

Renal Denervation for Uncontrolled Hypertension

Recommendation

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**Ontario
Health**

Draft Recommendation

Ontario Health, based on guidance from the Ontario Health Technology Advisory Committee, recommends publicly funding renal denervation as an adjunctive treatment to standard care for adults with uncontrolled hypertension.

Rationale for the Recommendation

The Ontario Health Technology Advisory Committee considered the clinical, economic, and patient preferences and values evidence reported in the health technology assessment.¹

Committee members acknowledged that, for most people, hypertension can be managed effectively through health behaviour modifications and medication. However, they also recognized that some people have uncontrolled hypertension – defined as persistently elevated blood pressure despite standard care – and are at increased risk of more serious health outcomes.

The committee noted that in recent systematic reviews, renal denervation has consistently demonstrated a greater reduction in blood pressure compared with standard care for up to 3 years. The magnitude of the demonstrated systolic blood pressure reductions has been associated with a lowered risk of stroke, renal failure, and cardiovascular events. Comparative evidence suggests that there is no difference in safety between renal denervation and standard care; however, renal denervation is an invasive endovascular procedure with a unique risk profile. Recognizing the potential of renal denervation to prevent more serious health outcomes related to hypertension and the reported clinical safety and effectiveness of this treatment, the committee concluded that renal denervation may be of benefit as an adjunctive treatment option for adults with uncontrolled hypertension.

In adults with uncontrolled hypertension, renal denervation as an adjunctive treatment to standard care was found to be more effective but also more costly than standard care alone. Economic modelling suggests that a treatment-associated reduction in blood pressure may lower the risk of cardiovascular events, thereby improving the quality of life of people with uncontrolled hypertension over a lifetime horizon, assuming that the benefits of renal denervation are sustained. However, the committee expressed concern about the cost-effectiveness of renal denervation at its current list price and strongly advised price negotiations with renal denervation system manufacturers to improve the cost-effectiveness of this technology.

The total budget impact of publicly funding renal denervation for adults with uncontrolled hypertension in Ontario will depend on the uptake of and eligibility criteria for renal denervation. Assuming an annual uptake of 48 procedures in year 1, increasing to 243 procedures in year 5, the estimated additional cost to publicly fund renal denervation for adults with uncontrolled hypertension over 5 years is \$8.87 million. The committee considered this budget impact reasonable.

The committee also considered the lived experience of adults with hypertension and their care partners. They noted that individuals who had undergone renal denervation reported lower blood pressure, fewer doctor's visits, and greater peace of mind than those who had not. Some also experienced a reduction in

both hypertension-related symptoms and medication use; however, it is important to note that renal denervation does not guarantee a reduction in the need for medication. The committee recognized that patient preference is an important decision-making factor, particularly given concerns about the invasiveness of the procedure compared with standard care. Committee members noted that some interview participants reported being willing to consider renal denervation only if standard care had failed.

As part of its recommendation, the committee highlighted the importance of defining eligibility criteria for renal denervation candidates. For instance, it will be important to optimize medication regimens, screen for and treat causes of secondary hypertension, and assess for medication nonadherence before considering renal denervation as a treatment option. In addition, decision-making should involve specialized care teams and open and transparent discussions with patients. The committee acknowledged that Ontario Health (CorHealth) will play a key role in developing guidance for the implementation of renal denervation in the province.

Decision Determinants for Renal Denervation for Uncontrolled Hypertension

Overall Clinical Benefit

Effectiveness

How effective is the health technology/intervention likely to be (taking into account any variability)?

Based on an overview of reviews, renal denervation consistently demonstrates a greater reduction in blood pressure compared with control (e.g., health behaviour modifications and medication) in adults with uncontrolled hypertension, including treatment-resistant hypertension (a subtype of uncontrolled hypertension that persists even after a person is treated with at least 3 classes of antihypertensive medications at optimal doses, including a diuretic). This was found to be the case regardless of comparator, type of renal denervation system, and whether a person is on or off medication at the time of renal denervation across blood pressure outcomes reported at follow-ups ranging from 2 to 36 months. Of note, renal denervation does not guarantee a reduction in medication; indeed, the overview of reviews found that the change in mean number of medications taken by people who had received renal denervation versus those in control groups was not statistically significant.

No other direct clinical outcomes of interest (e.g., stroke, myocardial infarction, renal failure) were reported, but some were reported in terms of safety as adverse events (see below).

Safety

How safe is the health technology/intervention likely to be?

Although renal denervation is more invasive than medical therapy (i.e., medication), the included reviews found no statistically significant differences in safety outcomes between renal denervation and control.

Burden of Illness

What is the likely size of the burden of illness pertaining to this health technology/intervention?

Nearly 1 in 4 adults (about 8 million people) in Canada have chronic hypertension, and an average of 1,150 Canadians are newly diagnosed with hypertension every day.^{2,3} In Ontario, 18.8% of people aged 12 years and older (more than 2 million people) were reported as having a diagnosis of hypertension in 2022. The prevalence of hypertension increases with age and is estimated to affect 47% of people aged 65 years and older.^{2,4,5}

Need

How large is the need for this health technology/intervention?

Although the management of hypertension in Ontario has evolved over the years, poor blood pressure control remains a concern.^{6,7} In Canada, it is estimated that 17% of people with hypertension do not know they have it^{7,8} and that approximately 30% of adults receiving treatment for hypertension have uncontrolled hypertension.^{9,10} Among adults with uncontrolled hypertension in Canada in 2022, 245,700, or about 5%, were found to have treatment-resistant hypertension.⁹

Patient Preferences and Privacy

Patient Preferences and Values

Do patients have specific preferences, values, or needs related to the health condition, health technology/intervention, or life impact that are relevant to this assessment?

In a review of the quantitative evidence of patient and provider preferences and values, approximately 30% of patients in the included studies preferred renal denervation over medication, with younger individuals and those with poor medication adherence more likely to favour it. Physicians were likely to recommend renal denervation for patients with high systolic blood pressure (≥ 140 mmHg) who were taking 3 or more antihypertensive medications.

People we spoke with who had undergone renal denervation reported lower blood pressure, fewer doctor's visits, and greater peace of mind than those who had not. Some also reported reductions in number of medications and symptoms of hypertension. All participants expressed favourable views of renal denervation, particularly when health behaviour modifications and medications were ineffective. Concerns regarding the invasiveness of the procedure varied among participants.

Autonomy, Privacy, Confidentiality, and/or Other Relevant Ethical Principles as Applicable

Are there concerns regarding accepted ethical or legal standards related to patient autonomy, privacy, confidentiality, or other ethical principles that are relevant to this assessment?

Those interviewed saw renal denervation as supporting shared decision-making and valued having the autonomy to make informed health decisions in consultation with their health care providers.

Equity and Patient Care

Equity of Access or Outcomes

Are there disadvantaged populations or populations in need whose access to care or health outcomes might be improved or worsened that are relevant to this assessment?

In Ontario, renal denervation is currently available at only 2 hospitals in Toronto, which presents a geographic barrier to accessing care for those not living in or near Toronto.

Patient Care

Are there challenges in the coordination of care for patients or other system-level aspects of patient care (e.g., timeliness of care, care setting) that might be improved or worsened that are relevant to this assessment?

Renal denervation is a potential adjunctive treatment option to help address gaps in care for adults with uncontrolled hypertension, including treatment-resistant hypertension, for whom health behaviour modifications and medications have failed to effectively lower blood pressure. However, clear eligibility criteria will need to be defined, and specialists will need to be involved in identifying appropriate candidates (i.e., by optimizing medication regimens, screening for and treating causes of secondary hypertension, and assessing for medication nonadherence).

Cost-Effectiveness

Economic Evaluation

How efficient is the health technology/intervention likely to be?

In adults with uncontrolled hypertension, compared with standard care alone, renal denervation in addition to standard care is more effective (0.13 quality-adjusted life-years [QALYs]; 95% credible interval [CrI], 0.08 to 0.18). Because of the high initial cost of the procedure, the addition of renal denervation to standard care is more costly than standard care alone (\$15,516; 95% CrI, \$14,684 to \$16,228), resulting an incremental cost-effectiveness ratio of \$121,237 per QALY gained over a lifetime horizon.

Feasibility of Adoption Into Health System

Economic Feasibility

How economically feasible is the health technology/intervention?

The total budget impact of publicly funding renal denervation for adults with uncontrolled hypertension in Ontario is uncertain and depends on various assumptions.

Assuming a low uptake (48 to 243 procedures per year over 5 years), we estimate additional costs of \$8.87 million over 5 years. In sensitivity analyses, the total budget impact ranged from an additional \$3.40 million to an additional \$33.41 million over 5 years, depending on the volume of procedures performed.

Organizational Feasibility

How organizationally feasible is it to implement the health technology/intervention?

Currently, renal denervation is available at 2 hospitals in Ontario; however, the procedure may become available at other sites with established hypertension centers and expertise in catheter-based procedures. In Ontario, 11 hospitals have a level 7 Regional Cardiac Program and thus have the clinical capacity and infrastructure to implement renal denervation.

References

- 1) TBD
- 2) Government of Canada. Canadian Chronic Disease Surveillance System (CCDSS) [Internet]. Ottawa (ON): Government of Canada; 2024 [cited 2024 Nov 26]. Available from: <https://health-infobase.canada.ca/ccdss/data-tool/>
- 3) Heart and Stroke Foundation of Canada. Health professionals concerned about blood pressure in Canada [Internet]. Toronto (ON): The Foundation; 2022 Oct 18 [cited 2024 Nov 26]. Available from: <https://www.heartandstroke.ca/what-we-do/media-centre/news-releases/health-professionals-concerned-about-blood-pressure-in-canada>
- 4) Statistics Canada. Table 13-10-0096-09: High blood pressure, by age group [Internet]. Ottawa (ON): Statistics Canada; 2023 [cited 2024 Nov 26]. Available from: <https://www150.statcan.gc.ca/t1/tbl1/en/tv.action?pid=1310009609&pickMembers%5B0%5D=1.7&pickMembers%5B1%5D=3.1&cubeTimeFrame.startYear=2021&cubeTimeFrame.endYear=2022&referencePeriods=20210101%2C20220101>
- 5) Statista. Percentage of Canadians who reported being diagnosed with high blood pressure from 2003 to 2022 [Internet]. New York: Statista; 2022 [cited 2024 Nov 26]. Available from: <https://www.statista.com/statistics/434103/share-of-canadians-reporting-being-diagnosed-with-high-blood-pressure/>
- 6) Schiffrin EL, Campbell NR, Feldman RD, Kaczorowski J, Lewanczuk R, Padwal R, et al. Hypertension in Canada: past, present, and future. *Ann Glob Health*. 2016;82(2):288-99.
- 7) Cloutier L, Daskalopoulou SS, Padwal RS, Lamarre-Cliche M, Bolli P, McLean D, et al. A new algorithm for the diagnosis of hypertension in Canada. *Can J Cardiol*. 2015;31(5):620-30.
- 8) Leung AA, Williams JVA, McAlister FA, Campbell NRC, Padwal RS. Worsening hypertension awareness, treatment, and control rates in Canadian women between 2007 and 2017. *Can J Cardiol*. 2020;36(5):732-9.
- 9) Leung AA, Williams JVA, Tran KC, Padwal RS. Epidemiology of resistant hypertension in Canada. *Can J Cardiol*. 2022;38(5):681-7.
- 10) Leung AA, Williams JVA, Padwal RS, McAlister FA. Prevalence, Patient awareness, treatment, and control of hypertension in Canadian adults with common comorbidities. *CJC Open*. 2024;6(9):1099-107.

Draft – do not cite. Report is a work in progress and could change following public consultation.

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