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Late effects and quality of life after chemo-radiation for the treatment of anal cancer



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A B S T R A C T

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Purpose: The aim of this study was to evaluate the late effects and quality of life of patients following chemo-radiation treatment for anal cancer.

Methods: All surviving anal cancer patients treated within NHS Lothian between 1990 and 2007 were invited to participate. Data were collected using the EORTC QLQ-C30, the EORTC QLQ-CR38 and the Memorial Sloan-Kettering Cancer Centre Bowel Function Instrument (MSKCC).

Results: Overall response rate was 46% ($n = 42$); mean age 54.7 years and with a median time interval of 63.8 months between treatment and completion of the questionnaires. Thirty-five percent of the participants were 'rarely' or 'never' able to wait 15 min to get to the toilet; 50% were 'rarely' or 'never' able to control the passage of gas; 35% limited the types of solid foods they eat; 22% had leakage of stool during the day; 39% required to use a protective pad and 29% altered their daily activities because of bowel function 'always' or 'most of the time'. Seventeen percent of patients reported financial difficulties ('quite a bit' and 'very much'). Both men and women reported high symptomology for sexual problems with a median score of 83.3 (50.0, 100.0).

Conclusion: This study has shown that in a sub-set of patients treated with chemo-radiation for anal cancer, persistent treatment related issues are reported at a medium time interval of 5.3 years. Further work is now required to understand the impact of symptoms on day-to-day life and the challenges that people face in managing these inter-related and complex problems.

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Introduction

Cancer of the anus accounts for approximately 2% of all cancers of the large bowel (Parkin et al., 2002; Information Services Division, 2012) with approximately 1175 people diagnosed each year in the United Kingdom (CRUK, 2011). The most common type of anal cancer is squamous cell and its variants include basaloid and cloacogenic. Although rare and more common in women, the risk of developing squamous cell carcinoma of the anus has more than doubled over the last 3 decades in Scotland in both sexes (Brewster and Bhatti, 2006) and is continuing to increase both in the general population and in high-risk groups. The exact reason is unknown however recognised associations include human papilloma virus (HPV), immunodeficiency virus (HIV) status, sexual activity,

receptive anal intercourse in men, lowered immunity, social deprivation and cigarette smoking (Aggarwal et al., 2013).

Historically the treatment for anal cancer was abdominoperineal resection (APR) with formation of a permanent stoma however over the last few decades patients have been treated successfully with combination chemo/radiotherapy in an attempt to save sphincter function (de Bree et al., 2006; Aggarwal et al., 2013). Surgery is now used as salvage treatment for recurrent or persistent disease. Recent results from a large randomised trial of chemo/radiation conducted in anal cancer reports complete response rates of 95% and recurrence-free survival of 75% at 3 years (James et al., 2013).

This is encouraging and with increasing survival comes a growing interest to evaluate the late consequences of sphincter-saving treatment and the potential impact on quality of life. This is particularly important in anal cancer because of the highly sensitive nature of the disease, and the stigma that can be attached. However it is a tumour group where there is a limited evidence-base about recovery following combined chemo-radiation treatment and the potential consequences of treatment. In part, this is

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due to it having been a rarer cancer with relatively small patient numbers seen in any one institution. There have been a number of small-scale cohort studies (participant numbers ranged from 32 to 128) to suggest that patients can experience ongoing distressing symptoms such as diarrhoea, faecal leakage, incontinence and poorer sexual function for many years after treatment (Allal et al., 1999; Jephcott et al., 2004; Das, 2008; Das et al., 2010; Provencher et al., 2010; Welzel et al., 2011; Bentzen AG et al., 2013). These symptoms have the potential to significantly impact on general day to day living, relationships and ability to return to work. Therefore learning more about the longer-term symptoms that patients may experience, particularly in relation to pelvic dysfunction, is important and will help inform appropriate and timely tailored advice and interventions to support patients manage their symptoms more effectively.

On this basis we felt it important to evaluate the incidence and severity of late effects in patients treated with chemo-radiation within our institution for comparability and to inform future supportive recovery programmes. In addition, the use of more precise 3D-targeting intensity modulated radiation therapy (IMRT) is planned for introduced within our department in 2015, therefore having data about the late effects from current treatment methods was deemed important to allow comparisons to be made in the future.

The aim of this study was to evaluate the prevalence of long-term urinary, bowel, sexual dysfunction and overall quality of life in patients treated with combined chemotherapy and radiotherapy for anal cancer. Patients who underwent subsequent surgery for recurrent disease were also included in the study as in such cases, the treatment intent remains 'curative'.

Methods

Study design and setting

We evaluated bowel, urinary, sexual function and QoL in all surviving anal cancer patients treated during the period January 1990 to December 2007 with a minimum follow up period of two years. The study was conducted at the Edinburgh Cancer Centre, NHS Lothian. Ethical approval was obtained from NHS Lothian Research Ethics Committee.

Sample

Suitable patients were identified from the Edinburgh Cancer Centre Database. A total of 271 patients with anal cancer were treated in the Edinburgh Cancer Centre throughout this period, of whom 106 were still alive at the time of conducting the study. While acknowledging treatment techniques and regimens have changed throughout this period, all patients in this study were treated by one of three consultants to agreed protocols. More recently treatment has been based on the standard arm of the ACT II anal cancer trial, (James et al., 2005) resulting in a consistent evidence-based approach to treatment. All patients were treated with pelvic chemo-radiation as it was in 1990 that our department entered patients in to the original ACT I (UKCCCR Anal Cancer Trial Working Party, 1996) which was open for entry.

The criteria for inclusion in the study were all NHS Lothian patients treated with 'curative' intent with a histological diagnosis of anal cancer and disease-free status at the time of the study. Patients excluded were those treated with palliative intent, those with metastatic disease, treatment by surgical excision only, missing medical details and residency out with Lothian.

Recruitment and data collection took place over two months.

Data collection

Eligible patients were invited by letter to participate in the study. If they consented to the study, participants were asked to complete three validated self-report questionnaires which had been used by the authors in a similar prevalence study of late effects in rectal cancer (Knowles et al., 2013). These included the European Organization for Research and Treatment of Cancer Quality of Life (EORTC-C30) (Aaronson et al., 1993), the European Organization for Research and Treatment of Cancer Quality of Life Colorectal Cancer Module (EORTC QLQ-CR38) (Sprangers et al., 1999) and the Memorial Sloan-Kettering Cancer Centre (MSKCC) Bowel Function Instrument (Temple et al., 2005). The EORTC QLQ-C30 contains five functional scales assessing physical, role, cognitive, emotional, and social function; three symptom scales assessing fatigue, nausea and vomiting, and pain; and six single items assessing commonly reported symptoms by people with cancer and a global health-status. As there was no anal cancer specific module we used the EORTC QLQ-CR38 designed to measure symptoms related to areas relevant to patients with colorectal cancer which are applicable to an anal cancer population.

Similarly we used the MSKCC Bowel Function Instrument which was designed to measure function in patients who have undergone sphincter-preserving treatment surgery for rectal cancer and has been used in a number of studies evaluating colorectal issues. The specific bowel symptoms associated with pelvic dissection are similar to those associated with radiotherapy to the pelvis and therefore this tool was applicable for use in this study. This tool consists of 18 items grouped into three subscales (frequency, urgency/soilage, dietary). The frequency subscale includes questions relating to the number of bowel movements per 24 h, stool consistency and the ability to get to the toilet on time. Questions relating to the impact of certain food/drink items on bowel movements are included in the dietary subscale. The urgency/soilage subscale comprises questions concerning faecal leakage and the impact of bowel function on activity. Permission to use all three instruments was granted from the authors.

Participants were asked to complete the three questionnaires on one occasion only. Scoring manuals for each individual tool were used to calculate the raw scores. High scores on the MSKCC indicate good function. Similarly, out of a range of 0–100, higher scores for the EORTC questionnaires indicate better functioning, whereas higher scores for symptom subscales indicates poorer symptoms.

Data analysis

Data analysis was conducted by the Lead Statistician, Epidemiology and Statistics Core from the Wellcome Trust, Edinburgh. Data were analysed descriptively and presented as medians and inter-quartile ranges due to the shape of distribution. Comparison of demographic details were made between participants and non-participants. A two-sample t-test was used to look at age. Statistical analysis was by SAS (v 9.2). We considered age, stage of tumour, treatment regimes and co-morbidities to evaluate possible pelvic function impact however the total numbers were deemed too small to enable a statistical comparison to be made.

Results

Patient demographics and treatment

Ninety-one of the 106 patients alive were eligible for the study of whom 42 responded, giving an overall response rate of 46%. The median time between treatment and completion of the questionnaires was 63.8 months (41.4, 93.5). Table 1 shows the

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