MaHTAS
Malaysian Health Technology Assessment Section

Aquadex Flexflow Ultrafiltration System
Executive Summary

[Adapted from the report by SYFUL AZLIE MD FUZI]

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Introduction

Ultrafiltration in the management of heart failure, while not a new concept, has recently generated greater clinical interest with the development of a portable machine that does not require intensive care unit monitoring or travel to a dialysis ward. Aquadex FlexFlow system ([redacted]) uses the concept of ultrafiltration which can remove up to 500 ml excess salt and water per hour from the circulation of patients with heart failure and fluid overload. The system minimises the risk of haemodynamic interference by using a low blood flow via a small-bore cannula inserted into a peripheral or central vein.

Objective/Aim

The objective of this technology review was to review evidence on the effectiveness, safety and cost-effectiveness of using Aquadex FlexFlow ultrafiltration system compared with the intravenous diuretics or conventional techniques in the treatment of patients with congestive heart failure.

Results and Conclusions

There was good to fair level of retrievable evidence to indicate that the Aquadex FlexFlow ultrafiltration system was effective in the treatment of patients with congestive heart failure. In a comparative trial versus intravenous diuretics or conventional techniques, results were in favour of the Aquadex FlexFlow treatment. Findings indicated that ultrafiltration efficiently produces greater weight and fluid loss, significantly decreased rehospitalisation rate for heart failure and unscheduled medical visits. There was no retrievable evidence to suggest that ultrafiltration is unsafe in comparison with conventional therapies. Ultrafiltration is beneficial to patients as it allows fluid to be removed quickly and safely, without compromising renal function or producing other side effects seen with aggressive pharmacological therapy. No other major complications were recorded. The Aquadex FlexFlow is currently the only United States Food & Drug Administration (US FDA) approved portable ultrafiltration device for the treatment of heart failure; has registered as medical device (Class II) and received premarket notification 510(k) (K062922) in 2006. There was also evidence to suggest that Aquadex FlexFlow ultrafiltration system was likely to be more costly but more effective at fluid reduction and reducing rehospitalisation rates than diuretics in patients with congestive heart failure, though one indicated there was some uncertainty about the budget impact of this technology. The cost of the Aquadex FlexFlow system, which may be loaned or leased to hospitals, is approximately [redacted] ([redacted]). Typically a treatment (a new filter and blood circuit) will cost [redacted] ([redacted]), and multiple treatments may be required for severe cases of fluid overload.

Based on the above review, Aquadex FlexFlow ultrafiltration system can be used as research purpose or used in research environment for excess fluid removal in patients with congestive heart failure. Further research is needed to establish the patient groups who would benefit most, the optimal rates of fluid removal, and the cost savings associated with long-term quality of life benefits.

Methods

Literatures were searched through electronic databases specifically PubMed, Medline, Cochrane, Ovid, Horizon scanning databases, other websites; US FDA, MHRA and from non scientific database - Google search engine. In addition, a cross-referencing of the articles retrieved was also carried out accordingly to the topic. Relevant articles were critically appraised and evidence graded using US/Canadian Preventive Services Task Force.