BERLIN 2025 ESMO congress

LBA111

Randomized comparison of upfront magnetic resonance imaging versus transurethral resection for staging new bladder cancers: Final survival analysis from the BladderPath trial

N.D. James[1], S. Pirrie[2], W. Liu[3], J. Gallagher[4], A. Hughes[5], K. Jefferson[6], V. Nanton[7], A. Knight[8], H.P. Mintz[9], A. Pope[10], D. Ward[11], S. Hafeez[12], P. Patel[13], J.W.F. Catto[14], R. Bryan[15]

[1] Prostate and Bladder Cancer Research Department, ICR - Institute of Cancer Research, London, United Kingdom, [2] CRCTU, Institute of Cancer and Genomic Sciences - University of Birmingham, Birmingham, United Kingdom, [3] CRCTU, The Institute of Cancer and Genomic Sciences - University of Birmingham, Birmingham, United Kingdom, [4] Urology, Institute of Cancer and Genomic Sciences - University of Birmingham, Birmingham, United Kingdom, [5] Cancer Research UK Clinical Trials Unit (CRCTU), Institute of Cancer and Genomic Sciences - University of Birmingham, Birmingham, United Kingdom, [6] Urology, University Hospital Coventry - University Hospitals Coventry and Warwickshire NHS Trust, Coventry, United Kingdom, [7] Uro-oncology, University of Warwick, Coventry, United Kingdom, [8] Patient and advisory panel, Action Bladder Cancer, Tetbury, United Kingdom, [9] Medical Research Council, Clinical Trials Unit, UCL - University College London, London, United Kingdom, [10] CRUK Clinical Trials Unit – Team A, Institute of Cancer and Genomic Sciences - University of Birmingham, Birmingham, United Kingdom, [11] Bladder Cancer Research Centre (BCRC) Theme Lead for Biomarkers & Proteomics, Institute of Cancer and Genomic Sciences - University of Birmingham, Birmingham, United Kingdom, [12] Urology, ICR - Institute of Cancer Research, London, United Kingdom, [13] Urology, University College Hospital, London, United Kingdom, [14] Urology Department, University of Sheffield Medical School, Sheffield, United Kingdom[15] Bladder Cancer Research Centre, Institute of Cancer and Genomic Sciences - University of Birmingham, Birmingham, United Kingdom

Background

Transurethral resection of bladder tumour has been the mainstay of bladder cancer staging for > 60 years. Staging inaccuracies are commonplace, leading to delayed treatment of muscle-invasive bladder cancer (MIBC). Multiparametric magnetic resonance imaging (MRI) offers rapid, accurate and non-invasive staging of muscle-invasive bladder cancer. We previously reported that upfront MRI speeds time to definitive treatment for MIBC (98d (95% CI 72-125) vs 53d (95% CI 20-89)). We report here mature 2 year outcomes.

Methods

BladderPath was an open-label, multistage randomised controlled study in 15 sites in three parts: feasibility, intermediate and final clinical stages. The final stage was cut short by the COVID Pandemic. Newly presenting patients with bladder mass at flexible cystoscopy referred for TURBT were randomised to Pathway 1 TURBT or Pathway 2 which added initial MRI for patients with possible MIBC (about 50% of total). Subsequent therapy could include TURBT, which occurred in approx. 85% Pathway 2 patients (main reasons: staging uncertainty, debulking, assess variant histology). Data collected during the trial was merged with NHS Digital records to provide death and progression information. Cause of death was reviewed using a Likert scale for all patients.

Results

Between 31 May 2018 and 31 December 2021, 143 participants were randomised. Failure events were seen in 48% of patients: 54% in Pathway 1 and 42% in Pathway 2. Failure free survival HR 0.81 (95% CI: 0.49, 1.34, p=0.403). 25% of patients died: 28% in Pathway 1 and 23% in Pathway 2, overall survival HR 0.67 (95% CI: 0.34, 1.33, p=0.25). Bladder cancer specific deaths: 18% in Pathway 1, 10% in Pathway 2, giving a bladder cancer specific survival (BCSS) HR 0.36 (95% CI: 0.12, 0.98, p=0.046).

Conclusions

Despite significant issues with underpowering, the direction of effect is consistently in favour of pathway 2 for all endpoints. Overall and BCSS observed HRs are considerably better than 0.75, the original trial target. In particular, for BCSS, the hazard ratio is 0.36 with $p<0.05$. These data further support a change in the standard of care for bladder cancer diagnosis: to add MRI upstream of TURBT in suspected MIBC.

Clinical trial identification

ISRCTN 35296862.

Legal entity responsible for the study

University of Birmingham.

Funding

NHS Health Technology Agency.

Disclosure

N.D. James: Financial Interests, Personal, Advisory Board: AstraZeneca, Bayer, Clovis, Janssen, Merck, Novartis, Sanofi,; Financial Interests, Institutional, Expert Testimony: Janssen, Sanofi; Financial Interests, Institutional, Other, Data Monitoring Committee: Gilead; Financial Interests, Personal, Other, Production of non-promotional educational materials: Astellas. S. Hafeez: Other, Institutional, Research Funding, The Royal Marsden Hospital, and The Institute of Cancer Research are members of the Elekta MR-linac Consortium, which aims to coordinate international collaborative research relating to the Elekta Unity (MR-linac). Elekta (Elekta AB, Stockholm, Sweden) and Philips (Philips, Best, Netherlands) are commercial members of the MR-Linac Consortium. Elekta financially supports consortium member institutions with research funding, education, and travel costs for consortium meetings. Dr Hafeez is the bladder tumour site group lead within the MR-Linac Consortium and received travel and accommodation costs to attend the annual meeting in June 2023.: Elekta and Philips. J.W.F. Catto: Financial Interests, Personal, Speaker, Consultant, Advisor: Astellas, AstraZeneca, Ferring, Galeas, Pfizer, Janssen, InMed health, Merck Sharp & Dohme, and Medac; Financial Interests, Institutional, Research Funding: Roche; Non-Financial Interests, Personal, Non remunerated activity, unpaid trustee: Fight Bladder Cancer UK and Weston Park Cancer Charity; Financial Interests, Personal, Funding: NIHR Research Professorship. R. Bryan: Other, Institutional, Research Funding, received research funding: NIHR HTA, CRUK, Janssen, University Hospitals Birmingham Charity, QED Therapeutics, UroGen Pharma; Non-Financial Interests, Institutional, Non remunerated activity, unpaid charity trustee: Action Bladder Cancer UK; Financial Interests, Personal, Advisory Board, advisory board member: Nonacus Limited; Financial Interests, Personal, Speaker, Consultant, Advisor, receives consultancy fees: Cystotech ApS; Financial Interests, Personal, Advisory Board, receives consultancy fees: Informed Genomics Limited. All other authors have declared no conflicts of interest.