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# Understanding the impact of radiotherapy related insufficiency fractures and exploring satisfaction with two existing patient reported outcome measures: A qualitative interview study

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## ABSTRACT

**Introduction:** Radiotherapy related insufficiency fractures (RRIFs) occur in approximately 10–15% of cancer survivors who underwent pelvic radiotherapy. Little research has been conducted to explore the impact of RRIFs on quality of life (QOL). Patient reported outcome measures (PROMs) are often used in oncology to measure side effects and QOL. The study aims to understand the influence of RRIF on QOL and to discover whether available PROMs address their needs.

**Materials and methods:** Twenty-five patients randomly selected from a Tertiary Oncology Centre bone health clinic database of patients referred with RRIFs were approached. Interested patients were sent two existing PROMs and a patient information sheet. Eleven patients agreed to take part in a semi-structured interview to explore their experiences and their opinion on the existing PROMs. Telephone interviews were conducted. Interviews were audio recorded, transcribed, and analysed using thematic analysis.

**Results:** Four themes were identified: 1) Route to diagnosis, 2) management of RRIFs and 3) resilience all had an impact on 4) QOL. Additionally, participants discussed PROMs and how they might be integrated into clinical practice. The data highlights the wide ranging QOL impacts experienced and highlights potential areas for improvement in terms of diagnosis and management pathways.

**Discussion:** The impact of RRIFs on QOL is considerable. Participants highlighted key areas for improvement including the provision of more information, more access to support and improved management pathways. Participants also highlighted the potential benefits of PROMs but suggested existing measures could be improved.

## Introduction

Radiotherapy is used to treat approximately 30,000 people each year in the UK with prostate, womb, cervix, bladder or lower bowel cancer. Pelvic radiotherapy can cause cracks or breaks to develop in the pelvic bones (radiotherapy related insufficiency fractures or “RRIFs”) [1]. RRIFs occur in around 10–20% of patients, usually between 3 and 18 months following radiotherapy [2].

A wealth of studies have been published describing patients with pelvic RRIFs, the studies however are almost exclusively retrospective in nature and lack any quality of life (QOL) assessment [1]. A Cochrane systematic review (van den Blink et al., 2018) identified a lack of robust and relevant patient reported outcome measures (PROMs) to measure

QOL for RRIFs patients. A recent meta-analysis [2] and systematic review [3] investigating pelvic insufficiency fractures in patients with gynaecological malignancies also highlights the lack of data with regards to management of RRIFs and appropriate outcome measures. Even very recently published analyses of pelvic radiotherapy cohorts are notable in their lack of availability of PROMs [4].

PROMs are a useful way of understanding patients’ experiences and measuring the impact of cancer on QOL. The use of PROMs is well recognised in oncology as a way of identifying and monitoring the impact of cancer and treatment [5]. They can be used to prompt discussions with clinical teams and encourage fast and effective management of problems [6]. In order for PROMs to be effective, they need to be robustly developed and psychometrically tested in the specific patient

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group they are targeting [7].

No PROMs have been developed to specifically measure QOL in RRIF patients. There are some pelvic specific questionnaires available, but the literature suggests that they may not cover the full range of patient experience [8]. Two questionnaires which are commonly used when exploring the impact of pelvic fractures are the Short Musculoskeletal Function Assessment (SMFA) [9] and EuroQOL- 5 (EQ-5D) [10]. The SMFA is designed for all musculoskeletal injuries [9]. It has never been validated specifically in patients with pelvic fractures but has been used in two studies (alongside the EQ-5D) of older patients with pelvic fractures (not radiotherapy-related) [11,12] demonstrating that pelvic fractures reduced QOL and function. Patients who experience RRIFs however are generally younger and therefore the impact on their QOL is likely to be different. The SMFA is a broad questionnaire covering a range of different issues and as a result it may not be tailored enough to meet the specific needs of RRIF patients. Previous Patient and Public Involvement and Engagement (PPIE) activities with eight patients, suggested the SMFA did not fully reflect: the psychological impact including fear of further fractures; pain intensity and management; change over time (SMFA only focuses on the past week); sudden changes in activity levels and abilities which impacted on work and relationships; and needs and adaptations at home. This data was collected via questionnaires therefore it is important to explore this area in more depth using qualitative interviewing techniques.

There are two key aims to this study. Firstly, to explore patients experience of RRIF and how it impacts on QOL. Secondly, determine participant satisfaction with two existing PROMs (SMFA and EQ-5D) and determine if these PROMs adequately address their experiences and are appropriate for use with this patient group.

## Materials and methods

### Participant selection

For this qualitative, semi-structured interview study, participants were randomly selected from a bone health clinic database at a specialist cancer centre in North-West England. Eligibility criteria: any cancer diagnosis or stage; any point in the management pathway; over 18 years of age; able to provide informed consent; able to communicate in English. We aimed to recruit 15–20 participants and end recruitment when data saturation was reached.

### Study procedure

The study was approved by North-West Greater Manchester Central Research Ethics Committee (22/NW/0027). Potential participants were approached by a member of the clinical team. Interested participants were sent a participant information sheet, consent form, EQ-5D and SMFA by post or email. A researcher contacted the participant to discuss the study further. If applicable, a date for interview was arranged. Interviews were conducted by telephone by a male researcher (PC) who had received training in qualitative interviewing. The interviewer had no prior contact with participants until interviews were arranged. Participants were aware that the interviewer worked within a research team at the cancer centre but had no other information about them. The interviewer was not responsible for any aspect of care delivery and did not have any access to the participants' electronic health records. Interviews were conducted in May/June 2022. Verbal informed consent was provided before the interview. Interviews were audio-recorded and transcribed and lasted approximately 30–60 min. Interviews were semi-structured using a pre-defined interview schedule which was developed by the research and clinical team and informed by the literature and PPIE activities. The interview schedule explored: the impact of RRIF and what help and support participants had received; opinions on SMFA and EQ-5D.

### Data analysis

Data collection and analysis occurred concurrently. Interview data were analysed using inductive thematic analysis [13] which involved: reading and familiarisation; generating initial codes, and using these to code each transcript; grouping codes into potential themes; reviewing and refining themes in relation both to individual transcripts and the whole transcript set; naming themes; and producing the report. The first two transcripts were coded independently by two researchers (ST and PC) to create preliminary codes and themes. Codes and themes were continuously reviewed as remaining transcripts were coded and themes iteratively revised. After creation of a comprehensive code list, themes were defined and named. Codes were then reviewed to determine which described qualitatively similar issues and therefore could be grouped together as an overarching theme.

## Results

Twenty-five patients were approached by the clinical team. Eleven consented and were interviewed. Of the remaining 14 participants approached, three cancelled the interview, two declined and nine were uncontactable. The majority of participants were female (n = 10) and all were White British (Table 1). All 14 participants who were approached and did not consent were female.

Four key themes were identified in the analysis (Fig. 1). The experience participants had in terms of their route to diagnosis, management of their RRIFs and the participants resilience all impacted their QOL. Quotes illustrating the themes are presented in the text and in Table 2.

### Route to diagnosis

Within this theme, participants talked about information they received about the potential of RRIFs; diagnosis experience; misdiagnosis; pre-diagnosis symptoms. The majority of participants felt they were not made aware that RRIFs were a potential side effect of radiotherapy. Participants received a wealth of information at the start of treatment and felt information about RRIFs may have been lost. Others felt satisfied with the level of information and would ask questions when required.

*'I think they can tell you what it might do to you, that it can affect your bones and ...yeah, I think they could probably sit with you and talk to you a bit more about that, but anyway.'* P06

*'You know obviously I sought advice when I needed it, so it wasn't that I was ever denied that.'* P09

Prior to diagnosis of RRIF participants experienced pain or mobility issues, for most participants, the pain experienced was moderate to severe. Some patients thought the pain may be due to a cancer recurrence or assumed it was a side effect from their treatment or due to being less active than they had been. Participants contacted their GP, Macmillan nurse or oncology team in relation to their pain. Unfortunately, some participants were misdiagnosed initially. Participants received their RRIF diagnosis after being sent for a scan, usually following their mention of pain or mobility issues. One patient mentioned their RIF being identified on a routine scan.

*'She diagnosed a pulled ligament and she said that it would get better within 4 weeks, and it didn't'* P01

**Table 1**

Key demographics of participants.

Gender	10 females; 1 male
Age at time of interview	33–80 years (median: 68 years)
Age at diagnosis of RRIFs	28–78 years (median: 65 years)
Ethnicity	11 White British
Time from radiotherapy to RRIF diagnosis	3–30 months (median: 8 months)

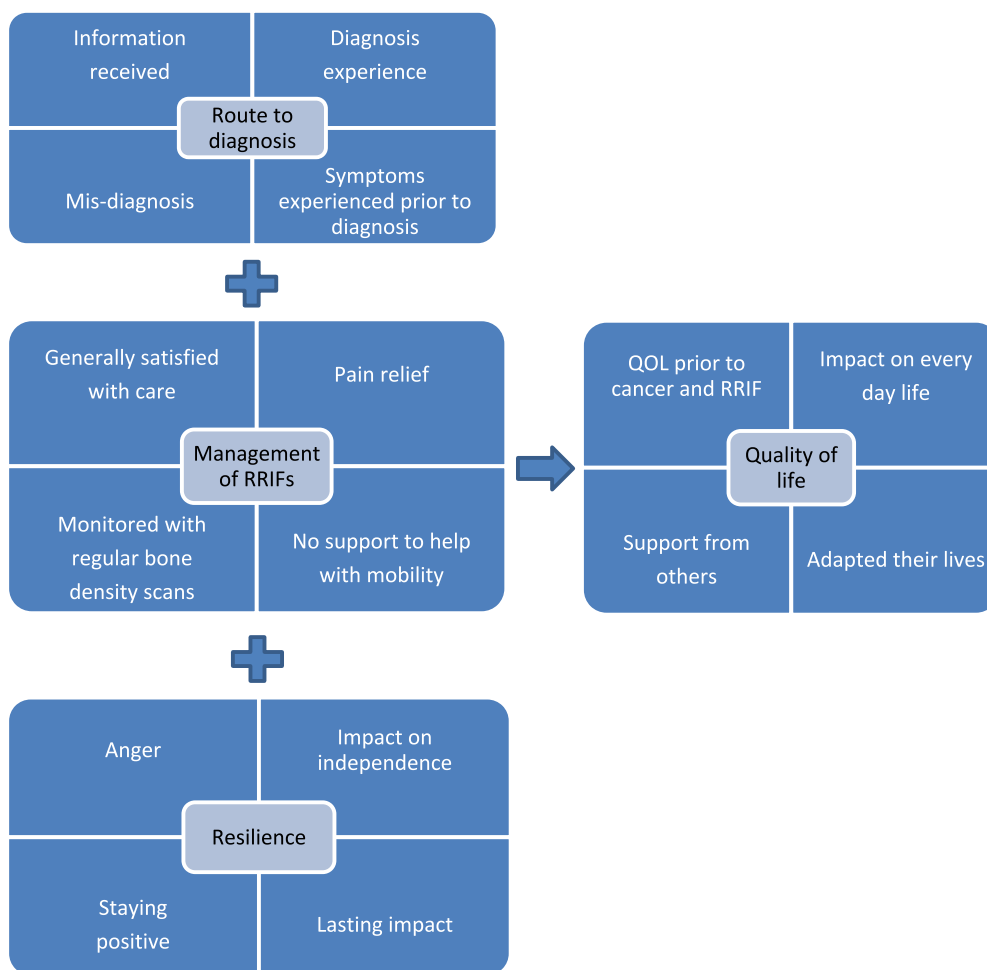


Fig. 1. Key themes from analysis of interviews.

**Management of RRIFs**

The majority of participants reported not having a RRIF management plan. The main way participants managed their RRIF was with pain relief. For some, this was prescribed whereas others self-managed with over-the-counter medication. Participants did not report being offered any support to help with mobility. Most participants were advised that their fracture would get better by itself over time, and they were monitored via regular bone density scans. Generally, participants were happy with the care they received although some felt they would have benefitted from more support.

*‘Quality of treatment, when I get it, is good but it’s been a struggle to get attention and to, to simply get appointments, I done things needed doing and to try and get through the wall of GPs and consultants and so forth has been a bit of a struggle.’ P03*

**Resilience**

A number of participants mentioned the psychological impact of the RRIF and their treatment in general but also showed evidence of their resilience. Some participants described feeling angry. They were angry about having the disease in the first place and about the impact of the treatment, in particular the RRIF. For many, the lasting effects of radiotherapy were difficult to cope with psychologically. Participants described feeling stressed or anxious.

*‘I suppose I am slightly anxious, I’m not a depressive by nature but obviously I’m somewhat worried about how dependent on people I might become in the future.’ P03*

Although participants described negative emotions about the side effects and the damage caused by radiotherapy, they tried to remain positive. Some participants were not fully aware of the impacts their treatment may have but they did not think this additional knowledge would have changed their treatment decision.

*‘I mean I didn’t think for one minute or was told that it could affect your bone density but having said that, it wouldn’t have stopped me having my treatment so...’ P06*

**Quality of life**

Within this theme, participants spoke about various elements of their life and how they had been impacted by their RRIF, even simple everyday tasks were impacted. For the majority of participants, their QOL prior to the fracture was good. They were generally fairly active and led normal lives. Impact of the RRIF on QOL was variable, for some the impact was huge at the time but they had started to get back to normal, whereas some were still experiencing an effect a considerable time after treatment. Others did not feel their QOL had been greatly impacted. It was often difficult to disentangle the treatment effects with the impact of the RRIF. Participants described adapting their lifestyle and being more cautious about certain activities which may aggravate their pain. Some participants stopped or modified hobbies or leisure

**Table 2**

Quotes from interviews to illustrate key themes.

**Route to diagnosis**

'I think the other thing I would mention as I said to someone else, I think I would have appreciated a fuller explanation of the potential side effects' P10

'Well, I think that you do get a list of side effects that the. The treatment can cause, don't you? Whether it was in that or not I don't really actually know. Whether it mentions any fractures or not I certainly don't remember it doing but, but they give you so much stuff to read and when you've found out that you've just got cancer, I don't think things are sinking in properly anyway.' P08

'Primarily very, very sore area round my hip and the fact that I couldn't walk well'. P03

'Bad... Bad. Out of 10 I'd give it at least a 9.' P01

'I was just recovering from the cancer treatment and I was not quite back to normal but I was walking with some difficulty and, but things seemed to be improving and then by the end of the year they'd deteriorated and I thought the cancer had come back' P03

'Well, I started getting terrible back pains which I still have now but at first, I put it down to just maybe part of the cancer operation because it was a bowel, so it was the bottom lower part of my back.' P04

'I thought actually because since having the treatment I've just been sat about too much and not doing enough exercise and I just presumed it was that' P08

'They thought it was a slipped disc, but they found fractures in my back'. P06

'so 5 months of limping and.. on the crutches I couldn't do anymore, I couldn't sit, I couldn't move in bed, I couldn't turnover' P01

'I didn't complain with my back, they just automatically referred me to the bone clinic at Christie's hospital so whether because of the fracture was showing then they referred me, but I didn't go and say that I was having a lot of pain in my back.' P02

**Management of RRIFs**

'I've always just probably just took paracetamol and ibuprofen and that's all I usually ever take.' P02

'I have some liquid morphine which I take pain killers so of when...I don't like taking pain killers but if I have to. But I was told not to take tablets and to take some liquid morphine. I was told to do it before I do work but sometimes, I prefer to do it after because the pain tends to tell you when to stop doesn't it?' P04

'No, I just, I just used to use the pushchair as a walking aid.' P09

'Dr X phoned every few months to find out how I was doing, and I was always walking more and more so I just got better by myself really.' P01

'When diagnosed with the fracture, there's nothing they could really do, they can, they just monitored the pain relief and continued with the treatment because obviously the treatment was necessary to continue and all my statistics were absolutely fine, because I was on good, good painkillers, the treatment continued to completion and that's why it worked I guess.' P11

'No, there was nothing. As I said they just referred me to, which I still do attend, the bone clinic at Christie's, so I still attend there where they do my DEXA scans. So basically, I'm still attending there where they are just keeping a monitor on the density in my bones.' P02

'nobody ever said to me, right, initially, are you bad enough for wanting a frame for your chair? You know some support for your chair? A walking stick? Even, I mean, I don't agree with this to a certain degree but even a disability badge. Because sometimes if I have to park, by the time I've walked to the supermarket, I haven't got the energy to go round it again because the pain starts. So, it's little things like that that' P04

'So...no like I said, I think you know, if as long as you keep in touch with the people, and they have that chance of, is it every 3 months isn't it at first and then every 6 months after that, I think that's fine because you've got that, that coverage in that time that hopefully by the end of the 3 monthly sessions you should almost be, well I mean you should be OK really.' P07

**Table 2 (continued)****Resilience**

'I never complained to anybody during the whole procedure, it's only now actually that I'm getting, dare I say angry?' P10

'Angry? Oh yes...all of the time I think if I'm honest...being honest, there's a certain amount of bitterness' P04

'the thing that's made me more down that anything is simply the fact that it's, it's never going to be, I had a letter I think it was doctor... Dr. [Name] saying there is no cure for, for your radiotherapy proctitis.' P10

'Erm, annoyed because the radiotherapy had to be done so they told me, but it didn't kill what it was supposed to kill. So, the... and the Radiotherapy causing damage that took a lot more parts away that didn't need to be if I didn't have Radiotherapy.' P05

'It upsets me. It upsets me the fact that my life isn't anywhere near the same. I can't do the same that I do, I feel, I feel very old some days, I not sort of young but I feel very old.' P04

'Not many people are going to say relief, but you know it's a means to an end. If I was given the option, right you have cancer, we give you the radiotherapy and it will break your, you know your bones and give you fractures or you die, which would you take? Straight away you'd say well obviously I'd...I'd go with what discomfort it was afterwards, wouldn't you?' P04

'I've been really quite lucky and very happy with everything they've said and done really.' P07

'Yeah, the, the, the treatment was...was really good, well it saved my life and although the aftereffects were obviously a pelvic fracture, it saved my life and without it I would have died so obviously the, the, you know, the, the service and the, the treatment was exemplary, it couldn't have been better, it was the best treatment that completely cleared the cancer, so I have no issues whatsoever.' P11

'I feel very happy that I've survived, and you know that I'm very lucky so.' P09

'Well, I'm luckier than most I suppose.' P11

'I mean I didn't think for one minute or was told that it could affect your bone density but having said that, it wouldn't have stopped me having my treatment so...' P06

'I am back to normal. I'm walking 6000 steps a day with the dog now.' P01

'I would say I was back now to the exercise point that I was before my treatment.' P02

**Quality of life**

'Well, it was pretty good, I have a good lifestyle. I have a very happy life' P10

'There was nothing stopping me. Walking was fine, every day... work was no problem, it was good.' P05

'Oh definitely, at the time yes. I had no quality of life at all' P01

'I mean, has it had an effect on me? It's had a huge effect on me' P03

'My health is physically it's fine but it's the mobility issues that are the problem. Other than that, my health is quite fine. I cope with what I have had done quite well.' P05

'When I first had the fracture just in the pain thing, but it hasn't, it hasn't affected my life at all really.' P07

'I have to kind of lump that with my entire treatment, but my quality of life is absolutely fine.' P11

'But I had no activity whatsoever in my daily life, I have a little dog and I had to hire a dog walker, there was no way that I could walk my dog.' P01

'I feel if I do any certain maybe housework where you're maybe bending over and hoovering so probably, it's more if you're putting pressure more on your back when you're actually in a bent over position, so if you're doing housework and you're up and down and you're hoovering and I think it's when you sort of change your routine in what you're actually doing to begin with it sometimes can affect.' P02

(continued on next page)

Table 2 (continued)

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'It's had quite a significant effect in that I can't walk very far.' P03

'It limits me to sort of walking long distances, sort of uncomfortable sort of sometimes in sleeping. I would say there are ongoing issues through these fractures.' P05

Yes, I mean obviously if I go out, I've got two grandsons, if I pick them up then my back gives me hell. If I do any gardening, then I know that my back is going to be hell.' P04

'And then my children were 1 and 3 so it was difficult because even pushing their push chair was, you know, quite tiring and quite sore on my lower back.' P09

'It's alright, OK. If I needed any help, he was around to help. You know so we just sort of got on with it. I didn't, I didn't need any major help at all. I mean just more if I got tired and was doing something then he'd carry on and do it, but it wasn't, I didn't have to have anybody in to do the cleaning or anything like that. I did all that myself, it didn't stop me cleaning up or washing particularly because I just did it as and when I needed to, you know?' P07

'Possibly, possibly, yeah. Thankfully, he's very understanding but it's difficult. If I, now even if I sit down too quickly, I don't sit down so quickly then my back can go and I can have pain, so I do everything slightly more carefully, not the crazy speed you do when you're slightly younger you know everything you just is considered because I fell down the stairs 3 years ago, now I walk down the stairs...' P11

'It is most to all of the time because you just feel ... I'm such an independent person it's made me feel I've lost my independence. You know carrying my suitcase up and down the stairs you know my husband will straight away be there to make sure I don't do it. Yes, I appreciate it and I have struggled with these things, but it does make you feel nearly all of the time that you...' P04

'I suppose I was lucky that my husband was here, he has, he took a couple of months off work, well he's retired and gone back to work again so, I had him here so I was fortunate, there was somebody here all the time so perhaps, perhaps, it didn't hit me as much as it could have done.' P07

'Because I was very much an outdoor person before. As I say, two of my main past times were walking and sailing and I really can't do much of either of those.' P03

'I do a Pilates class once a week, I do have some problems with that occasionally, especially when we're lying on the floor and I have this core, core centred as you know when you've got to get up off the floor and get up off your back without any support, you know I don't mean get up stand up, I mean just you'd be lying down and you'd get up and that I'd find hard.' P10

'There isn't one because of the operation I had, there isn't an intimacy anymore. Not sexual intercourse anymore because of the operation I had. I had a full pelvic clearance, I had everything taken away.' P05

'I couldn't say it was the fracture per say, I would say the whole treatment definitely has significantly, yes.' P09

'A bit sad I suppose, but it is what it is. It's still strong so we just accept it, I guess.' P11

'I went and changed my job to an office job where I was sat down in an office so that was easier for me.' P05

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activities.

*'Because of the limitations on my lifestyle. The everyday frustrations of difficulty of picking up things dropped on the floor and not being able to carry things easily.'* P03

*'And also, I just do some kind of Zumba but it's sitting down, it's not standing up, it's not high intense whereas I could do it before.'* P05

Despite limitations in their mobility, the majority of participants had been able to maintain independence, a few relied on friends, family and neighbours to provide support. A number of participants felt their intimate relationships had been affected, for many though this was not a result of the RRIF specifically but due to their treatment as a whole. This was a problem for some participants and less of a concern for others. Very few participants felt their RIF had been impacted them financially.

Many were retired but for those who did work, some had taken time off during treatment or had changed to a more manageable job.

*'I think, the honest answer to that is probably no because we're of such an age that close intimate relations are, well, were already a very unimportant factor shall we say.'* P03

#### Feedback on PROMs

In addition to describing their experiences of RRIF and the impact on their lives, participants also described their opinion of the SMFA and EQ5D and how they might be integrated into clinical practice. Key themes and quotes relating to the PROMs are presented in Table 3. Generally, participants were satisfied with the content of the PROMs but suggested some areas where the PROMs did not fully reflect their experience.

*'Yes, well, well this is, in a sense this is the thing that the questionnaire doesn't and perhaps can't really cover. Do I feel satisfied with the way I have to live now? No because there are lots of things, I would like to do that I know I can't so.'* P03

Some participants also felt that the PROMs were too long and repetitive

*'you don't have sufficient patience to go through maybe 40 or 50 questions being asked just so you can get the right treatment for yourself but if, if the questions could be very much scaled down, into maybe half a dozen questions which are really, really integral to supporting the person maybe one question on mental and one question on physical you know, one, then you would know in which direction to support the patient.'* P11  
*'but a lot of the, a lot of the, a lot of the questions are kind of repetitive because getting in and out of a bath tub or showering, climbing stairs and all this is kind of, it relates to the same type of movement so...I think maybe a lot of the questions are repetitive because it's all to do with the same type of movement you know?'* P11

Participants commented on the potential benefits of routine PROM completion and when they felt it would be most helpful for PROMs to be completed.

*'Because it cuts down, it cuts a little bit of your time down when you are going...so when I go in, I go to see the particular doctor before I had the scan, and they ask the questions... well half of that's done for you, isn't it? It cuts a little bit of the waiting time.'* P04

Participants felt the questionnaire should be completed close to the end of treatment and then could potentially be repeated at various time points going forward

*'It would be quite important to do quite soon after it happened does that sound, so I would have had something like this probably just maybe about six months or so after you know after my radiotherapy and my treatment happened probably my answers would have been completely different.'* P02

*'But then again, it's over the years that the damage happened so you could do a questionnaire 18 months afterwards and ask questions you know how's things going and things like that and then maybe do another one 5 years like you know you have a 5-year thing when you're cancer free and then they discharge you then. Maybe you could follow it up in 5 years' time and find out if anything else has changed.'* P05

*'Maybe do, you do a 6 monthly check up anyway but maybe a very brief thing that they tick the boxes before they go in? I've got to go for another brai... Brain scan [laughs] bone scan thing, it might be a brain scan [laughs]. I've got to go for another bone scan so maybe it's just updating the history, but I don't know if that would help?'* P04

**Table 3**  
Participant thoughts on SMFA and EQ5D.

Theme	Summary of key points	Reflective quotes
Content of the PROM	Generally satisfied although some additional areas could be included	<p>‘Yes, just going back to what I just said...yes, a bit dissatisfied that its not asked more questions rather than the fracture what it’s done so yes, probably a little bit dissatisfied there.’ P05</p> <p>‘Yes, well, well this is, in a sense this is the thing that the questionnaire doesn’t and perhaps can’t really cover. Do I feel satisfied with the way I have to live now? No because there are lots of things, I would like to do that I know I can’t so’. P03</p>
Response options	Participants suggested a wider range of response options such as the ability to add free text, the use of a sliding scale or the ability state whether problems were always there or were transient	<p>‘I think there’s probably something where you can put [Inaudible 29:15] your own comments’ P05</p> <p>‘Yeah, definitely. You’ve got five options there so basically, you’ve got that it’s not just like three or you’ve got five options where you can give, and you can also as I’ve done with yourself you can also say the reason why maybe you gave that answer so yeah.’ P02</p> <p>‘Might be worth putting in a column for sometimes rather than...you know thing, things how difficult it is for you to get to bed and kneel down is not a good one. How difficult is it for you to walk? Well generally it’s not a problem but sometimes it’s very painful so, do that make it a little difficult or? ...See what I’m getting at?’ 03</p> <p>‘I think so yeah, I mean the only other thing you could do which might end up with like far more graphs and far more [Inaudible 38:57] would be like a sliding scale of like, you know, 1 to, you know maybe it would be easier for people on a 1 to 5 or a 1 to 10 you know, it’s a different was of doing it but then again you’re going to get so much data then that [Inaudible 39:12 – I mutes to clear throat] in a way that is manageable for you to analyse the data at the end of it haven’t you, you know? It’s fine saying well yes you should have a sliding scale and is it 6 out of 10 or 4 out of 10 but then you’ve got 10 pieces of data over 40 odd questions, you’re going to be swamped with analysis whereas I think the less really is the better in a way really, isn’t it? So...I think 5 you’re</p>

**Table 3 (continued)**

Theme	Summary of key points	Reflective quotes
Timeframe of PROM	The questions focus on the last week but this may be too short a time frame, a longer time frame or the ability to say whether a problem had got worse was suggested	<p>down the middle with the 3 obviously you know, you’ve got the best, the worst and then 2 not so sures so yeah, I think 5 is probably’ P11</p> <p>‘Yes. Because what you were saying to me was, bearing in mind that I’ve been having this for the last 3 years so you, your specific, two or three times you specifically said to me, is your pain better this, is it worse this week that it was last week. Maybe 6 months ago, it’s obviously depending on how long that person, I think to be able to say, it’s a very difficult thing because pain is pan. I’ve got quite a good threshold. If you’d have asked me that question and said, is it the same as it was 6 months ago or 12 months ago but to give me the portion of a week, there’s very little change in a week obviously dependent on what I’ve been doing. I think it might be a better thing that you say 6 months ago, I, today’s pain is it worse than last week? What about 6 months ago? What about 12 months ago? Because I think that will give you a little bit more of a width of what is happening to that person for their fracture that they suffer.’ P04</p>
Timing of assessment	PROMs should be completed close to end of radiotherapy and then at regular intervals thereafter	<p>‘Yeah possibly, possibly. I do feel that you would possibly get more out of it, if it was closer to the time of the treatment’ P11</p> <p>‘Well, I think these questions should have been asked after a period of treatment.’ P05</p> <p>‘Yeah, perhaps more say at the end of treatment that might be a good, a good set of questions because people will find more difficulty you know won’t they at the end of the treatment but, no, no that’s OK, I think.’ P07</p>
Benefits of using PROM in practice	Regular PROM completion could aid communication and help clinicians to understand patient experiences in order to improve management and direct patients to support services	<p>‘Because it cuts down, it cuts a little bit of your time down when you are going...so when I go in, I go to see the particular doctor before I had the scan, and they ask the questions.... well half of that’s done for you, isn’t it? It cuts a little bit of the waiting time. You also get an idea whether you wanted to do it 6, 12 months, 18 months, 2 years and then, then leave it and then you would know who</p>

(continued on next page)

Table 3 (continued)

Theme	Summary of key points	Reflective quotes
		really needed the help after 2 years wouldn't you?' P04
		'Yeah, Yeah, I see what you mean, to have more conversations with them? Yeah, yeah, they probably should.' P06
		'Well, these questionnaires are good because they...you know if you have another patient that's going to be coming in and going through the same thing I was, it helps to have an understanding and explain this to you know the patient a bit more. A little bit more information which I didn't get. So, I think the questionnaires are good to relay onto a patient.' P05
		'I don't know I guess that if the professionals had an awareness of peoples' feelings, thoughts and emotions following the fracture then they could take, they could ask the correct questions to the patients themselves and then cater for each and every one by the level of information that they've got so maybe if people are on the whole suffering for 6 months following with, with walking or, or unaided or need support with finances or support doing exercise or support with some type of physical you know as well as mental stimulation then they could have support groups, they could have a lot of tools at their hand that would be able to support people that need it so just by asking the correct questions from the patients themselves then they could provide a far more valuable service to the patient because of their knowledge of, of people that have been through [Inaudible 46:25] process so yeah I do think it would be certainly worthwhile sharing that level of detail.' P11
		'The patient might physically be ok but then mentally be absolutely not so then maybe a support group' P11
		'I think, I think there's something to, it might be nice if they'd have offered something like post radiotherapy that they'd have offered some kind of physio treatment that wasn't sort of forthcoming, you had to do that via your own doctor as I remember, that would have been like helpful.' P10

## Discussion

This study provides a useful qualitative insight into the experiences of people diagnosed with RRIF. Research has previously focused on quantitative data therefore this study provides an additional dimension to the existing evidence base. The data highlights the wide ranging QOL impacts experienced and highlights potential areas for improvement in terms of diagnosis and management pathways. The patients' resilience in coping with the physical and psychological challenges they have faced is also a key theme.

The majority of participants were symptomatic and experienced moderate or severe pain which led to their diagnosis. Pain has been reported as the most common symptom of RRIF [3]. Oh et al [14] reported that 57.8% of participants with RRIF reported pain. Management plans for RRIF seemed limited. The main management offered was pain relief and regular scans. In Oh et al's study [14], 13% of patients with pain needed to be admitted to hospital. Hospital admission was not reported by participants in this study, but they reported pain as severe and many required treatment with strong pain medication. Very few participants were offered support to help with mobility; physio referrals and walking aids were sourced by the patients directly.

Two participant's RRIF was misdiagnosed initially. Literature regarding misdiagnosis is limited, perhaps because this level of detail may be more apparent in qualitative research. There is however some literature suggesting pelvic and back pain could be interpreted as tumour recurrence, metastases or other bone related conditions such as osteoarthritis [15,16].

Many aspects of QOL were significantly impacted by the RRIF. Participants found that they were unable to perform simple daily tasks and reported making modifications or seeking support from others if they were unable to do them at all. Participants also reported impacts on sleep, their hobbies and social activities, family and intimate relationships and their employment.

There was a noticeable psychological impact on participants in the study, they described feeling sad, angry and anxious about their experience. In some cases, this related purely to the fracture but in many cases, it was related to radiotherapy side effects in general. These feelings were still present for many months or years after treatment suggesting the ongoing need for support. Other studies exploring the impact of pelvic radiotherapy have also reported the presence of symptoms many years after treatment [17]. Studies have found that symptom severity or the presence of certain symptoms such as those affecting the bowel or rectum are associated with poorer quality of life [17,18]. Conversely, another study exploring the impact of pelvic radiotherapy, found that although QOL was impacted soon after radiotherapy, this did improve over time [19]. Similarly, to our findings, studies exploring the needs of gynaecological and breast cancer patients after radiotherapy found that women often felt abandoned at the end of treatment [20], they highlighted the importance of continued support during follow up and stressed their need for continued communication from the clinical team and access to information and support [21]. Breast cancer patients also mentioned relying heavily on their own resilience to get them through treatment and beyond [21], a finding which was clearly evident in our results.

Generally, patients felt information was lacking either about the side effects of radiotherapy more broadly or specifically that radiotherapy could cause fractures. Some participants had dismissed pain they were experiencing as general aches and pains or a sign of getting older. If they had been more aware of the possibility of RRIFs and the potential signs, they may have been more likely to seek help rather than overlooking the problem. Studies exploring the information needs of pelvic radiotherapy patients highlighted key aspects of information delivery such as the timing and the context of information. They stressed the importance of receiving enough information but also emphasised the potential of too much information causing anxiety [22]. Similarly, a study of pelvic radiotherapy patients found that they would value information based on

personal experience (Boulton).

In terms of the PROMs reviewed by participants, the majority were happy with the content. Participants did however suggest potential improvements in order to increase utility and relevance. Participants mentioned the need for PROMs to address not just RRIFs but the wider late effects associated with pelvic radiotherapy. It is however important to keep PROMs succinct so as not to overburden patients and clinicians. Some participants felt the SMFA and EQ5D were long and repetitive. The length and complexity of PROMs will influence completion in clinical practice [23]. Relevance and specificity of selected PROMs is key in order for clinicians to see the value of their use [24]. In order for PROMs to address issues of most relevance, they should be developed specifically for the patient group they are being used for [25], which is not the case for SMFA and EQ5D in the RRIF patient population. A questionnaire system such as the EORTC [26] or PRO-CTCAE [27] item banks which allow individual selection of items, may be an alternative given that no existing questionnaires have been developed specifically for the RRIF population, a method recommended in 2022 ESMO guidelines [28]. The item banks would need to be reviewed to ensure they cover the pelvic and muscular-skeletal issues relevant to RRIF patients as well as the broader QOL issues.

Different response options were also highlighted as a potential area for improvement. Evidence in the literature providing justification for the choice of response options is limited [29]. Both the SMFA and EQ5D use Visual Rating Scales for the main sections of the measure. There is no definitive type of response option which should be used with specific patient populations however the intended use of the PROM and patient preferences should be considered when determining which is most appropriate [29]. Participants discussed the use of PROMs in clinical practice and mentioned some of the potential benefits such as improving communication and helping the clinical team develop a management plan, areas that have been echoed in other literature [30,31]. Many of their comments related to the timing of assessment. They felt they would have been useful if completed at the time of the RRIF diagnosis and then perhaps at regular intervals during their follow up. The timing and frequency of PROM assessment should be guided by the purpose of the PROM and the clinical context [32].

There are a number of limitations to this research. Although this is a qualitative study, the sample is still relatively small, due to the time constraints of this study however, we were unable to continue recruitment to increase the number of participants. Despite the small sample size, we did feel that data saturation had been reached with no new themes emerging. The participants were all white British from the North-West of England therefore the results may not be generalisable. Similarly, the sample only included one male participant, therefore the results again may not fully reflect the experiences of the patient group as a whole. Although high rates of men also receive pelvic radiotherapy, the risk factors for RRIF include female sex, osteoporosis and being post-menopausal therefore a larger proportion of women are likely to be affected. Although there are limitations to this research, it is strengthened by the fact that it is the first piece of qualitative research exploring the impact of RRIF from a patient perspective and exploring patients' perceptions of two commonly used PROMs.

The impact of RRIFs on QOL is considerable and lasts for many years after treatment. Participants highlighted key areas for improvement including the provision of more information, more access to support and improved management pathways. Participants also highlighted potential benefits of PROMs but suggested existing measures could be improved. Future research should consider if there are other PROMs or item banks of questions available that better reflect patient experiences and if these PROMs can be used to identify problems and ensure patients get appropriate support in managing RRIFs and broader radiotherapy-related side effects.

## Declaration of Competing Interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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## Informed Patient Consent

The author(s) confirm that written informed consent has been obtained from the involved patient(s) or if appropriate from the parent, guardian, power of attorney of the involved patient(s); and, they have given approval for this information to be published in this case report (series).

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