotherapy followed by exploratory laparotomy

P-value stratified logrank test 0.0127

HR 0.71; p = 0.013

Locoregional Recurrence Free Interval

- Exploratory laparotomy
- Radiochemotherapy followed by exploratory laparotomy

P-value stratified logrank test 0.0062

HR 0.55; p = 0.002
Neoadjuvant Chemoradiation

Overall Survival Analyses

- Preopanc supports the concept of neoadjuvant treatment in resectable PDAC
- What is the optimal strategy?

Median: 13.7 vs 17.1 Mos. HR 0.74; p = 0.074
Median Survival 16.8 vs 29.9 Months, p = 0.001
Perioperative Chemotherapy

Prep-02/JSAP-05 phase II/III study

- **Standard Arm**
  - Surgery + Adjuvant (S-1)

- **Up-S**
  - Neoadjuvant (GS) + Surgery + Adjuvant (S-1)
  - N=180

- **NAC-GS**
  - N=180

- **Stratification**
  - CA19-9
  - Institutions

- **Primary endpoint**
  - Overall survival in PIII
  - Resection rate in PII

Enrollment was started on Jan. 4th, 2013

Presented By Michiaki Unno at 2019 Gastrointestinal Cancer Symposium
Phase II part

• Primary endpoint: resection rate
  - The phase II part is planned to confirm if the experimental arm has a sufficient resection rate to proceed to the phase III part.

<table>
<thead>
<tr>
<th></th>
<th>NAC-GS</th>
<th>Upfront Surgery</th>
</tr>
</thead>
<tbody>
<tr>
<td>Resection rate</td>
<td>93% (39/42)</td>
<td>82% (36/44)</td>
</tr>
<tr>
<td>Unresection rate (90%CI)</td>
<td>7.14 (0.63-13.7)%</td>
<td>18.2 (8.65-27.7)%</td>
</tr>
</tbody>
</table>

- The results of phase II part met the preplanned criteria to go phase III part.
Perioperative Chemotherapy

Overall Survival (ITT)

- Overall survival
  - NAC-GS: 36.72 months (28.68 – 43.32)
  - Up-S: 26.65 months (21.00 – 31.32)
  - HR: 0.72 (95%CI: 0.55 – 0.94)
  - Stratified log-rank test: p=0.015

- 2-year OS
  - 63.7% vs 52.5%
Perioperative Chemotherapy

Forest Plot on Overall Survival

- Grade 3/4 toxicity neoadjuvant:
  - 72.8%
  - Mostly leucopenia and neutropenia
  - no difference in surgical morbidity
  - significantly more N0 (59.6% vs. 81.5%)
Is adjuvant or Neo-adjuvant Treatment for Resectable Pancreatic Cancer the Way to Go? Neo-adjuvant Chemotherapy

On Horizon: Neoadjuvant Trials for Resectable Pancreatic Cancer

NEONAX Phase II n=166
- Surgery
- nab-P+G

(< cT3, N0 or N1, cMO), stratified by T and N
Primary Endpoint: DFS

SWOG 1505 Phase II n=147
- Surgery
- mFOLFOXIRINOX

Resectable, Vein contact <180, Primary Endpoint: OS

A102806
- Surgery

mFOLFOXIRINOX Planned N: 300 patients

The field is moving:
from:
„Shall we do it?“
to:
„What shall we use?“


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Thanks for your attention!