The Question

Should marginal liver donors be used for patients who fall outside of the Milan Criteria?

NO

What is a “marginal” liver?

There is no uniformly accepted definition for extended criteria livers, therefore how can the answer be “yes”?
(We’re not talking about kidneys.)

The Evidence

“There are no good or bad organs but only livers bearing different levels of risk...”


“It is critical that... clinicians understand the limitations of defining extended criteria donors in yes or no terms.”


**Why Milan Criteria?**

Currently utilized UNOS criteria for MELD upgrade.
These are currently thought to be too restrictive. What about UCSF Criteria?
What about downstaging?
Both UCSF Criteria and down-staging are currently under consideration by UNOS.

<table>
<thead>
<tr>
<th>Condition</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age ≥ 60 yr</td>
<td>66 (18.5)</td>
</tr>
<tr>
<td>BMI &gt; 35 kg/m²</td>
<td>51 (15.9)</td>
</tr>
<tr>
<td>Maximum serum Na⁺ &gt; 170 mEq/L</td>
<td>72 (12.8)</td>
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<tr>
<td>Maximum total bilirubin ≥ 3.0 mg/dL</td>
<td>71 (11.4)</td>
</tr>
<tr>
<td>Maximum AST &gt; 2500 μL/L</td>
<td>3 (0.5)</td>
</tr>
<tr>
<td>Maximum ALT &gt; 500 μL/L</td>
<td>2 (0.3)</td>
</tr>
<tr>
<td>Elevated LFTs (Any of following 3):</td>
<td>117 (20.5)</td>
</tr>
<tr>
<td>AST/ALT and MoM (MoM)</td>
<td>33 (4.0)</td>
</tr>
<tr>
<td>Non-hepatic tumor</td>
<td>16 (2.5)</td>
</tr>
<tr>
<td>Lactate dehydrogenase &gt; 11 units</td>
<td>39 (11.2)</td>
</tr>
<tr>
<td>More than 2 processes at any time</td>
<td>39 (11.2)</td>
</tr>
<tr>
<td>ICU stay greater than 5 days</td>
<td>53 (16.3)</td>
</tr>
<tr>
<td>ECOG score &gt; 3 or age &gt; 70 or MFH</td>
<td>60 (11.4)</td>
</tr>
<tr>
<td>Current or past history of HCC</td>
<td>14 (2.5)</td>
</tr>
<tr>
<td>Past history of non-melanoma</td>
<td>2 (0.3)</td>
</tr>
<tr>
<td>Any history of non-skin cancer</td>
<td>13 (2.3)</td>
</tr>
<tr>
<td>Significant prior transp (≥ stage 1 tumor)</td>
<td>15 (2.4)</td>
</tr>
</tbody>
</table>

**The Evidence**

5 year survival rate the same for UCSF as for Milan.

“Successful tumor downstaging can be achieved in the majority of carefully selected patients...”

**Why not living donors instead?**

No impact on donor pool
Better recipient outcomes
**The Evidence**

**2002**

LDLT: 83 days.
cadaveric: 414 days.


**2004**

LDLT: 62 days.
cadaveric: 459 days.


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**The Evidence**

"19 of the 30 people in the deceased donor group died waiting for transplant..."


"...LDLT that were performed for HCC on patients who did not meet the Milan criteria showed favorable outcomes..."


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**The Evidence**

"...no significant difference in the patient survival rates was observed between the patients who met the Milan criteria and those who did not."


"LDLT can achieve acceptable survival in HCC patients, even when liver function is markedly impaired..."


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**The Evidence**

"...more patients may be potentially cured, without punishing patients on the waiting list with non-malignant liver disease."


"For patients with tumors exceeding the current criteria for prioritization, LDLT offers the only realistic hope for survival."

Guiding Principle

A liver transplant either functions or fails to function.

- if likely to function it should be placed into a recipient within UNOS tumor criteria.
- if not likely to function, it should not be transplanted at all.

Conclusion

There is no accepted definition of an “extended criteria liver.”

- The Milan criteria are too restrictive.
- LDLT offers a far better alternative.