IQWiG Reports – Commission No. E20-10

Sleep position therapy for obstructive sleep apnoea – Addendum to Commission E20-07[1]

Extract

[1] Translation of the executive summary of the addendum E20-10 *Schlafpositionstherapie bei obstruktiver Schlafapnoe – Addendum zum Auftrag E20-07* (Version 1.0; Status: 5 October 2020). 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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Executive summary

In its letter dated 20 July 2020, the Federal Joint Committee (G-BA) commissioned the Institute for Quality and Efficiency in Health Care (IQWiG), as an addendum to commission E20-07, to examine the conclusions on the potential (in terms of §137e Social Code Book [SGB] V) of the method "sleep position therapy for mild to moderate positional obstructive sleep apnoea (OSA)".

Research question

The aim of this investigation was to determine whether further relevant studies exist on sleep position therapy for mild to moderate positional OSA, besides the documents already used in the assessment of potential E20-07. If this was the case, it was to be examined whether, taking these into account, the present examination or treatment method still offers potential. Furthermore, it was to be examined whether, besides the studies already considered in the assessment of potential, ongoing studies exist that in principle are suitable to provide relevant findings on the benefit of the method in the near future.

Methods

Randomized controlled trials (RCTs) were included that investigated the method "sleep position therapy for mild to moderate positional OSA" with regard to patient-relevant outcomes and had not already been used in the assessment of potential.

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 conducted in MEDLINE, Embase, the Cochrane Database of Systematic Reviews, and the HTA Database. In anticipation of the commission, the search was conducted on 29 June 2020. In addition, the following information sources and search techniques were considered: study registries and screening of reference lists. The selection of relevant studies was performed by 2 reviewers independently of each other.

The assessment, synthesis and analysis of information followed the principles described in the Institute's General Methods.

Results

Information retrieval identified 3 additional completed studies with reported results, of which 1 study (van Maanen 2012) was only formally included.

The results of the 2 studies presented, Bignold 2011 and Mok 2020, would not be suitable on their own to substantiate a potential for a necessary treatment alternative for mild to moderate positional OSA. On the basis of the results on the outcome "sleep quality" and due to the short treatment duration and the small number of patients, Bignold 2011 (with the control intervention "sham treatment") cannot sufficiently prove the benefit of the present method. Due to possibly limited transferability, the results of Mok 2020 are classified as not contradicting the potential identified in E20-07. This is because about one third of the patients included

probably had severe positional OSA, which, however, does not correspond to the target population of the present research question. Furthermore, it is conceivable that the results were caused by lower adherence to treatment. Overall, the results of the studies additionally identified do not lead to a change in the evaluation regarding the potential of the present method.

Furthermore, 9 additional studies without reported results (1 completed study, 5 ongoing studies, and 3 studies with unclear status) were identified whose relevance for the present assessment could not be conclusively clarified, among other things, due to a lack of available results and partly insufficient information on the population and the test intervention. In principle, 3 of these studies with the control intervention "positive airway pressure therapy" (Central Positional Apnoea Trial, PaCT, and SUPA OSA Trial) seem particularly suitable for providing further relevant findings on the benefit of the method in the near future.

Furthermore, there is no new information on the ongoing studies already known from the potential assessment E20-07 (SLEEP ON your SIDE [SOS] and SLEMRA).

Overall, the evidence available is as follows:

a) for the comparison of sleep position therapy and positive airway pressure therapy: 2 completed RCTs with reported results, 1 presumably completed RCT with initial results (conference abstract), and 4 ongoing RCTs, 3 of which appear potentially relevant, and
b) for the comparison of sleep position therapy and mandibular advancement splint: 1 completed RCT with reported results and 2 ongoing RCTs, 1 of which appears potentially relevant.

In E20-07, based on several considerations, a required sample size of approximately 500 patients was described as an approximate estimate for the testing study in a replicated cross-over design with 4 periods and a non-inferiority research question. It was also stated there that this sample size could be considerably reduced if the Berry 2019 study known at that time and (after successful completion) the SOS study could be combined metaanalytically for a future demonstration of benefit. Even if the additional studies identified by the present assessment – both the completed Mok 2020 study (but only the subgroup with mild to moderate positional OSA) and the ongoing Central Positional Apnoea Trial, PaCT, and SUPA OSA Trial – are included in the calculation, the total sample size required for the testing study will probably not be reached. For this reason, it is still considered appropriate to conduct a testing study. However, as soon as results from the currently ongoing studies are available, the evidence can be reassessed and the sample size adjusted if necessary.

Conclusion

After a systematic evaluation and under consideration of further completed and ongoing studies identified, sleep position therapy for mild to moderate positional OSA is still classified as having a potential. Overall, despite the study results already available and those expected in the

future, it appears necessary to examine the potential benefits and harms of sleep position therapy in a testing study.

The full report (German version) is published under

https://www.iqwig.de/en/projects/e20-10.html