Establishing the prevalence of patient-reported late-effects of pelvic radiotherapy symptoms utilising a simple patient reported outcome measure (sPROM)

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Introduction and Background

By the end of 2015 2.5 million people living in the United Kingdom will have had a cancer diagnosis [1] and of these 25% will suffer poor health or disability following cancer treatment [2].

Radiotherapy is a highly efficient and effective treatment option for many cancers. The dose-response relationship for tumor control is well defined; however radiation toxicity can be dose-limiting and patient specific [4].

Adverse effects of radiotherapy are defined by the time of onset [3];

→ Late effects: occur months to many years post treatment and are predominantly irreversible with the risk of late effects being lifelong [6]
→ Acute effects: occur during or immediately after treatment and are generally reversible [6]

Late effects from pelvic radiotherapy are known as pelvic radiation disease; “transient or longer term problems, ranging from mild to very severe, arising in non-consensus tissues resulting from radiotherapy treatment to a tumour of pelvic origin” [5].

Pelvic radiation symptoms include:

- Distress
- Pain
- Social effect
- Urgency of defaecation
- Functional challenges
- Lifestyle changes (2,3)

The traditional medical (clinics) model of care where cancer patients are followed-up for two to five years or more is unsustainable [4] with a focus on the improvement of the referral to treatment pathway and a focus on surveillance and monitoring for further disease [7] with the efficacy of these strategies is the subject of debate [8].

Clinical follow up and late effects are seldom managed effectively, with many of these combined strategies ultimately causing death in cancer survivors (9-11). The national cancer surveillance initiative advocates a risk-stratified approach to care after treatment as a shift from a one-size fits all approach. It advocates that patients need to be prepared for the recognition of the effects of cancer and the likely time course, with more intense surveillance and support being available to those determined to be at high risk.

There are very limited prediction models available to better identify severe late effects & ensure that support is appropriately planned and focused.

Study Aims

Null hypothesis

There is no correlation of sPROM late effect triggers in a radiotherapy treated population against age, elapsed time from treatment, prescribed pelvic dose or gender.

Primary aims:

• Identify the frequency and prevalence of patients self-reporting symptoms of late treatment effects in the treated population of patients having had pelvic radiotherapy

Secondary aims:

• Identification of any associative factors of late effects triggers identified in the sPROM
• Review the efficacy of using a sPROM questionnaire in patient self-reporting of late effects triggers symptoms
• Identification of the burden of late treatment effects in the treated population

Methods

The study employed cross-sectional population prevalence study design utilizing a simple patient report outcome measure (sPROM) to review prevalence of self-reported symptoms of late effects in the pelvic radiotherapy treated population.

Assessment of the efficacy of the sPROM questionnaire in identifying and managing late effects was undertaken and statistical/registration methods used to review associative factors/variants.

An sPROM survey was designed to capture data on 25 specific functional sPROMs with 7 of these sPROMs designated as red triggers, requiring clinical follow up and management (based on the draft Macmillan policy guidance for pelvic late effects).

The study population was defined as patients that had had pelvic radiotherapy by the national radiotherapy dataset criteria either for radical or palliative intent at the study centre. Inclusion criteria ensured a minimum of six months elapsed time from completion of radiotherapy to completion of the sPROM (avoiding responses due to acute side effects).

Analysis identified that the maximum pelvic dose was the most statistically significant variable, in relationship with partner or sexual concerns. Maximum pelvic dose (p=0.003) was indicated. Pain in the pelvic / lower abdomen, lower lumbar (p=0.049). Blinding from the bottom (p=0.008), problems with passing or controlling urine (p=0.031) and fatigue/having no energy (p=0.019). Age was found to be statistically significant in relationships with others (p=0.028) and finances/my money concerns (p=0.006).

Analyses were also linked to elapsed time from treatment (p=0.014), which may be expected due to the known impact of cancer diagnosis on employment and income.

Quality of life was reviewed against sPROM triggers to support the review of the reliability of the sPROM scale. The total of all sPROM triggers demonstrated some negative correlation, however red sPROM triggers and “speak to professional” requests did not demonstrate a determinable correlation.

Correlations between variables were noted only in a small number of considerations and these confirmed the sensitivity of the sPROM with a strong negative correlation with quality of life concerning "all red triggers" (p=0.01) and "speak to professional" requests (p=0.007). "Speak to professional" requests were positively correlated to total sPROMs and red triggers as would be anticipated. No correlations were identified between age, elapsed time and maximum pelvic dose when considering all sPROM questions in totality.

A total of 138 sPROMs (26.0%) included a free text response to the free-text question. The large majority of comments related to the general function / wellbeing / lifestyle themes (22%) followed by a considerable number of respondents commenting on the effects of a co-morbidity (12%).

Results

All sPROMs were reviewed by a clinician and triaged based on clinical assessment with management / review referral recorded.

Feedback from study participant

"You have helped me so much to get my life back – thank you sincerely from me & my family"

As a result models of follow up across the UK have changed resulting in many patients no longer being followed up by an Oncologist in the long-term [11]. However, clinicians in primary care are unlikely to have large numbers of patients experiencing complex effects following cancer therapy [9], with information from secondary care clinicians often not adequately communicated to primary care [3].

Discussion

The prevalence of patients self-reporting symptoms of late treatment for any sPROM questionnaire was 76.2% and red sPROM trigger question was 38.2%.

It was not possible to identify overall any correlation or model of sPROM late effect triggers with age, elapsed time from treatment, prescribed dose or gender. Six questions revealed statistically significant associated variables with maximum pelvic dose; the most statistically significant variable, in relationship with partner or sexual concerns [p=0.003], blinding from [p=0.008], urine control [p=0.031] and fatigue being significant. Age had a highly significant association with financial concerns, additionally elapsed time from treatment had a significant association with financial concerns.

Conclusions

- sPROM questionnaire is a feasible method of efficiently and effectively engaging with patients
- Assessment of validity and reliability of tool was positive
- Cost effective method of establishing population burden of late effects
- No overall correlation of factors (age, elapsed time, dose or gender); however six sPROM questions indicate statistically significant variables
- Null hypothesis can be rejected as associations were noted between maximum pelvic dose and blinding from the bottom which was highly significant with additional associations between pelvic pain, urine control and fatigue being significant. Age had a highly significant association with financial concerns, additionally elapsed time from treatment had a significant association with financial concerns.

References

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The results confirm that the null hypothesis can be rejected as associations were noted between maximum pelvic dose and blinding from the bottom which was highly significant with additional associations between pelvic pain, urine control and fatigue being significant. Age had a highly significant association with financial concerns, additionally elapsed time from treatment had a significant association with financial concerns.

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- Cost effective method of establishing population burden of late effects
- No overall correlation of factors (age, elapsed time, dose or gender); however six sPROM questions indicate statistically significant variables
- Null hypothesis can be rejected as associations were noted in these three sPROM questions in relationship of one red trigger was 38.2% and any sPROM question was 70%.
- Not possible to identify predictive factors that would enable accurate modelling of patient risk
- Results confirm the unpredictable and spurious nature of radiotherapy late effects
- Assessment of late effects and dose/fracturation may not be adequate predictors of late effects at the decision point of patient discharge to self-managed.

Acknowledgements

This work has been supported...