

En-bloc vs. conventional resection of primary bladder tumor (eBLOC): A multicenter, open-label, phase 3 randomised controlled trial

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Introduction & Objectives: Background: En-bloc transurethral resection (eTURB) might be an improvement in the surgical management of non-muscle invasive bladder (NMIBC) compared to conventional TURB (cTURB). Objective: To evaluate whether eTURB is superior to cTURB for pathologic specimen retrieval.

Materials & Methods: Design, setting, and participants: Randomized, multicenter trial in patients with up to 3 cTa-1 NMIBC with size between 1cm and 3cm. Intervention: Participants were randomized to receive eTURB (n = 219) or cTURB (n = 180). Outcome measurements and statistical analysis The primary outcome was the quality of pathologic specimen measured by the presence of detrusor muscle. Secondary endpoints included bladder perforation, persistent disease at 2nd look TURB and recurrence-free survival (RFS).

Results: Results and limitations: A total of 452 tumors were resected and analysed for the primary outcome. eTURB was superior to cTURB in the retrieval of detrusor muscle (80,7% vs 71,1%; difference 9.6%; 95%CI 1.8% to 17.4%; mixed-model p = 0.01). Bladder perforation (5.6% vs 12%; difference -6.4%; 95%CI -12.2% to -0.6%) and obturator reflex (8.4% vs 16%; difference -7.6%; 95%CI -14.3% to -0.9%) were less frequent in the eTURB arm. Operation time was 26 minutes (IQR 20 - 38) in the eTURB arm and 25 minutes (IQR 17 - 35) in the cTURB arm (difference 1 minute; 95%CI -25.9 to 4.99). Second look TURB was performed in 24 participants in the eTURB arm and in 34 participants in the cTURB arm. The rate of residual papillary disease (pTa/pT1) was 56% in the eTURB arm and 55.9% in the cTURB arm (difference 0.1%; 95%CI -25.5% to 25.7%). Within a median follow-up of 13 months (IQR 7 - 20), 26 of 141 (18.4%) participants in the eTURB and 24 of 144 (16.7%) in the cTURB experience a bladder cancer recurrence (Cox hazard ratio: 0.87; 95%CI 0.49 to 1.52; p = 0.6).

Conclusions: In patients with clinical NMIBC with size between 1cm and 3cm, the resection with eTURB technique was superior to cTURB in the retrieval of detrusor muscle. eTURB delivers a higher quality pathologic specimen. However, the oncologic benefit of this technique remains uncertain.