Original Article

Providing a post-vasectomy semen analysis cup at the time of vasectomy rather than post-operatively improves compliance

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Background: Post-vasectomy semen analysis (PVSA) completion rates after vasectomy are poor, and minimizing the need for an additional in-person visit may improve compliance. We hypothesized that providing PVSA specimen cup at time of vasectomy instead of at a postoperative appointment might be associated with higher PVSA completion rates.

Methods: We performed a retrospective cohort study with historical control using medical records of all patients seen by a single provider for vasectomy consultation between October 2016 and June 2022. All patients who underwent vasectomy were included. Patients who underwent vasectomy prior to 05/01/2020 had PVSA specimen cup given at postoperative appointment two weeks following vasectomy, and those who underwent vasectomy after 05/01/2020 were given PVSA specimen cup at time of vasectomy. PVSA completion, demographic, and clinical outcomes data were collected. Logistic regressions were used to investigate associations between PVSA completion rates and timing of PVSA specimen cup provision.

Results: There were no significant differences among study cohorts across all patient demographics analyzed, including age, body mass index (BMI), age of primary partner, presence of children, and history of prior genitourinary infection. A total of 491 patients were seen for vasectomy consultation between October 2016 and June 2022; among these patients, 370 underwent vasectomy. Of these, 173 (46.8%) patients underwent vasectomy prior to 05/01/2020 and were given PVSA specimen cup at postoperative visit; 197 (53.2%) patients underwent vasectomy after 05/01/2020 and were given PVSA specimen cup at vasectomy. Providing PVSA specimen cup at time of vasectomy was associated with higher odds of PVSA completion than providing PVSA specimen cup at postoperative visit [62.4% *vs.* 49.7%; odds ratio (OR) =1.68; 95% confidence interval (CI): 1.11, 2.55]. Adjusting for all identified confounders excludes 35 (9.5%) patients without a primary partner and shows no statistically significant association in cup timing [adjusted OR (aOR) =1.53; 95% CI: 0.98, 2.39]. Adjusting for all identified confounders except age of primary partner revealed timing of specimen cup provision at time of vasectomy was associated with higher odds of PVSA completion (aOR =1.64; 95% CI: 1.08, 2.52).

Conclusions: PVSA specimen cup provision at time of vasectomy versus at postoperative appointment is associated with higher rates of PVSA completion in this retrospective cohort study.

Keywords: Vasectomy; semen analysis; telehealth; post operative; quality improvement

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Introduction

Vasectomy is one of the most common, safe, and cost-effective methods of contraception in men, and continues to gain interest (1-3). It is estimated that approximately 5.6% of all men of reproductive age in the U.S. have undergone vasectomy, with contraceptive success rates over 99% (4). Vasectomy is also an incredibly cost-effective procedure. A review of contraceptive costs in the US over a five-year span found that vasectomy ranked amongst the three most cost-effective forms of contraception with an average total cost of $713, compared to the copper intrauterine device (IUD) at $647 and levonorgestrel 20 mcg IUD at $930. Of these three maximally cost-effective contraceptive options, vasectomy is the most effective and only permanent option (1). The only other widely used method of male contraception aside from vasectomy is condoms, which have relatively lower contraceptive efficacy on a population level due to improper and inconsistent usage (5).

Despite the clear advantages in contraceptive success, long-term efficacy, and cost, vasectomy is also the only contraceptive method that requires post-procedural diagnostic confirmation of sterility known as post-vasectomy semen analysis (PVSA), creating potential issues in patient non-compliance. While not formally recommended as part of guidelines for vasectomy, postoperative examination, which is performed by many urologists, is another barrier to patient compliance inherent to a vasectomy in addition to the need for PVSA; therefore, provision of PVSA cup at time of postoperative visit may further preclude patient compliance with confirmation of vas occlusion. There has yet to be a protocol defined for optimal postoperative practices that maximizes patient compliance with PVSA, while simultaneously improving patient satisfaction with postoperative protocols and expanding access to care.

Although overall contraceptive failure rates of vasectomy are less than 1%, vasectomy does not produce sterility immediately as there remain mature sperm in the reproductive tract that must be expelled (6). For this reason, PVSA is an essential component of post-vasectomy protocols used to confirm sterility secondary to vas occlusion before the patient is cleared for unprotected sexual activity. The American Urological Association (AUA) outlines the criteria for a negative PVSA in its updated 2015 vasectomy guidelines, stating that "patients may stop using other methods of contraception when examination of one well-mixed, uncentrifuged, fresh post-vasectomy semen specimen shows azoospermia or only rare non-motile sperm (RNMS or ≤100,000 non-motile sperm/mL)" (6). The first PVSA is recommended at 8 to 16 weeks following vasectomy at the discretion of the surgeon. Per expert opinion as represented in the AUA guidelines, vasectomy is considered to have failed if any motile sperm are seen on PVSA six months after the operation (6). Without confirmation of sterility via appropriate PVSA completion, vasectomy is not considered sufficiently safe or reliable as a contraceptive method (6).

Despite the known risks of presuming vasectomy is successful without objective evidence of sterility, PVSA compliance rates are generally poor (7-9). Per the 2015 AUA review of cohorts undergoing vasectomy in Canada, Mexico, and the United States, only approximately 55–71% of patients complete at least one PVSA (6). As far as individual studies have shown, a retrospective review of vasectomies performed at the San Diego Veterans Administration (VA) Hospital and University of California San Diego (UCSD) Health revealed that 80% of patients completed postoperative follow-up, but only 53% completed PVSA (10). PVSA completion rates were also notably different between clinical sites (67% at UCSD Health and 46% at the VA, P<0.001), exposing potential room for improvement in PVSA compliance by healthcare delivery setting (10). When patients in this study were asked why they did not follow through with PVSA, they cited distance, time constraints, and forgetfulness as primary

Highlight box

Key findings

- Provision of post-vasectomy semen analysis specimen cup at time of vasectomy instead of at time of postoperative follow-up visit was associated with higher odds of semen analysis completion.

What is known and what is new?

- Post-vasectomy semen analysis compliance is known to be poor.
- This study provides evidence that provision of post-vasectomy semen analysis specimen cup at time of vasectomy is associated with higher odds of semen analysis completion compared with provision of specimen cup at time of postoperative follow-up.

What is the implication, and what should change now?

- For practices that distribute semen analysis specimen cup at time of postoperative visit, there may be an opportunity to improve compliance with post-vasectomy semen analysis by providing specimen cup at time of vasectomy. In an era where vasectomy continues to increase in popularity as a contraceptive option, it is increasingly important to define factors that improve post-vasectomy semen analysis compliance.

reasons for forgoing PVSA. Notably, 92% of interviewees reported increased likelihood of completion with home-based semen testing (10). In a study of vasectomy patients at two Canadian family medicine clinics, the primary reasons for noncompliance included feeling too busy to complete PVSA and patients feeling confident in the physician or procedure immediately after vasectomy. The combined compliance rate for PVSA completion for the two clinics was a mere 39.5% (11).

While the AUA guidelines indicate the appropriate timing of the first PVSA, there is currently no recommendation on when or how the specimen cup should be provided to the patient (6).

We hypothesized that providing patients with PVSA specimen cup at time of vasectomy could improve PVSA compliance rates by improving convenience and accessibility, and negate the need for an in-person follow-up appointment to ensure specimen cup receipt. Additionally, because patients cite confidence in the vasectomy and the surgeon as major reasons for not completing PVSA (11), which could suggest that PVSA is viewed as a conservative test to prove success, rather than part of standard protocol to ensure contraceptive success and confirm vas occlusion, we theorized that immediate cup presentation following vasectomy could impact patient compliance to completing PVSA. We present this article in accordance with the STROBE reporting checklist (available at https://tau.amegroups.com/article/view/10.21037/tau-23-400/rc).

Methods

Study cohort

All men who underwent vasectomy between October 2016 and June 2022 with a single surgeon at NYU Langone Health were included in the study cohort. Prior to 05/01/2020, this surgeon's standard practice was to provide patients with a PVSA cup at the in-person postoperative visit for physical examination of wound healing and to address patient concerns, scheduled two weeks following vasectomy. Due to the emergence of coronavirus disease 2019 (COVID-19), to reduce the number of in-person visits, patients who underwent vasectomy after 05/01/2020 were provided with a PVSA cup at the time of their vasectomy such that they could submit their samples at a later date. They were also given the choice of either a virtual or in-person postoperative appointment two weeks following vasectomy unless the patient had concerning symptoms, for which the surgeon would require in-person follow-up. Throughout the study duration, all patients had the option to submit their semen analysis sample at a local laboratory or at a laboratory at the same institution as their vasectomy, such that patients did not need to return to the office for PVSA unless desired. All patients were instructed to submit specimen samples at three months and a minimum of 20 ejaculations following vasectomy, with the specimen having to be collected within one hour of drop off at a laboratory of the patient's choosing. For each patient who underwent vasectomy, patient characteristics, timing of PVSA cup receipt, and compliance with PVSA were recorded. This study was conducted in accordance with the Declaration of Helsinki (as revised in 2013). Institutional review board approval was granted by NYU Langone Health for this retrospective study (approval number: i22-00887) and individual consent for this retrospective analysis was waived.

Statistical analysis

To evaluate for differences in baseline patient characteristics that could be responsible for differences in PVSA completion between those who received PVSA cup at time of postoperative visit versus at time of vasectomy, Wilcoxon rank-sum tests and chi-squared tests were used to assess for associations between potential confounders [i.e., patient age, age of patient's primary partner, patient body mass index (BMI), presence of existing children, and history of genitourinary (GU) infection] and timing of PVSA specimen cup receipt. Additionally, Wilcoxon rank-sum tests and chi-squared tests were used to assess associations between these potential confounders and compliance with PVSA. These potential confounders were selected due to the belief that they may influence interest in completing PVSA, introduce complications to the vasectomy process, or affect confidence in vasectomy success.

The association between timing of PVSA specimen cup receipt and PVSA completion was investigated using logistic regression. The logistic regression was adjusted for the potential confounders noted above. Given that a substantial number of patients did not have a primary partner, alternative adjusted analyses were conducted which did not control for age of primary partner. 95% confidence intervals were derived for all logistic regressions. For all analyses, the threshold of statistical significance was set at an alpha of 0.05. Analyses were conducted using R version 4.0.5.

Results

Between October 2016 and June 2022, 370 patients were seen by a single provider and underwent vasectomy. Of these, 173 (46.8%) patients underwent vasectomy prior to 05/01/2020 and were given PVSA specimen cup at their in-person postoperative visit; 197 (53.2%) patients underwent vasectomy after 05/01/2020 and were given PVSA specimen cup at the time of vasectomy. For the cohort that was given the option to select setting of postoperative visit (i.e., those who underwent vasectomy after 05/01/2020), 154 (78.2%) patients were seen virtually and 23 (11.7%) were seen in person. In terms of patient characteristics, no detectable differences were found between those who had PVSA cup provided at time of vasectomy and PVSA cup provided at postoperative visit for all patient characteristics investigated (*Tables 1*,*2*). Further analysis of these patient characteristics individually revealed that there were no statistically significant associations with PVSA completion (*Tables 3*,*4*).

Providing PVSA specimen cup at time of vasectomy was associated with higher odds of PVSA completion compared to providing PVSA specimen cup at postoperative visit [62.4% *vs.* 49.7%; odds ratio (OR) =1.68; 95% confidence interval (CI): 1.11, 2.55]. In the adjusted model that adjusted for all potential confounders and excluded the 35 (9.5%) patients who do not have a primary partner (since age of primary partner was included as a covariate), no statistically significant association was identified between timing of specimen cup provision and PVSA completion [adjusted OR (aOR) =1.53; 95% CI: 0.98, 2.39]. In the adjusted model that included the full sample and accounted for all potential confounders except age of primary partner, timing of specimen cup provision at time of vasectomy was associated with higher odds of PVSA completion [adjusted OR (aOR) =1.64; 95% CI: 1.08, 2.52]. None of the

Table 1 Qualitative patient characteristics stratified by time of post-vasectomy semen analysis cup receipt

Measure	PVSA cup provided at time of vasectomy (n=197)[a]	PVSA cup provided at postoperative visit (n=173)[b]	P value*
Has children	169 (86.2)	152 (88.9)	0.44
Prior GU infection	20 (10.2)	20 (12.1)	0.56

Data are presented as n (%). *, P values derived from Chi-square tests. [a], Missing data: 1 with unknown number of children, 1 with unknown GU infection history; [b], Missing data: 2 with unknown number of children, 8 with unknown GU infection history. PVSA, post-vasectomy semen analysis; GU, genitourinary.

Table 2 Quantitative patient characteristics stratified by time of post-vasectomy semen analysis cup receipt

Measure	PVSA cup provided at time of vasectomy (n=197)	PVSA cup provided at postoperative visit (n=173)	P value*
Age, years	40.5 (8.0)	41.1 (7.0)	0.39
Partner's age, years	38.0 (6.0)	38.0 (5.0)	0.90
BMI, kg/m^2	25.7 (5.2)	26.5 (4.9)	0.16

Data are presented as median (IQR). *, P values derived from Wilcoxon rank sum testing. Missing data: 35 without primary partner. PVSA, post-vasectomy semen analysis; BMI, body mass index; IQR, interquartile range.

Table 3 Associations between post-vasectomy semen analysis completion and qualitative patient characteristics

Measure	Did not complete PVSA (n=161)[a]	Completed PVSA (n=209)[b]	P value*
Has children	141 (88.1)	180 (87.0)	0.74
Prior GU infection	20 (12.7)	20 (9.8)	0.38

Data are presented as n (%). *, P values derived from Chi-square tests. [a], Missing data: 1 with unknown number of children, 4 with unknown GU infection history; [b], Missing data: 2 with unknown number of children, 5 with unknown GU infection history. PVSA, post-vasectomy semen analysis; GU, genitourinary.

Table 4 Associations between post-vasectomy semen analysis completion and quantitative patient characteristics

Measure	Did not complete PVSA (n=161)	Completed PVSA (n=209)	P value*
Age, years	41.0 (7.6)	40.7 (7.8)	0.38
Partner's age, years	39.0 (5.3)	38.0 (6.0)	0.56
BMI, kg/m^2	25.8 (5.6)	26.0 (5.0)	0.48

Data are presented as median (IQR). *, P values derived from Wilcoxon rank sum testing. Missing data: 35 without primary partner. PVSA, post-vasectomy semen analysis; BMI, body mass index; IQR, interquartile range.

measures controlled for in either of the adjusted models had a statistically significant association with PVSA completion.

Discussion

Our retrospective review of 370 men undergoing vasectomy with a single surgeon suggests that the timing at which PVSA specimen cup is provided may influence PVSA completion rates, and can be adjusted to improve compliance. Specifically, providing PVSA specimen cup at the time of vasectomy is associated with higher odds of PVSA completion than observed among those who received PVSA specimen cup at postoperative visit. We speculate that providing patients with a PVSA specimen cup in-hand at time of vasectomy offered the opportunity for surgeons to reinforce the importance of the need to obtain PVSA as part of the process of undergoing vasectomy, rather than a supplementary evaluation after a completed procedure. This may contribute to a stronger perception by patients that PVSA is a routine and important part of the vasectomy process. Additional reasons may include the decreased burden of providing a sample and completing PVSA when a cup is already provided, relative to those who had to return for in-person visit to obtain a specimen cup. Having a PVSA specimen cup at home can also serve as a reminder to provide the specimen sample.

Currently, there are no explicit standards endorsed by the AUA for postoperative practices; though a visit strictly for physical examination of wound healing is not considered routinely necessary, scheduling an appointment specifically for PVSA is suggested but ultimately left up to surgeon preference (6). However, there is significant heterogeneity of practice, and surgeons who currently practice routine postoperative follow-up may have concerns that omission of follow-up appointment would reduce PVSA compliance. Our results may temper these concerns since providing PVSA specimen cup at time of vasectomy does not negatively impact PVSA compliance, and in fact, improves compliance and completion. This allows providers and patients the flexibility of deciding whether postoperative follow up is necessary, and if so, whether to follow-up in-person or virtually. In the current climate of increasing telehealth utilization, this finding is important in reinforcing our understanding of safe and effective implementations of telehealth. Offering telehealth postoperative visits for vasectomy patients interested in follow-up is convenient and improves access to care for many patients with time constraints or inability to take off work for an additional in-person appointment. However, it is important to emphasize to patients that virtual appointments are only appropriate for routine postoperative courses, as all of these patients were encouraged to schedule in-person visits if there were any postoperative concerns.

Qualitatively, PVSA completion in our patient population is consistent with rates seen in the currently available literature. Overall, 56.5% of patients who had a vasectomy completed PVSA, falling within a wide range of observed PVSA compliance rates between 39% and up to 71% (6-9). All previously discussed explanations for low PVSA compliance likely apply in our cohort as well, including high patient confidence in vasectomy success, inconvenience of semen analysis, and need for repeat postoperative visit (11).

Our results join a body of work where numerous approaches have been studied in attempting to increase PVSA completion rates, though none have been proven to show a consistent advantage (6,8,10,12). Data is equivocal regarding the value of a separate appointment for PVSA completion. In a retrospective analysis of 387 vasectomy patients, Jacobsen *et al.* compared PVSA compliance rates with drop-in style appointments 8–16 weeks after vasectomy versus mandated, scheduled PVSA appointments at time of vasectomy and found no significant differences (12). However, a study by Dhar *et al.*, 2007 investigating a similar comparison found that among 228 men, 65% returned for PVSA without an appointment while those with pre-scheduled PVSA appointment returned 84% of the

time (13). The AUA Panel leaves the practice of scheduling PVSA appointments in advance up to the discretion of the surgeon (6). Given that AUA guidelines promoting PVSA completion as a critical part of guideline-adherent vasectomy postoperative care, in the absence of strong evidence-based strategies for improving PVSA completion rates, it is the responsibility of the individual surgeon offering vasectomy to develop protocols for maximizing PVSA completion rates by addressing patient barriers in their patient populations (6).

The Federal Drug Administration's approval and introduction of home-based self-PVSA solutions were anticipated to increase completion rates due to convenience and accessibility compared to office-based PVSA; yet, studies on this have demonstrated mixed outcomes. Trussler *et al.*, 2020 found that in a study of 226 patients undergoing vasectomy, PVSA compliance was 66% among patients asked to perform traditional office-based testing compared with 76% who were offered home-based PVSA; though clinically significant if this difference is real and not due to random chance, it did not achieve statistical significance (P=0.095) (14). Punjani *et al.*, 2021 reported that among 364 patients, in whom 30% voluntarily opted for home-based PVSA testing, the rate of PVSA completion was not significantly different compared to office-based PVSA testing compliance (59.6% *vs.* 58.8%, respectively, P=0.89) despite self-selection of the home-based PVSA group (15). Interestingly, Atkinson *et al.*, 2022 found that among 58,900 vasectomy patients, PVSA compliance was greater when patients were advised to submit PVSA samples from home via mail compared to those advised to undergo laboratory-based testing (79.5% *vs.* 59.1%, respectively); notably, this study was based in the United Kingdom while other studies quoted were based in the United States (16). This raises interesting questions about the influence of culture in PVSA compliance. For surgeons in the United States, however, the currently available literature calls into question whether the convenience and accessibility benefits of at-home PVSA translate into clinically meaningful improvements in PVSA compliance.

Additionally, home-based self-PVSA raises questions and uncertainty in regards to the accuracy and dependability of the results for both patients and for surgeons in verifying vas occlusion. Not all commonly available home-PVSA tests currently on the market have the sensitivity to reliably measure sperm concentrations ≤100,000 non-motile sperm/mL, the cut-off commonly cited by the AUA guidelines' definition for occlusive success (6,17-19). Unlike laboratory-based PVSA, many home-based PVSA kits also do not assess for sperm motility, and have not yet been studied to assess for the risk of unanticipated pregnancy (18). Other mail-in, home-based PVSA solutions, such as those offered by Fellow, use laboratory analysis and have the potential for detecting lower concentrations of sperm compared to immunodiagnostic techniques. However, the optimization of the mailing procedure has only been validated with semen specimens for routine semen analysis, where sperm concentration is higher, and has not yet been validated with the low-to-zero concentrations expected following vasectomy (19). The inability to assess for accepted markers of vasectomy success and lack of supporting literature may introduce medicolegal risk and limit the extent of accurate clinical guidance that surgeons can confidently provide. In the future, home-based PVSA has the potential to simplify the post-vasectomy experience with advances in technology that allow detection of lower sperm concentrations, development of robust protocols that patients can reliably adhere to, and correlation of home-based PVSA test results with pregnancy risk. Unfortunately, present-day home-based semen analyses have not yet proven non-inferiority for evaluation of sterility compared to lab- or office-based PVSA, highlighting the continued importance of optimizing compliance to traditional PVSA approaches.

Our study has several limitations worthy of discussion. Our study cohort notably includes only patients of one surgeon's practice at a large urban medical center, such that our results may not be generalizable to the general population. Though the makeup of the study cohort may be influenced by geographic location, all patients who underwent vasectomy with this surgeon within the investigation time period were included, thereby minimizing the risk of bias in cohort selection beyond factors outside our control. Given that our PVSA completion rates are comparable to those observed in other studies, it is likely that sufficient similarities exist between our study cohort and the general population such that results can be generalized to some extent. With a different study cohort, future research could investigate why our study cohort did not achieve statistical significance when confounder-adjusted estimates accounted for age of primary partner; within the limits of our study, it is unclear whether this was a confounding covariate or simply due to loss of power. Our retrospective analysis beginning prior to, and extending through the COVID-19 pandemic introduces biases relating to patient selection inherent to the study

design. Given the broad sociopolitical changes that occurred during the pandemic, it is reasonable to assume that patients seeking vasectomy prior to the pandemic and during the pandemic may have had qualitative differences. These differences may have included factors related to mandated lock-downs, wide-ranging shifts to a work-from-home lifestyle, increased free time, social distancing orders, patient sentiments about visiting medical environments during a pandemic, or COVID-mediated social stressors (unemployment, family emergencies, etc.). Although it is difficult to account for the multifaceted impact these factors may have had on motivating patients to seek out vasectomy and to complete prescribed post-vasectomy testing, we compared our cohorts across routinely collected sociodemographic factors and did not find statistically significant differences between groups, suggesting that they were overall similar. Additionally, individual practice factors are uniquely associated with specific practices and providers and are highly impactful on each clinic's relationships with their patients, likely contributing to between-practice variability in patient perception towards the likelihood of vasectomy success and the importance of PVSA completion.

Conclusions

Providing a PVSA specimen cup at the time of vasectomy rather than at postoperative appointment increases PVSA completion rates. Given the increasing popularity and interest in vasectomy as a contraceptive option, it is critical that clinical practice surrounding PVSA is designed to optimize patient outcomes. This study's findings that providing PVSA cup at time of vasectomy is associated with higher rates of completing PVSA suggests that this simple change in clinical practice can improve patient outcomes. In addition to improving patient compliance with PVSA, this change in timing can also offer greater flexibility in postoperative practices and facilitate virtual telehealth follow-up. However, due to limitations inherent to the study design, it is possible that this study's findings were impacted by confounding factors related to the pandemic. In future research, it would be prudent to replicate the comparisons made in this study using either a prospective cohort or with an approach that randomizes patients with different protocols for PVSA cup distribution.

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Footnote

Reporting Checklist: The authors have completed the STROBE reporting checklist. Available at https://tau.amegroups.com/article/view/10.21037/tau-23-400/rc

Data Sharing Statement: Available at https://tau.amegroups.com/article/view/10.21037/tau-23-400/dss

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Conflicts of Interest: All authors have completed the ICMJE uniform disclosure form (available at https://tau.amegroups.com/article/view/10.21037/tau-23-400/coif). The authors have no conflicts to declare.

Ethical Statement: The authors are accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved. This study was conducted in accordance with the Declaration of Helsinki (as revised in 2013). Institutional review board approval was granted by NYU Langone Health for this retrospective study (approval number: i22-00887) and individual consent for this retrospective analysis was waived.

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