

Benefit of brachytherapy in patients with early-stage prostate cancer is still unclear

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It remains an unresolved issue as to whether interstitial brachytherapy has advantages compared to other therapy options in men with localized prostate cancer, nor do newer studies provide proof in this respect. This is the result of a report published by the Institute for Quality and Efficiency in Health Care (IQWiG) on 11 January 2011. In this report IQWiG examined whether newer studies challenged the findings of research already completed in 2007. However, it was shown that no relevant new evidence could be obtained from the recent studies. The conclusions of the final report of 2007 therefore remain unchanged.

Comparison of therapy alternatives

[Prostate cancer](#) is potentially curable as long as the tumour is still confined to the prostate gland. Several options are available for the treatment of such a localized tumour: besides complete surgical removal of the prostate ([prostatectomy](#)) or radiation with an external radiation source (external beam radiotherapy), low-dose-rate (LDR) permanent interstitial brachytherapy offers another therapy option. In this treatment, small radioactive particles are permanently implanted in the prostate via specific needles; these particles enable a local and targeted radiation of the tumour. As prostate tumours either stop growing or grow very slowly in many patients, the fourth option to be considered is a specific form of watchful waiting called active surveillance.

Evidence base is still insufficient

In the research now available, prepared as a rapid report, IQWiG was able to include 20 additional studies, which for the first time also included results of a randomized controlled trial (RCT). However, overall IQWiG still rates the evidence base as insufficient. On the one hand, this is due to the fact that many studies showed deficiencies, so that the results cannot be reliably interpreted. On the other, the studies in part included too few participants and did not last long enough to demonstrate differences between therapies. As the course of early-stage prostate cancer is favourable in most patients (particularly in older ones), differences between therapies in respect of disease progression and survival may only become noticeable after several years.

No robust statements on survival possible

As in the final report of 2007, IQWiG therefore concludes that it has so far not been proven that, compared to the alternative treatment options, brachytherapy is at least equivalent in respect of the (disease-free) survival of patients. This is also due to the fact that PSA-based recurrence-free survival was often analysed as an outcome in the studies. However, this is a non-validated surrogate and in particular is not designed as a surrogate for a comparison between different treatment groups. Therefore no sufficiently robust conclusions can be drawn with regard to advantages or disadvantages of brachytherapy compared to other treatment options. It cannot therefore be definitely precluded that patients who undergo brachytherapy die earlier or have a shorter disease-free survival period.

Against the background of this gap in knowledge, indications that brachytherapy may have certain advantages cannot be reliably classified. In the current rapid report IQWiG also concluded that indications exist that brachytherapy may result in less impairment of sexual function and lower rates of urinary incontinence than the surgical removal of the

prostate. Compared to external beam radiotherapy, brachytherapy may also have a less detrimental effect on bowel function. "However, as long as we do not know how reliably brachytherapy works against cancer, this does not suffice to speak of a benefit," says Stefan Lange, IQWiG's Deputy Director.

Moreover, the new studies also provide additional indications of disadvantages of brachytherapy: urinary tract function on the whole, i.e. various voiding disorders, seems to be more strongly impaired with brachytherapy than after removal of the prostate.

G-BA adjourns consultations for outpatient sector

IQWiG was already commissioned by the Federal Joint Committee (G-BA) with the first benefit assessment in December 2004. At that time the Committee wanted to decide whether brachytherapy should in future be available not only in hospitals, but also be performed on an outpatient basis and reimbursed (§135 (1) Social Code Book V). As its benefit was unclear, in December 2009 the G-BA decided to adjourn the consultations, i.e. delay the decision until reliable study results were available.

In June 2009, brachytherapy was also included in the G-BA's agenda for the inpatient sector through a further application for consultation (§ 137c [1] Social Code Book V). As IQWiG's final report was already several years old - and therefore potentially outdated as a basis for decision-making - the G-BA commissioned IQWiG a second time. The aim of this commission for the present search update was to examine whether studies completed in the meantime could change the results of the first IQWiG final report.

Large German study to commence in 2011

In December 2009, the G-BA, which is the supreme body of self-administration in the German [health care](#) system, also cleared the way for a large-scale study: with the participation of several institutions, including IQWiG, representatives of the involved specialties, as well as patient representatives, the National Association of Statutory Health Insurance Funds (GKV-Spitzenverband) subsequently planned a [randomized controlled trial](#) comparing brachytherapy with the three alternative therapy options. The study allows the consideration of patient preferences. It is to commence in 2011 as soon as its final planning and funding have been determined.

Trend-setting solution

"The members of the G-BA have reacted to a health care problem in an exemplary manner here," comments Stefan Lange. "Instead of making decisions on an uncertain evidence base, they have initiated a study that will help to close existing gaps in knowledge. In any event this approach will improve the quality of health care of patients with early-stage prostate cancer."

Provided by Institute for Quality and Efficiency in Health Care

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