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# 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 tumour-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 (4)
- → Acute effects: occur during or immediately after treatment and are generally reversible (4)

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-cancerous tissues resulting from radiotherapy treatment to a tumour of pelvic origin.' (5).

Pelvic-radiation symptoms include:

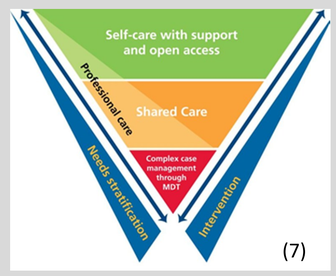
- → Distress
- → Pain
- → Social effect
- → Urgency of defecation
- → Functional challenges
- → Lifestyle changes (2,5)

The traditional medical (illness) model of care where cancer patients are followed-up for two to five years or more is unsustainable (6) 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)

Chronic pre-existing co-morbidities and effects of treatment are seldom managed effectively, with many of these comorbid conditions ultimately causing death in cancer survivors (9-11). The national cancer survivorship 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.

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 (12). 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 (13).

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



(7)

## 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 aim:
- 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 use of a sPROM questionnaire in patient self-reporting of late effects trigger symptoms
- Identification of the burden of late treatment effects in the treated population

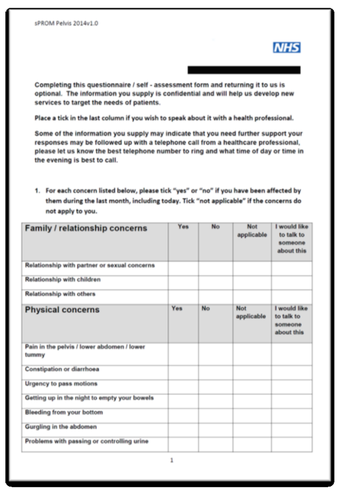
## Methods

The study employed cross-sectional population prevalence study design utilising a simple patient reported outcome measure (sPROM) postal survey 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 regression methods used to review associative factors/ variants.

An sPROM survey was designed to captured 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).


sPROM Pelvis 2014v1.0

NHS

[redacted]

Completing this questionnaire / self - assessment form and returning it to us is optional. The information you supply is confidential and will help us develop new services to target the needs of patients.

Place a tick in the last column if you wish to speak about it with a health professional.

Some of the information you supply may indicate that you need further support your responses may be followed up with a telephone call from a healthcare professional, please let us know the best telephone number to ring and what time of day or time in the evening is best to call.

1. For each concern listed below, please tick "yes" or "no" if you have been affected by them during the last month, including today. Tick "not applicable" if the concerns do not apply to you.

| Family / relationship concerns | Yes | No | Not applicable | I would like to talk to someone about this |
|---|---|---|---|---|
| Relationship with partner or sexual concerns | | | | |
| Relationship with children | | | | |
| Relationship with others | | | | |
| **Physical concerns** | **Yes** | **No** | **Not applicable** | **I would like to talk to someone about this** |
| Pain in the pelvis / lower abdomen / lower tummy | | | | |
| Constipation or diarrhoea | | | | |
| Urgency to pass motions | | | | |
| Getting up in the night to empty your bowels | | | | |
| Bleeding from your bottom | | | | |
| Gurgling in the abdomen | | | | |
| Problems with passing or controlling urine | | | | |

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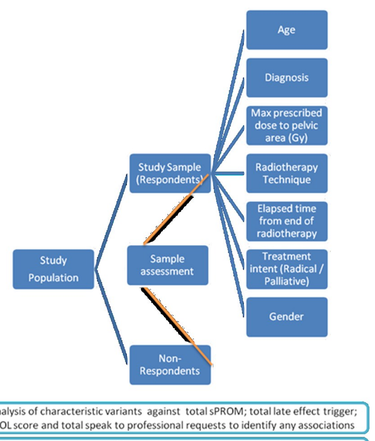



Analysis of characteristic variants against total sPROM; total late effect trigger; QOL score and total speak to professional requests to identify any associations

Qualitative assessment of free text responses and analysis of characteristic trends to support quantitative statistical analysis

Assessment of bias (respondent vs non-respondent group) was undertaken using Chi-square test for independence (with Levene's test for equality of variances) prior to assessment of relationship between variables.

## Results

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

| Response Rate | Value |
|---|---|
| Total number of sPROMs sent | 524 |
| Total number of returned sPROMS | 383 |
| Crude response rate | 73.1% |
| Total number of deceased patients in sample (identified by follow up review) | 22 |
| Total number of lost to follow up/ undelivered | 2 |
| Total number of sPROMs not returned | 165 |
| Adjusted final response rate | **77.7%** |

| Outcome Action | Total |
|---|---|
| Telephone Triage | 90 |
| General information provided by post | 164 |
| Consultant Radiographer OPA | 39 |
| Consultant Medical OPA | 10 |
| Dietitian referral | 4 |
| Signposting information | 64 |
| CAB referral | 4 |
| Erectile Dysfunction referral | 24 |
| Other*<br>*Includes: formal counselling; fatigue service;<br>redirect to specialist team (e.g. urology); diagnostic imaging; specialist support groups; Community support; & vaginal lubricant provided . | 14 |

| Criteria | Total individuals in Sample (n=383) | Prevalence |
|---|---|---|
| ≥1 sPROM Red Trigger | 146 | 38.1% |
| ≥1 Oncology Trigger | 4 | 1.04% |
| ≥1 Any sPROM | 291 | 75.97% |
| ≥3 Any sPROM | 207 | 54.05% |
| ≥5 Any sPROM | 141 | 36.81% |
| ≥1 Outcome intervention (excl triage calls) | 92 | 24.02% |
| ≥1 Outcome intervention (excl triage calls & information sheets) | 41 | 10.70% |

| | Statistical Significance | Cox and Snell R square | Nagelkerke R squared | % of classified cases | Statistically significant variable |
|---|---|---|---|---|---|
| sPROM 1: Relationship with partner or sexual concerns | X² (3,n=204) = 21.063, p<.001 | 7.5% | 10.6% | 70 | Maximum pelvic dose (p=.005) |
| sPROM 3: Relationship with others | X² (3,n=205) = 6.360, p=.095 | 2.1% | 8.3% | 96.7 | Age (p=.028) |
| sPROM 4: Pain in the pelvis / lower abdomen / lower tummy | X² (3,n=252) = 7.431, p=.059 | 2.0% | 3.1% | 77.1 | Maximum pelvic dose (p=.049) |
| sPROM 8: Bleeding from your bottom | X² (3,n=245) = 16.564, p<.001 | 4.6% | 8.5% | 86.5 | Maximum pelvic dose (p=.005) Constant (p=.008) |
| sPROM 10: Problems with passing or controlling urine | X² (3,n=245) = 4.962, p=.175 | 1.4% | 2.1% | 74.2 | Maximum pelvic dose (p=.033) |
| sPROM 14: Fatigue or a feeling of having no energy | X² (3,n =254) = 5.899, p=.117 | 1.6% | 2.2% | 54.1 | Maximum pelvic dose (p=.019) |
| sPROM 16: Finances or money concerns | X² (3,n = 234) = 13.297, p=.004 | 3.8% | 12.1% | 95.4 | Age (p<.009) Elapsed Time from treatment (p=.034) |
| sPROM 21: Worry, fear or anxiety | X² (3,n =244) = 15.574, p=.001 | 4.3% | 7.4% | 84.3 | Age (p<.001) Constant (p=.007) |

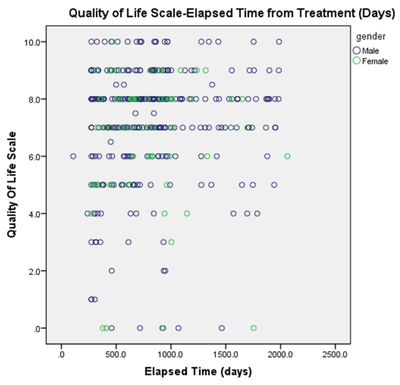
Analysis identified that the maximum pelvic dose was the most statistically significant variable, in relationship with partner or sexual concerns Maximum pelvic dose (p=0.005) was indicated; Pain in the pelvis / lower abdomen/ lower tummy (p=0.049); Bleeding from the bottom (p=0.008); problems with passing or controlling urine (p=0.033) and fatigue/having no energy (p=0.019). Age was found to be statistically significant in relationships with others (p=0.028) and finances or money concerns (p=0.009). Finances were also linked to elapsed time from treatment (p=0.034), which may be expected due to the known impact of cancer diagnosis on employment and income.

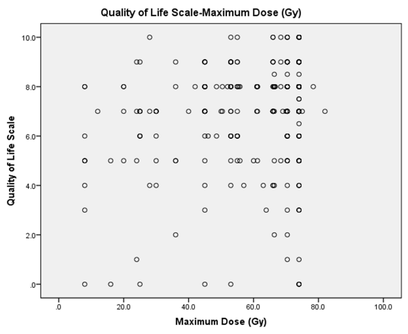
| Spearman's rho Correlations between variables | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| Scale | | 1 | 2 | 3 | 4 | 5 | 6 | 7 |
| Age | 1 | . | -.017 | .060 | -.042 | -.148** | -.100 | .097 |
| Quality of Life Scale | 2 | . | . | .210** | -.494** | -.317** | -.125* | .088 |
| Max Pelvic Dose (Gy) | 3 | . | . | . | -.045 | .075 | .069 | .115* |
| Total of all sPROMs | 4 | . | . | . | . | .750** | .241** | -.021 |
| Total Red Trigger sPROMs | 5 | . | . | . | . | . | .244** | -.025 |
| Total Speak to Prof. Requests | 6 | . | . | . | . | . | . | -.049 |
| Elapsed Time from Treatment | 7 | . | . | . | . | . | . | . |

** p<0.01 level (2-tailed). * p<0.05 level (2-tailed).

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 compared to all sPROMs, Red triggers (p=<0.01) and 'speak to professional' requests (p=0.05). '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 (36.0%) included a free text response the free-text questions. The large majority of comments related to the general function / wellbeing / lifestyle themes (23%) followed by a considerable number of respondents commenting on the effects of a co-morbidity (12%).

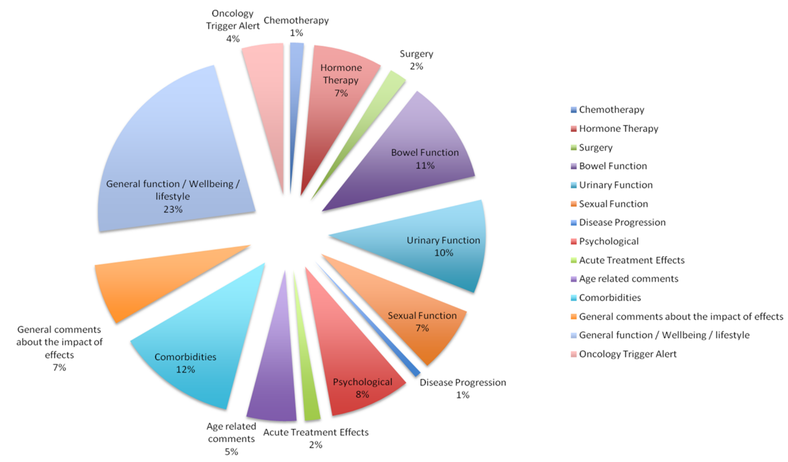



Quality of life was reviewed against sPROM triggers to support the review of the reliability of the sPROM scale. The total of all sPROM triggers demonstrated some negative correlation, however red sPROM triggers and 'speak to professional' requests did not demonstrate a determinable correlation.

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

Feedback from study participant




## Discussion

The prevalence of patients self-reporting symptoms of late treatment for any sPROM question was 76.0% and a red sPROM trigger question was 38.1%.
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 concern (p=0.005), bleeding from bottom (p=0.005), urine control (p=0.033) and fatigue (p=0.019).

Patients engaged well with the survey with a high return rate, high completion rate a high rate of requests to have follow up engagement with a health professional which confirmed that this method has high efficacy in the management of late treatment effects.

It was not possible to identify overall any correlation of sPROM late effect triggers in the radiotherapy treated study population with age, elapsed time from treatment, prescribed dose or gender, however six of the sPROM questions revealed statistically significant associated variables when analysed individually.

The results confirm that the null hypothesis can be rejected as associations were noted between maximum pelvic dose and 'bleeding 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.

## 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
- Patients self-report high scores fro QoL following pelvic radiotherapy
- 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 noted in three sPROM questions
- Population prevalence of a red trigger was 38.1% and any sPROM question was 76%
- Not possible to identify predictive factors that would enable accurate modelling of patient risks
- Results confirm the unpredictable and sporadic nature of radiotherapy late effects
- Acute treatment effects and dose/fractionation may not be adequate predictors of late effects at the decision point of patient discharge to self-managed.

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