Original paper

Clinical analysis of speculum-based vaginal packing for high-dose-rate intracavitary tandem and ovoid brachytherapy in cervical cancer

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Abstract

Purpose: Intra-vaginal packing is used to fix the applicator and displace organs at risk (OAR) during high-dose-rate intracavitary tandem and ovoid brachytherapy (HDR-ICB). We retain the speculum from applicator placement as a dual-function bladder and rectum retractor during treatment. Our objective is to review salient techniques for OAR displacement, share our packing technique, and determine the reduction in dose to OAR and inter-fraction variability of dose to OAR, associated with speculum-based vaginal packing (SBVP) in comparison to conventional gauze packing during HDR-ICB.

Material and methods: We reviewed HDR-ICB treatment plans for 45 patients, including 10 who underwent both conventional gauze packing and SBVP. Due to institutional inter-provider practice differences, patients non-selectively received either packing procedure. Packing was performed under conscious sedation, followed by cone beam computed tomography used for dosimetric planning. Maximum absolute and percent-of-prescription dose to the International Commission of Radiation Units bladder and rectal points in addition to $D_{0.1cc}$, $D_{1.0cc}$, and $D_{2.0cc}$ volumes of the bladder and rectum were analyzed and compared for each packing method using an independent sample *t*-test.

Results: Of the 179 fractions included, 73% and 27% used SBVP and gauze packing, respectively. For patients prescribed 6 Gy to point A, SBVP was associated with reduced mean $D_{0.1cc}$ bladder dose, inter-fraction variability in $D_{0.1cc}$ bladder dose by 9.3% ($p = 0.026$) and 9.0%, respectively, and statistically equivalent rectal $D_{0.1cc}$, $D_{1.0cc}$, and $D_{2.0cc}$. Patients prescribed 5.5 Gy or 5 Gy to point A after dose optimization, were less likely to benefit from SBVP. In the intra-patient comparison, 80% of patients had reduction in at least one rectum or bladder parameter.

Conclusions: In patients with conducive anatomy, SBVP is a cost-efficient packing method that is associated with improved bladder sparing and comparable rectal sparing relative to gauze packing during HDR-ICB without general anesthesia.

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Key words: intracavitary brachytherapy, cervical cancer, rectal dose, bladder dose, speculum, retractor.

Purpose

Treatment for locally advanced cervical cancer includes chemoradiation, with radiation delivered through two modalities, external beam radiation therapy (EBRT) and intracavitary brachytherapy (ICB). High-dose-rate (HDR) ICB delivers > 12 Gy/hour over 3-6 fractions, with treatment occurring over a period of minutes by an automated, digital remote afterloader. Advantages to HDR-ICB over low-dose-rate (LDR) ICB include outpatient treatment, minimal radiation exposure to healthcare providers, and avoidance of prolonged patient immobilization. While dose escalation to the tumor potentially increases overall response and survival, it may increase dose to organs at risk (OAR), including bladder and rectum, leading to corresponding dose-dependent late toxicities [1,2]. The overall risk of moderate to severe late complications from HDR ranges from 5% to 30%, with prior investigations identifying a strong correlation between rectal $D_{0.1cc}$, D_{1cc}, D_{2cc}, and corresponding mucosal toxicities including bleeding, ulceration, and fistula formation [2,3,4,5,6,7].

Dose reduction to OAR is historically achieved by displacing the rectum and bladder away from the applicator using vaginal packing, consistent with the inverse-square law stipulation that dose delivered is inversely proportional to the square of the distance from the radiation source. More recently, combined interstitial and intracavitary applicators (IC/IS) are found to improve the therapeutic ratio in locally advanced cervical cancer via

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dose escalation to the tumor without increasing dose to OAR [8]. In intracavitary brachytherapy, optimal packing stabilizes the applicator and aids in displacement of the bladder and rectum away from the source without displacing the cervix. Suboptimal packing not only leads to worse OAR toxicity but also decreased disease-free survival [9]. Yet, packing technique is broadly recognized as the most technique-dependent aspect of HDR-ICB as substantial inter-operator difference is present at this step [10]. Common methods for displacing OAR include vaginal gauze packing, commercially available rectal retractor blades and vaginal balloons, and retractors crafted in-house [11,12,13,14,15,16,17,18].

Conventionally, two-inch gauze with radiopaque lining, dampened in saline or beta-iodine, is packed into the vagina using forceps beginning at the vaginal apex below and above the tandem flange, and then continued distally until the vaginal canal is packed to the introitus, with care not to displace the applicator away from the cervical os. Next, the patient is imaged using a pair of orthogonal X-rays (anteroposterior – AP and lateral – LAT) and/or computed tomography/magnetic resonance tomography (CT/MRI) if dose is being prescribed to point A or a clinical target volume, respectively. While conventional vaginal packing is simple and inexpensive, it can cause discomfort and lacks reproducibility [15].

Vaginal balloons vary in design. Commercially available systems consist of a pair of deflated balloons that are inserted anterior and posterior to the ovoids prior to inflation, with water or mixture of water and contrast to optimize image quality (RadiaDyne LLC, Houston, TX, USA and HLL Lifecare Limited, Karamana, Trivandrum, India) [16,18,19]. Alternatively, vaginal balloons can be crafted in-house using inexpensive Foley balloons. Eng *et al*. displaced the rectum by placing a Foley balloon in the vaginal apex and then prevented mobilization with gauze packing soaked in betadine, lidocaine, and a contrast solution. Thereafter, they inserted a second Foley balloon posterior to the bladder and applied similar gauze packing until the two balloons were secure prior to removing the clear lighted retractor [11]. Kong *et al*. utilized a tandem Foley consisting of Foley catheter balloon threaded onto the uterine tandem of the tandem and ring apparatus, when the vaginal cavity was unable to accommodate a rectal blade [13]. Rectal blades are introduced after applicator placement underneath the ovoids or ring, and as implied, are limited to rectal retraction [12,14]. The blades can be purchased in a combination set with the applicator; selected models allow adjustable fixation of the retractor and applicator, or contain lead markers to aid with placement and visualization, respectively (Varian Medical System, Palo Alto, CA, USA and Nucletron, Veenendaal, The Netherlands). Rectal blades may reduce radiation dose to the anterior rectal wall more effectively than conventional vaginal packing, however, the use of rectal blades is limited to patients with conducive anatomy [12,13,14].

We displace the OAR by retaining the speculum typically used for vaginal mucosa retraction during applicator placement as a dual-function bladder and rectum retractor that remains in place during treatment. To our knowledge, this approach of speculum-based vaginal packing (SBVP) has not been previously described in HDR-ICB. The aim of this study is to describe our method of vaginal packing and clinically determine differences in dose to OAR associated with SBVP in comparison to conventional gauze packing during HDR-ICB. To achieve these objectives, we undertook a retrospective comparative clinical analysis of women with cervical cancer treated with tandem and ovoid HDR-ICB who received SBVP or gauze packing.

Material and methods

Vaginal packing

For brachytherapy application, we place the patient in standard lithotomy position and catheterize the bladder. We place a lighted clear plastic bi-valved, self-retaining speculum (KleenSpec single use vaginal speculum, Welch Allyn, Skaneateles Falls, NY, USA). Using the built-in adjustable opening mechanism consisting of pawl and ratchet teeth, we expand the speculum blades to anatomic tolerance as determined by compliance of the vaginal mucosa and patient tolerance (Figure 1). Next, we sound the uterus to determine its length and orientation. Based on observation of the patient's anatomy, we set the flange to the length sounded and select the largest sized ovoids that can be reasonably accommodated (Elekta, Stockholm, Sweden). The applicator is assembled and inserted per conventional protocol. At this time, most providers apply the gauze packing, balloon devices, or rectal blades and remove the speculum or retractor. In

Fig. 1. Annotated photograph of clear bi-valve self-retaining adjustable speculum with cavity for compatible light source insertion. Blue arrow (A) denotes ratchet and pawl teeth mechanism used to adjust vertical expansion of speculum as marked by corresponding blue arrow (B). Black arrow (A) denotes ratchet and pawl teeth mechanism used to adjust degree of expansion of bi-valves following placement in the proximal vaginal canal, as marked by corresponding black arrow (B). Green arrow (C) marks the cavity in the speculum where a compatible light source can be inserted

this protocol, the self-retaining speculum is left in place in the expanded position to function as a dual-functioning bladder and rectal retractor that remains in place during planning and treatment, with the upper and lower blades located just above and below the midpoint of the ovoids. Care is taken to center the edge of the speculum along the midpoint of the anterior and posterior surface of the ovoids. Placement of the tandem and ovoids within the distal opening of the speculum does not introduce a gap between the cervical os and the flange. Next, we add gauze packing containing radiopaque thread to immobilize the tandem and ovoids within the speculum. The 2-inch gauze is gripped with forceps and packed around the applicator beginning at the apex and continuing distally until reaching the vaginal introitus. Following packing, the legs are moved to low lithotomy position, and this position is maintained for imaging and treatment. The speculum remains in the vertical position. To further immobilize the applicator, we clamp it to the end of the tandem and then fasten it to an extension board and base plate that slides under the cushion of the procedure table. The base plate has a column along which the height of the clamp for the tandem can be adjusted to maintain the tandem in a parallel position to the baseboard. The speculum, packing, and applicator are firmly anchored in this position during filming, calculations, and treatment. Following vaginal packing, the patient is imaged with a cone beam CT (CBCT) for dosimetry planning. Packing and treatment are performed under conscious sedation using fentanyl. Treatment plans were generated with Oncentra Brachy treatment planning software (Elekta, Stockholm, Sweden).

Contouring and catheter reconstruction

The primary OAR, bladder and rectum, are identified and contoured per institutional protocols. Catheter reconstruction begins in the axial view, starting with the patient's right side by placing the coordinate system origin at the posterior edge of the ovoid and aligning the y-axis until it bisects the channel. Manipulation of the coordinate system in the coronal and sagittal views ensures the reconstruction occurs within the ovoid channel. This process is repeated for the left ovoid. The tandem is reconstructed with placement of the origin at the superior margin of the flange and the coordinate system is aligned to bisect the top of the tandem.

Prescription

The prescription isodose line is normalized to point A, located 2 cm superior and 2 cm lateral to the flange. Point B is defined as 5 cm lateral from the midline relative to the patient's anatomy at the same level as point A, and usually receives 25-30% of prescribed dose with our protocols. The International Commission of Radiation Units and Measurements (ICRU) bladder point is placed at the center of the Foley balloon and ICRU rectum is located 5 mm posterior to the vaginal wall [20]. We generate a dose volume histogram (DVH) that is evaluated for a bladder and rectum limiting dose typically 75% of prescription. Dose to point A is adjusted as necessary to appropriately spare OAR. $D_{0.1cc}$, D_{1cc}, and D_{2cc} are also generated [21,22].

Clinical retrospective study

To evaluate the comparative effectiveness of gauze packing and SBVP, we conducted a retrospective chart review of radiation treatment planning for patients with a diagnosis of cervical cancer treated with intracavitary tandem and ovoid brachytherapy between November 2013 and October 2016. This study received Institutional Review Board approval. Within our institution, one provider uses gauze-based packing, and the other SBVP for all treatments. Due to this fixed inter-provider difference in packing methodology, patients may receive either packing method without bias or selection. A total of 213 fractions corresponding to 45 patients were identified. Information extracted for each fraction included prescribed dose, disease stage, packing method, and the following OAR dose parameters: ICRU points, $D_{0.1cc}$, $D_{1.0cc}$, and D_{2cc} for both bladder and rectum. At this institution, we allow for adjustment of prescription dose as necessary to prevent high doses of radiation to the OAR. Hence, we stratified data according to prescribed dose before proceeding with subsequent analysis. To normalize parameters corresponding to fractions prescribed at different doses, each OAR dose parameter was computed into a percentage-of-prescribed dose by dividing the baseline value in cGy by the prescription dose and multiplying by 100. The average ICRU, %ICRU, $D_{0.1cc}$, $\%D_{0.1cc}$, $D_{1.0cc}$, $\%D_{1.0cc}$, $D_{2.0cc}$, and $\%D_{2.0cc}$ were calculated for gauze packing and SBVP, along with corresponding standard deviations. The average value for gauze packing was subtracted from the average value for SBVP, thus negative differences indicate a dose reduction with SBVP. The p values for the difference between gauze packing and SBVP were computed in Microsoft Excel using a two-tailed *t*-test assuming homoscedasticity, with $p < 0.05$ considered statistically significant. To assess the difference in reproducibility between packing methods, we computed the difference between corresponding standard deviations by subtracting the standard deviation of gauze packing from that of SBVP, thus negative differences indicate a decrease in variability with SBVP. At our institution, we catheterize the bladder but do not perform rectal catheterization or bowel preparations. To prevent data analyses from being skewed by extreme variability in rectal stool burden, we excluded fractions that differed by more than two standard deviations for each prescription dose strata.

A total of 11 patients received both gauze packing and SBVP. For these patients, we computed intra-patient differences in %ICRU, $\%D_{0.1cc}$, $\%D_{1.0cc}$, and $\%D_{2.0cc}$ between both packing methods. Negative values indicate a dose reduction with SBVP. One case was excluded because the patient received a paracervical block prior to gauze packing but not SBVP, thereby potentially compromising this intra-patient comparison.

In order to visually demonstrate the difference in OAR displacement between packing methods, we show a representative intra-patient comparison (Figure 2). The radiation

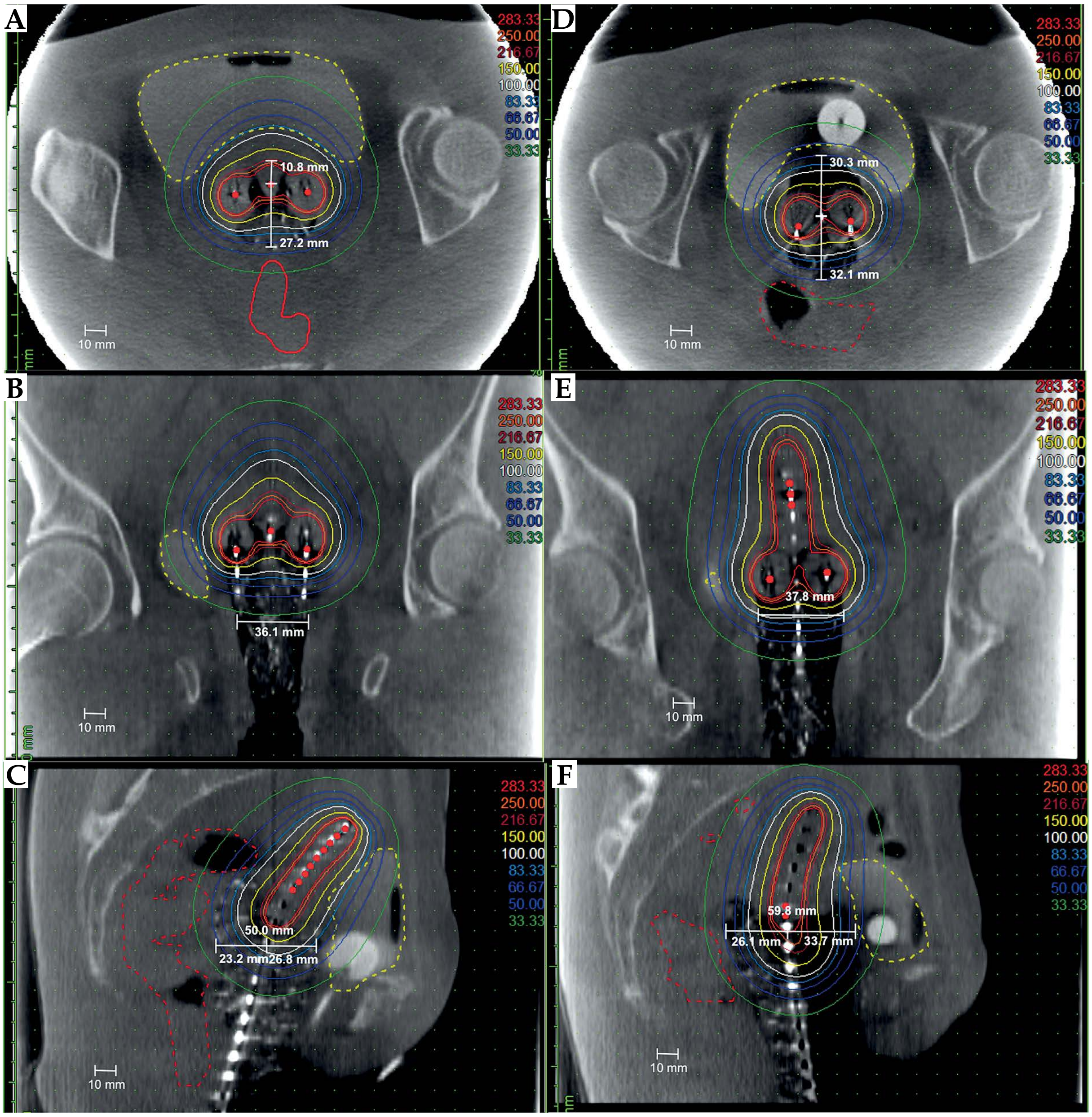

Fig. 2. Representative computed tomography images and dosimetry planning intra-patient comparison of gauze packing and speculum-based vaginal packing (SBVP). Images correspond to case 1 dosimetry information in Table 3. Measurements indicate distance from the source to vaginal mucosa with the origin placed at posterior aspect of right ovoid. Isodose lines indicate the percentage of the prescribed dose. **A)** Gauze packing axial. **B)** Gauze packing coronal. **C)** Gauze packing sagittal. **D)** SBVP axial. **E)** SBVP coronal. **F)** SBVP sagittal

planning images were exported with scale indicator from Oncentra and into Image J (National Institutes of Health). Using the Oncentra generated 10 mm grid, the image scale was set for each image in Image J. The distance of interest was annotated, and then quantified using the analyze and measure functions.

Results

Patients at our institution have tolerated SBVP well as evidenced by patient report of adequate pain control during initial insertion of the speculum, initial expansion of the speculum, and full SBVP set-up including concomitant gauze packing following applicator placement. No vaginal mucosal tearing or bleeding has been noted during set-up or following treatment.

Baseline patient and fraction characteristics are shown in Table 1. The study population included a variety of disease stages. The majority of fractions were prescribed at 6, 5.5, or 5 Gy to point A, thus further analysis was limited to these dosages. Most fractions were delivered using SBVP.

A summary of the dosimetric comparison between SBVP and gauze packing for bladder sparing is shown in Table 2A. For patients prescribed 6 Gy to point A,

Table 1. Patient and fraction characteristics

Point A dose (Gy)	Number of fractions
3	1
3.5	2
4	11
4.5	15
5	62
5.5	51
6	71
Stage	**Number of patients**
I	86
II	70
III	57
Packing method	**Number of applications**
Gauze	57
SBVP	156

SBVP – speculum-based vaginal packing

compared to gauze packing, SBVP was associated with a decrease in all volume-based parameters including a statistically significant reduction of 9.3% in $\%D_{0.1cc}$ corresponding to 0.561 Gy (p = 0.026). Non-statistically significant reductions include 3.4% decrease in $D_{2.0cc}$ (p = 0.233), and 4.8% reduction in $D_{1.0cc}$ (p = 0.123). Inter-fraction variability assessed by magnitude of standard deviation was reduced with SBVP for every parameter measured. For patients requiring dose optimization, lowering the prescribed dose to 5.5 or 5 Gy, SBVP did not differ significantly from gauze for bladder sparing. Dose parameters for rectum are presented in Table 2B. For fractions delivered at 6 Gy, SBVP and gauze packing were statistically equivalent for rectal parameters. Statistically significant increases in rectal dose-volume parameters for SBVP were noted in fractions delivered at 5.5 or 5 Gy ($p < 0.05$).

To account for anatomic differences between patients that may confound analyses, we compared dosimetry data for 10 patients who underwent both SBVP and gauze packing as shown in Table 3. In this cohort, the SBVP group had the following average reduction in bladder dose-volume parameters: 3.9%, 2.7%, and 2.1% in $\%B_{0.1cc}$, $\%B_{1.0cc}$, and $\%B_{2.0cc}$, respectively. The %Bladder ICRU increased by 3.1%, while the %Rectal ICRU decreased by 3.6%. The average rectal dose-volume parameters increased with SBVP. Overall, among patients receiving both packing methods 70%, 70%, and 80% had reduction in at least one rectum parameter, one bladder parameter or either parameter, respectively.

Figure 2 shows representative CT images of both retraction methods in the same patient, corresponding displacement measurements, and overlaid dosimetry planning with isodose lines. SBVP compared to gauze packing increased the physical distance between the source and vaginal mucosa in the axial, coronal, and sagittal planes, thereby decreasing the volume of bladder and rectum included within high intensity isodose lines.

Discussion

To our knowledge, this is the first clinical analysis of the effect of SBVP compared to gauze packing on bladder

Table 2A. Comparative analysis of dose-volume histogram parameters for bladder. Mean and standard deviation values are shown for each packing method. The difference is the result of subtraction of the values for gauze packing from those of SBVP. Negative values indicate a dose reduction derived from SBVP compared to gauze packing.

Bladder Dose (Gy)		Packing	ICRU	%ICRU	$D_{0.1}$	$\%D_{0.1}$	$D_{1.0}$	$\%D_{1.0}$	$D_{2.0}$	$\%D_{2.0}$
6.0	Mean	SBVP	4.00 ± 0.74	66.7 ± 12.3	5.23 ± 0.74	87.2 ± 12.3	4.56 ± 0.57	76 ± 9.6	4.29 ± 0.53	71.5 ± 8.9
n = 69		Gauze	3.10 ± 0.79	51.7 ± 13.2	5.79 ± 1.28	96.5 ± 21.2	4.85 ± .93	80.8 ± 15.5	4.50 ± 0.86	75 ± 14.3
		Difference	0.90*	15.0*	–0.56*	–9.3*	–0.29	–4.8	–0.21	–3.4
		p value	< 0.001	< 0.001	0.026	0.026	0.123	0.123	0.233	0.233
	SD	Difference	–0.053	–0.9	–0.54	–9.0	–0.36	–6.0	–0.33	–5.4
5.5	Mean	SBVP	4.03± 1.20	73.4 ± 21.8	5.85 ± 0.98	106.3 ± 17.8	4.99 ± 0.69	90.9 ± 12.6	4.64 ± 0.60	84.4 ± 10.9
n = 50		Gauze	3.35 ± 0.64	60.8 ± 11.6	5.15 ± 0.55	93.7 ± 10	4.55 ± 0.43	82.7 ± 7.8	4.26 ± 0.39	77.4 ± 7
		Difference	0.69	12.5	0.69*	12.6*	0.45	8.2	0.39	7.1
		p value	0.103	0.103	0.047	0.047	0.068	0.068	0.070	0.070
	SD	Difference	0.56	10.2	0.43	7.9	0.27	4.8	0.21	3.9
5.0	Mean	SBVP	4.41 ± 1.46	88.2 ± 29.1	5.27 ± 1.10	105.5 ± 22.1	4.56 ± 0.81	91.2 ± 16.1	4.24 ± 0.68	84.8 ± 13.7
n = 60		Gauze	3.79± 1.07	75.8 ± 21.3	5.27 ± 1.11	105.4 ± 22.2	4.53 ± 0.77	90.6 ± 15.4	4.22 ± 0.70	84.5 ± 13.9
		Difference	0.62	12.4	0.005	0.1	0.03	0.6	0.019	0.4
		p value	0.096	0.096	0.987	0.987	0.889	0.889	0.918	0.918
	SD	Difference	0.39	7.8	–0.005	–0.1	0.034	0.7	–0.013	–0.3

**Value is significant at the p < 0.05 level. Units for ICRU, $D_{0.1}$, $D_{1.0}$, $D_{2.0}$ are Gy. SBVP – speculum-based vaginal packing, SD – standard deviation*

Table 2B. Comparative analysis of dose-volume histogram parameters for rectum

Rectum										
Dose (Gy)			ICRU	%ICRU	$D_{0.1}$	$\%D_{0.1}$	$D_{1.0}$	$\%D_{1.0}$	$D_{2.0}$	$\%D_{2.0}$
6	Mean	SBVP	3.64 ± 0.80	60.7 ± 13.4	5.06 ± 1.28	84.4 ± 21.3	4.15 ± 0.92	69.1 ± 15.3	3.77 ± 0.80	62.9 ± 13.4
n = 69		Gauze	3.64 ± 0.91	60.6 ± 15.1	4.44 ± 1.29	74 ± 21.6	3.74 ± 1.03	61.8 ± 16.8	3.38 ± 0.90	56.4 ± 15
		Difference	0.001	0.1	0.62	10.3	0.40	7.3	0.39	6.5
		p value	> 0.99	0.98	0.08	0.08	0.12	0.09	0.08	0.08
	SD	Difference	–0.11	–1.8	–0.017	–0.3	–0.11	–1.5	–0.099	–1.6
5.5	Mean	SBVP	3.51 ± 0.65	64 ± 11.6	4.80 ± 1.23	87.3 ± 22.3	3.93 ± 0.86	71.5 ± 15.7	3.61 ± 0.75	65.5 ± 13.6
n = 50		Gauze	3.95 ± 0.94	71.8 ± 17	4.03 ± 0.94	73.3 ± 17.1	3.29 ± 0.63	59.8 ± 11.4	2.99 ± 0.53	54.3 ± 9.7
		Difference	–0.44	–7.8	0.77	14.0	0.65*	11.8*	0.62*	11.2*
		p value	0.099	0.099	0.083	0.083	0.039	0.039	0.023	0.023
	SD	Difference	–0.29	–5.4	0.29	5.2	0.24	4.3	0.21	3.9
5	Mean	SBVP	3.39 ± 0.82	67.8 ± 16.3	4.77 ± 1.24	95.4 ± 24.8	3.88 ± 0.97	77.6 ± 19.3	3.52 ± 0.87	70.5 ± 17.5
n = 60		Gauze	2.98 ± 0.70	59.6 ± 13.9	3.37 ± 0.80	67.4 ± 16	2.77 ± 0.63	55.4 ± 12.6	2.51 ± 0.57	50.1 ± 11.4
		Difference	0.41	8.2	1.40*	28.0*	1.11*	22.1*	1.02*	20.4*
		p value	0.060	0.060	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001
	SD	Difference	0.12	2.4	0.44	8.8	0.34	6.7	0.30	6.1

**Value is significant at the $p < 0.05$ level. $D_{0.1cc}$, D_{1cc}, D_{2cc} – minimum dose to the most exposed 0.1 cm^3, 1 cm^3, 2 cm^3. SBVP – speculum-based vaginal packing*

Table 3. Retrospective dosimetry analysis of bladder and rectal dose in 50 high-dose-rate brachytherapy plans for 10 patients who received at least one fraction of both speculum-based vaginal packing (SBVP) and gauze packing. Differences in %ICRU, $\%D_{0.1}$, $\%D_{1.0}$, and $\%D_{2.0}$ indicate the value resulting from subtraction of the gauze packing parameter from the SBVP parameter. Negative values indicate a dose reduction derived from SBVP compared to gauze packing

Case	Difference in bladder				Difference in rectum			
	%B: ICRU	%B: $D_{0.1}$	%B: $D_{1.0}$	%B: $D_{2.0}$	%R: ICRU	%R: $D_{0.1}$	%R: $D_{1.0}$	%R: $D_{2.0}$
1	11.20	–12.60	–10.09	–8.74	–0.76	–4.34	–1.20	1.69
2	17.68	3.33	2.91	3.03	28.20	21.31	16.48	17.25
3	–13.62	–19.33	–14.78	–11.10	18.19	37.22	29.62	26.39
4	–5.86	22.46	17.95	15.24	–28.63	–2.06	3.46	4.89
5	41.62	17.58	11.68	9.67	4.07	36.77	30.80	27.82
6	0.22	–13.57	–6.69	–5.32	–23.99	12.62	10.78	9.11
7	19.97	19.44	18.24	17.81	–3.91	39.30	27.49	23.34
8	–17.46	–45.78	–36.91	–32.58	–7.85	–7.05	–7.53	–6.53
9	–28.42	6.05	5.80	4.56	–15.74	–10.31	–13.16	–11.66
10	5.53	–16.56	–14.93	–13.32	–5.96	46.82	29.71	25.54
Average	3.1	–3.9	–2.7	–2.1	–3.6	17.0	12.6	11.8

SBVP – speculum-based vaginal packing. $D_{0.1cc}$, D_{1cc}, D_{2cc} – minimum dose to the most exposed 0.1 cm^3, 1 cm^3, 2 cm^3

and rectal ICRU points and dose-volume parameters for CT-guided HDR-ICB for cervical cancer. The SBVP group had substantially reduced dose to the bladder, as measured by dose-volume parameters among patients who tolerated treatment at the prescription dose of 6 Gy to point A. To account for inter-patient anatomic variation, we compared both packing types in 10 patients who received both types of packing and showed that 70%, 70%, and 80% had a reduction in at least one rectum parameter, one bladder parameter, or either parameter, respectively. Furthermore, we demonstrated improved reproducibility with SBVP as evidenced by decreased standard deviation in every bladder and rectum dose parameter for patients treated at 6 Gy. Our study is best suited for comparison of bladder parameters because we catheterized the bladder, thereby reducing inter-fraction bladder volume variability. In contrast, we did not perform any bowel preparation, which complicates interpretation of parameters affected by rectal volume. Encouragingly, the ICRU rectum for fractions delivered at 5.50 Gy is 0.436 Gy or 7.8% lower with SBVP, and among patients receiving both techniques, 7 of 10 experienced a decrease in ICRU rectum.

Most notable reductions in bladder and rectal parameters corresponded to fractions prescribed at 6 Gy, suggested that patients requiring dose optimization were less likely to benefit from SBVP. Similarly, in a prospective randomized study of bladder-rectal spacer balloons, the authors found that despite increased displacement, there was no improvement in bladder dose. They noted that excess anterior-posterior bladder displacement in some cases led to the filling of urine into the lateral recesses in select patients [19]. As shown in Figure 2 with SBVP, anterior-posterior displacement disproportionately exceeds lateral displacement. In our experience, patients requiring dose optimization tend to have confined anatomy and, in this setting, disproportionate anterior displacement of the bladder likely blunts the improvement in volume-based dose parameters by bringing the lateral aspects of the bladder closer to the source.

Potential advantages to our SBVP method of bladder and rectal retraction include ease-of-use, cost-efficiency, and broad anatomic compatibility due to the use of an adjustable speculum. There is no additional effort or cost associated with SBVP, as the speculum is necessary for applicator placement. Our use of a clear plastic speculum with light source facilitates visualization of the vaginal wall to assess for lesions and place the applicator. Gauze packing may be an uncomfortable process for patients. However, when gauze packing is used within the lumen of the speculum to further stabilize the tandem and ovoid applicator, the contact between the vaginal mucosa and gauze is reduced, as the mucosa is predominantly retracted by the speculum. While vaginal balloons created in-house have demonstrated improved efficacy over gauze vaginal packing and are low cost, they are tedious to craft, non-standardized, and incur cost in the form of time of medical professionals [11,13]. Utilization of rectal blades is dependent on patient anatomy, however, vaginal speculums are used regularly in a wide variety of gynecological settings despite anatomical differences and can be opened to varying degrees [12,13]. Rectal blades are not amenable to placement in narrow, fibrotic vaginal canals and can lead to tearing if used in patients with atrophic or friable vaginal mucosa.

Commercially available vaginal balloons cost $495 per application, summing to a cost of $2,500-3,000 per patient over the treatment course [11]. The disposable speculum used at our institution costs $2.47 and is compatible with a reusable cordless light source, $187 (Welch Allyn), both of which are available to the general public (online price 9/2016, www.claflinequip.com). Given the worldwide distribution of cervical cancer, this may be an important factor in regions where financial resources are limited.

The magnitude of bladder dose reduction for SBVP is greater than other commonly used methods. Three studies found that rectal blades reduce dose to the ICRU bladder but failed to reach statistical significance indicating that while rectal blades effectively reduce dose to the rectum, they do not reduce bladder dose [12,13,14]. Rockey *et al.* performed a retrospective study of vaginal balloon packing and found average reductions of 3.3% in rectal $D_{2.0cc}$ and an increase of 3.2% in bladder $D_{2.0cc}$, although these values were statistically equivalent [16]. Similarly, Rai *et al.* investigated the use of bladder-rectal spacer balloons in a prospective randomized trial and found no significant difference in any volume-based bladder parameters or ICRU bladder [19]. Eng *et al.* performed a prospective study of the tandem Foley and noted a 7.2% reduction in bladder $D_{0.1cc}$ compared to gauze packing alone [11]. We showed that SBVP provided a decrease in all volume-based bladder parameters including a statistically significant reduction of 9.3% in %$D_{0.1cc}$ along with statistically non-significant of 3.4% decrease in $D_{2.0cc}$, and 4.8% decrease in $D_{1.0cc}$ along with decreased inter-fraction variability. Thus, SBVP is associated with excellent dose reduction relative to other techniques without requiring increased cost or in-house construction of a retraction device.

Our study has several important limitations. The grainy quality of the cone beam CT images limits the contouring of the OAR, particularly the rectal wall as no bowel preparation or rectal contrast was used in the cases analyzed. In more recent cases, dilute barium inserted via a small rectal tube was used to better delineate rectal anatomy on imaging. In addition, some of the applications with gauze packing were performed using a non-CT compatible applicator, which further impeded image quality due to artifact. The use of high precision imaging, including diagnostic CT and eventually MRI for planning, will further improve the ability to deliver dose to target volumes while sparing OAR. While patients were not selected for either packing method, SBVP was adapted for patients with fibrotic or narrow vaginal canals by reducing the expansion of the retained speculum to facilitate comfort and prevent mucosal tears. While both packing methods require insertion of the ovoids through the speculum, insertion of the second ovoid through the speculum can be challenging in narrow vaginal canals. Despite standardization of contouring, applicator reconstruction, and treatment planning, variations can occur in each of these steps, especially with low quality imaging. While we do not adjust for each of these factors, the large sample size and intra-patient comparisons are strengths of our study. In our limited experience, SBVP did not negatively impact contouring as the speculum creates a linear border to the vaginal vault in contrast to gauze packing, wherein the vaginal wall is approximated by the course of radio-opaque thread embedded within gauze packing. The cases presented did not require patient transport. More recently, we are using SBVP with diagnostic CT and to date have not encountered difficulty with CT compatibility of SBVP or short transport distances. While combined IC/IS offers recognized dosimetric advantages, ICB remains a widespread method of treatment warranting further investigation into how ICB can be optimized to improve sparing of OAR.

We have used SBVP technique at our large academic medical center for several years and believe that SBVP is a clinically feasible, low-cost, versatile, and well tolerated method of reducing dose to critical structures.

Conclusions

SBVP is a clinically feasible method for OAR displacement during HDR tandem and ovoid brachytherapy. SBVP creates substantial distance between the source and bladder and rectum in the anterior-posterior and lateral planes. In patients with appropriate anatomy, the increased displacement with SBVP is associated with improved bladder sparing and non-inferior rectal sparing compared to gauze packing during HDR ICB without general anesthesia. Furthermore, SBVP is cost-efficient and has broad anatomic compatibility.

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Disclosure

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