Diagnosis and treatment of secondary lymphedema

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Record Status
This is a bibliographic record of a published health technology assessment from a member of INAHTA. No evaluation of the quality of this assessment has been made for the HTA database.

Citation

Authors' conclusions
Most of the diagnostic accuracy and treatment studies were conducted in persons with a history of breast cancer. This is important to note because the sensitivity and specificity, and psychometric properties, of the diagnostic tests for secondary lymphedema could differ in non-breast cancer patient populations. This suggests that the diagnostic tests should be evaluated in non-breast cancer populations prior to the tests’ use in these populations. The need for evaluation in these populations certainly applies to diagnostic tests involving limb volume or circumference, despite the fact that these tests were shown to have very good properties in the breast cancer population. The same caution regarding evaluation in different populations must also be applied to studies of treatments for secondary lymphedema. Most treatments were evaluated in the breast cancer population, so there is no automatic assurance that their efficacy is transferable to other populations. Evaluation of treatment efficacy in non breast cancer populations is an important step for future research. Based on the evidence, limb and volume circumference are the de facto „gold standard” tests from which to assess the presence of secondary lymphedema. However, these tests do not have a standard threshold or cut off point to indicate the presence or absence of lymphedema. Similarly, there is no consistent means of actually measuring volume or circumference. Although validity assessment suggests good interchangeability between different measures of limb volume or circumference, the heterogeneity of the evidence was too substantial to enable the drawing of conclusions about the type of measure that would be the most appropriate for diagnosing secondary lymphedema. The different methods of measuring limb volume or circumference detract from comparisons of sensitivity and specificity. These comparisons are best done by selecting a set measurement method and then varying the cut off points to estimate the optimal cut off point using a receiver operating characteristic (ROC) curve. None of the diagnostic testing studies employed an ROC curve, perhaps due to the lack of agreement on a gold standard means of diagnosing lymphedema. There was no evidence to suggest an adequate diagnostic testing protocol. The extracted studies failed to provide an indication of suitable frequencies of testing or time spans within which testing should be done. Additionally, there was no information to suggest whether the type of diagnostic test would have an effect on the choice of treatment or on patient outcomes. Regarding treatment for secondary lymphedema, there was no evidence concerning the optimal criteria to initiate or stop treatment. While the studies suggested that most treatments did reduce the size of the lymphatic limb, there was too much heterogeneity in terms of therapy, inclusion, and exclusion criteria, and treatment protocols to suggest the optimality of one type of treatment over another. Despite the multiplicity of inclusion and exclusion criteria, almost no studies contained reports of treatment benefits in any subgroup of patients. In fact, most studies were not designed to look for treatment benefits in subgroups. Adverse effects were only reported in a small number of studies. The adverse effects that were reported were generally rare and mild, and unlikely to be a major clinical issue. The methodological quality of the extracted diagnosis and treatment studies was generally “fair”. Many quality issues may have been related to a lack of adequate reporting rather than to methodological shortcomings in the conduct of the research. However, the authors of some studies omitted the reporting of fundamental aspects of their research. For example, there were reliability articles that did not contain mention of the intervals between administrations of the tests of interest, none of the validity studies indicated whether index test results were interpreted without knowledge of reference test results, and the majority of RCTs did not include comment on whether outcome assessors were blinded. While reporting oversight may be one reason for these omissions, the fundamental nature of the omitted elements suggests a certain degree of caution should be exercised when interpreting study results. This suggestion reflects a degree of healthy skepticism in the assessment of scientific research, i.e., to assume inadequate quality unless the study authors present evidence to the contrary. Although the quality of the extracted articles suggests the need for a guarded approach to interpreting results, quality did not appear to play a major role the answers to the
key questions. The articles were far too heterogeneous in terms of test, treatment, and outcome to ascertain whether studies of a certain quality tended to group around any particular test, treatment, or outcome. Indeed, most of the studies were of “fair” quality anyway, which suggests that quality was not a major factor in the response or interpretation of the key questions. In looking at the extracted articles as a whole, it can be concluded that there is no evidence in the literature to suggest an optimal diagnostic testing protocol, an optimal frequency or duration of treatment, the most efficacious treatment combinations (including the use of maintenance therapy), and the length of time for which persons should be tested or treated for lymphedema.

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