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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 primary aim is to evaluate patient compliance with the use of vaginal dilators offered post radiotherapy to minimise vaginal stenosis, facilitating vaginal examination and resumption of sexual intercourse.

The secondary aim is to evaluate the information given to women post radiotherapy with regard to vaginal dilation and capture user opinion on how information may be delivered to improve 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). Reevaluation 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 Gynaecologcial 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 practice 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.

Overview and justification of evaluation design.
The primary aim of the study, to evaluate compliance with National recommendations for vaginal dilator use, will be take place via a questionnaire using qualitative and quantitative data. The questionnaire will be issued to the patient at the time of follow-up review in clinic along with an information leaflet. The patient will complete the questionnaire in clinic and will then place the completed document in a sealed envelope addressed to the chief investigator. This will maintain confidentiality and anonymity. The specialist nurse or clinical oncologist will be available if the patient requires help to answer any question. The sealed envelopes will be posted to the chief investigator from the cancer units and delivered by hand from the cancer centre.

Patient selection.
All women diagnosed with Carcinoma of the endometrium and cervix treated with radiotherapy (+ or – Brachytherapy) or brachytherapy alone between December 2005 and June 2008 will be identified using the radiotherapy LANTIS system. Current status (disease free or relapse) of the patient will then be identified on the HISS system. Those patients' referred in to the cancer unit for follow-up will have their current status identified by the specialist nurse working within the unit.

Patient inclusion:
Women who have received pelvic RT, BT or a combination of RT and BT for carcinoma of the cervix or endometrium and are 6 months to 3 years post treatment.

Patient exclusion:
Women who have recurrent or progressive disease.
Women who do not speak English
Women with severe mental health problems

The secondary aim of this project is to capture the patient's perspective on vaginal dilators and the information they received regarding their use. A semi-structured interview of 5 patients will be used to elicit concepts and themes that will provide qualitative data on experiences that may have influenced dilator use (or lack of use).

Patient selection:
All women completing the above questionnaire will be given the opportunity to participate in a semi-structured interview. An information leaflet will be issued on completion of the questionnaire together with a stamped self-addressed envelope and a form for patient details. The information leaflet and form can be taken home and completed if the woman wishes to participate. A contact number of the specialist gynaecological radiographers will be provided with the form should the woman wish to discuss the study further. The information form will then be posted to the chief investigator. If more than 5 women agree to be interviewed then a representative cohort of 5 will be selected for initial interview. (To include both cervix and endometrial patients and a cross section of age range)
Patient numbers, validity and reliability.
The primary outcome of the study is to evaluate the compliance rate with good precision as measured by the 95% confidence interval. If the study includes 130 women, then the compliance will be estimated with precision at most + or – 10%, allowing for a 20% drop out. For example, a compliance rate of 50% would be estimated with 95% confidence interval between 40% and 60%.

With this number of women, there would also be 80% power to detect a 25% difference in compliance rate (30% vs 65%) between the two subgroups (cervix vs endo.) using Chi-squared test at the 5% level of significance.

The statistical tool used for the power calculation is nQuery V4.0.

Statistical advice and assistance with power calculations is sought from the Centre for Applied Medical (CAMS) Statistics, Cambridge to ensure the most robust results.

A validated questionnaire tool, the EORTC CX24 (cervix module)-(REGremil et al 2008) will be used in conjunction with an11 point section on vaginal dilator use.

Data analysis.
The chief investigator and CAMS will be responsible for analysis of personal data, and will be solely responsible for custody and access to personal data.

Time line
May-October 2008: Proposal preparation for DMG
October-January 2009: NHS ethic submission
Jan 2009: Patient identification and begin data collection
July-August 2009: Questionnaire study closed
June-July 2009: Patient interviews
September 2009: Data analysis
September 2009: Submit abstract to appropriate International meeting (see below)
October 2009: Writing
November 2009: Proof reading
End November 2009: submission to DMG
Jan 2010: Begin formulating National patient information in conjunction with Macmillan/BACUP

Publication and dissemination of results.
Findings from the project will be presented locally at the site specific group meeting held in November 2009.

Submission will be made to an appropriate International Journal following completion. (Journals for consideration: Clinical Oncology, Gynaecologic Oncology, International journal of radiation oncology biology physics)

Submission of abstract for oral or poster presentation will be made for International conference/meeting. (The British Gynaecological Oncology Society holds their scientific meeting in November 2009. Consideration will be given to submitting an abstract to this event)

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 telangectasia 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 Gynaeoclogical 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 practitioners responsible for current service delivery. In July 2005 the first publication was released providing clear guidelines on the management of vaginal stenosis.

The document concludes that women should begin using the vaginal dilator within 2 weeks of completing radiotherapy. They should be used on alternate days.
Insertion should last between 5-10 minutes and they should be used for an indefinite period of time.

The document has been made available to all health care professionals although there is no provision of an national information leaflet/book for the patient.

Current practice.
Since the document was published the information given within the authors cancer centre has reflected the published recommended guidelines.
Following completion of all treatment the women receive a dilator kit, written information and a one to one interview with either the Specialist radiographer or the Macmillan Consultant radiographer in Gynaecological Oncology. The written information provided gives direction on how to use the vaginal dilator whilst the practitioner demonstrates the dilator kit. Currently no written information is given on sexual health issues or on the management of vaginal atrophy, although these issues should be discussed during the interview if appropriate.

There are no provisions made for a follow up interview, although telephone contact details are given should the patient wish to discuss further.

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