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 D0.1cc, D1.0cc, and D2.0cc 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 D0.1cc bladder dose, inter-fraction variability in D0.1cc bladder dose by 9.3% (p = 0.026) and 9.0%, respectively, and statistically equivalent rectal D0.1cc, D1.0cc, and D2.0cc. 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.
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-i-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 cervix or 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 Hill Life Care 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.
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 im-
mobilize 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 continu-
ing distally until reaching the vaginal introitus. Following
packing, the legs are moved to low lithotomy position,
and this position is maintained for imaging and treat-
ment. 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 Onco
tera Brachy treatment planning software (Elekta,
Stockholm, Sweden).

Contouring and catheter reconstruction
The primary OAR, bladder and rectum, are identi-
fied and contoured per institutional protocols. Catheter
reconstruction begins in the axial view, starting with the
patient’s right side by placing the coordinate system or-
igin at the posterior edge of the ovoid and aligning the
y-axis until it bisects the channel. Manipulation of the co-
ordinate 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 re-
constructed 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 pro-
tocols. 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. D0.1cc, D1cc, and D2cc 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 Institution-
al 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 dif-
fERENCE in packing methodology, patients may receive
either packing method without bias or selection. A total
of 213 fractions corresponding to 45 patients were iden-
tified. Information extracted for each fraction included
prescribed dose, disease stage, packing method, and the
following OAR dose parameters: ICRU points, D0.1cc,
D1cc, and D2cc for both bladder and rectum. At this in-
istitution, 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 normal-
ize parameters corresponding to fractions prescribed
at different doses, each OAR dose parameter was com-
puted 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, D0.1cc,
%D0.1cc, D1cc, %D1cc, D2cc, and %D2cc were calculated
for gauze packing and SBVP, along with corresponding
standard deviations. The average value for gauze pack-
ing 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 us-
ing 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 devia-
tion 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 dif-
fferences in %ICRU, %D0.1cc, %D1cc, and %D2cc 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 pack-
ning 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 repre-
sentative intra-patient comparison (Figure 2). The radiation

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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,
compared to gauze packing, SBVP was associated with a decrease in all volume-based parameters including a statistically significant reduction of 9.3% in %D0.1cc corresponding to 0.561 Gy (p = 0.026). Non-statistically significant reductions include 3.4% decrease in D2.0cc (p = 0.233), and 4.8% reduction in D1.0cc (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 %B0.1cc, %B1.0cc and %B2.0cc 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 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*

### 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 | D0.1 | %D0.1 | D1.0 | %D1.0 | D2.0 | %D2.0 |
|---------|-----------|---------|------|-------|------|-------|------|-------|------|-------|
| 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±12.8 | 96.5±21.2 | 4.85±9.3 | 80.8±15.5 | 4.50±0.86 | 75±14.3 |
|         | Difference| -0.90* | -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 | -0.54 | -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±7.7 |
|         | 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 | 0.03 | 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, D0.1, D1.0, D2.0 are Gy. SBVP – speculum-based vaginal packing. SD – standard deviation*
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.

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

| Dose (Gy) | Mean | SD | Difference | p value | SD |
|-----------|------|----|------------|---------|----|
| 6 n = 69  | SBVP | 3.64 ± 0.80 | 3.64 ± 0.91 | 0.001 | >0.99 |
|           | Gauze| 60.7 ± 13.4 | 60.6 ± 15.1 | 0.62 | 0.08 |
|           |      | 5.06 ± 1.28 | 4.44 ± 1.29 | 10.3 | 0.12 |
|           |      | 84.4 ± 21.3 | 74 ± 21.6 | 7.3 | 0.09 |
|           |      | 4.15 ± 0.92 | 3.74 ± 1.03 | 0.39 | 0.08 |
|           |      | 69.1 ± 15.3 | 61.8 ± 16.8 | 6.5 |
|           |      | 3.77 ± 0.80 | 3.38 ± 0.90 | 0.37 |
|           |      | 62.9 ± 13.4 | 56.4 ± 15.5 | 0.08 |

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, %D1, %D2, and %D3 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: D1 | %B: D2 | %R: ICRU | %R: D1 | %R: D2 | %R: D3 |
| 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 | 14.0 | 11.84 | 4.07 | 36.77 | 30.80 | 27.82 |
| 4    | −5.86 | 22.46 | 17.95 | 15.24 | −28.63 | −20.6 | 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. D1, D2, D3 – minimum dose to the most exposed 0.1 cm³, 1 cm³, 2 cm³
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 $D_{3,1cc}$ 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

Authors report no conflict of interest.

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