

Aromatase inhibitors for breast cancer: Advantages over tamoxifen in early-stage disease

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The German Institute for Quality and Efficiency in Health Care (IQWiG) investigated whether and what advantages drugs from the drug class of aromatase inhibitors offer compared with other breast cancer treatments or with each other. The final report was published on 15 November.

According to the findings, the data available show advantages over tamoxifen for the early, but not for the late stage of disease: Patients survive longer and recurrences occur later. Overall, the evidence for advanced breast cancer is much poorer.

Comparison with other treatments and within the drug class

The Federal Joint Committee (G-BA) commissioned IQWiG to perform several comparisons: On the one hand, IQWiG was to compare aromatase [inhibitors](#) with other treatment options, in particular the anti-oestrogen tamoxifen. On the other, the Institute was to assess whether the 3 approved drugs from the drug class of aromatase inhibitors (anastrozole, exemestane, letrozole) differ with regard to benefit or harm.

Good evidence for early breast cancer

As the IQWiG researchers determined, the evidence for early breast cancer is clearly better than for advanced disease: 12 of the overall 19 studies that IQWiG included in the assessment refer to early breast cancer. In July 2015 the results were published of a study that enrolled more than 4000 participants and compared 2 aromatase inhibitors (letrozole, anastrozole).

In contrast, the evidence is much poorer for [advanced breast cancer](#). For instance, some questions were not investigated at all and the number of participants was much lower (approx. 3000 versus approx. 39,000). It is also remarkable that none of the studies considered the aspect "health-related quality of life".

The assessment is not only based on published studies. After a request by IQWiG, the drug manufacturers provided additional data or information on the studies conducted, so that the assessment was possible on the basis of a complete pool of data.

Early breast cancer: better results for upfront and switch therapy

Aromatase inhibitors are approved for 5 different treatment regimens in early breast cancer. The data show an added benefit over tamoxifen for 2 of these regimens: In upfront [therapy](#) the patients start drug treatment with an aromatase inhibitor, while in switch therapy, after 2 to 3 years of pretreatment with an anti-oestrogen, patients switch to an aromatase inhibitor.

Advantages also for certain side effects

The results are favourable for aromatase inhibitors for 3 outcomes: overall survival, freedom of recurrence, and certain side effects (e.g.

serious [adverse events](#)). Depending on the drug taken, other side effects, in particular specific adverse events, occur in part more often or less often than with tamoxifen.

Extended therapy and neoadjuvant therapy: no advantage overall

For extended therapy, where the only [aromatase inhibitor](#) approved here (letrozole) is given after completion of 5 years of treatment with tamoxifen, the data show an advantage only for freedom of recurrence. However, this is accompanied by more discontinuations due to adverse events.

No data are available for neoadjuvant therapy, where aromatase inhibitors are given prior to surgery. Likewise, data are lacking for the comparison of aromatase inhibitors with each other. The only such study, which compared letrozole with anastrozole, showed no relevant differences.

Advanced breast cancer: no hint of added benefit

In advanced [breast cancer](#), none of the drugs offers an advantage for any of the 3 possible treatment regimens with aromatase inhibitors: Data are available for first-line therapy; however, no added benefit over tamoxifen can be inferred from them. Relevant studies are lacking for second-line therapy (i.e. after pretreatment with anti-oestrogens) and for third-line therapy.

AMNOG assessments have been prioritized since 2011

The G-BA commissioned IQWiG to assess aromatase inhibitors as early

as 2010, that is, before the introduction of the Act on the Reform of the Market for Medicinal Products (AMNOG). Since the beginning of 2011 all newly approved drugs have to be assessed. Since then, the timely completion of these assessments is of the highest priority for G-BA and IQWiG. This is also the reason why the [final report](#) on aromatase inhibitors is only available now. But of course the report considers the current state of knowledge.

Comparative assessments of older drugs also feasible and meaningful

Within AMNOG it was originally planned that the G-BA could request a dossier from a drug manufacturer not only for newly approved drugs, but also for selected older ones. This "call-up" for the established drug market was abolished in the first AMNOG reform at the beginning of 2014, primarily due to legal concerns that legal action could be taken against later resolutions of the G-BA. Up until then, only one drug class from the established market (gliptins) had been evaluated according to AMNOG.

The Institute Director, Jürgen Windeler, commented on the final report as follows: "The report on the aromatase inhibitors once again shows that comparative assessments are also feasible and meaningful for drugs that have been on the market for a longer period of time. This is because they can provide important information on benefit and harm and in this way help improve the quality of patient care."

Process of report production

IQWiG published the preliminary results in the form of the preliminary report in April 2016 and interested parties were invited to submit comments. At the end of the commenting procedure, the preliminary

report was revised and sent as a final report to the commissioning agency in September 2016. The written comments submitted, which did not lead to a change in the assessment result, were published in a separate document together with the final report. The report was produced in collaboration with external experts.

More information: www.iqwig.de/en/projects-resul...ast-cancer.1311.html

Provided by Institute for Quality and Efficiency in Health Care

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