Impact of COVID-19 on scheduled lower extremity revascularization for chronic limb-threatening ischemia

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Dear Editor

In many jurisdictions internationally, the onset of the COVID-19 pandemic brought about unprecedented stay-at-home orders, restrictions to non-essential in-person health services, and unprecedented emergency department avoidance. These factors contributed to steep but temporary declines in both scheduled and unscheduled invasive procedures. For patients developing chronic limb-threatening ischaemia (CLTI) during the pandemic, delays in scheduled revascularization may have resulted in higher rates of amputation, reduced quality of life, and excess mortality. For a healthcare system, excess amputations would further strain hospital resources, given the high average length of stay among people requiring a leg amputation.

In Ontario, Canada, during the first and third COVID-19 waves, hospitals were mandated (on 16 March 2020 and 20 April 2021 respectively) to postpone all scheduled procedures to reserve resources for the rising number of patients with COVID-19. However, given the aforementioned considerations, revascularization for limb-threatening ischaemia remained a relative priority among essential hospital services during periods of restricted care. Throughout the pandemic, decision analytical modelling has been an essential tool for resource planning to guide health policy under conditions of uncertainty. With a lag in availability of real-world data, modelling offers the ability to explore and quantify the impact of care delays on patients with CLTI. A model-based approach was used to predict the consequences of COVID-19-related delays in lower extremity revascularization (fully endovascular, open or hybrid) for CLTI over the first three waves of the COVID-19 pandemic (18 March 2020 to 16 June 2021), relative to a non-COVID-19 scenario. A microsimulation model with parallel trials simulated the flow of patients with CLTI through the Ontario hospital system for the COVID-19 versus non-COVID-19 scenarios, and projected short- and long-term health outcomes including major (above-ankle) amputation, mortality, and quality-adjusted life-years (QALYs). The model was informed by real-world revascularization volumes, waiting times, and clinical outcome data for the province of Ontario, supplemented with additional data inputs from published literature (Appendix S1 - Supplemental Methods). Important limitations of the data inputs were that revascularization volumes from January to June 2021 were extrapolated from data accrued earlier in the pandemic, and that long-term outcome probabilities, accruable QALYs, and CLTI-related amputation among those not undergoing revascularization were not estimated directly from an Ontario CLTI population (Appendix S1 - Supplemental Methods). In recognition of these limitations, the effect of changes to key model assumptions were explored in a set of sensitivity analyses: increasing the probability of needing urgent surgery (amputation or urgent vascularization) while awaiting scheduled revascularization; increasing the probability of progressing to a non-salvageable limb while awaiting scheduled revascularization; and increasing the severity of ramp-down in scheduled CLTI revascularizations during the third most severe wave.

The model suggested that delays in CLTI revascularizations in Ontario during the pandemic resulted in 21 additional major amputations (316 versus 295), and 32 additional deaths (475 versus 443) at 90 days after the index CLTI hospitalization compared with the non-COVID-19 scenario (Table 1). The excess amputation range (21–33) and excess death range (32–47) at 90 days varied by the probability of needing urgent surgery, the probability of progressing to a non-salvageable limb while awaiting scheduled revascularization; and the level of ramp-down implemented during the third wave (Table 1). Moreover, compared with a non-COVID-19 situation, patients who sought care for CLTI during COVID-19 in Ontario incurred an excess mean loss of between 0.07 and 0.11 QALYs over their lifetime (837–1110 total QALYs lost) (Table 1). These differences were the downstream effects of: scheduled...
### Table 1 Summary of results

| Scenario | COVID-19 | Non-COVID-19 | Mean difference | Excess cases or QALYs lost |
|----------|----------|-------------|----------------|---------------------------|
| **Base-case analysis** | | | | |
| No. of individuals with CLTI seeking care | 6463 | 6497 | – | – |
| Mean waiting time for scheduled revascularizations (days) | 17.51 | 11.36 | 6.15 | – |
| Major (above-ankle) amputation (%) | | | | |
| By 90 days after discharge | 4.90 (n = 316) | 4.54 (n = 295) | 0.35 | 21 |
| By 5 years after discharge | 13.13 (n = 849) | 12.85 (n = 835) | 0.28 | 14 |
| Death (all causes) (%) | | | | |
| By 90 days after discharge | 7.35 (n = 475) | 6.82 (n = 443) | 0.52 | 32 |
| By 5 years after discharge | 25.82 (n = 1669) | 25.37 (n = 1648) | 0.46 | 21 |
| QALYs* | | | | |
| By 5 years after discharge | 4.12 (16 989) | 4.14 (17 098) | 0.02 | 108 |
| Over lifetime | 11.37 (73 485) | 11.44 (74 323) | 0.07 | 837 |

**Sensitivity analysis 1: higher daily probability of patients on waiting listed becoming an urgent case requiring amputation or urgent revascularization (2% versus 1% in base case)**

| Scenario | COVID-19 | Non-COVID-19 | Mean difference | Excess cases or QALYs lost |
|----------|----------|-------------|----------------|---------------------------|
| No. of individuals with CLTI seeking care | 6464 | 6496 | – | – |
| Mean waiting time for scheduled revascularizations (days) | 8.47 | 5.80 | 2.67 | – |
| Major (above-ankle) amputation (%) | | | | |
| By 90 days after discharge | 4.97 (n = 321) | 4.61 (n = 300) | 0.36 | 22 |
| By 5 years after discharge | 13.22 (n = 855) | 12.91 (n = 838) | 0.32 | 16 |
| Death (all causes) (%) | | | | |
| By 90 days after discharge | 7.53 (n = 487) | 7.01 (n = 455) | 0.52 | 33 |
| By 5 years after discharge | 24.46 (n = 1710) | 23.92 (n = 1683) | 0.55 | 27 |
| QALYs* | | | | |
| By 5 years after discharge | 4.11 (16 940) | 4.13 (17 058) | 0.02 | 118 |
| Over lifetime | 11.34 (73 319) | 11.42 (74 162) | 0.07 | 843 |

**Sensitivity analysis 2: higher risk of a non-salvageable limb among patients with CLTI becoming an urgent case (10% versus 5% in base case)**

| Scenario | COVID-19 | Non-COVID-19 | Mean difference | Excess cases or QALYs lost |
|----------|----------|-------------|----------------|---------------------------|
| No. of individuals with CLTI seeking care | 6465 | 6497 | – | – |
| Mean waiting time for scheduled revascularizations (days) | 17.52 | 11.36 | 6.16 | – |
| Major (above-ankle) amputation (%) | | | | |
| By 90 days after discharge | 7.19 (n = 465) | 6.65 (n = 432) | 0.54 | 33 |
| By 5 years after discharge | 15.27 (n = 973) | 14.81 (n = 962) | 0.45 | 25 |
| Death (all causes) (%) | | | | |
| By 90 days after discharge | 7.53 (n = 487) | 7.01 (n = 455) | 0.52 | 32 |
| By 5 years after discharge | 24.46 (n = 1710) | 23.92 (n = 1683) | 0.55 | 27 |
| QALYs* | | | | |
| By 5 years after discharge | 4.08 (16 810) | 4.10 (16 939) | 0.02 | 129 |
| Over lifetime | 11.19 (72 318) | 11.30 (73 389) | 0.11 | 1072 |

**Sensitivity analysis 3: moderate ramp-down of scheduled revascularizations during third wave (25% reduction relative to base-case rate of 8 revascularizations per day)**

| Scenario | COVID-19 | Non-COVID-19 | Mean difference | Excess cases or QALYs lost |
|----------|----------|-------------|----------------|---------------------------|
| No. of individuals with CLTI seeking care | 6463 | 6497 | – | – |
| Mean waiting time for scheduled revascularizations (days) | 18.61 | 11.36 | 7.24 | – |
| Major (above-ankle) amputation (%) | | | | |
| By 90 days after discharge | 4.94 (n = 319) | 4.54 (n = 295) | 0.40 | 24 |
| By 5 years after discharge | 13.19 (n = 852) | 12.85 (n = 835) | 0.33 | 17 |
| Death (all causes) (%) | | | | |
| By 90 days after discharge | 7.42 (n = 479) | 6.82 (n = 443) | 0.59 | 36 |
| By 5 years after discharge | 25.89 (n = 1673) | 25.37 (n = 1648) | 0.52 | 25 |
| QALYs* | | | | |
| By 5 years after discharge | 4.12 (16 981) | 4.14 (17 098) | 0.02 | 117 |
| Over lifetime | 11.36 (73 412) | 11.44 (74 323) | 0.08 | 911 |

**Sensitivity analysis 4: severity of ramp-down of scheduled revascularizations during third wave (75% reduction relative to base-case rate of 8 revascularizations per day)**

| Scenario | COVID-19 | Non-COVID-19 | Mean difference | Excess cases or QALYs lost |
|----------|----------|-------------|----------------|---------------------------|
| No. of individuals with CLTI seeking care | 6463 | 6497 | – | – |
| Mean waiting time for scheduled revascularizations (days) | 21.21 | 11.36 | 9.85 | – |
| Major (above-ankle) amputation (%) | | | | |
| By 90 days after discharge | 5.06 (n = 327) | 4.54 (n = 295) | 0.52 | 32 |
| By 5 years after discharge | 13.26 (n = 857) | 12.85 (n = 835) | 0.41 | 22 |
| Death (all causes) (%) | | | | |
| By 90 days after discharge | 7.59 (n = 490) | 6.82 (n = 443) | 0.76 | 47 |
| By 5 years after discharge | 26.05 (n = 1684) | 25.37 (n = 1648) | 0.68 | 36 |
| QALYs* | | | | |
| By 5 years after discharge | 4.11 (16 951) | 4.14 (17 098) | 0.03 | 147 |
| Over lifetime | 11.33 (73 212) | 11.44 (74 323) | 0.11 | 1110 |

Values in parentheses are numbers of patients unless indicated otherwise; *values are mean with total in parentheses. Results for the scenario analyses are based on an average of 500 runs of the model over the lifetime of simulated patients during the COVID-19 versus non-COVID-19 scenarios. CLTI, chronic limb-threatening ischaemia; QALY, quality-adjusted life-year.
revascularization for CLTI during COVID-19 being delayed between 6 and 10 additional days on average relative to the non-COVID-19 scenario, and a larger proportion of CLTI revascularizations occurring on an urgent, rather than scheduled, basis (41–52 per cent versus 45–56 per cent scheduled in COVID-19 versus non-COVID-19 scenarios respectively). In conclusion, modelling suggests that Ontario has seen a rise in adverse outcomes among the CLTI population requiring revascularization during the course of the pandemic. More generally, the results support the importance of efforts to maintain timely revascularization for patients with CLTI in future situations of hospital care restrictions.

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**Supplementary material**

Supplementary material is available at BJS online.

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