The PACE Trial

Main results of the PACE-A trial: Comparing patient quality of life after stereotactic body radiotherapy (SBRT) to surgery (Prostatectomy)

The PACE-A trial includes 123 men who had prostate cancer at medium-risk of returning after treatment and which had not spread elsewhere in the body. We have been collecting information about men who have been taking part in the trial for at least two years and we now have enough data to be able to share the key findings.[1]

What is the trial about?

The aim of the PACE-A trial is to compare the effect of SBRT treatment to surgery on a patient's well-being and ability to function in daily life by asking patients to answer questions about how they are feeling. Patients filled in a questionnaire before they started treatment and then at set times after treatment. The questions asked them about their recent health each time they received a booklet.

SBRT is a type of radiotherapy that lets doctors to better target the radiation on the tumour. This reduces the chance of damaging nearby healthy tissue. Damaging this healthy tissue can cause side effects such as more frequent or urgent urination and diarrhoea.

The main aim of the trial was to look if there were any differences in the bladder and bowel issues reported by the men who had surgery compared to the men who had SBRT at 2 years after their treatment. We also looked at any sexual problems the patients taking part told us about.

Background

Men with low to medium risk prostate cancer which had not spread to other parts of the body, and who could have had either surgery or radiotherapy, were invited to take part in the trial. 123 people joined the trial and had their treatment between August 2012 and February 2022. The trial was carried out in 10 hospitals in the UK.

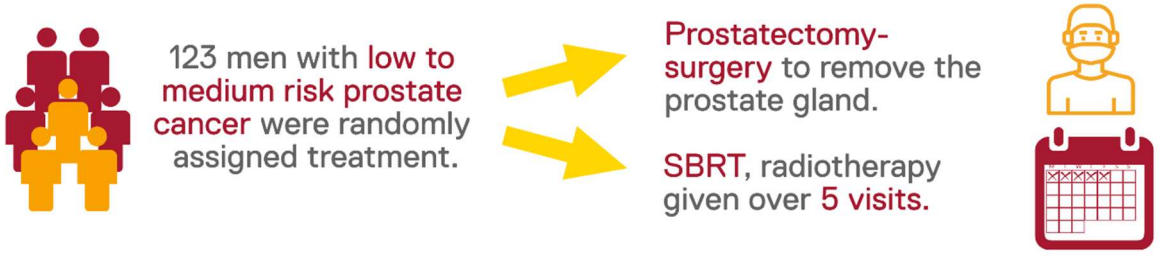
The PACE-A patients were put at random into one of the following treatment groups:

1) **Group 1 - SBRT** – radiotherapy 36.25 Gy* in 5 fractions** over 1-2 weeks).
2) **Group 2 - Prostatectomy** - surgery to remove the prostate gland.

**grays (Gy) are the units, or amount, of radiotherapy given*
*** Fractions are daily radiotherapy treatments*

Half of the men in PACE-A trial had their radiotherapy in 5 days ("SBRT") and half had a surgery. No-one received hormone therapy.

[1] The full results have been published in European Urology: https://www.sciencedirect.com/science/article/pii/S0302283824025685?via%3Dihub



How did we collect this data?

We asked everyone taking part to complete questionnaires which have been developed to understand the effect of treatment on a patient's well-being and ability to function in daily life.

Everyone was asked the same questions. They filled in a questionnaire before they started treatment so it could be compared with the answers in questionnaires after treatment. They then completed the questionnaires 4 and 12 weeks after treatment then 6, 9, 12 and 24 months after treatment.

Results

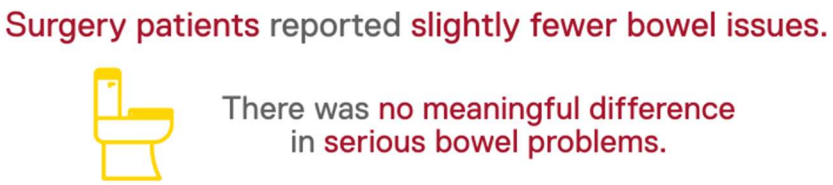
We found that the answers to the questions, showed that men treated with SBRT had fewer bladder incontinence and fewer sexual problems at 2 years, but they had slightly worse bowel bother, than men that had surgery. All patients were given their questionnaires, but not all of the questionnaires were returned to us and some did not have all the questions answered.

Patients who had SBRT told us they used less incontinence pads and had less urine leakage. 3 of 46 (6.5%) of SBRT patients said they had to use pads, compared to 16 of 32 (50%) surgery patients at 2 years after treatment.

Patients who had SBRT also said they had fewer sexual problems than patients who had surgery. 8 of 45 (18%) of SBRT patients told us they had moderate to severe sexual problems 2 years after treatment, compared to 10 of 30 (33%) of surgery patients.

SBRT patients told us about slightly more bowel problems than surgery patients did. However, there was no meaningful difference in serious bowel problems. None of the 31

(0%) surgery patients said they had any serious bowel problems, compared to only 1 of 48 (2.1%) of the SBRT patients.



Summary

Although PACE-A only had 123 men taking part, there were enough people taking part to make good comparisons between the two treatments, and it is the first large randomised trial to compare SBRT to surgery for early-stage prostate cancer that has not spread to other parts of the body. The findings show the importance of considering the side effects associated with both treatment options.

The results give patients and doctors more information to help decide whether SBRT or surgery is best suited for them based on their needs and the issues that are most important to them.

Patients will continue to complete questionnaires and have follow up visits until five years after treatment.

What will happen now?

The results of the trial have been published in the scientific journal, European Urology. You can read the full paper using the link below:
https://www.sciencedirect.com/science/article/pii/S0302283824025685?via%3Dihub

Without the contribution of the patients that took part in this study, research like this would not be possible. We would like to thank them all for their ongoing support.

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