



## Can a Low Sperm Concentration without Assessing Motility Confirm Vasectomy Success? A Retrospective Descriptive Study

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**Purpose:** A fresh post-vasectomy semen analysis showing 100,000 nonmotile sperm/mL or less confirms sterility. Mailed sample or self-testing at home with SpermCheck® Vasectomy decreases the inconvenience of producing a fresh sample, but without assessing motility. We evaluated if there is a sperm concentration under which no motile sperm are observed that could fortify the use of these alternatives.

**Materials and Methods:** We conducted a study of post-vasectomy semen analyses performed at the andrology laboratory of the Quebec City university hospital, Canada. Sperm concentration and motility were assessed on fresh noncentrifuged 10 µL samples at 400× magnification. We calculated the proportion of post-vasectomy semen analysis showing motile sperm according to sperm concentration for all and first prescribed post-vasectomy semen analysis by the 5 physicians who performed the most vasectomies.

**Results:** We identified 6,492 post-vasectomy semen analyses prescribed by 169 physicians. The 5 vasectomists prescribed 95.6% (6,204) of the post-vasectomy semen analyses; 96.1% (5,965) were first tests. We observed motility in all sperm concentration strata but it decreased with lower concentrations. At the first post-vasectomy semen analysis, among patients with less than 1 million, 250,000 and 100,000 sperm/mL, 0.5% (27/5,842) and 0.3% (19/5,760 and 17/5,725) had motility, respectively.

**Conclusions:** If the first post-vasectomy semen analysis on a mailed sample shows less than 1 million sperm/mL, we recommend requesting an additional mailed sample instead of a fresh sample. SpermCheck Vasectomy could falsely indicate a successful vasectomy in a very small proportion of cases. The optimal post-vasectomy semen analysis strategy must involve shared decision making, balancing the inconvenience of providing a fresh sample with the risk of a false-negative result.

### Abbreviations and Acronyms

AUA = American Urological Association  
PVSA = post-vasectomy semen analysis

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**Key Words:** vasectomy, sperm count, postoperative period, semen analysis, sperm motility

THE American Urological Association recommends that vasectomized men be considered sterile when a first fresh, noncentrifuged, semen analysis

done 8 to 16 weeks after the vasectomy shows 100,000 nonmotile sperm/mL or less.<sup>1</sup> The presence of motile sperm at this time indicates a failure of occlusion

of the vas deferens due to a surgical error or, most frequently, to a recanalization.<sup>2,3</sup>

To assess sperm motility, analysis must be done within 2 hours after the production of the fresh semen sample.<sup>1</sup> Men must therefore provide their sample at an appointment site typically no later than 1 hour after ejaculation.<sup>1</sup> The inconvenience of producing a fresh sample (including time constraints, distance, busy schedule, embarrassment) is the main reason why many men do not comply with the post-vasectomy semen analysis.<sup>4–7</sup> In North America, only about two-thirds of men have at least 1 PVSA.<sup>1</sup>

Two alternatives to PVSA exist that may increase compliance by reducing the barriers associated with producing a fresh sample. They do not, however, assess sperm motility, which appears to be the most robust criterion to indicate occlusive effectiveness after vasectomy.<sup>1,8,9</sup> First, vasectomized men can send their semen sample by mail. Men can then stop using other methods of contraception only if the PVSA shows no sperm.<sup>1,10</sup> As azoospermia is observed in only about 80% of first PVSAs,<sup>1,11</sup> there are still about 20% of vasectomized men who need to produce 1 or more additional samples compared to about 5% with the 100,000 nonmotile sperm/mL or less criterion applied on a fresh sample analysis.<sup>12,13</sup>

Second, men can use SpermCheck® Vasectomy, a home qualitative immunodiagnostic test.<sup>14</sup> The test evaluates if the sperm count is either below or above 250,000/mL, indicating the success or failure of the vasectomy, respectively. The negative predictive value is 97% at the 250,000/mL threshold and all semen samples with a sperm concentration of 385,000/mL or greater are correctly identified as positive.<sup>14</sup> However, in its 2012 guideline, the AUA concluded that there were still insufficient data to recommend its use in clinical practice, not only because the 250,000 sperm/mL threshold is higher than traditional 100,000 sperm/mL threshold, but mainly because motility cannot be assessed.<sup>1</sup> SpermCheck Vasectomy test was approved by regulation bodies in many countries such as the United States of America, the United Kingdom and Australia, but it is not in Canada.

A sperm concentration under which motile sperm are never or very rarely observed after vasectomy could decrease the need for additional testing in men who provide their sample by mail. It could also support the use of SpermCheck Vasectomy as an alternative to increase compliance with PVSA.<sup>5</sup> The objective of our study was to determine the probability of observing motile sperm according to sperm concentration in a large number of PVSAs performed on fresh sperm specimens.

## MATERIALS AND METHODS

### Study Design and Population

We conducted an observational retrospective study of PVSAs performed at the andrology laboratory of the Centre hospitalier universitaire de Québec-Université Laval, Quebec City, Canada between May 2016 and November 2019. This public institution performs nearly all the PVSAs in the area. The institutional review board approved the study (IRB No. 2020-4986).

### Post-Vasectomy Semen Analysis

The laboratory performed PVSA according to the protocol recommended in the province of Quebec.<sup>15</sup> To assess sperm concentration and motility, the medical technologists first deliver a 10 µL fresh (within 2 hours of production), liquefied, homogenized, and noncentrifuged semen aliquot under a 22 mm × 22 mm coverslip. Then, they carry out an exhaustive scan of the 10 µL sample at 400× magnification. If they count fewer than 500 sperm under the coverslip, they report the estimated concentration of sperm per mL in the laboratory information system by multiplying the number of sperm observed by 100 as 1 sperm observed in 10 µL corresponds to 100 sperm/mL. If they estimate the count to be over 500 sperm (corresponding to 50,000/mL), they assess the sperm concentration more precisely using a Neubauer hemocytometer.<sup>15</sup> The laboratory information system creates the final laboratory report with the raw data. Sperm counts under 56,000/mL are reported as  $<0.06 \times 10^6$  sperm/mL, taking into account the lower limit of quantification of the Neubauer hemocytometer.<sup>16</sup>

The PVSA laboratory reports include the following information: patient's date of birth, prescribing physician, test date, test rank, number of days of abstinence, specimen characteristics (completeness as reported by the man, appearance, volume, pH, viscosity), sperm concentration, and sperm motility (presence or absence). They also report the date of vasectomy if written on the prescription by the physician.

### Data Collection

One research team member (PL) who has authorized access to the laboratory information system extracted the PVSA data. We validated the data in 2 steps. First, the researcher verified and corrected inconsistent and missing data with the original data on worksheets and prescriptions.

Second, as there were still missing vasectomy dates or doubts about the test rank in men with multiple tests, we needed access to medical records. The researcher identified 5 physicians (4 family physicians and 1 general surgeon), who prescribed the most PVSAs available for the study. These physicians, defined as vasectomists, prescribed at least 120 PVSAs over the study period (about 30 PVSAs per year on average). After obtaining their written consent to collaborate on the study, the researcher requested that they verify missing information in their patient's records. All 5 provided the requested information. The vasectomists who prescribed the lowest number of PVSAs (table 1) used the conventional scalpel technique to access the vas and occluded the vas with ligation and excision of a small vas segment. The other 4 used

**Table 1.** Characteristics of post-vasectomy semen analyses studied

	PVSA Prescribed by Any Physician	PVSA Prescribed by Vasectomist*
No.	6,492	6,204
Mean±SD age of pts (yrs)	39.4±6.0	39.2±5.9
Total No. prescribers	169	5
No. prescribers according to No. PVSA's prescribed:		
1	133	-
2–9	28	-
10–36	3	-
124	1	1
811	1	1
948	1	1
1,079	1	1
3,242	1	1
No. rank of test (%):		
First	6,239 (96.1)	5,965 (96.1)
Second	204 (3.1)	190 (3.1)
Third or more	49 (0.8)	49 (0.8)
No. time interval of vasectomy-PVSA (%):		
Less than 8 wks	180 (2.8)	174 (2.8)
8–16 wks	4,225 (65.0)	4,153 (66.9)
17–52 wks	1,668 (25.7)	1,635 (26.4)
More than 52 wks	271 (4.2)	242 (3.9)
Unknown/uncertain	148 (2.3)†	-
Mean±SD days of abstinence	3.6±3.3	3.6±3.3
No. sample completeness (%):		
Complete	5,925 (91.3)	5,657 (91.2)
Incomplete	550 (8.5)	531 (8.6)
Missing value	17 (0.3)	16 (0.3)
No. sample appearance (%):		
Milky (normal)	6,480 (99.8)	6,194 (99.8)
Other	12 (0.2)	10 (0.2)
Mean±SD sample vol (mL)‡	3.1±1.5	3.1±1.5
Mean±SD sample pH§	8.0±0.2	8.0±0.2
No. sample viscosity (%):		
0 cm	3,915 (60.3)	3,735 (60.2)
1–3 cm	1,042 (16.1)	1,006 (16.2)
More than 3 cm	1,531 (23.6)	1,459 (23.5)
Missing value	4 (0.1)	4 (0.1)

\* Defined as a physician who prescribed at least 120 post-vasectomy semen analyses between May 2016 and November 2019.

† All PVSA's with unknown (22) or uncertain (126) time interval were among the 288 PVSA's prescribed by the 165 nonvasectomist physicians.

‡ In 6,490 and 6,202 patients, respectively.

§ In 6,491 and 6,203 patients, respectively.

vasectomy techniques recommended by the AUA.<sup>1</sup> They accessed the vas deferens using the no-scalpel vasectomy technique and occluded the vas with mucosal thermal cautery and fascial interposition with a medium Hemoclip® on the abdominal end of the divided vas, leaving the testicular end of the vas unoccluded.

### Statistical Analysis

Once the researcher completed these data validation procedures, he created an anonymized database of the PVSA reports for analysis. We calculated the proportion and 95% confidence interval of PVSA's showing motile sperm according to sperm concentration for all prescribed PVSA's by any physician and limited to the first PVSA prescribed by the 5 vasectomists. This second analysis is more representative of vasectomy clinical practice. Furthermore, when the first PVSA showed motile sperm and sperm concentration less than 1 million/mL, we analyzed additional PVSA's available to determine the final vasectomy outcome (success or failure according to the AUA criteria<sup>1</sup>). We used SAS® 9.4 for data analysis.

### RESULTS

Table 1 presents the characteristics of PVSA's studied. We identified 6,492 PVSA's prescribed by 169 physicians. The 5 vasectomists prescribed 95.6% (6,204) of the PVSA's, from which 96.1% (5,965) were first tests; 68.9% (4,108) were performed between 8 and 16 weeks after the vasectomy, as recommended by the AUA.<sup>1</sup>

The proportion of PVSA's with motile sperm according to sperm concentration in all PVSA's prescribed and limited to the first PVSA of the 5 vasectomists is presented in table 2. Motile sperm were observed in 150 (2.3% including and 6.2% excluding the “None observed” category) of all PVSA's and in 103 (1.7% and 4.8%) of the first PVSA's prescribed by the 5 vasectomists. Motile sperm were present at all sperm concentration strata in both cohorts analyzed. The proportion of PVSA's with motile sperm was however very small at lower sperm concentrations. It increased with higher sperm concentrations, reaching very high

**Table 2.** Proportion of post-vasectomy semen analyses with motile sperm according to sperm concentration

Sperm Concentration per mL	Post-Vasectomy Semen Analyses with Motile Sperm					
	PVSA's Prescribed by any Physician (6,491)*			First PVSA Prescribed by Vasectomist (5,965) †		
	No./Total No.	%	95% CI	No./Total No.	%	95% CI
None observed	0/4,069	0.0		0/3,808	0.0	-
100–999	4/1,313	0.3	0.1–0.8	3/1,249	0.2	0.05–0.7
1,000–9,999	16/594	2.7	1.6–4.3	10/520	1.9	0.9–3.5
10,000–99,999	9/193	4.7	2.2–8.7	4/148	2.7	0.7–6.8
100,000–249,999	3/52	5.8	1.2–16.0	2/35	5.7	0.7–19.2
250,000–499,999	4/54	7.4	2.1–17.9	3/41	7.3	1.5–19.9
500,000–999,999	7/54	13.0	5.4–24.9	5/41	12.2	4.1–26.2
1 million–9.9 million	45/95	47.4	37.0–57.9	36/78	46.2	34.8–57.8
10 million or more	62/67	92.5	83.4–97.5	40/45	88.9	76.0–96.3

\* One PVSA was excluded because the medical technologist could not perform the sperm count and assess motility due to the presence of too many white blood cells.

† Defined as a physician who prescribed at least 120 post-vasectomy semen analyses between May 2016 and November 2019.

proportions of motile sperm at sperm concentrations of 1 million sperm/mL or more. The proportion of first PVSA's with motile sperm was significantly higher before 8 weeks (median 7.3) than 8 to 16 weeks (median 10.0) after vasectomy (7/174, 4.0% vs. 67/4108, 1.6%, chi-square test = 5.6,  $p = 0.02$ ).

Among the 5,965 men who provided a first PVSA prescribed by one of the 5 vasectomists, 5,708 (95.7%) met the 100,000 nonmotile sperm/mL vasectomy success criteria recommended by the AUA.<sup>1</sup> Only 17 (0.9%) of the 1,917 men with a sperm concentration between 100 and 100,000 sperm/mL and 19 (1.0%) of the 1,952 with a sperm concentration between 100 and 250,000 sperm/mL had motile sperm. Including the “None observed” category in the denominator, the proportion of men with motile sperm decreases to 0.3% among both the 5,725 men with a first PVSA with less than 100,000 sperm/mL and the 5,760 with less than 250,000 sperm/mL.

Among the 27 men whose first PVSA showed motile sperm and a sperm concentration of less than 1 million/mL, 15 (55.6%) had an additional PVSA to determine the final vasectomy outcome. Vasectomy was deemed a success according to the AUA criteria<sup>1</sup> in 13 (86.7%): no sperm were detected in 8 and less than 100,000 nonmotile sperm/mL were identified in 5. Initial sperm concentration of the PVSA's in the 2 men with vasectomy failure was very low. In both men, sperm concentration increased at the time of the second PVSA and motile sperm were observed (first man: 7,700 sperm/mL at 147 days and 440,000 sperm/mL at 202 days after vasectomy; second man: 4,500 sperm/mL at 209 days and 530,000 sperm/mL at 558 days after vasectomy).

## DISCUSSION

To our knowledge, this is the first study to estimate the probability of observing motile sperm after vasectomy stratified by sperm concentration. It showed that

motile sperm are present at all sperm concentration strata in PVSA's. However, the probability of observing motile sperm ranges from very small at lower sperm concentrations to very high at large sperm concentrations. The results including all PVSA's studied and limited to the first PVSA prescribed by vasectomists showed the same trend.

Our results have major clinical implications. The absence of a sperm concentration threshold under which there is no motile sperm observed supports the AUA statement<sup>1</sup> and recommendations in United Kingdom<sup>10,17</sup> that mailed semen sample is adequate only to assess the presence or absence of sperm. If any sperm are observed on a PVSA performed through a mailed sample, an additional PVSA should be performed. Although a fresh sample is usually recommended for additional PVSA's,<sup>10,17</sup> our findings help the surgeon and their patients make an informed decision about the “best” method to submit a sample. The additional sample could again be provided by mail if the sperm concentration of the first PVSA is less than 1 million/mL, as no sperm will be detected in most additional PVSA's. With higher sperm concentrations in the first PVSA, submitting a fresh sample makes more sense as the risk of recanalization is much higher.

Our findings produced an estimate of risk of obtaining a false-negative result with SpermCheck Vasectomy. The risk of missing motile sperm with a first negative home-based test result is very low (0.3%). Furthermore, in our cohort of 5,965 men with a first PVSA, performing 2 SpermCheck Vasectomy tests, as recommended, would have identified both men with failure with no false-negative results. Again, these findings help surgeons and their patients to make informed choices about selecting a PVSA method.

Men using home-based PVSA overcome the inconvenience of submitting a fresh semen sample and the delay to obtain test results when the sample

is sent to a laboratory. A recent survey showed that among 73 men who failed to submit a post-vasectomy semen sample, 92% reported that they would be more likely to complete a home-based PVSA.<sup>5</sup> In fact, Trussler and al observed a 10% compliance increase (from 66% to 76%) with home-based tests.<sup>18</sup> They calculated that prescribing two serial SpermCheck Vasectomy tests would identify 1 additional man with failure in 953 men who had a vasectomy compared to PVSA on a fresh semen sample. In our study, 1.7% of men had motile sperm at the first PVSA and 0.3% would have had a false-negative result with the home-based test. Thus, 1.4% would have been diagnosed with a failed vasectomy. Assuming a 10% increase in compliance,<sup>18</sup> prescribing SpermCheck Vasectomy would have identified 0.14% more failures (1 additional man with a failure in 714 men who had a vasectomy) compared to prescribing PVSA on fresh semen sample. Despite differences between Trussler et al's study and ours, both suggest that home-based tests may offer increased detection of vasectomy failure.

The proportion of men with motile sperm at the first PVSA done before 8 weeks after vasectomy was significantly higher than when performed between 8 and 16 weeks as recommended by the AUA.<sup>1</sup> Considering the low risk of having motile sperm before 8 weeks (4.0%), patients and surgeons may however prioritize the high probability of reducing the time before confirming the vasectomy success over the low risk of needing an additional test. This choice applies whatever the method of collecting and performing the PVSA.

Our study has some limitations. First, counting sperm at very low concentrations is imprecise. For example, if no sperm are observed in 50 high-power field at 400× magnification of a 10 µL wet preparation (0.2 µL examined), the sperm concentration may be as high as 18,500 sperm/mL.<sup>19</sup> The sperm counts performed in our study were much more precise, however, due to the full scan of the 10 µL aliquot (1,936 high-power field). In addition, we calculated the 95% CI for each sperm concentration stratum to measure the precision of the probability of encountering motile sperm.

Second, we determined the rank of PVSAs based on those performed at the andrology laboratory in Quebec City. Some patients may have completed 1 or more PVSA in other laboratories leading to incorrect rankings. However, this risk is marginal, as we verified data using the patient records of the 5 vasectomists who prescribed the vast majority of the PVSAs. In addition, the andrology laboratory is the reference center for all vasectomists and the only institution offering PVSA at no cost in Quebec City.

Third, we can generalize our results only to PVSAs of men whose vasectomy occlusion technique was performed with mucosal cautery and fascial interposition, as this was the case in at least 93.7% (6,080/6,492) of the PVSAs. The occlusion technique may influence the probability of observing motile sperm at low sperm concentrations. In a comparative study, when sperm were observed and the sperm concentration was below 1 million/mL, 0% and 11.4% of first PVSAs showed motile sperm when mucosal cautery combined with fascial interposition and ligation with metal clips, and excision of a vas segment was performed, respectively.<sup>20</sup> This proportion was 9% in another study in which cautery, ligation with metal clips and excision of a vas segment, but no fascial interposition was used in all patients.<sup>9</sup>

## CONCLUSIONS

Motile sperm are observed in all sperm concentration strata after vasectomy, but the probability of falsely concluding that a vasectomy was a success at low concentrations is minimal. If the first PVSA on a mailed sample shows less than 1 million sperm/mL, we recommend requesting an additional mailed sample instead of a fresh sample. We estimated that the risk of falsely concluding a vasectomy was a success with 2 negative SpermCheck Vasectomy results is very low. The optimal PVSA strategy for the patient must however involve shared decision making, balancing the inconvenience of providing a fresh sample with the risk of a false-negative result.

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