IQWiG Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen

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Assessment of the benefit of screening in persons under 55 years of age with a family history of colorectal cancer[1]

Executive Summary

[1] Translation of the executive summary of the final report "Bewertung des Nutzens einer Früherkennungsuntersuchung für Personen unter 55 Jahren mit familiärem Darmkrebsrisiko" (Version 1.0; Status: 29 May 2013). Please note: This translation is provided as a service by IQWiG to English-language readers. However, solely the German original text is absolutely authoritative and legally binding.

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[2] Due to legal data protection regulations, employees have the right not to be named.

Executive summary

In its letter of 21 March 2011 the Federal Joint Committee (G-BA) commissioned the Institute for Quality and Efficiency in Health Care (IQWiG) to assess the patient-relevant benefit of screening for colorectal cancer in people under 55 years of age with a family history of colorectal cancer (with the exception of hereditary forms of the disease).

Research question

The research question of the report was divided into several sub-goals:

- Sub-goal A: Determination of the risk of disease in people with a positive family history

Within the framework of sub-goal A the risk of developing colorectal cancer or dying from the disease was determined in people with a positive family history.

- Sub-goal B: Assessment of the diagnostic accuracy of family history tools

Within the framework of sub-goal B it was examined how reliable (i.e. with what diagnostic accuracy) family history tools that could be used during screening can identify people with a higher risk due to a positive family history within the normal population.

- Sub-goal C: Comparative benefit assessment of comprehensive screening strategies using family history tools

Within the framework of sub-goal C the question was to be answered as to what benefit a screening strategy offers in which a family history tool was initially to be applied in the normal population under 55 years of age to identify patients at higher risk due to a positive family history. People with a positive test result were subsequently to be offered to participate in a screening procedure. In this context it was also of interest whether different screening strategies (e.g. use of different family history tools) differed in their benefit.

- Sub-goal D: Comparative benefit assessment of different screening procedures within a screening strategy in persons with an increased risk due to a positive family history.

If no studies were found for sub-goal C, it was to be examined what benefit different measures within the framework of modified screening had for people in whom an increased risk due to a positive family history had already been determined. This related to different screening procedures (especially colonoscopy and faecal occult-blood testing, FOBT) but also to other potential differences in the screening strategies (e.g. different time intervals between the tests).

Methods

For the various sub-goals the assessment was conducted on the basis of different study designs. Cohort studies, embedded case-control studies and case-control studies were used for sub-goal A. Studies providing data on diagnostic accuracy were used for sub-goal B.

Randomized intervention studies (randomized controlled trials, RCTs) as well as clearly prospective, but non-randomized intervention studies with concurrent control groups (controlled clinical trials, CCTs) were used for the sub-goals C and D.

For this purpose a systematic literature search was conducted in the following databases: MEDLINE, EMBASE, the NHS Economic Evaluation Database (Economic Evaluations) and the Cochrane Central Register of Controlled Trials (Clinical Trials). In addition, a search for relevant systematic reviews was conducted in the databases MEDLINE and EMBASE parallel to the search for relevant primary studies, as well as by means of a search in the Cochrane Database of Systematic Reviews (Cochrane Reviews), the Database of Abstracts of Reviews of Effects (Other Reviews), and the Health Technology Assessment Database (Technology Assessments). The last search was conducted on 24 October 2012.

Moreover, systematic reviews and publicly accessible trial registries were searched for further relevant studies, and documents transferred by the G-BA were scrutinized. In addition, organizations were contacted in writing with regard to German-language questionnaires on family history, as were authors of publications of potentially relevant studies in order to clarify essential issues.

Depending on the source searched, the selection of relevant studies was performed by 2 reviewers independently of each other or performed by one reviewer and checked by another. After an assessment of study quality the results of the individual studies were presented for the relevant outcomes.

Results

Sub-goal A: Determination of the risk of disease in people with a positive family history

Seven studies could be included in the assessment (2 cohort studies, 5 case-control studies).

The overall assessment of the studies included showed that people under 55 years of age with a positive family history for colorectal cancer showed an approximately 1.7- to 4.1-fold higher risk of disease than people of the same age without such a positive family history. The available evidence for people under 55 years of age allowed hardly any further conclusions with regard to different definitions of risk groups. However, the available results indicated that in the group of persons under 55 years of age, the younger the person at risk and the younger the age of the parent at the time of cancer diagnosis, the greater the degree of risk increase.

Sub-goal B: Assessment of the diagnostic accuracy of family history tools

Overall, the available evidence was very scarce with regard to the diagnostic accuracy of family history tools. No relevant studies could be identified for the age group of interest for the report, i.e. persons under 55 years of age, or for paper-based questionnaires or German-language tools.

The 2 studies fulfilling the inclusion criteria of the report examined the diagnostic accuracy of family history interviews in persons between 18 and 79 years of age. The calculation of bivariate meta-analyses was not possible, as only 2 studies were available. One study with a low risk of bias reported a sensitivity of 53% (95% CI: [50%; 55%]) with a specificity of 99% (95% CI: [99%; 100%]). The other study showed a high risk of bias and, due to the small sample size, low precision. This study reported a sensitivity of 81% (95% CI: [54%; 95%]) and a specificity of 94% (95% CI: [89%; 96%]).

Sub-goal C: Comparative benefit assessment of comprehensive screening strategies using family history tools

The systematic search in bibliographic databases and in further sources (systematic reviews, publicly available trial registries and documents transferred by the G-BA) identified no studies for the benefit assessment for sub-goal C.

Sub-goal D: Comparative benefit assessment of different screening procedures within a screening strategy in persons with an increased risk due to a positive family history.

The systematic search in bibliographic databases and in further sources (systematic reviews, publicly available trial registries, and documents transferred by the G-BA) identified no studies for the benefit assessment for sub-goal D. Three studies were identified that could potentially be considered in a benefit assessment as soon as the study data are published or made publicly accessible. However, it is unclear when the corresponding publications of results will be available and whether they will contain separate analyses for groups of persons under 55 years of age.

Conclusion

The present assessment found that persons under 55 years with a positive family history for colorectal cancer show an approximately 1.7- to 4.1-fold higher risk of disease than persons of the same age without such a family history.

With regard to the diagnostic accuracy of family history tools, no relevant studies could be identified for the age group of interest for the report, i.e. persons under 55 years of age, or for paper-based questionnaires or German-language tools. Interviews for recording family history of colorectal cancer showed a specificity of 94% and 99% and a sensitivity of 81% and 53% in age groups not restricted to under 55-year-olds.

No results could be identified from high-quality studies in which comprehensive screening strategies using family history tools in the normal population were evaluated. Likewise, no results could be identified from high-quality studies in which screening procedures within a screening strategy were evaluated in persons with an increased risk due to a positive family history. Due to a lack of suitable studies, the benefit and harm of screening for colorectal cancer is therefore unclear in persons under 55 years of age with a positive family history.

Keywords: colorectal neoplasms, family history, medical history taking, mass screening, systematic review

The full report (German version) is published under https://www.iqwig.de/de/projekte_ergebnisse/projekte/nichtmedikamentoese_verfahren/s11_01_bewertung_des_nutzens_einer_fruherkennungsuntersuchung_fur_personen_unter_55_jahren_mit_familiarem_darmkrebsrisiko.1359.html.