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A cost effectiveness analysis of two treatment strategies for trigeminal neuralgia in Ontario

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ABSTRACT

Background: Trigeminal neuralgia (TN) is a debilitating disease with an annual incidence of approximately 4–27/100,000. In Ontario, over 2000 patients receive interventions for profound pain, including medical and surgical therapies. The global expected cost of these approaches is unknown. This study aims to analyze the cost-effectiveness of one surgical therapy, microvascular decompression (MVD), compared with the best medical therapy (carbamazepine) as first-line therapy.

Methods: Costs were gathered from the Canadian Institute for Health Information, Ontario Drug Benefit Formulary, and Ontario Ministry of Health Schedule of Benefits for Physician Services. Academic literature was used to estimate unavailable items. A cost-benefit Markov model was created for each strategy with literature-based rates for annual cycles from years 1 to 5, followed by a linear recurrent cycle from years 6 to 10. Incremental cost-effectiveness ratios (ICERs) were calculated based on the incremental cost in 2022 Canadian Dollars (CAD) per pain-free year.

Results: Base case cost per patient was $10,866 at 10 years in the "MVD first" group and $10,710 in the "carbamazepine first" group. Ten-year ICER was $1,104 for "MVD first," with strict superiority beyond this time point. One-way deterministic sensitivity analysis for multiple factors suggested the highest cost variability and ICER variability were due to surgery cost, medication failure rate, and medication cost.

Conclusion: Economic benefit is established for a "MVD first" strategy in the Ontario context with strict superiority beyond the 10-year horizon. If a cost-effectiveness threshold of $50,000 per pain-controlled year is used, the benefit is established at 4 years.

Keywords: Economic analysis, Economic evaluation, Healthcare economics, Microvascular decompression, Trigeminal neuralgia

INTRODUCTION

Background

Trigeminal neuralgia (TN) is a debilitating disease affecting 4–27/100,000 new patients annually.[15] Given an Ontario population of approximately 15 million,[20] over 2000 patients will be diagnosed with TN each year. Historically known as the "suicide disease" due to the excruciating nature of the pain, these patients experience severe unilateral stabbing recurrent facial pain.[1] Patients experience profound events lasting a few seconds to a few minutes, with a frequency of few to hundreds of attacks each day. Functional capabilities are significantly

impaired by those suffering from TN.[13] Remission periods can last months or years, but pain-free periods shorten over time.

The recognized first-line therapy for TN is the anti-epileptic medication carbamazepine, which has been unchanged since 1968.[2,12] This gold standard initial treatment offers reasonable pain control in approximately 85% of patients initially. However, the failure rate of pain control is greater than 50% over 5–10 years after disease onset. This is due to both breakthrough pain and intolerable drug side effects. Second-line therapies which have been attempted include oxcarbazepine, other antiepileptic medications, and pain-modulatory medications such as gabapentin and pregabalin.[10,13,25] Overall, recurrence rates in routine drug treatment are estimated at 15–18.5% annually in meta-analysis.[7]

The most effective surgical therapy for TN is microvascular decompression (MVD). This surgery is done under general anesthetic and involves an incision behind the ear, surgical access, physical separation of the affected nerve from adherent or compressive blood vessels, and insertion of a small barrier between them. The typical hospital length of stay is 2.3 days in Ontario.[6] MVD offers 96.6% initial success, including many cases where patients no longer require medication, with a lower recurrence rate and higher quality of life. Recurrence rates appear to be nonlinear, with a cumulative incidence of 2% in year 1, 6% by year 2, 8% by year 3, 8.7% by year 5, and 9.7% by year 10.[3,7,12,21,26] Recurrence rates beyond 10 years are not available due to the length of reporting in existing literature. However, limited data show that recurrence appears to be linear in statistical analysis on systematic review.[7] Surgery can be repeated, with a success rate of 91.66% reported but a higher complication rate of 37.31% (21.89% facial numbness).[12] MVD is considered a safe surgery. There is a non-zero risk of death at 0.3%, with major neurologic complications in 0.4% of cases and a 30-day readmission rate of 6.8% due to surgical site infections (22.4%), cerebrospinal fluid leakage (14.3%), or other concerns.[9] Surgery may be more effective if performed earlier in the disease course.

Treatment strategy in Ontario

The current practice in Ontario is to attempt drug therapy first, followed by second-line agents and simultaneous consideration for surgery if there is ineffectiveness or intolerance to carbamazepine. Several patients will attempt second-line drug therapies. There is a baseline complication rate to these drug choices. Regardless of the chosen medication regimen, more than 50% of patients undergo surgery within the first 5–10 years.[13,25] Patients who undergo surgery may be free of pain. Others may not have success and will then be restarted on carbamazepine and additional agents if required. This strategy is graphically outlined in Figure 1a.

A proposed novel strategy is to consider MVD surgery first in eligible patients with TN. This strategy is graphically outlined in Figure 1b. Under this model, patients will undergo MVD first. If they do not have success, they will then be started on carbamazepine therapy and additional agents if required.

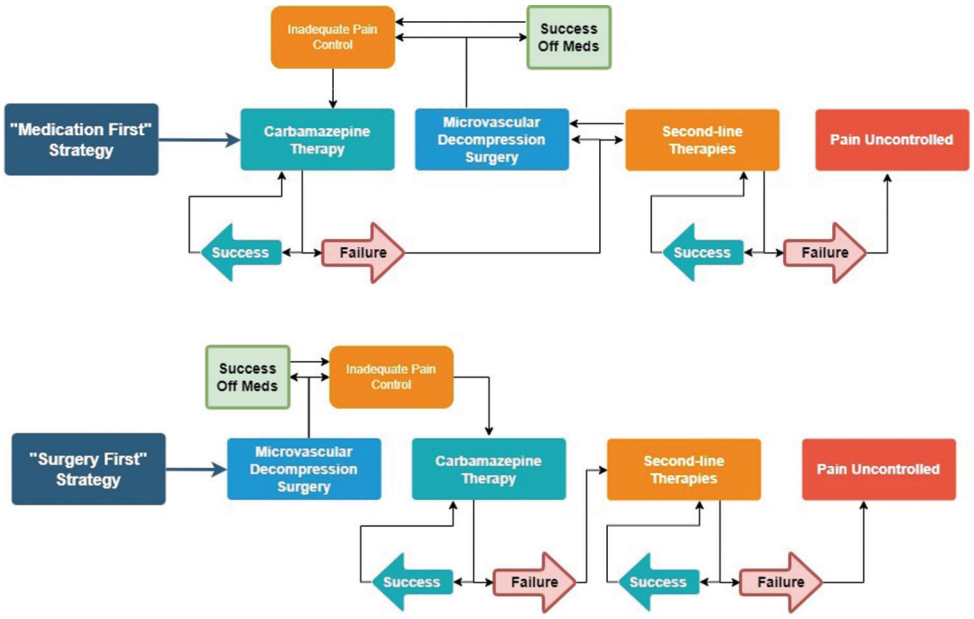

Figure 1: (a) Schematic diagram of the current "medication first" trigeminal neuralgia treatment strategy in Ontario. (b) Schematic diagram of the proposed novel "surgery first" treatment strategy in Ontario.

This novel strategy considers the possibility that it may be more cost-effective per pain-controlled years to seek definitive therapy first, given that MVD is more effective with lower recurrent rates but has higher up-front costs and an altered risk profile.

MATERIALS AND METHODS

Data sources, probabilities and costs

The perspective chosen for all cost information was the provincial government of Ontario. Cost data were gathered from relevant available current databases, including the Canadian Institute for Health Information, Ontario Drug Benefit Formulary/Comparative Drug Index, and Ontario Ministry of Health Schedule of Benefits for Physician Services under the Health Act. Where specific costs were not available, the most recent academic literature describing comparable costs was used to estimate this cost. All costs were converted to 2022 USD in accordance with the Bank of Canada Consumer Price Index-based inflation calculator.[11] Estimates for 2022 USD were calculated using purchasing power parity conversion rates from the International Monetary Fund. Cost data are summarized in Table 1.[9,14,16-20]

Probability data were gathered preferentially from robust systematic reviews and meta-analyses. Where this was not possible, multiple large trials and registries were used to generate appropriate estimates of probability for these events. A future cost discounting rate of 3% was chosen based on Canada's Drug and Health Technology Agency (CADTH) recommendations in the context of low-interest rates and the perspective of the Ontario government interest rates.[22] Probability data are summarized in Table 2.[5-8,10,21,22,24,27,28]

Other data not included in this setting

Costs before this decision include the costs associated with the first diagnosis and the imaging required. All patients

Table 1: Costs incorporated into the economic model in 2022 Canadian Dollars.

Item	Cost (Adjusted for CAD 2022)	Reference
Standard Hospital Admission in Ontario (all costs included)	6036.94	(16)
Major Nerve Surgery (hospital costs including any complications or extended stay) in Ontario	6413.74	(9)
Major Nerve Surgery (physician / surgeon costs) in Ontario	2679.26	(9)
Bloodwork Prior to First Carbamazepine Dose in Canada	89.27	(17)
Bloodwork for Ongoing Monitoring on Carbamazepine in Canada	72.54	(17)
Emergency Visit for Mild Adverse Drug Reaction in Ontario	307.85	(18)
Emergency Visit for Serious Adverse Drug Reaction in Ontario	905.21	(18)
Consult of Neurologist Clinic Follow-up in Ontario	79.51	(19)
Neurosurgery Initial Consult in Ontario	121.1	(19)
Neurosurgery Clinic Follow-up in Ontario	58.25	(19)
Carbamazepine in Ontario (one year, 800mg/day)	225.00	(20)
Oxcarbazepine in Ontario (one year, 1200mg/day)	1329.80	(20)

Table 2: Probabilities and rates incorporated into the economic model in 2022 Canadian Dollars.

Item	Frequency	Reference
Pain Control While on Carbamazepine	85%	(5–7,10,22,24)
Proportion of Patients On Carbamazepine of Those Treated Medically (subgroup: pain successfully controlled)	95%	(5–7,10,22,24)
Proportion of Patients On Carbamazepine of Those Treated Medically (subgroup: pain not controlled)	50%	(5–7,10,22,24)
Major Adverse Drug Event Rate in Year One of Drug Therapy	1%	(5–7,10,22,24)
Major Adverse Drug Event Rate After Year One of Drug Therapy	0.1%	(5–7,10,22,24)
Minor Adverse Drug Event Rate	10%	(5–7,10,22,24)
Bloodwork Events in First Year of Drug Therapy	4	(5–7,10,22,24)
Neurology Clinic Follow-up in First Year of Drug Therapy	4	(5–7,10,22,24)
Neurology Clinic Follow-up After First Year of Drug Therapy	2	(5–7,10,22,24)
Annual Chance of Remission One Year After MVD	0.04%	(8)
Annual Chance of Remission Two Years After MVD	0.08%	(8)
Annual Chance of Remission Three Years After MVD	0.04%	(8)
Annual Chance of Remission Four Years After MVD	0.01%	(8)
Annual Chance of Remission Five or More Years After MVD	0.004%	(8)
Readmission Rate After Microvascular Decompression	6.8%	(14)
Number of Patients in Drug Therapy Groups Who Undergo Surgery Annually	10%	(5–7,10,22,24)
Future Cost Discounting Rate	3%	(21)

will undergo an initial neurology consultation and magnetic resonance imaging (MRI) brain. These are not included.

Over-the-counter and pain crisis medications are not included. Expenses due to lost employment are not included.

Model construction

An economic cost-benefit decision model was constructed in Microsoft Excel using the current "medication first" strategy [Figure 1a] and the proposed "surgery first" strategy [Figure 1b]. The model had five unique cycles for the first 5 years, in accordance with the reported rates in literature changing over time. Years 6–10 followed a stable recurrent cycle. The final time horizon chosen was 10 years. Due to low expected mortality rates and minimal differences between groups, mortality was not included in the model.

The total discounted cost per patient was calculated for the base case at each cycle through the 10-year horizon. Incremental cost-effectiveness ratios (ICERs) were calculated based on the incremental cost in 2022 CAD over the incremental effect in the probability of a pain-free year. ICER here is, therefore cost per pain-free year.

Estimates of outcomes were checked against existing literature to ensure that 5- and 10-year predictions were appropriately reflective of the best current data within the model.

A one-way deterministic sensitivity analysis was conducted for model estimations that may affect the overall cost per patient and ICER significantly to evaluate the relative impact of these estimations. The base case was analyzed for changes based on 25% increases or decreases in probability or frequency. Surgery failure rate probability was adjusted in each of the cycles. Surgery cost was adjusted in each cycle, including acute hospital, physician, clinic, and return to care costs. The requirement for surgery in medical treatment groups was adjusted in each cycle. Medication failure rate probability was adjusted in each of the cycles. Medication cost was adjusted for both first-line and second-line medications. Medication adverse event probability was adjusted in each of the cycles. Discount rates were adjusted in each of the cycles.

RESULTS

Base case probability of pain control

Due to the higher probability of pain control with MVD, the model accurately reflects clinical observations on pain-free status. Over time, as more patients consider surgery, the relative slope of the curves appears to become similar [Figure 2].

Base case costs

The cost per patient at each interval is shown in Figure 3. At the end of 10 years, the discounted cumulative cost of a "surgery first" strategy is $10,866 ($8,665.07 USD), while a "medication first" strategy is $10,710 ($8,540 USD). The breakeven point is estimated at slightly beyond the 10-year time horizon modeled here, given the higher slope of the "medication first" strategy.

A much higher initial cost is noted. At year 1, the "surgery first" strategy has a total discounted cost of $9,733 ($7,761.56 USD), while the "medication first" has a total discounted cost of $1,903 ($1,517.54 USD).

The cost per pain-controlled year is also displayed in Figure 3 for comparison. The base case cost per pain-controlled year is equivalent to 7.5 years. By year ten of the model, the

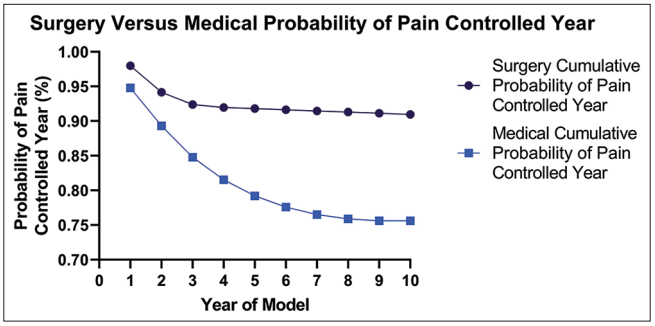

Figure 2: Probability of pain control over time per patient.

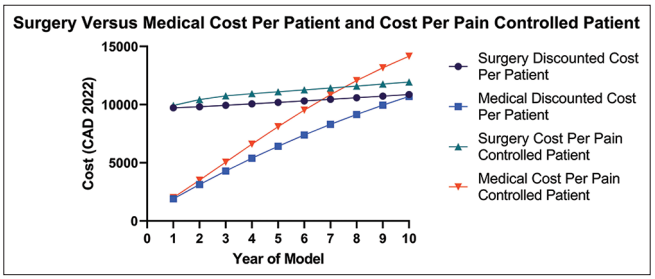

Figure 3: Total cost in 2022 Canadian Dollars at each cycle of the model, shown for both "carbamazepine first" and "microvascular decompression first" strategies. In addition, the cost per pain-controlled year is graphed.

Table 3: Incremental cost-effectiveness ratio (ICER) in each annual cycle of the model. Cost is in Canadian Dollars 2022, while effectiveness is per patient with pain control.

Year of Model	ICER (Difference in Cost Per Pain Controlled Patient)
1	244689
2	138441
3	74322
4	44820
5	29932
6	20841
7	14379
8	9281
9	4938
10	1014

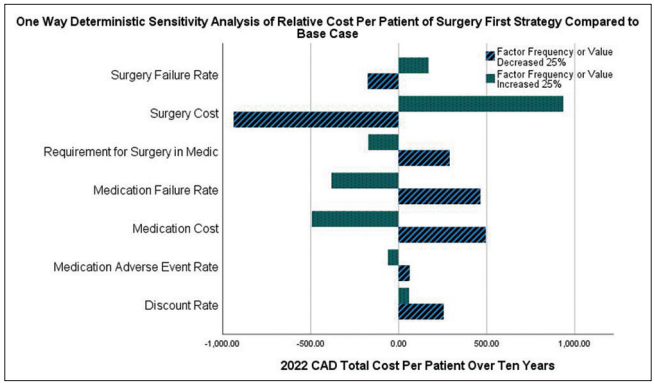

Figure 4: One-way deterministic sensitivity analysis of the relative cost per patient comparing the "microvascular decompression first" strategy to the "carbamazepine first" strategy. The cost is in Canadian Dollars in 2022. The time horizon is 10 years.

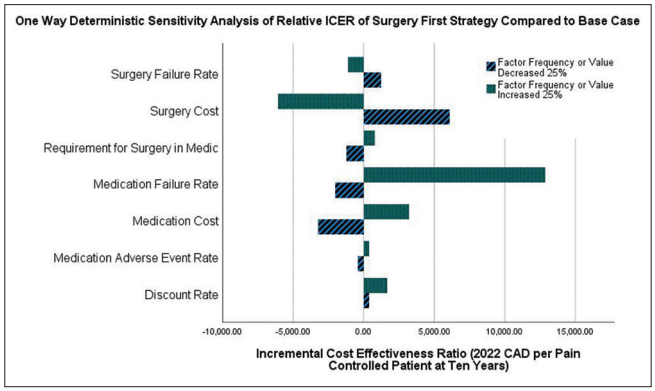

Figure 5: One-way deterministic sensitivity analysis of the relative incremental cost-effectiveness ratio comparing the "microvascular decompression first" strategy to the "medication first" strategy. The cost is in Canadian Dollars in 2022. The effect is in per patient with pain control. The time horizon is 10 years.

"surgery first" strategy costs $11,944 ($9,524.72 USD) per pain-controlled patient, while the "medication first" strategy costs $14,166 ($11,296.65 USD) per pain-controlled patient.

Base case ICER

As differential effectiveness rates are noted for the two strategies, along with differential costs, an ICER can be calculated at each cycle of the model [Table 3]. The effect considered is per pain-controlled year. The relative cost considered is the cost of the "surgery first" strategy versus the "medication first" strategy. A very high ICER is noted in the early stages of the model. The final horizon of 10 years shows an ICER of $10,104 ($880.38 USD)/pain-controlled patient.

Deterministic sensitivity analysis

The base case was analyzed for sensitivity based on 25% increases or decreases in relative probability or amount. Regarding the difference in total cost per patient at 10 years between "surgery first" and "medication first" strategies, the greatest variance versus the base case was noted with changing cost of surgery (−$936 to $936), medication cost (−$495 to $495), and medication failure rate (−$383 to $464) [Figure 4]. Medication adverse events, discount rate, surgery failure rate, and requirement for surgery in medically treated patients were more minor contributors.

The sensitivity analysis of ICER is reflected in Figure 5. Regarding ICER at 10 years, the greatest variance was noted in surgery cost (−$6,089 to $6,089), medication failure rate ($12,871 to −$2,019), and medication cost (−$3,218 to $3,218). The ICER was less variable with changes in surgery failure rate, failure requiring surgery in medical groups, medication adverse events, or discount rate chosen.

DISCUSSION

Relative cost-effectiveness

At the time horizon of 10 years, an ICER of $1,014 ($880.38 USD) per patient with controlled pain is established in the base case. Raw cost analysis notes an early cost equivalence crossover point of approximately 7.6 years. Ten years appears to approach the equivalence point between strategies when considering discounted costs, where "surgery first" would take a strictly dominant position if subsequent cycles were considered. However, sensitivity analysis suggests significant fluctuations from $11,326 ($9,031.90 USD) less to $22,178 ($17,685.81 USD) more with the inclusion of the three most impactful factors.

The utility of being pain-free is not specifically analyzed in this text. However, other analyses of TN treatment suggest that quality of life may improve in nearly 100% of patients who experience ongoing pain relief and 80% in those with successful treatment but subsequent recurrence.[22,26] Pérez *et al.* performed a 2009 analysis of pregabalin for TN in a Spanish population after a 12-week follow-up. They utilized a visual analog scale of pain severity divided by 100 as a utility estimator for quality-adjusted life years (QALY).[23] A similar arbitrary assignment can be considered here as the probability of a pain-controlled year as a utility estimator for QALYs. We presume a utility value of 0.4 for lack of pain control and 1.0 for pain control, similar to Berger *et al.*[4] If we consider the difference in this probability between the two theorized strategies, along with the discounted cost difference at various time horizons, an estimate of QALYs gained can be suggested. Estimated in this way, implementing a surgery first strategy in this model would result in $611,721/QALY in year 1, $90,331/QALY by year 3, $24,378/QALY by year 5, $7,942/QALY by year 7, and $342/QALY by year 10. We caution readers against considering this a true utility analysis of QALY differences. It is a gross estimate only. There are no published utility data for these outcomes in TN patients.

Effectiveness in this model is considered as the health status of controlled pain, whether on medications or not. A very preliminary estimation of QALY above is based on the static presence or absence of pain. In clinical practice, patients experience a spectrum of severity and have variable quality of life despite similar pain experiences. Some who had hundreds of attacks daily may consider relatively few attacks a reasonable outcome, regardless of their pain remaining in "uncontrolled" status within this model. Additional factors, such as a number of current or prior medications have also been shown to impact the quality of life of patients.[19]

QALY is typically considered the most appropriate measure of effectiveness in economic evaluations to allow broad comparison. Unfortunately, we do not have clinical trial evidence for TN patients on the exact utility of various states. Evaluation of utility alongside a comparative trial would be considered a more accurate measure of effectiveness.

Ontario-specific quality of life measurements in this specific population and analysis of willingness to pay is likely feasible and is a reasonable next step in this economic analysis from the context of the provincial government.

Absolute cost in the Ontario context

The total discounted cost of the "surgery first" strategy at 10 years was $10,866 ($8,665.07 USD) per patient, while the "medication first" strategy was $10,982 ($8,757.58 USD) per patient, a difference of only $116 ($92 USD). Ten years, therefore, appears to be the point of equivalence between strategies, as the "surgery first" strategy would be less expensive in subsequent model cycles. Sensitivity analysis suggests a variance of $1,814 ($1,446.57 USD) less to $1,895 ($1,511.16 USD) more per patient when including the three most relevant factors.

In the context of Ontario's population, we would expect over 2000 new cases annually.[15,20] Therefore, an absolute annual cost of $21,732,000 ($17,330,143.52 USD) would be expected with consideration for a "surgery first" strategy and a 10-year time horizon for these patients. This represents a difference of $232,000 ($185,007.97 USD) when compared to a "medical first" strategy. However, the range on this estimate varies from new cost savings of $3,396,000 ($2,708,133.97 USD) to an increased cost of $4,022,000 ($3,207,336.52 USD).

Given the trend in the model toward reduced ICER and cost savings at the common equivalence point of 10 years, as well as the discounted cost per patient with pain control equivalence point of 7.5 years, this may be an effective strategy within the context of this model. A verdict on whether this level of cost-effectiveness justifies a change to policy is beyond the scope of this paper, as numerous stakeholders and decision-makers are required. In clinical practice, the holistic evaluation and shared decision-making between the medical practitioner and patient, considering their values and concerns, remains the standard of care.

Limitations and future directions

Inherent limitations to data quality for estimations of cost and probability exist. The introduction of detailed health registries would allow the calculation of the true probability of each health state transition, including specific adverse event rates related to each medication option. For example, the choice of discount rate is based on other published analyses rather than predictive of future index changes. The estimates given may be inaccurate, including variations beyond the sensitivity analysis performed. In addition, there may be costs that were not accounted for in the model, including those mentioned previously (MRI, other analgesic medications, etc.).

This economic evaluation is specific to the context of the Canadian Public Healthcare System. This limits the assessment of cost and transferability to other healthcare systems, for example, the private payer system in the United States. However, similar analyses can be conducted on appropriate scales for consideration of policy changes in other contexts.

Calculated ICER in this study is the cost per pain-free year. Unfortunately, no specific known utility is available in the literature for this. Future studies of economic utility rather than only effectiveness could include measurement of the utility of complete or variable pain control in this population. Descriptions of utility in TN could strengthen the methodology of future clinical trials and allow more reasonable comparison with other interventions through typical metrics such as QALY.

The sensitivity analysis performed here was one way, with additional consideration for the top three factors occurring simultaneously. Known distributions of the included factors are unavailable. Given known measures of variance, a more accurate sensitivity analysis could be performed to strengthen this analysis. This analysis, therefore, suggests some of the most important factors for specific measurement and reporting in subsequent studies may include surgery cost, medication cost, and medication failure rate.

Mortality is not considered in this model. Several patients will pass away for other causes over 10 years. It is unclear if the mortality rates differ between medication and surgery treatment strategies, as only the surgery-related mortality is known. A cohort analysis of the population of TN patients in Ontario would assist in clarifying this component, which could be subsequently factored into a more accurate model.

Repeat surgery is not considered in this model. Repeat MVD carries a higher complication rate and is performed in select patients with differing risk profiles from the base case, and may not be reflective of the general population, and was therefore excluded.[12] However, patients do undergo repeat surgery in select circumstances. The inclusion of repeat surgical cases would be expected to increase cost, with less benefit, and may impact ICER analysis.

This analysis is specific to two strategies of treatment which are non-comprehensive. Techniques such as stereotactic radiosurgery and alternative medications provide an exciting opportunity for future improvements in patient outcomes. This study illustrates two strategies and their expected effectiveness in a specific population. Future economic analysis of these and other strategies would significantly benefit from the inclusion of specific cost data, and patient-reported utility scores of outcomes and complications.

The model further does not consider significant future developments which may occur in the treatment of TN. Advances in medical or surgical care may occur, which provide cost-efficient treatment of patients. The relative lack of these advances in the past decade is not predictive of the absence of further advances in the next decade.

Patient preference and autonomy also remain essential to good clinical practice. Patients may find invasive approaches less desirable or may wish to attempt conservative trials first. This analysis is strictly limited to informing the economic effectiveness of two alternate strategies, which both clinicians can consider as stewards and policymakers within the greater cultural context of their care. Implementation of the surgery first strategy is not specifically recommended, given the above, but merely economically effective within the discussed parameters. The economic impact of barriers to offering surgery, such as surgical wait lists and referral times, can be considered with the data shown here.

CONCLUSION

The economic benefit is established for a "MVD first" strategy in the Ontario context with strict superiority beyond the 10-year horizon within this economic model. If an arbitrary cost-effectiveness threshold of $50,000 per pain-controlled year is used, the benefit is established at 4 years. MVD should, therefore, be considered a cost-effective measure in patients expected to live beyond these horizons. Individualized patient management remains the standard of care.

Ethical approval

The Institutional Review Board approval is not required.

Declaration of patient consent

Patient's consent was not required as there are no patients in this study.

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Nil.

Conflicts of interest

There are no conflicts of interest.

Use of artificial intelligence (AI)-assisted technology for manuscript preparation

The authors confirm that there was no use of artificial intelligence (AI)-assisted technology for assisting in the writing or editing of the manuscript and no images were manipulated using AI.

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