

HTA-Report | Summary

Invasive home mechanical ventilation, mainly focused on neuromuscular disorders

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Introduction and background

The invasive home mechanical ventilation for patients with chronic respiratory insufficiency is a complex and technology-based therapy that has been used for several decades, and is predominantly carried out on patients with neuromuscular diseases. First and foremost, neuromuscular diseases are hereditary diseases with a progressive dysfunction of muscles evoked by peripheral nerve damage. In some disease patterns a pronounced involvement of the respiratory and heart muscles occurs, which leads to a limitation of life expectancy. For the invasive home mechanical ventilation in Germany small home ventilators are used, which function in volume delivering mode as well as pressure delivering mode.

In Germany exact numbers on the incidence of home mechanical ventilation are unavailable due to the lack of a central database. According to survey data of 2001 the incidence aggregates to 6.5/100,000 residents, including about 12 % of invasively ventilated patients.

Legal foundations, e. g. the code of social law (SGB XII) maxim "outpatient rather than inpatient" as well as the agreement of the United Nations on the rights of the disabled, but also economic constraints along with a scarcity of expensive intensive care beds result in the demand that the society should establish a framework for home mechanical ventilation. The quality of life of patients as well as of caring relatives and nurses needs to be considered too. In this context a tension exists, between the increase in survival and the quality of life on the one hand and the increase in workload and a possible unwanted prolongation of survival on the other hand. This requires reliable data on medical, social, economic and ethical aspects of invasive home mechanical ventilation.

The actual report comments on important issues about the above mentioned areas including existing scientific evidence.

Research questions

Medical research questions

- Which techniques are used in invasive home mechanical ventilation?
- What impact does the invasive home mechanical ventilation have on the patients' symptomatic respectively clinical findings?
- Which complications occur how frequently during invasive home mechanical ventilation in patients with neuromuscular diseases and how often do such complications result in hospitalisation?

Economic questions

- How do costs for home mechanical ventilation add up?

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Within the scope of the



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- Are there differences between the various forms of home mechanical ventilation pertaining to the costs and the quality of care?

Social and ethical questions

- Which social/familial/domestic requirements must be met to assure invasive home mechanical ventilation?
- What impact does invasive home mechanical ventilation have on the health-related quality of life in patients' with neuromuscular diseases?
- What impact does invasive home mechanical ventilation have on the quality of life of caregivers/parents of the affected patients?
- Are there differences in the quality of life of ventilated patients with neuromuscular diseases concerning the elected forms of home ventilation?
- Which ethical aspects must be considered when deciding on invasive home ventilation?

Legal question

- Which legal aspects have to be considered?

Methods

A systematic literature search in the most important medical databases, MEDLINE, EMBASE and Cochrane Library, is initially conducted. Further theme-related databases as well as the various HTA databases DAHTA, INAHTA and NHSEED are considered as well. The utilised keyword selection includes a comprehensive list of search terms for the topics medicine, health-economics, ethics and law to be processed. A limited research period since 2004, for randomised, controlled studies (RCT) since 2002, is selected. The reference lists of existing publications and theme-related professional journals as well as a free web search with the search engine Google are used for manual search.

Considering the existing questions, publications are consulted which are in thematic accordance with the target population (patients with neuromuscular diseases) and the target intervention (invasive home mechanical ventilation). RCT, systematic reviews and HTA reports, clinical studies with patient numbers above ten, health-economic evaluations, primary studies, if applicable with calculations of the costs and quality of life studies are included. Especially publications with the evidence level V, singular case reports, expert opinions, association observations and consensus papers as well as inadequate descriptions of applied methods lead to an exclusion. The analysis of the included publications is displayed in a standardised form and is discussed afterwards.

Results

The number of hits in both database queries amounts to 1,203 literature references for the search of medical and ethical-social contents. The search for economic contents the electronic research results in 361 references, which are initially selected based on the abstracts. Following the second selection step (classification of full texts) 24 publications answering the medical questions, four publications for the economic questions as well as 22 literary resources for the social and ethical questions are consulted.

With intermittent, continuous ventilation (in individual cases) the symptoms of chronic hypoventilation (especially sleep-related respiratory dysfunction and daytime fatigue) can be improved, in some cases also the exercise capacity. A prolongation of life is probable, especially with invasive mechanical ventilation, which appears safer than non-invasive mechanical ventilation based on absent leakage (air leakage through untight application of the facial mask) and prevention of aspiration. This can also be seen in patients with rapidly progressing diseases such as amyotrophic lateral sclerosis (progressive paralysis of skeletal muscles through the destruction of the associated nerve cells [ALS]).

Medical and technical complications in home mechanical ventilation occur rather seldom. Ineffective ventilation may occur in case of leakage by using unblocked cannulas, but is prevented by blocking the cannula. Localised problems on the tracheostoma arise rarely. An existing study regarding the pneumonia ratio reports 1.89 pneumoniae/1,000 ventilator days in the first 500 days of invasive ventilation. This is a frequent reason for the rehospitalisation of patients, but the prognosis is favourable.

Economical publications report higher costs in invasive home mechanical ventilation compared to non-invasive ventilation. The higher expenditures result from the necessary equipment and through highly qualified personnel. Additionally, there is a high expenditure of time for the partially 24-hour-care of the affected patients. In comparison to the costs that accumulate in the intensive care unit of a hospital, a reduction from 62 % to 74 % for the in-home care via an ambulatory nursing service is reported in the included studies. All analysed studies cover a small patient population and do not originate from Germany. The predominant consideration of only the direct costs as well as the dependency on national medical fees and wages of caregivers of the calculated costs barely permit an adaption to the German context.

Reflection on the health-related quality of life shows that invasive mechanical ventilation can coincide with a partly good quality of life, which is depicted in the studies in form of qualitative descriptions. Quantitative data is mentioned in only two studies. The results concerning the quality of life of relatives respectively caregivers of ventilated patients are not as clear: positive and negative effects as to the quality of life of patients with home mechanical ventilation are presented.

The patient's or his authorised caregiver's right of self-determination regarding the initiation of the ventilation is of highest priority. Several publications however, show clearly that not all patients agreed with the initiation of the invasive mechanical ventilation – partly this was not possible in emergency situations. It must be explained to the patient that his decision to be ventilated is not irrevocable, and that he can demand a termination of the ventilation for example with the help of an advance directive.

From a legal point of view the financing of home ventilation, especially invasive mechanical ventilation, requiring specialised technical nursing is regulated in the SGB V. The absorption of costs is distributed to different insurance carriers, who often, due to cost pressures within the health care system, consider other and not themselves as responsible. Therefore in practice, the necessity to enforce a claim of cost absorption often arises in order to exercise the basic right of free choice of location.

Discussion

Positive effects of invasive mechanical ventilation on the symptoms of hypoventilation are reported in the literature. Based on the analysed literature this is highly probable. Due to poor data records mostly retrospective data analyses and case series, which maximal reach evidence level III are taken as the basis. Further limitations of many studies are the small number of patients. Only few smaller studies which pertain to the technical aspects of home ventilators reach evidence level II. There is an existing Cochrane analysis about home mechanical ventilation in neuromuscular diseases, however, patients with invasive as well as noninvasive ventilation are analysed as one group.

The available literature reports high cost savings through home mechanical ventilation. The analysed studies concerning cost structure of invasive home ventilation and in comparison to the costs of various outpatient forms of care are not related to the situation in Germany. The small number of patients, the consideration of only the direct costs as well as the dependency of calculated costs of national medical fees and wages for caregivers do not permit transmittance to the German context.

In terms of the ethical questions it was only determined, which aspects must be considered with initiation of invasive ventilation. Aspects of a occasionally patient-elected termination of home mechanical ventilation were not dealt with for two reasons: the lack of literature as well as prevailing legal uncertainty – the new law for advanced directive has come into effect on 01.09.2009. As yet, there are only singular case decisions as well as uncertainty and disaccord among social ethicists about such an approach.

From a legal point of view, the SGB V, regulates the financing of outpatient technical care, nevertheless, only singular case decisions exist, in which health insurances were adjudged to take over costs of care for up to 24 hours daily. A high court decision which bindingly determines the financing is absolutely required in the interest of the affected and their family members to avoid burdening, partly long-lasting litigations.

Conclusion

Positive effects of invasive mechanical ventilation, related to the symptoms of hypoventilation, are highly probable based on the analysed literature, although with a low level of evidence. An establishment of a home ventilation registry and health care research to ascertain valid data to improve outpatient structures is absolutely necessary.

There is no existing literature concerning the differences in quality of life depending on the kind of outpatient care. An establishment of networks around the patient is mentioned repeatedly as a necessary prerequisite for successful home mechanical ventilation. Further research is required.

A differentiation of the cost structure according to the type of chosen outpatient care is currently not possible. Gathering specific German data is needed in the future to adequately depict the national concepts of provision and reimbursement.

The existing literature concerning the initiation of invasive mechanical ventilation emphasizes the necessity of an early and honest patient education to allow a participative decision pro respectively contra invasive mechanical ventilation, according to the right of self-determination of the patient.



Besides the aspect of long term survival, the quality of life and individual, social and religious aspects will also have to be considered, while the financial perspective should remain in the background. Finally, a socio-political decision concerning financing and implementation of home invasive mechanical ventilation is required.