What Happens After an Elevated PSA Test: The Experience of 13,591 Veterans

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BACKGROUND: The occurrence and timing of prostate biopsy following an elevated prostate-specific antigen (PSA) test varied considerably in randomized screening trials.

OBJECTIVE: Examine practice patterns in routine clinical care in response to an elevated PSA test (≥ 4 ng/ μ l) and determine whether time to biopsy was associated with cancer stage at diagnosis.

DESIGN: Retrospective cohort study.

PARTICIPANTS: All veterans (n=13,591) in the Pacific Northwest VA Network with a PSA ≥ 4 ng/ μ l between 1998 and 2006 and no previous elevated PSA tests or prostate biopsy.

MAIN MEASURES: We assessed follow-up care including additional PSA testing, urology consults, and biopsies. We compared stage at diagnosis for men who were biopsied within 24 months vs. those men biopsied and diagnosed >24 months after the elevated PSA test.

KEY RESULTS: Two-thirds of patients received follow-up evaluation within 24 months of the elevated PSA test: 32.8% of men underwent a biopsy, 15.5% attended a urology visit but were not biopsied, and 18.8% had a subsequent normal PSA test. Younger age, higher PSA levels, more prior PSA tests, no copayment requirements, existing urologic conditions, low body mass index, and low comorbidity scores were associated with more complete follow-up. Among men who underwent radical prostatectomy, a delayed diagnosis was not significantly associated with having a pathologically advanced-stage cancer (T3/T4), although we found an increased likelihood of presenting with stage T2C relative to stage T2A or T2B cancer.

CONCLUSIONS: Follow-up after an elevated PSA test is highly variable with more than a third of men receiving care that could be considered incomplete. A delayed diagnosis was not associated with poorer prognosis.

KEY WORDS: prostate cancer; prostate-specific antigen (PSA); prostate biopsy.

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INTRODUCTION

Continued controversy remains regarding the benefit of PSA screening relative to its harms.¹ Differences in follow-up for men with elevated test results may be contributing to disparate findings between the negative US Prostate, Lung, Colorectal, and Ovarian (PLCO) screening trial² and the positive European Randomized Study of Screening for Prostate Cancer.³ In the US trial, 56% of men with an elevated screening test underwent a biopsy within 2 years,^{4,5} while a biopsy was documented in 89% of men with a suspicious finding in the European study.⁶ Follow-up of elevated prostate-specific antigen (PSA) tests in the community has not been carefully examined. One early report from 1993 documented that 46% of men with an elevated PSA test underwent a subsequent biopsy, but this is the only published study of which we are aware.⁷ We undertook an evaluation of follow-up of elevated PSA tests for veterans in the Pacific Northwest. Our goals were to characterize practice patterns following an elevated PSA test and determine whether the interval from the elevated PSA test to biopsy was associated with cancer stage at diagnosis.

METHODS

We identified all elevated PSA tests (≥ 4 ng/ μ l) in the five-state region that includes Washington, Oregon, Idaho, Alaska, and Northern California—called VISN20 (Veterans Integrated Service Network)—for the years 1998–2006. Data were accessed through

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the VISN20 regional data warehouse, a system of relational databases designed for research that encompass the information contained in the VA's electronic medical record.⁸ Notably, these databases include all clinic appointments, laboratory values, and records of biopsy tests. The facilities included in the study are the 7 primary medical centers in the VISN20 network and 27 community-based outpatient clinics (CBOCs). This study was reviewed and approved by the University of Washington and VA Institutional Review Boards; informed consent was waived.

Exclusion procedures. We excluded non-veterans, veterans younger than age 40 or older than age 75, men who died within 24 months of the date of the PSA test, and men with an elevated PSA, biopsy, or a prostate cancer diagnosis prior to 1998. Patients with PSA levels >50 ng/ μ l, who were likely to have symptomatic disease, were also excluded. Prostate cancer diagnoses were identified through two mechanisms. First, electronic pathology records were used to identify diagnoses at a VA Medical Center. Second, we searched for any ICD9 records associated with prostate cancer (codes 185 or 236.5) documented before the elevated PSA test in order to identify men who were diagnosed by outside pathologists.^{9,10} For initial exclusion criteria, we excluded all subjects with a single prostate cancer ICD9 code prior to the elevated PSA test. For later analyses of incident cancers not captured in the electronic VA pathology records, we required an ICD9 code for prostate cancer to be repeated on three separate dates, using the date of the initial code as the date of diagnosis.

Follow-up procedures. We identified multiple types of follow-up: biopsy, urology visit without a biopsy, and additional PSA testing without a biopsy or urology visit. Biopsy dates were identified using clinic visits indicating a biopsy procedure using codes 55700-55706, 76872, 76942, or 76943¹¹ or identification of records contained in the pathology specimen database with wild cards including %PROSTAT%, %PROS%, %BX%, %BIOP%, %PNBX%, or %PBX%. Urology appointments were identified based on clinic stop codes 414 or 65. Scheduling data were reviewed to identify subjects who had been scheduled for a urology consult but did not attend the consult during the follow-up period.

Patient Covariates. We assessed prior urologic conditions based on ICD codes identifying men with any diagnosis prior to the date of the elevated PSA including: benign prostatic hyperplasia, prostatitis, or other urologic conditions including hematuria.¹²⁻¹⁴

Comorbidity was assessed using the Quan adaptation of the Elixhauser comorbidity algorithm for administrative data.¹⁵ In addition, we identified two additional problems common to veterans: PTSD (309.81) and homelessness (codes V.60.0-V.60.6). Body mass index (BMI) was obtained from the clinic visit in which it was measured closest in time to the elevated PSA test date. Subjects were grouped by whether they were exempt from a co-pay. Exemption from co-pays is an indication of service-connected disability or low socioeconomic status. Rural/urban commuting area was assigned based on current zip code, which included large urban areas (population $>50,000$); larger rural areas/non-urban cities/towns (10,000-49,000 and $<30\%$ flow to urban area); and small rural areas ($<10,000$ population and low flow to urban area).^{16,17}

Statistical methods. Our categories of follow-up were hierarchical and mutually exclusive. First, we assessed whether a patient had received a biopsy or urology consult within 2 years, a time period used in a prior analysis of PLCO biopsy patterns.⁴ The 2-year period allowed patients the opportunity for repeat testing and a wide window to schedule (and receive) a urology consult and/or biopsy. If a patient had neither a biopsy nor a urology visit, we assessed whether he had additional PSA tests. Subjects receiving a biopsy, attending a urology visit, or receiving an additional PSA test where the result was normal (<4 ng/ μ l) were considered to have received complete follow-up. All other subjects were considered to have received incomplete follow-up.

We examined unadjusted associations between patient characteristics and completeness of follow-up using chi-square tests. A multivariate logistic regression model was used to estimate adjusted associations of covariates with completeness of follow-up. Goodness of fit of the logistic model was assessed using the Hosmer-Lemeshow test.¹⁸ Adjusted proportions of subjects receiving complete follow-up were calculated based on posttest estimates from the model using observed values of all other covariates for each prediction.

Association of delay in biopsy with cancer stage. We explored whether a delay in undergoing biopsy of more than 24 months was associated with cancer stage at diagnosis, using both clinical stage and pathologic stage information. Subjects diagnosed immediately after an elevated PSA test may include a mix of subjects for whom advanced disease is suspected. Symptom information or reason for the test (e.g., diagnostic or screening) was not available. In order to ensure both groups included asymptomatic men, we excluded men diagnosed 0-2 months ($n=422$, 20%) after the elevated test a priori because of the potential that these subjects may have received diagnostic testing for symptomatic disease. This assumption was evaluated in sensitivity analysis. We constructed logistic regression models comparing advanced stage disease (T3/T4) to earlier stage disease and multinomial logistic regression models¹⁹ comparing the distribution of all stage categories. The clinical stage multinomial models included four levels of stage groupings including T1A-C, T2A, T2B, and T3/T4, and the pathologic stage multinomial model included stage groupings of $\leq$ T2A, T2B, T2C, and T3/T4. Adjusted relative proportions of each stage by follow-up time interval were estimated by fixing the mean of each independent covariate.²⁰ All analyses were performed using Stata 11.0 (StataCorp, College Station, TX).

RESULTS

Patient Characteristics. We identified 16,040 veterans with an initially elevated PSA test between January 1, 1998 and December 31, 2006 who were between the ages of 40-74 at the time of the initial elevated PSA test and had no prior elevated tests. We excluded 1,253 men who were found to have a prior diagnosis of prostate cancer and 328 men with a prior prostate biopsy. A total of 142 men were excluded because the elevated PSA was ≥ 50 ng/ μ l. We excluded 726 men who died within 2 years of the initial elevated PSA test for a final sample

of 13,591 men. Characteristics of the study population are described in Table 1. Half of the men were between ages 65 and 74; 55% were living in an urban area, and 60% were currently married. Over 36% were obese with a BMI of 30 or higher. For 57%, the elevated PSA test was the patient's first PSA test in the VA database, while 18% of the men had three or more prior non-elevated tests. About 24% had urologic conditions, and only 17% had no comorbidity.

Table 1. Demographic and Clinical Characteristics of Patients

	N = 13,591	Percent
Year of elevated PSA test		
1998–2000	3,781	27.8%
2001–2003	4,469	32.9%
2004–2006	5,341	39.3%
Age at PSA test		
<55	1,490	11.0%
55–64	5,348	39.4%
65–74	6,753	49.7%
Race		
White	8,366	61.6%
Black	646	4.8%
Other/unknown	4,579	33.7%
Rural/urban area		
Small rural	3,412	25.1%
Large rural	2,735	20.1%
Urban	7,413	54.5%
VA Medical Center		
Seattle	3,184	23.4%
Anchorage	786	5.8%
Boise	1,669	12.3%
Portland	3,285	24.2%
Roseburg	1,956	14.4%
Spokane	1,579	11.6%
Walla Walla	1,132	8.3%
Means test		
Copay no longer required/exempt	6,579	48.4%
Copay required	7,012	51.6%
Currently married	8,140	59.9%
BMI		
<25	2,673	19.7%
25–29.9	5,622	41.4%
30–34.9	3,296	24.4%
35+	1,678	12.4%
Unknown	322	2.4%
Prior number of PSA tests (<4 ng/μl)		
No prior tests	7,732	56.9%
1	2,167	15.9%
2	1,279	9.4%
3+	2,413	17.8%
PSA level at elevated test		
4–6.9 ng/μl	10,283	75.7%
7–9.9 ng/μl	1,835	13.5%
10+ ng/μl	1,473	10.8%
Prior BPH diagnosis	2,197	16.2%
Prior prostatitis diagnosis	425	3.1%
Other prior urologic disease	677	5.0%
Number of comorbidities		
None	2,269	16.7%
1	3,536	26.0%
2	2,721	20.0%
3	1,579	11.6%
4 or more	3,486	25.7%
Common comorbidities		
Diabetes	2,153	15.8%
Hypertension	6,600	48.6%
Obesity	1,628	13.8%
Chronic pulmonary disease	2,143	18.1%
Congestive heart failure	492	4.2%

Follow-up care. Results of follow-up procedures within 2 years of the elevated test are provided in Table 2. Using a hierarchical structure, we examined seven types of follow-up. We identified 4,462 (32.8%) men who received a biopsy within 2 years of their initial elevated test result. An additional 2,110 (15.5%) men were seen within 2 years in a urology clinic within the VA's Northwest network, without a biopsy performed. We identified 2,554 (18.8%) men who had received subsequent testing where the PSA level was found to be normal (<4 ng/μl).

Among the remaining subjects, we identified 114 (0.8%) who had scheduled but cancelled at least one appointment with urology, where the reason was noted as "cancelled by patient." Another 317 (2.3%) subjects had at least one appointment scheduled, but were not seen in urology within 2 years where the reason for cancellation was noted as "other." We identified additional PSA tests that remained elevated among 2,272 (16.7%) of the remaining subjects. No additional follow-up procedures were identified among the remaining 1,762 (13.0%) men.

Several patient factors were associated with completeness of follow-up (Table 3). The proportion of patients receiving complete follow-up declined over time. Younger age, higher PSA levels, more prior (non-elevated) PSA tests, urologic conditions, higher BMI, and no co-pay requirement were associated with more complete follow-up. Notably, the number of comorbid conditions was not strongly associated with completeness of follow-up with the exception of men with very high comorbidity counts (≥4 conditions). Clinics associated with Anchorage and Portland had the highest proportion of patients receiving complete follow-up; there were no rural/urban differences based on patient address.

Cancer Outcomes

Within the 2-year window of the initial elevated PSA test, 4,462 men underwent a prostate biopsy with 1,825 cancer diagnoses, representing a 40.9% positive biopsy rate. Of the men who underwent a negative biopsy in the 2-year window, an additional 947 men were later re-biopsied and diagnosed with prostate cancer by the end of the follow-up period. Of those who delayed a biopsy for >24 months, 1,252 were eventually diagnosed with cancer during the study period. Overall, we identified 4,024 men with a diagnosis of prostate cancer, 29.6% of the study sample. Of the total 4,024 cancers identified, 2,151 (53.5%) were found through electronic pathology registry data, and an additional 1,873 (46.5%) were identified using ICD9 codes

Table 2. Follow-up Outcomes Within 2 Years of an Initially Elevated PSA Test

	N = 13,591	Percent
Follow-up considered as complete (n=9,126; 67.1%)		
Biopsy	4,462	32.8%
Urology visit without biopsy	2,110	15.5%
Additional PSA tests (<4 ng/μl) without urology visit or biopsy	2,554	18.8%
Follow-up considered as incomplete (n=4,465; 32.9%)		
Urology visit scheduled but cancelled by patient	114	0.8%
Urology visit scheduled but cancelled for other reason	317	2.3%
Additional PSA tests (≥4 ng/μl) without urology visit or biopsy	2,272	16.7%
No observed PSA-related follow-up procedures	1,762	13.0%

Table 3. Unadjusted and Adjusted Proportion of Patients Who Received Complete Follow-up Within 2 Years of an Elevated PSA Test

Year of elevated PSA test	Unadjusted proportions [†]	Adjusted proportions [‡]	P-value [‡]
1998–2000	69.9%*	73.7%	Ref
2001–2003	67.2%	68.3%	<0.001
2004–2006	65.2%	62.8%	<0.001
Age at PSA test			
<55	75.7%*	75.4%	Ref
55–64	72.4%	73.0%	0.060
65–74	61.1%	62.2%	<0.001
Race			
White	70.2%*	70.5%	Ref
Black	74.0%	69.0%	0.468
Other/unknown	60.7%	62.7%	<0.001
Rural/urban area			
Small rural	66.8%*	68.1%	Ref
Large rural	65.0%	68.0%	0.901
Urban	68.1%	67.6%	0.603
VA Medical Center			
Seattle	69.7%*	69.5%	Ref
Anchorage	81.3%	80.2%	<0.001
Boise	62.3%	65.2%	0.003
Portland	68.8%	73.6%	0.009
Roseburg	67.0%	64.2%	<0.001
Spokane	62.1%	61.8%	<0.001
Walla Walla	59.9%	58.7%	<0.001
Means test			
Copay no longer required/exempt	69.8%*	70.0%	Ref
Copay required	64.7%	65.7%	<0.001
Marital status			
Not currently married	69.3%*	68.5%	Ref
Currently married	65.7%	67.3%	0.165
BMI			
<25	65.4%**	66.0%	Ref
25–29.9	67.6%	68.2%	0.045
30–34.9	69.3%	68.7%	0.031
35+	69.4%	67.6%	0.305
Prior number of PSA tests (<4 ng/μl)			
No prior tests	61.7%*	61.2%	Ref
1	70.4%	71.3%	<0.001
2	72.6%	73.8%	<0.001
3+	78.7%	80.6%	<0.001
PSA level at elevated test			
4–6.9 ng/μl	65.3%*	65.4%	Ref
7–9.9 ng/μl	69.7%	72.5%	<0.001
10+ ng/μl	76.9%	78.6%	<0.001
Prior urologic conditions			
No prior BPH diagnosis	66.5%*	67.0%	Ref
Prior BPH diagnosis	70.3%	72.0%	<0.001
No prior prostatitis diagnosis	66.6%*	67.5%	Ref
Prior prostatitis diagnosis	84.7%	78.4%	<0.001
No other prior urologic disease	66.1%*	67.0%	Ref
Other prior urologic disease	87.6%	85.5%	<0.001
Number of comorbidities			
None	68.0%	71.0%	Ref
1	66.2%	68.6%	0.069
2	67.6%	67.6%	0.021
3	69.8%	67.0%	0.021
4 or more	66.1%	64.9%	<0.001
Common comorbidities			
Diabetes – no	67.1%	67.8%	Ref
Diabetes – yes	67.3%	68.0%	0.872
Hypertension – no	66.3%***	67.0%	Ref
Hypertension – yes	68.1%	68.6%	0.088

Table 3. (continued)

Year of elevated PSA test	Unadjusted proportions [†]	Adjusted proportions [‡]	P-value [‡]
Obesity – no	67.9%**	67.5%	Ref
Obesity – yes	71.3%	70.0%	0.058
Chronic pulmonary disease – no	68.1%	67.6%	Ref
Chronic pulmonary disease – yes	69.6%	69.0%	0.211
Congestive heart failure – no	68.6%***	68.0%	Ref
Congestive heart failure – yes	63.4%	63.4%	0.034

[†]Unadjusted p-values based on chi-square comparisons. Significance levels for chi-square tests at *P < 0.001, **P < 0.01, and ***P < 0.05.

[‡]Adjusted proportions based on multivariate logistic regression with complete follow-up within 2 years as the dependent variable and all listed variables as independent variables.

in the electronic medical records.^{9,10} Among the cancers identified through electronic pathology records, clinical stage information was available for 2,060 (95.8%), with pathologic stage available for a subset of 643 (29.9%) men.

Based on clinical stage information, the frequency of advanced stage (clinical T3/T4) among men with a delayed diagnosis (>24 months) was similar, 3.1%, compared to men diagnosed 3–24 months after the elevated PSA test, 5.5%. In multivariate logistic regression models there were no differences in clinical stage at diagnosis by time of biopsy (p=0.211). Similarly, among the subgroup of men undergoing radical prostatectomy for whom pathologic stage information was available, the frequency of advanced stage disease (path T3/T4) was similar among men diagnosed soon after the PSA test (3–24 months) compared to men with a delayed diagnosis (>24 months), 20.8% vs. 18.8%, respectively (p=0.657). The adjusted odds ratio was 1.06 (95% CI: 0.56–1.99). Findings from our sensitivity analysis, which included potentially symptomatic men diagnosed in months 0–2, were similar to our main analysis (OR 1.04; 95% CI: 0.73–1.47). We did observe differences in the distribution of T2 disease (Table 4) between men diagnosed early compared to men with a delayed diagnosis. We note the low frequency of stage T2B disease observed among the delayed diagnosis group, which was 2% vs. 17.8% (p<0.001) in adjusted analyses and the higher frequency of T2C disease, 66.4% vs. 38.0% (p<0.001), respectively.

Table 4. Proportion of Patients in Each Pathology Stage Category by Time to Diagnosis

	Observed (unadjusted) proportion by stage			Adjusted proportion by stage based on multinomial regression		
	Biopsy 3–24 months (N=384)	Biopsy 24+ months (N=101)	p-value	Biopsy 3–24 months (N=384)	Biopsy 24+ months (N=101)	p-value
T2A	18.5%	19.8%	0.766	21.5%	14.1%	0.098
T2B	20.8%	5.0%	<0.001	17.8%	2.0%	<0.001
T2C	39.8%	56.4%	0.003	38.0%	64.4%	<0.001
T3/T4	20.8%	18.8%	0.657	22.7%	19.5%	0.490

Chart abstraction to assess non-VA care. The VA databases capture only laboratory results, biopsy and clinical visits performed within the VA. In order to assess care outside of the VA, we randomly sampled 111 subjects from the 13,591 for manual chart review. We identified 11 subjects who, after review, should have been excluded. Based on chart notes, one subject had a prostate cancer diagnosis prior to the elevated PSA test; one subject had a prior diagnosis of rectal cancer; one subject was identified with a prior biopsy; and eight subjects were found to have a prior elevated PSA. Of the 100 remaining eligible subjects, 39 had been identified with a biopsy in electronic data, which was noted for all 39 charts. Among the 61 men who did not receive a biopsy, provider notes indicated a biopsy was performed outside of the VA for 5 subjects (8.2%), all with benign findings.

DISCUSSION

We found considerable variation in practice patterns following an elevated PSA test, including a substantial proportion that we considered to have received incomplete care. Among our cohort of 13,591 veterans, we were able to document that one third underwent prostate biopsy within 2 years of the elevated PSA test, while 16.7% did not see a urologist despite having repeat PSA tests that remained elevated, and 13.0% were neither referred to urology nor retested. Based on both available clinical and pathologic stage information, we did not observe an increased likelihood of men with a delay in biopsy presenting with advanced stage disease. However, among men with pathologic stage information, we did observe that a delay of more than 24 months in undergoing biopsy was associated with an increased likelihood of pathologic stage T2C relative to stage T2A or T2B, indicating that our models are sensitive to slight shifts in stage. The clinical significance of this difference is uncertain as no differences in survival have been found between men with stage T2C compared to T2A/B.²³

Our results highlight the practice differences between real world and clinical trial settings. The frequency of biopsy following an elevated PSA test among this cohort was lower than in the PLCO trial, where 56% of subjects were biopsied within 2 years of an elevated test at the first screen and 44% if the elevated test was at a subsequent screen.^{4,5} Continuing to monitor elevated tests with additional tests without referral to urology appeared to be common, and in 19% of men a subsequent PSA was below 4 ng/μl, which is consistent with fluctuations recently reported by Ankerest et al.²⁴ There is little consensus about the optimal threshold at which to recommend biopsy,²¹ and there is no indication that outcomes are inferior for any PSA levels under 10.²²

The psychological implications of suspicious cancer tests are substantial. Men who are told they have a suspicious result and undergo a biopsy that turns out to be benign report considerable anxiety before and after the biopsy,²⁵ although most would willingly repeat the experience.²⁶ The implications for men with an elevated result that is not promptly followed are not known. Additionally, we must consider anxiety among those who are eventually diagnosed months later as they wonder whether their outcomes would have been improved if they had acted sooner on the elevated test.

While shared decision making between patient and physicians has received attention related to PSA screening and treatment decisions,^{27–30} there is little information about the shared decision process in the context of acting on an elevated test. Ideally, the decision to follow up a suspicious test would be discussed as part of the original conversation when ordering the test, although the practice of ordering PSA tests without patient awareness is common.^{31,32} Understanding patient preferences for follow-up after an elevated test is an important future direction, especially as the AUA has recommended the use of individualized risk counseling for determining when to biopsy rather than a specific PSA threshold.²¹

Our study has several limitations. The VA is not a closed system, and patients with private health insurance or Medicare can seek care outside of the VA. Therefore, we may have inadvertently included subjects with prior elevated PSA tests, negative biopsy, or prior prostate cancer diagnosis not observed within the VA, and we may have misclassified follow-up care if a subject obtained care outside of the VA. Our chart audit was performed to assess the extent of non-VA care. Through the audit we found provider notes indicating 5 men out of 61 (8.2%) received a biopsy outside of the VA. Our chart audit may underestimate the true proportion of non-VA care as documentation in the chart relies on a VA provider manually entering information about outside care after learning about that care from a patient at a subsequent visit or receiving notification from an outside provider. Non-VA care may be common as nationally 43% of veterans under 65 eligible for VA care reported also having private insurance and 21% of those 65 and older reported dual coverage between VA and Medicare.³³

VA care patterns may not be generalizable to other settings. The VA has previously been demonstrated to have higher utilization of PSA screening compared to community practice, with 62% of veterans over age 40 reporting receiving a PSA test in the past 2 years compared to 42% for non-veterans in the US.^{12,34} The high frequency of screening may translate into differences in follow-up patterns. VA providers have electronic access to each patient's complete PSA history (and all other laboratory tests) as well as the patient's entire encounter history, which may influence follow-up recommendations.³⁵

Notably, the frequency of gaps in follow-up for elevated tests appears to be getting worse, rather than better, in more recent years. Increasing skepticism about the value of PSA screening may have contributed to the large numbers of tests that were not referred for biopsy, and the lack of clarity about the value of screening following the recent randomized trials may potentially exacerbate the problem in the future. The negative consequences of unfollowed tests are substantial and in addition to patient harm include risk of provider malpractice.^{36–39} We recommend that patients be fully informed about the risks and benefits of screening and that providers should not order tests that they (or their patients) are not prepared or willing to follow with a biopsy.

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