

## Original Article

# Bladder–Rectum Spacer Balloon versus Vaginal Gauze Packing in High Dose Rate Brachytherapy in Cervical Cancer: A Randomised Study (Part II)



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## Abstract

**Aims:** To compare the inter-fraction dose variation for bladder and rectum using a bladder–rectum spacer balloon (BRSB) versus vaginal gauze packing (VGP) in patients treated with high dose rate intracavitary brachytherapy for carcinoma cervix.

**Materials and methods:** After the completion of external radiotherapy, 80 patients were randomised to receive intracavitary brachytherapy using either the BRSB or VGP. The procedure was carried out under general anaesthesia using tandem ovoid applicators. Computed tomography-based planning was carried out and the dose was prescribed to point A. Doses to 0.1, 1 and 2 cm<sup>3</sup> volumes were reported for bladder and rectum for each fraction. The absolute inter-fraction dose variation for each subvolume was compared using the independent sample *t*-test.

**Result:** The mean bladder and rectal volumes, as well as the inter-fraction volume variation, were comparable for the BRSB and VGP. The BRSB resulted in a significant reduction in absolute dose as well as the inter-fraction variation for dose to 2 cm<sup>3</sup> rectum volumes (BRSB 0.80 Gy, standard deviation 0.71 Gy versus VGP 1.16 Gy, standard deviation 0.83 Gy; *P* = 0.04). Cumulative bladder D2cm<sup>3</sup> doses of more than 90 Gy<sub>3</sub> were observed in six patients in the BRSB arm versus four patients in the VGP arm (*P* = 0.73). In both the arms, the rectal D2cm<sup>3</sup> doses did not exceed 75 Gy<sub>3</sub>.

**Conclusions:** Use of a BRSB resulted in a significant reduction in inter-fraction variation in D2cm<sup>3</sup> rectal dose. However, no significant difference in the inter-fraction dose variation for the other subvolumes of bladder and rectum could be shown between the BRSB and VGP. The use of a BRSB may enable rectal dose reduction and inter-fraction variation where anaesthesia is not routinely used or where there is limited physician expertise. The modification suggested in the BRSB may facilitate its additional usage.

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**Key words:** Bladder–rectum spacer balloon; brachytherapy; cervical cancer; inter-fraction dose variation

## Introduction

Intracavitary brachytherapy is an integral part of curative radiation therapy for cervical cancer. Recent advances in magnetic resonance imaging-guided image-based

brachytherapy have allowed us to conform the brachytherapy dose to both volume (three-dimensional) and time (four-dimensional) [1,2]. Repeated imaging is advised for each fraction, as significant dose variation may occur due to the inter-fraction and intra-fraction variation in the organs at risk (OAR) doses [3,4]. Inter-fraction dose variation may occur due to geometrical variations or organ deformation. Among these, geometric variations result from the change in applicator type or placement geometry and depend on physician expertise [3]. Traditionally, vaginal packing with gauze has been used for displacing the bladder and rectum

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away from the vaginal sources. This simple and cost-effective procedure helps to reduce doses to these OARs and facilitates in stabilising the applicator position [5]. Although vaginal gauze packing (VGP) is a reliable method to push the bladder and rectum away from the applicators, it lacks reproducibility and is dependent on the physician's expertise for proper placement. Unsatisfactory and variable vaginal packing may not only result in increased normal tissue toxicity secondary to increased OAR doses, but has been associated with reduced disease-free survival rates [6].

Various balloon-based systems and rectal retractors have been devised for use in cervical cancer brachytherapy [5,7–9] to overcome these limitations with VGP. In our previously published experience with the bladder–rectum spacer balloon (BRSB), the BRSB was used alternately with VGP in the same patient. We observed decreased doses to the rectum with the use of a BRSB as compared with VGP [10]. In the present study, which was planned as the second part of the first trial, we hypothesised that use of a BRSB would allow us to reduce the inter-fraction dose variation as compared with VGP. The aim of this study was to assess the reproducibility of the BRSB by comparing the inter-fraction dose variation for the bladder and rectum using a BRSB as compared with VGP.

## Materials and Methods

### *Study Design and Setting*

This was a prospective, randomised (1:1), open-label, parallel group trial conducted between April 2013 and March 2014. The trial protocol was approved by the institutional review board and was registered with the Clinical Trial Registry of India (CTRI/2009/091/000840). The study was carried out in a single tertiary care academic institution in India.

### *Study Population*

Patients with squamous cell cancers of the uterine cervix FIGO (2009) stage IIb–IIIb undergoing high dose rate (HDR) brachytherapy, after definitive chemoradiation, at our centre were eligible for inclusion. Patients treated with adjuvant radiotherapy or those treated with intracavitary brachytherapy after subtotal hysterectomy were excluded. Patients with early stage cervical cancer typically treated with interdigitated external beam radiotherapy and brachytherapy were also excluded. All participants were required to give written informed consent before inclusion in the trial.

### *Study Intervention*

Computed tomography-based conformal planning was carried out and the patients were treated with three-dimensional conformal or intensity-modulated radiotherapy. A dose of 46 Gy was prescribed over 4.5 weeks. Concurrent cisplatin (40 mg/m<sup>2</sup>) was administered weekly throughout the course of external radiotherapy.

Brachytherapy was carried out within 1 week of the completion of external radiotherapy. Two fractions of HDR brachytherapy were delivered 1 week apart and the dose prescribed per fraction was 9 Gy to point A [11]. The overall treatment time was kept within 7 weeks.

### *Randomisation*

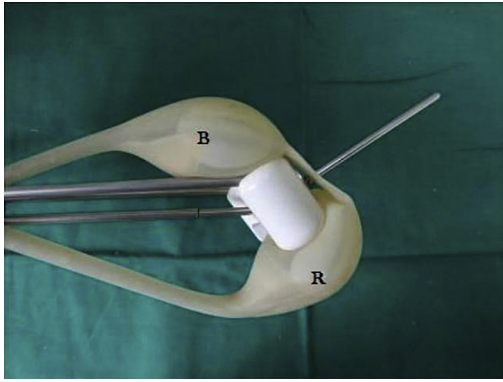
Patients were randomised into two arms after the completion of external beam radiotherapy using a computer-generated online randomisation sequence using a random number calculator (<http://www.graphpad.com/quickcalcs/index.cfm>).

### *Brachytherapy*

In one arm, the BRSB was used in both the HDR fractions (BRSB) and in the second arm VGP was used for both the HDR fractions.

The brachytherapy procedure was carried out under general anaesthesia. All patients received a standard bowel preparation regimen comprising a low residue diet beginning 24 h before the procedure: Bisacodyl (10 mg) tablets at night and a soap water enema 4 h before the procedure in the morning. The patients were placed in a lithotomy position and the bladder was catheterised with an indwelling Foley's catheter. An examination under anaesthesia was carried out to assess the local anatomy and to document the clinical findings. The position of the uterus was verified using ultrasound. The length of the uterine cavity was assessed with the help of uterine sound. The application was carried out using the Nucletron HDR tandem ovoid applicator (Nucletron, Veenendaal, the Netherlands) with tandem lengths of 6, 5 and 4 cm. Tandem placements were carried out under ultrasound guidance to prevent perforation.

In the VGP arm, standard VGP was carried out both anterior and posterior to the ovoids to ensure maximum displacement of the bladder and rectum and the vaginal cavity was packed to stabilise and immobilise the applicator. In the BRSB arm, the balloon was completely deflated and checked for any leaks. It was then placed over the tandem and inserted together with it in the vaginal cavity. Once the ovoids were inserted, the balloons were positioned such that the bladder and the rectal part of the balloon lay above and below the ovoids, respectively [12]. After checking the position of the applicator, the bladder and the rectal part of the balloons were filled separately with diluted contrast (60–70 ml saline mixed with 4–5 ml iodinated contrast); 10 ml diluted saline was alternately inserted in the bladder and the rectal part of the balloon up to 25–30 ml in each balloon depending on vaginal capacity (Figure 1). Filling of the balloons was stopped once vaginal resistance was felt. The applicator was pushed steadily against the external os throughout the filling of the balloon to prevent applicator displacement. Minimal packing was done with dry gauze in the distal vagina to stabilise the applicator. Labial sutures and T-bandage were applied to immobilise the application. The balloon filling was kept constant for both fractions. Three experienced operators (with individual experience



**Fig 1.** Figure showing the bladder–rectum spacer balloon with the bladder (B) and rectal (R) part joined together by latex adhesive through which the uterine tandem is inserted.

ranging from 16 to 35 years) carried out the brachytherapy procedure. For a given patient, the same applicator was used for both the HDR fractions and both applications were carried out by a single physician.

Computed tomography was carried out after the brachytherapy procedure. A reproducible bladder filling protocol was followed before the scan and patient treatment. The bladder was first emptied under gravity and 50 ml saline was inserted in the bladder. It was then allowed to drain freely under gravity [13]. Computed tomography sections were taken at 2.5 mm intervals from the level of 3–4 cm above the fundus superiorly to the level of ischial tuberosities inferiorly. The computed tomography scans were transferred to the Oncentra treatment planning system. OAR, namely the bladder, rectum and sigmoid, were contoured on computed tomography at each fraction, as recommended by the GEC-ESTRO guidelines [2]. Applicators were reconstructed on the computed tomography scan on the multiplanar reconstruction views, as previously described [14,15]. A dose of 9 Gy was prescribed to point A. Doses to 0.1, 1, 2 and 5 cm<sup>3</sup> volumes for the bladder, rectum and sigmoid were documented at each fraction. Optimisation was carried out in order to meet the OAR constraints and ensure optimum coverage of the target. The patients were treated with optimised plans. For the purpose of the present study, unoptimised dosimetric data were recorded for these values for both bladder and rectum. For calculating the cumulative linear quadratic equivalent dose at 2 Gy (LQED2) the doses given at each session of brachytherapy for the 2 cm<sup>3</sup> volumes of rectum and bladder were converted using the formula:

$$\text{LQED2} = d(1 + d/3)/(1 + 2/3)$$

where,  $d$  is the dose in the given fraction.

The cumulative doses were calculated by adding the brachytherapy doses to the external beam dose of 46 Gy in 23 fractions (external beam EQD2 = 46 Gy<sub>3</sub>).

### Outcome

The primary end point of the study was to evaluate the absolute dose variation between various subvolumes of

bladder and rectum between the two brachytherapy fractions in the two arms. The absolute dose variation was calculated for each subvolume of bladder and rectum by taking the absolute value (modulus) of the difference in the doses between the first and second fraction of brachytherapy for the particular session. Thus,

$$\text{Intersession variation in } D_{2\text{cm}^3} \text{ for rectum (VarRectumD}_{2\text{cm}^3}) = D_{2\text{cm}^3} \text{ rectum session 1} - D_{2\text{cm}^3} \text{ rectum session 2}$$

$$\text{Absolute variation in } D_{2\text{cm}^3} \text{ for rectum} = |\text{VarRectumD}_{2\text{cm}^3}|$$

The choice of reporting the absolute variation stemmed from the fact that mean values of the actual variation would be influenced by the sign (as the dose in the second session may be more or less than the first session dose).

Secondary end points included: (i) variation in the volumes for the OAR: calculated as the absolute value of the difference in the volumes of rectum and bladder in between the session; (ii) percentage variation in the dose between sessions: calculated as the ratio of the absolute dose variation to a given subvolume to that of the first session dose and expressed as a percentage; (iii) proportion of patients in each arm with bladder 2cm<sup>3</sup> EQD2 exceeding 90 Gy<sub>3</sub>; (iv) proportion of patients in each arm with rectal 2cm<sup>3</sup> EQD2 exceeding 75 Gy<sub>3</sub>; (v) impact of ovoid size used on the dose variation in each arm.

### Statistical Methods

To detect a reduction by 100 cGy in the organ dose in the BRSB arm as compared with VGP with a two-sided 5% significance level and a power of 80%, a sample size of 30 patients was necessary in part I of this trial. We decided to keep the same sample size plus 10 patients in each arm for the present study, as we did not have data regarding the baseline dose variation between two session for patients treated with the gauze packing protocol.

Descriptive statistics were reported for the mean with standard deviation for continuous variables. The Shapiro Wilk's test was used to test normality assumptions for all continuous variables. The differences between the mean of continuous variables between the two arms were calculated using independent sample  $t$ -test with  $P < 0.05$  taken as significant. All statistical analyses were conducted using the R software (R Foundation for Statistical Computing, Vienna, Austria).

## Results

Of the 87 eligible patients, 84 were randomised and 80 were evaluable (Figure 2).

### Volume and Dose Variation between Fractions

The mean bladder volume variation between sessions was 22.0 cm<sup>3</sup> (standard deviation 15.0 cm<sup>3</sup>) in the BRSB arm versus 20.9 cm<sup>3</sup> (standard deviation 17.0 cm<sup>3</sup>) in the VGP

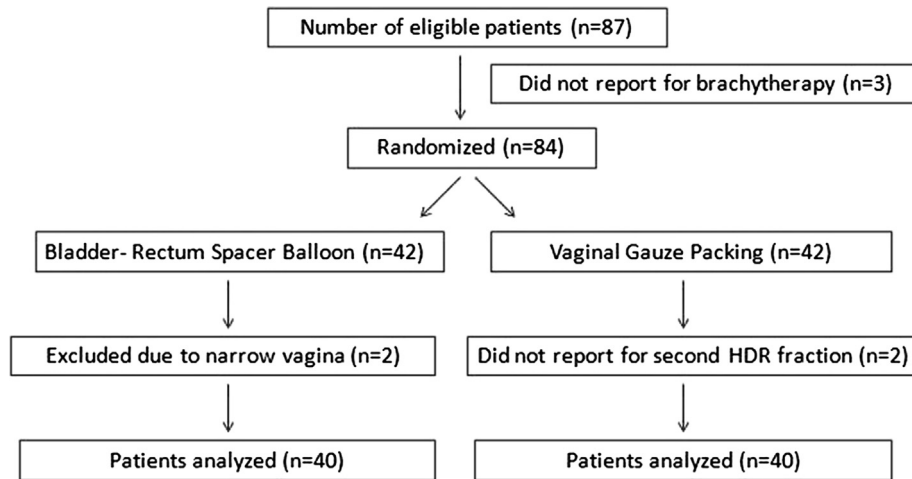


Fig 2. CONSORT flow chart.

arm ( $P = 0.69$ ). The mean intersession variation in the rectal volume was  $11.9 \text{ cm}^3$  (standard deviation  $9.2 \text{ cm}^3$ ) for the BRSB arm versus  $9.95 \text{ cm}^3$  (standard deviation  $6.9 \text{ cm}^3$ ) for the VGP arm ( $P = 0.29$ ).

The difference in dose to each subvolume of bladder and rectum was calculated between the first and next fractions and the absolute dose variation was used. A significant reduction in the absolute dose and variation was observed for the  $D2\text{cm}^3$  rectum with the BRSB ( $P = 0.04$ ) (Table 1). The percentage intersession dose variation in the bladder  $D2\text{cm}^3$  dose was 15% (standard deviation 13%) in the BRSB arm versus 16% (standard deviation 14%) in the VGP arm ( $P = 0.73$ ). The mean percentage intersession dose variation in the rectal  $D2\text{cm}^3$  dose was 21% (standard deviation 21%) in the BRSB arm versus 26% (standard deviation 21%) in the VGP arm ( $P = 0.22$ ).

#### Cumulative Doses to Bladder and Rectum

Table 2 shows the cumulative doses received by the various subvolumes of bladder and rectum for the two sessions. The cumulative bladder EQD2 for  $2 \text{ cm}^3$  volume

exceeded  $90 \text{ Gy}_3$  for six patients in the BRSB arm versus four patients in the VGP arm ( $P = 0.73$ ). However, the cumulative rectal EQD2 for  $2 \text{ cm}^3$  volume did not exceed  $75 \text{ Gy}_3$  for any patient in either arm (Table 2).

The bladder dose was reduced in the second session in 20 (50.0%) patients in the BRSB arm versus 22 (55.0%) patients in the VGP arm ( $P = 0.82$ ). The rectal dose was reduced in the second session in 14 (35.0%) patients in the BRSB arm versus 20 (50.0%) patients in the gauze arm ( $P = 0.26$ ).

#### Dose Variation Depending on the Ovoid Used

Of the 40 patients in each arm, four patients each in the BRSB arm and the VGP arm had a narrow vagina for which half ovoids were used. No statistically significant differences could be shown in the absolute doses and cumulative doses to the bladder and rectum among these four patients between the two arms.

For the bladder, a lesser inter-session dose variation was observed with the BRSB as compared with VGP in applications using half ovoids. As compared with full ovoids, a larger variation in bladder doses was observed with VGP

Table 1

Absolute dose variation between fractions (Gy) with 95% standard deviation values for bladder and rectum with bladder–rectum spacer balloon (BRSB) and vaginal gauze packing (VGP)

	BRSB		VGP		P Value
	Mean (Gy)	Standard deviation (Gy)	Mean (Gy)	Standard deviation (Gy)	
Bladder					
0.1 $\text{cm}^3$	2.24	2.06	2.13	1.82	0.81
1 $\text{cm}^3$	1.38	1.25	1.41	1.15	0.89
2 $\text{cm}^3$	1.13	0.98	1.21	0.97	0.70
Rectum					
0.1 $\text{cm}^3$	1.46	1.11	1.53	1.23	0.79
1 $\text{cm}^3$	0.96	0.84	1.12	0.88	0.40
2 $\text{cm}^3$	0.80	0.71	1.16	0.83	0.04*

0.1, 1 and  $2 \text{ cm}^3$  represent the minimum dose to 0.1, 1 and  $2 \text{ cm}^3$  volumes, respectively.

\* Statistically significant  $P$  value.

**Table 2**

Mean cumulative doses with 95% standard deviation values for bladder and rectum with bladder–rectum spacer balloon (BRSB) and vaginal gauze packing (VGP)

	BRSB		VGP		P value
	Mean (Gy <sub>3</sub> )	Standard deviation (Gy <sub>3</sub> )	Mean (Gy <sub>3</sub> )	Standard deviation (Gy <sub>3</sub> )	
Bladder					
0.1 cm <sup>3</sup>	108.3	18.7	107.5	19.1	0.85
1 cm <sup>3</sup>	88.3	10.5	87.5	10.9	0.75
2 cm <sup>3</sup>	81.6	8.3	80.8	8.7	0.68
Rectum					
0.1 cm <sup>3</sup>	66.9	9.0	71.2	11.5	0.07
1 cm <sup>3</sup>	61.3	5.9	63.9	7.5	0.08
2 cm <sup>3</sup>	59.3	4.8	61.2	5.3	0.09

0.1, 1 and 2 cm<sup>3</sup> represent the minimum dose to 0.1, 1 and 2 cm<sup>3</sup> volumes, respectively. Gy<sub>3</sub> = dose in EQD2 assuming  $\alpha/\beta$  ratio of 3.

using half ovoids. For rectum, on the other hand, the dose variation with full ovoid applications was less as compared with half ovoid applications with the BRSB (Table 3).

## Discussion

In the present study, we tried to compare the inter-fraction dose variation with a BRSB compared with VGP. To our knowledge, this is the first prospective randomised study comparing the inter-fraction dose variations using the BRSB versus VGP. The results of the study indicate that use of the BRSB results in a significant reduction in inter-fraction variation for the rectal D<sub>2cm<sup>3</sup></sub>. Taken together with the results of our previous study, use of the BRSB results in a significant reduction in the dose as well as the inter-fraction dose variation for D<sub>2cm<sup>3</sup></sub> of rectum [10].

We used identical applicators for both the fractions and a fixed bladder filling protocol was followed. A single physician carried out all applications. Hellebust *et al.* [16], in a

study comparing inter-fraction bladder and rectum volumes, reported a large variation in bladder volumes and highlighted the need for a fixed bladder filling protocol.

Although the inter-fraction variations in bladder and rectal volumes were comparable in both arms, larger inter-fraction variations were observed in the bladder volume as compared with rectum. Similar to our experience, Jamema *et al.* [17] also reported a low inter-fraction variation for rectum as compared with bladder. The average variation in bladder volumes was nearly 10 cm<sup>3</sup> lower than our previously reported experience, although the variation in rectal volume was nearly similar [3].

Unlike rectum, no difference was observed for inter-fraction variation in doses to the bladder between BRSB and VGP. The reasons for this difference are related to limitations of the BRSB. As shown in Figure 3, the anterior balloon fails to expand uniformly with greater expansion below the level of the ovoids. As a result, the bladder fails to be displaced anteriorly. This phenomenon is especially evident in patients with a narrow conical vagina where

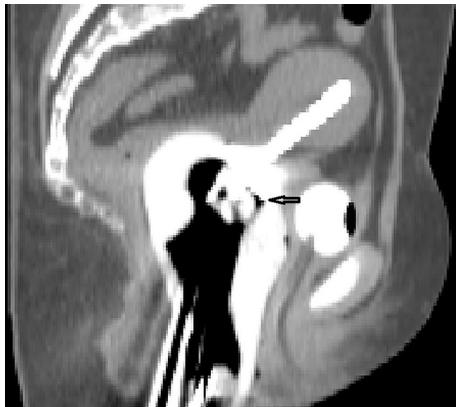
**Table 3**

Absolute mean dose variation (Gy) with 95% standard deviation values for bladder and rectum with bladder–rectum spacer balloon (BRSB) and vaginal gauze packing (VGP) depending on the type of ovoids used

	Ovoids	BRSB		VGP	
		Mean (Gy)	Standard deviation (Gy)	Mean (Gy)	Standard deviation (Gy)
Bladder					
0.1 cm <sup>3</sup>	FO	2.31	2.15	2.10	1.84
	HO	1.64	0.91	2.49	1.87
1 cm <sup>3</sup>	FO	1.43	1.30	1.41	1.16
	HO	0.84	0.66	1.44	1.22
2 cm <sup>3</sup>	FO	1.17	1.01	1.20	0.97
	HO	0.74	0.69	1.27	1.07
Rectum					
0.1 cm <sup>3</sup>	FO	1.43	1.13	1.54	1.25
	HO	1.76	0.85	1.39	1.08
1 cm <sup>3</sup>	FO	0.95	0.83	1.11	0.88
	HO	1.09	0.99	1.30	0.90
2 cm <sup>3</sup>	FO	0.79	0.70	1.17	0.85
	HO	0.88	0.97	1.03	0.67

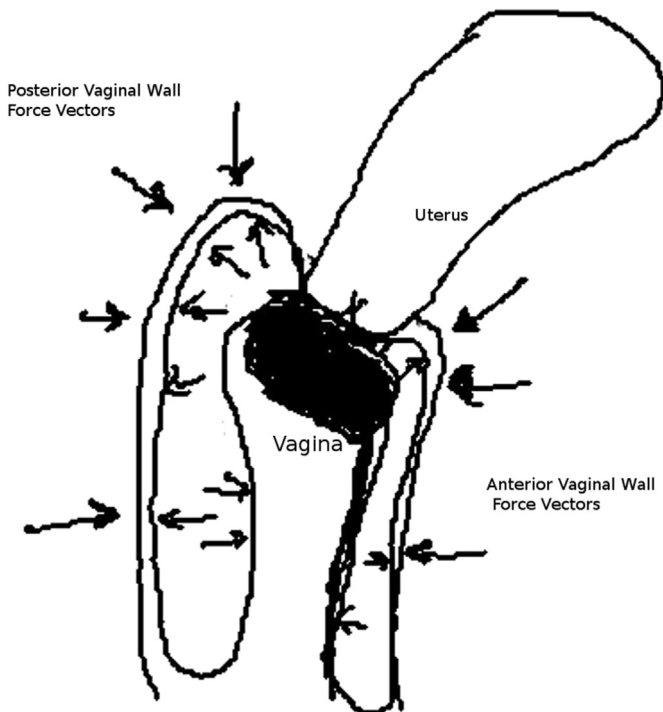
FO, full ovoids; HO, half ovoids.

0.1, 1 and 2 cm<sup>3</sup> represent the minimum dose to 0.1, 1 and 2 cm<sup>3</sup> volumes, respectively.



**Fig 3.** Coronal computed tomography section depicting the asymmetrical expansion of the balloon in front of the ovoids resulting in reduced displacement of the posterior bladder wall.

there is limited distensibility of the vaginal wall. In the case of the rectum, the balloon expands in a uniform manner in the posterior fornix, allowing greater displacement of the rectum. This is of course related to the anatomy of the posterior fornix, which has a greater capacity as compared with the anterior fornix (Figure 4). In order to overcome this issue, the anterior balloon shape needs to be modified so that the expansible portion is limited in length so that expansion occurs in the region anterior to the ovoids.



**Fig 4.** Diagram showing the orientation of the force vectors around the bladder–rectum spacer balloon (BRSB) after filling. Due to increased capacity of the posterior fornix the balloon can expand in the posterior and upper direction to fill the fornix. The greater capacity also implies that greater filling will occur. In the case of the anterior fornix the reduced capacity implies that the lower part of the balloon gets inflated more where resistance is less.

However, a significant proportion of the bladder dose originates from its proximity to the anteverted uterus, as well as the shape that wraps around the uterus [5,10]. Moreover, the angle of the uterine tandem may significantly influence the doses to the bladder, although in the present study, its impact could not be evaluated as the same applicator was used for both applications. This implies that use of a BRSB alone may not be sufficient to control the inter-fraction dose variation for the bladder.

In the present study, and in our previously reported experience, an overall reduced dose to the rectum as compared with the bladder was observed [10]. Although a significant variation to the  $D2\text{cm}^3$  rectum doses was observed, the difference in doses for the other subvolumes was not statistically significant. This could be attributed to the relatively small sample size in our study. In a retrospective study by Rockey *et al.* [5], 45 HDR plans of 18 patients with gauze packing were compared with 39 plans of 16 patients with balloon packing. Although the balloon resulted in a statistically non-significant reduction in doses to the rectum and sigmoid, slight increases in doses to the bladder were observed with the balloon. The authors attributed this to increased proximity of the tandem with the bladder in patients with a very anteverted uterus, causing high bladder doses independent of the type of packing used [5].

On comparing the doses between the two brachytherapy fractions, the use of gauze packing enabled a dose reduction for the rectum in the second session in a greater number of patients. This is probably a reflection of the fixed BRSB filling protocol mandated in the present study. Thus, while the volume of saline inserted in the balloon was fixed, the extent of gauze packing was not controlled. This ability to tailor the dose in the second session is an advantage of the gauze that a skilled brachytherapy practitioner can exploit. Alternatively, allowing variable balloon filling in the second fraction may allow further dose reductions in the subsequent fractions. In patients with a narrow vagina where only half ovoids could be inserted, a greater inter-fraction dose variation was observed with the use of gauze packing (Table 3). This reflects on the tendency of the physician to pack more gauze anteriorly in an effort to reduce the bladder dose, a situation that is commonly observed in such patients.

In the present study, use of general anaesthesia for all applications and application by experienced physicians may have blunted the inter-fraction dose variation with the use of gauze packing for bladder. Also, at the time of planning the study, we did not have data on the inter-fraction dose variation for patients undergoing gauze packing. Subsequently our study looking at intersession dose variation found that the mean variation in the  $D2\text{cm}^3$  of the rectum dose was 1.16 Gy (standard deviation 0.80) in a series of patients treated with gauze packing [3]. Post-hoc calculations showed that our sample size of 40 patients had a 65% power to detect a 30% reduction (variation 0.8) in the dose variation for  $D2\text{cm}^3$  of rectum with the use of a BRSB with a one-sided significance level of 5%. However, as the study had recruited over 50% of the participants by this time, we

decided not to amend the sample size and proceeded with the originally planned sample size. Thus, this study can be considered underpowered to detect a difference in the magnitude of the inter-fraction variation of the bladder.

## Conclusion

In conclusion, the BRSB resulted in a significant dose reduction to the D2cm<sup>3</sup> rectum although no significant difference in the inter-fraction dose variation was observed compared with VGP. In centres where brachytherapy is carried out without anaesthesia or in centres with limited expertise in brachytherapy, the use of the BRSB in reducing rectal doses may even be more evident. Thus, the use of BRSB may not only allow better protection of the rectum, but may also help in reducing the intersession dose variation. Modifications proposed in the balloon design in the present and the previous study may make the BRSB more attractive for use in cervical cancer intracavitary brachytherapy.

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