A Statewide Quality Improvement Collaborative's Adherence to the 2017 American Urological Association Guidelines Regarding Initial Evaluation of Patients With Clinical T1 Renal Masses

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OBJECTIVE To evaluate MUSIC-KIDNEY's adherence to the American Urological Association (AUA) guidelines regarding the initial evaluation of patient's with clinical T1 (cT1) renal masses.

METHODS We reviewed MUSIC-KIDNEY registry data for patients with newly diagnosed cT1 renal masses to assess for adherence with the 2017 AUA guideline statements regarding recommendations to obtain (1) CMP, (2) CBC, (3) UA, (4) abdominal cross-sectional imaging, and (5) chest imaging. An evaluation consisting of all 5 guideline measures was considered "complete compliance." Variation with guideline adherence was assessed by contributing practice, management strategy, and renal mass size.

RESULTS We identified 1808 patients with cT1 renal masses in the MUSIC-KIDNEY registry, of which 30% met the definition of complete compliance. Most patients received care that was compliant with recommendations to obtain laboratory testing with 1448 (80%), 1545 (85%), and 1472 (81%) patients obtaining a CMP, CBC, and UA respectively. Only 862 (48%) patients underwent chest imaging. Significant variation exists in complete guideline compliance for contributing practices, ranging from 0% to 45% as well as for patients which underwent immediate intervention compared with initial observation (37% vs 23%) and patients with cT1b masses compared with cT1a masses (36% vs 28%).

CONCLUSION Complete guideline compliance in the initial evaluation of patients with cT1 renal masses is poor, which is mainly driven by omission of chest imaging. Significant variation in guideline adherence is seen across practices, as well as patients undergoing an intervention vs observation, and cT1a vs cT1b masses. There are ample quality improvement opportunities to increase adherence and decrease variability with guideline recommendations. UROLOGY 158: 117–124, 2021. © 2021 Elsevier Inc.

The incidence of kidney cancer is estimated to be 80,470 new cases in 2019, with 17,670 deaths.[1] The majority of newly diagnosed renal masses (RM) are discovered incidentally in patients who are asymptomatic. To add structure and aid in the evaluation, treatment, and surveillance of patients with newly diagnosed renal masses, the American Urological Association (AUA) published updated guidelines for the management of RM in 2017.[2] Included in these guidelines are recommendations regarding the initial evaluation of a patient with a renal mass suspicious for RCC. The recommended initial evaluation includes the following five tests: (1) complete blood count (CBC), (2) comprehensive metabolic panel (CMP), (3) urinalysis (UA), (4) multiphasic, cross-sectional abdominal imaging, and (5) chest imaging.

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The purpose of this evaluation is to assess the patient's renal function, general healthy, characterize the renal mass, and to stage for possible metastatic disease in the abdomen and chest.

The literature on guideline adherence and dissemination is often limited by sample size and/or lack of granularity from administrative and claims-based datasets. Despite publications regarding guideline recommendations for the surgical management of RM, there is a paucity of literature regarding the adherence to the recommended initial workup for patients with newly diagnosed renal masses. The Michigan Urological Surgery Improvement Collaborative (MUSIC) has previously leveraged our state-wide registry to report practice pattern variations in multiple urologic disease states. Multiple MUSIC quality improvement initiatives stem from our initial evaluation of adherence to guideline recommendations and variation in practice patterns in multiple facets of urology and urologic oncology, thereby delineating objectives for these initiatives.[3-10]

Herein, we report guideline adherence during the initial work-up of patients with newly diagnosed localized clinical T1 (cT1) RM within a statewide quality improvement collaborative comprised of academic and community-based practices. Specifically, we assessed adherence to recommendations to obtain comprehensive metabolic panel (CMP), complete blood count (CBC), urinalysis (UA), multi-phase cross-sectional abdominal, and chest imaging.

MATERIALS AND METHODS

Study Design

The MUSIC Kidney mass: Identifying and Defining Necessary Evaluation and therapY (MUSIC-KIDNEY) program seeks to standardize and improve care for patients with renal masses.[11] Fourteen community, academic, and hospital-based practices contributed to this analysis. The registry is populated by trained data abstractors at each clinical site who review the primary medical record at fixed intervals and enter pertinent clinical and laboratory parameters. All participating sites obtained exemption or approval from local institutional review boards for participation in MUSIC-KIDNEY quality improvement activities.

Study Sample

We identified patients with cT1 renal masses diagnosed from May 2017 to December 2019. Patients with cT2 or higher masses, radiographically identified angiomyolipomas, or simple/minimally complex renal cysts (Bosniak I, II, and IIF) were excluded from analysis. Data abstraction was performed at least 4 months (120 days) after the initial office visit in order to capture the initial work-up, plan, and treatment decision (immediate intervention vs initial observation) for each patient. Patients undergoing surgery or ablation within 4 months of diagnosis were included in the immediate intervention group. Patients with less than 4 months of follow up were excluded from analysis, as these patients are currently within the window to undergo their initial evaluation and were still eligible to meet guideline compliance.

Study Objectives

The primary study objective was to assess compliance with the 2017 AUA guideline testing recommendations for the initial evaluation for patients with newly diagnosed renal masses suspicious for RCC.[2] We assessed guideline compliant care with respect to five tests: (1) obtaining a comprehensive metabolic panel (CMP), (2) obtaining a complete blood count (CBC), (3) obtaining a urinalysis (UA), (4) obtaining multiphasic, cross-sectional abdominal imaging (CT or MR), and (5) obtaining chest imaging (chest x-ray (CXR) or CT). An internal systematic review process was implemented to check and confirm recording compliance status for each measure. Guideline compliance was met if the components of the initial evaluation were performed from 6 months prior to 4 months after the patient's initial urologic visit. Compliance with each individual test was recorded, and "complete compliance" was defined as being compliant with all five tests. For patients that underwent surgery within 4 months of diagnosis, all tests obtained prior to surgery were counted towards compliance, while post-surgical tests were not considered as guideline compliant testing. Secondary objectives included assessment of practice-level variation for individual urology practices and identification of sub-groups having less guideline adherence.

Statistical Analysis

The proportion of patients receiving guideline compliant care was calculated, both for the individual measures and complete compliance, along with Wald 95% confidence intervals. Pearson's Chi-squared test was used to compare proportion of patients receiving guideline compliant care for patients undergoing immediate intervention vs initial observation and for patients with cT1a vs cT1b masses. All statistical analyses were performed using SAS v9.4 at the 5% significance level.

RESULTS

Study Cohort

We identified 1808 patients with newly diagnosed renal masses from May 2017 to December 2019 at 14 MUSIC-KIDNEY practices (Table 1). The median age of the cohort was 65 years, most patients were male, and the median tumor size was 2.7 cm. Most patients were healthy, with over 70% having a Charlson Comorbidity Index ≤1, and patients were nearly evenly split between immediate intervention (51%) and initial observation (49%).

Primary Objective

Less than a third of patients (30%) had complete guideline compliance with all five recommended tests (Fig. 1). Individual tests had higher compliance rates, with over $^{3}/_{4}$ of patients found to be compliant for comprehensive metabolic panel (80%), complete blood count (85%), urinalysis (81%), and abdominal imaging (93%). However, fewer than half of patients had compliance with chest imaging (48%).

We reviewed the data of 131 (7%) patients that did not meet the criteria for multiphasic abdominal imaging within 6 months prior to and 4 months after the index consultation. Most of these patients (n = 85) had a renal ultrasound only, while the other 46 patients did not have an imaging study during this time frame. Of these 46 patients, 37 patients had multiphasic imaging outside side of the time frame of 6 months prior to and 4 months after the index consultation and, therefore, did not meet the predefined criteria for compliance.

Table 1. Clinical, demographic, and oncological features of 1808 patients with cT1 renal masses in MUSIC-KIDNEY

Demographic	N/Median	%/ Interquartile Range (IQR)
Age	65	56.0-74.0
Body Mass Index (BMI)	29.8	26.0-34.9
Tumor size, cm	2.7	1.8-4.0
T1b tumors	448	24.8%
Gender		
Male	1062	59%
Female	746	41%
Race		
White	1389	77%
African-American	257	14%
Other	43	2.4%
Unknown	119	6.6%
Charlson comorbidity index		
0	942	52%
1	341	19%
≥2	525	29%
Insurance type		
Private	953	53%
Public	826	46%
None/Unknown	29	1.6%
Practice type		
Academic	353	20%
Non-Academic	1455	80%
Treatment		
Surveillance	881	49%
Partial nephrectomy	571	32%
Radical nephrectomy	292	16%
Ablation	64	3.5%

cT1, clinical T1.

Practice Level Variation

We noted substantial variation among MUSIC-KIDNEY contributing practices with regard to delivering compliant care overall and for the five individual recommended tests (Fig. 2). There was the least amount of variation and good performance at all sites in the proportion of patients obtaining cross-sectional abdominal imaging, ranging from 77% to 100%. There was poor performance in obtaining chest imaging with no practice obtaining it in >70% of patients (range: 13% to 68%). Variable performance of CMP, CBC, and UA was seen with practice level ranges from 38% to 93%, 55% to 97%, and 38% to 90%, respectively.

Subgroup Analysis

Guideline compliance was lower in patients managed initially with observation compared with patients receiving immediate intervention for most guideline measures (CMP: 77% vs 83%; CBC: 80% vs 90%; multiphasic abdominal imaging: 89% vs 97%; chest imaging: 42% vs 53%, respectively) and complete compliance (23% vs 37%, respectively), except for the UA (80% vs 83%, respectively, Fig. 3A). Additionally, guideline compliance was higher in patients with larger masses (cT1b: 4.1-7.0 cm) compared with smaller masses (cT1a: ≤4.0 cm) for most measures (CMP: 83% vs 79%; multiphasic abdominal imaging: 95% vs 92%; chest imaging: 56% vs 45%, respectively) and complete compliance (36% vs 28%, respectively). The proportion of patients with a CBC and UA were similar regardless of renal mass size.

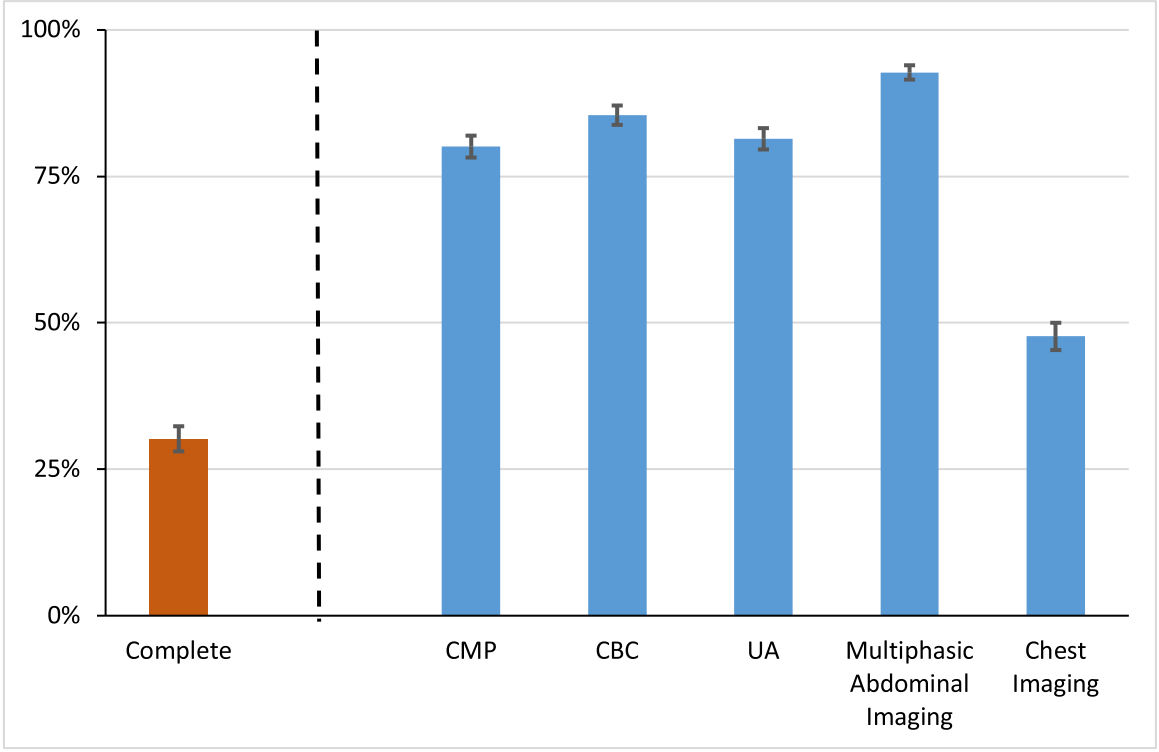


Figure 1. Proportion of patients compliant with guideline recommendations and complete compliance in MUSIC-KIDNEY. Error bars display 95% confidence interval. CBC, complete blood count; CMP, comprehensive metabolic panel; UA, urinalysis. (Color version available online.)

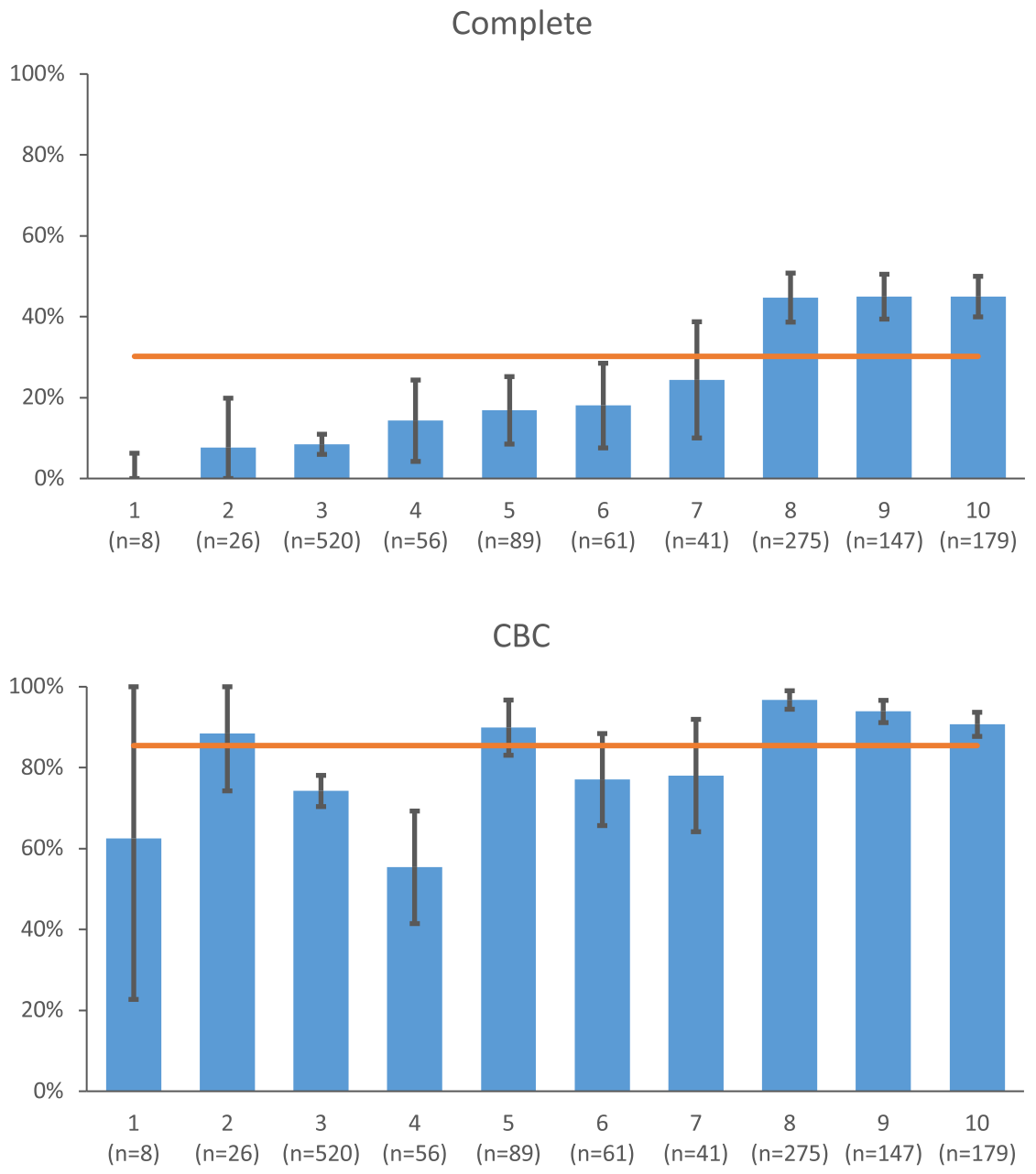
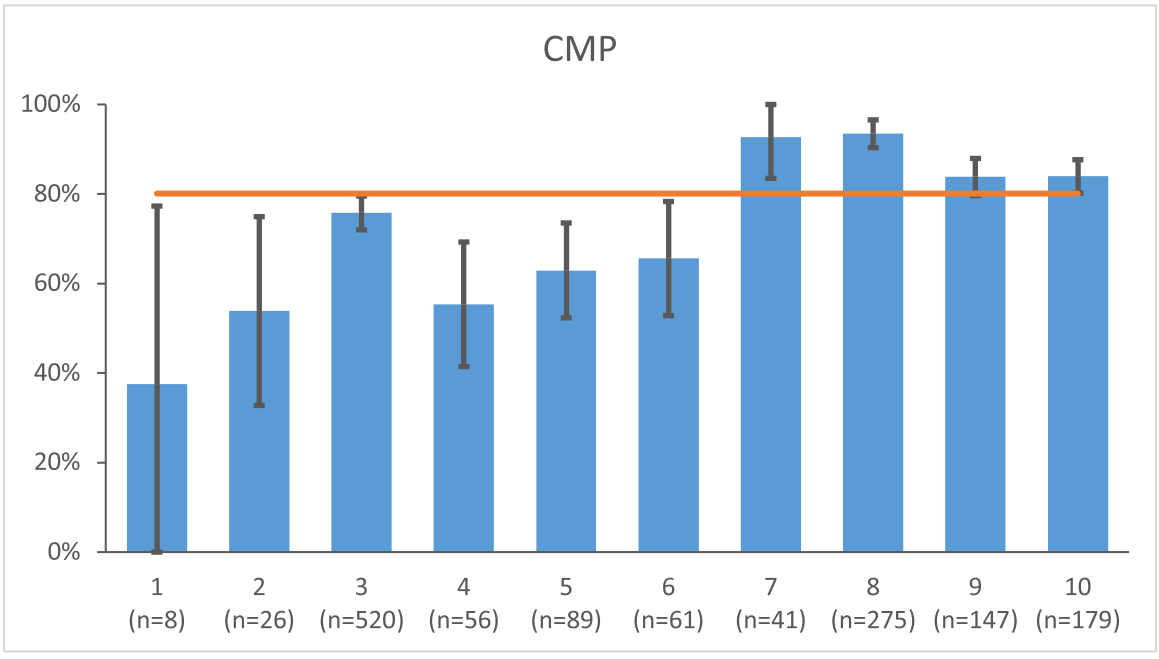


Figure 2. Practice level variation of proportion of patients with complete compliance and compliance with each guideline recommendation (**A**) complete compliance, (**B**) CBC, (**C**) CMP, (**D**) UA, (**E**) multiphasic abdominal imaging, and (**F**) chest imaging. Line presents the proportion of patients compliant in the entire MUSIC-KIDNEY cohort. Practices contributing less than 5 patients were excluded. Practices are organized by complete compliance. Error bars display 95% confidence interval. (Color version available online.)

COMMENT

There is considerable variability in the management of newly diagnosed renal masses.[12-14] In order to serve as a framework to aid clinicians in the initial evaluation, characterization, and management of patients with renal masses, the AUA released updated guidelines in 2017. In the MUSIC-KIDNEY registry, we found most patients (70%) did not undergo an evaluation which was compliant with the five tests recommended by the AUA guidelines as part of the initial evaluation of a patient with a newly diagnosed renal mass. We noted significant variability in guideline compliance by test, practice site, initial management strategy (observation vs intervention), and size of the renal mass.

Of the five tests, chest imaging had the poorest performance, with only 48% of patients with new renal masses meeting this guideline recommendation. Per the guideline statement, the rationale for chest imaging in this population is to screen the patient for metastatic disease.[2] There



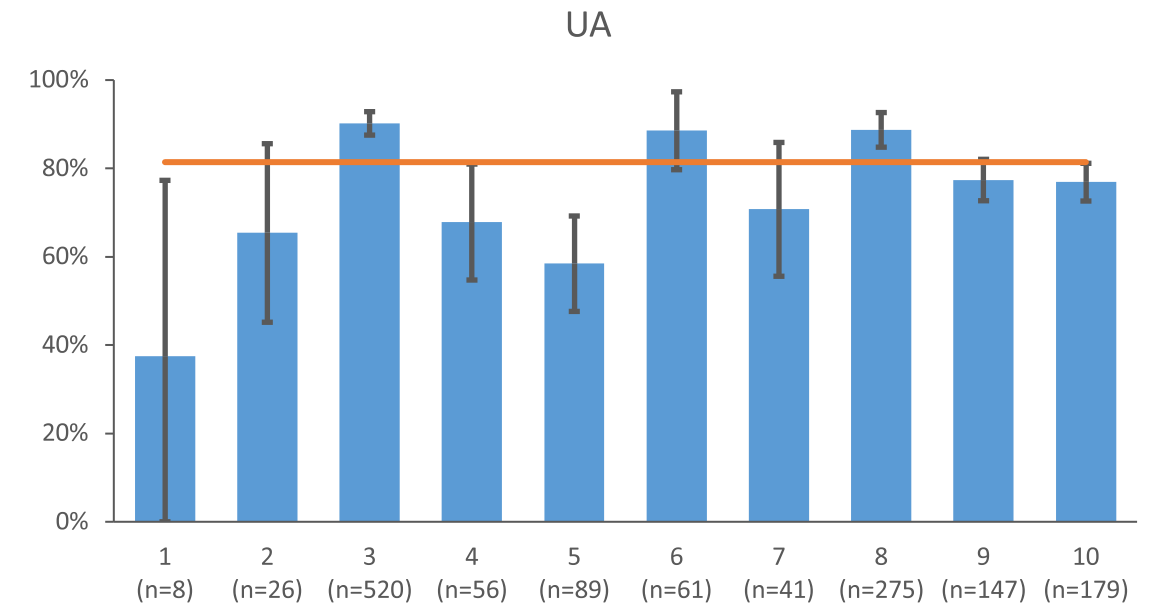
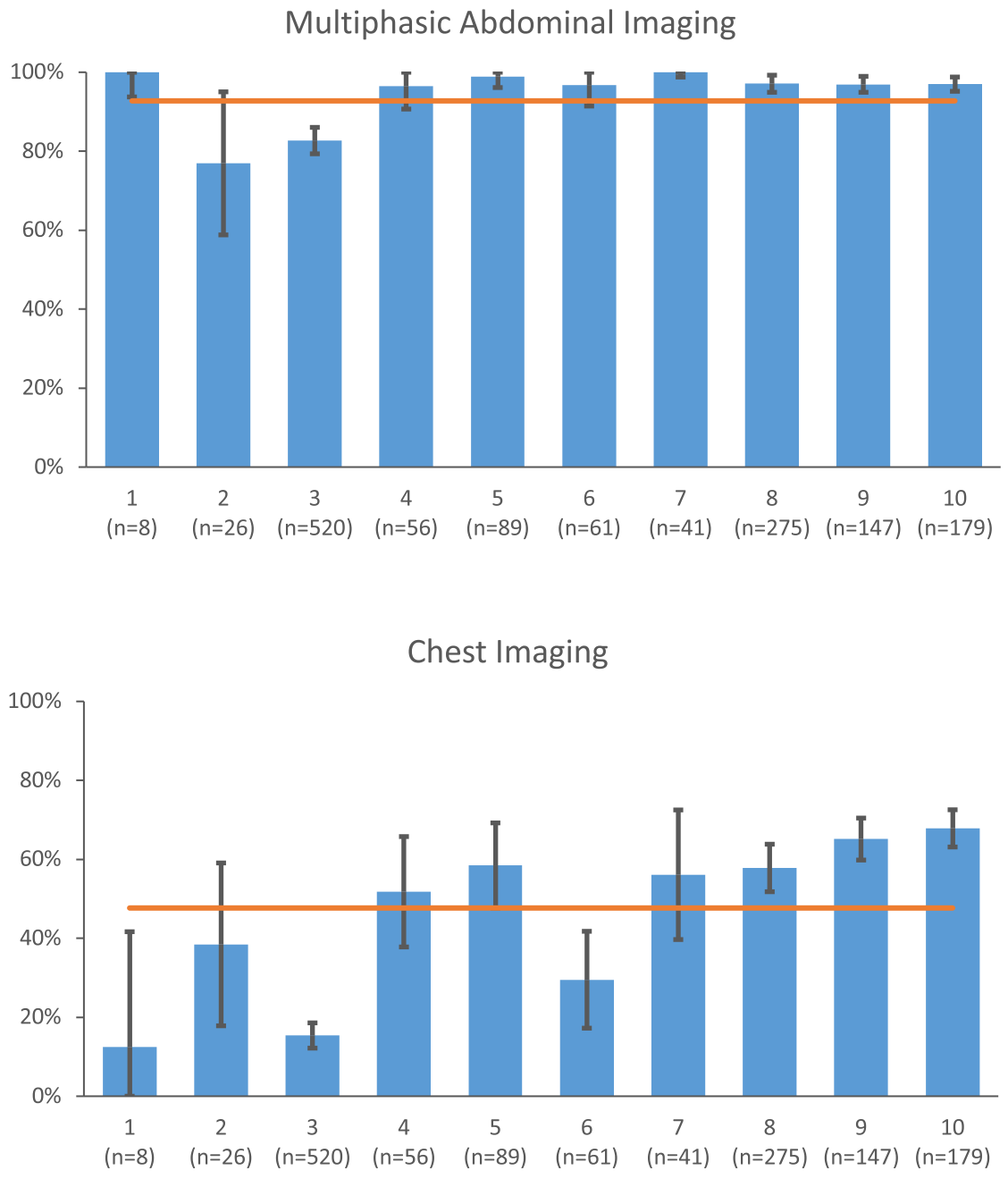


Figure 2. Continued

are several potential explanations for the low utilization of chest imaging in patients with newly diagnosed renal masses in our registry. First, the incidence of synchronous metastasis in patients with T1 renal masses is rare, with approximately 2% of all patients with T1 renal masses having metastasis at the time of diagnosis.[15-17] The number of patients with small renal masses ≤3 cm which present with metastatic disease is almost nonexistent, with two groups reporting a single metastasis each in their cohorts of 629 and 781 patients, respectively.[15,17] Second, approximately 20% of patients with enhancing small renal masses will have benign renal masses, which have a 0% metastatic potential.[18,19] Third, most of these patients have cross sectional abdominal imaging, which often image a portion of the mediastinum and lower lung fields. Given the low pretest probability of metastatic disease in this patient population, one possible explanation for these data is that urologists consider dedicated chest imaging in this population of patients, particularly in patients with small renal masses, to have low yield with results unlikely to change clinical management. Additionally, guideline statements list active surveillance as a management option



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for small renal masses. This is potentially conflicting to on one hand offer surveillance, given that the oncological risk of these masses is low enough that it does not justify immediate treatment, yet to also recommend screening for metastatic disease in this same patient. This sentiment is reflected in our data; patients that were initially managed with observation or had cT1a lesions were less likely to undergo chest imaging compared with patients that underwent immediate intervention or had cT1b lesions, respectively.

As our healthcare system continues to evolve there is increasing emphasis on delivering high quality care, including the incorporation of meeting quality metrics as a component of reimbursement.[20] Guideline statements have the potential to serve as the foundation for these metrics. For quality metrics derived from the 2017 AUA guideline statements, one would look at the variability and poor compliance in our cohort and consider this to be low value care.

As more evidence is compiled, future iterations of renal mass guidelines may consider revisions and implementation of chest imaging recommendations that are risk stratified according to renal mass size. The use of chest imaging in patients with cT1b masses, in which the incidence of

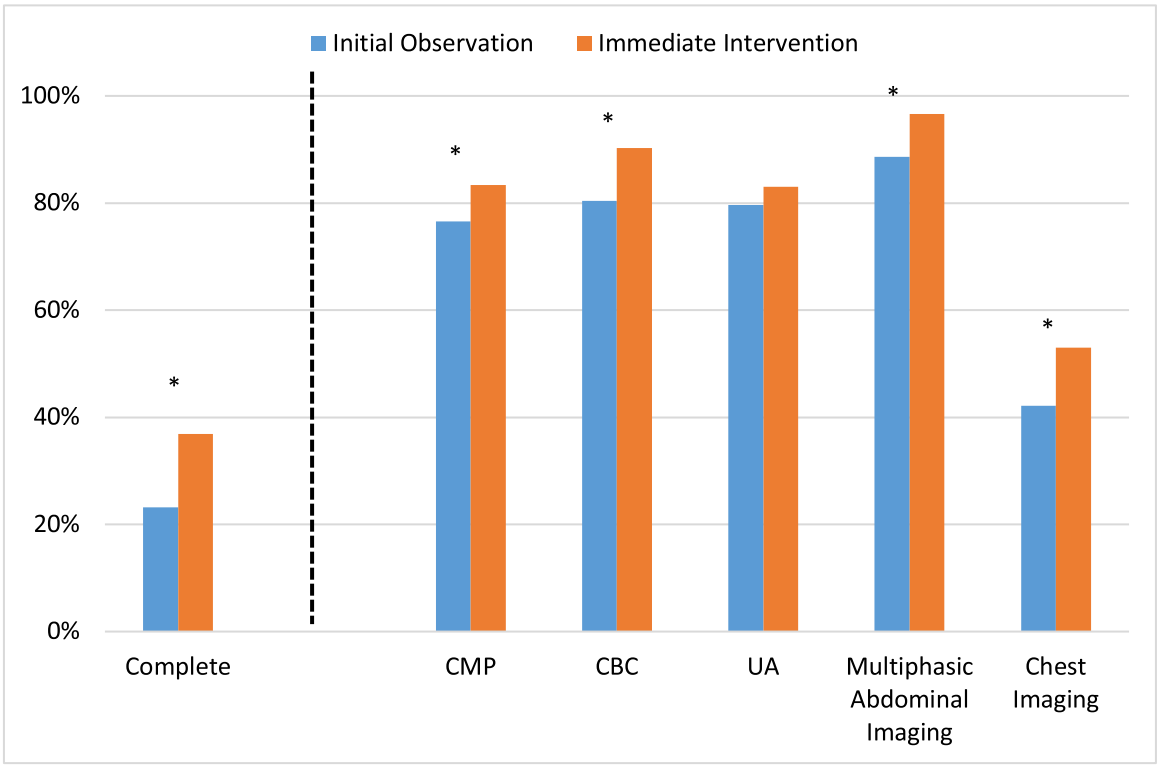

Figure 3. (**A**) Comparison of the proprotion of patients that received guideline compliant care with individual recommended tests and complete compliance between patients undergoing immediate intervention vs initial observation. (**B**) Proportion of patients that received guideline compliant care with individual recommended tests and complete compliance between patients with T1a vs T1b renal masses. *denotes *P* value ≤.05. (Color version available online.)

metastasis is approximately 1 in 20, is unacceptably low. On the other hand, requiring chest imaging for T1a masses (or masses <3 cm) seems of low value, given the very low likelihood of detecting chest metastases in these patients. Indeed, this is an avenue of ongoing research for the MUSIC-KIDNEY collaborative to increase the use of chest imaging in appropriate patients (with tumors >4-5 cm), while de-emphasizing the importance of chest imaging in patients with tumors <3 cm. Additionally, these data will inform evolving efforts within MUSIC to increase the utilization and decrease variability with guideline statements which we believe correlate with high quality care, such as ensuring all patients with new renal masses obtain multiphasic cross-sectional imaging to adequately characterize the mass. Individual urologists and their practices will be able to track their compliance rates to evaluate systems of care within their practice to ensure they are providing guideline compliant care.

There are several limitations worth noting. Despite a systematic re-review process of the primary medical record to ensure the fidelity of these data, there remains the possibility that some degree of guideline non-compliance may be due to missing data (such as testing obtained by another clinician or healthcare system which was not included in the patient's urological medical record), although, we have minimized this risk as much as possible. We applied a predefined time frame of 6 months prior and 4 months after the index consultation when measuring compliance with guideline recommended testing. The limitation of this strategy is testing obtained outside this interval did not meet the criteria for compliance. We chose this interval as this allows for the clinician to have accurate and recent information regarding the patient's health, renal function, and oncologic risk while discussing management and treatment options with the patient. As with any observational study which utilizes registry data, there is a concern for selection bias and confounding.

Complete guideline compliance in the initial evaluation of cT1 renal masses is poor, which is mainly driven by omission of chest imaging. Significant variation in guideline adherence is seen across practices, as well as by management strategy and renal mass size. There are ample quality improvement opportunities to increase adherence and decrease variability with guideline recommendations. Additionally, the low compliance with the recommendation to obtain chest imaging may reflect the perceived low utility of screening this population for thoracic metastatic disease. Further investigation to clarify the role of screening for thoracic metastasis in patients with cT1 renal masses, particularly in patients with cT1a renal masses, is needed.

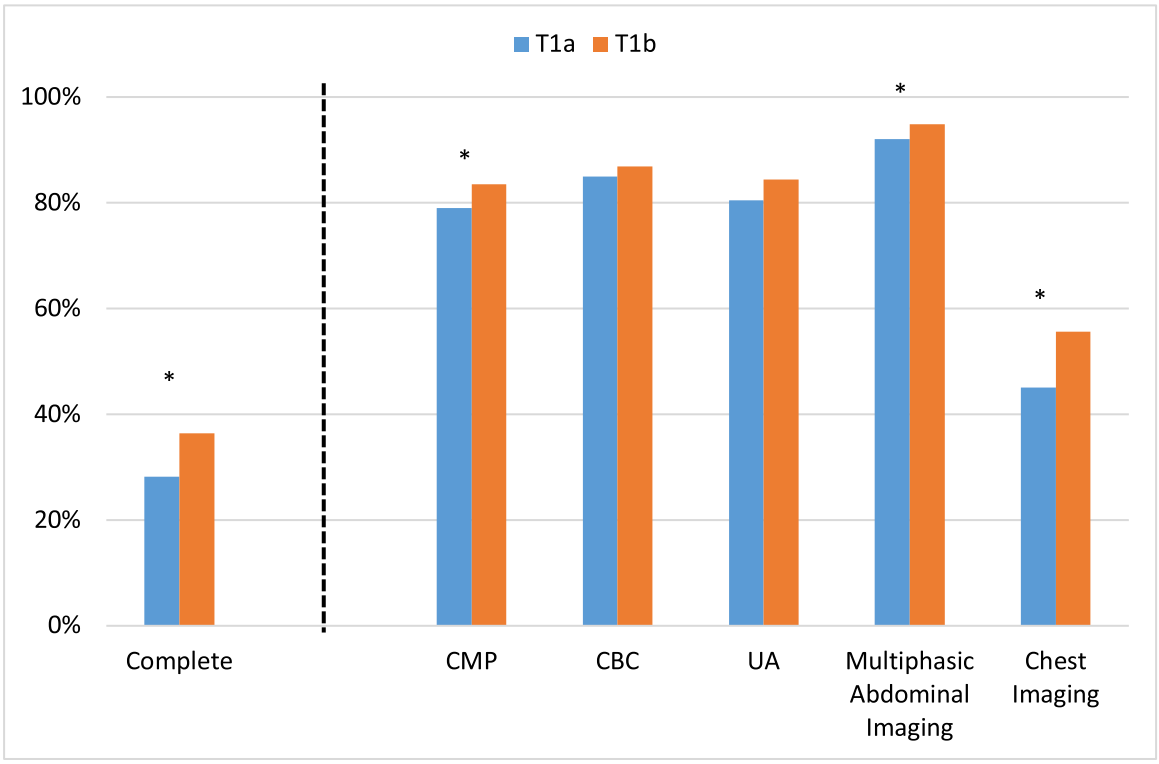

Figure 3. Continued

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References

1. Siegel RL, Miller KD, Jemal A. Cancer statistics, 2019. *CA Cancer J Clin*. 2019;69:7–34.
2. Campbell S, Uzzo RG, Allaf ME, et al. Renal mass and localized renal cancer: AUA Guideline. *J Urol*. 2017;198:520–529.
3. Womble PR, Montie JE, Ye Z, et al. Contemporary use of initial active surveillance among men in Michigan with low-risk prostate cancer. *Eur Urol*. 2015;67:44–50.
4. Ginsburg KB, Auffenberg GB, Qi J, et al. Risk of becoming lost to follow-up during active surveillance for prostate cancer. *Eur Urol*. 2018;74:704–707.
5. Ross I, Womble P, Ye J, et al. MUSIC: patterns of care in the radiographic staging of men with newly diagnosed low risk prostate cancer. *J Urol*. 2015;193:1159–1162.
6. Ginsburg KB, Jacobs JC, Qi J, et al. Impact of early confirmatory tests on upgrading and conversion to treatment in prostate cancer patients on active surveillance. *Urology*. 2021 Jan 1;147:213–222.
7. Dauw CA, Ghani KR, Qi J, et al. Variable use of postoperative imaging following ureteroscopy: results from a statewide quality improvement collaborative. *Urology*. 2020;136:63–69.
8. Luckenbaugh AN, Auffenberg GB, Hawken SR, et al. Variation in guideline concordant active surveillance followup in diverse urology practices. *J Urol*. 2017;197:621–626.
9. Morgan TM, Hawken SR, Ghani KR, et al. Variation in the use of postoperative radiotherapy among high-risk patients following radical prostatectomy. *Prostate Cancer Prostatic Dis*. 2016;19:216–221.
10. Ginsburg KB, Cher ML, Michigan Urological Surgery Improvement C, Montie JE. Defining quality metrics for active surveillance: the Michigan Urological Surgery Improvement Collaborative Experience. Reply. *J Urol*. 2021;206:172–173.
11. Noyes SL, Kim T, Johnson A, et al. Quality of care for renal masses: the Michigan Urological Surgery Improvement Collaborative - kidney mass: identifying & defining necessary evaluation & therapY (MUSIC-KIDNEY). *Urol Practice*. 2020 Nov;7(6):507–514.
12. Volpe A, Cadeddu JA, Cestari A, et al. Contemporary management of small renal masses. *Eur Urol*. 2011;60:501–515.
13. Sun M, Abdollah F, Bianchi M, et al. Treatment management of small renal masses in the 21st century: a paradigm shift. *Ann Surg Oncol*. 2012;19:2380–2387.
14. Daugherty M, Sedaghatpour D, Shapiro O, Vourganti S, Kutikov A, Bratslavsky G. The metastatic potential of renal tumors: influence of histologic subtypes on definition of small renal masses, risk stratification, and future active surveillance protocols. *Urol Oncol*. 2017;35. 153 e115-153 e120.
15. Umbreit EC, Shimko MS, Childs MA, et al. Metastatic potential of a renal mass according to original tumour size at presentation. *BJU Int*. 2012;109:190–194. discussion 194.
16. Lee H, Lee JK, Kim K, et al. Risk of metastasis for T1a renal cell carcinoma. *World J Urol*. 2016;34:553–559.
17. Thompson RH, Hill JR, Babayev Y, et al. Metastatic renal cell carcinoma risk according to tumor size. *J Urol*. 2009;182:41–45.
18. Kutikov A, Fossett LK, Ramchandani P, et al. Incidence of benign pathologic findings at partial nephrectomy for solitary renal mass presumed to be renal cell carcinoma on preoperative imaging. *Urology*. 2006;68:737–740.
19. Thompson RH, Kurta JM, Kaag M, et al. Tumor size is associated with malignant potential in renal cell carcinoma cases. *J Urol*. 2009;181:2033–2036.
20. Miller P, Mosley K. Physician reimbursement: from fee-for-service to MACRA, MIPS and APMs. *J Med Pract Manage*. 2016;31:266–269.