Comprehensive assessment of the morbidity of renal mass biopsy: A population-based assessment of biopsy-related complications

Alaina Garbens, MD[*1]; Christopher J.D. Wallis, MD*[*1]; Zachary Klaassen, MD[2]; Refik Saskin, MD[3]; Lesley Plumptre, MD[4]; Ronald Kodama, MD[1]; Sender Herschorn, MD[1]; Robert K. Nam, MD[1]*

[1]Division of Urology, Department of Surgery, Sunnybrook Health Sciences Centre, University of Toronto, Toronto, ON, Canada; [2]Section of Urology, Department of Surgery, Medical College of Georgia-Augusta University, Augusta, GA, United States; [3]Institute of Health Policy, Management & Evaluation, University of Toronto, Toronto, ON, Canada; [4]ICES, Toronto, ON, Canada

**Equal contributors*

Cite as: Garbens A, Wallis CJD, Klaassen Z, et al. Comprehensive assessment of the morbidity of renal mass biopsy: A population-based assessment of biopsy-related complications. *Can Urol Assoc J* 2021;15(2):42-7. http://dx.doi.org/10.5489/cuaj.6477

Published online July 27, 2020

Abstract

Introduction: We sought to assess seven-day and 30-day complications following renal mass biopsy (RMB), including mortality, hospitalizations, emergency department (ED) visits, and operative and non-operative complications and compare these to rates in population-matched controls.

Methods: We performed a population-based, matched, retrospective cohort study of patients undergoing RMB following consultation with a urologist and axial imaging from 2003–2015 in Ontario, Canada. Data on seven-day and 30-day rates of mortality, as well as operative and non operative complications after RMB were reported. The seven-day and 30-day rates of mortality, operative and non-operative interventions, hospitalizations, and ED visits were compared to matched controls using multivariable logistic regression.

Results: Among 6840 patients who underwent RMB in the study period, 24 (0.4%) and 159 (2.3%) died within seven and 30 days of their biopsy, respectively. Seven- and 30-day operative intervention rates were 79 (1.2%) and 236 (3.4%), respectively. Seven- and 30-day non-operative intervention rates were 227 (3.3%) and 529 (7.7%), respectively. Thirty-day mortality (odds ratio [OR] 8.1, 95% confidence interval [CI] 5.1–13.0), hospitalizations (OR 12.6, 95% CI 10.6–15.2), and ED visits (OR 3.8, 95% CI 3.4–4.3) were more common among patients who underwent RMB than the matched controls ($p<0.001$ for each).

Conclusions: Patients undergoing RMB may have a small but non-negligible increased risk of mortality, hospital readmission, and ED visits compared to matched controls. However, limitations in the granularity of the dataset limits the strength of these conclusions. Further studies are needed to confirm our results. These risks should be discussed with patients for shared decision-making and considered in the risk/benefit tradeoff for the management of small renal masses.

Introduction

Increasing use of abdominal imaging has resulted in increased incidental diagnoses of small renal masses.[1] Approximately 80% of these masses are malignant.[2] Radiological approaches to distinguish benign and malignant renal masses rely on characteristics that include mass enhancement with intravenous contrast, size, location, and growth parameters.[1]

Historically, the treatment for patients with small renal masses was surgical excision with partial or radical nephrectomy. A recent approach has been to perform a percutaneous renal mass biopsy (RMB) to establish a histological diagnosis prior to definitive surgery. Currently, such an approach is controversial,[3,4] as the ability to acquire valuable diagnostic information that can risk-stratify patients[5] must be weighed against a non-diagnostic rate of approximately 15% and the risk of procedure-related complications.[6,7]

To date, data assessing outcomes of RMB for small renal masses have been limited to single-center studies.[5,6,8] Thus, we examined complication rates of RMB in a large population within a single-payer healthcare system, using mortality and morbidity endpoints.

Methods

We performed a population-based, retrospective cohort study of adults (aged ≥18 years) in Ontario, Canada to examine the burden of complications associated with RMB. We used unique identifiers to link administrative databases of anonymized patient data held at the Institute for Clinical Evaluative Sciences (ICES), including the Ontario Health Insurance Plan (OHIP) database (physician billings, laboratories, and out-of-province providers);[9] the Canadian Institute for Health Information (CIHI) Discharge Abstract Database (DAD; hospitalizations);[10] the CIHI National Ambulatory Care Reporting System (NACRS; ambulatory and emergency room visits); the Ontario Cancer Registry (OCR; cancer diagnoses);[11] the

Ontario Drug Benefit (ODB; outpatient pharmaceuticals);[12] and the Registered Persons Database (RPDB; demographic information).[13] The Sunnybrook Health Sciences Centre Research Ethics Board approved this study protocol.

Patient population

Using physician billings and hospital procedural records, we identified all patients undergoing a renal biopsy for presumed renal mass characterization (OHIP: Z601; CCI: 2.PC.71.HA, 2.PC.71.GR) between January 1, 2003 and March 31, 2015. As administrative data sources used do not distinguish between renal parenchymal biopsy and renal mass biopsy (RMB), we limited our cohort to those who had visited a urologist (specialty code 35) in the six months preceding or following biopsy and received an abdominal computed tomography (CT) or magnetic resonance imaging (MRI) scan in the 12 months prior. Patients were excluded if they had received a RMB or renal cell cancer diagnosis prior to the index date.

Study endpoints

To characterize the complication burden of RMB, we examined seven-day and 30-day mortality, operative and non-operative intervention rates, hospitalizations, and emergency department (ED) visits. We identified operative interventions using physician billings and hospital procedural records and characterized these as operative and non-operative (Supplementary Table 1). Operative interventions included total/radical nephrectomy, diagnostic laparotomy/laparoscopy, partial/total splenectomy, control of splenic bleeding, control of hepatic bleeding, control of bleeding from small and/or large intestine, bowel resection/repair, and operative control of kidney bleeding. Non-operative interventions included renal angioembolization, percutaneous drain insertion, percutaneous nephrostomy, and cystoscopic stent insertion.

Non-procedural complications included ED visits and hospital admissions within 30 days of RMB, identified using hospital records. We examined all such events and specifically examined those deemed urologically related (urinary tract infection, pyelonephritis, abdominal pain/colic, renal colic, abdominal pain, hematuria, urinary extravasation, and other urinary symptoms or disorders).

Covariates

To adjust for potential confounding, we collected data on patient characteristics. Patient-level covariates included age, sex, comorbidity (Johns Hopkins University Aggregated Diagnosis Groups case mix system),[14] geographic region of residence, year of biopsy, neighborhood income quintile, and blood thinner prescriptions up to 30 days prior to biopsy. We identified patients with chronic kidney disease based on billing codes from nephrologists (ICD-10 diagnosis code N18.x).

Data analysis

We descriptively characterized complications following RMB using counts with proportions for categorical variables and median with interquartile ranges (IQRs) for continuous variables. To assess the effect of renal biopsy on periprocedural outcomes, we hard matched each patient undergoing biopsy 1:1 with a control drawn from the general population based on age, sex, comorbidity, geographic location, neighborhood income quintile, and year. Finally, we performed logistic regression to assess the association between biopsy and complications and to identify predictors of complications following RMB. We performed a subset analysis among patients with no history of medical renal disease and those who may have metastatic disease based on consultation with a medical oncologist six months prior to or after the date of RMB.

Model assumptions were verified, and no violations were identified. Statistical significance was set at $p<0.05$ based on two-tailed comparison. All analyses were performed using SAS Enterprise Guide 7.1 (SAS Institute Inc).

As the time interval between RMB and urologist consultation was arbitrarily set at six months, we assessed the effect of this assumption by repeating the analyses and varying this time interval to within three months and to within one year.

Results

During the study interval, 6840 patients underwent renal biopsy and met all inclusion criteria for RMB, including appropriate imaging and urological consultation. Most patients were male, had multiple comorbidities, and were aged 50 years or older (Table 1). Notably, 2286 (33.4%) patients had a diagnosis of chronic kidney disease.

Of the 6840 patients who underwent a RMB, 24 (0.4%) and 159 (2.3%) died within seven and 30 days, respectively (Table 2). At seven and 30 days following biopsy, complications requiring operative intervention occurred in 79 (1.2%) and 236 (3.4%) patients, respectively, and those requiring non-operative intervention occurred in 227 (3.3%) and 529 (7.7%), respectively (Tables 2, 3). A total of 1095 (16.0%) patients visited the ED within 30 days of having a biopsy. Of those, 242 (22.1%) were due to a urological cause (Table 3), with hematuria being the most common. Hospitalization occurred for 1306 (19.1%) patients within 30 days of biopsy, with 182 (13.9%) being due to a urological cause. Seven-day rates of intervention, hospitalization, and ED visits are found in Table 2. When restricted to patients without chronic kidney disease (n=4554) and those without chronic kidney disease

Table 1. Baseline demographic characteristics of patients putatively undergoing renal mass biopsy between January 1, 2003 and March 31, 2015, and matched controls from the general population

Baseline characteristics	RMB	Matched controls
Number	6769	6769
Median (IQR)	64 (54–73)	64 (54–73)
18_39	472 (7.0%)	472 (7.0%)
40_49	712 (10.5%)	712 (10.5%)
50_59	1336 (19.7%)	1336 (19.7%)
60_69	1857 (27.4%)	1857 (27.4%)
70+	2392 (35.3%)	2392 (35.3%)
Sex, n (%)		
Female	2504 (37.0%)	2504 (37.0%)
Male	4265 (63.0%)	4265 (63.0%)
Income quintile, n (%)		
1 – Lowest	1314 (19.4%)	1314 (19.4%)
2	1396 (20.6%)	1396 (20.6%)
3	1334 (19.7%)	1334 (19.7%)
4	1345 (19.9%)	1345 (19.9%)
5 – Highest	1380 (20.4%)	1380 (20.4%)
Aggregated Diagnosis Group (ADG) categories		
1–4	334 (4.9%)	334 (4.9%)
5–9	2885 (42.6%)	2885 (42.6%)
10+	3550 (52.4%)	3550 (52.4%)
Year		
2003–2005	894 (13.2%)	894 (13.2%)
2006–2008	1146 (16.9%)	1146 (16.9%)
2009–2011	1786 (26.4%)	1786 (26.4%)
2012–2015	2943 (43.5%)	2943 (43.5%)

IQR: interquartile range; RMB: renal mass biopsy.

who also did not visit a medical oncologist (n=3903), outcomes were comparable to the primary analysis (Tables 4, 5).

We matched 6769 patients who underwent RMB during the study period to 6769 controls (Table 1). Patients who underwent RMB had significantly higher rates mortality at seven days (0.4% vs. <0.07%, p=0.0007) and 30 days (2.3% vs. 0.3%; number needed to treat to harm [NNTH] 49, 95% confidence interval [CI] 41–59) following RMB. Additionally, rates of ED visits at seven days (5.6% vs. 1.4%; NNTH 24, 95% CI 21–28) and 30 days (15.9% vs. 4.7%; NNTH 9, 95% CI 8–10) following index were higher among those who underwent RMB. Finally, rates of hospitalization were higher at seven days (10% vs. 0.5%; odds ratio [OR] 20.8, 95% CI 14.8–29.1 and 30 days (19.1% vs. 1.8%; OR 12.6, 95% CI 10.6 –15.2, p<0.0001) compared to controls (Table 2). Use of blood thinners was not a predictor of complications, admissions, or ED visits on multivariable analysis (OR 1.0, 95% CI 0.76–1.31, p=0.99).

Across analyses, sensitivity analyses varying the exposure window did not significantly change the study results (data not shown).

Discussion

Using a large, population-based cohort, we identified low but not insignificant rates of mortality (2.3%) and complications (up to 10%) within 30 days of RMB. These results were robust in subgroup analyses excluding patients with medical renal disease and suspicion of metastatic disease. Rates of hospitalization and ED visits were higher among patients undergoing RMB than population-matched controls. Due to the limitations of these data, we are unable to directly attribute either the mortality or morbidity experienced by these patients to their RMB. Indeed, it is likely that physicians opt to perform RMB specifically in patients who are at increased risk of periprocedural morbidity. However, these data highlight the potential outcomes a patient who is considering RMB should be aware of prior to undertaking the procedure.

To our knowledge, this is the first population-level report of complications related to RMB. Single-institution series have demonstrated a low rate of complications (<10%), with a preponderance of Clavien-Dindo grade 1 perirenal hematomas incidentally detected on postprocedural imaging.[5,6] In centers in which asymptomatic perinephric hematomas are not routinely sought, reported complication rates are even lower (<4%).[15] Rare cases of bleeding requiring embolization[5,15,16] or hospitalization for bladder irrigation[6] — Clavien-Dindo grade 3 events — have been reported. Systematic reviews of such series have corroborated these findings and concluded that major complications are rare.[17,18] However,

Table 2. 7-day and 30-day mortality, hospitalization, and emergency visits for patients who underwent renal mass biopsy (n=6839) from 2003–2015 in Ontario, Canada, and matched controls*

Outcome	7-day outcomes				30-day outcomes			
	RMB, n (%)	Controls, n (%)	OR (95% CI)	Absolute risk difference, % (95% CI)	RMB, n (%)	Controls, n (%)	OR (95% CI)	Absolute risk difference, % (95% CI)
Mortality	24 (0.4)	1–5**	Unable to report**	159 (2.3)	20 (0.3)	8.1 (5.1–13.0)	2.1 (1.7–2.5)	
Hospitalizations	683 (10)	36 (0.5)	20.8 (14.8–29.1)	9.5 (8.7–10.2)	1306 (19.1)	124 (1.8)	12.6 (10.6–15.2)	17.2 (16.2–18.2)
Emergency visits	383 (5.6)	96 (1.4)	4.2 (3.3–5.2)	4.2 (3.6–4.8)	1095 (15.9)	320 (4.7)	3.8 (3.4–4.3)	11.2 (10.2–12.2)

*Controls were hard matched for age, sex, comorbidity (ADG), geographic location, neighborhood income quintile, and year of procedure. **Values suppressed due to small cells due to administrative policy that individual counts less than 6 cannot be reported. As a result, OR and absolute risk difference cannot be reported due to the potential to derive these small values. CI: confidence interval; OR: odds ratio; RMB: renal mass biopsy.

Table 3. Short-term operative and non-operative complications for patients who underwent renal mass biopsy (n=6840) from 2003–2015 in Ontario, Canada

Outcome	Renal mass biopsy	
	7-day, n (%)	30-day, n (%)
Operative interventions (total)	79 (1.2)	236 (3.4)
Radical nephrectomy	39 (0.6)	151 (2.2)
Diagnostic laparotomy or laparoscopy	27 (0.4)	43 (0.6)
Bowel resection/repair	13 (0.2)	42 (0.6)
Non-operative interventions (total)	227 (3.3)	529 (7.7)
Renal angioembolization	44 (0.6)	61 (0.9)
Percutaneous drain insertion	161 (2.4)	419 (6.1)
Cystoscopic stent insertion	22 (0.3)	49 (0.7)
Hospitalizations		
Any	683 (10)	1306 (19.1)
Urologically related*	88 (1.3)	182 (2.7)
Emergency visits		
Any	383 (5.6)	1095 (16.0)
Urologically related*	94 (1.4)	242 (3.5)

*Includes urinary tract infection, pyelonephritis, renal colic, abdominal pain, hematuria, urinary extravasation, and other urinary symptoms or disorders.

as these studies were limited to academic institutions, the generalizability of these findings are unclear;[19] in contrast, the present study provides generalizable results that may be reliably extrapolated to general medical practice.

Current guidelines for the management of small renal masses neither advocate nor oppose the use of RMB.[4,20] Opponents to widespread use of RMB have focused on concerns regarding accuracy and safety.[19] While we did not assess the accuracy of RMB in this analysis, diagnostic success rates in excess of 90% have been documented in both single-institutional series[5] and systematic reviews.[21] Concerns have been raised that RMB may represent an unnecessary test that may be associated with increased patient anxiety, a risk of unnecessary harm, waste of valuable healthcare resources, and potentially even delays in definitive treatment.[22] However, we recently found that patients who underwent a RMB prior to radical or partial nephrectomy had significantly lower rates of benign disease on surgical pathology.[23] Therefore, routine use of RMB may reduce rates of renal surgery for benign disease. This may avoid significant morbidity, as well as cost. Further, a recent review of cost-effectiveness studies assessing the management of small renal masses demonstrated that a biopsy-based strategy (with possible subsequent intervention) dominated immediate surgical intervention, yielding improved outcomes at lower costs.[24]

Strengths of this analysis include its generalizable nature and the robust identification of both exposure and outcomes. This study was performed in Ontario, Canada, a jurisdiction in which all relevant health services are available free and are systematically tracked in administrative databases. Thus, both exposure and outcome are accurately and comprehensively captured. Further, all physician interactions, procedures, ED visits, and hospitalizations are captured, regardless of where in the province they occurred, thus eliminating ascertainment bias associated with institutional studies.

Table 4. Short-term post-procedural complications of patients without chronic renal disease who underwent renal mass biopsy (n=4554), saw a urologist, and had a CT or MRI scan within 12 months

Outcome	7-day, n (%)	30-day, n (%)
Mortality	25 (1.8%)	94 (2.1%)
Operative interventions (total)	47 (1.0)	164 (3.6)
Radical nephrectomy	25 (0.5)	117 (2.6)
Diagnostic laparotomy or laparoscopy	14 (0.3)	19 (0.4)
Bowel resection/repair	8 (0.2)	28 (0.6)
Non-operative interventions (total)	95 (2.1)	232 (5.1)
Renal angioembolization	27 (0.6)	36 (0.8)
Percutaneous drain insertion	53 (1.2)	163 (3.6)
Cystoscopic stent insertion	15 (0.3)	33 (0.7)
Hospitalizations		
Any	366 (8.0)	722 (15.9)
Urologically related*	61 (1.3)	96 (2.1)
Emergency visits		
Any	250 (5.5)	621 (13.6)
Urologically related*	62 (1.4)	143 (3.1)

*Includes urinary tract infection, pyelonephritis, renal colic, abdominal pain, hematuria, urinary extravasation, and other urinary symptoms or disorders. CT: computed tomography; MRI: magnetic resonance imaging.

Table 5. Short-term post-procedural complications of patients without chronic renal disease who underwent renal mass biopsy (n=3903), saw a urologist, did not see a medical oncologist, and had a CT or MRI scan within 12 months

Outcome	7-day, n (%)	30-day, n (%)
Mortality	9–13**	78 (2.0%)
Operative interventions		
Radical nephrectomy	20–24**	94 (2.4%)
Diagnostic laparotomy or laparoscopy	9–13**	14–18**
Bowel resection/repair	3–7**	22–27**
Non-operative interventions (total)		
Renal angioembolization	22–26**	31–35**
Percutaneous drain insertion	40 (1.0%)	125 (3.2%)
Cystoscopic stent insertion	10–14**	23 (0.6%)
Hospitalizations		
Any	323 (8.3%)	596 (15.3%)
Urologically related*	55 (1.4%)	82 (2.1%)
Emergency visits		
Any	195 (5.0%)	490 (12.6%)
Urologically related*	52 (1.3%)	117 (3.0%)

*Includes urinary tract infection, pyelonephritis, renal colic, abdominal pain, hematuria, urinary extravasation, and other urinary symptoms or disorders. **Cells numbers suppressed due to small numbers. CT: computed tomography; MRI: magnetic resonance imaging.

However, a few limitations are present. First, the definition of non-procedural complications was restricted to hospitalizations and ED visits, excluding outpatient office interactions. These are likely to capture the vast majority of significant complications and the validity of these diagnoses has been well-established in Ontario.[10] Second, operative and non-operative procedures were used as surrogates for actual complications without an ability to ascertain the indication for each intervention. This is perhaps most relevant for the outcome of nephrectomy as a complication following RMB. While nephrectomy may be necessary in rare circumstances to manage bleeding, it may also represent definitive management of a previously biopsied lesion. However, given surgical wait times in Ontario, it is uncommon for patients with genitourinary malignancies to undergo surgery within seven or 30 days of the decision to operate, a time that will be delayed from the date of RMB due to the time required for pathological examination of the biopsy specimen. However, misattribution of these cases would lead to an overestimate of complications rates. Thus, true rates may be lower than estimated in this analysis. Third, we are unable to directly attribute any of the outcomes to biopsy. For mortality, in particular, we are unable to ascertain cause of death. However, compared a matched cohort from the general population, mortality rates within 30 days of biopsy were significantly higher. Fourth, due to limitations in the administrative data sources used, we lack details regarding the renal mass, including size, location, and complexity, and regarding specific pathological outcomes. As stated earlier, while we attempted to exclude patients who underwent renal biopsy for medical renal disease, the same procedure code is used for both RMB and renal biopsy. As a result, we could not definitively exclude renal biopsy from our population. Thus, we performed sensitivity analyses to assess the effect of this on study conclusions. Finally, due to the administrative nature of our data, we were unable to collect relevant patient-reported outcomes.

Conclusions

In a large, population-based cohort, RMB may be associated with a low but non-negligible rate of mortality, operative and non-operative complications, hospitalizations, and ED visits. However, due to the limitations of our population-based data, further studies are needed to confirm our results. These events, along with the potential benefits of RMB, should be considered in shared decision-making before proceeding to biopsy.

Competing interests: Dr. Herschorn has been an advisory board member for and has received payment from Astellas, Boston Scientific, and Pfizer; has received speaker honoraria from Astellas; and has participated in clinical trials supported by Allergan, Astellas, and Purdue. The remaining authors report no competing personal or financial interests related to this work.

Funding/acknowledgment: Dr. Nam is supported by the Ajmera Family Chair in Urologic Oncology. This study made use of de-identified data from the ICES Data Repository, which is managed by the Institute for Clinical Evaluative Sciences with support from its funders and partners: Canada's Strategy for Patient-Oriented Research (SPOR), the Ontario SPOR Support Unit, the Canadian Institutes of Health Research, and the Government of Ontario. The opinions, results, and conclusions reported are those of the authors. No endorsement by ICES of any of its funders or partners is intended or should be inferred.

This paper has been peer-reviewed.

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Correspondence: Dr. Alaina Garbens, Division of Urology, Department of Surgery, Sunnybrook Health Sciences Centre, University of Toronto, Toronto, ON, Canada; alaina.garbens@utoronto.ca

Supplementary Table 1. Procedural codes and diagnostic codes

Description	Code used
Percutaneous renal mass biopsy	OHIP: Z601; CCI: 2.PC.71.HA
Treatments	
Partial nephrectomy	OHIP S411, S423; CCI 1.PC.87.^^
Radical nephrectomy	OHIP S413, S415, S416; CCI 1.PC.89.^^, 1.PC.91.^^
Percutaneous cryoablation/RFA	OHIP J069; CCI 1.PC.59.HA-X7, 1.PC.59.HA-AW, 1.PC.HA-CG
Open cryoablation/RFA	CCI 1.PC.59.LA-X7, 1.PC.59.LA-AW
Laparoscopic cryoablation/RFA	OHIP S400; CCI 1.PC.59.BA-X7, 1.PC.59.BA-AW
Radiotherapy	OHIP X310, X311, X312, X313; CCI 1.PC.27.^^
Operative complications	
Diagnostic laparotomy/ laparoscopy	OHIP S312, Z552; CCI 2.OT.70.^^
Partial/total splenectomy	OHIP R905; CCI 1.OB.87.^^, 1.OB.89.^^
Control of splenic bleeding	CCI 1.OB.13.^^
Control of hepatic bleeding	CCI 1.OA.13.^^
Control of bleeding, small and large intestine	1.NP.13.^^
Repair of small bowel	OHIP S184; CCI 1.NK.80.^^
Partial excision of small bowel	OHIP S164, S165; CCI 1.NK.87.^^
Repair of large bowel	CCI 1.NM.80.^^
Partial excision of large bowel	OHIP S167, S166, S169, S172, S171 CCI 1.NM.87.^^
Operative control of kidney bleeding	CCI 1.PC.13.LA, 1.PC.80.^^
Non-operative complications	
Renal angioembolization	OHIP J040; CCI 1.PC.13.GQ-C2, 1.PC.13.GQ-GE, 1.PC.13.GQ-W0
Percutaneous drainage of abdominal cavity/ retroperitoneum	CCI 1.OT.52.HA, 1.OT.52.HA-TS, 1.OT.52.HH-D1, 1.OT.52.HH-D2, 1.OT.52.HH-D3
Percutaneous drainage of soft tissue	CCI 1.SZ.52.HA, 1.SZ.52.HA-TS
Percutaneous abdominal abscess drainage	OHIP Z594
Drainage of kidney abscess or perinephric abscess	OHIP S401, S402
Ultrasound guided biopsy, aspiration, or drainage	OHIP J149
Drainage of subfascial abscess	OHIP Z410
Percutaneous nephrostomy	OHIP J046; CCI 1.52.PC.HA
Cystoscopic stent insertion	OHIP E818; CCI 1.PE.50.BA-BJ
Hospital admission with following diagnoses	
Urinary tract infection	ICD-10 N10, N30, N39.0
Pyelonephritis	ICD-10 N10.x
Abdo pain: colic	ICD-10 R10.83
Unspecified renal colic	ICD-10 N23.x
Abdominal pain	ICD-10 R10.1, R10.2, R10.3, R10.81, R10.84, R10.9
Hematuria	ICD-10 R31.x
Urinary extravasation	ICD-10 R39.0
Other urinary symptoms or disorders	ICD-10 N39.9, R39.9

CCI: Canadian Classification of Health Interventions; OHIP: Ontario Health Insurance Plan; RFA: radiofrequency ablation. Both ^^ and x are placeholders that represent any number.