Aquadex SmartFlow System

September 2024

Device Overview

Patients with renal and heart conditions might experience fluid overload, also known as hypervolemia. Treatment options for hypervolemia can include less invasive approaches such as medication therapy (e.g., diuretics), reducing salt intake, and limiting fluid consumption. In some cases, however, more invasive methods may be necessary to remove excess fluid, and dialysis might be required. [1] The Aquadex System offers continuous ultrafiltration therapy for adult and pediatric patients (weighing 20 kilograms or more) whose hypervolemia has not been resolved through less invasive treatments. It includes a console, a peripheral catheter, and a blood circuit set, enabling precise control of the ultrafiltration process. The peripheral catheter accesses the patient's blood, returning it after removing excess water and sodium. [2]

Actions for Consideration

PARTNER

ENGAGE SUBJECT MATTER EXPERTS

Meet with nephrologists to discuss current practice and devices available to determine need.

CONSIDER GUIDELINES FOR USE

Develop guidelines outlining the criteria for use, specifically tailored for particular patient populations and treatment locations. Consider creating an algorithm to aid in patient selection.

UNDERSTAND CONCERNS

Continue conversations and assessments with key service lines and departments affected by any change, such as nephrology and nursing.

CONNECT

SEEK CLINICAL IMPACT

Determine if change will impact current practices and workflow.

CONDUCT ANALYSIS

Compare the costs of current devices and their associated disposables to assess cost-effectiveness. Additionally, evaluate any additional requirements for water quality testing and dialysate types.

DETERMINE POPULATION

Work with key stakeholders to determine appropriate patient population for use.

COMMUNICATE

EDUCATE AND TRAIN

Provide information on available training & encourage hands-on demonstrations to gain familiarity with the product.

PLAN AHEAD

Develop and disseminate a plan for continuous education regarding the product, its usage, and outcomes, along with ongoing supplier support if necessary.

FOLLOW-UP & OUTCOMES

Create on-going feedback loop for challenges. Consider outcome measurement indicators such as impact on nursing workflow and patient rehospitalizations.

Professional Society Statements & Clinical Practice Guidelines

Currently, there are no official statements or practice guidelines from professional societies concerning the use of the Aquadex. However, general hemodialysis guidelines are available, and a selection of these is provided below.

Kidney Disease Outcomes Quality Initiative (KDOQI)

Update of the KDOQ Clinical Practice Guideline for Hemodialysis Adequacy found here. [3]

Renal Association Clinical Practice

Renal Association Clinical Practice Guideline on Haemodialysis found here. [4]

Kidney Disease Improving Global Outcomes

KDIGO 2021 *Clinical Practice Guideline for the Management of Glomerular Diseases* found here. [5]

Systematic search terms: Aquadex, aquapheresis, hemodialysis. Databases: PubMed, Medline, CINAHL. Studies published from 2014 to 2024.

See Reference section for complete listing of research sources.

Clinical Evidence

There are limited studies on direct use of Aquadex, and studies mainly consist of case series. A summary of the most recent case series is provided below.

Crismale et al. conducted a retrospective case series and literature review in 2023 focusing on the use of aquapheresis (AQP) with the Aquadex system in ICU patients with end-stage liver disease. The study included fourteen patients with decompensated cirrhosis who received AQP treatment. The findings suggest that "aquapheresis provides a potential solution by removing isotonic ultrafiltrate in a gradual, controlled manner, allowing for adjustable fluid removal rates that may help mitigate the risk of kidney injury and electrolyte imbalances caused by diuretics."[6] There were no occurrences of circuit clotting or bleeding at the access site, and no catheter-related bloodstream infections were linked to the AQP access. The authors emphasize the need for further clinical studies to confirm these findings. [6]

Helpful Links

The National Kidney Foundation guidance on hemodialysis found here. [7]

Recommendations of high-quality clinical practice guidelines related to the process of starting dialysis: A systematic review found here. [8]

Development of a framework for minimum and optimal safety and quality standards for hemodialysis and peritoneal dialysis found here. [9]

FDA Approval

The Aquadex SmartFlow System, approved for use in January of 2020, may be found on the FDA Database Listing; FDA 510(k) No. K192756). [10]

The indications for use state the following: “continuous ultrafiltration therapy for temporary (up to 8 hours) or extended (longer than 8 hours in patients who require hospitalization) use in adult and pediatric patients weighing 20 kilograms or more whose fluid overload is unresponsive to medical management, including diuretics.” (FDA Database Listing; FDA 510(k) No. K192756). [11]

Summary

1. Aquadex should be reviewed with all stakeholders to fully support implementation & address any clinical impact.
2. Regular reviews should be conducted to assess the impact and outcomes associated with the product's use and to determine if there is a continued need for education and training.
3. Guidelines outlining the criteria for use, specifically tailored for particular patient populations, should be considered, along with creating an algorithm to aid in patient selection.

HealthTrust Clinical Resources

Allow us to connect you with the resources you need. Examples for this category include resources on value analysis and product trials.

ASK A QUESTION | PROVIDE YOUR FEEDBACK | SHARE YOUR VOICE | NETWORK WITH PEERS

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www.hpginsights.com

PEER NETWORKING

www.huddle.healthtrustpg.com
App store: “HealthTrust Huddle”

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