International Guidelines on Vaginal Dilation after Pelvic Radiotherapy

Produced by the International Clinical Guideline Group, chaired by Dr Tracie Miles, President, National Forum of Gynaecological Oncology Nurses, UK

International guidelines on vaginal dilation after pelvic radiotherapy

Summary

The purpose of these guidelines is to clarify the evidence and offer expert opinion with respect to the use of vaginal dilation for women having radical or adjuvant pelvic radiotherapy.

This document reviews the literature on the:

- perceived rationale for dilation therapy
- causes and definition of stenosis
- incidence of stenosis
- consequences of stenosis
- prevention of stenosis

Good practice points on the use of vaginal dilation therapy have been developed to guide patients and clinicians. These include:

- Dilation therapy may include the use of dilators, vibrators, fingers, or similar shaped devices. It may not be necessary if vaginal intercourse is resumed weekly (or more) following treatment.
- Dilation therapy should be gentle.
- Dilation therapy may be commenced at approximately 2-8 weeks post radiotherapy, when the acute inflammatory response has settled.
- We suggest that a reasonable duration and frequency of dilation may range from three minutes twice a week, up to ten minutes and twice daily.
- Women may be offered a range of sizes according to their anatomy. It is usual to start with the smallest and progress to whatever size is comfortable.
- Women should know that a small amount of bleeding or 'spotting' after dilator use is normal. If there is a lot of bleeding or pain, a clinician (doctor, nurse or therapy radiographer) should be contacted.
- Review the need for dilation therapy on a regular basis, consider discontinuation of dilation therapy when no longer required; e.g. when sexually active or experiencing no discomfort during vaginal examinations at follow up 1-2 years post treatment.
- If stenosis develops record vaginal toxicity using a recognised score.

International guidelines on vaginal dilation after radiotherapy; a clinical guideline

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Preamble

This guideline represents an international consensus on the management of vaginal dilation associated with therapeutic pelvic radiotherapy. The contents are agreed by each member and represent a view based on an interpretation of the available evidence. No reader should assume that this represents the only management option. There are other reasonable care strategies and there is no duty of care for any health care worker to follow these recommendations. Each woman is an individual and holistic care is paramount and there may be many good reasons why these guidelines may not be implemented. The guideline group believes that all women at risk of developing vaginal stenosis as a consequence of therapeutic pelvic radiotherapy are entitled to receive information about the rationale for dilation therapy, and their decision to dilate or not is respected. The guideline group are aware of their responsibility and accept shared responsibility for the publication of these guidelines.

KEY TO EVIDENCE STATEMENTS AND GRADE OF RECOMMENDATIONS

	LEVELS OF EVIDENCE
1++	High quality meta-analyses, systematic reviews of randomised controlled trials (RCTs), or RCTs with a very low risk of bias
1+	Well-conducted meta-analyses, systematic reviews of RCTs, or RCTs with a low risk of bias
1 -	Meta-analyses, systematic reviews of RCTs, or RCTs with a high risk of bias
2++	High quality systematic reviews of case control or cohort studies
2+	Well-conducted case control or cohort studies with a low risk of confounding or bias and a moderate probability that the relationship is causal
2 -	Case control or cohort studies with a high risk of confounding or bias and a significant risk that the relationship is not causal
3	Non-analytic studies, e.g. case reports, case series
4	Expert opinion

KEY TO EVIDENCE STATEMENTS AND GRADE OF RECOMMENDATIONS *(cont)*

	GRADES OF RECOMMENDATION Note: The grade of recommendation relates to the strength of the evidence on which the recommendation is based. It does not reflect the clinical importance of the recommendation.
A	At least one meta-analysis, systematic review of RCTs, or RCT rated as 1++ and directly applicable to the target population; Or A body of evidence consisting principally of studies rated as 1+, directly applicable to the target population, and demonstrating overall consistency of results
B	A body of evidence including studies rated as 2++, directly applicable to the target population, and demonstrating overall consistency of results; Or extrapolated evidence from studies rated as 1++ or 1+
C	A body of evidence including studies rated as 2+, directly applicable to the target population and demonstrating overall consistency of results; Or extrapolated evidence from studies rated as 2++
D	Evidence level 3 or 4; Or extrapolated evidence from studies rated as 2+

GOOD PRACTICE POINTS (GPP)	
GPP	Recommended best practice based on the clinical experience of the guideline development group

AIM AND SCOPE OF THE GUIDELINES

There are no previous international guidelines concerning the current practice of dilation. Australian practice is variable and tends to be dominated by the non-scientific opinion of the leading clinician[1]. North American practice guidance does not recommend dilation during therapy and also advises "patients not to have intercourse during radiation therapy"[2]. The (UK) National Forum of Gynaecological Oncology Nurses (NFGON) collaborated with the European Institute of Health and Medical Sciences to survey UK practice (2004)[3,10] and recommended routine vaginal dilation for all women receiving pelvic radiotherapy[4,5]. More flexible advice was issued to UK members in 2010[6,7], and scientific uncertainty was emphasised[10].

The purpose of these guidelines is to clarify the evidence and offer expert opinion with respect to the use of vaginal dilation for women having radical or adjuvant pelvic radiotherapy.

THE PERCEIVED RATIONALE FOR VAGINAL DILATION

- Facilitate resumption of sexual relations after radiotherapy;
- Prevent adhesions progression to fibrosis and stenosis of the vagina, especially during the first year after completion of RT (if no intercourse is resumed and the patient is motivated to maintain vaginal patency);
- Allow the medical team to examine and assess the vaginal vault or cervix as part of on-going medical follow up;
- Reduce potential sexual difficulties, e.g. painful sexual intercourse;
- Offer the opportunity to discuss sexual fears/myths associated with pelvic radiotherapy;
- Reduce tissue damage;
- Improve psychological well being.

CAUSE OF STENOSIS

Vaginal stenosis may follow pelvic radiotherapy, especially after the combination of external beam radiotherapy and brachytherapy. Radiation damages vaginal epithelium, connective tissues and small blood vessels causing inflammation and cell death prior to resolution. The subsequent reduced blood supply, tissue hypoxia, loss of elastin, collagen deposition and hyalinisation and fibrosis[9,10,11] leads to thinning of the vaginal mucosa, loss of lubrication, scarring and fibrosis. This causes a shorter, less elastic and dryer vagina. Some women experience complete loss of a functioning vagina[12,13]. Additionally, oestrogen deficiency (resulting from radiation induced menopause or natural menopause, or cessation of prior hormone replacement therapy, HRT), may intensify the loss of elasticity and lubrication and thinning and atrophy of the vaginal mucosa[14].

DEFINING VAGINAL STENOSIS

Vaginal stenosis is difficult to define. Nunns et al[15] described vaginal stenosis as the inability to insert two fingers into the vagina. Flay and Matthews[16] defined it as shortening of the vagina to less than 8cm. Bruner[17] et al identified it as a decrease in vaginal length from the normal of 8-9 cm while Schover et al[18] classified it in terms of the vaginal mucosa and vaginal capacity as being 'normal, mildly changed, or severely changed'. Hartman and Diddle[19] graded stenotic changes numerically from one to three. A score of grade 1 represented no stenosis, grade 2 related to stenosis of the upper third of the vagina and grade 3 indicated stenosis of more than the upper third. Greven et al[20] mentioned vaginal stenosis in their survey of prognostic factors but did not quantify it as they believed that it was not possible to reliably grade this toxicity. In a systematic review, Denton and Maher[21] commented on the inconsistency of methods for assessing vaginal changes associated with vaginal stenosis. They also observed wide variability in research rigour among studies reviewed concluding there was no accepted reliable and standard measure of vaginal stenosis.

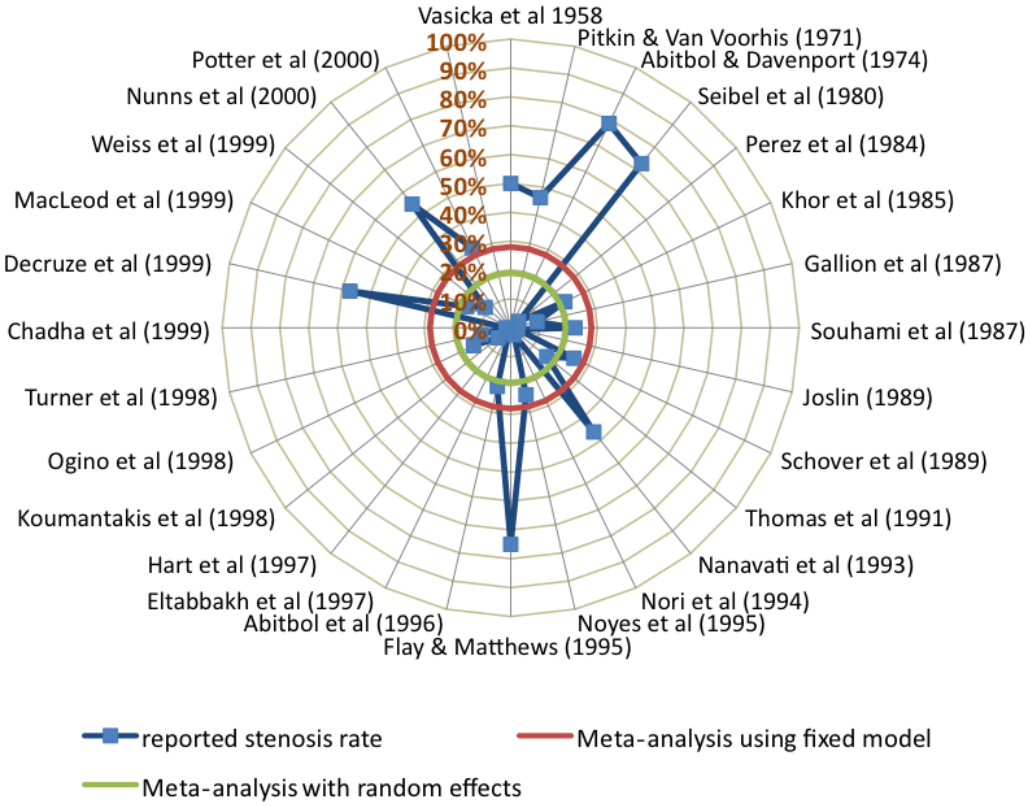
There is no agreed definition or measurement tool for stenosis; our suggested definition and measurement tools are;

Common Terminology Criteria for Adverse Events (CTACAE), reproductive (and breast disorders) section: vaginal stricture, grade 1 to 3 (grade 3 being vaginal narrowing or shortening interfering with the use of tampons, sexual activity or physical examination).

Late Effects of Normal Tissues, Subjective, Objective, Management, Analytic (LENT SOMA), vagina/sexual dysfunction section.

INCIDENCE OF VAGINAL STENOSIS

The incidence of vaginal stenosis has been reported variably in the literature[1,22], ranging from 1.2% to 88%. Authors specifically addressing vaginal stenosis due to brachytherapy report an incidence ranging from 13% to 88%. This is higher than the incidence derived from reports where clinicians simply describe their clinical experience (1.2%-54.7%). This suggests ascertainment bias. The range of data in the scientific and health care literature is illustrated below.



Abitbol & Davenport (1974)[24], Abitbol et al. (1996)[24], Chadha et al. (1999)[25], Decruze et al. (1999)[12], Eltabbakh et al. (1997)[23], Flay & Matthews (1995)[16], Gallion et al. (1987)[26], Hart et al. (1997)[27], Joslin (1989) (cited in Fieler (1997)[28] and extracted from Lancaster, Khor et al. (1985)[29], Koumantakis et al. (1998)[30], MacLeod et al. (1999)[31], Nanavati et al. (1993)[36], Nori et al. (1994)[33], Noyes et al. (1995)[34], Nunns et al. (2000)[15], Ogino et al. (1998)[35], Perez et al. (1984)[36], Pitkin & Van Voorhis (1971)[37], Potter et al. (2000)[38], Schover et al (1989)[39], Seibel et al (1980)[40], Souhami et al. (1987)[41], Thomas et al. (1991)[42], Turner et al. (1998)[43], Vasicka et al. (1958), Weiss et al. (1999)[44].

CERVICAL AND ENDOMETRIAL CANCER

Vaginal shortening after brachytherapy was identified by Bruner et al[17] to be greater for women with cervical than for those with endometrial cancer. It was noted by Flay and Matthews[16] to be more common in those undergoing radiotherapy and surgery for cervical cancer than those undergoing radiotherapy alone. In women who had undergone hysterectomy for endometrial cancer, MacLeod et al[31] found that the addition of external beam radiotherapy combined with brachytherapy resulted in greater toxicity than the addition of brachytherapy alone. However, Nunns et al[15] found no increased incidence of vaginal stenosis when combining both techniques after hysterectomy.
The severity of vaginal stenosis appears to be related to a higher dose per fraction of brachytherapy, an increased number of fractions and a smaller diameter of the brachytherapy applicator[45].

Hartman and Diddle[19] and Poma[46] found that neither the age of the patient nor stage of the disease contributed to the degree of vaginal stenosis. Bruner et al[17] observed that women with stage II and III endometrial and cervical cancer experienced increased vaginal shortening compared with those with stage I disease. Pearcey and Petereit[47] commented that vaginal toxicity is greater when the entire length of the vagina is irradiated rather than the vaginal apex. This observation was supported by Katz et al[10] and Tyree et al[48] who noted that the lower vagina has a poorer tolerance to radiation than the upper vagina. The effect on the vagina in women who smoke during radiotherapy is unknown but smoking is a associated with an increased risk of radiation damage[49,50]. Brand et al[64] found that 35% of women in a retrospective case note study had stenosis identified after the 6 month follow up check.

Colorectal/Anal Cancers

The number of women who develop vaginal stenosis after treatment for anal or low rectal cancer is not well reported. However to help inform and guide the use of recommended dilation therapy it is important to consider the treatment fields in anal and rectal cancer separately.

It is important to note that there has been a changing effect over time of radiation dose, type, technique and addition of chemotherapy. These confounding variables in both assessment and prevalence of stenosis makes comparison with historical studies more difficult.

The addition of chemotherapy to radiotherapy to down-stage locally advanced rectal cancer is now standard practice and may impact long term sexual function[77].

The Consequences of Stenosis

In terms of the impact of vaginal stenosis on quality of life, Nori et al[33] classified vaginal stenosis as a 'minor complication', in the same category as cystitis, proctitis, vaginal necrosis and small bowel obstruction. Abitbol and Davenport[24] and Nunns et al[15] identified a relationship between vaginal stenosis and increased levels of discomfort during vaginal examinations. Several authors [16,17,18,24,25,37,51,52] have postulated an association between vaginal stenosis, the severity of dyspareunia and sexual dysfunction. However, the consequences of stenosis remain individual with some women unaffected by significant damage while others experience long lasting psycho, social and sexual loss from clinically minor damage/vaginal changes.

Literature Review: Use of Dilation to Minimise Vaginal Stenosis

Dilation of the vagina is practiced to prevent or treat vaginal stenosis associated with radiotherapy. Most authors do not make a distinction between treatment or prevention but they should be considered separately.

The current rationale for preventing stenosis is to support a woman who wishes to have penetrative vaginal intercourse and to allow her clinician access to the vaginal vault for clinical surveillance so that early detection of a potentially treatable vaginal recurrence could be detected. The suggestion that dilators will improve quality of survival by easing follow-up, allowing early detection of recurrence and salvage therapy, is not proven.

Textbooks and guidance recommend dilation for the treatment of vaginal stenosis but this does not seem to be supported by conclusive primary research data. For example, Rice[52], Hassey-Dow[53], Faithfull[54], and Krumm and Lamberti[55] recommend separating the adhesions between the vaginal walls. Gosselin and Waring[13] state that "regular use of dilators is essential", Wilmoth and Spinelli[56] state that vaginal dilation can "almost always" prevent stenosis; Davidson et al[57] comment on the importance of dilators and Lamberti[58] "stress that the regular use of dilators usually prevents stenosis".

LITERATURE REVIEW: USE OF DILATION TO MINIMISE VAGINAL STENOSIS *(cont)*

Pountney's commentary[59] and Grigsby at al's[11] review both claim that dilators are required to prevent stenosis. Yaniv[60] expands on this and says that "it stands to reason that we do believe that the use of vaginal dilators, in the right way and time indeed reduce radiation damage such as adhesions". None of these authors offers data in support of their individual recommendations. Burke[61] states that one of the most effective ways to manage vaginal stenosis is the use of dilators and draws on the work of Bransfield et, al[62]. This authority is actually a comparison of dilation use extracted from the case notes of French and American hospitals and contains no data to support the claim. In a previous but now outdated Cochrane review, Denton and Maher[21] claimed that "use of vaginal dilators to prevent the development of vaginal stenosis is supported by grade IIC evidence". They relied on the case series by Poma of five women treated years after radiotherapy and Decruze's work[12], neither of which address dilation during treatment as a preventative therapy. Brand et al[72] advocate that dilators should be used within 2 weeks of completion of radiotherapy and also refer to the paper by Decruze. The comments by Abitbol and Davenport[24] are more analytical and suggest that "mechanical dilation of the vagina and the use of topical oestrogens appear to be of doubtful value". The Cochrane review by Miles[65] and her systematic review[66] concluded that there was no good quality evidence to support dilation therapy during the acute radiation phase but there was level 2 and level 3 evidence that dilation could treat stenosis once it had occurred.
A systematic search methodology[67] found only seven studies with any relevant original data.

Two randomised trials[68,69], showed that it was possible to successfully encourage and support women to dilate their vagina but this did not increase sexual function scores. Another trial[70,71] compared a vibrating dilator with the conventional static one. There were no demonstrable differences in sexual function score, vaginal length or elasticity with either device.
Four observational studies comment on vaginal length and all examine dilation practice after radiotherapy. However, all have limited methodological quality and none have good data on the age of their study population. This limits the conclusions that can be drawn from the results. Decruze et al's report[12] actively promotes a stent that they designed. They showed that their device restored the vaginal length more than could be achieved in historical controls with a traditional device. The assessments were subjective, not blind to treatment allocation and women in the control arm were selected by convenience. Bias is compounded because there is a difference in the comparative groups in age, tumour site and type of radiotherapy but this report suggests that dilation may restore some vaginal length. Poma[63] describes five case reports and offers similar evidence. Dilation was used a median of eight years after radiotherapy. These women never had any vaginal penetration following or during their radiotherapy until study recruitment. All five women were able to achieve some vaginal patency after dilation. The study by Sobotkowski et al[78] was a comparison of 31 women treated with radiotherapy for gynaecological cancer and an unspecified half received Mitomycin C to the top of the vagina with a speculum. Mitomycin C prevents DNA cross linkage and its application via a speculum passage reflects an extreme attempt to separate new adhesions between the vaginal walls. There was no difference in vaginal length with this treatment. Velaskar et al[72] describes an observational study of vaginal length measured before and after a program of dilation therapy. In this case-series of 89 women, the median length increased from 6 to 10cm over the 4 repeated measures and 46 of 89 women were able to accommodate larger dilators after one year of follow up. It is inappropriate to assume that this is due to dilation

therapy because it only demonstrates that the vagina recovers length or at least, women are able to tolerate a longer vaginal ruler during clinic visits as the radiation inflammatory changes were subsiding.

There is level 2+ evidence that dilation can be used to treat vaginal shortening once it has occurred but there is no published evidence that it should be used during the acute inflammatory phase in irradiated or recently irradiated mucosa.

GUIDANCE FOR OFFERING VAGINAL DILATORS

Information on dilation therapy should be offered to women to decide if they want to use it. Those who wish to maintain or return to sexual activity after radiotherapy may find dilation therapy supports this. Women who state no need for vaginal patency may prefer not to use dilation therapy. Women may find vaginal examinations at follow up uncomfortable due to the formation of vaginal adhesions. Clinicians may separate the adhesions during examination and may recommend using dilation therapy between follow up examinations to prevent formation of adhesions. This may be appropriate following any pelvic radiotherapy which includes the vagina in the treatment. This may include treatment for cervical, endometrial, vaginal, vulval, anal, low rectal and urological cancers. It is likely that the radiotherapy dose and volume of vagina being treated will impact on the severity of potential vaginal stenosis and selection, where possible, of dilator shape.

PRINCIPLES OF DILATION THERAPY

The principal of dilation is to expand the vaginal tissues. It is known that stretching healthy skin stimulates mitosis and the development of new epithelial cells. Examples include the plastic surgeons who use tissue expanders with good effect in the breast, scalp and vagina[73], and girls born without a vagina (Rokitansky syndrome/or Mayer-Rokitansky-Küster-Hauser Syndrome or mullerian agenesis) can stimulate new skin growth by applying pressure on the mullerian pit (vestibule)[74,79]. Although the skin of a teenager's vaginal stem cells has no resemblance to epithelial cells after radical radiation, the belief is that the skin will re-grow if stretched, or at least, the vaginal supporting tissues can be encouraged to part if they are stimulated. It follows that there is no science to support one device over another. Any device should suffice. Normal coitus, commercially available sex toys, or clinical dilators should be equally effective. The selection of dilator will depend on choice, local availability and funding arrangements.

GPP	Dilation therapy may include the use of dilators, vibrators, fingers, or similar shaped devices.

HOW TO USE A DILATOR

Instructions for using dilators may differ slightly from hospital to hospital, but the principles are the same. The dilator is inserted gently into the vagina using a lubricant. Once inserted to the top of the vagina to a comfortable point, it is gently rotated and then withdrawn. It is reasonable to assume that dilators must not be applied with force to avoid vaginal/mucosal trauma.

GPP	Dilation therapy should be gentle

There is no evidence to support any recommended technique over another. There is no evidence to inform the duration of treatment but some specialists advise use for 6 – 24 months[4], or during the first year; others say it should be life-long. Controversies about frequency in the application of

HOW TO USE A DILATOR *(cont)*

dilation therapy exist. Cartright-Alcarese[9] advises use of a dilator for 10 minutes a day, 3 times a week. Hartman and Diddle[19] recommended a dildo for women who did not have a "spouse". Crowther and colleagues[75] suggested that women should be instructed to apply oestrogen to the vagina (despite the fact radiotherapy destroys hormone receptors) and apply rigorous vaginal dilation and Kegel pelvic floor exercises to promote blood flow to the area. The UK patient charity Macmillan[76] advise patients that they "can minimise or prevent stenosis by using vaginal dilators from 2–8 weeks after the end of their radiotherapy" and refer to a survey of practice, rather than justifying data[8]. Previous UK guidelines suggested use of dilators for 5 minutes, 3 times a week[5]. There is no evidence to support or refute this. None of these recommendations are supported by data and therefore definitive instructions cannot be issued. However, it seems logical to conclude that the least extreme advice must be more convenient and acceptable for women. Clinicians may discuss acute and late effects of radiotherapy on the vagina and the need for dilators during the consent and planning phase of radiotherapy. Dilation therapy may be introduced during the follow up visits. This could be part of the survivorship program and introduced as an option to support sexual well-being once treatment is over, once the acute local inflammatory phase has started to settle.

GPP	Women experiencing difficulty with the concept of dilation/expressing sexual concerns should be offered a comprehensive sexual assessment (where resources available)
GPP	Dilation therapy may be commenced at approximately 2-8 weeks post radiotherapy, when the acute inflammatory response has settled.
GPP	We suggest that a reasonable duration and frequency of dilation may range from three minutes twice a week, for the first six months, up to ten minutes and twice daily. Once a week thereafter and then occasionally after a year if not experiencing difficulty.
GPP	Women may be offered a range of sizes according to their anatomy. It is usual to start with the smallest and progress to whatever size is comfortable. Dilator shape should be determined by the tumour site treated; pointed end for anal, low rectal/ vaginal cancer and flat end for endometrial/ cervix cancer.
GPP	Women should be advised that a small amount of bleeding or 'spotting' after dilator use is normal. If there is a lot of new bleeding or pain, a clinican should be contacted.
GPP	Review the need for dilation therapy on a regular basis, considering discontinuing dilation therapy when no longer required.eg when sexually active or experiencing no discomfort during vaginal examinations at follow up.
GPP	If stenosis develops record toxicity using a recognised score.

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