Background

- Chemotherapy and chemoradiation are the main options in LAPC.
- Surgery becomes feasible only in a small proportion of patients after neoadjuvant therapy.
- FOLFIRINOX is an active treatment in advanced pancreatic cancer.
- FOLFIRINOX is a similar regimen, with lower dose of irinotecan and no 5-fluorouracil bolus, that has shown good activity in advanced colorectal cancer.
- We prospectively evaluated the activity of FOLFIRINOX in LAPC.

Materials and Methods

- This is a prospective single-arm trial.
- Main inclusion criteria were: LAPC (cT4, cN0-1, cM0) considered unresectable according to definition of the American Hepato-Pancreato-Biliary Association consensus conference; ECOG Performance Status 0-1; age 18-75 years.
- Patients were treated with modified FOLFIRINOX (irinotecan 150 mg/sqm, oxaliplatin 85 mg/sqm, folinate 200 mg/sqm, 5-fluorouracil 2800 mg/sqm in 48h) every 2 weeks.
- Tumor assessment was performed by CT scan every 8 weeks and multidisciplinary team evaluated patients after every CT scan.

Results

- From 2008 to 2015 we enrolled a total of 59 patients (Table 1).

<table>
<thead>
<tr>
<th></th>
<th>N</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sex</td>
<td></td>
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</tr>
<tr>
<td>Male/female</td>
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<td>44/56</td>
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<tr>
<td>Age, median (range)</td>
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<td>(34-74)</td>
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<td>ECOG PS, 0/1</td>
<td>40</td>
<td>68/32</td>
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<tr>
<td>Tumor Location, Head/Body-Tail</td>
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<td>63/37</td>
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<td>Vascular involvement</td>
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<td></td>
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<td>Artery or Vein</td>
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<td>86</td>
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<tr>
<td>Both</td>
<td>8</td>
<td>14</td>
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<tr>
<td>Vessels involved</td>
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<tr>
<td>Superior mesenteric artery</td>
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<td>64</td>
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<tr>
<td>Celiac axis</td>
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<td>Hepatic artery</td>
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<tr>
<td>Portal vein</td>
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<tr>
<td>Superior mesenteric vein</td>
<td>39</td>
<td>66</td>
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</table>

Table 1. Patients’ characteristics

- Consort diagram of the study is reported in Figure 1.
- Early post-operative mortality rate was 8%.
- Accrual was stopped after the number of planned resections was reached.
- Median follow up was 26.9 months.
- In the whole population median PFS was 11.9 months, median OS was 15.3 months and 2-years OS rate was 22.5% (Figure 2a).
- In resected patients median PFS was 14.9 months, median OS was 19.8 months and 2-years OS rate was 35% (Figure 2b).

Conclusions

- Chemotherapy with FOLFOXIRI seems feasible and active in LAPC.
- Induction CT may allow achieving resectability in some patients.
- Although longer follow up is needed, results in terms of PFS and OS are encouraging.

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Figure 1

• Median number of FOLFOXIRI cycles: 8 (range 2-14).
• After the first 34 patients, considering good tolerability, protocol was amended and we started to use classic schedule of FOLFOXIRI (irinotecan 165 mg/sqm and SFU 3200 mg in 48h).
• Main grade 3-4 toxicities during chemotherapy were neutropenia (46%), asthenia (15%) and diarrhea (8%). There were no significant differences in toxicities between the two schedules.

Figure 2. Survival data (a) global population (b) resected patients

59 pts enrolled

52 pts (88%)
SD/RP

28 pts (47%)
underwent surgery

• 7 pts (12%) experienced disease progression during chemotherapy

• 23 pts not resectable
• 1 patient waiting for surgery

Poster Session Online
Caterina Vivaldi