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ORIGINAL RESEARCH

A Retrospective Analysis Comparing the Dosimetric Parameters of Two Rectum-Sparing Techniques During Intracavitary Brachytherapy with Tandem-Ring Applicators for Cervical Cancer

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Purpose: Conventional intracavitary brachytherapy (ICBT) operative procedures with tandem-ring (TR) applicators utilizing standard rectal retractor (RR) blades for rectum separation did not allow for optimal rectum sparing, especially in patients with roomy vagina. This limitation was overcome by modifying the technique by placing customized vaginal packing (VP) alongside a standard RR blade based on the patient specific spacial constraints to supplement the rectum displacement. The paper compares the modified technique with the conventional technique of using RR alone on the International Commission on Radiation Units and Measurements-38 (ICRU-38) rectum and bladder point doses.

Methods: Between January 2021 and August 2022, 41 cancer patients received at least one ICBT fraction with the conventional and at least one with the modified technique for rectum separation using the same applicator set and loading pattern. The remaining ICBT fractions were done using that technique, which gave the best dosimetric parameters during previous fractions in that particular patient.

Results: Out of the 111 ICBT fractions utilizing TR applicators, 44 fractions done with the conventional technique constitute conventional group, whereas 67 fractions with the modified technique constitute the modified group. For the same dose (100%) prescribed to point A in both groups, the mean dose to the ICRU rectal point was 44.1% of the prescription dose (range: 23.8–77.8%, median: 42.5%) in modified group and 55.5% (range: 36.4–73.1%, median: 56.5%) in the conventional group. There was 11.4% reduction in mean dose to the ICRU rectal point ($p < 0.001$) in the modified group. The other point doses and volume parameters were similar between the two groups.

Conclusion: Modified technique of combining rectal retractor with customised vaginal packing significantly reduced the ICRU rectal point dose, compared to using a rectal retractor alone during brachytherapy with tandem-ring applicators.

Keywords: cervical cancer, intracavitary brachytherapy, rectum-sparing technique, tandem-ring applicators, rectal retractor, customized vaginal packing

Introduction

External beam radiotherapy (EBRT) with concomitant chemotherapy combined with intracavitary brachytherapy (ICBT) is the standard treatment for patients with locally advanced cervical cancer (LACC). EBRT and ICBT are combined to the total dose of 80 to 90 Gy, traditionally prescribed to point A.[1,2] EBRT to whole pelvis to the dose of 45–50.4 Gy @ 1.8–2

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Gy per fraction is delivered, which regresses the involved parametrium and tumor shrinks to the extent that now it can be very well encompassed within the high dose region of ICBT.[1,3] This favorable tumor response to EBRT not only makes the patients eligible for ICBT but is also associated with spectrum of changes in the normal anatomy at the time of ICBT.[4–6] At one end of the spectrum, there are patients with a roomy vagina, and at the other end, there is a subset of patients with a narrow vagina and shallower fornices.[6] During ICBT, the potential of rectum toxicity is a significant concern. This is because vaginal walls have a natural inclination to collapse and remain in close proximity, thereby drawing nearby organs, such as the rectum, closer to the radiation sources housed within the applicators. Concerted efforts are being made to minimize rectal exposure by integrating sophisticated imaging techniques or by enhancing the techniques aimed at increasing the distance between the rectum and applicators. The rectal retractor (RR) is the predominant method used to separate the rectum from the tandem-ring (TR) applicators during ICBT. Literature indicates that TR applicators with RRs are ideal for patients characterized by shallow fornices and a narrow vagina.[7–9] Nevertheless, the current trend indicates that their utilization is not limited to the aforementioned subset; rather, it encompasses all individuals undergoing ICBT, regardless of their vaginal capacity. For patients with diverse vaginal capacities, the prefabricated set of standard RR blades provided by the manufacturer is akin to a one-size-fits-all solution.

A limitation of the brachytherapy implant procedure is that during the conventional ICBT procedure with TR applicators, when the RR blade is assembled, the remaining space in the posterior fornices becomes inaccessible for packing (Figure 1). This modified technique enabled us to overcome this limitation by making customized vaginal packing (VP) possible for a range of spaces, posterior and superior to the RR, in different patients. This helps supplement the displacement achieved with RR alone, which may lead to a reduction in the dose to the ICRU rectal point (D_{ICRU}) (Figure 2). A clear correlation between late rectal morbidity (proctitis, bleeding, and fistula) and dose point (D_{ICRU}) and dose-volume (D_{2cc}, D_{1cc} and $D_{0.1cc}$ ie minimum dose to most exposed 2cc, 1cc and 0.1cc volumes of rectum) has already been established in the literature.[10–12] In our previous study, the average reduction in the mean dose to ICRU rectal point was 13% ($p = 0.001$) per ICBT fraction with modified technique compared to the conventional approach of using RR alone.[6] Study had limitations, as the majority of patients in two comparison groups were different. Individual anatomical variations among patients could have been a possible confounding factor, and the possibility of bias in selecting patients with favorable anatomy for a particular method of rectal separation could not be ruled out. This larger study aimed to determine whether similar results were achieved when both methods were applied to the same patient to eliminate confounding factors of individual anatomical variation and address the bias of selecting a patient for a particular method of rectal separation. Other possible variables related to the physical parameters of the applicator are also addressed. We aim to describe in sufficient detail the steps taken during the ICBT procedure to enable centers across the world to

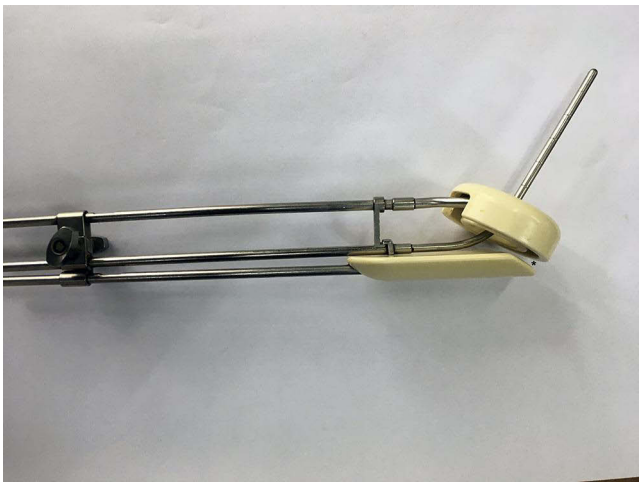

Figure 1 Nucletron tandem-ring (TR) applicator and a rectal retractor (RR) with a tandem length of 6 cm, angle of 30° and a ring size of 3 cm. (The design best conforms to the anatomy of the patients in ideal subset described in the text, but in other patients, especially with roomy vagina, due to an inadequate gap (*) as the sloping cranial edge of RR closely abuts the posterior aspect of the ring, the potential space posterior and superior to the cranial edge of RR becomes inaccessible for vaginal gauze packing. The modified technique enabled us to overcome this limitation and allowed customised vaginal gauze packing for optimal displacement of the rectum).

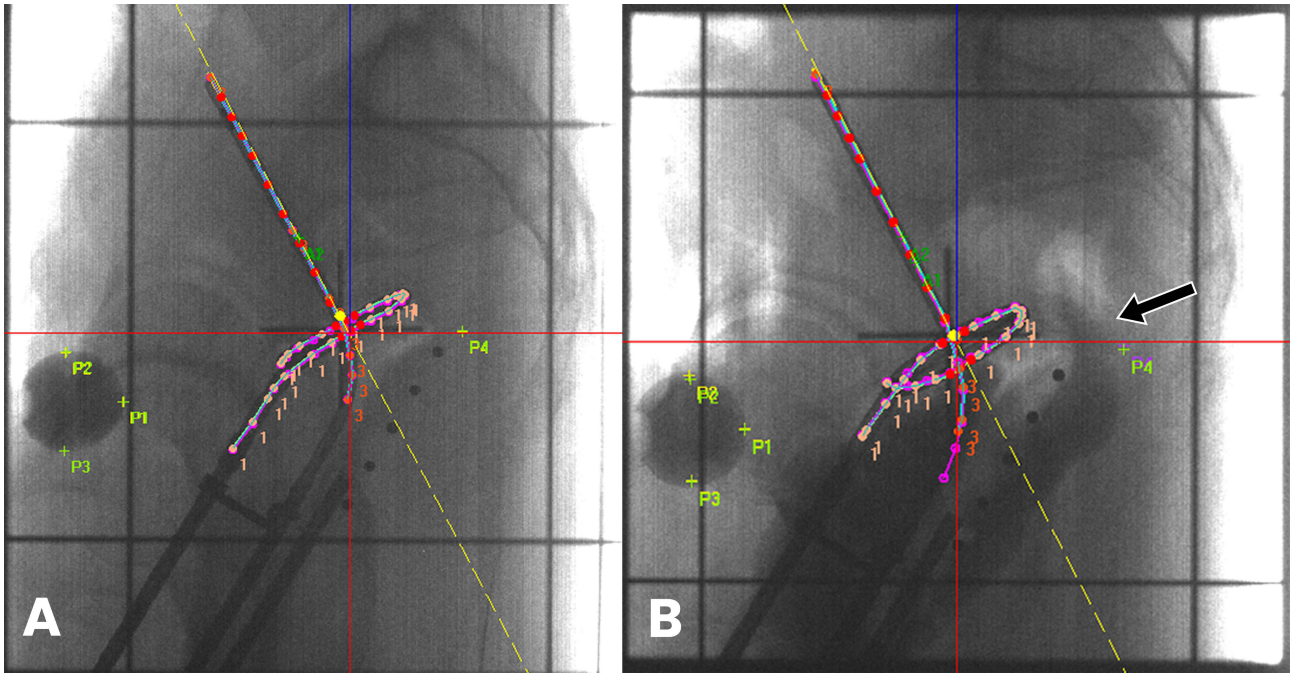

Figure 2 (**A**) Simulation image of applicators (shown in Figure 1), with conventional technique of using rectal retractor alone. (**B**) Modified technique of combining radio-opaque vaginal gauze packing and rectal retractor (↑) applied using same applicator set and loading pattern (without optimization), in the consecutive session on one of the patients. The modified technique resulted in a reduction of 1.1 Gray (16%) in the ICRU rectal point dose, while delivering 7 Gray (100%) to point A in both sessions.
Abbreviations: ICRU, International Commission on Radiation Units and measurements; P_1, ICRU bladder point; P_4, ICRU rectal point.

practice and evaluate this technique, irrespective of whether they are planning 2-D brachytherapy or 3-D image-guided brachytherapy (IGBT). The results of this study in a poster format are presented in the annual European Society for Radiotherapy and Oncology (ESTRO) congress-2023 in Vienna.[13]

TO and TR applicators are the most commonly employed applicators in LACC and are often used interchangeably as the goal of delivering prescribed dose to point A while keeping OAR doses below their permissible limit is effectively achieved through both applicators.[7,9,14,15] Despite the dosimetric studies indicating that TR encompasses smaller volumes and facilitates reduction in the dosages to the rectum and bladder compared to TO applicators.[9,15–18] This dosimetric difference gains importance in the face of achieving better dosimetric parameters. At present, applicator choice for an ICBT fraction mostly depends on the attending physician's preference, expertise and logistic availability of the applicator sets.[9,15] Traditionally, VP is used as rectum-sparing method alongside TO applicators.[16,17] Many investigators have compared other methods of rectum-sparing like vaginal balloon packing system, bladder-rectum spacer balloon (BRSB), speculum-based VP and combination of in-house crafted intravaginal Foley balloon (FB) with traditional VP in HDR ICBT performed using TO applicators.[19–23] None of these methods have been widely adopted.[6,24] A recent study evaluated a novel hydrogel packing system in comparison to standard VP as a bladder and rectum-sparing method alongside TO applicators. There was no significant difference in organs at risk (OAR) or high-risk clinical target volume (HR CTV) dosimetry. Nevertheless, it improved patient reported discomfort and ease of use.[25]

TR applicators use standard RR blade incorporated into the applicator sets to reduce the dose to the rectum.[15,16,24] Studies suggest that significant OAR sparing can be achieved with TR over TO applicators, particularly for the rectum.[9,15–18] Furthermore, due to their ease of insertion, inter-fraction consistency and applicability in patients with narrow vagina TR applicators are gaining wider utilization.[9] At present, the standard RR blade is used as rectum-sparing method alongside TR applicators in most of the institutions as it provides the best rectal sparing when compared with VP and tandem Foley balloon (FB).[24,26] It has already been reported that an assessment of the quality of a brachytherapy implant is imperative, which involves not only technical accuracy of implant placement but an appropriate and optimal use of available organ retraction methods.[27,28] We are not aware of any previous study with the technique that optimizes the utilization of standard RR blades for enhanced rectum sparing.

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Materials and Methods

The records and treatment plans of patients with locally advanced cervical cancer (LACC) with stages IB2 to IVA, as per the International Federation of Gynaecology and Obstetrics-2018 (FIGO-2018), who received treatment with curative intent between January 2021 and August 2022, were studied. This time frame was chosen because of the continuous improvements implemented previously, which resulted in the development of a standardized protocol in our department for the management of patients with LACC. This protocol was implemented in January 2021 and will continue until August 2022, when a randomized controlled trial (RCT) be initiated in our department. Patients with incomplete records, treatment plans with suboptimal placement of the applicators, plans with suboptimal dose prescriptions that did not follow the standard loading pattern, or deviated from the ICRU-38 guidelines owing to a learning curve were not eligible for analysis. Forty-one patients who met the eligibility criteria were included in the analyses, all of whom received treatment under a standard institutional protocol, which began with EBRT at a dose of 45–50.4 Gy at 1.8–2 Gy per fraction to the whole pelvis with concurrent weekly cisplatin. They were assessed as fit for ICBT within two weeks of completing EBRT to receive HDR ICBT in three to four fractions of 7 Gy or two fractions of 9 Gy each. Both TR and tandem-ovoid (TO) applicators were used interchangeably for ICBT fractions to successfully deliver the prescribed dosage to point A, while maintaining doses to critical organs within their permissible range was achieved using both applicators equally. The standard institutional protocol ensured that the largest TO or TR applicator that a particular patient's anatomy could accommodate was used during every ICBT fraction. The first ICBT fraction was performed using either TO or TR applicators, according to logistic availability and physician preference. The traditional VP technique was used for rectal separation alongside TO applicators, and either the conventional technique of using a RR blade alone or an indigenously modified technique to combine RR with customized VP was used alongside TR applicators for rectal separation. A TR applicator with particular physical parameters (ring diameter, tandem length, tandem angle), when utilized during an ICBT fraction on a particular patient alongside either the conventional (RR alone) or modified technique (combination of RR and customized packing) for rectum separation, was mandatory under the standard institutional protocol to repeat the TR applicator with the same parameters during at least one of the subsequent fractions with alternate techniques on the same patient. Thus, the two ICBT fractions performed on one patient using TR applicators differed only with regard to the rectal separation technique. The rest of the fractions, if applicable, were performed using the applicator type and technique that produced the best dosimetric parameters during the previous fractions. The authors who performed ICBT procedures were well-versed in both conventional and modified techniques, as both techniques for separating the rectum are routinely employed during fractions utilizing TR applicators within our institution. The study protocol was approved by the Institutional Ethics Committee.

Brachytherapy Procedure

All fractions were performed in a dedicated operating room for brachytherapy at our department under intravenous sedation and analgesia. After negotiating through the cervical canal, the total length of the uterine cavity from the external os to the fundus was measured using uterine sounds, and the central tandem of the measured length was inserted. The ring applicator with the largest diameter that could be accommodated in the upper vagina was selected and threaded over the central tandem. The ring was positioned to encircle the cervix and interlock it with a central tandem. In conventional procedures, a standard RR blade is inserted and clamped using a central tandem. Saline-soaked gauze packing was then performed in the center to stabilize the applicator assembly and in the anterior to displace the bladder. However, during the modified technique, an additional step was that before the placement of the RR blade, the available space posterior and superior to the ring cap in the fornices and upper vagina was assessed to determine whether additional VP would be possible. The radio-opaque VP was then carefully placed in layers posterior to the ring cap in the fornix and upper vagina to enable additional rectal separation (see supplementary video presentation). The radio-opaque VP used was a thin ribbon-shaped gauze in the shape of a roll, approximately 2 cm wide, soaked in iohexol contrast diluted with normal saline at a ratio of 1:1. Physicians' skill and judgement are required to customize VP for a range of vaginal spaces so that the space behind the ring cap, in the fornices and upper vagina, is optimally filled without any obstruction and undue resistance or pressure to the placement and assembly of the RR. If needed, some

layers of gauze packing could be pulled back to allow adequate space to accommodate the RR blade, which is a crucial decision to avoid mucosal tears. After clamping the RR blade, packing in the center to stabilize the applicator assembly and in the anterior region to displace the bladder was accomplished in all procedures. The entire assembly was gently pushed against the cervix to evaluate the remaining space between the RR and lower part of the posterior vaginal wall. If any scope for additional packing was identified, further packing in the lower vagina was carried out without disturbing the assembly with the help of long forceps, taking an approach from the posterior aspect of the RR blade. Orthogonal radiographs were taken using a conventional simulator (Varian, Acuity, USA), and the images were transferred to the treatment planning system (TPS) via a Digital Imaging and Communications in Medicine (DICOM) connection.

Brachytherapy Treatment Planning

ICBT treatment planning was performed on the Oncentra Brachy v4.6 TPS and was delivered by a Nucletron Microselectron HDR V3 (18-channel) remote after-loading machine using Ir-192. Orthogonal images with applicators in place were reconstructed, and dwell positions were activated to recapitulate the familiar and symmetric pear-shaped dose distribution typically used in low-dose rate (LDR) ICBT. We consistently practiced a uniform loading pattern in our department (Figure 3). Point A was 2 cm superior to the lowermost intrauterine source along the axis of the intrauterine tandem and 2 cm lateral to the same plane. Point B was 2 cm superior along the axis of the intrauterine tandem, and 5 cm lateral to the same plane. The ICRU rectal and bladder points were taken according to the recommendations of the ICRU-38.[14] The doses (both absolute and percentage) to these points were reported for each ICBT fraction. The classical pear-shaped reference volume (Vol_{ref}) was measured and reported for each ICBT fraction. The 60 Gy reference volume (Vol_{60Gy}) was measured and reported at the end when treatment of a particular patient was completed, as the dose contributions from whole pelvic irradiation and all ICBT fractions were to be taken into consideration. The total reference air kerma (TRAK) value for each fraction was also recorded.

Statistical Analysis

Data were analyzed using the Stata Software version 15. Qualitative data are presented as frequencies and percentages, whereas quantitative data are presented as means and standard deviations. The Student's *t*-test was used to compare the means of the outcomes between the two techniques. During subset analysis, a paired sample *t*-test was used to compare means while analyzing outcomes between the two techniques performed on the same patients. Statistical significance was set at $p < 0.05$.

Results

A cohort of 41 patients received HDR ICBT after completing whole-pelvis EBRT, either at a dose of 46 Gy/23 fractions (30 patients) or 50 Gy/25 fractions (11 patients). Of the 41 patients, 20 received four fractions of 7 Gy each, 14 received three fractions of 7 Gy each, four received two fractions of 9 Gy each, one received three fractions of 7 Gy each, fourth fraction of 4 Gy, one received two fractions of 7 Gy each, three fractions of 4 Gy each, and one patient received four fractions of 4 Gy each. This yielded a total of 141 ICBT fractions. The prescription dose was lowered to 4 Gy during six fractions in three patients to keep the OAR doses within their tolerance limits. The dose was prescribed to Point A, and there was one-week interval between the two fractions of brachytherapy in all patients. The LDR equivalent median dose of 81 Gy (range,70-–90, mean 81.5 Gy) to Point A could be delivered, considering the contribution from both EBRT and all fractions of HDR ICBT, while respecting the ICRU rectal point tolerance limits of 75 Gy or less and bladder point limit of 80 Gy or less. Of the 141 ICBT fractions, 111 performed using TR applicators were analyzed in this study. Among these 111 ICBT fractions, 44 in which the RR blade alone was used constituted the conventional group and 67 in which a combination of radio-opaque VP and RR blade was used for rectal separation constituted the modified group (Figure 4).

Patient Characteristics

The baseline patient characteristics, disease stage, and treatment-related characteristics are shown in Table 1.

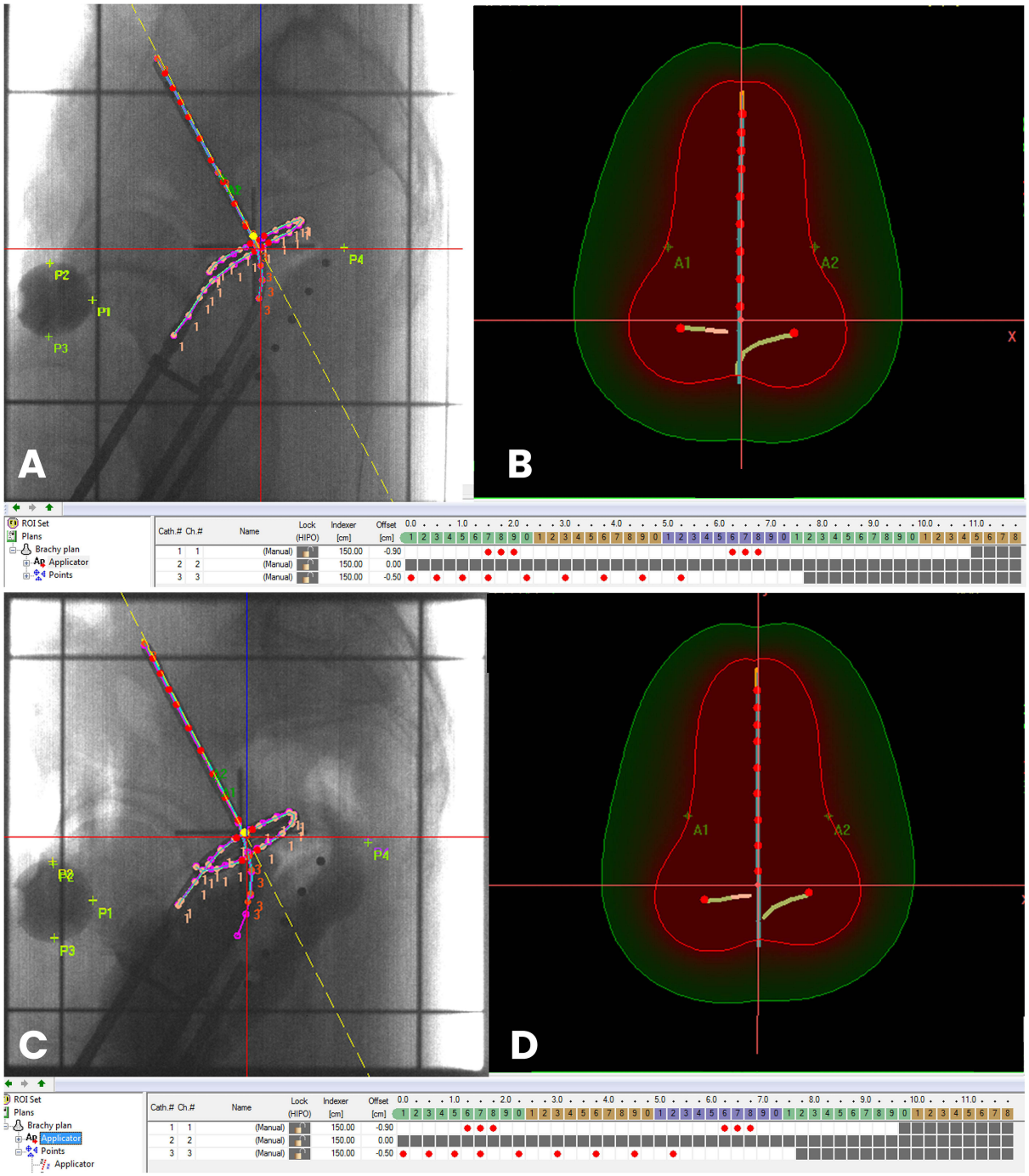

Figure 3 Treatment Planning images: (**A**) Shows the reconstruction of the tandem-ring applicator with active dwell positions in red dots. Dwell position activation (loading pattern) can be seen at the bottom of the image (**A** and **B**) with red dots corresponding to respective dwell positions for both ring and tandem. The image also shows the ICRU bladder (P1) and rectum (P4) points. (**B**) Shows the classical pear shape reference volume shaded in the red and 60 Gy volume in this patient is represented by 35.3% isodose curve line shaded in green for this ICB session performed with conventional technique. (**C**) Shows the reconstruction of the tandem-ring applicator during ICB session performed with modified technique. Active dwell positions shown in red dots. Dwell position activation (loading pattern) can also be seen at the bottom of the image (**C** and **D**) with red dots. (**D**) Shows a pear shape reference volume shaded in the red and 60 Gy volume (35.3% isodose line) shaded in green for this session with modified technique. When the same dose 7Gy (100%) was prescribed to point A, ICRU rectal point dose was 51.29% (3.59 Gy) with conventional versus 35.31% (2.47 Gy) with modified technique. There was 16% (1.12Gy) reduction in the ICRU rectal point dose in this patient. The V ref (d_h X d_w X d_t) ie the volume encompassed within 100% isodose curve, was similar at 177.94 cc with conventional versus 175.66 cc with modified technique. The V 60Gy (D_H X D_W X D_T) was also similar at 767.14 cc with conventional versus 710.74 cc with modified technique. The dose to point B was similar at 26.9% versus 26.7% and ICRU bladder point dose was also similar at 28.86% (2.02 Gy) with conventional versus 23.58% (1.65 Gy) with modified technique. TRAK values were also similar at 0.00457 Gy versus 0.00461 Gy.

Abbreviations: ICRU, International Commission on Radiation Units and measurements; P 1, ICRU bladder point; P 4, ICRU rectal point; TRAK, Total reference Air Kerma; V ref, Reference volume; V 60 Gy, ICRU 60 Gy reference volume. TPS, treatment planning system.

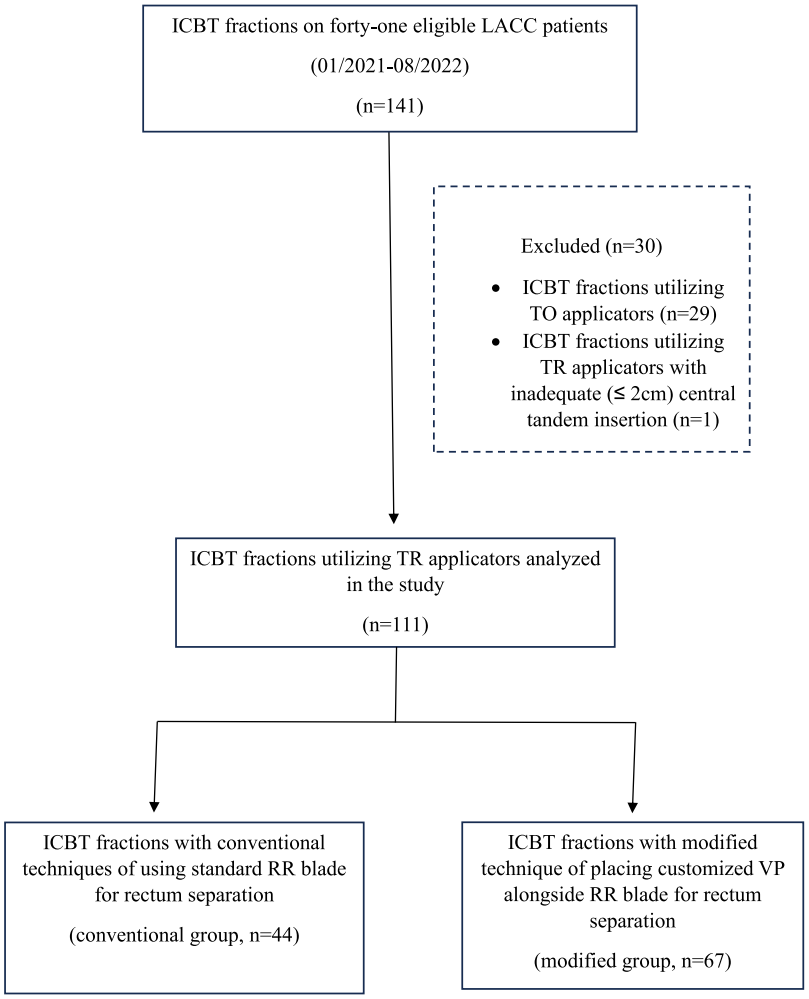

Figure 4 Flowchart showing the constitution of two comparison groups.
Abbreviations: ICBT, Intracavitary brachytherapy; LACC, Locally advanced cervical cancer; TO, Tandem-ovoid; TR, Tandem-ring; RR, Rectal retractor; VP, Vaginal packing.

Dosimetric Parameters

A comparison of dose and volume parameters is presented in Table 2. For the same dose prescribed to point A in both groups, the mean dose to the ICRU rectal point was 44.1% of the prescription dose (range, 23.8–77.8%; median, 42.5%) in the modified group and 55.5% (range, 36.4–73.1%; median, 56.5%) in the conventional group. There was a 11.4% reduction in the mean dose to the ICRU rectal point ($p < 0.001$) in the modified group compared with that in the conventional group. The mean dose to the ICRU bladder point was 55.5% of the prescribed dose (range, 14.8–127.2%; median, 55.5%) in the modified group and 49.8% (range 11.6–95.6%; median, 51.5%) in the conventional group. There was 5.7% increase in the mean dose to the ICRU bladder point ($p = 0.21$). The mean dose to point B was similar at 25.7% of the prescription dose (range, 22.2–27.2%; median 26%) in the modified group and 25.9% (range, 23.3–27.7%; median 26.1%) in the conventional group. The mean reference volume (Vol_{ref}) for the brachytherapy fraction was expressed as $d_h \times d_w \times d_t$, the mean 60 Gy reference volume (Vol_{60Gy}) was expressed as H × W × T, and the mean TRAK value (Gy/h at 1 m) was similar between the two groups.

In this detailed article, we found it appropriate to add a subset paired analysis as the two groups were not matched, as the number of fractions in the modified group was 67 compared to that in the conventional group 44. This is largely because the protocol allowed the last ICBT fraction to be performed using the technique that yielded the best dosimetric parameters during the previous fractions in that particular patient. Also, in two patients, all ICBT fractions were performed with a modified technique inadvertently; for the same reason in one patient all fractions were performed

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Table 1 Distribution of Stage and Applicator-Related Characteristics in the Two Groups

Characteristics	Number	Percentage (%)
Stage (FIGO 2018)		
IIA	4	9.8
IIB	28	68.3
IIIA	1	2.4
IIIB	7	17.1
IIIC	1	2.4
Histology		
Squamous cell carcinoma	36	87.8
Adenocarcinoma	3	7.3
Adeno-squamous	2	4.9
EBRT dose schedule		
50gy/25#	11	26.8
46GY/23#	30	73.2
ICB Sessions using Tandem ring applicators	111	100
Technique used for rectum separation:		
RR+VP	67	60.4
RR	44	39.6
Tandem length-6 cm		
RR	42	37.8
RR+VP	62	55.9
Tandem length-4 cm		
RR	2	1.8
RR+VP	4	3.6
Tandem length-5 cm		
RR	0	0
RR+VP	1	0.9
Tandem angle 30°		
RR	25	22.5
RR+VP	42	37.8
Tandem angle 45°		
RR	19	17.1
RR+VP	25	22.5
Ring size		
30 mm		
RR	27	24.3
RR+VP	40	36.0
26 mm		
RR	17	15.3
RR+VP	27	24.3

Abbreviations: FIGO, International Federation of Gynecology and obstetrics; RR, rectal retractor group; RR+VP, rectal retractor along with radio-opaque vaginal packing group.

with the conventional technique, despite the departmental protocol, which mandated that the subsequent fraction should be performed with the alternate technique using the same applicator. Moreover, in one patient, all fractions were performed using the conventional technique, as during the first fraction with the conventional technique while placing the RR blade, a small mucosal tear occurred, which was managed conservatively, and the modified technique was not

Table 2 Comparison of Dose and Volume Parameters

Physical Parameter	N (Fractions)	Mean	SD	t value**	P value*
Point B dose (% of prescription)					
RR	44	25.9	1.04	0.95	0.34
RR+VP	67	25.7	1.09		
ICRU rectal point dose (% of prescription)					
RR	44	55.5	7.9	5.86	***<0.001***
RR+VP	67	44.1	11.2		
ICRU bladder point dose (% of prescription)					
RR	44	49.8	20.1	−1.26	0.21
RR+VP	67	55.4	25.3		
ICRU reference volume (V_{ref}) (d_h× d_w× d_t) in cc					
RR	44	174.9	12.2	1.22	0.20
RR+VP	67	171.6	14.8		
ICRU 60 Gy volume (V_{60Gy}) (H × W × T) in cc					
RR	44	703.9	199.6	−0.36	0.71
RR+VP	67	717.6	189.0		
TRAK value					
RR	44	0.0046	0.0005	1.63	0.10
RR+VP	67	0.0044	0.0007		

Notes: * Statistically significant p values are shown in bold italic print.**A student *t* test was used for comparison between two groups.
Abbreviations: RR, Conventional group; RR+VP, Modified group; ICRU, International Commission on Radiation Units & Measurements; TRAK, total reference air kerma; SD, standard deviation.

attempted during subsequent fractions. We omitted these four patients from the subset analysis because of their consistent utilization of a singular technique in all fractions, which hindered our ability to carry out an intra-patient comparison of the two techniques. This exclusion eliminated any potential bias during the selection process.

To perform a paired subset analysis on the remaining 37 patients, we analyzed two fractions per patient that incorporated the consistent utilization of identical physical parameters of the applicator, such as ring size, tandem length, angle, and loading pattern (Table 3).

For the same dose prescribed to point A in both groups, there was a 13.17% reduction in the mean dose to the ICRU rectal point ($p < 0.001$) in the modified group compared to the conventional group. There was a 4.89% increase

Table 3 Paired Subset Analysis Among Two Treatment Groups

Physical Parameter	N (fractions)	Mean	SD	Mean Difference	P value*
Point B dose (% of prescription)					
RR	37	26.02	1.08	0.192	0.267
RR+VP	37	25.83	0.999		
ICRU rectal point dose (% of prescription)					
RR	37	55.44	7.74	13.17	***<0.001***
RR+VP	37	42.27	10.60		
ICRU bladder point dose (% of prescription)					
RR	37	49.56	21.44	4.89	0.051
RR+VP	37	54.45	23.50		

(*Continued*)

Table 3 (Continued).

Physical Parameter	N (fractions)	Mean	SD	Mean Difference	P value*
ICRU reference volume (V_{ref}) (d_h× d_w× d_t) in cc					
RR	37	175.16	12.94	0.56	0.777
RR+VP	37	174.60	13.02		
ICRU 60 Gy volume (V_{60Gy}) (H × W × T) in cc					
RR	37	715.21	171.97	0.68	0.944
RR+VP	37	714.52	189.93		
TRAK value					
RR	37	0.004598	0.00058	0.000037	0.268
RR+VP	37	0.004561	0.00058		

Note: * Statistically significant p values are shown in bold italic print.
Abbreviations: RR, Conventional group; RR+VP, Modified group; ICRU, International Commission on Radiation Units & Measurements; TRAK, total reference air kerma; SD, standard deviation.

in the mean dose to the ICRU bladder point (p = 0.051) in the modified group compared with that in the conventional group. All other dosimetric parameters showed no statistically significant difference between the two groups.

Discussion

The modified technique, which involves combining VP with the RR blade, resulted in an average reduction of 11.4% (p < 0.001) in the dose to the ICRU rectal point (D_{ICRU} for rectum) per ICBT fraction compared to the conventional approach of using the RR blade alone for rectal separation. In paired subset analysis, the average reduction in D_{ICRU} for the rectum was 13.17% (p < 0.001). This technique was applied to the majority of women (39 of 41), whose anatomy allowed for the placement of ring applicators with the RR blade. In one patient, the fornices were so shallow that insertion of the RR blade was challenging. Therefore, the modified technique may be used in patients whose anatomy allows the placement of ring applicators with an RR blade without over-stretching the mucosa, and not in patients whose anatomy does not allow their insertion and placement.

In this study, there was a 5.7% (p = 0.21) increase in the mean dose to the ICRU bladder point (D_{ICRU} for the bladder) per fraction. In the paired subset analysis, the average increase in the D_{ICRU} for the bladder was 4.89% (p = 0.051). In our previous study using this technique, the simultaneous increase in the mean dose to the ICRU bladder point was 10.1% (p = 0.024).[6] Since then, we have started paying close attention to the anterior packing as well. This study also demonstrated that by considering anterior packing, we could minimize the simultaneous increase in the bladder point dose associated with this technique.

The customized VP was placed in the posterior fornices (behind the ring) and upper vagina to a limited extent, allowing the RR blade to be positioned and assembled without any obstructions. The aim was to supplement the rectal retraction achieved primarily with the standard RR blade with a combination of customized VP.

The dose was prescribed at Point A, and a uniform loading pattern was followed. The doses to organs at risk (OARs) were recorded and reported as codified in the ICRU-38 report.[29] It is still relevant as orthogonal X-rays and CT scans are the primary imaging modalities for treatment planning in low- and middle-income countries (LMICs), which contribute to a majority of the cervical cancer burden. In LMICs, MRI is utilized in only 5–9% of cases, and the majority of the centers prescribe the dose to point A. Even during the transition from 2-D to 3-D based parameters, point-A-based prescriptions are preferred.[30,31] Moreover, despite 3-D image-guided adaptive brachytherapy (IGABT) using magnetic resonance imaging (MRI) being advocated as the gold standard, efforts to adopt MRI-based planning in all patients were associated with unique implementation difficulties, raising concerns about inferior local control due to increased overall treatment time. In a recent study representing the real-world scenario in LMICs, the authors suggested a rational implementation of point-based brachytherapy, even in this era of MRI-guided adaptive brachytherapy, in patients with good response and limited residual disease at the time of ICBT to optimize the utilization of available resources to achieve the best possible clinical outcome.[32]

In centers employing orthogonal X-ray-based planning, doses are recorded and reported for the ICRU rectal and bladder reference points to represent the doses to these OARs. In centres utilizing volumetric imaging, the OARs (bladder and rectum) are delineated in axial sections, and doses to 2cc volumes are reported.[31] Significant increase in grades of rectal toxicity in parallel to an increase in mean doses to both D_{2cc} (minimum dose to most exposed 2cc volume of rectum) and D_{ICRU} (dose to ICRU rectal point) is well established.[10–12] A vast experience gained in the past with the ICRU rectal point, which has been used as a reference for decades, still holds good as a high correlation has been shown between the average values of D_{2cc} and D_{ICRU} and the dose level of the D_{2cc} found to be closer to the D_{ICRU} for rectum.[10,33–36] Therefore, the modified technique may also be evaluated by the providers who are practicing 3-dimensional (3D) IGABT, delineating low, intermediate and high risk clinical target volume (CTV) for dose prescription and contouring OARs for reporting D_{2cc}, D_{1cc}, $D_{0.1cc}$ (doses to most exposed 2 cm^3, 1 cm^3, 0.1 cm^3 of respective OAR), as per The Groupe Europeen de Curietherapie (GEC)-ESTRO working group recommendations. Previous studies have noted that the implementation of strategies for organ retraction and ongoing enhancements in applicator design can yield added advantages in achieving improved dosimetric distributions.[24,37,38]

This study highlights that the integration of personalized VP with the RR blade exceeds the effectiveness of relying solely on the RR blade to achieve rectal separation. This is especially important in light of the current trend of expanding the use of TR applicators with RR blades for rectal separation to include all patients undergoing ICBT, rather than limiting their use to the ideal subset.

A limitation of this study is that it was an observational study in which three to four HDR ICBT fractions were conducted on each patient in accordance with a predetermined departmental protocol. Although the protocol stipulated that after using a specific technique for rectal separation with the TR applicator in one fraction, a different technique with the TR applicator having identical physical parameters should be employed in subsequent fractions for each patient. These subsequent fractions were not necessarily consecutive; logistical constraints in a high-volume center with limited resources permitted the use of TO applicators in one or two of the three to four HDR ICBT fractions per patient. Therefore, there could be a two to three weeks interval between two comparable fractions. Decades of experience suggest that during the course of EBRT followed by ICBT, there is progressive regression of the tumor with associated anatomical changes; an ideal study would randomize the first fraction utilizing a particular applicator and rectum separation technique and consecutive second fraction with the same applicator parameters but alternate rectum separation technique to negate the possible confounding effect of variation in anatomy even in the same patient during the course of treatment. Moreover, despite the implementation of a consistent loading pattern in our department, variability existed among physicists, primarily attributable to the learning curve prior to attaining a standardized loading pattern. It is only in the subset analysis that all the planning parameters are nearly perfectly aligned. Subsequently, we could address the aforementioned limitations and concerns regarding the adequacy of the sample size by conducting a randomized controlled trial (RCT). The outcomes in abstract form were presented at the annual meeting of the American Society for Radiation Oncology-2024 (ASTRO-2024).[27] Another limitation is that the results of this study are two-dimensional (2D) X-Ray-based planning, where the dose is prescribed to point A and OAR doses are recorded at rectum and bladder points as per ICRU-38 recommendations, which allows for limited optimization of dwell positions and times while recapitulating the classical pear-shaped dose distribution with standard loading pattern during each ICBT fraction. Owing to the constraints associated with this type of treatment planning workflow in resource-limited centers, the focus has been on continuous improvement in the quality of brachytherapy implant procedures, especially by making deliberate efforts to optimally utilize the available methods for organ retraction, which provided us with the opportunity to develop this novel technique to supplement the rectal separation achieved with standard RR blades. The modified technique involves the incorporation of novel steps into the conventional brachytherapy implant procedure to add customized VP to standard RR blades. Further studies are needed to determine whether the results obtained with the 2-D planning workflow are reproducible in an advanced 3-D image-guided adaptive brachytherapy (IGABT) planning workflow, where liberal optimization of dwell positions and times may be allowed to conform the prescribed dose to the target volumes (HR CTV and IR CTV), while precisely monitoring the doses to most exposed volumes of OARs.

Conclusion

The mean radiation dose delivered to the ICRU rectal point with the conventional use of tandem-ring applicators and a standard RR blade is significantly reduced by addition of a customized VP in patients undergoing ICBT for locally advanced cervical cancer. The suggested technique of combining a standard RR blade with customized vaginal gauze packing is easily applicable and cost-effective and therefore can be embraced by providers worldwide, particularly in settings with limited resources.

Data Sharing Statement

The data of this study is available at https://doi.org/10.7910/DVN/13BFHP.

Ethical Statement

Informed consent for the intracavitary brachytherapy procedure was obtained from all patients prior to each fraction. The study protocol was reviewed and approved by the Institutional Ethics Committee IGMC, Shimla to which the authors have submitted a declaration affirming their commitment to upholding the confidentiality of the study patients' identification and data. This study complies with the Declaration of Helsinki.

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Author Contributions

All authors made a significant contribution to the work reported, whether that is in the conception, study design, execution, acquisition of data, analysis and interpretation, or in all these areas; took part in drafting, revising or critically reviewing the article; gave final approval of the version to be published; have agreed on the journal to which the article has been submitted; and agree to be accountable for all aspects of the work.

Disclosure

This paper has been uploaded to Medrxiv as a preprint: https://www.medrxiv.org/content/10.1101/2024.12.06.24318598v1.full.pdf. The authors report no conflicts of interest in this work.

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