Factors affecting post-vasectomy semen analysis compliance in home- and lab-based testing

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ABSTRACT

Introduction: We used a home-based (HB) post-vasectomy semen analysis (PVSA) between 2014 and 2017, but we have since reverted to local lab-based (LB) testing. In this study, we compared PVSA compliance rates in HB and LB test settings and describe factors that may influence completion rates.
Methods: We retrospectively identified patients who underwent vasectomy at our institution. Surgeons X and Y performed vasectomies from 2014–2017 using a HB immunochromatographic PVSA kit. From 2017–2020 surgeon X used a local LB PVSA. We collected data on PVSA completion status and patient demographics to perform two analyses. HB testing was examined by assessing all patients who had a vasectomy from 2014–2017. Another compared HB and LB testing by looking at surgeon X vasectomies from 2014–2017 and 2017–2020.
Results: We identified 285 patients who underwent vasectomy from 2014–2017 and were assessed with HB testing. Compliance with PVSA was 35% with HB PVSA. Age at vasectomy, number of children, and surgeon influenced PVSA completion in the 2014–2017 cohort.

KEY MESSAGES

- Home-based testing may decrease compliance with PVSA.
- Surgeon factors may influence the likelihood of PVSA compliance.
- An increasing number of children appears to decrease PVSA compliance.

Surgeon X PVSA completion was 29% for the HB (n=136) testing cohort and 46% for the LB (n=201) cohort (odds ratio 0.47, 95% confidence interval 0.29–0.74). Again, more children decreased PVSA completion.
Conclusions: Compliance with PVSA testing was inadequate in both test settings, although it was significantly higher in local LB setting. Based on these findings, the convenience of HB testing appears to decrease compliance with PVSA, although surgeon factors may be influential. These findings may help surgeons identify factors that improve PVSA compliance rates.

INTRODUCTION

Vasectomy is the most common (non-diagnostic) procedure urologists perform in the United States. It is estimated that over 500,000 vasectomies are performed in the United States yearly[1]. It is a safe, quick, and cost-effective method of contraception. However, vasectomy failure can occur, generally due to recanalization or technical failure. Pregnancy due to recanalization is estimated to occur after approximately 1 in 2000 vasectomies[2]. American Urologic Association (AUA) guidelines recommend a post-vasectomy semen analysis (PVSA) to confirm sterility[3]. The PVSA serves both as surgeon quality control and reassurance for the patient. However, compliance with lab-based (LB) PVSA is poor and highly variable with previous studies demonstrating PVSA compliance rates of 21-76.5%[4-15].

Historically, completion of a PVSA involves the patient returning to the office or a laboratory to have his ejaculate evaluated by a trained technician or physician. This can be both inconvenient and costly. A self-assessed home-based (HB) PVSA test has been approved by the FDA for clinical use however is not approved by the AUA guidelines[3]. This test is sensitive to sperm counts of >250,000/ml, with a negative predictive value of 99.9% if two tests are performed and negative[16]. It has been suggested that a HB test may improve patient compliance. While this notion was explored in recent literature, there are no current publications that prove HB PVSA tests yield greater compliance rates[13-15]. In addition, specific factors influencing compliance rates in different test settings were not identified.

At our institution, we began utilizing a HB PVSA test from 2014-2017, as we believed this would be more convenient for patients and improve patient compliance with PVSA. However, we have since reverted back to LB testing. In this study, we analyzed patient compliance in HB and LB settings for PVSA testing and attempted to identify factors that affect compliance. We hypothesized that HB testing would have a higher compliance rate due to the convenience.

METHODS

After institutional review board approval, we reviewed the electronic medical record (EMR) of patients who underwent a vasectomy between December 2014 and January 2017 by Surgeon X and Surgeon Y (CW and AM, respectively). We then reviewed the EMR for patients who underwent a vasectomy between July 2017 and August 2020 by Surgeon X (CW)—Surgeon Y had moved to another institution and was excluded from this second time period analysis. In both cohorts, patients were identified by the common procedural code for vasectomy (CPT 55250). At the time of initial vasectomy consultation, risks and complications of the procedure were discussed with the patient by the respective surgeon, along with plans for a PVSA using a HB kit in the 2014-2017 group and traditional LB testing in the 2017-2020 group.

After the vasectomy, patients from the 2014-2017 cohort were given information to order the HB immunochromatographic PVSA kit (SpermCheck®, Charlottesville, Virginia) and their information was provided to Spermcheck® who utilized direct patient-vendor communication (text, phone calls) to remind patients to complete their PVSA. Patients in the 2017-2020 cohort were referred to a local lab for PVSA testing and given a sterile collection cup and lab slip.

Compliance with the HB PVSA kit was ascertained via monthly reports generated by patient-vendor communication which documented both purchase and completion of the test. Compliance in the 2017-2020 group was confirmed by presence of LB PVSA results within patient charts.

Demographic patient data were collected from our EMR including the patient's surgeon, insurance type (self-pay, private, public, or military-based), age, body mass index (BMI), number of children, date of initial consultation, date of vasectomy, age at time of vasectomy, completion status of PVSA, if a post-procedure call was placed, and if an unplanned post-procedure visit occurred. Post-procedure visits are not routinely scheduled at our institution.

Continuous data is reported as mean and standard deviation with Student's independent sample t-test used for comparison. Categorical data are reported as frequencies and proportions with associations between variables tested with chi-square test. Binary logistic regression was used to estimate the odds of test completion as a function of independent variables including patient age, BMI, number of children, post-op call (yes/no), unplanned office visit (yes/no), insurance type (self + private, public, military), and surgeon (X or Y). In the case of self-pay patients, these were combined with private insurance. Univariate and multivariable odds ratios for categorical and continuous associations were calculated. Minitab statistical software (Minitab LLC, State College, Pennsylvania) was used with statistical significance of $p < 0.05$.

RESULTS

Analysis of patients from 2014–2017

A total of 285 patients were identified who had vasectomy and were scheduled for HB PVSA during 2014-2017. Of the 285 patients who underwent a vasectomy at our institution, 149 patients underwent a vasectomy by Surgeon Y, and 136 patients underwent a vasectomy by Surgeon X (Table 1). Overall completion of HB PVSA was 35%. Of the 285 patients who were recommended to HB PVSA only 118 even purchased the home kit. Of those who did purchase the product, the PVSA compliance was 86% (102/118).

When tested separately (univariate analysis), increasing age at vasectomy (OR=1.04, p=0.026), increasing number of children (OR=0.70, p=0.001), and surgeon (OR=0.56, p=0.023) were found to influence PVSA compliance (Table 2). No statistically significant effect was found with insurance type, BMI, if a post-procedure call was placed, or if an unplanned post-procedure visit occurred. When all independent variables in Table 2 were used in a multivariable logistic regression, results were similar for the odds ratios and levels of significance (presented in supplementary table 1). The odds of completing the test increased to a factor of 1.54 (95% CI=1.05-2.26) for each decade of age increase.

The average age of the 102 patients who completed the HB test was 38.4, while the average age of the 184 patients who did not complete the HB test was 36.7 (Table 1, p=0.026). The completion of PVSA was increased by a factor of 1.04 per year of age at which vasectomy was performed (95% CI 1.01-1.08). The odds of completing the test increased to a factor of 1.54 (95% CI 1.053 to 2.258) for each decade of age increase.

An increasing number of children decreased the likelihood of completing the HB PVSA (Table 1, p=0.002). The odds of completion of PVSA were decreased with each child by a factor of 0.70 (Table 2, 95% CI=0.56-0.87).

Forty-six percent of patients who underwent a vasectomy by Surgeon Y completed their HB PVSA while 28% patients who underwent a vasectomy by Surgeon X (Table 1, p=0.023). Patients treated by Surgeon X were less likely to complete HB PVSA than Surgeon Y by a factor of 0.56 (Table 2, 95% CI=0.34-0.92).

Analysis of surgeon X's patients from 2014–2017 and 2017–2020

Surgeon X performed 337 vasectomies from 2014-2020 with 136 patients from 2014-2017 (HB group) and 201 from 2017-2020 (LB group). Table 3 demonstrates factors associated with compliance for Surgeon X.

Twenty-nine percent of patients who underwent a vasectomy by Surgeon X completed their HB PVSA test, while 46% of patients completed the LB PVSA test (p=0.001). Patients in the HB cohort were statistically less likely to complete PVSA than the LB cohort (OR 0.47, 95% CI=0.29-0.74, Table 4). Increasing BMI had a minor effect on PVSA completion (OR=0.91, 95% CI=0.87-0.96). Again, an increasing number of children decreased the likelihood of completing the PVSA (OR=0.76, 95% CI=0.63-0.91).

When all independent variables in Table 4 were used in a multivariable logistic regression, results were similar for the odds ratios and levels of significance (supplementary table 2).

DISCUSSION

Compliance with PVSA has been consistently incomplete in published reports, ranging between 21 and 76.5%[4-15]. The rates of compliance of course depend on a variety of factors including how compliance is defined (Supplemental Table 3). Our findings revealed a compliance percentage of only 35% in the 2014-2017 period where HB PVSA was used exclusively. When comparing a single surgeon series compliance rate between HB and LB testing, we found a large difference with 29% of men completing HB testing and 46% completing LB testing. The results for compliance with HB testing in our study are especially concerning and amongst the lowest values seen in the existing literature (Supplemental Table 3).

Two recent studies, one by Trussler et al and another by Punjani et al, found that HB and LB PVSA test compliance rates did not significantly differ from each other[14, 15]. Punjani et al also attempted to identify specific patient demographics that may associate with PVSA test completion, however, they did not find any examined factors to have a significant association. A notable difference between our cohort and the cohorts in these other studies is the practice location. These other studies examined major metropolitan areas (New York City and Boston) compared to our analysis of a much smaller city. A possible explanation for these location differences is that HB testing may be more attractive to men living in larger metropolitan areas where travel and the associated costs of visiting a clinic (e.g parking) are more substantial making a trip to perform a LB test more cost prohibitive.

Utilization of a HB sperm test has theoretical advantages beyond the costs and inconvenience of traveling to perform the test. LB tests require technicians that are trained in sample preparation to visualize residual sperm, leading to increased costs of testing that are often passed on to patients. In our market, the out-of-pocket expense for patients to complete the LB PVSA can be as high as $150 and is generally not covered by health insurance. To that end, completion of the HB test may prove to decrease the overall cost incurred by the patient as the HB test was $59 during the study period. Despite the lower costs and increased convenience of HB testing, we unfortunately did not see an improvement in PVSA compliance in our cohort.

There were three statistically significant factors from the study that were associated with compliance in the 2014-2017 group: increasing patient age, increasing number of children, and surgeon (Table 1 and 2). When comparing the single surgeon series from 2014-2020 we again note that increasing number of children associates with PVSA compliance and that testing location (HB vs LB) is also an important associating factor (Tables 3 and 4). However, the differences between statistical and clinical significance should be considered when assessing our results. The minimal age difference (36.7 vs 38.4 years) and odds ratio (1.04) do meet statistical significance in our analyses, but it is unlikely that these differences are of clinical difference. The differences however in surgeon, testing location and increasing number of children are statistically significant and likely important clinical findings with regards to PVSA completion. Our findings that compliance increase with age is consistent with the findings of Christensen et al[5]. In their study, they further divided PVSA compliance by age groups, and the 50+ group demonstrating the highest compliance.

An interesting finding in our study is that an increasing number of children associates with less compliance with PVSA. In the study by Smucker et al[13], 141 post-operative vasectomy patients in a family practice center underwent a survey to assess reasons for a poor rate of follow-up. Respondents did not return for the reasons of inconvenience, embarrassment, confidence in sterility, forgetfulness, or being afraid of repeat surgery. Patients with increased number of children may have less concerns about vasectomy failure than those who planned for one or two children, or they may have increased responsibilities due to this increased number of children making compliance more challenging.

Interestingly we did find that the surgeon performing the procedure affected compliance with PVSA and we do not believe this has previously been reported in the literature. A possible explanation for this is the effect of surgeon counseling on the importance of PVSA or other provider specific characteristics (use of electronic records for reminders, experience, technique, referral pattern).

The accuracy and reliability of testing being reported is of course a concern but for different reasons between the HB and LB cohort. With regards to LB testing, it is possible that the patient could have performed the testing without report being sent to the ordering provider. We find the possibility a completed LB test would not be captured in the EMR to be unlikely as there is a legal obligation in New York State for the lab to report findings to the ordering provider in a timely fashion.

As the patient is the one performing the test in the HB group, concerns about test results being reported to the vendor (and then provider) are warranted. The vendor makes multiple efforts to contact the patient both by text and email to mitigate this possibility. As 86% (102 of 118 patients) who purchased the HB PVSA kit completed testing, the likelihood that patients performing the test but not reporting the results to the vendor would significantly change our findings is difficult to discern but unlikely.

This paper must be interpreted with regards to its limitations. These include its retrospective nature and chart-based information gathering. Furthermore, there are limited comparisons for patients of Surgeon Y due to a lack of a cohort group that utilized LB testing for Surgeon Y in 2017-2020. Additionally, it is possible that compliance rates were impacted by the Covid-19 pandemic in the 2017-2020 cohort although this cohort did have a higher likelihood of testing compared to the previous cohort.

CONCLUSIONS

Compliance with PVSA testing was inadequate in both test settings, though it was significantly higher in LB setting. Based on these findings, HB testing appears to decrease compliance with PVSA although may be related to our cohort as surgeon was also predictive of PVSA completion. These findings may help surgeons identify factors that improve PVSA compliance rates and providers should consider avoiding HB testing based on these results.

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FIGURES AND TABLES

Table 1. Factors associated with compliance with home based PVSA testing from 2014–2017

	Did not complete n=184	Completed n=102	p
Age (SD)	36.7 (6.7)	38.4 (5.7)	0.026
BMI (SD)	30.3 (5.5)	29.2 (5.6)	0.12
Mean number of children (SD)	2.5 (1.5), range 0–10	2.0 (1.1), range 0–5	0.001
Insurance			0.39
Private or self	167 (63%)	97 (37%)	
Medicare/Medicaid	13 (81%)	3 (19%)	
Military	4 (67%)	2 (33%)	
Surgeon			0.023
Y	87 (54%)	62 (46%)	
X	97 (72%)	39 (28%)	
Phone call			0.38
Yes	22 (58%)	16 (42%)	
No	162 (65%)	86 (34%)	
Unplanned office visit			0.78
Yes	20 (67%)	10 (33%)	
No	164 (64%)	92 (36%)	

Note: Calculated percentages displayed are the percentage of patients in that row who completed or did not complete PVSA. BMI: body mass index; PSAV: post-vasectomy semen analysis.

Table 2. Univariate odds ratios for HB PVSA complication for all patients from 2014–2017

	OR	95% CI
Age (per year)	1.04	(1.01–1.08)
BMI (per unit increase)	0.96	(0.92–1.01)
Number of children (per child)	0.70	(0.56–0.87)
Insurance (private/self as reference)		
Public	0.40	(0.11–1.44)
Military	0.87	(0.15–4.83)
Surgeon (X vs. Y)	0.56	(0.34–0.92)
Phone call (Y/N)	1.37	(0.68–2.7)
Unplanned office visit (Y/N)	0.89	(0.40–1.99)

BMI: body mass index; CI: confidence interval; HB: home-based; OR: odds ratio; PSAV: post-vasectomy semen analysis.

Table 3. Factors associated with compliance with any PVSA testing for surgeon X patients from 2014–2020			
	Did not complete n=205	**Completed n=132**	**p**
Age (SD)	43.1 (7.7)	43.3 (7.2)	0.34
BMI (SD)	30.4 (5.2)	28.1 (4.8)	<0.001
Mean number of children (SD)	2.5 (1.5), range 0–10	2.0 (1.1), range 0-5	0.004
Insurance			0.06
Private or self	286 (52%)	267 (48%)	
Medicare/Medicaid	33 (72%)	13 (28%)	
Military	2 (40%)	3 (60%)	
PVSA test setting			0.001
Home	97 (71%)	39 (29%)	
Lab	108 (54%)	93 (46%)	
Phone call			0.97
Yes	20 (59%)	14 (41%)	
No	185 (53%)	118 (47%)	
Unplanned office visit			0.96
Yes	24 (59%)	17 (41%)	
No	181 (49%)	115 (51%)	

Note: Calculated percentages displayed are the percentage of patients in that row who completed or did not complete PVSA. BMI: body mass index; PSAV: post-vasectomy semen analysis; SD: standard deviation.

Table 4. Univariate odds ratios for factors associated with PVSA compliance for any PVSA testing for surgeon X patients from 2014–2020		
	OR	**95% CI**
Age (per year)	1.02	(0.98–1.05)
BMI (per unit increase)	0.91	(0.87–0.96)
Number of children (per child)	0.76	(0.63–0.91)
Insurance (private/self as ref)		
Public	0.56	(0.22–1.49)
Military	1.33	(0.10–17.55)
PVSA test setting		
Lab	Reference	
Home	0.47	(0.29–0.74)
Phone call (no as ref)		
Yes	0.99	(0.49–2.00)
Unplanned office visit (no as ref)		
Yes	1.02	(0.52–1.96)

BMI: body mass index; CI: confidence interval; OR: odds ratio; PSAV: post-vasectomy semen analysis.