

## Original Research Article

# Efficacy of vaginal dilator use in preventing vaginal stenosis among cervical and endometrial cancer patients underwent radiotherapy

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### ABSTRACT

**Background:** Vaginal dilators (VD) are effective in the prevention of vaginal stenosis in patients undergoing pelvic radiotherapy for gynaecological malignancies. This study was aimed to assess the efficacy of VD use in preventing post radiotherapy vaginal stenosis in cervical and endometrial cancer patients.

**Methods:** A cohort study was designed among patients (20-70 years) with biopsy proven endometrial and cervical carcinoma who underwent pelvic radiotherapy were included. Patients with cervical carcinoma (FIGO stage-IA to IVA), endometrial carcinoma (FIGO stage IB grade III, FIGO stage II), histology of squamous cell carcinoma, adenocarcinoma and performance score-ECOG 1 were included in the study. Assessment included clinical history, general examination, pelvic examination at 3 monthly intervals till 1 year. Grading of vaginal stenosis was assessed using LENT SOMA grading system.

**Results:** A total of 42 patients with 20 patients using vaginal dilators and 22 patients who refused to use VD were assigned. It was effective for 60% of VD users compared to 20% of nonusers ( $p=0.007$ ) at 9 months follow up. While at 12 months follow up, it was effective for 58% of VD users compared to 16.6% of nonusers ( $p=0.066$ ). Percent adherence was maximum in the 1<sup>st</sup> and 2<sup>nd</sup> quarter and declined to 61% by the 4<sup>th</sup> quarter. The total adherence was 97%.

**Conclusions:** There was 55% vs 22.7% effectiveness to prevent the vaginal stenosis among VD users. All patients need proper counselling, motivation and support for regular usage of VD which will ultimately help in reducing the incidence of vaginal stenosis.

**Keywords:** Brachytherapy, Cervical cancers, Endometrial cancer, Pelvic radiotherapy, VD, Vaginal stenosis

### INTRODUCTION

Carcinoma endometrium is the most common gynaecological malignancy in developed countries. In view of lifestyle changes and reproductive profile of women especially in urban areas an increasing number of cases are being detected among the Indian population. Globally there are more than 500,000 annual new cases of cervical cancers and approximately 250,000 women die of cervical cancer annually.<sup>1</sup> In India cervical cancer

constitutes approximately 6-29% of all cancers.<sup>2</sup> Pelvic radiotherapy (RT) includes external beam RT and brachytherapy. Brachytherapy can deliver higher doses of radiation to cervix and paracervical tissues while avoiding severe bowel and bladder toxicity. FIGO stage I patients, require adjuvant radiotherapy in the presence of high-grade carcinoma (Grade III) or other adverse risk factors. The adjuvant treatment of FIGO stage II cases includes pelvic RT with or without VBT and adjuvant chemotherapy. Current treatment practice for FIGO stage

IB2-IVA cervical cancer includes CCRT followed by ICRT. FIGO stage IA2, IB, IIA patients are treated with radical hysterectomy and bilateral lymph node dissection followed by adjuvant treatment. Adjuvant treatment includes external beam RT with concurrent chemotherapy followed by vaginal brachytherapy, in the presence of positive pelvic nodes, positive surgical margins, positive parametrial involvement. In case of negative nodes, negative surgical margins, no parametrial involvement, adjuvant radiotherapy is indicated for those tumours meeting Sedlis Criteria.<sup>3</sup>

Vaginal stenosis is a notable side effect seen in women undergoing pelvic radiotherapy and is defined as an abnormal shortening and tightening of the vagina due to fibrosis.<sup>4</sup> This has a negative impact on patient's well-being, particularly sexual dysfunction and dyspareunia. There is also the problem of excessive pain during medical pelvic examination leading to inadequate examination to monitor for changes in vaginal tissue. The reported incidence of radiation induced vaginal stenosis is largely inconsistent and can depend on patient related (age, inherent radio sensitivity of tissues), tumour related (site of disease) and treatment related factors (Radiotherapy modality and dose, dose fractionation schedule, concurrent chemotherapy).<sup>5</sup> Vaginal dilator (VD) use has been recommended as a standard practice once the acute inflammatory phase has settled by the American cancer society and the UK national forum of gynaecological oncology nurses.<sup>6</sup> Usage of dilators during radiotherapy is discouraged since it is plausibly associated with greater scar formation, causes psychologic sequelae and also there is no good evidence supporting the same.<sup>7</sup>

A study regarding sexual function and vaginal changes after RT for cervical cancer by Jensen et al showed that patients who are disease free after RT for locally advanced, recurrent, or persistent cervical cancer experience persistent sexual dysfunction and adverse vaginal changes during the first 2 years after RT with only small changes over time.<sup>8</sup> The sexual and vaginal problems could not be attributed to active disease, because the patients were disease free at all assessments. Although effectiveness of vaginal dilators has been proven, there is lack of consensus regarding the timing, frequency, duration of dilator uses and the necessity of dilators in sexually active patients. Despite numerous international reviews and guidelines regarding use of vaginal dilator for prevention of vaginal stenosis, it still hasn't become standard practice in India. This is due to lack of patient counselling and also not providing enough support for the patient. Although viewing the dilator as an extension of treatment motivates some women to using it, it may also act as a deterrent for those women who just want to be done with the entire treatment.<sup>9</sup> This study was aimed to assess the efficacy of VD use, post radiotherapy in cervical and endometrial cancer patients in preventing vaginal stenosis.

## METHODS

### *Study design and sampling*

Cohort study was designed among patients with biopsy proven endometrial and cervical carcinoma who underwent pelvic radiotherapy in the department of radiation oncology, Amala Institute of Medical Sciences from December 2017 to June 2019. Patients (20-70 years) with cervical carcinoma (FIGO stage-IA to IVA), endometrial carcinoma (FIGO stage IB grade III, FIGO stage II), histology of squamous cell carcinoma, adenocarcinoma and performance score- ECOG 1 were included in the study. Patients with prior pelvic radiation or recurrence of disease during follow up period were excluded from the study.

Sample size was calculated using  $\alpha=0.05=1.96$ ,  $p_1$ =Incidence of returning to pre-RT vaginal size after using VD = 71% (13)  $p_2$ = Incidence of vaginal stenosis after pelvic radiotherapy= 38% (5) with power.

$$N = \frac{[z_{1-\alpha/2}\sqrt{2p(1-p)} + z_{1-\beta}\{p_1(1-p_1) + p_2(1-p_2)\}]}{p_1 - p_2}$$

The minimum sample size was calculated as 25 in each arm. Written informed consent was obtained from all patients and the study was approved by the ethics committee (AIMS/IEC/63/2017 dated 25-11-2017).

### *Study procedure*

Patients meeting the inclusion criteria underwent computed tomography (CT) simulation with intravenous contrast medium. 3 mm slice thickness images were obtained and transferred to Treatment Planning System. The GTV, CTV, PTV, OAR was delineated on the CT images. For post hysterectomy endometrial carcinoma/ cervical carcinoma patients, the CTV included the regional nodes, parametrial/ paravaginal tissue, and upper half of vagina as per Small et al guidelines.<sup>10</sup> The regional lymph nodes included were bilateral obturator, external and internal iliac, common iliac nodes. For cervical cancer patients and endometrial carcinoma patients with involvement of cervix, the presacral region was also included extending to S3 to cover presacral lymph nodes and uterosacral ligaments.

For intact cervical carcinoma, the CTV included the entire GTV, the entire cervix (if not included in GTV), uterus, entire parametrium including ovaries, the mesorectum (if uterosacral ligaments are involved) and the upper half of vagina.<sup>11</sup> The upper two-third of vagina was included if the upper vagina was involved and the entire vagina was included if there was extensive involvement of vagina. The lymph nodes were contoured as per Small et al guideline. The total prescribed dose for endometrial carcinoma was 45 Gy in 25 fractions. The total prescribed dose for cervical carcinoma 50.4 Gy in 28 fractions along with concurrent Cisplatin

chemotherapy (40 mg/m<sup>2</sup>). The OAR's were delineated as per RTOG Female pelvis normal structure contouring guidelines and included bladder, rectum, bowel bag and femoral heads. This was followed by HDR brachytherapy which included 1) Vaginal brachytherapy for endometrial carcinoma, post-operative cervical carcinoma-total prescribed dose-18 Gy to 0.5 cm depth of upper 2/3<sup>rd</sup> of vagina (600 cGyx3) and 2) Intracavitary brachytherapy for intact carcinoma cervix-total prescribed dose-21 Gy to point A (700 cGyx3). Cervical carcinoma patients who were not ideal candidates for brachytherapy were given external boost dose of 10-16 Gy.

All patients were assessed at 6 weeks follow up and grade of vaginal stenosis recorded. All patients were counselled

regarding vaginal hygiene, advantages of usage of vaginal dilators. Plastic dilators of appropriate size were prescribed and patients were instructed to use it along with lubricants 3 times a week for 5-10 minutes per application as per the best practice guidelines from the national forum of gynaecological oncology nurses, 2005.<sup>6</sup> Patients were also counselled regarding proper maintenance of the dilator. Patients using the dilators were assigned to test group and the non-users were assigned to the control group.

Assessment included clinical history, general examination, pelvic examination at 3monthly intervals till 1 year. Grading of vaginal stenosis was assessed using LENT SOMA grading system (Table 1).

**Table 1: LENT SOMA grading of vaginal stenosis.**

Variables	Grade 1	Grade 2	Grade 3	Grade 4	Scoring intrusions
<b>Subjective</b>					
Dyspareunia	Occasional and minimal	Intermittent and tolerable	Persistent and intense	Refractory and excruciating	Score the 17 SOM Parameter with 1-4
Dryness	Occasional	Intermittent	Persistent	Refractory	
Bleeding	Occasional	Intermittent	Persistent	Refractory	
Pain	Occasional and minimal	Intermittent and tolerable	Persistent and intense	Refractory and excruciating	
<b>Objective</b>					
Stenosis/Length	>2/3 normal length	1/3-2/3 normal length	1/3-2/3 normal length	Obliteration	(Score=0 if there are no toxicities Total the score and divided by 17)
Dryness	Asymptomatic	Symptomatic	Secondary dysfunction		
Ulceration/necrosis	Superficial, ≤ 1 cm <sup>2</sup>	Superficial, >1 cm <sup>2</sup>	Deep ulcer	Fistulae	
Atrophy	Patchy	Confluent	Non-confluent	Diffuse	
Appearance	Telangiectasia without bleeding	Telangiectasia with gross bleeding			
Synechiae		Partial	Completed	Persistent	
Bleeding		On contact	intermittent		
<b>Management</b>					
Dyspareunia/pain	Occasional non-narcotic	Regular non-narcotic	Regular narcotic	Surgical Intervention	LENT score
Atrophy	Occasional hormone cream	Intermittent hormone cream	Regular hormone cream		
Bleeding	Iron therapy	Occasional transfusion	Frequent transfusion	Surgical Intervention	
Stenosis	Occasional dilation	Intermittent dilation	Persistent dilation	Surgical reconstruction	
Dryness	Hormone replacement	Artificial lubrication			
Ulceration	Conservative	Debridement	HBO <sub>2</sub>	Graft, surgical repair	
<b>Analytic</b>					
MRI	Assessment of wall thickness, sinus and fistula formation				Y/N date
USG	Assessment of wall thickness, sinus and fistula formation				Y/N date
EUA					
Cytology/Biopsy	Assessment of wall diameter and length and mucosal surface				Y/N date

Total adherence was calculated as:

$$\frac{\text{Total number of times patient used VD in given time period}}{\text{Maximum number of times of VD use in given time period}}$$

Percent adherence was calculated from 1<sup>st</sup> quarter to 4<sup>th</sup> quarter. Percent adherence=number of times each patient used VD in each quarter (3 times /week x 13 weeks).

Efficacy was calculated on the basis of whether pre-RT VD size is maintained at the end of follow up. In the event of disease recurrence or metastatic disease, the grade of VS on the last follow up was considered.

### Statistical analysis

Data analysis was done using Chi square test and Fischer exact test. Statistical analyses were done using SPSS software (version 24).

### RESULTS

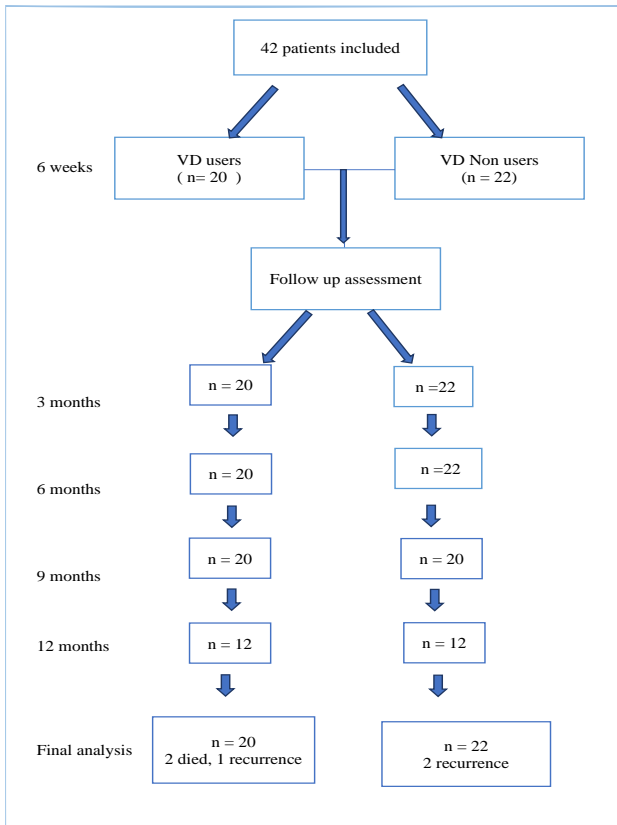
A total of 42 patients who met the inclusion criteria were analysed with 20 patients using VD being assigned to the test group and 22 patients who refused to use vaginal dilators being assigned to control group. Two patients in the test group died during the period of follow up and 3 patients (1 in the test group and 2 in the control group) had disease recurrence. Patient, tumour and treatment characteristics were given in Table 2.

**Table 2: Patient, tumour and treatment characteristics.**

Variables	VD users (n=20) (%)	VD non users (n=22) (%)	Total
<b>Age (year)</b>			
Mean age	56	60	
<b>Primary tumour site</b>			
Cervix	13 (65)	17 (77)	30
Endometrium	7 (35)	5 (22)	12
<b>Figo stage (cervix)</b>			
Ib	3 (15)	0	3
II a	3 (15)	2 (9)	5
II b	6 (30)	8 (36)	14
IIIa	0	2 (9)	2
IIIb	1 (5)	4 (18)	5
Iva	0	1 (4)	1
All stages			30
<b>Figo stage (Endometrium)</b>			
Ib	5 (25)	3 (14)	8
II	2 (10)	2 (9)	4
III	0	0	0
IV	0	0	0
All stages			12
<b>Histology</b>			
Squamous cell carcinoma	11 (55)	14 (64)	25
Adenocarcinoma	9 (45)	8 (36)	17
<b>Treatment technique</b>			
IMRT alone	0	3 (14)	3
IMRT + VBT	12 (60)	6 (27)	18
IMRT + ICRT	8 (40)	13 (59)	21
<b>Menopause</b>			
Premenopausal	4 (20)	3 (14)	7
Postmenopausal	16 (80)	19 (86)	35
<b>Surgery</b>			
Radical hysterectomy	12 (60)	7 (32)	19
No surgery	8 (40)	15 (68)	23

Efficacy of VD use was calculated for all 20 patients in the test group. All 20 patients were followed up till 9 months. Only 12 patients were followed up till 1 year. Two patients died during follow up period, one due to the comorbid illness and one due to progressive disease. A profile of the study is given in Figure 1.

Among the total, twenty eight patients (66.6%) had presented with complaints of bleeding per vaginum, six patients (14.2%) with history of the spotting per vaginum, sixteen patients (38%) with history of white discharge per vaginum and four patients (9%) with history of the lower abdominal pain.



**Figure 1: Study profile.**

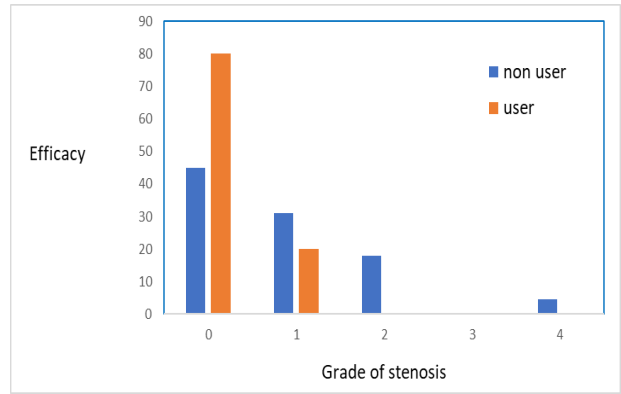
**Follow up and survival data**

All patients were followed up for 6 months. Only 40 and 24 patients were followed up till 9 and 12 months respectively. Two patients in the test group died during the period of follow up. One due to disease progression and 1 due to other comorbid illness. Three patients had disease recurrence (1 in the test group and 2 in the control group). Assessment of vaginal stenosis 6 weeks post radiotherapy is given in Table 3. Most of the patients showed VS of grade 0. No statistically significant difference was found between the groups.

**Table 3: Assessment of vaginal stenosis 6 weeks post radiotherapy.**

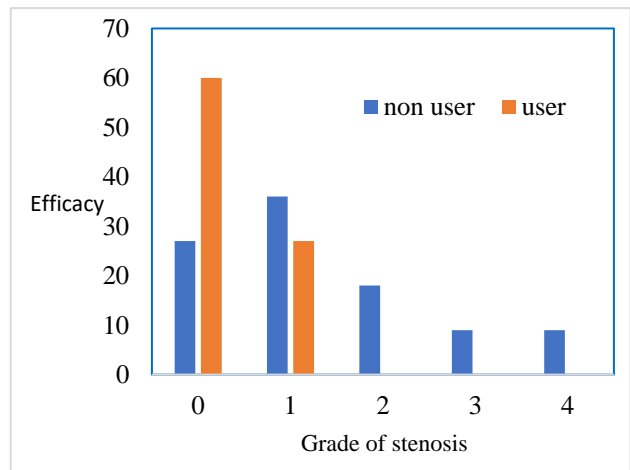
Grade of VS	Vaginal dilator		Total	P (Chi square test)
	Non users	Users		
0	19	18	37	0.517
1.0	2	2	4	
2.0	0	0	0	
3.0	1	0	1	
4.0	0	0	0	
<b>Total</b>	<b>22</b>	<b>20</b>	<b>42</b>	

Efficacy of vaginal dilator at 3 months follow up is given in Figure 2. VDs were effective for 80% of VD users compared to 45% non-users (p=0.028).



**Figure 2: Efficacy of vaginal dilator at 3 months follow-up. P=0.028 significantly different between users compared to non-users.**

Efficacy of vaginal dilator at 6 months follow up is given in Figure 3. VDs were effective for 60% of VD users compared to 27% non-users (p=0.011).

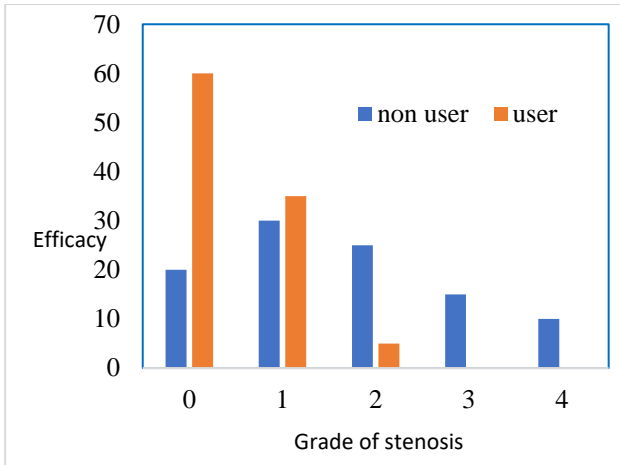


**Figure 3: Efficacy of vaginal dilator at 6 months follow-up. p=0.011 significantly different between users compared to non-users.**

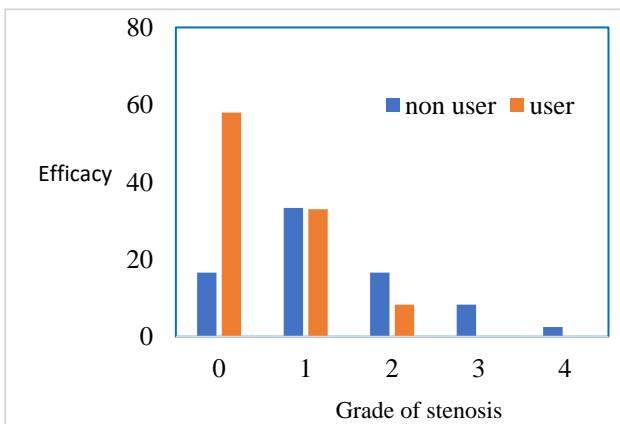
Efficacy of VD at 9 months follow up is given in Figure 4. VDs were effective for 60% of VD users compared to 20% non-users (p=0.007).

Efficacy of VD at 12 months follow up is given in Figure 5. VDs were effective for 58% of VD users compared to 16.6% non-users (p=0.066).

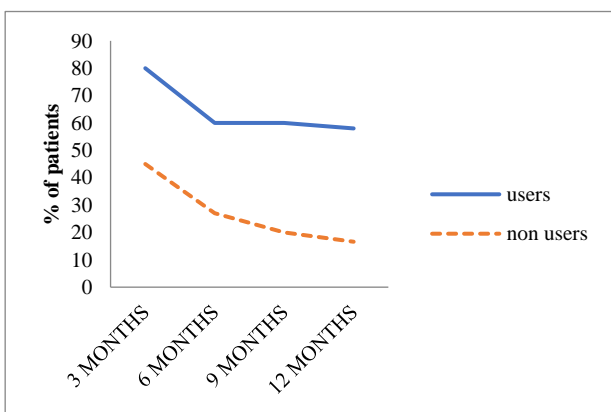
There is a significant association between VD use and prevention of vaginal stenosis with few grade 1 and grade 2 stenosis. No grade 3 and grade 4 stenosis were observed during the 12 months follow up period for VD users (p=0.024). At 3 months follow up 80% of VD users-maintained pre-treatment vaginal dilator size which reduced to 60% at 6 months and 9 month and 58% at 12 months. Significant association was noted at 3 months, 6 months and 9 months follow up (Figure 6).



**Figure 4: Efficacy of vaginal dilator at 9 months follow-up. p=0.007 significantly different between users compared to non-users.**



**Figure 5: Efficacy of vaginal dilator at 12 months follow up. p=0.066 not significantly different between users compared to non-users.**



**Figure 6: Total efficacy of vaginal dilators.**

**Adherence to vaginal dilator**

The percent adherence was calculated for all patients, regardless of whether they completed study. However, for a few patients who were unable to complete the study

due to disease progression or any other medical reasons, we took into account, the total number of times the dilator could be used by those patients (Table 4). Percent adherence was maximum in the 1<sup>st</sup> and 2<sup>nd</sup> quarter and declined to 61% by the 4<sup>th</sup> quarter. The total adherence was 97%. The most common reasons for non-compliance include anxiety and other factors (not getting enough time, not in mood, travel, personal engagements). Other causes include pain, mild bleeding, ill health/demise.

**Relationship of vaginal stenosis with dose of chemotherapy received**

18% of non-chemotherapy patients, maintained pre-RT VD size, compared to 82% who received chemotherapy. Higher cumulative dosage of chemotherapy did not increase the incidence of vaginal stenosis. There was no significant correlation noted between vaginal stenosis and dose of chemotherapy received.

**Analysis of factors affecting vaginal dilator use**

*Patients with comorbid illness like diabetes*

VD were effective for 33.3% of diabetic patients and 64.3% of non-diabetic patients. (p=0.181). Among non-users, 28.6% diabetic patients versus 20% non-diabetics, maintained pre-RT VD size (p=0.463). There is no correlation between development of vaginal stenosis and vaginal dilator use among diabetics and non-diabetics.

*Patients with comorbid illness like hypertension*

VDs were effective for 1 (20%) hypertensive patient compared to 10 (66.7%) non- hypertensive patients. (p=0.076). Among the non-users 4 (33.3%) hypertensive patients versus 1 (10%) non hypertensive patient, maintained pre-treatment vaginal size (p=0.139).

There was no correlation between development of vaginal stenosis and VD use among hypertensives and non-hypertensives.

**Surgery**

VDs were effective for 3 (66.7%) post op patients compared to 3 (37.5%) patients who hadn't undergone surgery. (p=0.213). There was no correlation between development of vaginal stenosis and vaginal dilator use among patients who underwent surgery vs no surgery.

**Menopause**

VDs were effective for 2 (50%) premenopausal women and 9 (56.3%) post-menopausal women (p=0.820). 2(66.7%) premenopausal women compared to 3 (15.8%) postmenopausal women in the control group, maintained pre-treatment vaginal size (p=0.357). There was no correlation between development of vaginal

stenosis and vaginal dilator use among premenopausal and postmenopausal women.

#### Extent of vaginal involvement on initial assessment

Women having vaginal involvement developed higher grades of stenosis compared to women without vaginal

disease. VDs were effective for, 10 (62.5%) women without vaginal disease compared to 1 (25%) patient with vaginal involvement. ( $p=0.820$ ). There was no correlation between development of stenosis and VD use based on extent of vaginal disease.

**Table 4: Percent adherence to vaginal dilator use.**

Percent adherence							
Adherence	N	Minimum	Maximum	Mean	Standard deviation	95% Confidence interval	
<b>Total</b>	20	17.0	97.0	72.0	24.2996	61.33	82.77
<b>1<sup>st</sup> Quarter</b>	20	66.0	100.0	87.1	12.2942	81.1	92.5
<b>2<sup>nd</sup> Quarter</b>	20	0.0	100.0	72.3	31.0200	58.4	86.1
<b>3<sup>rd</sup> Quarter</b>	18	0.0	92.0	59.0	31.6980	44.15	73.95
<b>4<sup>th</sup> Quarter</b>	13	0.0	92.0	61.0	33.0227	51.85	70.15

## DISCUSSION

Vaginal stenosis is a commonly encountered late sequelae in women undergoing pelvic radiotherapy for gynaecological malignancies. It has also been acknowledged in women undergoing radiotherapy for colorectal malignancies. The incidence of vaginal stenosis ranges from 1.25% to 88%.<sup>12-14</sup> as per various studies. VD can prevent the formation of adhesions and limit the process of fibrosis thereby preventing development of vaginal stenosis. In this study we have analysed the efficacy and adherence to vaginal dilators use in patients undergoing pelvic radiotherapy for gynaecological malignancies.

In this study, we observed that VDs are effective in preventing vaginal stenosis for women undergoing pelvic radiotherapy for gynaecological malignancies (55% vs 22.7%,  $p=0.024$ ). On assessing the efficacy of VDs during 3 monthly time periods, a significant association was observed at 3 months, 6 months and 9 months follow up. Although at 12 months assessment there was 58% vs 16.6% efficacy of vaginal dilators, it did not reach statistical significance, due to the limited number of patients that were followed up till 1 year ( $n=24$ ). In a study by Law et al, it was noted that 82% women-maintained pre-RT VD size at 12 months, 49% of patients with decrease in VD size at 1-month post-RT and 71% returned to pre-RT VD size at 12 months.<sup>15</sup> Studies on Indian population have also shown similar efficacy. Velaskar et al studied the efficacy of vaginal dilators in 89 patients who underwent radiotherapy for stage III cervical cancer.<sup>16</sup>

There was a significant increase in the vaginal length noted between 1<sup>st</sup> and 4<sup>th</sup> follow up with a higher number

of patients ( $n=46$ ) changing to larger size dilator. The mean percent adherence to dilator use was 72% (95% CI-

61.3-82.7) on one year follow up. The percent adherence was noted to be highest in the first 3 months 87% following which it declined to 61% on 12 month follow up. In comparison with our study, Law et al noted a mean percent adherence of 42% on 1 year follow up with maximum adherence of 56% noted in the first 3 months and an adherence of 25% during 9<sup>th</sup> to 12<sup>th</sup> month period (4<sup>th</sup> quarter).<sup>15</sup>

Brand et al noted vaginal stenosis in 38% of post RT cervical cancer patients, with most cases occurring in 1<sup>st</sup> year. Stenosis of any grade was noted at a mean of 9.6 months and median of 7.5 months (Range: 26 days-5.6 years).<sup>17</sup> In another study by Yoshida et al it was noted that VS increases with time and mild stenosis was noted within 1<sup>st</sup> year of follow up in more than half of the patients.<sup>18</sup> The rates of grade 1-3 VS at 3 years post RT was 97.5, 60.7 and 7.4% respectively. Gondi et al noted that at 3 years, the probability of vaginal severe late toxicity (grade 3 VS) was 20.2% in RT alone arm and 35.1% in CCRT arm.<sup>19</sup> Patients with moderate and poor dilator compliance were found to have higher vaginal severe late toxicity.

Factors like concurrent chemotherapy, comorbid illness, surgery, extent of vaginal disease failed to show any significant association. However, there was increased efficacy of vaginal dilators in post-menopausal women (56.3 vs 15.8%) which was not statistically significant. This could be due to inadequate sample size. This study proves that vaginal dilator use should be considered as an extension of treatment for women undergoing pelvic radiotherapy. But despite numerous international reviews

and guidelines regarding VD use, it is yet to be adopted as a standard practice in India. Provision for dilators and dilator use information is inadequate in India and practices vary within and between treatment centres, resulting in suboptimal compliance. Dilator usage is still considered as taboo by our society at large and may be frowned upon by the spouse/close relatives.

The foremost requirement in our setting is a need for sexual health communication training among clinicians, nurses and counsellors, who are the prime information providers to the patients and their spouses. In western practice, there are often trained nurses available for providing guidance and support to patients. For proper enforcement of such practices, we require the support of dedicated well trained nurses who can guide the patient starting from the time of first follow up visit. It is preferable that the same nurse follow up the patient throughout to make patient communication better.

Apprehension in resumption of sexual activity exists among patients and their spouses equally and proper counselling will take them into confidence. Misconceptions about sexual transmission of disease also needs to be cleared. Efficient counselling would include a one-on-one interaction, use of provisions like video tutorials, pamphlets rather than the simple practice of providing women with a dilator and usage instructions. The most common reasons for non-compliance include embarrassment, anxiety, predicted or actual pain upon use, fear of damaging the vagina. Women's resistance toward vaginal dilators reflects their attempt to cope with the distress of their treatment. Although viewing the dilator as an extension of treatment motivates some women to using it, it may also act as a deterrent for those women who just want to be done with the entire treatment.<sup>9</sup> A study by Jeffries et al, investigated the use of psychoeducational intervention to promote vaginal health. The methods utilised were group discussions, behavioural modifications, tackling sexuality issues. They noted a 42.3% increased compliance in the experimental group compared to 1.43% in non-experimental group.<sup>20</sup>

According to FIGO Cancer report 2012, the tolerance doses of the upper vagina and distal vagina are 140 Gy and 100 Gy, respectively. Threshold doses reported for vesicovaginal fistula and rectovaginal fistula are 150 Gy and 80 Gy, respectively.<sup>21</sup> The EQD<sub>2Gy</sub> for the upper vagina in endometrial cancer is 43.2 Gy with brachytherapy alone and 94 Gy with EBRT and brachytherapy combined. For cervical cancer the EQD<sub>2Gy</sub> for upper vagina is 50.4 Gy with brachytherapy alone and 100.8 Gy with EBRT and brachytherapy combined. The EQD<sub>2Gy</sub> for the distal vagina in endometrial cancer is 28.8 Gy with brachytherapy alone and 79.2 Gy with EBRT and brachytherapy combined. For cervical cancer the EQD<sub>2Gy</sub> for distal vagina is 33.6Gy with brachytherapy alone and 84 Gy with EBRT and

brachytherapy combined. In the EMBRACE study the risk factors for vaginal stenosis included extension into vagina at diagnosis, External beam radiotherapy of dose more than 45 Gy in 25 fractions and brachytherapy rectovaginal reference point dose.<sup>22</sup>

One of the major limitations of this study was inadequate sample size. Use of QOL questionnaires on sexual activity and frequency of use of vaginal dilators would have given a more accurate picture on adherence. Long term follow up is required to assess optimal duration of use.

## CONCLUSION

This study concluded as 55 vs 22.7% effectiveness favouring VD users. There was good adherence to VD usage during the first 6 months. Hence, a practice needs to be adopted as standard of care for all women undergoing pelvic radiotherapy for gynaecological malignancies. All patients need proper counselling, motivation and support for regular usage of VD which will ultimately help in reducing the incidence of VS.

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