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Association of Frailty and Complications Following Prostate Biopsy: Results From a Population-Based, Privately Insured Cohort

Kayvon Kiani, Simon P. Kim, Rodrigo Rodrigues Pessoa, et al.

Correspondence: Eric Ballon-Landa (e-mail: e.ballon.landa@gmail.com).

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Study Need and Importance: Prostate biopsy is a potentially risky procedure that is commonly performed in older men, who may be frail. Although guidelines recommend against biopsy in men with limited life expectancy, it is often challenging to counsel patients to omit intervention. Thus, we sought to analyze the rates of complications among frail men receiving prostate biopsy in a large, nationally representative dataset.

What We Found: Frailty was measured within this claims-based database using the claims-based frailty index, a validated measure of frailty. Even in a relatively young cohort, men with any degree of frailty were more likely to experience a complication of prostate biopsy in the clinic, emergency department, or hospital setting (Figure). Frailty was associated with increased complications independent of age and Elixhauser index on multivariable analysis.

Limitations: While the risk of complication was increased, claims data do not differentiate the route of biopsy performed (transrectal vs transperineal), which may be a driver of complications. Additionally, because the number of frail patients overall was low, we were unable to stratify the analysis by the degree of frailty (prefrail, mild-moderate, severe). Finally, the clinical actionability of the claims-based frailty index is limited and not easily translatable to the patient encounter.

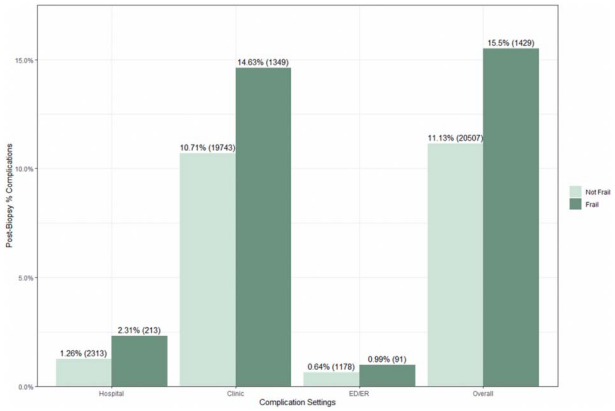

Figure. Adverse outcomes stratified by claims-based frailty index score (all P values $< .001$). ED indicates emergency department; ER, emergency room.

Interpretation for Patient Care: Clinicians challenged to evaluate for prostate cancer in an older, frail population may consider these findings as an additional support to omit biopsy in this high-risk group. Further work should be done to allow for reproducible, reliable evaluation of frailty that can be done in the clinic setting.

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Association of Frailty and Complications Following Prostate Biopsy: Results From a Population-Based, Privately Insured Cohort

Kayvon Kiani,[1] Simon P. Kim,[1] Rodrigo Rodrigues Pessoa,[2] Boris Gershman,[3] Christopher Gonzalez,[4] Elizabeth Molina,[5,6] Adam Warren,[5,6] Rodrigo Donalisio DaSilva,[1] Brian Chapin,[7] and Eric Ballon-Landa[1,8]

[1]*Department of Surgery, Division of Urology, University of Colorado, Aurora, Colorado*
[2]*Department of Urology, Mayo Clinic, Rochester, Minnesota*
[3]*Division of Urologic Surgery, Harvard Medical School, Beth Israel Deaconess Medical Center, Boston, Massachusetts*
[4]*Department of Urology, Loyola University Chicago Stritch School of Medicine, Maywood, Illinois*
[5]*Population Health Shared Resource (PHSR), University of Colorado Cancer Center, Aurora, Colorado*
[6]*Adult and Child Consortium for Health Outcomes Research and Delivery Science (ACCORDS), University of Colorado, Aurora, Colorado*
[7]*Department of Urology, MD Anderson Cancer Center, Houston, Texas*
[8]*VA Eastern Colorado Health Care, Aurora, Colorado*

Abstract

Introduction: Prostate needle biopsy (PNBx) is essential for prostate cancer diagnosis, yet it is not without risks. We sought to assess patients who underwent PNBx using a claims-based frailty index to study the association between frailty and postbiopsy complications from a large population-based cohort. We hypothesized that increased frailty would be associated with adverse outcomes.

Methods: Using Market Scan, we identified all men who underwent PNBx from 2010 to 2015. Individuals were stratified by claims-based frailty index into 2 prespecified categories: not frail, frail. Complications occurring within 30 days from prostate biopsy requiring emergency department, clinic, or hospital evaluations constituted the primary outcome. Unadjusted and adjusted analyses identified patient covariates associated with complications.

Results: We identified 193,490 patients who underwent PNBx. The mean age was 57.6 years (SD: 5.0). In all, 5% were prefrail, mildly frail, or moderately to severely frail. The rate of overall complications increased from 11.1% for not frail to 15.5% for frail men. After adjusting for covariates, individuals with any degree of frailty experienced a higher risk of overall complication (odds ratio [OR]: 1.29; $P < .001$), clinic (OR: 1.26; $P < .001$) and emergency department visits (OR: 1.32; $P = .02$), and hospital readmissions (OR: 1.41; $P < .001$).

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Corresponding Author: Eric Ballon-Landa, MD, MPH, Department of Surgery, Division of Urology, CU Anschutz School of Medicine, 12631 E 17th Ave, M/S 319, Aurora, CO 80045 (e.ballon.landa@gmail.com).

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Conclusions: Frailty was associated with a higher risk of complications for patients undergoing PNBx. Frailty assessment should be integrated into shared decision-making to limit the provision of potentially harmful care associated with prostate cancer screening.

Key Words: frailty, prostate cancer screening, risk assessment, geriatric urology

Frailty is a clinical syndrome defined as a reduced capacity to tolerate physiologic stressors that is often associated with adverse health outcomes.[1,2] It is estimated that by 2050, the world's population of people aged 60 years and older will double, exceeding 2 billion people.[3] Importantly, the prevalence of frailty among aging adults, irrespective of the definition used, ranges from 4% to 60%; up to 40% of elderly patients with cancer are found to have some degree of functional decline.[4,5] Various clinical proxies for frailty and frailty indices have been established in clinical practice, incorporating history and physical examination elements.[6] Additionally, simplified tests such as gait speed and the timed-up-and-go test may be utilized in lieu of more complicated screening tools.[7]

Despite guideline recommendations against prostate cancer (PCa) screening for men with limited life expectancy, its rates remain exceedingly elevated at around 38.6% among older patients.[8,9] While age is an important factor in decision-making, providers are often faced with a clinical dilemma when deciding whether to proceed with prostate needle biopsy (PNBx) in the setting of frailty. Despite the known morbidity associated with this procedure, clinicians lack validated tools to estimate the risk of complications, particularly among elderly patients with functional decline. Addressing this knowledge gap will better inform practice and facilitate the delivery of patient-centered care.

Prior studies have demonstrated that frailty scores can be used to predict clinical outcomes following numerous urologic interventions, with superior predictive ability to traditional comorbidity indices to predict outcomes.[10-13] However, the use of frailty as a tool to estimate the risk of complications following PNBx is largely unknown but an important consideration as part of shared decision-making (SDM). Addressing this critical knowledge gap would also provide a clinically meaningful SDM framework for patients and urologists. Herein, we aimed to evaluate the association between frailty scores based on a previously validated claims-based frailty index (CFI) with postbiopsy complication rates among patients undergoing PNBx from a large private health insurance database from the United States.

Materials and Methods

Study Design

We queried the Market Scan database to identify all adult males who underwent PNBx between 2010 and 2015 based upon the available data and to allow for follow up. Market Scan is an employer-based database that contains data for inpatient admissions, outpatient services, and pharmaceutical claims on over 260 million patients from the United States. Postbiopsy complications and their setting of occurrence were identified by International Classification of Diseases (ICD)−9 and Common Procedure Terminology (CPT) codes. We tabulated postbiopsy complications and examined associations between frailty status and other patient characteristics, including age and Elixhauser Comorbidity Index (ECI). Our study was deemed exempt from the University of Colorado Institutional Review Board.

Patient Population

We identified our target population of men undergoing PNBx from 2010 to 2015 using a similar methodology from our prior studies.[14] We selected all men between the ages of 40 and 70 years old who underwent PNBx from the outpatient clinic file by CPT for transrectal diagnostic ultrasound (76872 or 76942) or ultrasound guidance and prostate biopsy (55700) and excluded those who had 3 or more listed ICD-9 codes for PCa at least 1 year prior to the index PNBx in order to limit our cohort to those undergoing their initial biopsy. Patients were also required to have uninterrupted insurance coverage between at least 1 year prior and 2 years after the initial PNBx.

Covariates and Outcome Measures

Patient characteristics included were age, geographic region, health plan type, year of biopsy, and ECI. Complications occurring within 30 days from PNBx constituted the primary outcome of the study and encompassed urinary tract infection, kidney infection, prostatitis, cystitis, sepsis, hypotension, endocarditis, urinary retention, hematuria, and urinary catheter insertion. A comprehensive list of the ICD-9 codes used to identify each of these diagnoses is provided in the Supplemental Appendix (https://www.urologypracticejournal.com). Urinary catheter utilization was identified via CPT code. All complications were identified from clinical encounters occurring in emergency department (ED) visits, clinic visits, or hospital admissions. Complications were limited to 30 days from the date of biopsy. Complications were ranked hierarchically with hospital admission, ED, and clinic visit prioritized in that order.

Previous research by Kim et al has shown that a frailty score can be calculated from claims data.[13] Using similar methodology from a prior study,[11] publicly available software was then used to estimate a frailty score for each man in our cohort based on ICD 9/10 codes, CPT codes, and Healthcare Common Procedure Coding System codes. Patients were classified into 2 categories based on level of frailty: frail (CFI $\geq$0.15) and not frail (CFI $<$0.15). Additional frailty subgroups were not identified as the number of patients with moderate or severe frailty in our population was very low.

Statistical Analysis

Descriptive statistics were tabulated and bivariate analyses were used to evaluate the analytic cohort by primary outcome of postbiopsy complication stratified by frailty category. Unadjusted rates of complications encompassing clinic, ED, hospital visits, and overall complication were reported. We constructed a multivariable logistic regression model to identify covariates associated with postbiopsy complication. The independent variables incorporated into the analysis were age, region, ECI, health plan, and year of biopsy. SAS version 9.4 was employed for analysis (SAS Inc, Cary, NC). STROBE guidelines were followed in reporting the study.

Results

A total of 193,490 patients underwent an incident PNBx between 2010 and 2015. Demographic characteristics and outcomes stratified by frail and not frail for the entire cohort are described in Table 1. The mean age was 57.6 years (SD: 5.0). The mean ECI in the cohort was 1.14 (SD: 1.23). In all, only 4.8% (9222/193,490) of men included in our cohort met criteria for frailty. Over time there was a trend of fewer frail and nonfrail patients undergoing biopsy (frail: 24.4% in 2011 to 8.9% in 2015; nonfrail: 24.4% in 2011 to 7.3% in 2015). The Figure demonstrates higher complication rates noted among frail patients compared to nonfrail across all clinical settings. Overall, the complication rate was 15.5% in the frail vs 11.13% in the not frail ($P < .001$) and the majority of complications was seen in the clinic setting.

Table 2 presents the multivariable analysis of beneficiary covariates associated with postbiopsy complications. After adjusting for age, region, health plan, year, and ECI, frail men were more likely to experience a postbiopsy complication compared to nonfrail patients (odds ratio [OR]: 1.29; 95% CI: 1.21-1.37, $P < .001$), to require a clinic (OR: 1.26; 95% CI: 1.18-1.35, $P < .001$) or ED visit (OR: 1.32, 95% CI: 1.04-1.67, $P = .02$), and to be readmitted to the hospital (OR: 1.41, 95% CI: 1.20-1.65, $P < .001$). Higher ECI scores were also independently associated with increased incidence of overall complication, with those requiring either a clinic or ED visit, and readmission to the hospital (Table 2).

Table 1.
Patient Characteristics Stratified by Claims-Based Frailty Index Score

Characteristics	Not frail (N = 184,268, 95.23%) No. (%)	Frail (N = 9222, 4.77%) No. (%)	*P* value
Age, y			
40-49	13,363 (7.3)	410 (4.5)	< .0001
50-59	93,399 (50.7)	3881 (42.1)	
60-64	77,506 (42.1)	4925 (53.4)	
Region			
Northeast	41,947 (22.8)	2293 (24.9)	< .0001
North central	38,959 (21.1)	1890 (20.5)	
South	70,473 (38.2)	3606 (39.1)	
West	29,294 (15.9)	1241 (13.5)	
Unknown	3595 (2.0)	192 (2.0)	
Elixhauser Index			
0-1	134,057 (72.8)	1426 (15.5)	< .0001
2-3	44,049 (23.9)	4070 (44.1)	
≥4	6162 (3.3)	3726 (40.4)	
Health plan			
Employer	89,329 (48.5)	3964 (43.0)	< .0001
Health plan	94,939 (51.5)	5258 (57.0)	
Year			
2010	41,759 (22.7)	1768 (19.2)	< .0001
2011	44,884 (24.4)	2250 (24.4)	
2012	35,201 (19.1)	1797 (19.5)	
2013	26,043 (14.1)	1367 (14.8)	
2014	22,894 (12.4)	1219 (13.2)	
2015	13,487 (7.3)	821 (8.9)	

Discussion

Using a validated CFI, we have demonstrated that frailty is associated with increased post-PNBx complications. Our study adds several innovative findings to the complex process of SDM about appropriately counseling patients about the inherent risk of PNBx and the importance of frailty.

First, our study results provide evidence that objective measures of frailty are associated with complications attributable to prostate biopsy across the clinic, emergency, and hospital settings. Importantly, frailty was associated with a 1.8-fold increased risk of hospitalization and a 1.5-fold risk of ED evaluation within 30 days of prostate biopsy. Importantly, claims data are unable to distinguish between transrectal and transperineal approaches given that procedure codes for each are the same. Although during the study period 2010 to 2015, the majority of PNBx were performed transrectally, our data also reflect the transperineal biopsies performed during this period.

In the setting of an aging population, increased burden will be placed upon providers to decide when to proceed with

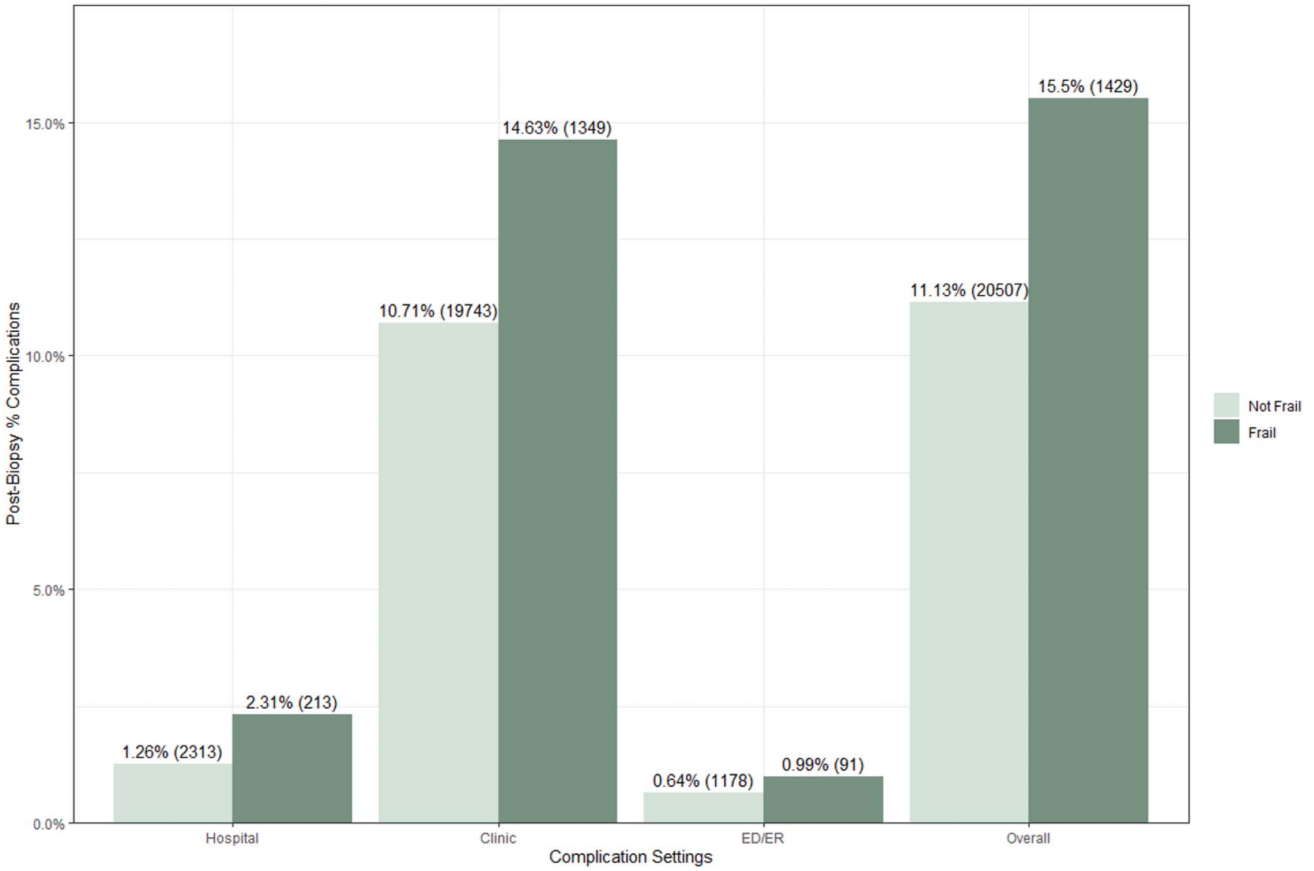

Figure. Adverse outcomes stratified by claims-based frailty index score (all *P* values < .001). ED indicates emergency department; ER, emergency room.

Table 2.
Multivariable Analysis for Association of Patient Characteristics With Postbiopsy Complications

Patient characteristics	Overall complication OR (95% CI)	*P* value	Clinic complication OR (95% CI)	*P* value	ED complication OR (95% CI)	*P* value	Hospital complication OR (95% CI)	*P* value
Claims-based frailty index								
Not frail (Ref)								
Frail	1.29 (1.21-1.37)	< .001	1.26 (1.18-1.35)	< .001	1.32 (1.04-1.67)	.02	1.41 (1.20-1.65)	< .001
Age	1.00 (0.99-1.00)	.05	1.00 (0.99-1.00)	.07	1.01 (1.00-1.02)	.15	1.00 (0.99-1.00)	.29
Region								
Northeast (Ref)								
North central	0.81 (0.78-0.85)	< .001	0.80 (0.77-0.84)	< .001	1.05 (0.89-1.25)	.57	1.05 (0.93-1.18)	.42
South	0.99 (0.95-1.02)	.46	0.98 (0.95-1.02)	.33	1.26 (1.09-1.46)	.002	1.04 (0.94-1.16)	.41
West	0.93 (0.88-0.97)	< .001	0.94 (0.89-0.98)	.005	1.01 (0.84-1.22)	.90	0.89 (0.78-1.02)	.08
Unknown	0.81 (0.73-0.90)	< .001	0.83 (0.74-0.92)	< .001	1.05 (0.70-1.57)	.83	0.74 (0.53-1.03)	.07
Elixhauser Index								
0-1 (Ref)								
2-3	1.10 (1.07-1.14)	< .001	1.09 (1.06-1.13)	< .001	1.13 (1.00-1.29)	.06	1.24 (1.13-1.36)	< .001
≥4	1.30 (1.22-1.38)	< .001	1.27 (1.20-1.36)	< .001	1.35 (1.07-1.72)	.01	1.81 (1.55-2.12)	< .001
Health plan								
Individual health plan (Ref)								
Employer-based health plan	0.79 (0.76-0.81)	< .001	0.78 (0.75-0.80)	< .001	0.78 (0.69-0.87)	< .001	0.92 (0.85-1.00)	.04
Year								
2010 (Ref)								
2011	1.01 (0.97-1.06)	.54	1.01 (0.97-1.06)	.55	0.86 (0.73-1.01)	.07	1.01 (0.90-1.13)	.89
2012	1.07 (1.02-1.11)	.004	1.07 (1.02-1.11)	.005	1.06 (0.90-1.25)	.50	1.07 (0.95-1.20)	.29
2013	1.05 (1.00-1.11)	.03	1.05 (1.00-1.10)	.06	1.10 (0.92-1.32)	.29	1.03 (0.90-1.17)	.70
2014	1.14 (1.08-1.20)	< .001	1.15 (1.09-1.21)	< .001	1.11 (0.92-1.34)	.29	1.00 (0.87-1.15)	.96
2015	0.97 (0.91-1.03)	.36	0.97 (0.91-1.04)	.38	0.74 (0.57-0.96)	.02	0.87 (0.73-1.04)	.12

Abbreviations: CI, confidence interval; ED, emergency department; OR, odds ratio; Ref, reference.

invasive interventions; the identification of frailty as a prognostic indicator of negative clinical outcomes in patients undergoing urologic procedures is increasingly recognized.[10,11,15-17] Various tests have been used to identify frailty in clinical practice, including simple physical testing, questionnaires, and clinician gross evaluation.[18] Despite multiple clinical practice guidelines for PSA screening stipulating a life-expectancy estimation prior to proceeding with screening, no clear test or method is established to identify this.[19] In the absence of this, frailty evaluation may allow clinicians to inform PSA screening practices and SDM, which could have important implications for the delivery of high-value care in the aging population.

Our results are consistent with the previous literature identifying an association between frailty and complications after invasive urological interventions.[10,15,16,20] To the best of our knowledge, however, this is the first study to date that evaluates the correlation between preprocedure frailty assessment and outcomes following prostate biopsy. Using National Surgical Quality Improvement Program data, Suskind et al demonstrated that increased frailty was associated with postoperative major (death, sepsis, hospital readmission, etc) and minor (blood transfusion, UTI, pneumonia) complications of urologic procedures, including cystectomies, prostatectomies, nephrectomies, endoscopic bladder tumor resections, sling placement, and hydrocele removal.[10] These data underscore the value of incorporating frailty into the preoperative assessment. Shinall et al conceptualized levels of operative stress and showed that even in traditionally low-risk urologic procedures, such as cystoscopy with fulguration or hydrocelectomy, there is an association with preoperative frailty and subsequent morbidity and mortality.[20]

Attention is needed to continue developing practical methods for evaluating frailty in a real-world setting that urologists can efficiently incorporate into a busy clinic schedule. Several tools and strategies intended to evaluate for frailty and reduce adverse clinical outcomes include gait speed, timed-up-and-go testing, or a simplified frailty phenotype.[7] While an optimal test has not yet been identified, clinicians broadly implementing these evaluations may reduce the overall burden that low-value care places on patients and the health care system.[9]

A second important finding is that frailty is associated with complications independently from age and ECI. In a European cohort of 78 patients over the age of 70 years undergoing urologic procedures, chronological age served as a poor correlate for frailty.[17] Comparatively, the larger sample size in our study increases its generalizability and similarly concludes risk of complications to have an association with frailty but not age. At 57.6 years, the younger mean age of our study cohort also suggests that there is value in assessing frailty in all individuals undergoing urologic procedures, not only the elderly. We incorporated ECI into our model as it is a validated predictor of complications and oncologic outcomes in urologic surgery.[21] Our data show that frailty, statistically independent of ECI, is associated with postprocedure complications. Although an association between ECI and complications was present in both the univariate and multivariate analysis when adjusting for frailty, the effects acted independently for ECI and CFI in our multivariate models. These data suggest that frailty assessment may offer actionable information to the preprocedure evaluation for clinicians.

Our study has several strengths about frailty and PNBx. We evaluated the validity of frailty, as measured objectively by claims data, associated with complications from PNBx using a large population-based cohort of privately insured patients. Our findings may be more generalizable than institutional or Medicare series evaluating the risk of complications from prostate biopsy given the population. Furthermore, we would put forward our analysis would allow for opportunities to assess quality of care and better adjusting for case mix.

There are a few limitations to these findings. First, the CFI used in the analysis was originally validated in a Medicare population. Our data are compiled from a privately insured cohort of patients, which is younger and overall less frail; however, the claims-based data draw from identical ICD and CPT codes; further, the effect of population level differences is likely mitigated by the large overall sample size. Additionally, the dataset was limited to the years 2010 to 2015, missing potentially more recent trends in prostate biopsy selection nationally. Second, our data did not include the clinical indication for biopsy. Evaluations for metastatic disease, for example, would factor into patient counseling and subsequent clinical decision-making. Third, while our methodology employs a similar study design from a population-based study centered on claims-based data,[16] we lack clinical outcomes data that could potentially more accurately identify whether a postbiopsy complication occurred, as unrelated events may have occurred in the postprocedure time frame. We also recognize that due to the relatively younger age of the beneficiaries the analysis did not stratify the cohort by level of frailty, as performed in previous analyses. This decision was made because the small size of moderately and severely frail patients did not allow for sufficient statistical power to achieve our analysis in these subgroups. We also did not distinguish infectious from bleeding or other complications, which may confer different levels of risk; however, the increased rates of hospitalization or ED visits confer additional risk, cost, and distress to frail patients and their caregivers, regardless of the proximate cause. Finally, our study was unable to evaluate the approach

used for prostate biopsy, and differential risks may exist depending whether a transrectal or transperineal approach was used.[22] Future studies should elucidate whether the risks of transperineal biopsy are limited such that clinicians may preferentially consider this approach for the frail man who may otherwise merit a biopsy.

Our analysis confirms in a large, nationally representative dataset that urologists should consider employing frailty as a risk index and tool for SDM around PSA screening and subsequent biopsy. We have identified that frail patients have an increased risk of complications following prostate biopsy. Following an elevated PSA test, urologists should identify and evaluate for frailty and pursue informed decision-making with patients while accounting for patient preference, national clinical practice guidelines, and competing risks of frailty to optimize diagnosis and limit morbidity.

Conclusions

Frailty is associated with a higher risk of complications following PNBx, with increased risk of escalation of care in both inpatient and outpatient settings. Frailty assessment should be integrated into SDM to aid in preventing potentially futile and harmful care associated with PCa screening.

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Editorial Commentaries

Kiani et al reviewed the morbidity associated with first-time ultrasound-guided biopsies of the prostate (TRUS B) in men ages 40 to 70 performed between 2010 to 2015; 193,490 TRUS B were identified.[1] They found that men listed as "frail" had a significantly higher risk of a complication. This is not unexpected. What surprised me was the high rate of complications: 11% for nonfrail and 15% for frail men. Most of the morbidity was from infection.

I became aware of the TRUS procedure with a visit with Professor Hans Henrik Holm in the 1980s. After obtaining a B and K machine and visiting William Cooner, a pioneer in TRUS B, in Mobile, Alabama, I began performing TRUS B.[2] Amazingly, it was not until 2000 that I realized there was an easy method to perform local anesthesia prior to the biopsies: the periprostatic nerve block. We published the method and it rapidly became routine.[3] Hard to believe I performed this procedure for years without anesthesia!

My antibiotic prophylaxis protocol has evolved, and over the last decade it consists of 750 mg oral ciprofloxacin 3 hours prior to the biopsy and 1 g intramuscular ceftriaxone 15 minutes before initiating the TRUS B. The patient continues oral ciprofloxacin daily for 3 days. The infection rate has been less than 1%!

Thus, I believe attention to detail with the technique and the antibiotic prophylaxis can dramatically decrease the rate of infection and other side effects.

A high percentage of my patients are over 70. Few are frail. I am not convinced that the procedure of transperineal prostate biopsy is needed because of the risk of infection from the transrectal approach.

Mark S. Soloway[1,2]
[1]*University of Miami*
Miami, Florida

[2]*Memorial Hospital*
Hollywood, Florida

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Shared decision-making (SDM) is a critical part of prostate cancer care with numerous benefits.[1] One part of SDM is to include frank and accurate assessments of the likelihood of unwanted outcomes. In this setting, Kiani et al demonstrate how frailty is associated with postbiopsy complications.[2]

We commend the authors for defining complications hierarchically based on health care utilization, as burden of care is particularly relevant among men undergoing biopsy. In addition to the risks of procedural intervention like biopsies, frailty can provide an estimate of competing risks of mortality in some urologic cancers,[3] which may select men in which undergoing biopsy to identify localized prostate cancer is unlikely to provide a survival benefit.

The results of this study call for greater implementation of frailty into SDM in urologic practice and suggest how a claims-based "calculator" (in this case, the claims-based frailty index [CFI]) can estimate the likelihood of complications. The next challenge is going to be implementing this type of calculator into clinical practice. Given the relative complexity of generating the CFI, most urologists will not be able to easily calculate this metric within a typical busy clinic.

One option is to integrate CFIs into an electronic medical record to provide a snapshot of frailty. Alternatively, "simple" frailty assessments like the timed-up-and-go test, gait speed, and sarcopenia may be used to approximate scores on these more sophisticated frailty indices. These data points may then be integrated into SDM for men considering invasive procedures like prostate biopsy.

Regardless of the approach used, identifying patients at greater risk of worse postoperative outcomes remains imperative in urologic practice and a foundation of SDM, and the authors should be congratulated for moving the needle in this key area.

John Ernandez[1] **and Alexander P. Cole**[1,2]
[1]*Department of Urology*
Brigham and Women's Hospital
Boston, Massachusetts

[2]*Center for Surgery and Public Health*
Brigham and Women's Hospital
Boston, Massachusetts

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