The quality of life of men with locally advanced prostate cancer during neoadjuvant hormone therapy: data from the Medical Research Council RT01 trial (ISRCTN 47772397)

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OBJECTIVE

To explore patients’ quality of life (QoL) during neoadjuvant hormone therapy (HT) using data from the Medical Research Council RT01 trial of standard- (64 Gy/32-fraction) and high- (74 Gy/37-fraction) dose radiotherapy (RT, both given conformally).

PATIENTS AND METHODS

Of the 843 patients randomized to the RT01 trial, 316 completed the Functional Assessment of Cancer Therapy core questionnaire with its additional prostate subscale, and the Short Form-36 Health Survey questionnaire with the University of California-Los Angeles Prostate Cancer Index before HT and again before starting RT. Three predefined QoL hypotheses were generated to focus the analyses.

RESULTS

For the three primary QoL analyses there was evidence that sexual functioning deteriorated, urinary function did not change, and there was a slight decline in physical well-being after ≥3 months of HT. Sensitivity analyses confirmed these findings. Exploratory analyses also suggested that role functioning deteriorated, sleep was more disturbed, and there was an increase in fatigue. However, overall QoL was not reported to be affected and patients indicated an improvement in attitude and satisfaction with treatment.

CONCLUSIONS

In this group of men, many of whom reported reduced sexual functioning before treatment, the additional decline during HT seemed to be generally accepted as the price to pay for an appropriate cancer treatment. Nevertheless, these changes need to be discussed with patients before HT is commenced.

KEYWORDS

hormone therapy, quality of life, prostate cancer

INTRODUCTION

Worldwide, more than half a million men are diagnosed with prostate cancer every year, the recent increases in incidence being mainly due to the widespread use of PSA testing. This has resulted in dramatic increases in the UK in last decade, from ≈14 000 new cases in 1994 to an estimated 27 000 new cases in 2002, echoing similar increases in North America in the previous decade, when the incidence increased from ≈110 000 in 1982 to 280 000 in 1992 [1]. This changing pattern has resulted in a decrease in the average age at diagnosis, a decline in the proportion of advanced-stage tumours, and an increase in the proportion of moderately differentiated tumours, and consequently changing patterns of care [2].

Although most men diagnosed as a result of PSA testing will have very early disease, for whom active surveillance (or ‘watchful waiting’) might be an option for those with a good prognosis [3,4], there will still be substantial numbers of men with more advanced localized disease for whom radical radiotherapy (RT) remains the most commonly used curative method.

Although RT is effective in most cases, local failure is associated with an increased rate of metastatic disease [5], and whilst increasing the dose of RT might reduce the proportion of local recurrences, this will be at the expense of more side-effects. However, the use of conformal RT allows the same dose to be delivered to the tumour with no increase in toxicity; e.g. a UK study [6] reported less radiation-induced proctitis and bleeding with conformal 64 Gy/32-fraction RT than with conventional 64 Gy/32-fraction RT.

The aim of the MRC RT01 trial was to investigate whether the conformal RT dose could be safely increased. Thus men were randomized to either standard conformal RT (64 Gy in 32 daily fractions) or high-dose conformal RT (74 Gy in 37 daily fractions). The primary outcome measure was tumour control rate, but quality of life (QoL) was an important secondary endpoint, patients completing the Functional Assessment of Cancer Therapy (FACT-P) core questionnaire with its additional prostate subscale [7], the Short Form-36 Health Survey questionnaire (SF-36 [8]), and the University of California-Los Angeles Prostate Cancer Index (UCLA-PCI) [9] questionnaire at regular intervals before, during and after RT.

In the UK, many patients routinely receive ≥3 months of hormone therapy (HT, androgen suppression or androgen
deprivation) before RT. Phase III trials [10–12] showed the benefits of this policy in biochemical disease control, metastases-free and overall survival, and a reduction in size of the prostate gland and prostate tumour, allowing a reduction of the RT volume required [13–16]. In the RT01 trial, all patients received 3–6 months of HT before RT.

Little is known about the patients’ QoL during this period of neoadjuvant HT, but the MRC RT01 trial provided the opportunity to investigate this, as patients completed QoL questionnaires before starting HT and again before starting RT. We here describe the changes reported in patients’ QoL by comparing the responses to the questionnaires at these two times.

PATIENTS AND METHODS

Detailed information on the trial design was published elsewhere [17] and therefore only a summary is given here. Patients were eligible for the trial if they fulfilled the following criteria: histologically confirmed carcinoma of the prostate, clinical disease stage T1b–T3a, N0, M0, a PSA level of <50 ng/mL, a WHO performance status of 0 or 1, a normal blood count, no previous pelvic RT, radical prostatectomy or androgen deprivation, and no previous or concomitant medical history that made radical RT inappropriate. Local ethical approval and individual patient consent were required.

Neoadjuvant androgen suppression was achieved using LHRH agonists at 4-weekly intervals in conjunction with initial antiandrogens (e.g. cyproterone acetate), to prevent ‘flare’ phenomenon. The antiandrogens were given 1 week before the first LHRH agonist injection and for 3–4 weeks in total. The LHRH agonists were given for 3–6 months before starting RT, and were continued throughout RT.

Ideally, patients were registered onto the trial before HT and only randomized to receive either standard or high-dose conformal RT after ≥3 months of androgen suppression. However, it was permissible to register patients after starting HT, to include patients who had already started on HT before referral to an oncologist.

Before starting HT patients were defined as having either a low or moderate risk of seminal vesicle involvement [18]. The PSA level and DRE results were reported after 6 and 12 weeks of HT and before starting RT clinicians reported on the patients’ urinary and bowel symptoms, and erectile potency.

At registration (before starting HT whenever possible) and at randomization (before RT), patients completed the FACT-P questionnaire, comprising the FACT core questionnaire (29 questions) with its additional prostate subscale (12 questions), the SF-36, and the UCLA-PCI (21 questions). The individual items from all of these questionnaires can be combined into different domains or subscales, as detailed in Table 1.

The primary outcome measure of the trial was tumour control rate. The estimated local disease control rate with standard-dose conformal RT at 5 years was 80%, and the target sample size of 800 men was sufficient to reliably detect an improvement of 10% (to 90%) with high-dose conformal RT (two-sided $P < 0.05$, and 97.5% power).

To focus the QoL aspect of the trial, before the analyses, the two clinicians on the QoL subcommittee of the RT01 trial (D.P.D. and R.C.) were asked to generate hypotheses relating to the expected changes over time, and the differences between the regimens. In all, six hypotheses were generated: (i) HT will cause a deterioration in sexual functioning; (ii) HT will improve overall urinary function; (iii) HT will cause a deterioration in physical well-being; (iv) RT will cause transient bowel side-effects; (v) RT will improve medium-term urinary functioning; (vi) RT will cause a deterioration in long-term bowel functioning. The present study reports on the first three hypotheses, which relate to the period when HT was given.

To address the first hypothesis, the data from the UCLA-PCI question 20 ‘Overall, how big a problem has your urinary function been for you during the last 4 weeks?’ was used. The 5-point response ranged from ‘no problem’ (score 1) to ‘big problem’ (score 5). It was assumed that, before HT 30% of patients would report a problem with urinary functioning (score 3–5), and so to reliably detect a reduction of 15% (to 15%) before RT required a total of 322 patients, using a chi-square test (two-sided, 90% power, 5% significance level).

Finally, to address the third hypothesis, the data from the FACT-P physical well-being subscale was used, which combines seven questions, all answered on 5-point scales (0–4), to give a subscale score of 0–28. It was assumed that before HT 10% of patients would report a physical problem (score >7 on the subscale), and so to reliably detect an increase of 15% (to 25%) before RT required a total of 266 patients, using a chi-square test (two-sided, 90% power, 5% significance level).

The following criteria were defined to ensure that the data analysed reflected the
result of ≥3 months of HT: The pre-HT QoL questionnaires had to be completed within 14 days (before or after) of the start of hormones; the pre-RT QoL questionnaires had to be completed before the start of RT; there had to be ≥3 months between completing the pre-HT and pre-RT questionnaires.

Supplementary exploratory analyses were also performed to investigate the change in: (a) domain scores; (b) individual QoL questionnaire items; and (c) the Trial Outcome Index (TOI) of the FACT-P questionnaire. The TOI is composed of the sum of the scores of the physical, functional and prostate cancer subscales, and thus reflects the overall QoL experienced.

RESULTS

Between January 1998 and September 2001, 862 patients were registered, and 843 of these were randomized to 25 centres in the UK, New Zealand and Australia. As shown in Fig. 1, of the 843 patients randomized, only 290, 319 and 290, respectively had data available for testing the three hypotheses, as most patients had been started on HT before being registered for the trial, and so did not complete the pre-HT QoL questionnaires.

Tables 2 and 3 compare the baseline (before HT) clinical characteristics and clinicians’ assessment of the patients’ baseline urinary, bowel and sexual symptoms of the 321 patients with QoL data available, and the remaining 522. There were no obvious differences in bowel or sexual functioning between the groups, but somewhat more of the men not in the QoL group had frequency or nocturia at baseline. One explanation for this might be that referring urologists tended to start symptomatic patients on HT as soon as possible.

Hypothesis (i) was that sexual functioning would become an increasingly significant problem. Of the 290 patients with QoL data, 47% had a score of 3–5 before HT and this increased by 13%, to 60% before RT (chi-square P < 0.001, as indicated by the shift to the right in Fig. 2A). In all, 57 patients improved, 108 stayed the same and 125 worsened. The mean score worsened from 2.64 to 3.24, and thus there was evidence that sexual functioning became an increasing problem during this period on HT.

Hypothesis (ii) was that overall urinary function would improve. Of the 319 patients with QoL data, 75 (24%) reported a score of 3–5 (small to big problem) before HT compared to 76 (24%) before RT (P = 1.0; Fig. 2B). In all, 74 patients reported an improvement, 76 a deterioration and the remaining 169 no change. The mean score changed from 1.87 to 1.91. Thus there was no evidence that overall urinary function improved during this period.

Hypothesis (iii) was that patients’ physical well-being would deteriorate. Of the 290 patients with QoL data, 19 (7%) had a score of ≥7 on the FACT-P physical well-being subscale before HT, indicating some impairment of physical well-being; this increased to 35 (12%) before RT (P = 0.03). In all, 71 patients improved, 56 stayed the same and 163 worsened (Fig. 2C). The mean score worsened from 2.60 before HT to 3.55 before RT, and thus there was some evidence of a slight decline in physical well being.

As the number of patients with QoL data was only just adequate for two of the hypotheses, and well below the calculated sample size required for the third, the criteria for inclusion in these analyses were relaxed to increase the sample sizes. Thus, there was an additional 140 patients who either completed a questionnaire (a) at 14–21 days (before or after) starting HT, (b) within 7 days after starting RT, or (c) between 10 weeks and 3 months apart, giving 461 available patients. Of these, 419, 456 and 427 patients had adequate data for the three hypotheses, respectively. All the above analyses were repeated using this extended group, but when compared to the results obtained with the original group of patients, they were consistent with the original results (data not shown).

To explore whether there was any indication that any subgroup of patients reported more or less change in their sexual, urinary or physical functioning during HT, subgroups of patients defined by those baseline (before HT) characteristics that the chief investigator of the RT01 trial (D.P.D.) suggested might be important, were investigated. Although, as would be expected, patients with different baseline characteristics reported different levels of baseline functioning (e.g. those with different levels of erectile potency reported different levels of sexual functioning, and those with different levels of nocturia reported different levels of urinary functioning), there were no clear indications that any subgroup reported more or fewer changes after HT (data not shown).

All the domains from the three questionnaires (Table 1) were explored for changes during HT, but as there are multiple analyses and as they were not listed in the original hypotheses, these results should only be considered as hypothesis-generating. The patients included in these exploratory analyses were those with the original, stricter criteria, and for clarity and consistency, all the scores were standardized (converted to a 0–100 range).

Figure 3A shows the mean scores for the nine SF-36 domains pre-HT and pre-RT. ‘Role functioning’ (whether patients experienced problems with work or other regular daily activities as a result of their physical health) showed the greatest decline, whereas ‘health transition’ (how patients felt now compared to a year ago) showed a clear improvement.

Figure 3B shows the changes in the four UCLA-PCI domains, with the low baseline level of ‘sexual functioning’ decreasing even further, although ‘satisfaction with treatment’ increased slightly. Each of the 10 individual items of the UCLA-PCI sexual functioning domain were much reduced on HT (Fig. 3C).

Figure 3D shows the six subscales of the FACT-P questionnaire, indicating only marginal changes, but assessing in detail the 12 items in the additional concerns domain (Fig. 3E) the ability to keep an erection showed the greatest decline.

All 98 individual items from the three QoL questionnaires were examined for evidence of change in scores from before HT to before RT. Osoba et al. [19] suggested that a change of ≥20 points on a standardized scale (i.e. with a range of 0–100) represents a clinically large change, and changes of 10–20 and 5–10 points, moderate and small clinical changes, respectively. Nine of the 11 sexual functioning items (eight of the nine items of the UCLA-PCI sexual domain, and the item relating to erection on the FACT-P) showed a change of ≥20 standardized points, the exceptions being Q15 on the FACT-P (‘Have you been sexually active?’) and Q20 on the UCLA-PCI (‘Overall, how big a problem has your sexual function been for you?’), which changed by 17.7 and 15.0 points, respectively. Five further items...
FIG. 1. The QoL data available.

Total number of patients randomized – 843

Was RT received?

Yes 831 patients

QL questionnaire completed within 14 days of start of hormones?

Yes 509 patients

QL questionnaire completed prior to start of RT?

Yes 458 patients

QL questionnaires completed at least 3 months apart

Yes 321 patients

Data available for hypothesis 1?

Yes 290 patients

Data available for hypothesis 2?

Yes 319 patients

Data available for hypothesis 3?

Yes 290 patients

No 12 patients

No 322 patients

No 51 patients

No 137 patients
showed a change of 10–20 points: three of the four questions on the FACT-P relating to role functioning, indicating that patients were more limited in their work and other regular activities after HT (the other question in this subgroup showed a change of 9 points), and FACT-P questions 31 (relating to sleeping, patients indicating they were sleeping less well after hormones) and 41 (patients reporting they were less 'able to feel like a man' after hormones). A small clinical change was indicated in a further 12 questions, suggesting an increase in fatigue but an improvement in attitude, less nervousness, more satisfaction with their treatment and less impairment of physical, urinary, bowel and sexual functioning than do patients. Therefore it is important to take account of patient-assessed outcomes.

As all patients received neoadjuvant HT in the present study, and there was no comparable untreated group, we are unable to distinguish between the effect of HT and the effects of the disease over time. Indeed, other studies that have examined ‘watch and wait’ policies in similar groups of men have reported decreasing physical and sexual function over 5 years [24]. However, given the relatively short period considered here (3 months) the assumption must be that most changes seen in the present patients was directly related to the HT.

In the current trial the expected effect of hormones on sexual functioning was clear, and there was a strong indication that role functioning (whether patients have experienced problems with work or other regular daily activities as a result of their physical health) was adversely affected. Patients also reported increased levels of fatigue but it appeared that they had a positive attitude to their disease and treatment, which might explain why overall QoL did not seem to change. Interestingly no effect on urinary symptoms was observed during this period, although it might be because the symptoms reported before HT were unrelated to the prostate cancer. Importantly, we were not able to reliably identify any subgroups of patients who appeared to be affected more or less during HT.

In addition to the way LHRH agonists were used in this trial (before RT for patients with locally advanced disease), they might be given as conservative treatment for localized disease, as adjuvant treatment after RT or surgery, or as primary treatment for patients by all the patients in this trial before standard or high-dose conformal RT.

Neoadjuvant HT is used, especially in the UK, to reduce the size of the tumour prior to RT, and is generally reported to be associated with minimal morbidity [21], although clinician-reported side-effects include high levels of erectile dysfunction [22]. However, clinicians and patients differ in how they report QoL, symptoms and side-effects, and Litwin et al. [23] suggested that clinicians report significantly lower levels of fatigue and pain, and less impairment of physical, urinary, bowel and sexual functioning than do patients. Therefore it is important to take account of patient-assessed outcomes.
with advanced or metastatic disease. The effect of hormones on patients' QoL in some of these settings has been reported and reviewed [25], and can provide useful comparison data to the findings of the current study.

Studies reporting the experience of a group of men receiving LHRH treatment generally confirm decreased sexual functioning as the only major side-effect. For example, using data from the Cancer of the Prostate Strategic Urologic Research Endeavour database, which collects data on all patients in the USA irrespective of disease stage or treatment, Lubeck et al. [26] reported on 67 men who completed the SF-36 and UCLA-PCI questionnaires before and after HT. No significant changes were observed in any domains, except the UCLA-PCI sexual function scale, which decreased from a mean standardized score of 24.9 to 14.7.

Finally, Stone et al. [28] reported a significant increase in the self-reported levels of severe fatigue after androgen suppression in 62 men receiving hormones as either neoadjuvant or primary treatment. Results from a battery of questionnaires also indicated declines in virility and potency, and a slight increase in nausea and vomiting, but a reduction in pain and improvement in urinary difficulties. These changes did not appear to affect the patients’ functional ability or overall QoL.
Generally, studies comparing a group of men who chose or were prescribed or randomized to receive LHRH, and a group who did not, indicate, in addition to the decline in sexual functioning, some increase in symptoms and side-effects with HT. For example, Lamb et al. [16], within a randomized three-arm trial of 818 patients with locally advanced prostate cancer of 0, 3 and 6 months of neoadjuvant maximal androgen deprivation (MAD) reported that patients on MAD (completing a questionnaire designed for Australasian patients) had a slight worsening of bowel function but some improvement of urinary symptoms. In addition, most of the 36% of patients who were sexually active before any treatment became inactive while on MAD. However, at 1 year after treatment there were no differences between those men who had had RT alone and those who received RT and 3–6 months of HT.

In 91 patients with asymptomatic lymph node-positive prostate cancer, most of whom were randomized between immediate and deferred HT, Van Andel and Kurth [29] reported that, using standard QoL instruments, the men on immediate HT reported worse sexual, emotional and physical functioning, and a worse overall QoL, than men receiving no HT.

The Prostate Cancer Outcomes Study collected data on men with newly diagnosed prostate cancer who were recorded on six USA registries, and Potosky et al. [30] compared those receiving androgen-deprivation therapy with those receiving no therapy. Self-reported data using the SF-36 and a prostate-specific questionnaire were collected at 6 and 12 months after diagnosis, and men were asked about their baseline status, retrospectively. Compared with the 416 men on no therapy, the 245 men on androgen-deprivation therapy reported decreased potency and vitality, and increased physical discomfort, but increased satisfaction with treatment.

Herr and O’Sullivan [31] evaluated the longitudinal QoL of 144 men with asymptomatic locally advanced prostate cancer choosing no therapy (65) or HT with orchidectomy, leuprolide or leuprolide + flutamide (79). Patients completed the European Organisation for Research and Treatment of Cancer prostate cancer QLQ [32], the intrusion subscale of the Impact of Event Scale [33], and Selby’s QoL uniscale [34] at baseline, 6 and 12 months. Compared with the ‘no treatment’ group, the HT group, and especially the men on medical HT, reported increased psychological distress, fatigue and sexual problems, and decreased physical functioning and overall QoL.

Herr et al. [35] also reported on 35 men with metastatic prostate cancer (16 of whom chose HT and 19 no immediate treatment) using the same set of questionnaires administered at 1, 2 and 6 months after diagnosis. At 1 and 2 months the HT group reported more sexual problems, and at 6 months more fatigue, sexual problems and physical symptoms.

Finally, Fowler et al. [36] identified 1089 men who had had a radical prostatectomy 7–8 years previously and divided the group into those who had been androgen-deprived and those who had not. Using a trial-specific questionnaire, they reported that the HT group had significantly worse scores on all seven measures.

Studies comparing surgical castration, LHRH and antiandrogens suggest higher levels of sexual dysfunction but perhaps better overall QoL with LHRH. For example, Cassileth et al. [37] compared the QoL of 115 men with advanced stage prostate cancer who chose...
orchidectomy with 32 who chose injections with the LHRH agonist goserelin. At 3 months the LHRH group reported more sexual dysfunction (as measured on a trial-specific questionnaire) but better psychological status (as measured on the Profile of Mood States [38]) and QoL (as measured on the Functional Living Index-Cancer [39]) than the orchidectomy group. However, at 6 months, whereas the levels of sexual dysfunction were similar, the LHRH group reported a sustained improvement in QoL.

In a randomized trial of 486 men, comparing antiandrogens with castration, Chodak et al. [40] found that at 6 months sexual function had declined from pretreatment levels in the castrated group but was maintained in the group receiving bicalutamide.

Comparing the two methods of HT (132 orchidectomy patients, 298 on LHRH agonists) using data from the Prostate Cancer Outcomes Study, no significant differences were reported [41], although all patients reported decreased sexual interest and activity, and the LHRH group reported more physical discomfort, worry about cancer, and worse overall health than the orchidectomy group. Nevertheless, >90% in each group said they would choose the same treatment again.

There are several potential limitations in some of the studies cited; results might be confounded by a mixture of disease groups and/or other treatments; most included only a small sample of patients; some used non-standard questionnaires; there is a lack of clarity as to how missing data were treated; retrospectively collected data might be inaccurate [42]; as a result of attrition, some studies compared different groups of patients at different times; comparisons where patients choose their own treatment might be biased; and some of the more common androgen deprivation symptoms (hot flashes, breast swelling and tenderness) were not specifically assessed.

Nevertheless, the results from these studies generally support the findings reported in the RTO1 trial. Most indicate that during HT there is a clear reduction in sexual functioning, with some suggestion of increased fatigue and decreased physical functioning, and some improvements in psychological status, which overall do not seem to affect significantly the overall QoL. This contrasts with studies suggesting that sexual problems are a source of psychosocial distress [43] and cause a decline in general health-related QoL [44]. If this was a general pattern then consideration might have to be given to ways of alleviating sexual dysfunction, but while some papers report that erectile aids might reduce these problems [45], others report that they do not [46].

It is likely that, in this group of generally elderly men, sexual activity is already reduced, as shown by the low level of sexual functioning before HT and the low proportion of men who say they were bothered by this [27,47]. Supporting evidence for this comes from a cross-sectional survey of 113 patients with metastatic prostate cancer who were either in remission and receiving a LHRH agonist (60 men) or had disease progression (53 men) [48]. Using the eight domains of the SF-36, those men in remission had a similar profile to a socio-demographically matched group of the USA general population. In addition, evidence from a study in which men without prostate cancer were asked whether they would choose a LHRH agonist or a nonsteroidal antiandrogen suggest that the method of administration (3-monthly injection vs oral tablet) and increased risk of fractures and loss of physical strength, are of greater concern than sexually related symptoms [49].

The conclusion might be that there is an acceptance that a decrease in sexual functioning is the price to pay for an appropriate cancer treatment, although this topic obviously merits appropriate discussion with patients before starting treatment.

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CONFLICT OF INTEREST

None declared.

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Abbreviations: RT, radiotherapy; HT, hormone therapy; QoL, quality of life; FACT-P, Functional Assessment of Cancer Therapy-prostate subscale; SF-36, Short Form-36 Health Survey; UCLA-PCI, University of California-Los Angeles Prostate Cancer Index; TOI, Trial Outcome Index; MAD, maximal androgen deprivation.