Treatment using high-frequency energy for primarily organic erectile dysfunction[1]

EXTRACT

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Radiofrequency Therapy, Erectile Dysfunction, Benefit Assessment, Systematic Review

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According to §139b (3) No. 2 of Social Code Book (SGB) V, Statutory Health Insurance, external experts who are involved in the Institute's research commissions must disclose "all connections to interest groups and contract organizations, particularly in the pharmaceutical and medical devices industries, including details on the type and amount of any remuneration received". The Institute received the completed Form for disclosure of potential conflicts of interest from each external expert. The information provided was reviewed by a Committee of the Institute specifically established to assess conflicts of interests. The information on conflicts of interest provided by the external experts and external reviewers is presented in Chapter A8 of the full report. No conflicts of interest were detected that could endanger professional independence with regard to the work on the present commission.

External expert

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IQWiG thanks the external expert for his collaboration in the project.

Patient and family involvement

A patient or family member was consulted during the preparation of the report. One person participated in the discussion.

The aim of the discussion was to gather information on the following topics: The impact of the illness on life and daily routines, how the patient copes with it, expectations regarding treatment – including treatment goals – as well as experiences and concerns related to treatment.

IQWiG would like to thank the participant for taking part in the discussion. The participant was not involved in the actual preparation of the report.

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Key statement

Research question

The aim of this investigation is to assess the benefit of treating erectile dysfunction (ED) using high-frequency energy, either alone or in combination with other treatment methods included in the statutory health insurance (SHI) medical services catalogue, compared with other treatment methods included in the catalogue or no treatment.

Eligible patients are those with primarily organic ED who require treatment. The focus is on patient-relevant outcomes.

Conclusion

No relevant completed studies were identified for this assessment.

One ongoing randomized controlled trial was identified, for which previously unpublished data from an interim analysis on the outcome of erectile function were available following enquiries to the manufacturer. However, only qualitative data on a single outcome were available. According to this analysis, there is no favourable effect of high-frequency energy on erectile function compared with a sham treatment. Overall, there is no hint of any benefit or harm from treating ED with high-frequency energy.

Similarly, on this basis, it was not possible to identify any potential for high-frequency energy therapy to serve as a necessary treatment alternative for ED. For this reason, no specific key points for a testing study were defined. Furthermore, due to planned changes to the study design, overall this study does not appear to be suitable for providing relevant findings on the benefit or harm of this method.

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List of abbreviations

Abbreviation	**Meaning**
AE	adverse event
AHRQ	Agency for Healthcare Research and Quality
EAU	European Association of Urology
ED	erectile dysfunction
EHS	Erection Hardness Score
ESWT	extracorporeal shock wave therapy
G-BA	Gemeinsamer Bundesausschuss (Federal Joint Committee)
GKV	statutory health insurance
HTA	health technology assessment
IIEF	International Index of Erectile Function
IIEF-5	A shortened version of the IIEF comprising 5 items, 4 of which relate to the ‘Erectile Function’ domain (IIEF-EF)
IIEF-EF	International Index of Erectile Function, ‘Erectile Function’ domain
IQWiG	Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen (Institute for Quality and Efficiency in Health Care)
ITT	intention-to-treat
NICE	National Institute for Health and Care Excellence
PDE-5	phosphodiesterase-5
RCT	randomized controlled trial
SGB	Sozialgesetzbuch (Social Code Book)

1 Background

Erectile dysfunction (ED) is a sexual dysfunction. ED refers to the persistent inability to achieve and/or maintain an erection of the penis sufficient for sexual satisfaction [1-3]. Depending on the cause, ED is classified as primarily organic or primarily psychological in origin [1], with the former being far more common [4,5] and the subject of this benefit assessment. Vascular causes are considered to be the most common underlying organic pathomechanism, particularly those associated with cardiometabolic diseases (e.g. high blood pressure or diabetes mellitus) or lifestyle factors (e.g. smoking) [2,4]. Other causes include, amongst others, neurological, anatomical or endocrine factors [1]. Furthermore, ED can occur as a side effect of taking certain medicines, such as antihypertensives, antidepressants or antiandrogens, and as a consequence of substance abuse. ED can also occur as a common side effect following surgical procedures or radiotherapy in the pelvic region, such as operations on the prostate or rectum [1].

The severity of ED can be determined using questionnaires completed by the patients themselves [2]. The European Association of Urology (EAU) recommends the International Index of Erectile Function (IIEF) and the Erection Hardness Score (EHS) for this purpose [1]. Using the IIEF's 'Erectile Function' domain (IIEF-EF), ED is classified into the following 4 categories: none, mild, moderate or severe ED [2,6]. The Erection Hardness Score (EHS) classifies erectile function into 5 categories, ranging from 0 = "penis does not enlarge" to 4 = "penis completely hard and fully erect" [2,7].

ED is common [1]. Due to differences between studies – for example, in terms of methodology, the age groups surveyed, and the socio-economic and cultural status of the populations – estimates of prevalence vary widely [1]: The Massachusetts Male Ageing Study, for example, found a prevalence of 52.0% across all severity levels among men aged 40 to 70 in the Boston area, USA, during the survey period from 1987 to 1989 [8]. A Cologne-based study from 2000 involving men aged 30 to 80 found a prevalence of 19.2% [9]. Both studies showed a clear age gradient, with prevalence increasing with age.

ED can significantly impair the quality of life of those affected [4]. Many people with ED experience symptoms of depression and anxiety relating to sexual performance and avoid intimate contact [4]. Furthermore, because the subject is often associated with feelings of shame, men often do not seek professional help, or only do so at a late stage [4,10].

As ED is frequently associated with other conditions, particularly cardiovascular and metabolic diseases, a detailed medical history is recommended [1]. If the assessment reveals that the ED is causally attributable to a specific condition, treatment should initially target the underlying cause and only subsequently address the symptom of ED [1]. Before or alongside treatment, those affected should also be encouraged to make positive changes to risk factors potentially

associated with ED, including lifestyle factors (e.g. physical activity, smoking, weight loss) [1,2]. In this regard, statutory health insurance (SHI) in Germany reimburses the cost of a digital health application (Kranus Edera [11]). The 12-week course includes, amongst other things, pelvic floor exercises, cardiovascular endurance training, mindfulness exercises and information on ED, nutrition and preventative measures.

In addition to treating the underlying condition causing ED, symptomatic treatment options are available [1]. These primarily involve drug therapies. Oral phosphodiesterase (PDE)-5 inhibitors are recommended as first-line treatment. As an alternative or as second-line treatment, the EAU recommends intracavernosal (self-)injections into the corpus cavernosum (e.g. of alprostadil). The EAU also mentions intraurethral (i.e. via the urethra) or topical (i.e. external) application of alprostadil as a further alternative first-line treatment, albeit with a lower level of recommendation [1]. All drug therapies are available on prescription but are excluded from reimbursement by SHI in Germany [12].

In addition, various locally applied non-pharmacological procedures are available as secondary treatment options. The EAU guideline mentions, for example, vacuum erection devices as aids. Furthermore, it lists low-energy extracorporeal shock wave therapy (ESWT) as a potentially causal treatment option for mild vascular ED [1]. However, the evidence for both procedures is weak. Other procedures that, alongside low-energy ESWT, could be classified as potentially regenerative (e.g. plasma therapy, stem cell therapy, botulinum toxin) are not recommended due to a lack of robust evidence. If conservative treatments are contraindicated or ineffective, surgical treatment is an option in the form of penile prosthesis implantation [1]. Vascular surgery, in particular veno-occlusive procedures, is no longer recommended. Of the locally applied, non-pharmacological treatments, vacuum erection devices and surgical treatments are reimbursed by SHI where indicated [13,14] .

In addition to the treatments listed above, accompanying psychosocial interventions and therapies (e.g. cognitive behavioural therapy) are recommended [1].

In addition to these therapies listed in current guidelines, there is a new conservative treatment approach involving the self-administration of high-frequency energy (or radiofrequency energy), which is thought to have a causal effect in cases of primarily organic ED [15,16]: Using a computer-controlled handheld device for treating the penis, supplemented by a pad for the perineal area, low-intensity high-frequency energy is generated [17]. The energy causes the erectile tissue and the connective tissue capsule surrounding it – the tunica albuginea – to heat up. This is intended to stimulate the regeneration of the connective tissue and the synthesis of nitric oxide. Both mechanisms are intended to improve erectile function [15,18].

2 Research question

The aim of this investigation is

- to assess the benefit of treating ED using high-frequency energy, either alone or in combination with other treatment methods included in the SHI medical services catalogue, compared with other treatment methods included in the catalogue or no treatment.

Eligible patients are those with primarily organic ED who require treatment. The focus is on patient-relevant outcomes.

3 Methods

The target population for the benefit assessment comprised patients with primarily organic ED who require treatment. The test intervention was treatment of ED using high-frequency energy, either alone or in combination with other treatment methods included in the SHI medical services catalogue. The control interventions were other treatment methods included in the catalogue, or no treatment. PDE-5 inhibitors, which are recommended as first-line therapy in guidelines, are excluded from prescription in accordance with §34(1), sentence 7 et seq. of the German Social Code Book (SGB) V (see Chapter 1). However, if these are used to the same extent in each of the compared study groups, this does not constitute grounds for exclusion.

The following patient-relevant outcomes were considered for the analysis:

- Morbidity (e.g. sexual function)
- Health-related quality of life
- Adverse effects

Only randomized controlled trials (RCTs) were included in the benefit assessment. There were no restrictions regarding the duration of the studies.

A systematic literature search for studies was conducted in MEDLINE, Embase and the Cochrane Central Register of Controlled Trials. In parallel, a search for relevant systematic reviews was carried out in MEDLINE, the Cochrane Database of Systematic Reviews, and the HTA Database, as well as on the websites of the National Institute for Health and Care Excellence (NICE) and the Agency for Healthcare Research and Quality (AHRQ).

In addition, the following sources of information were taken into account: study registries, enquiries to manufacturers and publicly available documents from regulatory authorities.

The selection of relevant studies was carried out independently by 2 reviewers. Any discrepancies were resolved through discussion between them. Data extraction was carried out using standardized tables. To assess the certainty of the results, where usable data were available, cross-outcome and outcome-specific criteria for risk of bias were evaluated, and the risk of bias was classified as either low or high in each case. The results of the individual studies were described, organized by outcome.

In addition to comparing the results of the individual studies, meta-analyses and sensitivity analyses were to be carried out, and effect modifiers investigated, provided that the methodological requirements were met.

For each outcome, a conclusion was drawn regarding the evidence for (greater) benefit and (greater) harm, with 4 levels of certainty of conclusions: proof (highest certainty of conclusions), indication (moderate certainty of conclusions), hint (lowest certainty of conclusions), or neither of the above 3. The latter was the case if no data were available or the available data did not allow any of the other 3 conclusions to be drawn. In this case, the conclusion “There is no hint of (greater) benefit or (greater) harm” was drawn.

Subsequently, an assessment of benefit and harm was carried out across outcomes.

In cases where there is no hint of (greater) benefit or (greater) harm, a conclusion was drawn on the potential of the intervention in terms of a necessary treatment alternative, and, if applicable, corresponding key points of a testing study were formulated.

4 Results

4.1 Results of information retrieval

The literature search did not identify any completed RCTs relevant to the research question. A single-arm observational study submitted by the manufacturer was also unable to contribute to the assessment of the benefit, harm or potential of high-frequency energy as a necessary treatment alternative for ED, due to a lack of comparative data.

For one ongoing study (NCT061677333), the manufacturer provided the study protocol, including appendices, as well as previously unpublished results from a planned interim analysis. These data were assessed for their suitability for determining benefit, harm or potential and are presented in the following sections.

In addition, one ongoing study (RBR-2stb2r8) with no reported results was identified.

For one study (NCT0450658) classified as having an unclear status in the preliminary report, additional documents were identified for the final report, leading to the conclusion that the study has since been completed. However, the additionally identified documents did not meet the inclusion criteria (full publication or language of publication). Consequently, this study was not included in the final report.

An assessment of the usability of studies RBR-2stb2r8 and NCT0450658 in the context of the present research question can be found in Section 5.2. Furthermore, no planned or discontinued studies, nor any completed studies without reported results, were identified.

The search strategies for bibliographic databases and trial registries can be found in the appendix. The last search was conducted on 18 December 2024.

Table 1: Study pool

Study	**Available documents**			
	Full-text publication (in specialist journals)	**Register entry / results report from trial registries**	**Documents from manufacturers' records (not publicly accessible)**	**Other documents**
NCT06167733	no	yes [19] / no	yes [20-22]	no

4.2 Characteristics of the study NCT061677333

The ongoing multicentre study **NCT06167733** [19,20], involving 6 study centres in the USA, is investigating high-frequency energy compared with a sham treatment in heterosexual men aged between 22 and 85 with mild to moderate (IIEF-EF score 17 to 21) or moderate (IIEF-EF score of 11 to 16) organic ED. The treatment is self-administered using a medical device.

According to the instructions for use, this device operates at a radio frequency of 1 MHz [17]. According to the trial registry entry, around 100 participants are to be included in the trial: recruitment is currently underway at 5 trial centres, with recruitment having been completed at one centre (as of September 2025). According to information from the manufacturer, recruitment is set to continue until March 2026, with the final results expected by September 2026. Based on the study protocol and the information provided by the manufacturer regarding the interim analysis, individual aspects of this study are outlined in more detail below:

Further inclusion criteria include, for example, being in a stable relationship and engaging in regular sexual activity. Exclusion criteria include, amongst others, men with hypogonadism, penile deformities, severe neurological disorders, or those who have undergone surgery or radiotherapy to the pelvis or prostate. Continuation of a stable-dose treatment regimen with PDE-5 inhibitors, commenced at least 6 months prior to the study, is permitted during the study.

The included patients will be randomized in a 1:1 ratio to treatment with high-frequency energy or a sham treatment. Stratified block randomization with random block sizes and allocation via an interactive voice response system is planned. Both the patients and the outcome assessors will be blinded to group allocation in accordance with the study protocol. Furthermore, in accordance with the study protocol, it is planned that a subset of patients from the high-frequency energy group will additionally participate in an embedded study on the usability of the medical device. If the 15 patients planned for this study [21] were to learn, through their additional participation, that they are in the high-frequency energy group of the RCT, the blinding of these patients with regard to group allocation would no longer be guaranteed. Whether this actually occurs, and if so, in how many patients in the RCT, could not be conclusively clarified on the basis of the available documents or following enquiries made to the manufacturer.

In both study groups, a medical device from the manufacturer is used in accordance with the study protocol. In the intervention group, the high-frequency energy is delivered via a flexible, ring-shaped device with 6 electrodes on the shaft of the penis, as well as via a pad with 3 electrodes in the perineal region. The intensity of the high-frequency energy can be adjusted by the user across 6 levels. Sensors on the electrodes are designed to limit skin heating to below 42 degrees Celsius. In the sham treatment group, a medical device with similar functions is used in accordance with the study protocol; however, this is intended to generate a lower, non-therapeutic energy level and less heat at the penis. According to the study protocol, the indicator lights on the devices in both study groups do not differ. Patients carry out the initial treatment independently in a dedicated room at the clinic, with the aid of the instructions for use and a training video. When scheduling appointments, care is taken, in

accordance with the study protocol, to ensure that patients do not encounter one another. Subsequently, patients use the device independently at home. A treatment session lasts 2 × 15 minutes. The treatment regimen is divided into 3 phases: During the first 4 weeks, the device is to be used 3 times a week; during the following 4 weeks, 2 times a week; and for a further 4 months, 1 to 2 times a week. A total of at least 36 treatment sessions are scheduled over a period of 6 months. Adherence to the treatment plan is monitored via a smartphone app.

The planned co-primary outcomes are 1.) the difference in ED between the treatment groups and 2.) the pre-post change in ED within the intervention group – in each case defined as the mean change in IIEF-EF scores at 12 weeks compared with baseline values. The IIEF-EF was assessed using the self-administered IIEF questionnaire, with only the IIEF-EF domain to be reported. The study protocol defined a threshold of at least 4 points as a clinically relevant difference, supported by the literature [23]. In addition, it is planned to collect further data on sexual function and adverse effects up to the 6-month mark.

The sample size planned in accordance with the study protocol is 98 patients. It was intended to conduct an interim analysis of the co-primary outcomes after the inclusion of either 74 patients or if 75% of the 98 randomized patients had completed the 12-week follow-up period in order to adjust the sample size if necessary. In accordance with the study protocol, potential effect modifiers under investigation include, amongst others, age, duration and severity of the condition, concomitant medication with PDE-5 inhibitors, pre-existing cardiometabolic conditions and lifestyle factors.

Information on characteristics from the interim analysis

The interim analysis was carried out by an independent statistician in accordance with the study protocol and was reviewed by an independent committee. The manufacturer was not involved in the interim analyses. The document provided by the manufacturer contains the recommendations of the independent committee as well as further considerations from the manufacturer.

According to the information provided, 91 participants have been enrolled in the study to date and were included in the interim analysis [22]. Patient characteristics were reported for the entire study population, i.e. not broken down by study arm. The mean age of the participants was approximately 55 years (SD 13.2). Furthermore, only characteristics relating to ethnicity (81.3% White, 9.9% Asian and 8.8% Black or African American), the mean BMI (28.3, SD 5.0) and the mean IIEF-EF total score (16.43, SD 3.29) of the study population were reported.

4.3 Overview of patient-relevant outcomes

Table 2: Matrix of patient-relevant outcomes

Study	Outcomes						
	Morbidity			HrQoL	Adverse effects		
	Sexual function						
	Erectile function	Other outcomes relating to sexual function	Additional morbidity outcomes	Health-related quality of life (instrument)	SAEs	Study withdrawals due to AEs	Non-serious AEs
NCT06167733	○[a]	–	–	–	–	–	–

○: Data were reported but were not usable for the benefit assessment.
–: No data were reported (in the interim analysis) (no further details). / The outcome was not assessed (in the interim analysis).
a. Only qualitative information on the difference between the groups was available.
AE: adverse event ; HrQoL: health-related quality of life; SAE: serious adverse event

Data on patient-relevant outcomes were extracted from one study. Table 2 provides an overview of the available data on patient-relevant outcomes from the study used for the assessment. These are the results of an interim analysis of the ongoing study NCT06167733.

The interim analysis comprises data on only one outcome within the outcome category of morbidity.

No data were available for the outcome categories “health-related quality of life” and “adverse effects”.

4.4 Assessment of the risk of bias in the results

For the study used in the assessment, only a study protocol and the documents on the interim analysis provided by the manufacturer were available. Furthermore, no published data on the study were available – i.e. neither a study report nor a publication of the results – meaning that no reliable assessment of the risk of bias in the results or of the qualitative certainty of the results was possible.

4.5 Results for patient-relevant outcomes

4.5.1 Results for the outcome "sexual function"

With regard to the primary outcome of sexual function, data on the outcome of erectile function at 12 weeks were submitted. The submitted documents did not report any specific values for the difference between the groups or any details regarding the statistical measures. The only information available was that the difference in IIEF-EF scores between the high-frequency energy group and the sham treatment group after 12 weeks of treatment was less than 4 points. This result is described as unfavourable ("Unfavourable Zone [Low probability of benefit and/or safety concerns]"). Overall, there is no hint of any benefit or harm with regard to the outcome of erectile function.

4.5.2 Results for the outcome "health-related quality of life"

No data were available for this outcome.

4.5.3 Results for the outcome "adverse effects"

No data were available for this outcome.

4.6 Summary assessment of the results

Evidence map

The documents relating to the interim analysis of study NCT06167733 provide no hint of any benefit or harm associated with the method under assessment with regard to the outcome of erectile function. No data were available for other outcomes, in particular adverse effects.

Assessment of the extent of unpublished data

Apart from the ongoing study NCT06167733, which was used for the assessment, only one completed study (NCT0450665) was identified; however, this was deemed unsuitable for evaluating the method under assessment and was therefore not included (see Section 5.2). In summary, no documents were identified that indicate the existence of unpublished data.

Weighing up benefit and harm

There were insufficient data available to carry out an evidence-based assessment of the benefit or harm of high-frequency energy in ED. In the only study consulted, NCT06167733, only qualitative information on the outcome was available for one outcome, erectile function (with the result being unfavourable to the method under assessment). There is no hint of any benefit or harm from treating the penis with high-frequency energy.

Assessment of the potential for a necessary treatment alternative

No information in the form of a full publication was available for the NCT06167733 study. Based on the interim analysis of the NCT06167733 study, the qualitatively reported results for

the outcome of erectile function following 12 weeks of high-frequency energy treatment show no beneficial effects of high-frequency energy compared with a sham treatment (see Section 4.5.1). No data on adverse effects are available from the study.

On this basis, it cannot be concluded that treatment with high-frequency energy for ED has the potential to serve as a necessary treatment alternative.

5 Classification of the assessment result

5.1 Evidence on high-frequency energy for ED

The evidence on high-frequency energy for ED is currently very limited: a comprehensive literature search failed to identify any completed comparative studies on this method. Only one completed single-arm observational study involving 28 patients was identified via a manufacturer's enquiry [15]. As comparative data are lacking, this study was classified as unsuitable for assessing the benefit, harm or potential, in accordance with the inclusion criteria. In addition to the aforementioned single-arm observational study, an ongoing randomized trial (NCT06167733) was identified, for which no results have yet been published.

Given the limited evidence, the method under assessment is not addressed in current guidelines or systematic reviews on the treatment of ED (see Section A4.1 and A4.2 of the full report).

For the present assessment, the medical device manufacturer provided results from an interim analysis of the aforementioned study NCT06167733. However, these comprised only data on the co-primary outcome at the 12-week mark. However, no specific values were provided, nor was there a separate characterization of the study population by treatment group (in particular regarding the classification of ED severity), nor were there any other details available to assess the risk of bias in the results. Furthermore, data on adverse effects were lacking, making it impossible to assess any potential harm associated with the method. According to the manufacturer's documents, there was no effect in favour of the intervention under assessment for the primary outcome of erectile function.

As a result of the interim analysis, the document provided by the manufacturer includes plans for a fundamental adjustment to the study design. Among other things, the sham treatment previously used as the control is to be discontinued. Instead, a historical cohort is planned as the control group for the remainder of the study. This raises the risk that, once the study is complete, the quality of the evidence will no longer meet that of an RCT. Apart from this, further uncertainties regarding the study remain, for example with regard to the blinding of some patients in the high-frequency energy group who are also participating in the embedded usability study. The manufacturer has not provided a definitive statement on whether and when the embedded usability study has already begun. According to information from the manufacturer, the final results of the study are expected by September 2026. However, there is no current information available on when the results will be published in the form of a paper or a study report.

In summary, given the findings of the interim analysis and the planned changes to the study design, the final results of this study are unlikely to provide any relevant additional insights.

5.2 Comparison of the interventions investigated in the 3 identified studies

The following Table 3 briefly outlines the differences between the 3 identified studies with regard to the (planned) interventions.

Table 3: Overview of the test interventions examined in the 3 identified studies

Study	Characteristics of the test intervention	Use of medical device	Target population
NCT06167733	▪ Radio frequency of 1 MHz ▪ Applied via 3 pairs of electrodes on the penile shaft and a pad in the perineal region with 3 electrodes ▪ Via a flexible, ring-shaped device ▪ Heating of the skin to < 42 degrees Celsius ▪ Intensity/heat self-adjustable across 6 levels	▪ Self-administration ▪ Weeks 1–4 ▫ 3 times a week (12 treatments) ▪ Weeks 5–8 ▫ Twice a week (8 treatments) ▪ Months 3–6 ▫ 1 to 2 times a week (at least 16 treatments) ▪ Duration of treatment: 2 sessions of 15 minutes (15 minutes on the shaft of the penis alone, plus 15 minutes with an electrode pad in the perineal area)	▪ Men with mild to moderate or moderate organic ED (IIEF-EF score of 11 to 21)
NCT04506658	▪ Radio frequency of 448 kHz ("continuous capacitive resistive monopolar electrotherapy with a radio frequency of 448 kHz") ▪ No information available on the design of the medical device ▪ No information available regarding temperature and its adjustability	▪ Application by a doctor ▪ 12 treatments, twice a week (6 weeks)[a] ▪ No information available regarding the duration of treatment	▪ Men with mild to severe organic ED and an IIEF-5 score of 6 to 22[b]
RBR-2stb2r8	▪ No information available regarding the radiofrequency level ▪ No information available regarding the design of the medical device ▪ 38 degrees Celsius ("application of radiofrequency, with 38°C in the penis, in the perineal and pubic regions, totalling 5 regions") ▪ No information available on temperature control	▪ Administered by a physiotherapist ▪ 12 treatments, once a week (12 weeks) ▪ Duration of application in 5 areas along the anatomical course of the penile corpora cavernosa: 4 minutes each	▪ Men with diabetes and mild to severe ED of vascular (organic) origin (IIEF-EF score ≤ 25)

a. This information is taken from the trial registry entry; according to the abstract, the duration of treatment was 9 weeks.
b. This information is taken from the trial registry entry; the abstract states an IIEF-5 score of 5–20 as an inclusion criterion.

ED: erectile dysfunction; IIEF-5: short form of the IIEF; IIEF-EF: International Index of Erectile Function, 'Erectile Function' domain

The basis for this benefit assessment is the medical device used in the NCT06167733 study (see the request for information regarding the application for inclusion of a medical device in the German Medical Aids Register in the documents for the commission in the specification of the commission [24]). Consequently, in this assessment, the properties of the high-frequency energy as delivered by the medical device used in the NCT06167733 study were classified as characteristic of the method under assessment (see Section 4.2 and Table 9 of the full report). There are considerable differences between the 3 identified studies, particularly in the 2 domains relating to the technical implementation of the intervention and its application. Consequently, the interventions used in the NCT04506658 and RBR-2stb2r8 studies were not classified as belonging to the method under assessment. For the same reason, the results of the NCT04506658 study were also classified as not transferable to the research question. Consequently, the NCT04506658 and RBR-2stb2r8 studies were not included in the present assessment.

In addition to the differences mentioned above regarding the test intervention and its application, as well as the target population, the NCT04506658 and RBR-2stb2r8 studies exhibit fundamental methodological limitations, e.g. with regard to the design of the sham treatment and blinding (see Section A.3.5 of the full report). Given that the outcomes were assessed subjectively, a placebo effect could therefore influence the results and substantially limit their informative value.

6 Conclusion

No relevant completed studies were identified for this assessment.

One ongoing RCT was identified, for which previously unpublished data from an interim analysis on the outcome of erectile function were available following enquiries to the manufacturer. However, only qualitative data on a single outcome were available. According to this analysis, there is no favourable effect of high-frequency energy on erectile function compared with a sham treatment. Overall, there is no hint of any benefit or harm from treating ED with high-frequency energy.

Similarly, on this basis, it was not possible to identify any potential for high-frequency energy therapy to serve as a necessary treatment alternative for ED. For this reason, no specific key points for a testing study were defined. Furthermore, due to planned changes to the study design, overall this study does not appear to be suitable for providing relevant findings on the benefit or harm of this method.

7 References for English extract

Please see full final report for full reference list.

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The full report (German version) is published under
https://www.iqwig.de/en/projects/n24-03.html

Appendix A Search strategies

A.1 Searches in bibliographic databases

1. MEDLINE

Search interface: Ovid

- Ovid MEDLINE(R) 1946 to December 12, 2024

#	Searches
1	exp Erectile Dysfunction/
2	(erection* or erectil*).ti,ab.
3	or/1-2
4	exp Radiofrequency Therapy/
5	(radiofrequency or radio frequency).ti,ab.
6	or/4-5
7	and/3,6
8	7 not (animals/ not humans/)
9	8 and (english or german or multilingual or undetermined).lg.

2. Embase

Search interface: Ovid

- Embase 1974 to 2024 December 12

The following filter was adopted:

- RCT: Wong [25] – Strategy minimizing difference between sensitivity and specificity

#	Searches
1	exp Erectile Dysfunction/
2	(erection* or erectil*).ti,ab.
3	or/1-2
4	exp Radiofrequency Therapy/
5	(radiofrequency or radio frequency).ti,ab.
6	or/4-5
7	and/3,6
8	(random* or double-blind*).tw.
9	placebo*.mp.
10	or/8-9
11	and/7,10

#	Searches
12	11 not medline.cr.
13	12 not (exp animal/ not exp human/)
14	13 not (Conference Abstract or Conference Review or Editorial).pt.
15	14 not ((afrikaans or albanian or arabic or armenian or azerbaijani or basque or belorussian or bosnian or bulgarian or catalan or chinese or croatian or czech or danish or dutch or english or esperanto or estonian or finnish or french or gallegan or georgian or german or greek or hebrew or hindi or hungarian or icelandic or indonesian or irish gaelic or italian or japanese or korean or latvian or lithuanian or macedonian or malay or norwegian or persian or polish or polyglot or portuguese or pushto or romanian or russian or scottish gaelic or serbian or slovak or slovene or spanish or swedish or thai or turkish or ukrainian or urdu or uzbek or vietnamese) not (english or german)).lg.

3. The Cochrane Library

Search interface: Wiley

- Cochrane Central Register of Controlled Trials: Issue 11 of 12, November 2024
- Cochrane Database of Systematic Reviews: Issue 12 of 12, December 2024

#	Searches
#1	[mh "Erectile Dysfunction"]
#2	(erection* or erectil*):ti,ab
#3	#1 or #2
#4	[mh "Radiofrequency Therapy"]
#5	(radiofrequency or radio frequency):ti,ab
#6	#4 or #5
#7	#3 AND #6
#8	#7 not (*clinicaltrial*gov* or *trialsearch*who* or *clinicaltrialsregister*eu* or *anzctr*org*au* or *trialregister*nl* or *irct*ir* or *isrctn* or *controlled*trials*com* or *drks*de*):so
#9	#8 not ((language next (afr or ara or aze or bos or bul or car or cat or chi or cze or dan or dut or es or est or fin or fre or gre or heb or hrv or hun or ice or ira or ita or jpn or ko or kor or lit or nor or peo or per or pol or por or pt or rom or rum or rus or slo or slv or spa or srp or swe or tha or tur or ukr or urd or uzb)) not (language near/2 (en or eng or english or ger or german or mul or unknown)))
#10	#7 in Cochrane Reviews
#11	#9 in Trials

4. International HTA Database

Search interface: INAHTA

#	Searches
#1	(erectil* OR erection*) AND radiofrequency

A.2 Searches in study registries

1. ClinicalTrials.gov

Provider: U.S. National Institutes of Health

- URL: http://www.clinicaltrials.gov
- Type of search: Basic Search

Search strategy
(radiofrequency OR (RF AND device)) AND (erectile OR erection) [Other terms]

2. International Clinical Trials Registry Platform Search Portal

Provider: World Health Organization

- URL: https://trialsearch.who.int
- Type of search: Basic Search

Search strategy
(radiofrequency OR radio frequency OR (RF AND device)) AND (erectil* OR erection*)

A.3 Further information sources and search techniques

Regulatory authorities

FDA

- URL: https://www.accessdata.fda.gov/scripts/cdrh/devicesatfda/index.cfm

Search terms
radiofrequency OR vertica