The Wearable Artificial Kidney: Is It The Future Of Dialysis?

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Potential Conflicts of Interest: Consultant or speaker for Baxter, Fresenius, DaVita and advisor to Victor Gura
Outline

- Why create a wearable artificial kidney (WAK)?
- Is it feasible?
- Some results
- Strategies for the future
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Cumulative Survival In Different HD Treatment Strategies

Kjellstrand et al. NDT 23: 3283, 2008

USRDS 2005

pooled from five centers in the US, Italy, France and the UK.
Is this Improved outcome from

- Increased frequency
- Increased dose
- Pure patient selection
- Unknown variables
- Combinations of above
# Frequent Dialysis: What Dose?

<table>
<thead>
<tr>
<th></th>
<th>Intermittent Dialysis</th>
<th>Daily Dialysis</th>
<th>Wearable Artificial Kidney</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Sessions Per Week</strong></td>
<td>3X</td>
<td>6-7</td>
<td>Continuous</td>
</tr>
<tr>
<td><strong>Hours Per Session</strong></td>
<td>3-4</td>
<td>2-4</td>
<td>Continuous</td>
</tr>
<tr>
<td><strong>Weekly Hours of Dialysis</strong></td>
<td>9-12</td>
<td>14-28</td>
<td>168</td>
</tr>
<tr>
<td><strong>Creatinine Clearance</strong></td>
<td>10-12 ml/min</td>
<td>20-28 ml min</td>
<td>40 ml min</td>
</tr>
</tbody>
</table>
Longer and more frequent dialysis is unfeasible for most patients

- Nowhere to do it
  - Society cannot keep building dialysis units
- Nobody to do it
  - There are not enough nurses and technicians
  - Not enough home helpers
- Payers unable to increase reimbursement
- Patients want freedom to have a life beyond being attached to a big machine for hours on end
79 year old in-center HD female to me

“This disease is SO consuming.”
Daily Home Dialysis: The Potential for Improved Quality and Length of Life

Advantages for Patients

- Improved volume control
- No Na retention
- Less hypertension
- No hyperkalemia
- No hyperphosphatemia
- No acidosis
- Improved nutrition
- Improved sleep

- Reduce need for phosphate binders
- Decrease need for BP drugs
- Decreased expected morbidity and mortality from bone disease, anemia, cardiovascular disease and stroke
- Decreased transportation needs
Advantages for Payers

- Less cost for
  - ESRD program
  - Hospitalizations
  - Certain medications
Advantages for Physicians

• Less ill patients means less emergencies
• More new patients seen
• Return patients less complicated so day less stressful
• More job satisfaction
Advantages for Dialysis Provider

• Significant reduction in:
  – physical plants
  – construction costs
  – nursing and technical staff
  – drug consumption
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- Why create a wearable artificial kidney (WAK)?
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We can miniaturize anything and everything......

clocks

computers
We can miniaturize anything and everything……
dialysis machines
The Wearable Artificial Kidney (WAK)
Blood Circuit
US patent 6,960,179

Color Code
Red: Blood from patient
Blue: Blood to patient
Gray: Electronics
White: Heparin
The Wearable Artificial Kidney V1.2

Dialysate Circuit

US Patent No. 6,960,179 and other patents pending.

Blood-leak/bubble detector, pump power-up and alarm/shutoff system

Battery

Dialysate regenerating system

WAK pump

Blood-leak-detecting probe

Dialyzer

Tubing color code:
Black: Electrolyte supplement
Yellow: Dialysate to regenerating system
Brown: Bicarbonate
Green: Dialysate from regenerating system

Electronics/cables are shown in gray

Pump/bag color code:
Black: Electrolyte
Yellow: Waste (UF)
Brown: Bicarbonate
The Wearable Artificial Kidney V1.2
US Patent No. 6,960,179 and other patents pending.

Blood-leak/bubble detector, pump power-up and alarm/shutoff system

Blood-leak-detecting probe
Bubble-detecting probe

External Flowmeter
Measures blood and dialysate flow rates

WAK pump

Blood to patient

Dialysate to regenerating system

Battery

Dialysate regenerating system

Pump/bag color code:
- White: Heparin
- Black: Electrolyte
- Yellow: Waste (UF)
- Brown: Bicarbonate

Tubing color code:
- Red: Blood from patient
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Electronics/cables are shown in gray.
The Wearable Artificial Kidney V1.2
US Patent No. 6,960,179 and other patents pending.
WAK version 2.0 model
Simple user interface
Standard dialyzer
Bicarb, acetate & heparin
Integrated electronics
Integrated safety systems
Conformable sorbent cartridges
Custom fluid pump
Waste bag
Hot-swap battery
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The Wearable Artificial Kidney
8 hours of dialysis, in anesthetized uremic pigs
Gura et al CJASN 4:1441 2009

<table>
<thead>
<tr>
<th>Results</th>
<th>V 1.0</th>
<th>V 1.1</th>
<th>Units</th>
</tr>
</thead>
<tbody>
<tr>
<td>Effective urea clearance</td>
<td>24.1±2.4</td>
<td>39.8±2.7</td>
<td>mL/min</td>
</tr>
<tr>
<td>Effective creatinine cl</td>
<td>25.1±2.3</td>
<td>40.9±2.3</td>
<td>mL/min</td>
</tr>
<tr>
<td>Total urea removal</td>
<td>12.4±2.8</td>
<td>15.3±4.4</td>
<td>G</td>
</tr>
<tr>
<td>Total creatinine removal</td>
<td>0.9±0.2</td>
<td>1.7±0.2</td>
<td>G</td>
</tr>
<tr>
<td>Total phosphate removal</td>
<td>0.8±0.2</td>
<td>1.83±0.7</td>
<td>G</td>
</tr>
<tr>
<td>Total potassium removal</td>
<td>80.5±19.5</td>
<td>150.5±16.7</td>
<td>mmol</td>
</tr>
<tr>
<td>Extrapolated standard Kt/V</td>
<td>6.9±1.9</td>
<td>7.7±0.5</td>
<td></td>
</tr>
</tbody>
</table>
WAK London Human Trials

- 4 to 8 hours, averaging 6.4 hours
- UF removed 4.2 kg
- Unchanged EC:TB water ratio by bioimpedance
- Urea removal = $10.4 \pm 5.8$ g. Clearance = $22.7 \pm 5.2$ ml/min
- Kt/V hourly = 0.03. Weekly (extrapolated) 5.04
- Creatinine removed $870 \pm 492$ mg. Clearance = $20.7 \pm 4.8$ ml/min
- Phosphorus Removed = $445.2 \pm 325.9$ mg
- β2M Removed = $99.8 \pm 63.1$ (mg). Clearance = $11.3 \pm 2.3$ (ml/min)
- Stable BP and HR
- No hemolysis
<table>
<thead>
<tr>
<th>Question</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>Did you suffer from shortness of breath during treatment?</td>
<td>0</td>
<td>8</td>
</tr>
<tr>
<td>Did you suffer from palpitations during treatment?</td>
<td>0</td>
<td>8</td>
</tr>
<tr>
<td>Did you suffer from chest pain during treatment?</td>
<td>0</td>
<td>8</td>
</tr>
<tr>
<td>Did you suffer from any other pain during treatment?</td>
<td>0</td>
<td>8</td>
</tr>
<tr>
<td>Did you suffer from itching during treatment?</td>
<td>0</td>
<td>8</td>
</tr>
<tr>
<td>Did you suffer from nausea during treatment?</td>
<td>0</td>
<td>8</td>
</tr>
<tr>
<td>Did you suffer from vomiting during treatment?</td>
<td>0</td>
<td>8</td>
</tr>
<tr>
<td>Did you suffer from diarrhea during treatment?</td>
<td>0</td>
<td>8</td>
</tr>
<tr>
<td>Did you suffer from headaches during treatment?</td>
<td>0</td>
<td>8</td>
</tr>
<tr>
<td>Did you suffer from cramps during treatment?</td>
<td>0</td>
<td>8</td>
</tr>
<tr>
<td>Did you walk treated with the Wearable Artificial Kidney?</td>
<td>6</td>
<td>2</td>
</tr>
<tr>
<td>Would you advise other patients to try this device?</td>
<td>8</td>
<td>0</td>
</tr>
</tbody>
</table>
Mother and daughter, Vicenza Italy UF Trials. KI 73:497, 2008
Can Subjects Sleep with the WAK ON?

WAK London Human Trials
WAK London Human Trials
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Central Venous Catheters For In-Center HD

- Rare exit site infections
- Luminal infections dominate
- Opened in dialysis units two ports thrice weekly for 6 openings per week
- Closed in dialysis unit two ports thrice weekly for 6 closings per week
- 12 manipulations/week in a dialysis unit
Central Venous Catheters
For Daily Home HD

- Now have six treatments per week, two ports, an opening and closing for each treatment for 24 manipulations/week
- At least all done at home
Central Venous Catheters For WAK

- One opening and one closing per week for a total of two manipulations/week
- All manipulations performed in surgical center environment
Spectrum of ESRD Illness For Patients On Dialysis

- Hospitalized ill
- Home inactive
- Home infirmed
- Home Some activity
- Home active
Spectrum of ESRD Illness For Patients On Dialysis

Hospitalized ill

Home inactive

Home infirmed

Home Some activity

Home active
The Wearable Artificial Kidney: Is It The Future Of Dialysis?

YES

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