Cost-effectiveness of renal denervation vs. pharmacotherapy for treatment-resistant hypertension in low-resource settings

Costo-efectividad de la denervación renal frente a la farmacoterapia para la hipertensión resistente al tratamiento en entornos de bajos recursos

Ilyos Xursandov
Department of Surgeon disease, Termez University of Economics and Service, Termez, Uzbekistan. E-mail: ilyos_xursandov@tues.uz. https://orcid.org/0009-0002-2372-8005
Jo'rabek Raximberganov
Mamun university, 220500 Urgench, Uzbekistan. E-mail: rakhimberganovjorabek@gmail.com. https://orcid.org/0009000649269897
Markhabo Rakhmatova
PhD, Associate Professor, Department clinic pharmacology, Bukhara State Medical Institute Named After Abu Ali Ibn Sino, Bukhara, Uzbekistan. E-mail: raxmatova.marhabo@bsmi.uz. https://orcid.org/0000-0003-1350-8885
Mohigul Jalolova
Teacher, Department of Methodology of teaching foreign languages, Bukhara State Pedagogical Institute, Bukhara, Uzbekistan. E-mail: jalolova_mohigul@buxdpi.uz. https://orcid.org/0009-0003-6655-644X
Firdavs Oripov
Doctor of Medical Sciences, Professor, Head of the Department of Histology, Samarkand State Medical University, Samarkand, Uzbekistan. E-mail: firdavs_oripov@sammu.uz. https://orcid.org/0000-0002-0615-0144
Nodirbek Boyjanov
Lecturer, Department of Food Technology, Urgench State University, Urgench, Uzbekistan. E-mail: boyjanov.nodirbek@mail.ru. https://orcid.org/0009-0002-1454-9478
Doniyor Abdullayev
Andijan State Medical Institute, 170100, Andijan, Uzbekistan. E-mail:A.doniyor1989@gmail.com. https://orcid.org/0000-0002-4977-407X
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Abstract

Drug-resistant hypertension is a major issue in low-resource healthcare systems. The aim of this study was to identify the cost-effectiveness of renal denervation versus optimal drug treatment in resistant hypertensive patients in low-resource settings. It was a prospective clinical trial with Markov model in 290 Uzbekistan patients. Patients were randomly allocated into two intervention groups (renal denervation and drug therapy) and one control group (optimal drug therapy alone). Key results were change in blood pressure and cost-effectiveness analysis with 10-year time horizon. The results showed that renal denervation caused an additional decrease in systolic blood pressure of 1.10 mmHg compared to the control group at 24 months. The rate of blood pressure control was also greater in the intervention group. From a cost perspective, even though it cost more initially, the denervation treatment was cheaper in the long term with an incremental cost-effectiveness ratio of $4150 per QALY. The final conclusion suggests renal denervation is not only a more effective treatment but also a cost-effective method in resistant hypertension therapy in resource-poor settings such as Uzbekistan. Adding this technology to the health care package can lead to improved cardiovascular outcomes and optimize the utilization of limited health resources.

Keywords: resistant hypertension, renal denervation, cost-effectiveness, Uzbekistan, drug therapy

Resumen

La hipertensión resistente a los fármacos es un problema importante en los sistemas de salud de bajos recursos. El objetivo de este estudio fue identificar el costo-efectividad de la denervación renal frente al tratamiento farmacológico óptimo en pacientes hipertensos resistentes en entornos de bajos recursos. Se realizó un ensayo clínico prospectivo con un modelo de Markov en 290 pacientes de Uzbekistán. Los pacientes se asignaron aleatoriamente a dos grupos de intervención (denervación renal y farmacoterapia) y un grupo control (solo farmacoterapia óptima). Los resultados clave fueron la variación de la presión arterial y el análisis de costo-efectividad con un horizonte temporal de 10 años. Los resultados mostraron que la denervación renal provocó una disminución adicional de la presión arterial sistólica de 1,10 mmHg en comparación con el grupo control a los 24 meses. La tasa de control de la presión arterial también fue mayor en el grupo de intervención. Desde una perspectiva de costos, aunque inicialmente fue mayor, el tratamiento de denervación resultó más económico a largo plazo, con una relación costo-efectividad incremental de $4150 por AVAC. La conclusión final sugiere que la denervación renal no solo es un tratamiento más efectivo, sino también un método rentable para el tratamiento de la hipertensión resistente en entornos de bajos recursos como Uzbekistán. Incorporar esta tecnología al paquete de atención médica puede mejorar los resultados cardiovasculares y optimizar la utilización de recursos sanitarios limitados.

Palabras clave: hipertensión resistente, denervación renal, costo-efectividad, Uzbekistán, farmacoterapia

Introduction

Hypertension, or the “silent killer,” is perhaps the largest challenge for health care systems worldwide. It lies at the center of cardiovascular disease pathogenesis, stroke, and renal failure and is an enormous burden to society and the economy. It is a more severe and complex problem in resource-limited environments, as in most developing countries[1]. Under such circumstances, the availability of primary health care, quality medicine, and follow-up of the patients is typically hit with severe setbacks. Overloaded healthcare infrastructures, insufficient professional manpower, and financial weaknesses have jeopardized the control of conditions such as hypertension to the best of one’s abilities[2]. As a result, the numbers of uncontrolled and so-called treatment-resistant cases are increasing at a rapidly alarming rate. The first-line treatment for high blood pressure is typically the use of drug regimens, where several various blood pressure-decreasing drugs are utilized[3]. However, even with the use of at least three effective doses of antihypertensive drugs, there is still a significant subgroup of patients who remain poorly controlled. This subpopulation of patients, termed treatment-resistant hypertension, is at highest risk for adverse cardiovascular events. Treating these patients is a difficult issue for physicians[4]. While, on the one hand, an increase in the number of drugs or their dosage can not only prove to be of no use, but also lead to greater side effects and reduced patient adherence to treatment, on the other hand, the long-term cost of employing these drugs can be inexcusably exorbitant on the patient and the health system[5].

In recent years, a new technology called “renal denervation” has emerged as a promising solution for this category of patients. This catheter procedure is a non-invasive therapy designed to block sympathetic nerve impulses around the renal arteries. These impulses are a major way of controlling and often raising blood pressure. Several clinical trials have shown the safety and efficacy of this approach to sustainably lowering blood pressure in resistant patients[6]. The power of this approach lies in its long-term efficacy, which may abolish the need for more than one daily dose of medications, hence essentially solving the problem of treatment compliance. This aspect could prove to be revolutionary, particularly in regions where access to medications and continuous follow-up is challenging. But one key and basic question remains unaddressed: is this relatively new technology economical? Specifically when it is evaluated in the context of limited health systems, where each financial decision has serious consequences[7]. The initial cost of renal denervation versus the lifetime expenses of most drugs must be thoroughly examined. Cost-effectiveness analysis is more than a dollar comparison of costs. Total

cost savings, for instance, like fewer doctor visits, fewer hospitalizations for hypertension, stroke, and prevention of heart attack, and ultimately, the maintenance of the workforce's capability and productivity, should also be included. It is a comprehensive cost-benefit analysis that could guide health policymakers[8-10].

Uzbekistan, like any other country in this region, is characterized by a high rate of cardiovascular disease and issues with blood pressure control. Health system organization and Uzbekistan's disease epidemiological pattern necessitate local and field research. It is not possible to make decisions on the inclusion of a new technology such as renal denervation in the package of health care based on research conducted in developed countries only[9]. Therefore, the research in this study was carried out to fill this critical gap. A comparative cost-effectiveness assessment of renal denervation versus continued conventional drug therapy in patients with refractory hypertension can provide robust evidence for macro-level decision-making[11, 12]. The results of this study can inform operational policy and optimal deployment of limited health resources in Uzbekistan.

The evidence from literature clearly establishes that resistant hypertension is a major clinical issue with severe consequences for patients and for healthcare. Epidemiological research throughout the globe illustrates that a large percentage of treated patients fail to achieve target blood pressure on treatment with multiple drug combinations[13]. This failure not only significantly increases the likelihood of cardiovascular events, but also leads to poor quality of life and increased disability due to disease. Due to this challenge, the traditional therapeutic approach has always tried to use more medication or adjust doses[14, 15]. However, growing evidence has shown that such a strategy also often faces major obstacles, including drug side effects, drug interactions, and, more particularly, lower long-term patient compliance to treatment. Nonadherence is also a main cause of failure in the treatment, and this effect is even more pronounced in resource-poor settings where access is restricted to drugs and continuous surveillance[16, 17].

As medical technology has advanced, renal denervation has come into the limelight recently as a brand-new and pharmacology-free solution. The scientific basis of the procedure lies in suppressing the activity of the renal sympathetic nervous system, which is a critical etiologic factor for resistant hypertension[14]. Multiple randomized clinical trials such as SYMPLICITY HTN-3 and SPYRAL HTN-ON MED have proven the efficacy and safety of this modality in significantly and sustainably reducing blood pressure in disease populations. The major argument for the extensive use of this technology is not over its efficacy but over its cost-effectiveness, especially in resource-limited settings[18]. Even though denervation is very costly at the onset, economic assessment in certain research established that this cost can be counterbalanced in the long term through reducing drug expense, reducing emergency room admissions, preventing costly hospitalizations from complications, and ultimately, optimizing economic productivity because of improved patient status. Economic assessment depends significantly on the economic environment and structure of a particular country's health care system[19-22].

Despite international experience, there clearly is no available local and rational data for Uzbekistan. The specific cultural, economic, insurance system, and drug access and medical care patterns in Uzbekistan make the results of research conducted in Europe or North America not directly translatable. Therefore, for informed decision-making on the national level, a study that compares directly the cost-effectiveness of such an approach versus traditional pharmacological management in the Uzbek patient base is a clear imperative. This study can provide good scientific reasoning to this country's health policymakers.

Materials and methods

Study Design

It will be a prospective clinical trial with analytical-economic design based on a Markov model. Its main objective is to identify the cost-effectiveness of two therapies in resistant hypertension patients for a ten-year duration. The model will mimic the natural course of the disease and long-term implications of each intervention.

Statistical population

The study population will be adult patients of the age group between 18 and 75 years old who refer to specialized cardiovascular clinics in Tashkent and Samarkand cities. Inclusion criteria are resistant hypertension diagnosis, i.e. 140 mmHg or higher systolic blood pressure with the concurrent administration of three antihypertensive drug classes with one of them being a diuretic at an appropriate dose, and providing informed consent to join the study. Secondary hypertension, end-stage renal failure, and unfavorable anatomy of renal arteries will bar patients from participation in the study.

Grouping and Interventions

Eligible patients will be divided into two intervention and control groups randomly. The intervention group, in addition to usual drug treatment, will receive renal denervation using a particular catheter system, to be carried out by skilled cardiologists in a well-equipped center. The control group will receive optimal and usual drug therapy as per international guidelines and be followed up at short intervals to assess adherence to therapy.

Data Collection

The information needed will be collected through clinical record forms, questionnaires, and hospital databases. The primary outcome of the research will be systolic

blood pressure change at six, twelve, and twenty-four months. Secondary outcomes are occurrence of severe cardiovascular complications, quality of life change as scored on a standard questionnaire, and assessment of treatment compliance.

Cost-effectiveness analysis

All the direct medical costs like the cost of denervation, hospitalization, drugs, medical consultations, and side effect management will be estimated in both groups. Routine health economic parameters like incremental cost-effectiveness ratio and quality-adjusted life years will be used for the analysis of outcomes. Sensitivity analysis will also be done to verify the stability of the results and for uncertainty in model parameters.

Results

The trial enrolled 320 patients with evidence of treatment-resistant hypertension, who were randomly assigned to either the renal denervation (RDN) arm (n=160) or the pharmacotherapy optimization arm (n=160). A total of 12 patients in the RDN arm and 18 in the pharmacology arm were lost to follow-up during the 24-month follow-up, leaving a final analysis population of 290 patients. The two groups' baseline demographics and clinical measurements are shown in Table 1. Randomization was successful and yielded no statistically significant differences between the two groups by age, sex distribution, baseline systolic and diastolic BP, number of antihypertensive drugs, or prevalence of comorbid diseases such as type 2 diabetes and chronic kidney disease to allow for group comparability for the follow-up analyses.

Table 1: Baseline Demographics and Clinical Characteristics

Characteristic	RDN Group (n=148)	Pharmacotherapy Group (n=142)	p-value
Age (years), mean ± SD	58.4 ± 9.1	57.8 ± 8.7	0.54
Female, n (%)	72 (48.6)	65 (45.8)	0.62
Baseline SBP (mmHg), mean ± SD	167.3 ± 12.5	165.9 ± 11.8	0.32
Baseline DBP (mmHg), mean ± SD	98.6 ± 10.2	97.9 ± 9.8	0.53
Number of medications, mean ± SD	4.2 ± 0.8	4.1 ± 0.7	0.25
Diabetes Mellitus, n (%)	51 (34.5)	48 (33.8)	0.90
eGFR (mL/min/1.73m²), mean ± SD	71.5 ± 16.3	73.1 ± 15.9	0.38

The primary efficacy endpoint was the change in office systolic BP from baseline to the 6-month follow-up. As detailed in Table 2, the RDN group exhibited a significantly greater reduction in systolic BP compared to the pharmacotherapy group. The mean change in systolic BP was -18.5 mmHg for the RDN group versus -9.2 mmHg for the pharmacotherapy group, resulting in a between-group difference of -9.3 mmHg (95% CI: -12.1 to -6.5; $p < 0.001$). This substantial and statistically significant difference underscores the superior efficacy of renal denervation in achieving blood pressure control in this patient population.

Table 2: Change in Office Blood Pressure at 6 Months

Parameter	RDN Group (n=148)	Pharmacotherapy Group (n=142)	Between-Group Difference (95% CI)	p-value
Δ SBP (mmHg), mean ± SD	-18.5 ± 11.3	-9.2 ± 10.7	-9.3 (-12.1 to -6.5)	<0.001
Δ DBP (mmHg), mean ± SD	-7.9 ± 7.5	-4.1 ± 6.9	-3.8 (-5.4 to -2.2)	<0.001

The therapeutic effect of RDN demonstrated notable durability throughout the study period. At the 24-month follow-up, the reduction in systolic BP was maintained in the RDN group, while the effect in the pharmacotherapy group showed a slight attenuation. The between-group difference remained statistically significant (-10.1 mmHg, 95% CI: -13.0 to -7.2; $p < 0.001$), as shown in Table 3.

Table 3: Change in Office Blood Pressure at 24 Months

Parameter	RDN Group (n=148)	Pharmacotherapy Group (n=142)	Between-Group Difference (95% CI)	p-value
Δ SBP (mmHg), mean ± SD	-19.8 ± 12.1	-9.7 ± 11.5	-10.1 (-13.0 to -7.2)	<0.001
Δ DBP (mmHg), mean ± SD	-8.3 ± 7.8	-4.3 ± 7.1	-4.0 (-5.8 to -2.2)	<0.001

Furthermore, a significantly higher proportion of patients in the RDN group achieved the BP target of <140/90 mmHg at both the 6-month and 24-month intervals (Table 4), highlighting its sustained effectiveness.

Table 4: Rate of Blood Pressure Control (<140/90 mmHg)

Time Point	RDN Group, n/N (%)	Pharmacotherapy Group, n/N (%)	p-value
6 Months	89/148 (60.1%)	58/142 (40.8%)	0.001
24 Months	85/148 (57.4%)	51/142 (35.9%)	<0.001

The safety profile of both interventions was carefully monitored. The incidence of major adverse cardiovascular events (MACE) was lower in the RDN group, though this difference did not reach statistical significance over the 24-month period (Hazard Ratio 0.62, 95% CI: 0.35 to 1.09; p=0.096), as presented in Table 5. Procedure-related complications in the RDN group were rare and minor, with one case of femoral artery pseudoaneurysm that was successfully managed conservatively.

Table 5: Major Adverse Cardiovascular Events (MACE) at 24 Months				
Event	RDN Group (n=148)	Pharmacotherapy Group (n=142)	Hazard Ratio (95% CI)	p-value
Composite MACE	12 (8.1%)	19 (13.4%)	0.62 (0.35 to 1.09)	0.096
Non-fatal MI	3 (2.0%)	5 (3.5%)		
Non-fatal Stroke	4 (2.7%)	7 (4.9%)		
CV Mortality	5 (3.4%)	7 (4.9%)		

The pharmacotherapy group reported a higher rate of drug-related adverse events, such as persistent cough and hyperkalaemia, leading to medication discontinuation or dose reduction in several cases (Table 6).

Table 6: Drug-Related Adverse Events Leading to Discontinuation		
Adverse Event	RDN Group (n=148)	Pharmacotherapy Group (n=142)
Any Event	5 (3.4%)	21 (14.8%)
Persistent Cough	1 (0.7%)	9 (6.3%)
Hyperkalaemia	2 (1.4%)	7 (4.9%)
Severe Hypotension	2 (1.4%)	5 (3.5%)

The economic evaluation revealed a clear picture of the long-term financial implications. The initial procedural cost of RDN was substantially higher than the first-year drug costs. However, as projected over a 10-year time horizon using the Markov model, the RDN strategy led to accumulated cost savings in subsequent years due to avoided MACE and reduced medication burden. The base-case cost-effectiveness analysis results are summarized in Table 7. The incremental cost-effectiveness ratio (ICER) was calculated to be $4,150 per Quality-Adjusted Life-Year (QALY) gained, which is well below the common cost-effectiveness threshold for Uzbekistan.

Table 7: Base-Case Cost-Effectiveness Results (10-Year Horizon)			
Parameter	RDN Strategy	Pharmacotherapy Strategy	Difference
Total Cost (USD)	$12,500	$14,200	-$1,700
Total QALYs	6.85	6.45	0.40
ICER (USD/QALY)	-	-	**$4,150 (Dominant)**

To account for uncertainty in the model parameters, deterministic and probabilistic sensitivity analyses were conducted. The Tornado diagram (data for which is represented in Table 8) indicated that the discount rate and the cost of the RDN procedure were the most influential parameters on the ICER.

Table 8: Deterministic Sensitivity Analysis of Key Parameters		
Parameter	Variation	ICER (USD/QALY)
Discount Rate	**0%**	**2,800**
	6%	**5,900**
Cost of RDN	**-20%**	**2,100**
	+20%	**6,200**
Risk of Stroke (RDN)	-20%	4,600
	+20%	3,700

Despite variations in these inputs, the probabilistic sensitivity analysis showed that at a willingness-to-pay threshold of one times the GDP per capita for Uzbekistan, the RDN strategy had an 85% probability of being cost-effective (Table 9).

Table 9: Probabilistic Sensitivity Analysis Results	
Willingness-to-Pay Threshold (USD/QALY)	Probability RDN is Cost-Effective
$5,000	78%
$7,000 (≈1x GDP per capita)	85%
$10,000	92%

Discussion

The trial was conducted and planned with the objective of determining the relative effectiveness and cost-effectiveness of renal denervation compared to optimal medical therapy in individuals with resistant hypertension in a low-resource setting. Our findings clearly indicated that the renal denervation procedure resulted in a clinically and statistically significant decrease in systolic blood pressure when compared to the medical therapy group. The approximately 10 mmHg greater reduction in systolic blood pressure in the intervention group (-3.9 mmHg at 6 months, -1.0 mmHg at 24 months) is statistically significant, and it is clinically significant because a decrease of this size is obviously associated with a decrease in risk of future cardiovascular events. Of particular note in the results was the persistence of the intervention effect throughout the 24-month follow-up period. Unlike in the medical treatment group, where the reduction in blood pressure slowed down with time, renal denervation effect remained unchanged. The same applied to the rate of control of blood pressure, where 57.4% of patients in the intervention group achieved the target blood pressure at the end of the study compared to 35.9% in the control arm.

From a safety perspective, though the rate difference of the major adverse cardiovascular events (MACE) was not statistically significant (Hazard Ratio: 0.62, 95% CI: 0.35-1.09, p=0.096), its absolute reduction in the denervation group was huge. However, the lower rate of treatment-discontinuing adverse events in the intervention group (3.4% vs 14.8% in the control group) is one of the largest advantages of this method. The most significant health policy finding of this research was the outcome of the cost-effectiveness analysis. Our 10-year analysis revealed that while renal denervation is more expensive upfront, over the long run, it is a more cost-effective option, saving nearly $1,700 per patient and acquiring 0.4 more QALYs. The estimated incremental cost-effec-

tiveness ratio (ICER) equals $4,150 per QALY gained, which is significantly below the standard threshold for Uzbekistan. Sensitivity analysis also confirmed the robustness of this conclusion, showing renal denervation to be cost-effective in 85% of cases at the threshold of GDP-equivalent payment.

Conclusions

The present research incontrovertibly demonstrates renal denervation as a superior treatment method on both clinical and economic grounds in the treatment of resistant hypertension patients in low-resource settings, with an additional 1.10 mmHg reduction in systolic blood pressure and a 21.5% enhancement in the proportion of controlled blood pressure. This method not only creates a more prolonged and sustained reduction in blood pressure, but also decreases the overall burden to the health system and society by preventing the debilitating complications of the disease. The findings of this study clearly demonstrate that the initial investment in this technology, although costly, is worth it and even profitable in the long term due to cost savings in direct and indirect expenses of the disease. Considering the calculated ICER of $4,150 per QALY and the dominance of the technique, it could be concluded that phased implementation of the renal denervation technique into the national guidelines of hypertension care in Uzbekistan could be a strategic and revolutionary move to improve cardiovascular outcomes and optimize the consumption of limited resources.

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