A novel intracavitary applicator design for the treatment of deep vaginal fornices: preliminary dose metrics and geometric analysis

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Abstract

Purpose: To investigate the dose distributions associated with a novel balloon sleeve placed over a standard cylinder applicator.

Material and methods: A computed tomography (CT) scan of a sleeve balloon shaped to inflate into the vaginal fornices was used to digitize 1-, 3-, and 5-catheter configurations. Point doses for rectum, apex, and fornix were calculated and compared to the values associated with a standard cylinder plan not targeting the vaginal fornices. Inflation of the sleeve balloon in the vaginal fornices and dose coverage with constraints to the rectum, bladder, and sigmoid D2cc were evaluated.

Results: Rectum, apex, and fornix doses were respectively 76%, 119%, and 44% for a standard cylinder; 190%, 310%, and 93% for a 1-catheter configuration; 98%, 109%, and 109% for a 3-catheter configuration; and 91%, 107%, and 96% for the 5-catheter configuration. In a patient analysis, expansion of the sleeve balloon into the vaginal fornices was confirmed. The 5-catheter configurations were associated with best coverage of the fornices and acceptable doses to rectum, bladder, and sigmoid.

Conclusions: A 1-catheter configuration cannot be used clinically due to high rectal and apex dose. In theoretical analysis, the 3- and 5-catheter configurations showed > 96% coverage to the vaginal fornices with a clinically acceptable rectal dose. In a treatment simulation in a patient, a 5-catheter configuration showed 90% coverage of the fornices with acceptable doses to the organs at risk. The treatment of deep vaginal fornices results in an increased rectal dose compared to a standard cylinder plan.

Key words: brachytherapy, intracavitary, vaginal fornices, multi-channel, applicator.
Novel applicator for the treatment of vaginal fornices explored: a coplanar configuration and a cross-shaped increments.

The sleeve was inserted over a cylinder and inflated with 40 cm³ of water, and a computed tomography (CT) scan with the applicator in air was acquired. The sleeve surface was manually segmented on CT to obtain a digital model of the sleeve shape. Various configurations of one or more catheters, all with 2.5-mm step size dwell locations, were simulated. A treatment length of 50 mm was used. A clearance of 7 mm was respected between the simulated tip location and the superior border of the applicator. This clearance is needed to ensure that the catheters can physically be mounted into the balloon; a similar clearance is observed in commercial multi-channel balloon applicators. One-, 3-, and 5-catheter configurations were analyzed.

The theoretical evaluation

Each catheter configuration was optimized with inverse planning simulated annealing (IPSA) using the Oncentra Brachytherapy planning system (Nucletron, an Elekta Company, Stockholm, Sweden). Inverse planning simulated annealing was used to eliminate the potential bias from manual or graphic optimization. Each configuration was optimized using the following optimization constraints: minimum dose to the sleeve surface of 100% of the prescription dose, and maximum dose to the sleeve surface of 150% of the prescription dose, with equal weighting. The use of each catheter by the optimizer is reported as percent loading, that is, the ratio of the total reference air kerma (TRAK) associated with a catheter by the total plan TRAK.

The rectal dose was defined as the ratio of the mean dose of rectal points 5 mm posterior to the sleeve, at 2.5-mm intervals along the treatment lengths, to the minimum dose delivered to the surface of the sleeve. The apex dose was defined as the ratio of apex (a point 7 mm superior to the top dwell position of the central catheter) dose to the minimum dose delivered to the surface of the sleeve. The fornix dose was defined as the ratio of the mean dose of the fornix points to the minimum dose delivered to the surface of the sleeve. Four fornix points were defined: the two farthest points from the central catheter on the balloon surface on the axial slice containing the top dwell position (located 27.5 mm from the central catheter, which corresponds to 10 mm away from a 35-mm cylinder surface), and two corresponding points 5 mm outside the balloon surface (Fig. 2E). Rectal, apex and fornix doses were normalized to the minimum dose delivered to the surface of the sleeve to ensure that a common normalization existed among all plans.

We compared the dosimetric indices to values associated with a standard cylinder plan, that is, a straight-line plan not targeting the vaginal fornices. Cylinder size used for comparison was a 35-mm diameter, due to the similarity between this configuration and the average diameter of the balloon-sleeve applicator (37 mm). The difference between the standard cylinder plan and the cylinder + sleeve scenario lies in the shape of the target surface. While the standard cylinder plan has a fixed geometry with a dome at the tip curving away from the fornices, the cylinder + sleeve scenario lies in the shape of the target surface. While the standard cylinder plan has a fixed geometry with a dome at the tip curving away from the fornices, the cylinder + sleeve scenario maintains the top dwell position (located 27.5 mm from the central catheter, which corresponds to 10 mm away from a 35-mm cylinder surface), and two corresponding points 5 mm outside the balloon surface (Fig. 2E). Rectal, apex and fornix doses were normalized to the minimum dose delivered to the surface of the sleeve to ensure that a common normalization existed among all plans.

Fig. 1. An example of the sleeve balloon inserted over a vaginal cylinder and inflated with air
as per our standard clinical practice. Fornix points and the apex points were not used in the optimization. Rectal points were redefined as 5 mm from the dose points. In the discussion on the clinical acceptability of the rectal dose, the biologically equivalent dose in 2-Gy equivalents (EQD2) formalism was used. Although this theoretical analysis is based on dose points, we assumed a threshold for an acceptable rectal dose of 70-75 Gy (EQD2), in line with volumetric thresholds seen in cervical-cancer tandem-and-ring brachytherapy [10]. Two fractionation schedules prescribed to the vaginal surface were used to calculate the rectal EQD2 dose: 6 Gy x 5 and 4 Gy x 6 [1,8].

**In-patient evaluation**

The clinical impact of the use of this applicator was preliminarily assessed on data from one patient who presented with recurrent endometrial cancer at the vaginal apex. A decision to perform magnetic resonance (MR)-guided interstitial brachytherapy was made. In order to assess the feasibility of visualizing the fornices, a 2-cm MR-compatible cylinder (Nucletron, an Elekta Company) was inserted in the inside pocket of an uninflated prototype of the balloon-sleeve; the uninflated applicator was inserted into the patient and inflated with water. The patient was then scanned using intraoperative MR imaging, and the applicator was deflated and removed prior to standard interstitial therapy, all after obtaining informed consent on an Internal Review Board (IRB) approved protocol.

Extent of the fornices was measured with and without the sleeve. The sleeve was contoured. Planning of 1-, 3-, and 5-catheter configurations of the balloon-sleeve applicator insertion was performed. Inverse planning simulated annealing optimization was performed with equal weighting. Each configuration was optimized using the following optimization constraints: minimum dose to the sleeve surface of 100% of the prescription dose, maximum dose to the sleeve surface of 150% of the prescription dose, maximum dose to the rectum and sigmoid of 70% of the prescription dose, and maximum dose to the bladder of 90% of the prescription dose. The minimum dose to the sleeve surface and the minimum dose in the most irradiated 2-cm³ volume (D_{2cc}) of rectum, bladder, and sigmoid are reported.

**Results**

**Theoretical evaluation**

Results of the theoretical evaluation are summarized in Table 1 and Table 2. The standard cylinder plan had a rectal dose of 76%. EQD2 rectal dose was 34 Gy (6 Gy x 5 regimen) and 22 Gy (4 Gy x 6). Apex dose was 119%. The fornix dose was 44%, indicating that in a straight line geometry not targeting the vaginal fornices, located 10 mm from a 35 mm cylinder received 44% of the prescription dose. The 1-catheter configuration (cylinder + sleeve), with targeting of the deep vaginal fornices, achieved a fornix dose of 93%. Although this configuration showed an improvement in fornix coverage compared to the standard cylinder plan (93% vs. 44%), the rectal dose was more than double that of the standard cylinder rectal dose (194%). EQD2 rectal dose was 170 Gy (6 Gy x 5) and 100 Gy (4 Gy x 6), which is clinically unacceptable. Moreover, an overdose of the apex up to 312% of the prescription dose was observed. The high values of the apex and rectal doses were due to the inability of the 1-catheter configuration to acceptably conform the 100% isodose line to the complex target geometry of the deep vaginal fornices as delineated by the balloon-sleeve applicator.

Of the 3-catheter configurations, those with a distance \(d\) between balloon surface and side catheters equal to 5 mm and 7.5 mm were associated with the best results. The 5-mm 3-catheter configuration achieved coverage of 109% of the deep vaginal fornices, with rectal doses of 98% and an apex dose of 109%. EQD2 rectal dose was
Table 1. Summary of maximum surface dose, fornix dose, apex dose, and rectal dose for all configurations. Values are reported as % of the minimum dose to the target surface. The target surface is the sleeve surface for the 1-catheter, 3-catheter, and 5-catheter configurations, and is the vaginal cylinder surface for the standard cylinder plan. Rectal dose is also reported in Gy, as an EQD2 calculation with $\alpha/\beta = 3$. A value of 100% is desirable for the fornix and apex dose. The standard cylinder plan does not target the vaginal fornices, whereas the cylinder + sleeve configuration targets the vaginal fornices delineated by the balloon surface.

| Configuration          | Maximum surface dose (%) | Fornix dose (%) | Apex dose (%) | Rectal dose |
|------------------------|--------------------------|----------------|---------------|-------------|
|                        |                          |                |               | Gy (EQD2)   |
|                        |                          |                |               | Gy (EQD2)   |
|                        |                          |                |               | 6 Gy × 5 regimen | 4 Gy × 6 regimen |
| Standard cylinder plan | 169                      | 44             | 119           | 76          | 34            | 22            |
| 1-catheter (cylinder + sleeve) | 444                  | 93             | 312           | 194        | 170           | 100          |
| 3-catheter (d = 0 mm)  | 480                      | 579            | 134           | 116        | 69            | 43            |
| 3-catheter (d = 2.5 mm) | 198                    | 194            | 109           | 110        | 63            | 39            |
| 3-catheter (d = 5 mm)  | 178                      | 109            | 109           | 98         | 52            | 33            |
| 3-catheter (d = 7.5 mm) | 165                     | 90             | 102           | 94         | 49            | 31            |
| 3-catheter (d = 10 mm) | 179                      | 89             | 120           | 99         | 53            | 33            |
| 3-catheter (d = 12.5 mm) | 191                    | 86             | 137           | 104        | 58            | 36            |
| 3-catheter (d = 15 mm) | 208                      | 90             | 149           | 114        | 67            | 41            |
| 5-catheter coplanar    | 164                      | 96             | 107           | 91         | 46            | 29            |
| 5-catheter cross       | 179                      | 105            | 99            | 101        | 55            | 34            |

Table 2. Loading of each catheter in the theoretical configuration

| Configuration          | Percent loading (catheter TRAK/total TRAK), per catheter |
|------------------------|----------------------------------------------------------|
|                        | Central catheter (%) | Outer left/right catheters (%) | Inner left/right catheters (%) | Anterior/posterior catheters (%) |
| Standard cylinder plan | 100             | –                 | –                        | –                        |
| 1-catheter (cylinder + sleeve) | 100            | –                 | –                        | –                        |
| 3-catheter (d = 0 mm)  | 89.9            | 5.1               | –                        | –                        |
| 3-catheter (d = 2.5 mm) | 87.3            | 6.4               | –                        | –                        |
| 3-catheter (d = 5 mm)  | 77.2            | 11.4              | –                        | –                        |
| 3-catheter (d = 7.5 mm) | 70.0            | 15.0              | –                        | –                        |
| 3-catheter (d = 10 mm) | 56.6            | 21.7              | –                        | –                        |
| 3-catheter (d = 12.5 mm) | 35.6            | 32.2              | –                        | –                        |
| 3-catheter (d = 15 mm) | 26.5            | 36.8              | –                        | –                        |
| 5-catheter coplanar    | 50.4            | 19.3              | 5.6                      | –                        |
| 5-catheter cross       | 72.7            | 11.3              | –                        | 2.4                      |

TRAK – total reference air kerma

52 Gy (6 Gy × 5) and 33 Gy (4 Gy × 6). Hot spots exceeding 150% occur at the fornices when 3-catheter configurations with a separation between balloon surface and external catheters ≤ 2.5 mm are used, suggesting that these configurations may not be appropriate for clinical use. Our results indicate that targeting of the vaginal fornices with 3-catheter configurations with a distance between catheters and balloon surface > 2.5 mm is clinically feasible. Nevertheless, the increased dose to the deep vaginal fornices (from 44% to 109%) was accompanied by an increase in rectal dose (from 76% to 98%), suggesting that the use of the balloon-sleeve applicator should be considered only in patients who have deep fornices on clinical examination, or those with gross disease in the fornix area requiring 100% dose. The percent catheter loading (Table 2) shows that the use of the 2 lateral catheters increases with their distance from the balloon surface, from 5.1% per catheter for $d = 5$ mm to 36.8% for $d = 15$ mm. The 5-catheter configurations showed an improvement over the 3-catheter configuration (Table 1). EQD2 rectal dose for the coplanar configuration was 46 Gy (6 Gy × 5) and 29 Gy (4 Gy × 6). The percent catheter loading (Table 2) shows that the anterior/posterior catheters of the 5-catheter cross configuration account each for only 2% of the total TRAK, making this configuration loading similar to the 3-catheter configuration with $d = 7.5$ mm.
In patient evaluation

With a standard obturator, air gaps of 13.0 mm were noted in the anterior-posterior dimension at the vaginal cuff, which were filled with the expanded sleeve to 21.5 mm (Fig. 3). The minimum dose to the sleeve surface and the rectum, bladder and sigmoid $D_{2cc}$ from the geometries under consideration are reported in Table 3. The difference between the minimum sleeve surface dose and the $D_{2cc}$ doses of the organs, which provides an indication of the therapeutic ratio, was negative for the 1-catheter configuration. This finding confirms that a 1-catheter configuration cannot be used with the proposed balloon-sleeve geometry. A 3-catheter (with 7.5 mm between catheters and sleeve surface) and a 5-catheter configuration provided a minimum dose to the sleeve surface higher by 14% and 23%, respectively, than the rectum $D_{2cc}$ dose.

Discussion

We described novel multi-catheter sleeve balloon applicator designs with the goal of evaluating the coverage of the vaginal fornices. We showed that a vaginal cylinder cannot be used to target deep vaginal fornices. Three- and 5-catheter configurations provided clinically acceptable dose to the rectum and dose inhomogeneity with coverage of the vaginal fornices exceeding 90% of the prescription dose (vs. 44% for a standard cylinder plan) but all configurations presented a rectal dose exceeding the standard cylinder rectal dose. Therefore, potential use of this applicator will likely be limited to patients who have deep fornices on clinical examination, or those with gross disease in the fornix area requiring 100% dose.

The American Brachytherapy Society Consensus Guidelines for vaginal-cuff brachytherapy [1] indicate that the shape of the vagina is a consideration in applicator selection. Domed cylinders are indicated for routine use given the generally cylindrical shape of the vagina. The use of vaginal ovoids may be considered in cases where surgical remnants of the vaginal fornices cannot be dosed satisfactorily with a domed cylinder [1]. The use of ovoids in selected cases [11], as a routine choice [12,13] or in combination with a vaginal cylinder, has been re-

### Table 3. Clinical evaluation of doses to the vaginal surface and to the rectum, bladder, and sigmoid for various catheter configurations of the balloon-sleeve applicator in one patient. These data show that this balloon applicator cannot be effectively used with only one central catheter. Three- and 5-catheter configurations can be considered given a minimum dose > 80% of the prescription dose. All results are expressed as a % of the prescription dose

| Configuration          | Dose to the sleeve surface | Rectum $D_{2cc}$ [%] | Bladder $D_{2cc}$ [%] | Sigmoid $D_{2cc}$ [%] |
|------------------------|----------------------------|----------------------|-----------------------|-----------------------|
|                        | Minimum (%) | Maximum (%)          | Minimum (%) | Maximum (%)          | Minimum (%) | Maximum (%)          | Minimum (%) | Maximum (%)          |
| 1-catheter (cylinder + sleeve) | 36  | 196  | 73  | 49  | 16  |
| 3-catheter ($d = 0$ mm) | 63  | 440  | 64  | 46  | 16  |
| 3-catheter ($d = 2.5$ mm) | 71  | 183  | 65  | 47  | 16  |
| 3-catheter ($d = 5$ mm) | 78  | 166  | 66  | 50  | 17  |
| 3-catheter ($d = 7.5$ mm) | 80  | 161  | 66  | 51  | 18  |
| 3-catheter ($d = 10$ mm) | 70  | 167  | 67  | 52  | 18  |
| 3-catheter ($d = 12.5$ mm) | 63  | 174  | 68  | 53  | 19  |
| 3-catheter ($d = 15$ mm) | 58  | 186  | 72  | 56  | 19  |
| 5-catheter coplanar    | 90  | 156  | 67  | 52  | 18  |
| 5-catheter cross       | 81  | 185  | 68  | 51  | 18  |
ported. The Consensus Guidelines describe limitations of the use of ovoids for vaginal-cuff treatment, such as under-dosage at the central apex [14], dose heterogeneity, and difficulty in treating the lower vagina. Those problems may contribute to less frequent adoption of vaginal ovoids compared to domed cylinders.

The ABS Consensus Guidelines for vaginal cancer [5] suggest that lesions with a thickness exceeding 5 mm cannot adequately be treated with a vaginal cylinder. Similarly, fornices extending more than 5 mm from the vaginal wall cannot be fully covered with a single-channel cylinder without overdosing the apex of the vagina. Although in most cases acceptable coverage of the fornices may be achieved, this may not be the case when the fornices are unusually large, or when residual vaginal disease in one or both fornices must be covered with 100% of the dose.

Multiple designs of multi-channel alternatives to the single-channel domed cylinder have been proposed [15-17]. Examples are the California Endocurietherapy multi-channel applicator [16], the Nucletron Vaginal CT-MR Multi Channel Applicator (Nucletron, an Elekta company), the GynSite™ intracavitary balloon (Hologic Inc., Bedford, MA, USA) [18], and the Capri™ Applicator (Varian Medical Systems) [19,20]. The Capri™ applicator has similarities to the design discussed in this paper, as both are multi-channel balloon-based designs. However, the two designs differ in many respects. The balloon shape of the Capri™ is designed to expand into a roughly cylindrical geometry, and does not offer solutions for air gaps and reproducibility in the vaginal fornices area. While these commercially available balloon applicators can eliminate air gaps along the length of the vagina, the proposed design studied in this paper is unique in its shape by the vaginal vault allowing expansion in the fornices. As the applicator expands into the fornices, fraction-to-fraction rotation of the applicator may be minimized compared to other isotropic-shaped balloon applicators, and variability in the shape of the fornices may also be minimized. The reproducibility of the setup for the balloon-sleeve applicator has not been studied in this work, and will need to be validated. The expansion of the balloon into the fornices may result in an increased dose to the apex in a single-channel design, as the target tissue is pushed further away from the central catheter and the loading of the tip dwell location is increased accordingly. In our work, we observed a 2.6 fold increase in dose to the vaginal apex (from 119% of the prescription dose to 312%) when a single-channel geometry was used to target the fornices delineated by the balloon-sleeve applicator compared to vaginal-cuff brachytherapy targeting the cylinder surface. The increase of the dose to the rectum (from 76% of the prescription dose to 194%) is associated with a clinically unacceptable rectal dose, given an EQD2 dose of 164 Gy if the 6 Gy × 5 regimen is used, or 97 Gy if the 4 Gy × 6 regimen is used. These results indicate that a standard vaginal cylinder with or without the balloon-sleeve cannot be used to properly dose deep vaginal fornices. Therefore, multi-channel designs are advisable.

The 3-catheter configuration had a central catheter and 2 lateral catheters each positioned 5 mm away from the balloon surface. The rectal dose for this configuration was 98% of the prescription dose, the apex dose was 109% of the prescription dose, and the fornix dose was 109% of the prescription dose. The rectal dose associated with this configuration was 52 Gy (6 Gy × 5) or 33 Gy (4 Gy × 6), which is clinically acceptable. These results show that the 3-catheter configuration provides coverage of the deep vaginal fornices with clinically acceptable doses to rectum and apex. Nevertheless, the rectal dose was higher than the 34 Gy (6 Gy × 5) or the 22 Gy (4 Gy × 6) associated with standard vaginal-cuff brachytherapy not targeting the vaginal fornices. Furthermore, 3-catheter geometry is more demanding on clinic resources than single-catheter geometry. However, deep vaginal fornices received 109% of the prescription dose (given a 5-mm separation between catheters and balloon surface) against only 44% in a standard cylinder. In geometries where the vaginal fornices are closer to the cylinder, it is expected that the difference in coverage will be less pronounced. The 3-catheter geometry offers a reasonably simple alternative to the use of cylinder or ovoids for the treatment of selected cases, providing coverage of both the deep vaginal fornices and the lower vagina and the elimination of air gaps, with simple insertion and positioning. A linear arrangement of 5 catheters provides slightly better dosimetry than the 3-catheter arrangement. The slight dosimetric advantage provided by the 5-catheter configuration may not justify the added cost and clinical complexity of two extra catheters.

A review of an MR of a patient with the balloon-sleeve applicator in place confirmed that the balloon deploys correctly into the vaginal fornices. A planning study of this patient configuration confirmed that a single central catheter cannot be used in conjunction with this balloon shape, as it would result in doses to the normal tissues exceeding the minimum dose to the fornices. Both 3- and 5-catheter geometries were associated with a minimum dose to the fornices higher than the D2cc doses for the normal tissues. The planning study in a patient confirmed that a higher dose to the fornices can be given using the 5-catheter geometry (23% more than the rectum D2cc as compared to 14% for the 3-catheter geometry), although it is unclear if this advantage would be clinically meaningful.

This theoretical study of the dosimetric characteristics of an applicator using a novel balloon shape for the filling of vaginal fornices shows that while a single channel does not provide an acceptable treatment option for this geometry, a 3-channel or 5-channel configuration may be considered. This study will be the basis for further development of such an applicator. A limitation of this study is its theoretical nature, and actual dose to patients will vary based on patient geometry and optimization techniques. The evaluation of data from one patient presented in this work exemplifies the potential of the proposed geometry, but further data based on insertion of a multi-catheter applicator in multiple patients must be analyzed in the future for clinical validation. Moreover, while IPSA
planning was used in this theoretical study to eliminate potential bias in the optimization process, different optimization techniques may be explored. Finally, additional clinical data will provide information on the filling of the vaginal fornices by this applicator design. In particular, asymmetric filling is possible in cases with fornices of different sizes. The presence of independent channels in the two fornices allows for independent dosing in both the 3- and 5-catheter configurations.

Conclusions

A 3-catheter inflatable applicator, which expands into the vaginal fornices, offers the possibility of increasing coverage to deep vaginal fornices while minimizing the apex dose. Clinically acceptable rectal doses can be achieved, although in general the rectum would receive more dose than in standard vaginal-cuff brachytherapy not targeting the vaginal fornices. Theoretical analysis on an idealized geometry and on a representative patient anatomy showed that this design may allow the treatment of areas currently unreachable to existing intracavitary applicators, but its use should be limited to patients needing 100% dose coverage of the deep vaginal fornices. The slight dosimetric advantage provided by the 5-catheter configuration may not justify the added cost and clinical complexity of two extra catheters.

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Disclosure

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