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Letter to the Editor
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The Shape Trial: Is a Higher Number of Centers a Substitute for Scrutiny?

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Letter to Editor

We read the SHAPE trial [1] and the subsequent appraisals by Naumann [2] and Takekuma [3] in this journal with great interest. Both authors raise valuable concerns regarding the non-inferiority margin, minimally invasive surgery, and surgical quality assurance. We would like to draw attention to a few additional points that, to our knowledge, have not yet been addressed.

The trial's accrual pattern deserves scrutiny in its own right, and raises a more basic question: does a design spanning 130 centers lend a trial greater credibility, or does it simply spread recruitment thin enough to obscure how it actually happened? Enrollment spanned December 2012 through 2019 nearly seven years for only 700 patients across 130 centers in 12 countries, an average of 0.77 patients per center per year. A caseload below one patient per center annually is not merely low; it is difficult to reconcile with genuine, continuous participation by every listed center, and more plausibly indicates that a considerable number of centers recruited no patients at all in a given year, with actual enrollment concentrated in a smaller subset of sites than the headline count of 130 suggests. The trial does not publish a center-wise breakdown of enrollment we are not asking for patient identities, only the number of patients contributed by each center and without this, readers cannot judge for themselves how thinly or unevenly recruitment was actually spread [1]. Such minimal and uneven caseload raises legitimate doubt about sustained surgical proficiency in a technically demanding, often laparoscopic or robotic, oncologic procedure: where a center performs this dissection only sporadically, the surgical expertise underlying its results is itself questionable, and this offers a plausible explanation for a discrepancy the trial itself does not resolve: a 12.5% pelvic recurrence rate after radical hysterectomy in Asian centers versus 0% in North America [1]. Restricting enrollment to fewer, high-volume centers would have reduced this heterogeneity by concentrating cases among surgeons with demonstrably adequate exposure to this dissection, lowering the risk of complications attributable to surgical inexperience and strengthening rather than diluting the trial's internal validity. This protracted recruitment carries a second consequence: the eleven-year span from registration to primary completion means patients were staged and treated under evolving standards, as sentinel-lymph-node mapping matured, MRI-based assessment of stromal invasion improved, and FIGO staging itself was revised in 2018. Pooling outcomes across such a period risk blending distinct eras of practice into a single non-inferiority estimate.

The morbidity advantage attributed to simple hysterectomy also merits closer reading. It is specific to autonomic-nerve-sparing at the parametrium, reflected in the striking reduction in urinary retention and incontinence. Pelvic lymph-node dissection, however, was performed regardless of treatment assignment [1] and its own recognized morbidity lymphedema is therefore retained identically in both arms. The net reduction in overall surgical morbidity from de-escalating hysterectomy alone may be more modest than the headline comparison suggests.

A further concern is the morbidity implicit in combining all three modalities hysterectomy, pelvic lymph-node dissection, and adjuvant radiotherapy in a single patient. Adjuvant radiotherapy was administered to a similar proportion of each arm (9.1% in the simple hysterectomy group and 8.9% in the radical hysterectomy group), meaning a meaningful subset of patients in both arms underwent surgery, lymph-node dissection, and radiotherapy together.[1] Combining radical pelvic surgery with adjuvant radiotherapy is well recognized to compound morbidity beyond what either modality causes alone, adding cost and psychological burden to a population already coping with a new cancer diagnosis. This is precisely the outcome traditional gynecologic oncology teaching seeks

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to avoid: careful upfront patient selection for a single modality either primary surgery or primary chemoradiation specifically to spare patients the cumulative morbidity of combined treatment. Whether the trial's design and patient selection adequately anticipated and minimized this triple-modality subgroup is not addressed, and deserves comment given its direct bearing on the quality-of-life argument advanced in support of simple hysterectomy.

Finally, quality of life arguably the outcome most relevant to a woman newly diagnosed with cervical cancer received comparatively little emphasis in the primary publication itself. The detailed sexual-health and quality-of-life analysis was published separately, nearly a year later [4] rather than integrated into the paper that established this practice change.

We believe these points warrant consideration before simple hysterectomy is adopted as the new global standard for low-risk early-stage cervical cancer.

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