

Factors related to the late presentation of women with vulvar cancer



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Supervisor: Dr J Butt
Co-supervisor: Prof H Botha

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Declaration

By submitting this dissertation electronically, I declare that the entirety of the work contained herein is my original work. I am the authorship owner thereof (unless to the extent explicitly otherwise stated) and I have not previously in its entirety or in part submitted it for obtaining any other qualification.

By Dr Sumaya Shah

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Abstract

Background

Vulva cancer is increasing in incidence and becoming more prevalent amongst younger women. Over 50% of patients present with advanced stage disease at Tygerberg Hospital. The prognosis for late stage vulvar cancer is poor and the treatment has a high morbidity. The reasons for delayed presentation of cancer include a lack of knowledge about the disease, financial constraints, psychosocial factors, transport and access to health care.

Objective

To determine the reasons behind the late presentation of patients with vulva cancer at Tygerberg Hospital and to propose strategies to reduce avoidable factors, both patient-related and within the health care system, leading to the delay in diagnosis.

Methods

This prospective cohort study included all women presenting to the Tygerberg Oncology unit with a new diagnosis of histologically confirmed vulvar carcinoma between November 2015 and December 2016. An interview was conducted and a questionnaire completed. Data obtained included demographic, social, health seeking behavior, disease and transport related factors. Descriptive statistics were reported and comparisons between early and late stage disease were calculated using Microsoft Excel version 14 and Social Science Statistics Calculators.

Results

Fifteen of the 30 patients interviewed presented with early vulva cancer (FIGO stage 1 or 2), and 15 patients presented with late stage disease (FIGO stage 3 or 4). The youngest patient was 28 years old and the oldest patient in the study was 72 years. There were no significant differences noted between the early and late stage disease with regards demographic, social or transport factors. There was no correlation between the size of the vulva lesion and delay in presentation. Nineteen patients (63.3%) used alternative modalities before seeking help from a health care worker. Although 21 (70%) women had a gynecological examination at the primary health facility, many were treated with antibiotics or creams before a definitive diagnosis was

made. Nineteen patients (63.3%) made 4 or more visits to the primary health care facility before being referred to Tygerberg Hospital for management.

Conclusion

A delay of diagnosis of vulva cancer can be attributed to patient delay in the lack of recognition and interpretation of seriousness of the symptoms of vulvar cancer. Similar to the available literature, a system delay was also noted on the part of the primary health care practitioner. Educating women about this once rare disease and raising suspicion in health care workers regarding the presentation of vulva cancer might aid in earlier health seeking behavior, a prompter biopsy and prevent delayed diagnosis.

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Background and Literature review

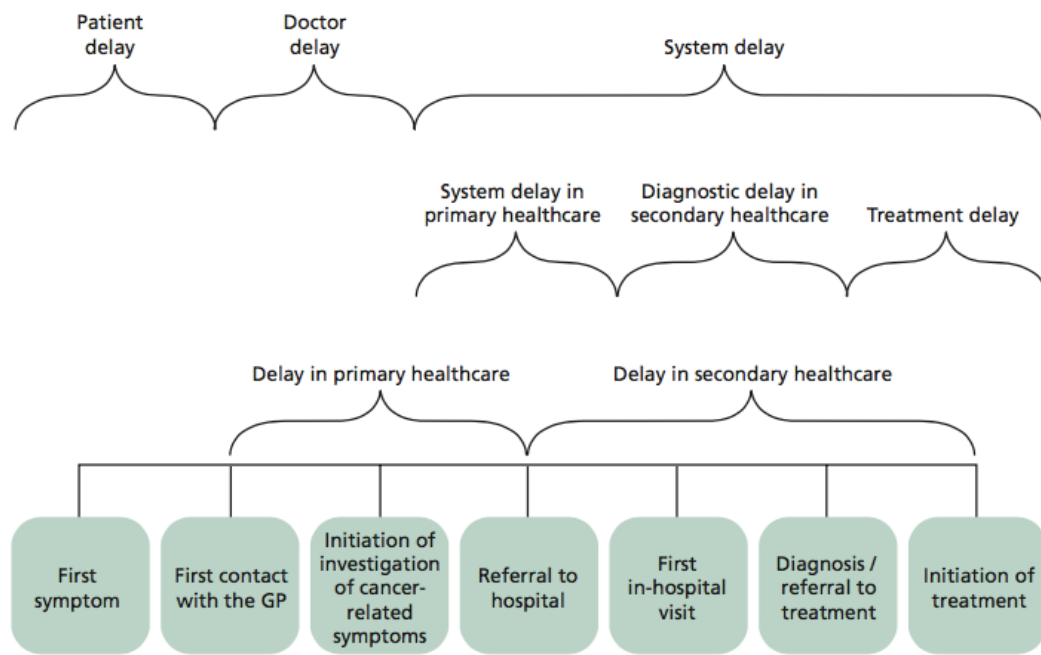
Introduction

Vulvar cancer in South Africa

Vulvar cancer, once known to be a rare condition, is now increasing in incidence. Vulvar cancer has been found to have an association with human papilloma virus (HPV). This association has shown the prevalence of vulvar cancer in younger women to be on the rise (1). Approximately one third of patients present with advanced disease (Figo Stage 3 and 4) (2). The prognosis for women with early stage vulvar cancer is good, with the overall survival rate at five years for Stage 1 and 2 being between 80.0% - 92.4%. The overall survival rate for stages 3 is between 17.4% - 64.6% and for stage 4 is 13.6% (3). At Tygerberg Hospital (TBH), there were 182 women diagnosed with vulvar cancer during a 14 year period (2001 - 2014). The mean age was 52.5 years and 53.3% presented with advanced FIGO stage 3 vulvar cancer or higher (4).

Treatment options for advanced stage vulvar cancer include radical tumor resection such as anovulvectomy, primary radiotherapy or neoadjuvant chemo-radiation followed by surgery. These treatment modalities are associated with increased severe morbidity and no single form of treatment has been noted to improve the prognosis (5). Early detection of vulvar cancer allows for better prognosis and treatment options with less morbidity. Identifying the reasons that patients present with late stage disease is an important factor in the early intervention and prognosis for these women.

A delay of diagnosis of any malignancy may be explained using the Anderson model of total patient delay (6). However this model focused primarily on patient delay as being most significant and the delay due to the health care system may be under researched or underestimated. Hansen et al describes diagnostic delay using three categories, which include patient delay, doctor delay and system delay. Furthermore system delay includes primary and secondary healthcare delay as well as treatment delay.



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 BMC Health Serv Res 2008; 8: 49.

Figure 1. Hansen model of delay

A few studies have looked at the factors contributing to the late presentation and delayed diagnosis of vulvar cancer (2,7,8). The possible reasons may include a varied clinical presentation, or a lack of knowledge and awareness by the patient and the health care provider. Other reasons maybe transport related and access to health care, financial constraints and psychosocial factors.

Clinical presentation of disease

Symptoms of disease play a major role in health seeking behavior of an individual. Often if the presentation is that of a lump, swelling or bleeding it may be reported much earlier as shown in the study carried out by Forbes et al in 2010 (7).

In the case of ovarian cancer, usually vague symptoms with a non visible tumour, the cancer is detected in the advanced stages of the disease. The anatomical location of the ovaries also plays a major role in the poor early detection rate. This is not the case with vulvar cancer as it usually presents with a visible tumor (9). The majority of women with cervical cancer on the other

hand present with advanced disease and this has been attributed to the lack of cervical cancer screening programs (10).

Early on in vulvar cancer there are a lack of specificity of symptoms, and these may range from pruritis to a discharge or a burning sensation. Most women overlook these as minor ailments assuming that with time they will resolve.

A cohort study done in Denmark between October 2007 and December 2007, looked at a sample of 161 patients diagnosed with a gynecological cancer. Nine percent of the sample population had vulvar cancer, and this cancer was associated with longest delay in diagnosis. In this study more than a third of the patients consulted the health care provider with minor symptoms, most often not necessitating a gynecological examination, therefore contributing to the delay (11).

Patient Related factors

Patients do not always recognize symptoms other than abnormal vaginal bleeding or an obvious vaginal skin lesion, as being significant enough to warrant urgent medical attention and therefore many patients delay visiting the doctor. Similarly a study carried out in Germany amongst 1010 women between 2000 and 2015, showed a delay in diagnosis between 6 to 11 months (10). A fear of examination or the reluctance of a gynecological examination were possible reasons attributed to this delay.

Other evidence that also pointed toward a time delay in health seeking behavior is the survey carried out in England in 2010. Those patients who did not seem to think their symptoms were serious delayed seeking medical attention. Other reasons noted in this study was the ‘embarrassment’ to see the doctor or the anxiety of what the outcome might have been (7). Pati et al also confirmed that a lack of awareness of cancer signs and symptoms in general amongst patients may be partly responsible for the delay in presentation (12).

A major challenge found in a study carried out in Ghana amongst patients with vulvar cancer between January 2000 and December 2014 was the high default rate in those scheduled for treatment. About a third of patients did not commence their planned treatment or defaulted radiotherapy (2).

Health Care worker related factors

The diagnosis of the common gynecological malignancies, including cervical, endometrial and ovarian cancer, are more easily made compared to vulvar cancer due to its rarity. This may be partly due to the fact that many health care providers may not be familiar with the different clinical presentations of the disease itself. Health care physicians often make an incorrect diagnosis like that of a Bartholin gland pathology or a simple inflammation of the vagina and vulva (10). A retrospective study done in Germany found a delay of 186 days when the patient was first diagnosed with Bartholin gland pathology and 328 days when a diagnosis of inflammation was made (10).

Furthermore, it is important to mention that in majority of cases a gynecological examination is not carried out unless the patient presents with an alarming symptom such as vaginal bleeding (10). This adds to the delay of diagnosing vulva cancer.

Suspicious vulva lesions are often treated with dermatological creams and ointments for months prior to performing a biopsy and obtaining a histological diagnosis (6). It is crucial that suspicious lesions be examined and biopsied by the initial health care physician. Thirty one percent of women had at least 3 visits to the health care worker for vulvar symptoms before being diagnosed with vulvar cancer in a study carried out in New Zealand (13).

A study carried out in Ghana also showed an average of 52 day delay between the date of histological diagnosis and reporting to the referral center for radiotherapy (2). Reasons for this were thought to be as a result of a complicated referral system. Health care providers need to be able to identify patients with a concerning diagnosis and ensure all steps are taken to speed up the referral from one health care facility to another in order to minimize delay.

Communication between the health care physician and the patient as well as between referral centers play a vital role in initiating a treatment modality promptly. A survey done in England looking at possible reasons for delay in cancer noted that besides listening skills, many doctors lacked questioning skills. The ability to probe a patient further about a symptom that she may not recognize as alarming is key in early detection. Other shortfalls with communication were in the form of administration tasks e.g. Appointment miscommunication or accuracy of information (14).

Financial constraints and psychosocial factors

Treatment costs and financial constraints play an important role in the follow up of patients with vulvar cancer as shown in a study carried out in Ghana, which is a low middle income country (2). Not all costs are covered by the medical schemes or national health plans, and some costs have to be covered by the patients themselves and this may be the reason for defaulting follow up. This is in addition to the transport costs to and from the treatment centre. Forbes et al also noted in a study done in England that patients from the lowest socioeconomic group had the longest delay (7).

Pati et al. in a tertiary cancer center in Odisha in India, sought after the barriers and enablers in cancer patients seeking treatment. Out of a total of 341 patients admitted during April and June 2011, 68 patients were interviewed and included in the study. One of the major reasons for the delay in accessing medical treatment (mean 340 days) was financial constraint. This was found in more than 50% of the cases (12).

In a South African survey carried out in 2009, it was noted that 80% of ill patients seek medical attention from traditional healers and this may be a contributing factor to a delay in detection of cancer in this country (15). A similar finding in a study done in Ghana also confirmed that many patients sought alternative treatment and only presented to a health care facility upon progression of disease and lack of symptom relief. Therefore alternative medicine may also contribute to a delayed diagnosis.

The aim of this study was to look into avoidable factors, patient as well as the health care system related, that led to a delay in the diagnosis of vulvar cancer.

Methods

Aims and Objectives

Primary :

To establish the factors that contribute to the late stage presentation of patients with vulvar cancer, at TBH gynaecological oncology unit.

Secondary :

To assess the contributing factors and propose strategies to reduce this delay.

Methods and materials

Ethics approval was obtained prior to the start of the study. All female patients who presented to Tygerberg Hospital oncology unit with a histologically confirmed vulvar carcinoma were invited to participate in the study. A semi structured interview was conducted in the preferred language or with an aid of interpreter with each patient by the primary investigator.

Inclusion criteria

1. Patients diagnosed at TBH or referred with a confirmed diagnosis
2. English, afrikaans or xhosa speaking patients
3. Histological confirmation of vulvar cancer
4. Ability to give informed consent

Exclusion criteria

1. Patients with recurrent disease
2. Patients with vulvar intraepithelial lesions
3. Previous surgical or radiotherapy treatment for vulvar cancer
4. Severe physical or mental disability
5. Acutely ill patient

Study design

This was a prospective cohort study that was conducted between November 2015 and December 2016 at the TBH oncology unit. Women who presented to the oncology unit and met the inclusion criteria were invited to participate in the study. Informed consent was obtained (Appendix A) and verbal explanation was given regarding the study. The interview was carried out either at the first visit to TBH oncology unit or during the preoperative stay. A questionnaire (Appendix B) was completed by each woman which included demographic information such as age, marital status, residential address, occupation and education. Data was also obtained during the interview on health seeking behaviour, symptoms, reasons for seeking medical attention, enablers and barriers involved in accessing health care, as well as the time lapse at each point in medical care. An additional open ended question was also included regarding the patient's initial thoughts and concerns about the symptoms and diagnosis. Each patient was given a study number and the patients name or hospital number did not appear on the questionnaire in order to maintain confidentiality.

Statistical analysis

Data was extracted from each questionnaire and transcribed onto a MS Excel spread sheet by the principal investigator. Random checks were performed by the supervisor to protect against transcription errors. Descriptive statistics were presented as means with ranges and total numbers with percentages. Statistical analysis was carried out using the Chi square test and the Fisher exact test with significance set at $p < 0.05$. Means were compared using the Student T test. Statistics were calculated using Microsoft Excel version 14 and Social Science Statistics Calculators (<http://www.socscistatistics.com>).

Results

A total of 32 patients were identified to participate in the study. Two patients were excluded due to death and severe illness. Consent was obtained and the questionnaire was completed by 30 patients. Fifteen patients presented with early stage vulvar cancer (FIGO stage 1 or 2), and 15 presented with advanced stage vulvar cancer (FIGO stage 3 or 4) (Figure 1).

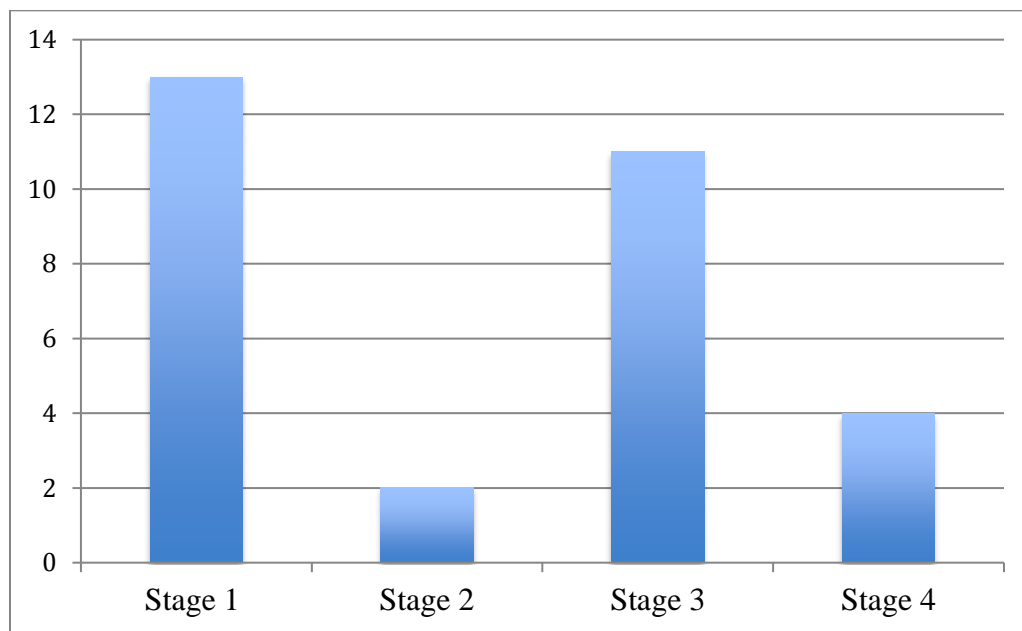


Figure 2. Patients with vulvar cancer according to FIGO stage

Socio-demographic data :

The mean age of woman included in our study was 44.63 yrs (SD 11.3) with the youngest being 28 years old and the oldest was 72 years of age, both presenting with stage 1 disease. There were no significant differences noted in those with early or late disease with regards to age, education, employment or marital status as shown in Table 1. Eighteen women (60 %) gave no family history of cancer. Seventeen women (57%) were HIV positive. Nine of these women presented with early stage disease and eight with late stage disease.

Table 1. Socio-demographic variables

	Early Stage	Late Stage	p Value
Age (SD)	44.86 yr (12.9)	44.46 yr (9.7)	p = 0.912
Single	7	5	p = 0.456
No higher education	6	7	p = 0.712
Unemployed	11	12	Fisher exact = 1
Family history of cancer	6	6	p = 0
HIV	9	8	p = 0.712

Disease:

The average size of the lesion in the early stage of vulvar cancer was 40.8 mm (10 - 80mm), and in the late stage 58.3mm (25 – 120mm), which was statistically significant as expected (p=0.002). There was no correlation with a larger lesion and duration of symptoms (p=0.510). No correlation between size of lesion and number of visits before referral (p=0.464) was noted. There was no association between the size of the lesion and time to first health care encounter (p=0.795) or time to first visit at Tygerberg (p=1).

Transport and access to healthcare:

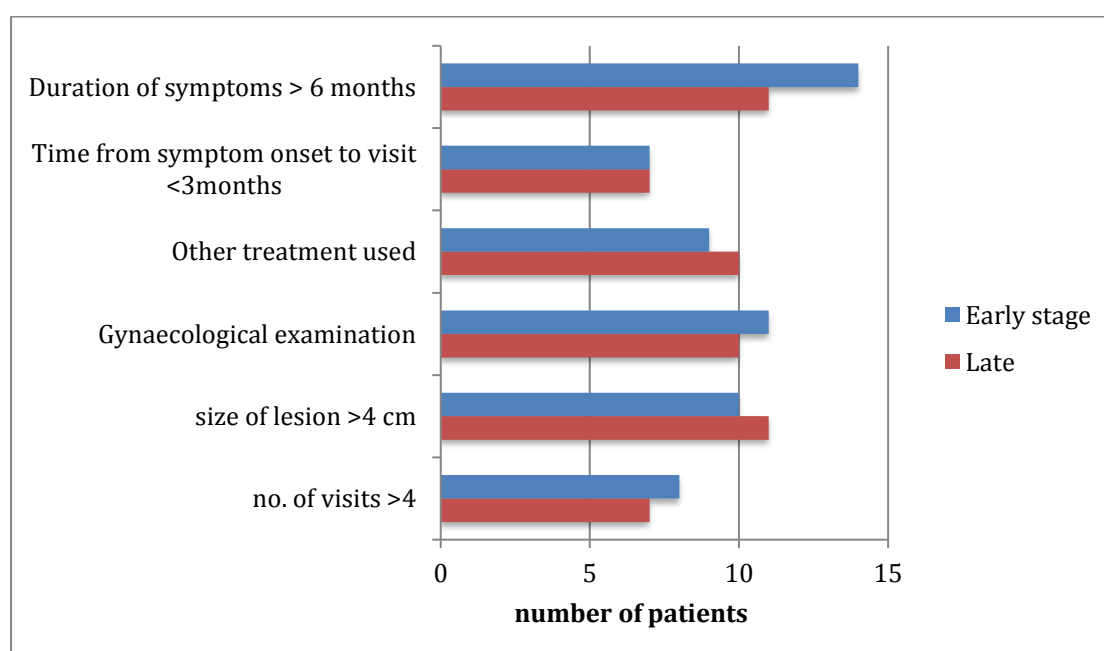
Transport concerns were evaluated and it was noted that most women lived within a 10km radius of a health care facility, with the closest hospital less than 60 min away for majority of women. Ten women (66.6%) with early stage disease lived within 30 minutes from the nearest clinic and eight (53%) of them walked to their nearest clinic. Fourteen women (93%) that had late stage disease lived within 30 minutes from the nearest clinic and 11 (73.3%) of them walked to their nearest clinic (see Table 2). The majority of women with late stage disease lived within 60 minutes to the nearest hospital.

Table 2. Access to health facility

	Number of patients		p value
	Early Stage	Late Stage	
Walk to nearest clinic	8	11	p = 0.289
Public transport to hospital	10	11	p = 0.713
Less than 30min to clinic	10	14	p = 0.092
Less than 60min to hospital	10	14	p = 0.092
Less than 5km	8	9	p = 0.712

Health worker and patient delay:

Symptoms and health seeking behavior were assessed during the interview and are shown in Figure 3.

**Figure 3 Patient and Health care worker related factors**

Fourteen women (93%) with early stage disease waited for longer than 6 months before seeking medical attention with early stage disease. Eleven women (73%) with late stage disease waited longer than 6 months before seeking medical attention. Only two women (6%) were seen at Tygerberg hospital Oncology unit within 3 months of presenting symptoms. One was diagnosed with late stage and one with early stage disease.

Nineteen women (63%) used alternative treatment modalities such as over the counter ointments and salt water sitz baths, prior to their first consultation. Nine women (30%) did not have a gynecological examination during their first consultation for the symptoms. Four of these women were diagnosed with early stage disease and 5 with late stage. No significant difference was noted in the size of the vulvar lesion in patients who had undergone an examination.

Fifteen women made more than four visits to a healthcare facility for their initial presentation before being referred. Eight of these women had early stage and seven had late stage disease. When comparing early and late stage disease, there was no statistically significant difference between the numbers of visits prior to referral to Tygerberg oncology unit ($p = 0.92$). Three women (10%) missed scheduled follow up appointments at their health center. Of the three women, one had stage 4 disease and presented five months after initially seen at the primary health care facility, to Tygerberg hospital. Two women had stage 1 disease and presented more than a year later. All 30 women were followed up within three months for the results of the biopsies.

Social factors:

Of the total of 30 women that were interviewed, 23 women had a support system at home. Twelve of these women, as noted in figure 3 below, presented with early stage disease and 11 with late stage disease. Fifteen of the nineteen women had shared their concerns with a partner. Eleven women had no partner at the time.

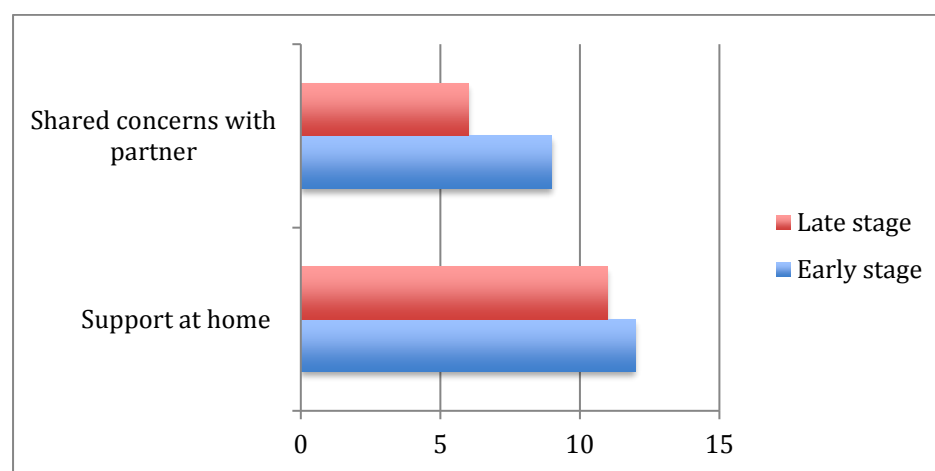


Figure 4 Social factors in early and late stage

During the interview an open ended question regarding thoughts and concerns of each patient highlighted common themes of fear and a sense of embarrassment. Thirteen women thought the initial lesion was a “pimple” or an “abscess” and thought “it would go away”. Seven women suspected the lesion as part of a “sexual infection”, and three women thought the lesion to be a “wart”. It is interesting to note that one patient assumed that her symptoms were not due to a medical condition, but rather “caused by her ancestors punishing her because her brother did not undergo the proper traditional way of initiation”.

Discussion

Socio demographic

An equal number of women presented with early and late stage disease in our study. A survey conducted in England assessing the risk factors for the delay in symptomatic presentation amongst 1999 cancer patients concluded that 21% of patients delayed presentation for more than three months, and this was associated with socioeconomic deprivation (7). We did not corroborate these findings and found no difference when comparing socioeconomic variables between late and early stage cancer.

Recent data on advanced vulvar cancer and age suggests that older women have higher proportions of advanced stage disease, but this was not found in our study (8). Women in our study had a mean age of 44.63 years with no difference in the mean age between early and late stage disease. The young age of patients with vulvar cancer in this study is attributed to the high rate of HPV infection in our population (4).

HIV infection is a risk factor for persistent HPV disease and vulvar cancer. Our findings concurred with the literature, as 57 % of the study population was HIV positive. The prevalence of HIV amongst those patients with early and late disease was similar. Out of the total 30 women, 17 were HIV positive with an average age of 39.7 years (SD 9.4; range 28-63 years) confirming that HIV is a major risk factor for vulvar cancer in younger women.

Transport and access to health care

Most women had relatively easy access to a health care facility, and transport to the closest clinic or hospital proved to be of no significant relevance with regards to delay of presentation. This is in contrast to a study done in Ghana where transport and transport costs played a role in delay of presentation (2).

Patient delay factors

Patient delay was a key factor as noted by several other studies. Most patients did not recognize early symptoms as being serious in nature and delayed visiting the local clinic or hospital due to a lack of information or ignorance regarding vulvar cancer. Approximately 20 patients thought, “it was a pimple or an abscess and it will go away.” One patient shared her concerns that it was the result of a “poorly healed episiotomy” that she sustained during childbirth. Only when symptoms of pruritus and a progressively enlarging skin lesion became unbearable did most patients seek medical attention. The majority of patients attempted other forms of treatment e.g. “over the counter” ointments, and salt water sitz baths before going to the clinic. Perhaps a lack of alarming symptoms as noted in many other studies (16), adds to the absence of suspicion of the cancer diagnosis and hence the prolonged delay. There was no admission to the use of traditional medicine in our study population, as documented in previous studies (15). Even though one patient had assumed her symptoms were “caused by the ancestors because her brother did not complete his initiation as part of tradition”, she did not admit to the use of traditional medicine. There was a lack of awareness of this challenging disease. Embarrassment, shyness and fear were key elements that were found to be contributing to the delay of presentation. When asked about their initial thoughts during the interviews, many patients assumed their symptoms were due to a sexually transmitted infections and some thought it was as a result of HIV.

Health care delay

In our study, a median of four visits (range 0-18) was made before any women with early or late vulvar cancer was referred to Tygerberg Hospital. Misdiagnosis contributed to the delay in the diagnostic process, as patients had to follow up repeatedly before a biopsy was considered. Perhaps as a result of the rarity of vulvar cancer in previous years, many health care providers fail to recognize the symptoms and therefore are not prompted to consider it as a differential diagnosis. The lack of performance of a gynecological examination after the initial complaint was not found to be statistically significant in the delaying of the diagnosis. Twenty-one women (70%) had a gynecological examination performed by either the treating sister or the doctor at the clinic, however most of the women were still treated for a sexually transmitted infection with an antibiotic or ointment after the initial consult.

We aimed at assessing the possibility of delay between referral and diagnosis during our interviews, however as noted above, there was no delay after the suspicious lesions were biopsied and a histological diagnosis was confirmed. All patients followed up within three months (or earlier) of diagnosis at our oncology unit, confirming that the referral process between the surrounding primary health care facilities and the Tygerberg Hospital Oncology unit is a relatively smooth one.

Social

The initial thoughts and concerning factors were shared by all the women during the interviews, and words like “embarrassed”, “scared”, “worried” and “shy” were among those most frequently used. There was a heightened sense of embarrassment amongst the women we interviewed. Most women had a support system at home. Fifteen of the nineteen (78.9%) women in a relationship did share concerns of their diagnosis with their partners. Since many assumed their diagnosis was linked somehow to that of an STI, the stigma attached to the symptoms and the link to promiscuity may play a substantial role in keeping patients from seeking health care. Many studies have mentioned patients reporting a worry about wasting the doctor’s time with trivial complaints; this was however not mentioned during any of our interviews (7).

Conclusion

In contrast to other studies socioeconomic factors, transport issues and seeking help from traditional healers played no significant role in the delayed presentation of vulvar cancer in our study. Our study supports other studies in that the patient delay factor plays a big role. Recognition and interpretation of symptoms, as well as health seeking behaviour did seem to be a common factor amongst those patients who did present late.

Overall in our study, patients that presented with early and advanced disease had to make repeated visits before a diagnosis was made and the correct channels followed. This is in keeping with many other studies that have shown a system delay on the part of the primary health care practitioner. Nineteen patients had four or more visits to the primary health care facility before referral to Tygerberg. Although 70% had a gynaecological examination at the primary health facility, many of these patients were treated with antibiotics or creams before a definitive diagnosis was made, suggesting that Health care workers do not recognise the vulvar pathology as cancer.

The only recommendations we can infer from our study is to create an awareness of the disease amongst the female population. Perhaps enlightening women about symptomology might alert them to seek health care earlier.. An increase of vulvar cancer among younger age women in the South African population is related to the high prevalence of HPV. HPV vaccinations to young women might see a decrease in vulva cancer in the future. Educating the younger women on sexual behaviour and the importance of barrier methods of contraception might also prove beneficial.

In order to reduce a delay on the part of the health care practitioner, a reminder of this once rare disease and its often vague presentation might increase suspicion. An increased suspicion will provoke an increase in action in excluding vulva cancer at a much earlier stage. The importance of a gynaecological examination and biopsy if needed cannot be overemphasized in detecting vulva cancer. Doctors and nurses who are faced with the patient at first contact should be encouraged to have a low threshold for biopsy to rule out any malignancy on suspicious vulva lesions. Health care providers who work at HIV clinics and colposcopy clinics, where women at high risk of HPV infection are encountered, should be especially vigilant.

Creating a public awareness of this disease, as has been done with other forms of cancer, will aid in removing the stigma attached to vulvar cancer and this may assist patients in overcoming the overwhelming emotions of fear and embarrassment and in turn present with earlier stage disease.

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Appendix A

PARTICIPANT INFORMATION LEAFLET AND CONSENT FORM

TITLE OF THE RESEARCH PROJECT:

REFERENCE NUMBER:

PRINCIPAL INVESTIGATOR:

ADDRESS:

CONTACT NUMBER:

You are being invited to take part in a research project. Please take some time to read the information presented here, which will explain the details of this project. Please ask the study staff or doctor any questions about any part of this project that you do not fully understand. It is very important that you are fully satisfied that you clearly understand what this research entails and how you could be involved. Also, your participation is **entirely voluntary** and you are free to decline to participate. If you say no, this will not affect you negatively in any way whatsoever. You are also free to withdraw from the study at any point, even if you do agree to take part.

This study has been approved by the **Health Research Ethics Committee at Stellenbosch University** and will be conducted according to the ethical guidelines and principles of the

international Declaration of Helsinki, South African Guidelines for Good Clinical Practice and the Medical Research Council (MRC) Ethical Guidelines for Research.

What is this research study all about?

The study will be conducted at Tygerberg Hospital where approximately 20-30 patients presenting to the Gynecology oncology unit will be recruited. Vulva cancer is a rare condition and most patients who present with this diagnosis are in the advanced stages already. Therefore the aim of this study will be to try and understand the reasoning behind the late clinical presentation, in an attempt to encourage earlier diagnosis and treatment.

Why have you been invited to participate?

To assist us in finding out more regarding events surrounding the diagnosis of vulva cancer and how we can improve referral of patients with this disease to an oncology unit.

What will your responsibilities be?

To simply complete the questionnaire to the best of your capacity.

Will you benefit from taking part in this research?

You will not benefit from this research project however it is for the benefit of future patients with the same diagnosis.

Are there in risks involved in your taking part in this research?

There are no risks whatsoever for you taking part in this research.

If you do not agree to take part, what alternatives do you have?

It is entirely your wish if you would not like to take part in this research study, and we would respect that fully.

Who will have access to your medical records?

The information collected will be treated as confidential and protected. If it is used in a publication or thesis, the identity of the participant will remain anonymous. Only the investigators and supervisors of this research study will have access to this information.

What will happen in the unlikely event of some form injury occurring as a direct result of your taking part in this research study?

There is no risk of injury should you participate in this study.

Will you be paid to take part in this study and are there any costs involved?

No you will not be paid to take part in the study, and there will be no costs involved for you, if you do take part.

Is there any thing else that you should know or do?

- You can contact Dr S Shah at tel 0219384424 if you have any further queries or encounter any problems.
- You can contact the Health Research Ethics Committee at 021-938 9207 if you have any concerns or complaints that have not been adequately addressed by your study doctor.
- You will receive a copy of this information and consent form for your own records.

Declaration by participant

By signing below, I Agree to take part in a research study entitled (*insert title of study*).

I declare that:

- I have read or had read to me this information and consent form and it is written in a language with which I am fluent and comfortable.
- I have had a chance to ask questions and all my questions have been adequately answered.
- I understand that taking part in this study is **voluntary** and I have not been pressurized to take part.
- I may choose to leave the study at any time and will not be penalized or prejudiced in any way.
- I may be asked to leave the study before it has finished, if the study doctor or researcher feels it is in my best interests, or if I do not follow the study plan, as agreed to.

Signed at (*place*) On (*date*) 2005.

.....

Signature of participant

.....

Signature of witness

Declaration by investigator

I (*name*) Declare that:

- I explained the information in this document to
- I encouraged him/her to ask questions and took adequate time to answer them.
- I am satisfied that he/she adequately understands all aspects of the research, as discussed above
- I did/did not use an interpreter. (*If an interpreter is used then the interpreter must sign the declaration below.*)

Signed at (*place*) On (*date*) 2005.

.....

Signature of investigator

.....

Signature of witness

Declaration by interpreter

I (*name*) Declare that:

- I assisted the investigator (*name*) To explain the information in this document to (*name of participant*) Using the language medium of Afrikaans/Xhosa.
- We encouraged him/her to ask questions and took adequate time to answer them.
- I conveyed a factually correct version of what was related to me.
- I am satisfied that the participant fully understands the content of this informed consent document and has had all his/her question satisfactorily answered.

Signed at (*place*) On (*date*)

.....

Signature of interpreter

.....

Signature of witness

Appendix B

No.....

Questionnaire

Personal info:

1. Age:

2. Relationship status:

Single

☐

Married

☐

Divorced

☐

Separated

☐

Other.....

☐

3. Level of education:

Less than High School

☐

High School

☐

College/ University

☐

Postgraduate

☐

4. Employment Status:

Employed

☐

Unemployed

☐

5. Where do you live?

6. Do you live alone?

Yes

☐

No

☐

Is there a support system at home?

Yes

☐

No

☐

Travel info:

7. How do you travel to your nearest clinic?

How do you travel to hospital?

8. How long does it take you to get from your home to the nearest clinic?

How long does it take you to get from your home to hospital?

9. What is your travelling distance to the nearest available clinic?

Less than 5Km ☐

5-10Km ☐

More than 10 ☐

Symptoms:

10. Is there a history of cancer in the family?

Yes ☐

No ☐

If yes, what:

11. When did you first notice the lesion/symptom?

12. How long after noticing the lesion for the first time did you go to the local clinic/ GP/ day hospital?

0-3 Months

3-6 Months

6-12 Months

More than 1 Year

13. How long after did you visit TBH for the first time?

0-3 Months

3-6 Months

6-12 Months

More than 1 Year

14. Did you miss any appointments following your first visit to the clinic regarding this condition?

Yes

No

15. How many visits did you make to the clinic for the same symptom before you got a referral date for TBH?

16. Did the doctor examine the genital area / private parts after your first complaint?

Yes

No

17. When was the first biopsy taken?

18. How long after the biopsy was done did you follow up for the result?

0-3 Months

3-6 Months

6-12 Months

19. Did you try any other treatment before coming to hospital? Yes ☐ No ☐

20. HIV status:

Social:

21. What were your initial thoughts when you first noticed the lesion / symptom?

.....

22. Did you share your concerns with your partner/husband prior to first consultation?

Yes

No