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Evaluation of patient compliance in the use of vaginal dilators post pelvic radiotherapy

Abstract

Vaginal stenosis (narrowing and shortening) is a common chronic toxicity following pelvic radiotherapy that can lead to sexual dysfunction and difficulty in post treatment vaginal examinations. National guidelines in the use of vaginal dilators were first published in July 2005 following evidence that vaginal dilators were an effective tool in reducing vaginal stenosis. The aims of this study are to elicit patient compliance to the National guidelines and evaluate the information given to women with regard to vaginal dilation and sexual health, capturing user opinion on how information may be better delivered to improve compliance.

Methodology

Proposal for Evaluation Project.

Hypothesis: Dilator information is offered to women undergoing pelvic radiotherapy (or brachytherapy)in accordance with National guidelines. However Compliance remains low. Design of an appropriate National, patient centred information leaflet with user input will ensure design and delivery of optimal information resulting in higher compliance rates.

Aims of evaluation.

The use of vaginal dilators offered post radiotherapy is to minimise vaginal stenosis, and facilitate vaginal examination and resumption of sexual intercourse. The primary aim of phase I is to evaluate patient compliance with the use of vaginal dilators. The secondary aim of phase I will be to investigate compliance related to disease site, body image and post-treatment related vaginal symptoms.

Phase II of the study will evaluate the information given to women post radiotherapy with regard to vaginal dilation and capture user opinion on how information may be delivered to optimise compliance.

Anticipated outcomes.

Improvement in delivery of information and provision of written information will provide the patient with optimal support in addressing post radiotherapy changes to the vagina. Currently there is no National provision of patient information on the use of vaginal dilation and sexual rehabilitation. The anticipated service development from this project is to design a National information document for all women undergoing pelvic radiotherapy covering all aspects of sexual health post pelvic radiotherapy (To be supported by Macmillan or BACUP). Re evaluation of vaginal dilator compliance would be undertaken following design of improved patient information to measure outcomes.

Local and National policy for context of evaluation.

In July 2005 The National Forum of Gynaecological Oncology Nurses produced a National guidance document on Best Practice guidelines on the use of vaginal dilators in women receiving pelvic radiotherapy. The document highlighted the inconsistencies in patient care of women receiving pelvic RT and identified a need to achieve a National consensus in the delivery of consistent patient focused care. Recommendations on the use of vaginal dilators were clearly stated in the document. The evidence base used to develop the guidelines at the time was already being employed, locally, within the authors centre.

Service evaluation.

Service evaluation on the use of vaginal dilators will facilitate an understanding of patient compliance and allow a measurement of how successful implementation of the National guidelines within the authors centre has been.

One distinct lack of information provision within the National guidelines is written information for the patient or recommendations on how the information is best delivered.

The new cancer reform strategy highlights the importance of user input in to the development of cancer service provision, in an attempt to improve patient outcomes. (Department of Health, Dec 2007)

This study will not only demonstrate the current compliance rates to the National standards but will also elicit patient perception of the guidelines and how they feel the information may be better delivered.

Role and scope of responsibility.

In March 2005 the author was appointed as Macmillan Consultant Radiographer in Gynaecological Oncology. The appointment was in part driven by a need to improve service delivery and address the Quality of life (QoL) issues for women receiving pelvic radiotherapy with a focus on sexual health and management of chronic toxicity. The author has been delivering information on vaginal stenosis and its management and acting as an expert practitioner and adviser for 10 years. It is therefore an essential aspect of the role to evaluate the service being offered to the patient with a view to improving service delivery, evidenced based practise and improved patient outcomes. Recent publication of the cancer reform strategy focuses attention on user input in shaping the future of cancer care. It is intended that this project will capture the patient's perspective enhancing a patient centred service.

Literature Review

Background.

Vaginal stenosis results from a change in the highly sensitive mucosa of the vagina following exposure to radiation. It is a chronic side effect resulting from fibrosis developing and obliterating the normal vaginal channel. Radiotherapy may also decrease elasticity of the vaginal wall, decrease vaginal lubrication, result in development of telangiectasia and increase susceptibility to trauma and infection.

In addition to the direct impact of radiotherapy on the vagina, in those women who have not yet reached the menopause, a whole pelvic treatment will induce an artificial menopause. Ovarian failure and oestrogen cessation may then lead to an atrophic vagina or thinning of the vaginal epithelium. (Punt, 2004)

Incidence.

Vaginal stenosis is a common long term complication following radical or adjuvant radiotherapy for carcinoma of the cervix or endometrium. The incidence of vaginal stenosis is however variably reported in the literature. One Author found in a small study of 22 patients that only 4% developed fibrosis (Bertelsen, 1983) whilst several other studies have found that the number of women developing vaginal changes and reduced vaginal capacity range from between 50% and 88% (Hartman et al., 1972, Abitol et al., 1974, Schover et al., 1989)

Impact of vaginal stenosis.

The impact of vaginal stenosis on a woman's sexual health can be enormous with shortening and narrowing of the vault potentially leading to pain (dyspareunia) and vaginal bleeding during intercourse. Several Authors have demonstrated a link between the degree of vaginal stenosis and the severity of sexual dysfunction. (Abitbol et al., 1974, Bruner et al., 1993 Flay et al., 1995, Bergmark et al., 1999.) Psychological issues relating from anticipatory pain may interfere with the sexual cycle resulting in an indirect effect on sexual health and adding to the complexities of managing sexual rehabilitation. (Punt, 2004)

Sexual health aside, a key aspect of maintaining a patent vagina facilitates optimal follow up by ensuring the vaginal vault (for post hysterectomy patients) or the cervix can be adequately examined or visualised without causing significant discomfort. (Nunns et al., 2000). As a result maintaining a fully patent vagina potential vault or central recurrences can then be more easily identified offering the best possible chance of salvage.

Managing vaginal changes.

Despite publication of National guidelines on the use of vaginal dilators there remains a shallow evidence base for the information offered to women with regard to the process of vaginal dilation. The time frame over which vaginal stenosis develops has been infrequently examined. Three studies have reported varying results. Poma (1980) found the maximum development of scar tissue was at 3 months post treatment whilst Flay et al.(1995) found 73% of 16 patients had significant stenosis at 6 weeks. However Hartman et al. (1972) found that 6 of 221 patients developed total vaginal obliteration by 1 month.

Currently there is no researched evidence base demonstrating the length of time that the vaginal dilator should be used for or the frequency of insertion however several authors have made recommendations. Cartwright –Alcarese (1995) suggest 10 minutes daily but at least three times a week. Decruze (1999) recommended daily insertions with no mention of length of insertion time.

In 2003 a Chocrane review of relevant literature addressing interventions for the physical aspects of sexual dysfunction following pelvic radiotherapy concluded that there was sufficient evidence to support approval of the widespread provision of dilator information. (Denton, 2003)

This review was the driving force behind an attempt to nationally standardise information given to women regarding vaginal dilation.

National guidelines.

In an attempt to address some of the inconsistencies in information and to draw together the limited research that has been conducted the National Gynaecological Oncology Nurse forum set about establishing a National standard for the provision of dilator advice across the UK. It was compiled by a body of specialist nurses and researchers and reviewed by

