

Summary

- ✓ **Home hemodialysis has been in limited use in Canada for some time. Newer, portable hemodialysis machines that are easier for patients to operate may encourage the uptake of this technology.**
- ✓ **One portable system is already available in the US. The NxStage System One™ hemodialysis machine operates on standard electric current, does not require plumbing or specialized disinfection, and is small enough for patients to travel with.**
- ✓ **It is not yet clear whether the use of the NxStage system improves long-term survival and quality of life.**
- ✓ **Home hemodialysis is less costly than conventional in-centre programs, but it is unknown whether these savings extend to portable devices.**

Background

The kidneys filter wastes and excess fluid and electrolytes from the blood. They also produce hormones that regulate blood pressure, red blood cell production, and bone density. Kidney failure (end stage renal disease) is fatal unless patients receive renal replacement therapy in the form of either dialysis or transplantation.^{1,2}

The number of Canadians with kidney failure has risen from nearly 20,000 in 1997 to 30,924 in 2004.^{3,4} The number of hemodialysis patients increased annually by an average of 14% between 1995 and 2004.^{5,6}

The Technology

Hemodialysis is a renal replacement therapy in which the patient's blood is slowly pumped through an artificial kidney (dialyser). The dialyser is a canister containing tubes or fibres made of a semi-permeable membrane through which the blood passes. The outsides of these tubes are continuously washed with dialysis solution (dialysate). Wastes and excess fluid and electrolytes pass through the membrane from the blood into the dialysate, and the cleansed blood is returned to the patient. The natural kidney continuously filters the blood, but hemodialysis is intermittent and only one-tenth as efficient. Consequently, patients on hemodialysis have an increased risk of

cardiovascular disease and usually suffer adverse effects, such as anemia, fluid overload, and high blood pressure (hypertension), which must be managed with medication and severe dietary restrictions.⁷⁻⁹ Hemodialysis does not cure kidney failure, and one in five dialysis patients die annually.^{5,8}

Hemodialysis is usually performed in a hospital or dialysis clinic. The standard regimen is three 4-hour sessions per week, but more frequent hemodialysis performed at home may provide better patient outcomes and quality of life than conventional hemodialysis.^{7,10-12} The most common home hemodialysis regimens are short daily (two to three hours) and slow nocturnal (eight hours overnight during sleep), administered five to seven times per week.^{7,8,13,14}

Earlier home hemodialysis machines were the size of refrigerators and complicated to use. They required extensive home plumbing and electric upgrades, separate water purification systems, and a large storage area for supplies. More mobile, compact machines were then developed, but these weighed at least 77 kg, required electrical and plumbing modifications to patients' homes, and were not easily portable.^{15,16}

The NxStage System One is the only really portable hemodialysis system currently licensed in the United States.¹⁶ The system weighs 30 kg and is the size of an older style computer monitor. It operates on standard electric current; does not require any water supply, plumbing, or disinfection; and is portable enough for travel. NxStage consists of a computer-controlled delivery unit and a disposable cartridge containing the dialyser and fluid circuits. The dialysate comes in sterile, premixed bags, which eliminates the need for a water purification system.^{11,17,18} An optional accessory can produce dialysate from purified home tap water.^{11,19}

Another manufacturer, Home Dialysis Plus Ltd., has developed a portable hemodialysis machine that is smaller and more efficient than existing systems. The Home Dialysis Plus machine weighs around 14 kg and is the size of a large suitcase. This machine could be available for marketing as early as 2010.²⁰⁻²³

Regulatory Status

NxStage System One (NxStage Medical, Inc., Lawrence, MA) was approved by the US Food and Drug Administration in July 2003 for patients in acute or chronic care facilities, and for home use in June 2005.^{24,25} NxStage was licensed by Health Canada in July 2005, but it is not currently marketed in Canada.²⁶

Patient Group

The three leading causes of kidney failure are diabetes, hypertension, and kidney inflammation (glomerulonephritis).^{1,5} In 2004, most of the 15,292 Canadians on hemodialysis were treated in a hospital or dialysis clinic, with only 2.3% using home hemodialysis.⁶

Current Practice

Dialysis and kidney transplantation are the two main therapies for kidney failure. Although transplantation is the preferred option, the supply of donor kidneys is limited, and nearly one-third of patients are ineligible due to comorbidities.^{7,27}

Peritoneal dialysis is another form of dialysis in which a glucose-rich dialysate is passed into the abdominal cavity via a permanent catheter implanted near the navel. Over six to eight hours, wastes and excess fluid pass across the peritoneal membrane lining the abdominal cavity into the dialysate, which is then drained and replaced. In continuous cyclic peritoneal dialysis, the exchanges are performed overnight using a machine.^{7,27} Only patients with some residual kidney function are eligible for this form of dialysis, which is gentler on the patient (e.g., causes less fatigue and nausea), but less efficient than hemodialysis.^{16,27} In Canada, only 19.2% of dialysis patients receive peritoneal dialysis.⁶

The Evidence

The only publications on the NxStage system are brief reports and conference presentations of case series studies, some of which pool results from different dialysis machines.^{28,29} One anecdotal report and three conference abstracts provide separate results.

In 19 patients (median age 44 years, range 23 to 87 years) on short daily home hemodialysis, more than 85% achieved the recommended urea clearance.³⁰ All patients' serum albumin improved, and over one-half reduced their intake of medications for hypertension and anemia. The average treatment took 165 minutes and used 17 litres of dialysate; several patients travelled with the device. Patients previously on in-centre hemodialysis reported improved energy, appetite, sleep quality, and fewer symptoms with NxStage short daily hemodialysis, but the length of follow-up was not reported. While the report stated that these outcomes were superior to those of peritoneal dialysis and in-centre hemodialysis patients, details of the comparison group were not provided.

Another uncontrolled study used the NxStage machine to administer short daily hemodialysis in 18 patients (mean age 47 years, range 23 to 87 years) for an average of 9.8 months.³¹ The average treatment took 155 minutes (range 110 to 215 minutes) and used 16.5 L of dialysate. Serum

albumin increased ($p=0.02$), and there was a slight, but not statistically significant, reduction in the use of anti-hypertensive medication ($p=0.05$), compared with baseline. There was no discernible difference in the blood levels of hemoglobin, calcium, phosphate, or iron, and the intake of anemia and phosphate binding medication was unchanged at follow-up.

Two studies reported biochemical outcomes for patients on NxStage short daily home hemodialysis. All patients ($n=12$) in one study³² still required dietary restriction and phosphate binders to achieve optimum blood phosphate levels. The other report ($n=3$) stated that urea, phosphate, and β_2 -microglobulin clearance was comparable to conventional dialysis, but did not provide any comparative data.³³

Adverse Effects

Two studies reported safety outcomes. Among 19 patients, one exit site and three catheter-related infections were reported.³⁰ Two deaths occurred due to severe cardiac disease and congestive heart failure. In another study ($n=18$), no dropouts or patient deaths were reported over the mean 9.8 month follow-up, but one patient had two catheter-related infections and one developed a wound infection requiring intravenous antibiotics.³¹

Administration and Cost

A Canadian price for the NxStage System One was not available. In four Canadian studies, conventional home hemodialysis was significantly less costly than in-centre hemodialysis (2003 USD: \$34,466 to \$36,840 versus \$58,959 to \$100,198), largely due to the reduced staffing requirement of home hemodialysis.³⁴ Home hemodialysis could also potentially generate indirect savings by reducing medication intake and hospital admissions and enabling more patients to resume work.^{8,34}

Patient training for home hemodialysis is resource-intensive. Depending on the patient, it can involve extensive screening, a four- to 12-week (usually six-week) training period, and a home visit by a nurse or technician for the first treatment.^{8,30,35} There is also the added cost of logistical support, particularly if the home program covers a large geographic area.³⁴

Concurrent Developments

Prototype artificial kidneys are being developed to mimic natural kidney function.³⁶ RenaMed Biologics, Inc. has devised a bionic kidney in which the dialyser membrane is covered with human kidney cells that help filter the blood.³⁶ Other companies have focused on wearable devices. Philtre, Inc. has designed a paperback-sized device that operates 12 hours per day, seven days per week and does not require dialysate.³⁷ The wearable artificial kidney developed by Xcorporeal, Inc. is a battery-powered device that uses a dialyser and continuously generated dialysate. It weighs less than 2.5 kg and operates 24

hours per day, seven days per week.³⁸ However, these technologies will not be available to patients for several years.^{36,37,38}

Rate of Technology Diffusion

The number of patients requiring renal replacement therapy is expected to double in the next decade.⁴ This, combined with the increasing shortage of dialysis clinicians and the advent of portable, user-friendly technology, will likely promote the expansion of home hemodialysis.^{8,11} Patient and provider attitudes, training, and reimbursement policies will also affect its adoption.

A survey of Canadian patients revealed that 43% who were physically capable of performing home hemodialysis declined to because of a lack of knowledge about the various dialysis techniques; the misplaced belief that supervision is required; and fear of failure, social isolation, and receiving substandard care.³⁹ While nephrologists are generally positive about home hemodialysis, only one in four in-centre patients are offered it, probably because few specialists have experience with such programs.^{11,27,40} The lengthy patient training required can also be a deterrent.^{11,18}

The US National Institutes of Health and Centers for Medicare and Medicaid Services are sponsoring two multicentre randomized controlled trials to assess the safety, efficacy, and impact on quality of life of conventional, in-centre daily, or home nocturnal hemodialysis.^{41,42} The results of these trials, which end in 2008, will likely influence reimbursement and adoption of home hemodialysis.

Implementation Issues

The published data available on the NxStage system comprises only brief reports of feasibility studies. Consequently, it is not yet clear whether the suggested biochemical improvements seen in patients using the NxStage system translate into improved long-term survival and quality of life. The device's portability and ease of use lessen the burden of dialysis on patients, but the effect of home care on family members and patient compliance has not been addressed.^{12,30} There are currently no evidence-based recommendations to guide patient selection for home hemodialysis.⁴³ In general, home hemodialysis is less expensive than conventional in-centre programs, but it is unknown whether this applies to home regimens using newer portable devices.

The FREEDOM trial may address this lack of evidence by comparing clinical outcomes and cost-effectiveness data from 500 patients on NxStage daily hemodialysis with a matched conventional in-centre hemodialysis cohort from the US Renal Data System database.⁴⁴ The results of this and other ongoing trials will influence the uptake of portable hemodialysis devices.

References

1. Gonzalez-Perez JG, et al. *Int J Technol Assess Health Care* 2005;21(1):32-9.
2. Your kidneys. In: *The Kidney Foundation of Canada*. Montreal: 2000. Available: <http://www.kidney.ca/page.asp?intNodeID=22139>
3. Gill J. Presentation at Canadian Society of Nephrology Annual Meeting, May 26 2005; 2006; Quebec City. Available: http://secure.cihi.ca/cihiweb/en/downloads/Prelim_RRT_Statistics_May_2005_updated_Aug_25_2005Gill_rev_june_2006.ppt
4. *Facing the facts*. The Kidney Foundation of Canada; 2006. Available: <http://www.kidney.ca/files/Kidney/aFacingtheFacts.pdf>
5. Canadian Institute for Health Information (CIHI). *Renal Replacement Therapy in Canada in 2003*. Ottawa: The Institute; 2005. Available: http://secure.cihi.ca/cihiweb/dispPage.jsp?cw_page=reports_corrsites_jan2006_e
6. Canadian Institute for Health Information (CIHI). *Treatment of End-Stage Organ Failure in Canada, 1995 to 2004*. Ottawa: The Institute; 2006. Available: http://secure.cihi.ca/cihiweb/products/corr_annual_report_2006_e.pdf
7. Mowatt G, et al. *Health Technol Assess* 2003;7(2):1-174.
8. Pierratos A, et al. *Minerva Urologica e Nefrologica* 2006;58(2):99-115.
9. Tattersall J. *Blood Purif* 2001;19(2):185-8.
10. Suri RS, et al. *Clin J Am Soc Nephrol* 2006;1(1):33-42.
11. Moran J. *Adv Chronic Kidney Dis* 2007;14(3):284-9.
12. Finkelstein FO, et al. *Semin Dial* 2007;20(3):265-8.
13. MacGregor MS, et al. *Nephrol Dial Transplant* 2006;21(7):1934-45.
14. Kawanishi H. *Blood Purif* 2004;22(Suppl):8-13.
15. Kelly TD. *Semin Dial* 2004;17(2):154-5.
16. Sullivan JD. *Nephrology News & Issues* 2006;20(8):54-8.
17. Clark WR, et al. *Semin Dial* 2004;17(2):167-70.
18. Schlaefer C, et al. *Blood Purif* 2005;23(1):18-22.
19. Ouseph R, et al. *Adv Chronic Kidney Dis* 2007;14(3):256-62.
20. *Project title: ONAMI microchannel hemodialyzer*. 2007. Available: http://www.ous.edu/legnote/files/onami_micro.pdf
21. *Home Dialysis Plus, Ltd*. Gig Harbour (WA): Home Dialysis Plus, Ltd.; 2007. Available: http://www.homedialysisplus.com/Home_Page.html
22. *Portable kidney dialysis machine developed*. 2004. Available: http://www.eurekalert.org/pub_releases/2004-02/osu-pkd020204.php

23. Culverwell W. Home dialysis in 2 years? In: *Portland Business Journal*. Portland, Oregon: Portland Business Journal; 2005. Available: <http://portland.bizjournals.com/portland/stories/2005/04/25/focus1.html>
24. Center for Devices and Radiological Health. Dialyzer, high permeability with or without sealed dialysate system. In: *510(k) Premarket Notification Database*. Rockville (MD): U.S. Food and Drug Administration; 2007. Available: <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/search/search.cfm?db=PMN&ID=K032356>
25. Center for Devices and Radiological Health. System, dialysate delivery, sealed. In: *510(k) Premarket Notification Database*. Rockville (MD): U.S. Food and Drug Administration; 2007. Available: <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/search/search.cfm?db=PMN&ID=K030470>
26. NxStage. In: *Medical Devices Active Licence Listing (MDALL)*. [database online]. Ottawa: Health Canada; 2007. Available: http://www.hc-sc.gc.ca/dhp-mps/md-im/licen/mdlic_e.html
27. Nesrallah G, et al. *Hemodial Int* 2006;10(2):143-51.
28. Young BA, et al. Presentation at American Society of Nephrology; 2006 Nov 14; San Diego (CA). Poster Board Number: F-PO002.
29. Doss S, et al. Presentation at American Society of Nephrology; 2006 Nov 14; San Diego (CA). Poster Board Number: F-PO004.
30. Floramo S. *Nephrology News & Issues* 2006;20(11):48-50.
31. Bazzani P. Presentation at American Society of Nephrology; 2006 Nov 14; San Diego (CA). Program no. F-FC108.
32. Miller BW, et al. Presentation at American Society of Nephrology; 2006 Nov 14; San Diego (CA). Program no. F-FC107.
33. Kohn OF. Presentation at American Society of Nephrology; 2006 Nov 14; San Diego (CA). Program no. PUB241.
34. McFarlane PA. *Semin Dial* 2004;17(2):118-24.
35. Concepcion DB. *Nephrology News & Issues* 2006;20(4):38, 40-3.
36. The Cutting Edge of Renal-Replacement Therapy. *Medscape Medical News* 2007.
37. Nissenson AR, et al. *Hemodial Int* 2005;9(3):210-7.
38. Gura V, et al. *Contrib Nephrol* 2005;149:325-33.
39. McLaughlin K, et al. *Am J Kidney Dis* 2003;41(2):380-5.
40. Blagg CR. *Nephrology* 2005;10(3):206-14.
41. Suri RS, et al. *Kidney Int* 2007;71(4):349-59.
42. *Frequent Hemodialysis Clinical Trials*. Bethesda (MD): The National Institute of Diabetes and Digestive and Kidney Diseases; 2004. Available: <http://www.niddk.nih.gov/patient/hemodialysis/hemodialysis.htm>
43. Nesrallah GE, et al. Short daily hemodialysis. In: *UpToDate* [database online]. Waltham (MA): UpToDate; 2007.
44. FREEDOM: Following Rehabilitation, Economics and Everyday-Dialysis Outcome Measurements Study. In: *ClinicalTrials.gov*. [NCT00288613]. Bethesda (MD): National Library of Medicine; 2007. Available: <http://clinicaltrials.gov/ct/gui/show/NCT00288613?order=1>

Cite as: Scott A. *Portable Home Hemodialysis for Kidney Failure* [Issues in emerging health technologies issue 108]. Ottawa: Canadian Agency for Drugs and Technologies in Health; 2007.

Thanks to Melissa Severn, Information Specialist, for this bulletin.

CADTH takes sole responsibility for the final form and content of this bulletin. The statements and conclusions in this bulletin are those of CADTH, and not those of its advisory committee members or reviewers.

CADTH thanks the external reviewers who kindly provided comments on an earlier draft of this bulletin. **Gihad Nesrallah, MD FRCP(C) FACP**, University of Western Ontario, **Christopher T. Chan, MD FRCP(C)**, University Health Network, **Robert M. Lindsay, MD FRCP(C) FRCP (Edin.)** **FRCP (Glasg.)**, University of Western Ontario and London Health Sciences Centre.

Production of this report is made possible by financial contributions from Health Canada and the governments of Alberta, British Columbia, Manitoba, New Brunswick, Newfoundland and Labrador, Northwest Territories, Nova Scotia, Nunavut, Ontario, Prince Edward Island, Saskatchewan, and Yukon. The Canadian Agency for Drugs and Technologies in Health takes sole responsibility for the final form and content of this report. The views expressed herein do not necessarily represent the views of Health Canada or any provincial or territorial government.

ISSN 1488-6324 (online)
 ISSN 1488-6316 (print)
 PUBLICATIONS MAIL AGREEMENT NO. 40026386
 RETURN UNDELIVERABLE CANADIAN ADDRESSES TO
 CANADIAN AGENCY FOR DRUGS AND TECHNOLOGIES IN HEALTH
 600-865 CARLING AVENUE
 OTTAWA ON K1S 5S8