Abstract 5806; First results from BladderPath: A randomised trial of MRI versus cystoscopic staging for newly diagnosed bladder cancer

Conflicts of interest

• The authors report no conflicts of interest for this presentation
Standard diagnostic pathway

• Flexible cystoscopy → rigid cystoscopy and resection
  – Serves as tissue diagnosis and staging
  – Re-resection often needed
  – Disrupts accuracy of subsequent imaging
  – Is not definitive treatment for muscle-invasive disease which is often very delayed

• Most tumour sites separate tissue diagnosis and staging and use primary imaging not piecemeal resection for staging
BladderPath key trial design features:

Feasibility stage
• A minimum of 80% of patients on MRI pathway complete as planned
• Outcome Feasibility: 37/39 95% CI (83%, 99%) followed protocol

Efficacy stage
• Primary outcome
  • A reduction of at least 30 days in time to correct treatment (TTCT) for muscle-invasive bladder cancer (MIBC)
• Secondary outcomes
  • TTCT for all patients
  • TTCT for Non-MIBC

Probable non-invasive vs Possible muscle-invasive disease by clinical assessment on 5-point scale:
1. Strongly agree that the lesion is non-muscle-invasive
2. Agree that the lesion is non-muscle-invasive
3. Equivocal
4. Agree that the lesion is muscle-invasive
5. Strongly agree that the lesion is muscle-invasive
Recruitment – CONSORT Diagram

Patients approached n=638

- PIS posted but patient not approached in clinic n=59
- Patients declined participation n=155
- Pending patient response (Nov 2021) n=3
- Investigator not available n=30
- Patient cancelled appointment or DNA n=15
- Ineligible n=64
- Patient refused cystoscopy n=1
- No interpreter n=2
- SUB-TOTAL n=329

Patients registered n=309

Patients not randomised n=166
- Patient didn’t have a tumour n=161
- Patient poor understanding of study n=1
- Tumour found but not confirmed by Investigator n=1
- Reason not known n=3

Patients randomised n=143
## Patient characteristics

Table 4.4: Stratification Factors by Pathway

<table>
<thead>
<tr>
<th>Trt</th>
<th>Pathway1 (72)</th>
<th>Pathway2 (71)</th>
<th>Overall (143)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Sex</strong></td>
<td></td>
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</tr>
<tr>
<td>Male</td>
<td>55 (76.4)</td>
<td>53 (74.6)</td>
<td>108 (75.5)</td>
</tr>
<tr>
<td>Female</td>
<td>17 (23.6)</td>
<td>18 (25.4)</td>
<td>35 (24.5)</td>
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<tr>
<td><strong>Age</strong></td>
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<tr>
<td>Less Than 75</td>
<td>48 (66.7)</td>
<td>49 (69.0)</td>
<td>97 (67.8)</td>
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<tr>
<td>75 or Above</td>
<td>24 (33.3)</td>
<td>22 (31.0)</td>
<td>46 (32.2)</td>
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<td><strong>Initial clinician assessment</strong></td>
<td></td>
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<tr>
<td>Probable NMIBC</td>
<td>34 (47.2)</td>
<td>32 (45.1)</td>
<td>66 (46.2)</td>
</tr>
<tr>
<td>Possible MIBC</td>
<td>38 (52.8)</td>
<td>39 (54.9)</td>
<td>77 (53.8)</td>
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</tbody>
</table>
Primary Outcome for efficacy stage

**Primary Outcome**: Time to correct treatment (TTCT) for patients confirmed to have MIBC

- Median TTCT for pathway 1: **98 days** (95% CI. 72, 174) N=14
- Median TTCT for pathway 2: **53 days** (95% CI. 20, 89) N=12

**Secondary Outcome**: Time to definitive treatment (TTDT) for all patients

- Median TTDT for pathway 1: **23 days** (95% CI. 17, 29) N=72
- Median TTDT for pathway 2: **22 days** (95% CI. 17, 32) N=71

Logrank test: **p-value = 0.0046**

Cox model adjusted for gender and age : HR (Pathway 2 vs. Pathway 1) = 3.4 (95% CI. 1.4, 8.3).
Secondary Outcome: Time to correct treatment (TTCT) for all patients

- Median TTCT for pathway 1: 37 days (95\% CI. 26, 47) N=72
- Median TTCT for pathway 2: 31 days (95\% CI. 20, 37) N=71
- Logrank test: p-value= 0.1435
- Cox model adjusted for gender and age: HR (Pathway2 vs. Pathway1)=1.3 (95\% CI. 0.9, 1.8). Proportional-hazards assumption checked.
Conclusions: BladderPath

• Using a Likert scale at flexible cystoscopy accurately identifies the lower risk non-invasive cases
• An image-based pathway substantially accelerated time to definitive treatment for patients with suspected muscle-invasive disease
• There was no adverse effect on times to treatment for non-invasive disease
• Patients with obvious muscle-invasive disease can potentially avoid the need for TURBT and associated risks