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Research Letter

New Evidence and Innovative Approaches to Blinding in Robot-assisted Radical Cystectomy

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Open radical cystectomy (ORC) and robot-assisted RC (RARC) with intracorporeal (iRARC) or extracorporeal (eRARC) urinary diversion are the mainstays of treatment for localized muscle-invasive bladder cancer. No clear superiority of either approach has been shown in meta-analyses of randomized controlled trials (RCTs) [1,2]. Since then, a pilot RCT (BORARC trial) by Maibom et al. [3] that focused on blinding techniques and an interim analysis of a larger RCT by Mastroianni et al. [4] have been published. Remarkably, in contrast to all previous RCTs, all patients in these two trials underwent iRARC.

The aim of this letter is to provide an updated meta-analysis comparing ORC and RARC using data from all available RCTs and with consideration of the type of urinary diversion. Results for the trial endpoints were quantitatively summarized and pooled. For dichotomous data, the odds ratio was calculated using the Mantel-Haenszel model. For continuous data, differences are presented as the mean difference and 95% confidence interval calculated using the inverse variance model. The random effects model was used to address heterogeneity among studies.

Our analysis of seven unique RCTs showed no significant differences in major or minor complications or positive surgical margins. Operating time was significantly longer in the RARC group. There were significantly fewer transfusions, lower blood loss, and shorter hospital stay in the RARC group. There were no subgroup differences between eRARC and iRARC. All the data are presented in Fig. 1.

The benefits of minimally invasive surgery have been shown in many surgical fields and seem to be valid for RC too. Nevertheless, according to evidence from seven RCTs,

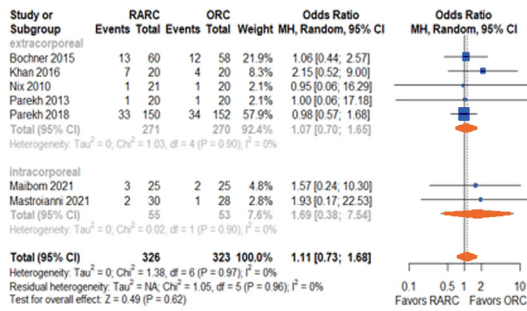
RARC still fails to prove major benefits in terms of surgical complications. However, previous trials did not include intracorporeal urinary diversion or such meticulous blinding as the newly published trials.

The authors of the BORARC trial performed blinding of all postoperative caregivers and patients with the help of non-transparent wound dressings applied to cover both RARC and ORC wounds. The operating room was booked for the same slot for all procedures and personnel did not to leave the theater during this time. Operating surgeons were not involved in postoperative care and only nurses from neighboring wards changed the wound dressings, while patients were blinded by placing a pillow on their chest during wound dressing. Successful blinding was verified by asking caregivers and patients about their opinion on which technique was used. Only 26% of patients were unblinded before discharge and physicians, patients, and nurses did not guess the intervention correctly in 44–54% of cases. Interestingly, there seems to be a learning curve for treating blinded patients, as 44% of the initial 25 patients but only 8% of the last 25 patients were unblinded. The lessons learned from this trial should be applied in future trials as evidence-based concepts develop further in surgical urology.

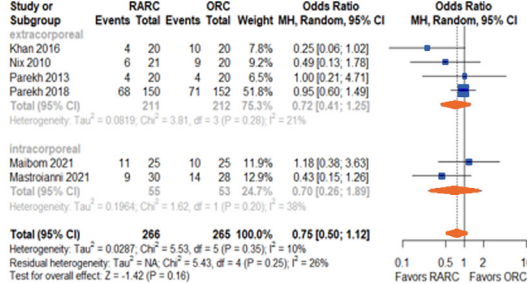
Regarding iRARC, the final results from the study by Mastroianni et al [4] and the ongoing iROC trial [5] should give a good overview of the postulated benefits of intracorporeal diversion. Meanwhile, both ORC and RARC represent valuable options.

Conflicts of interest: The authors have nothing to disclose.

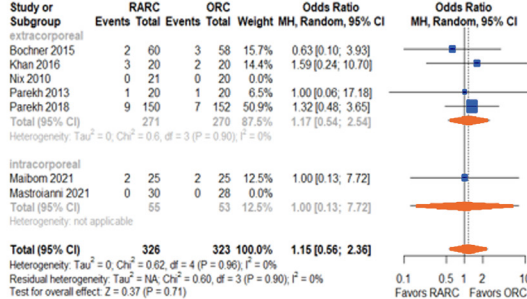
A Major complication



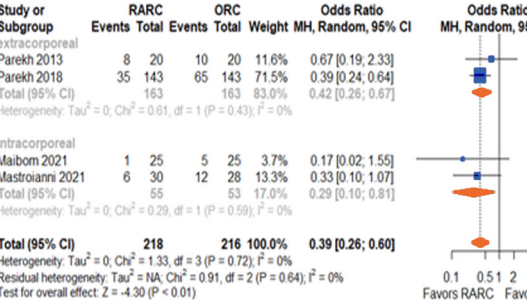
B Minor complication



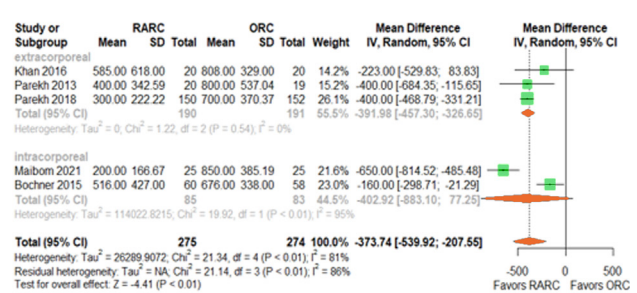
C Positive margin



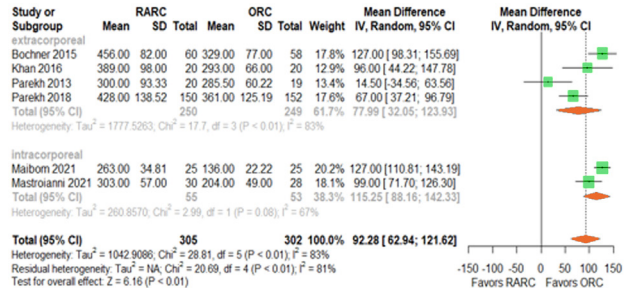
D Transfusion rate



E Blood loss



F Operating time



G Length of hospital stay

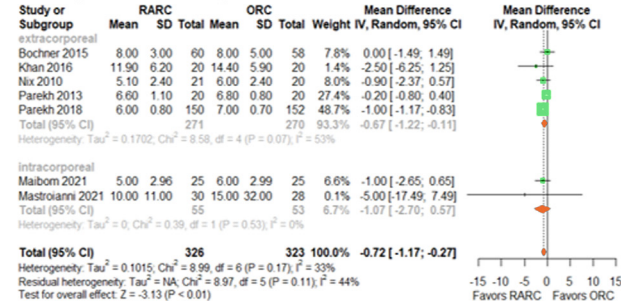


Fig. 1 – Meta-analysis results. (A) Major complications; (B) minor complications; (C) positive margin; (D) transfusion rate; (E) blood loss; (F) operating time; and (G) length of hospital stay. CI = confidence interval; df = degrees of freedom; IV = inverse variance; MH = Mantel-Haenszel model; ORC = open radical cystectomy; RARC = robot-assisted radical cystectomy.

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