ORIGINAL RESEARCH

VALIDATION OF DIAGNOSIS AND PROCEDURE CODES FOR REVASCULARIZATION FOR PERIPHERAL ARTERY DISEASE IN ONTARIO ADMINISTRATIVE DATABASES

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ABSTRACT

Purpose: To estimate the positive predictive value of diagnosis and procedure codes for open and endovascular revascularization for peripheral artery disease (PAD) in Ontario administrative databases.

Methods: We conducted a retrospective validation study using population-based Ontario administrative databases (2005-2019) to identify a random sample of 600 patients who underwent revascularization for PAD at two academic centres, based on ICD-10 diagnosis codes and Canada Classification of Health Intervention procedure codes. Administrative data coding was compared to the gold standard diagnosis (PAD vs. non-PAD) and revascularization approach (open vs. endovascular) extracted through blinded hospital chart re-abstraction. Positive predictive values and 95% confidence intervals were calculated. Combinations of procedure codes with or without supplemental physician claims codes were evaluated to optimize the positive predictive value.

Results: The overall positive predictive value of PAD diagnosis codes was 87.5% (84.6%-90.0%). The overall positive predictive value of revascularization procedure codes was 94.3% (92.2%-96.0%), which improved through supplementation with physician fee claim codes to 98.1% (96.6%-99.0%). Algorithms to identify individuals revascularized for PAD had combined positive predictive values ranging from 82.8% (79.6%-85.8%) to 95.7% (93.5%-97.3%).

Conclusion: Diagnosis and procedure codes with or without physician claims codes allow for accurate identification of individuals revascularized for PAD in Ontario administrative databases.

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INTRODUCTION

Peripheral artery disease (PAD) is characterized by restricted blood flow to a lower extremity due to progressive atherosclerotic occlusive disease. Re-establishing blood flow to the lower extremity, or revascularization, is required in severe PAD to prevent leg amputation. The approach to revascularization can be broadly classified as open revascularization (OR) or endovascular revascularization (ER).

The United Kingdom Bypass vs Angioplasty in Severe Ischaemia of the Leg (BASIL) randomized controlled trial, which enrolled patients from 1999 to 2004, is the only published randomized controlled trial comparing both approaches [1]. Its objective was to determine the best initial revascularization approach to maximize long-term amputation-free survival (up to five years of follow-up) in patients with critical limb

ischemia, the most severe form of the disease [1]. It found OR to be more costly than ER while offering an advantage in overall survival and limb preservation only among people living two years post-intervention [1]. However, due to increasing expertise with ER and new technologies, most notably drug-coated balloons [2] and drug-eluting stents [3], the results from the BASIL trial may be outdated. Therefore, there remains equipoise around the trade-offs of each revascularization strategy in preventing major adverse cardiovascular or limb events, and better defining the real-world outcomes of revascularization in PAD remains an international priority [4].

Ontario administrative databases have the potential to provide novel contemporary insight into the comparative effectiveness of revascularization approaches in PAD. The ability to conduct robust studies using administrative health data relies on the validity of coding systems to correctly identify PAD as the indication for revascularization and differentiate between ER and OR approaches. Validation studies aim to minimize misclassification bias that may arise from erroneous measurement [5] or inconsistent coding. Several validation studies have been performed for other interventions for vascular pathologies in Ontario, such as for cerebrovascular [6] and aneurysmal disease [7,8]. Our goal was to ascertain the positive predictive value (PPV) of diagnosis and procedure codes for OR and ER for PAD using Ontario administrative databases.

METHODS

Design and setting

We conducted a retrospective, two-centre validation study comparing population-based provincial administrative health data, held at ICES, to re-abstracted hospital records. We identified a random sample of Ontarians revascularized for PAD between 2005 and 2019 at two Toronto academic vascular centres: Sunnybrook Health Sciences Centre and St. Michael's Hospital. These two high-volume centers account for approximately 10% of all procedures performed within the province. These centers also allow for capture of lower extremity revascularization performed in the three settings used across the province: an operating room, an interventional radiology suite, and a cardiac catheterization suite. They were therefore deemed to provide a comprehensive representation of revascularization in the province. Sampling based on administrative data records, rather than hospital records, was performed to emulate cohort creation for population-based comparative effectiveness studies. With respect to PAD as the indication for revascularization and the revascularization approach (ER vs. OR), we assessed the PPV of individual and combined diagnosis, procedure and physician fee claims codes in

administrative data records relative to a gold-standard reference: re-abstracted hospital records, including operative reports and discharge summaries. Sampling was performed conditional on treatment approach classification (300 ER and 300 OR); therefore, the prevalence of treatment approach classification within the sample is expected to be different from the full population-based revascularization cohort. As a result, PPV rather than sensitivity or specificity was calculated since the latter two are influenced by the prevalence of treatment approach classification, whereas PPV is not [9].

Research ethics approval was granted by the Sunnybrook Health Sciences Centre and Unity Health Ontario Research Ethics Boards. The use of administrative data in this project was also authorized by ICES under section 45 of Ontario's Personal Health Information Protection Act, which does not require review by a Research Ethics Board. ICES is an independent, non-profit research institute whose legal status under Ontario's health information privacy law allows it to collect and analyze health care and demographic data, without consent, for health system evaluation and improvement.

Data sources

The sample was identified using the Canadian Institute for Health Information's (CIHI) Discharge Abstract Database (DAD), the Same Day Surgery (SDS) database and the National Ambulatory Care Reporting System (NACRS) databases. These datasets were linked using unique encoded identifiers and analyzed at ICES. Revascularization during hospital admission was identified from the DAD, as it contains information about all hospital discharges in Ontario [10]. Same day outpatient revascularization was identified from the SDS or NACRS, as both collect information on ambulatory revascularization provided in hospital [11,12]. Diagnoses are coded in these databases using the Canadian version of 10th Edition of the International Classification of Diseases (ICD-10-CA) [13], and procedures are coded using the Canadian Classification of Health Interventions (CCI) [14]. Supplemental information on revascularization was available from the Ontario Health Insurance Plan (OHIP) physician claims database in which revascularization is coded according to the OHIP Schedule of Benefits [15].

Revascularization cohort

From administrative data, we identified all Ontarians revascularized for PAD between 2005 and 2019 at the two study hospitals. Identification of eligible individuals was based on the presence of revascularization procedure codes (Supplemental Table S1, available on request from the corresponding author) as the primary intervention. We restricted the cohort to individuals with a diagno-

sis code for PAD (Supplemental Table S2, available on request from the corresponding author) as the most responsible diagnosis for the index SDS, DAD or NACRS revascularization record) or with a diagnosis of PAD during a hospitalization, same day surgery or emergency room visit in the preceding three years. Among those with a diagnosis of PAD before the index episode, individuals with a most responsible diagnosis of a non-PAD pathology for which revascularization may be indicated (Supplemental Table S3, available on request from the corresponding author) were excluded.

Validation sample, data collection and outcomes of interest

We restricted the revascularization cohort defined from administrative data to two academic hospitals in Toronto, Ontario (Sunnybrook Health Sciences Centre and St. Michael's Hospital). For each hospital, we selected a simple random sample of 150 ER patients and 150 OR patients (SAS 9.4, PROC SURVEYSELECT, simple random sampling method, SAS Institute, Cary, NC). We then combined the four random samples together to obtain our convenience sample of 600 patients. The sample size was predefined based on a feasible maximum number of charts to review in detail. For each patient, the following data were captured from the index DAD, SDS or NACRS record: age; sex; date of admission and discharge; all procedure codes and associated dates; and the most responsible diagnosis code. If the patient had multiple revascularizations on the same record, the revascularization with the earliest date was considered the event of interest. If a patient had more than one revascularization code on the same date, they were assumed to identify the same revascularization event, and were considered in combination. All physician claims for revascularization (Supplemental Table S4, available on request from the corresponding author) submitted within seven days of the index DAD, SDS or NACRS record earliest revascularization date were extracted through deterministic linkage to the OHIP database.

Re-abstraction of the hospital charts of the patients identified from administrative data was performed by an abstractor blinded to the patients' administrative diagnosis and procedure codes. While corresponding hospital charts were pulled for the abstractor through deterministic linkage, age, sex and admission date from administrative data were also provided to ensure that the correct patient and revascularization records were being re-abstracted. The following data were abstracted from hospital records: revascularization approach (binary [open or hybrid vs. endovascular]) and diagnosis for the revascularization (binary [PAD vs. non-PAD]).

Statistical analysis

The ability of diagnosis codes to accurately identify PAD as the indication for intervention was analyzed. A true positive (TP) was defined as a gold standard of PAD, while a false positive (FP) was defined as a gold standard of non-PAD. We then assessed the proportion of true positives to determine the positive predictive value (PPV): $PPV = TP / (TP + FP)$. The PPV of all codes overall, predefined categories of codes based on ICD-10 coding classification [13] and individual codes were determined (Supplemental Table S2, available on request from the corresponding author), and 95% confidence intervals (CI) were calculated [16].

The ability of procedure codes to accurately identify ER vs. OR was assessed. In ER patients, a true positive (TP) was defined as a gold standard of ER, while a false positive (FP) was defined as a gold standard of OR. In OR patients, a TP was defined as a gold standard of OR, while a FP as a gold standard of ER. PPV ($TP / (TP + FP)$) and 95% CIs [16] of overall, disease level based on procedure code classification (aortoiliac, infrainguinal or multilevel) (Supplemental Table S1, available on request from the corresponding author) and individual codes were determined.

We assessed if the PPV of specific procedure codes could be improved in two ways. First, for every procedure code with $PPV = 0\%$, we assessed whether the code description was ambiguous and could reasonably be interpreted as either OR or ER (e.g., 1KE50LA and 1KG50LA "dilation [...] using open approach" can be interpreted as either an OR or ER). For those codes, the predicted revascularization approach was inverted. Second, for every procedure code with $0\% < PPV < 100\%$, we considered PPV when requiring the supplement of physician claim codes for revascularization matching the gold standard approach.

We also analyzed the combined PPV of diagnosis codes with procedure codes ($\pm$ physician claim codes). This is defined as the probability that, for a given patient, the diagnosis code accurately identifies PAD as the indication for revascularization, and the procedure $\pm$ physician claim codes accurately identifies the gold standard revascularization approach: $P(\text{diagnosis code} = \text{PAD} \cap \text{procedure} \pm \text{physician claim code} = \text{gold standard revascularization approach})$. Multiple permutations were considered to optimize this combined PPV. During those permutations, individual diagnosis, procedure and physician claim codes with a $PPV \leq 50\%$ were considered for potential exclusion, therefore increasing the proportion of true positive (i.e., PPV), but simultaneously reducing the total number of patients in the sample. All statistical analyses were conducted in SAS Enterprise version 7.1 (SAS Institute, Cary, NC) using the frequency procedure and macros that are unique to ICES [17].

RESULTS

Revascularization cohort and administrative data validation sample

Among the 600 patients (1.1% of the total revascularization cohort), the majority were male (N=404; 67.3%). The mean age was 68.7±11.6 years. Based on administrative data, 553 (92.2%) had a most responsible diagnosis of PAD for the index revascularization, with the remainder having a diagnosis of PAD within the preceding three years. Infrainguinal revascularization was performed in 283 patients (47.2%), aortoiliac revascularization in 261 (43.5%) and a combination in 56 patients (9.3%). Physician claims codes were available for 535 patients (89.2%).

Diagnosis codes

The overall PPV (95% CI) of diagnosis codes for identifying PAD as the indication for revascularization was 87.5% (84.6%-90.0%). Among patients with a most responsible diagnosis of PAD for the index episode of care, the PPV was 91.0% (88.3%-93.2%). In patients without a most responsible diagnosis of PAD for the index episode, but with a diagnosis of PAD within three years of the index episode, it was 46.8% (32.1%-61.9%). Figure 1A illustrates the PPV of all diagnosis code categories, and Supplemental Table S5 (available on request from the corresponding author) for individual diagnosis codes in the sample. The most frequently used code was I70.2 (atherosclerosis of lower extremities).

Procedure codes

The overall PPV for procedure codes was 94.3% (92.2%-96.0%) and was slightly higher for OR (97.1% [94.6%-98.7%]) than ER (91.4% [87.5%-94.3%]). Figure 1B reports the PPV of ER and OR procedure codes stratified by anatomic level, and Supplemental Table S6 (available on request from the corresponding author) shows the PPV of individual and combination procedure codes, with Supplemental Table S7 offering a detailed legend for those combinations (available on request from the corresponding author). The most frequently used codes were 1KG50GQ (dilation, arteries of leg not otherwise specified [angioplasty, lower limb arteries]) and 1KA76MZ (bypass, abdominal aorta bypass terminating at lower limb vessels [e.g., external iliac, femoral, popliteal, tibial]).

Supplementing procedure codes with physician claims codes

Following optimization, the overall PPV of the procedure codes supplemented with physician claims increased to 98.1% [96.6%,99.0%], while preserving more than 90% of the initial sample size. Supplemental Table S8 (available

on request from the corresponding author) describes the effect of optimizing individual procedure codes by requiring association with physician claims codes. Figure 1C reports the PPV of ER and OR procedure codes stratified by anatomic level after optimization.

Combined positive predictive value of diagnosis, procedure and physician claims codes

The overall combined PPV of diagnosis, procedures and physician claims codes for identifying a gold standard diagnosis of PAD and gold standard revascularization approach was 82.8% (79.6%-85.8%). The combined PPV was similar between ER procedure codes (83.1% [78.3%-87.2%]) and OR procedure codes (82.6% [77.9%-86.6%]). Table 1 describes variations in combined PPV and sample size restriction for several algorithms: range 82.8% (79.6%-85.8%) to 95.7% (93.5%-97.3%).

DISCUSSION

Our study suggests diagnosis and procedure codes with or without supplemental physician claims codes from administrative databases allow for accurate identification of individuals revascularized for PAD. The overall PPV of diagnosis codes to identify PAD as the indication for revascularization was 87.5%, and was higher in the sub-cohort with a most responsible diagnosis of PAD for the index revascularization episode of care. The overall PPV of procedure codes to identify the revascularization approach was 94.3%, and was improved using physician claims codes (98.1%). Among algorithms to maximize the combined diagnostic PPV of diagnosis, procedure and physician claims codes, several options achieved relatively high PPV (range 83%-96%), with the exclusion of some codes resulting in minimal decrease in sample size.

A limited number of studies have assessed the PPV of PAD diagnosis and procedure codes in administrative databases. Previous comparative effectiveness studies of revascularization for PAD using Ontario administrative databases validated open revascularization codes of the 1986 version of the Canadian classification of diagnostic, therapeutic and surgical procedures [18]. Similarly, a 2006 validation of Ontario administrative databases included selected procedure codes for aortic (1KA76) and lower extremity bypass surgery (1KG76), with PPVs of 75% and 88% respectively [19]. Outside Ontario, Hong et al. examined the ability of ICD-10-CA codes and some CCI procedure codes to ascertain PAD in the community in Alberta administrative databases, and found poor PPVs (ranging from 25% to 50%) when compared to the gold standard diagnosis of PAD defined by the ankle-brachial index directly measured by trained technicians [20]. North American studies outside Canada have used ICD-9 diagnosis and procedure codes in the Mayo

FIGURE 1.
POSITIVE PREDICTIVE VALUES (PPV) AMONG THE VALIDATION SAMPLE.

A. PPV OF DIAGNOSIS CODE CATEGORIES*

B. PPV OF PROCEDURE CODE CATEGORIES**

C. PPV OF PROCEDURE CODE CATEGORIES AFTER OPTIMIZATION**

Abbreviations: DM, diabetes mellitus; MRD, most responsible diagnosis; NA, not applicable (given the number of occurrence is 0); PPV, positive predictive value (values are all in %); ER, endovascular revascularization; OR, open revascularization

*Diagnosis code categories are defined in the Canadian version of 10th Edition of the International Classification of Diseases [13]

**Categories as defined by the Canadian Classification of Health Interventions, Volume 4 [14]

Clinic administrative databases to ascertain PAD in the community [21], as well as Medicare and Medicaid claims to assess PAD-related events (PPV of 92%-95% for lower extremity bypass) in the Women's Health Initiative [22]. Outside North America, a validation study of the Danish National Patient Registry assessed the accuracy of ICD-10 codes for identifying PAD diagnoses both in hospitalized patients and in the community, with an overall PPV of 69% [23]. Among these validation studies outside Canada, only one was performed in the context of revascularization for PAD [22]. Our study adds to these data by providing a comprehensive, contemporary validation of diagnosis and procedure codes in Ontario administrative databases, specific to revascularization for PAD.

The PPV for PAD as the indication for revascularization was much higher with PAD as most responsible diagnosis for revascularization record compared to a PAD diagnosis within three years of the revascularization record. This suggests the former approach is optimal for studies of PAD revascularization outcomes. Two PAD diagnosis codes were most problematic: I74.3 (embolism and thrombosis of arteries of lower extremities) (PPV=43%); and I74.8 (embolism and thrombosis of other arteries) (PPV=0%). The lower PPV for these diagnoses may be explained by the fact that although thrombosis and embolic disease may be the result of underlying

PAD, they also may result from non-atherosclerotic causes such as atrial fibrillation [24]. However, by excluding those codes, one may overlook an important proportion of patients with PAD-related thrombosis. Our results suggest that, when identified in combination with specified procedure codes, the PPV of I74.3 and I74.8 may be improved, as outlined in several algorithms in Table 1.

The overall PPV of procedure codes to identify the gold standard revascularization approach was 94.3%. In some codes with PPVs of <100%, optimization was possible (Supplemental Table S8, available on request from the corresponding author) and resulted in a significantly improved PPV of procedure codes with minimal reduction in sample size. Our results suggest that implementing optimization algorithms using a combination of procedure and physician claims codes can increase the overall PPV. Optimizing the combined PPV of diagnosis and procedure codes is also possible.

Several limitations are important to note. The coding algorithms do not identify patients with PAD in the community, most of whom never undergo revascularization, nor do they apply to hospitalized patients not receiving revascularization, or receiving revascularization for another indication (e.g., trauma). Given the lack of institutional databases of all ER and OR for the study

TABLE 1.
VARIATION IN THE COMBINED PPV* OF DIAGNOSTIC AND PROCEDURE ± PHYSICIAN CLAIM CODES AND SAMPLE SIZE AFTER OPTIMIZATION.

	Overall combined PPV (95% CI) [% from initial sample size] [†]			
	No restriction		Restrict to MRD of PAD for the index event	
	No optimization	With optimization to maximize procedure PPV	No optimization	With optimization to maximize procedure PPV
Baseline	82.8 (79.6-85.8) [100] [†]	86.1 (83.4-88.9) [≥90.0] [‡]	86.1 (82.9-88.9) [100] ^{†‡}	89.0 (86.0-91.5) [≥90.0] ^{‡§}
Additional removal of patients with:				
Diagnosis codes with ≤50% PPV				
All	90.2 (87.3-92.6) [<90.0] [‡]	93.4 (90.8-95.4) [<90.0] ^{‡¶}	90.0 (87.1-92.5) [≥90.0] ^{‡¶}	93.1 (90.5-95.2) [<90.0] ^{‡¶}
Only patients with a combined PPV ≤50%	90.5 (87.7-92.8) [≥90.0] [‡]	93.5 (91.1-95.5) [<90.0] ^{‡¶}	90.3 (87.4-92.7) [≥90.0] ^{‡¶}	93.3 (90.7-95.3) [≥90.0] ^{‡¶}
Procedure± physician claim codes with ≤50% PPV				
All	84.9 (81.7-87.7) [≥90.0] [‡]	86.4 (83.4-89.1) [≥90.0] ^{‡¶}	88.3 (85.2-90.9) [≥90.0] ^{‡¶}	89.3 (86.4-91.8) [≥90.0] ^{‡¶}
Only patients with a combined PPV ≤50%	85.0 (81.8-88.8) [≥90.0] [‡]	86.4 (83.4-89.1) [≥90.0] ^{‡¶}	88.3 (85.3-90.9) [≥90.0] ^{‡¶}	89.3 (86.4-91.8) [≥90.0] ^{‡¶}
Either diagnosis or procedure± physician claim codes with ≤50% PPV				
All	92.1 (89.4-94.3) [<90.0] [‡]	93.7 (91.3-95.7) [<90.0] ^{‡¶}	91.8 (89.0-94.0) [≥90.0] ^{‡¶}	93.5 (90.9-95.5) [<90.0] ^{‡¶}
Only patients with a combined PPV ≤50%	92.3 (89.7-94.4) [<90.0] [‡]	93.9 (91.5-95.8) [<90.0] ^{‡¶}	92.0 (89.3-94.2) [≥90.0] ^{‡¶}	93.6 (91.1-95.6) [≥90.0] ^{‡¶}
Combined PPV ≤50%	94.9 (92.7-96.7) [<90.0] [‡]	95.9 (93.8-97.4) [<90.0] ^{‡¶}	94.7 (92.4-96.5) [<90.0] ^{‡¶}	95.7 (93.5-97.3) [<90.0] ^{‡¶}

Abbreviations: MRD, most responsible diagnosis; PAD, peripheral artery disease; PPV, positive predictive value

*The combined PPV is defined as the probability that, for a given patient, the diagnosis code accurately identifies PAD as the indication for revascularization, and the procedure± physician claim code accurately identifies the gold standard revascularization approach: $P(\text{diagnosis code} = \text{PAD} \cap \text{procedure} \pm \text{physician claim code} = \text{gold standard revascularization approach})$.

[†]The % from initial size was dichotomized as ≥90% or <90% in order to comply with ICES policies regarding small cells.

Footnotes 1-32: please see Supplemental Table S9 (available on request from the corresponding author) to know which codes should be removed during those steps.

period, we are unable to determine codes sensitivity and specificity. External validity to other databases across Canadian or other jurisdictions may vary based on differences in procedure coding; however, the conceptual approach to increase the PPV by restricting to the most responsible diagnosis and supplementing procedure codes with physician claims are likely relevant. While the validity across all vascular centers in Ontario has not been formally characterized, the inclusion of two centres that perform ER in the operating room (both sites), the interventional radiology suite (one site) and the coronary catheterization lab (one site) has captured all contexts lower extremity revascularization is currently offered across Ontario. Lastly, we assumed that all revascularization events on the same date were part of the same procedure, but a minor proportion (<1%) of those patients may represent same-day re-interventions.

CONCLUSION

This validation study has demonstrated that several algorithms can be elaborated to accurately identify patients revascularized for PAD using Ontario administrative databases. This work can also serve as a methodological framework for the validation of PAD revascularization coding in other jurisdictions internationally.

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REFERENCES

- Adam DJ, Beard JD, Cleveland T, et al. Bypass versus angioplasty in severe ischaemia of the leg (BASIL): multicentre, randomised controlled trial. *Lancet*. 2005;366(9501):1925-1934. doi:10.1016/S0140-6736(05)67704-5
- Government of Canada, Health Canada, Health Products. (2016, April 13). Summary Basis of Decision - - Health Canada. Accessed November 20, 2020. <https://hpr-rps.hres.ca/reg-content/summary-basis-decision-medical-device-detailThree.php?linkID=SBD00388>
- Health Canada. "Active device name search results". Accessed November 20, 2020. <https://health-products.canada.ca/mdall-limh/dispatch-repartition.do?type=active>
- Conte MS, Bradbury AW, Kolh P, et al. Global vascular guidelines on the management of chronic limb-threatening ischemia [published correction appears in *J Vasc Surg*. 2019 Aug;70(2):662]. *J Vasc Surg*. 2019;69(6S):3S-125S.e40. doi:10.1016/j.jvs.2019.02.016
- Chatterjee N, Wacholder S. Validation studies: bias, efficiency, and exposure assessment. *Epidemiology*. 2002;13(5):503-506. doi:10.1097/00001648-200209000-00004
- Hussain MA, Mamdani M, Saposnik G, et al. Validation of Carotid Artery Revascularization Coding in Ontario Health Administrative Databases. *Clin Invest Med*. 2016;39(2):E73-E78. doi:10.25011/cim.v39i2.26483
- Salata K, Hussain MA, De Mestral C, et al. Validation of abdominal aortic aneurysm repair codes in Ontario administrative data. *Clin Invest Med*. 2018;41(3):E148-E155. doi:10.25011/cim.v41i3.30858
- Rocha RV, Al-Omran M, Hussain MA, et al. Validation of endovascular and open thoracoabdominal aortic aneurysm repair in Ontario health administrative databases. *Clin Invest Med*. 2019;42(2):E19-E25. doi:10.25011/cim.v42i2.32812
- Fox MP, Lash TL, Bodnar LM. Common misconceptions about validation studies. *Int J Epidemiol*. 2020;49(4):1392-1396. doi:10.1093/ije/dyaa090
- Discharge Abstract Database (DAD). Canadian Institute for Health Information (CIHI). Accessed November 23, 2020. <https://www.cihi.ca/en/discharge-abstract-database-metadata-dad>
- National Ambulatory Care Reporting System metadata (NACRS). Canadian Institute for Health Information (CIHI). Accessed November 23, 2020. <https://www.cihi.ca/en/national-ambulatory-care-reporting-system-metadata-nacrs>
- ICES. National Ambulatory Care Reporting System, Same Day Surgery (NACRS, SDS). ICES. February 4th 2020. Accessed January 14th 2020. [https://ssl.ices.on.ca/dataprogram/Data%20Holdings/Health%20Services/nacrs-sds/DanaInfo=.aioulhiFpkn2K00Nrq,SSL=index.htm#Same-Day_Surgery_\(from_2003/04\)](https://ssl.ices.on.ca/dataprogram/Data%20Holdings/Health%20Services/nacrs-sds/DanaInfo=.aioulhiFpkn2K00Nrq,SSL=index.htm#Same-Day_Surgery_(from_2003/04))
- International Statistical Classification of Diseases. International Statistical Classification of Diseases and Related Health Problems 10th Revision. 2016. Accessed on November 23, 2020. <https://icd.who.int/browse10/2016/en>
- Canadian Institute for Health Information. Canadian Classification of Health Interventions Volume Four – Alphabetical Index. Canadian Institute for Health information. 2015. Accessed November 23, 2020. https://www.cihi.ca/sites/default/files/cci_volume_four_2015_en_0.pdf
- Ontario Health Insurance Plan (OHIP). Institute for Clinical Evaluative Sciences. March 24, 2017. Accessed November 23, 2020. <https://ssl.ices.on.ca/dataprogram/Data%20Holdings/Health%20Services/ohip/DanaInfo=.aioulhiFpkn2K00Nrq,SSL=index.htm>

16. Brown, L., Cai, T., & DasGupta, A. Interval Estimation for a Binomial Proportion. *Statistical Science*. 2001; 16(2), 101-117. Accessed January 14, 2021. <http://www.jstor.org/stable/2676784>
17. Liu Y. Senspec Macro. ICES. Accessed January 14, 2020. <https://ssl.ices.on.ca/dataprogram/Macros/Danainfo=.aioulh-jFpkn2K00NrQ,SSL+Index.html>
18. Al-Omran M, Tu JV, Johnston KW, Mamdani MM, Kucey DS. Outcome of revascularization procedures for peripheral arterial occlusive disease in Ontario between 1991 and 1998: a population-based study. *J Vasc Surg*. 2003;38(2):279-288. doi:10.1016/s0741-5214(03)00274-x
19. Juurlink D, Preyra C, Croxford R, Chong A, Austin P, Tu J, Laupacis A. Canadian Institute for Health Information Discharge Abstract Database: A Validation Study. ICES. 2006.
20. Hong Y, Sebastianski M, Makowsky M, Tsuyuki R, McMurtry MS. Administrative data are not sensitive for the detection of peripheral artery disease in the community. *Vasc Med*. 2016;21(4):331-336. doi:10.1177/1358863X16631041
21. Fan J, Arruda-Olson AM, Leibson CL, et al. Billing code algorithms to identify cases of peripheral artery disease from administrative data. *J Am Med Inform Assoc*. 2013;20(e2):e349-e354. doi:10.1136/amiajnl-2013-001827
22. Mell MW, Pettinger M, Proulx-Burns L, et al. Evaluation of Medicare claims data to ascertain peripheral vascular events in the Women's Health Initiative. *J Vasc Surg*. 2014;60(1):98-105. doi:10.1016/j.jvs.2014.01.056
23. Lasota AN, Overvad K, Eriksen HH, Tjønnelund A, Schmidt EB, Grønholdt MM. Validity of Peripheral Arterial Disease Diagnoses in the Danish National Patient Registry. *Eur J Vasc Endovasc Surg*. 2017;53(5):679-685. doi:10.1016/j.ejvs.2016.12.031
24. Obara H, Matsubara K, Kitagawa Y. Acute Limb Ischemia. *Ann Vasc Dis*. 2018;11(4):443-448. doi:10.3400/avd.ra.18-00074