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A Retrospective Study of Vaginal Stenosis Following Treatment of Cervical Cancers and the Effectiveness of Rehabilitation Interventions

Manjusha R. Vagal, Shyam K. Shrivastava, Umesh Mahantshetty, Sudeep Gupta, Supriya Chopra, Reena Engineer, Amita Maheshwari, Atul Buduk

***Abstract*—**Vaginal stenosis is a common side effect associated with pelvic radiotherapy in cervical cancer patients which contributes negatively to woman's health and prevents adequate vaginal/cervical examination. Vaginal dilation with a dilator is routine practice and is internationally advocated as a prophylactic measure to preserve vaginal patency. This retrospective study was carried out with the aim to know the usefulness of vaginal dilation following pelvic radiation therapy in cervical cancer patients in India. Data from medical records of 183 cervical cancer patients, which met the study criteria, were collected related to the stage of the disease, treatment received, commencement period of dilation post radiation therapy, sexual status and side effects associated to dilation practice. Data related to vaginal dimensions as per the length of insertion of a small, medium and large dilator were collected on regular follow-ups until 36 months and/or more. Vaginal dimensions as measured with the length of medium dilator insertion were used for analysis of dilation therapy results using paired t-test. Patients who underwent vaginal dilation with dilator maintained vaginal patency, also the mean vaginal length significantly increased, from 8.02 cm ± 2.69 to 9.96 ± 2.89 cm with a p value <0.001. There was no significant difference found on vaginal patency with different intervals of initiation of dilation therapy. At the third year and more following dilation therapy, significant increase in vaginal length observed with a p value of 0.0001 in both sexually active and inactive patients. Compilation of vaginal dosage during brachytherapy was inadequate, and hence, the secondary objective of the study to determine the effect of radiotherapy on the outcome of rehabilitation intervention was not studied in detail. This retrospective study has found that dilation therapy with vaginal dilators post pelvic radiotherapy is effective in preventing vaginal stenosis and improving vaginal patency and cannot be substituted with vaginal intercourse. Sexual quality of life assessment in the Indian population needs much attention.

***Keywords*—**Dilator, sexually active, vaginal dilation, vaginal stenosis.

I. Introduction

RADIATION therapy is widely used mode of treatment in cervical cancers in combination with other modes of treatment like surgery and chemotherapy [1]. In 2006-2007 Tata Memorial Hospital (TMH), Mumbai had 2,480 cervical cancer patients and 89% of them received chemo-radiation therapy as a sole mode of treatment.

Fortunately, many women are cured with this treatment and many have excellent long term survival. However, due to the treatment, especially with radiotherapy, some women suffer various side effects which have a lasting and serious effect on their quality of life [2].

Vaginal stenosis is the most common and serious complication of cervical cancer treatment which has not received appropriate attention until date [3]. About a third of women suffer from vaginal stenosis after pelvic radiotherapy [4], [5]. Literature has reported a variable incidence rate from 1.2% to 88% [6], [7]. Vaginal stenosis needs to be prevented and or managed to enable adequate examination of the vaginal vault, the cervix during follow up period to detect treatable re-occurrence of the disease and to avoid sexual morbidity [7].

Evidence on prevention and management strategies in vaginal stenosis is shallow. Vaginal dilation is advocated for managing vaginal stenosis after the acute inflammatory response post radiation therapy has settled. There are established guidelines on vaginal dilation [7]. Dilation therapy is prescribed on the belief that, a gentle vaginal exploration with the dilator after the acute inflammatory phase has settled might separate the vaginal walls and prevent their fusion [7].

Occupational Therapists at TMH have been involved in the rehabilitation of gynecological cancer patients following pelvic radiation therapy from more than three decades. Rehabilitation intervention pertaining to maintaining vaginal physiology post pelvic radiotherapy, basically includes teaching vaginal dilation exercises with the help of indigenous dilators, education on the importance of dilation practice, and sexual counseling and follow-up assessment of vaginal patency etc., and is routinely done at the Occupational Therapy department, TMH.

International guidelines on vaginal dilation after pelvic radiotherapy recommends a range of dilator sizes as per the anatomy and suggests the smallest size to begin with and gradually progress to the bigger size [8]. At TMH, vaginal dilators of varying sizes including small (2cm diameter), medium (2.5 cm diameter) and large (3cm diameter) are prescribed, generally 6-8 weeks post-radiation along with sexual counseling. Dilator use is prescribed for 10 minutes daily.

It is observed that all patients at our hospital do not comply with the early dilation referrals post radiation therapy and start dilation exercise only on one of their subsequent medical follow-up visits. Hence, there was a need to understand the effect of different periods of initiation of the dilation exercises

M. R. Vagal is with the Tata Memorial Hospital, Parel, Mumbai 400012, India (phone: +0091 9833466297; e-mail: vagalmanjusha@ yahoo.com).

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following radiation therapy on vaginal patency in our setup.

Vaginal intercourse is usually encouraged along with a vaginal dilator in these patients early post radiation therapy to avoid sexual morbidity [9], [10]. Literature also suggests that vaginal sexual intercourse should not be used to keep the vagina patent [3]. However, sexual intercourse is generally forceful compared to self-dilation with a dilator, and the addition of adequate foreplay with lubricating cream and condoms, not only help to preserve sexual functions post radiotherapy, but also addresses vaginal stenosis more effectively; hence, the need to assess the effectiveness of dilation in sexually active and inactive patients at TMH.

Increased dosage of radiation therapy does cause increased vaginal stenosis [11]-[13]; however, it is not known if the higher dosage plays a role on the dilation outcome. It is observed that patients with cervical cancer receive varied dosages of external beam radiotherapy and brachytherapy.

Dilation treatment has resulted in rare but serious physical damage, with case reports of the dilators causing fistula [14]. There was a need to assess the occurrences of any physical side effects such as fistula and/or bleeding associated with dilator use in our population. Studies on vaginal dilation for prevention and treatment of vaginal stenosis mention the lack of literature on the side effects associated with vaginal dilation [3].

A retrospective review was carried out at TMH, to understand the effectiveness of vaginal dilation, the effective time to start vaginal dilation therapy, the side effects associated with dilation practice, and the role of increased radiation dosage on dilation outcome post pelvic radiation therapy in sexually active and inactive cervical cancer survivors in the Indian setup.

II. Study Methodology

Medical records from 2002-2010 of carcinoma cervix patients referred for vaginal dilation were reviewed. Case files of 183 patients having been treated for cervical cancer stages I-III, with age ranging between 29-70 years met the study criteria. All patients were treated with pelvic radiation therapy with or without surgery or chemotherapy, and were prescribed vaginal dilators and/or sexual activity following radiotherapy. They all reported for follow-up at the Occupational Therapy Department of TMH for 36 months or more for vaginal dilation therapy. The status of sexual activity or inactivity was recorded.

Data were recorded in the case record form about the stage of the disease and the treatment received (especially radiation therapy dosage and fractions, chemotherapy drugs and cycles, type of surgery and rehabilitation interventions). Vaginal dimensions (as per the insertion of a particular size dilator {(small (2cm diameter), medium (2.5cm diameter), large (3cm diameter)} was noted in relation to the dilation practice started soon after and long after radiotherapy along with the sexual activity. Data were collected on regular follow-ups.

The above details of the patients were recorded on a follow-up forms: before or up to six months post radiation therapy, between six months to 11 months post radiation therapy, between 12 months to 23 months post radiation therapy, between 24 months to 35 months post radiation therapy and 36 months and above.

The medical records were also reviewed in relation to radiotherapy dosage on patency of the vagina and for any untoward effects of the vaginal dilator and of sexual intercourse.

The data were analyzed using SPSS version 20. The vaginal dimension at the first assessment with medium dilator post radiation therapy and on the last assessment was compared using paired t-test.

III. Result

The medical records of all 183 patients had readings of vaginal dimensions noted with a medium dilator for most of the follow-up visits, and hence, vaginal patency as measured and noted with a medium dilator insertion on different follow-up visits was considered for analyzing the results. The mean vaginal length, as on the first reading with medium dilator (not all patients were prescribed medium dilator for initiating dilation therapy), was considered as the base line reading and was compared with the reading on the last follow-up (at the third year or more). There were some missing data of the last follow-up for few patients as their vaginal patency was found to be assessed using either a large and/or small dilator, instead of medium dilator, and hence, the number of patients taken for baseline assessment did not always match the numbers on the final assessment.

TABLE I
Clinical Characteristics

Parameter		Frequency (n = 183)	Percentage
Marital Status	Married	140	76.5
	Widow	40	21.9
	Separated	3	1.6
Diagnosis Stage	I	12	6.6
	II	92	50.3
	III	79	43.1
Histopathology	Squamous Carcinoma	179	97.8
	Adeno Carcinoma	4	2.2
On set of Treatment	0 to 8 weeks	76	41.5
	9 to 24 weeks	60	32.8
	25 weeks and above	47	25.7
Sexual Status	Active	67	36.6
	Inactive	76	41.6
	Unknown	40	21.8

TABLE II
Results with Dilator on Vaginal Patency

Mode of Assessment	Base Line Mean Insertion Length (cm) (n = 183)	Mean Insertion Length on Last Follow up (cm) (n = 159)	P Value
Dilator [Medium 2.5cm wide]	8.02 $\pm$ 2.69	9.96 $\pm$ 2.89	0.0001

The clinical characteristics of the studied patients are given in Table I. The mean age of study population was 50.39 $\pm$ 7.92, of which, 66% were stage I cancer cervix, 50.03% were

stage II and 43% were diagnosed as stage III cervical cancer; 97.08% were squamous cell carcinoma and 2.2% were adenocarcinoma. Meanwhile, 76.5% were married (had a spouse), 21.9% were widow and 1.6% were separated from their spouses. As seen in Fig. 1, the medical records of 183 patients suggests that not all patients were prescribed the same mode of dilation at the commencement of dilation treatment, rather there was variation in the mode of initial dilation. Of the cases, 40.4% of patients were prescribed finger dilation as a sole mode for initial dilation, 37.7% were given only a dilator, while 13.1% were advised only vaginal intercourse and 7.7% were prescribed a combination of finger dilation and vaginal intercourse. Vaginal intercourse and a dilator were suggested to only 0.5% of the study population and the remaining 0.5 % was advised to use a combination of finger dilation and dilator.

These 183 cervical cancer patients post radiation therapy underwent counseling and demonstration for vaginal dilation; however, the final dataset for 24 patients was missing for comparison with the baseline readings. As seen in Table II and Fig. 2, the data for 159 patients suggest vaginal dilation exercises with dilator maintained and improved vaginal patency. Mean vaginal length increased significantly from 8.02 ± 2.69 cm to 9.96 ± 2.89 cm with a p value < 0.0001.

Depending upon the patients' first visit to the occupational therapy department for dilation, the interval for initiation of dilation following completion of radiation therapy ranged from less than eight weeks to more than 204 weeks (less than four years). For convenience of analysis, as seen in Table III, the interval of commencement of dilation exercises was divided into three groups namely less than eight weeks (two months), eight weeks to less than 25 weeks (two to six months) and more than 25 weeks (more than six months). Different periods of initiation of vaginal dilation post radiation therapy made no significant difference on vaginal patency. Significant improvement in vaginal patency was found for all three groups. It was observed that finger dilation and vaginal intercourse as a source for dilation was majorly recommended for patients who were referred before 25 weeks, while dilator and intercourse was the commonly prescribed mode of dilation for those who commenced dilation after 25 weeks of radiation therapy.

TABLE III
INTERVAL FOR INITIATION OF VAGINAL DILATION AFTER RADIATION THERAPY

Onset of Dilation	Mode of Dilation	Distribution of Patients	Base Line Mean Insertion Length (cm)	N	Mean Insertion Length on Last Follow up (cm)	N	P Value
Up to 8 Weeks	Intercourse	16	8.17± 2.92	76	9.71± 3.01	62	0.001
	Finger	46					
	Intercourse + Finger	5					
	Dilator	9					
9 to 24 Weeks	Intercourse	5	7.91± 2.39	60	10.23± 3.11	54	0.0001
	Finger	25					
	Intercourse + Finger	6					
	Dilator	24					
25 Weeks and above	Intercourse	3	7.95± 2.74	47	9.98± 2.43	43	0.0001
	Finger	3					
	Intercourse + Finger	3					
	Dilator	36					
	Intercourse + Dilator	1					
	Finger + Dilator	1					

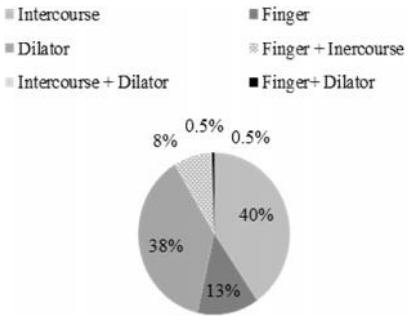

Fig. 1 Prescribed mode of dilation at the initiation of treatment

The sexual status of 143 patients following dilation exercises with a dilator was commented at least once either by the treating occupational therapist or the radiation oncologist during one of their follow-up visits. Some 40 files had no mention of sexual status. Medical records showed 36.8% of patients were sexually active, 41.8% were inactive and the data of 21.4% was not understood. To understand the reason behind sexual inactivity, the marital status of sexually inactive patients (i.e. 41.8%) was checked and it was learnt that 43.42% were married but were sexually inactive, as Table IV shows. Table V and Fig. 3 show that both sexually active and inactive patients showed significant increase (p value of 0.0001) in vaginal length from 7.83 ± 2.50 cm to 10.14 ± 2.54 cm and 7.96 ± 2.40 cm to 10.11 ± 2.90 cm, respectively.

TABLE IV
CLINICAL CHARACTERISTICS OF SEXUALLY INACTIVE PATIENTS

Parameter	Frequency (n = 76)	Percentage	Age
Married	33	43.42	54.21 ± 8.41
Widow	40	52.63	52.13 ± 6.62
Separated	3	03.95	55.33 ± 5.68

Fig. 2 Results with dilator on vaginal patency

TABLE V
SEXUAL ACTIVITY AND VAGINAL PATENCY

Sexual Status	Base Line Mean Insertion Length (cm)	N	Mean Insertion Length on Last Follow up (cm)	N	P Value
Active	7.83 ± 2.50	67	10.14± 2.54	58	0.0001
Inactive	7.96 ± 2.40	76	10.11± 2.90	73	0.0001

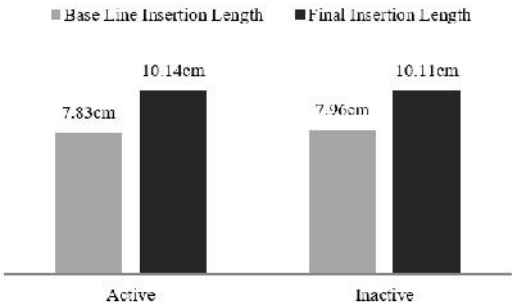

Fig. 3 Sexual activity and vaginal patency

A total of 96 patients were treated with an average dose of 50Gy in 25 fractions, while 62 patients received 40Gy in 20 fractions of external beam radiation therapy (EBRT). There were many variations noted in high dose radiation therapy (HDR) like 3Gy in 2 fractions, 7Gy in 1 fraction, 7Gy in 2 fractions, 7Gy in 5 fractions,7+6+7Gy, 5+7+7Gy, 7+7+8+8Gy etc. The records of the administration of low dose radiation to many were also present. Due to this vast variation in dosage of brachytherapy compilation of radiation dosage has been inadequate, and hence, the effect of radiation on dilation outcome could not be analyzed.

During this retrospective review of records there was no mention of any side effect associated with dilator.

IV. DISCUSSION

From patients' case reports, it is evident that occupational therapists received referrals for vaginal dilation majorly from the radiation Oncology Outpatient Department (OPD), therapists' educated patients on vaginal hygiene, demonstrated vaginal dilation on patients and counseled the resumption of vaginal intercourse along with sexual counseling to married patients for prevention of vaginal stenosis. The records also suggest that vaginal intercourse was also prescribed as a medium of vaginal dilation along with dilators. Patients were prescribed two sizes of dilator at a given time namely small and medium or medium and large. Patients with early reference for dilation (before eight weeks post radiation therapy) were commonly prescribed finger dilation and vaginal intercourse. Both finger and vaginal intercourse either individually or in combination with or without dilator was seen to be the preferred choice for dilation for most of the new referrals after eight weeks to 25 weeks following completion of radiation therapy. Mostly after 25 weeks post radiation therapy patients were prescribed vaginal dilators (small, medium and large). Emphasis on patients visiting the occupational therapy department for dilation on their subsequent follow-up visit to the hospital was evident from the therapists' notes. Most of the case papers found mention of the sexual status of the patient by the therapist and many times by the radiation oncologist. Similarly, few case records found mention of the discontinuation of sexual activity due to various reasons like ill health or death of the spouse.

After reviewing the case records of 1,100 cervical cancer patients post radiation therapy containing referrals for vaginal dilation, only 183 are found to have followed for minimum three years with the occupational therapy department for vaginal dilation, which hints towards the need for more emphasis on patient education on vaginal dilation by the attending oncologists and the occupational therapists. Recent observation data from oncology clinics have reported similar findings. It was observed that discussion on dilator use to be absent from the majority of medical consultations due to the busy clinical environment during routine follow-up visits [15]. Poor long-term compliance with dilator use has been reported by many clinicians.

The presence of missing data on the last follow-up for few patients indicates inadequate assessment and/or underreporting of information about vaginal patency by the attending therapist. Since a combination of either small and medium or medium and large dilators was routinely prescribed, evaluation of vaginal patency with a medium dilator on every follow-up along with either a small or large dilator was not possible and would have helped for superior analysis.

This study results clearly suggests that vaginal dilation exercises with a dilator improved mean vaginal length after the acute inflammatory phase had subsided. This was probably because patients tolerated greater penetration depth with regular use of the dilator in the vagina [7]. Since pre radiation therapy vaginal dimensions were not measured and mentioned on the patients' case records it is difficult to comment categorically that the dilation practice with a dilator contributed towards regaining and restoring vaginal patency. However, the findings of this study suggest the dilator helped to prevent and treat vaginal stenosis as the mean length of 9-10 cm was found on the last follow-up. A mention of normal vaginal length of 8 cm to 9 cm is documented by Bruner [16].

The commencement interval of dilation exercises ranged from less than eight weeks to almost four years. These referrals for most of the patients were immediately after six to eight weeks post-radiation therapy, while for few patients it was after many months following radiotherapy, thus delaying the initiation of vaginal dilation. Delayed referrals from radiation oncologists suggests awareness issues related to vaginal dilation amongst oncologists and suggests some breach in following the international guidelines on initiation of dilation post radiation therapy. Records suggests that there was delay in the commencement of dilation therapy from patients side also, as many patients visited the occupational

therapy department only on one of their subsequent medical follow-up visits, in-spite of early referral from the oncologists, thus highlighting the need for better patient education on vaginal dilation. As per the records, out of 47 patients who began dilation after 24 weeks post pelvic radiation therapy, only four patients initiated vaginal dilation after 104 weeks (two years) and three patients after 156 weeks (three years), which is too less a number to understand the effectiveness of late dilation on vaginal patency. However, 22 patients started with dilation between 52 weeks to 94 weeks (one year to one year and 10 months) post radiation therapy showing significant improvement. The results of this study did not find any influence of different intervals of initiation of dilation exercises on vaginal patency post radiation therapy. Reasons for improved patency could be because the dilation was commenced after the settlement of the inflammatory phase for all the patients, as per various international dilation guidelines [7]. The study done by Poma [17], [7] showed improvement in vaginal patency in five women in whom dilation was introduced a median of eight years after radiotherapy.

Both sexually active and inactive patients showed significant improvement in vaginal patency at the third year or more after radiation therapy suggesting that vaginal intercourse had no superior effect on vaginal patency in the study patients using vaginal dilators. It is important to note that since it was a retrospective study, in-depth assessment of sexual activity was not possible. The possibility of better results with regular and frequent vaginal intercourse on maintaining vaginal patency cannot be ignored. Decruze [18] however has reported poorer vaginal patency in women who were prescribed only sexual activity against those who were treated with a vaginal stent for preventing stenosis.

The current study has found that many married women were sexually inactive, highlighting the need for emphasis on sexual education following cervical cancer treatment. Reviews of research evidence consistently identify the advantages of patient education in improving coping and reducing anxiety [19]. In spite of this evidence, survey findings report certain areas of patients education is poorly addressed by health care professionals [20]-[22]. Poor compliance with resumption of sexual intercourse due to various reasons including fear of spreading the disease and fear of pain is also an important issue and can be addressed well with good counseling.

Due to a lot of variation in brachytherapy dosage, the compiling of results was not feasible. Since the stage of the disease was not same for all patients, the brachytherapy dosage was not uniform and there were many dosage variations present making groupings for analysis impossible, and thus limiting further analysis. The aim of this study was to understand the effect of different dosages on dilation outcome. Studies reporting positive correlation between dosage of radiation and vaginal stenosis have not commented on dosage and dilation results.

There are reports of uncommon but sever physical damage and psychological side effects associated with dilatation practice. Anecdotal reports confirm some women having been affected by psychological stress because of vaginal dilation [8]. None of the reviewed case reports in this study found a mention of any of physical or psychological side effects associated with dilation.

V. Conclusion

This study has highlighted the vaginal dilation practice in cervical cancer patients following pelvic radiotherapy at a single institution. Certain inconsistencies were observed in the assessment of dilation techniques and presence of certain short falls in a patients' education on vaginal dilation and sexual health.

This review of medical records has found that a vaginal dilator was a useful medium for maintaining or improving vaginal patency following pelvic radiation for three years and more, and that the practice cannot be replaced with vaginal intercourse. There is a need for a good quality prospective trial on a large cervical cancer population to understand the effect of early and late initiation of dilation therapy on vaginal patency, and to understand how much delay in initiating dilation is permissible in preserving vaginal dimensions with reference to pre-radiation therapy.

There is a strong need of good quality studies establishing a reliable evidence base to support the use of vaginal dilators in restoring vaginal patency following pelvic radiation therapy. This study also suggests the need for standardized assessment techniques pertaining to dilation procedure. It also suggests a strong need to educate patients about the importance of vaginal patency and regular assessments of dilation results following cervical cancer treatment. Also, this study has highlighted the need to evaluate awareness about the importance of vaginal dilation among consulting oncologists, as well as the need for detailed assessment of sexual activity on vaginal dimension along with sexual quality of life assessment in the Indian population.

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