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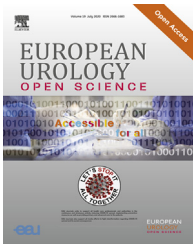

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Scheduling Appointments for Postvasectomy Semen Analysis Has No Impact on Compliance

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Abstract

Background: A postvasectomy semen analysis (PVSA) is recommended 8–16 wk after vasectomy to ensure azoospermia. Patient compliance with submitting a semen sample for PVSA has historically been low. To increase patient compliance, a policy change was made to schedule patients for PVSA appointments instead of a previous "drop-in" option.

Objective: To compare patient compliance for PVSA when scheduling appointments as opposed to a "drop-in" appointment 8–16 wk after the procedure.

Design, setting, and participants: Ethical approval was obtained to retrospectively evaluate patients undergoing vasectomy. A total of 400 patients were evaluated, 200 consecutive patients before and 200 after the policy change. Patients were excluded from analysis if they had other surgeries at the same time of vasectomy or if the vasectomy was a repeat procedure.

Outcome measurements and statistical analysis: Percent of patients attending PVSA and time to PVSA were assessed. Nominal data were compared using chi-square analysis and interval data were compared using Student unpaired *t* test.

Results and limitations: Thirteen patients were excluded from analysis: six before and seven after the policy change. Compliance rates were similar before and after the policy change (144/194 [74%] and 154/193 [80%], $p = 0.19$). There was no difference in the time from vasectomy to PVSA between groups (before: mean [standard deviation] 69 [55] d vs after: 74 (63) d, $p = 0.44$). This study is limited by its retrospective design.

Conclusions: Scheduling appointments for PVSA has no impact on compliance rates or the time between vasectomy and semen analysis when compared with "drop-in" appointments.

Patient summary: Sterility after a vasectomy is guaranteed by delivering a semen sample. Many men do not deliver this sample, and sterility cannot be guaranteed. This study found that scheduling appointments did not increase the number of men who delivered a semen sample compared with "drop-in" appointments.

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1. Introduction

Undergoing a vasectomy is an effective and common method of contraception [1]. However, sterility cannot be guaranteed immediately after surgery. Recanalization of the vas deferens can occur, allowing motile sperm cells to enter the ejaculate [2]. Sperm cells can also persist in the male reproductive system for a long time after the initial vas occlusion. These factors can result in failure of the vasectomy and unwanted pregnancy [3]. Therefore, it is essential that patients deliver a semen sample for a postvasectomy semen analysis (PVSA) in order to ensure azoospermia and thus success of the procedure. The 2012 American Urological Association (AUA) vasectomy guidelines recommend performing a PVSA 8–16 wk after the procedure [3]. Similarly, the European Association of Urology (EAU) states that a PVSA should be done 3 mo after the procedure [4]. Both guidelines state that men are considered sterile if no sperm is found in the ejaculate on a PVSA 8–16 wk after the vasectomy, which is the case in 80% of men undergoing a vasectomy [5], or if they have rare nonmotile sperm (RNMS; defined as $\leq$100 000 nonmotile sperm per milliliter) in the ejaculate on a PVSA 8–16 weeks after the vasectomy [3].

Patient compliance with submitting a semen sample for PVSA has historically been low, with several retrospective studies reporting that around 50% of patients undergoing a vasectomy do not attend a PVSA [6–9]. Even though patients are carefully consulted on the necessity of providing a semen sample and instructed when this should be done, compliance is still low. The objective of this study was to evaluate the impact of a policy change to schedule patients for PVSA appointments, instead of a previous "drop-in" option, on patient compliance.

2. Patients and methods

Institutional review board approval was obtained at the University of Michigan (IRB: HUM00150396) to retrospectively asses 400 patients undergoing vasectomy before (group A—drop-in group) and after (group B—scheduled appointment) the policy change, which was implemented in October 2009. The charts of all men included for analysis were reviewed for complications and unwanted pregnancies after the procedure, and whether repeat vasectomy was performed. None of the 27 patients operated in October 2009 were included for analysis as the policy for PVSA was changed in this month, and we wanted to make sure that all men followed the new policy. Patients were excluded from analysis if they had other surgeries performed at the same time of vasectomy or if the vasectomy was a repeat procedure. Vasectomies were performed as a percutaneous no-scalpel bilateral vasectomy, in which a segment of the vas deferens is excised after which the lumen is cauterized and oversewn with absorbable sutures [10]. Patients were instructed to use additional contraceptives after the vasectomy and were carefully informed, both verbally and in writing, about how and when the semen sample for PVSA should be delivered.

Before October 2009, the institutional policy for PVSA at the University of Michigan was a "drop-in" appointment in which patients delivered a semen sample to the clinic between 8 and 16 weeks after the procedure. Appointments were not scheduled, and patients were responsible for providing the semen sample. In October 2009, the policy was changed to schedule patients for PVSA appointments 8–16 wk after the procedure. The policy change was done to improve patient compliance with PVSA. All patients were advised to deliver a masturbatory sample for the PVSA; the sample could be collected in clinic, or at home and delivered to the clinic within 1 h. If patients did not attend the PVSA after the policy change, up to two letters were sent instructing patients to reschedule. All patients who attended the first PVSA were asked to deliver a semen sample for a second PVSA to verify azoospermia.

Semen samples were analyzed in the clinic, and success with the procedure was defined as semen samples showing azoospermia or RNMS.

2.1. Statistics

Demographic and patient characteristics were reviewed using descriptive statistics. Nominal data were compared using chi-square analysis and interval data were compared using Student unpaired *t* test. Statistical significance was set at $p < 0.05$. Statistical analyses were done with the use of computing environment R (3.5.2, 2014; R Foundation for Statistical Computing, Vienna, Austria).

3. Results

Between December 2008 and September 2010, 427 vasectomies were performed at the University of Michigan. A total of 400 patients were included for analysis, 200 consecutive patients before the policy change (group A—drop-in patients) and 200 after the policy change (group B—patients with scheduled appointment). Thirteen patients were excluded from analysis, including six from group A (three for repeat vasectomy and three for undergoing other surgeries, such as urethroplasty, hydrocelectomy, or orchiectomy, at the same time of the vasectomy). In group B, seven patients were excluded (two for repeat vasectomy and five for undergoing other surgeries at same time including two hydrocelectomy, two hernia repairs, and one orchiectomy). Patients had a mean (standard deviation [SD]) age of 39 (6) yr and a median (range) number of children of 2 (0–6), and this was not different between groups ($p = 0.76$ and $p = 0.41$, respectively; Table 1).

Complications after the vasectomy were mostly of grade 1 according to the Clavien-Dindo classification [11], and included 39 patients (10%) experiencing minor swelling and/or pain after the vasectomy, nine (2%) having a sperm granuloma, and two (0.5%) experiencing transient hematospermia. Four patients (1%) had a grade 2 Clavien-Dindo complication as they experienced wound infection, which was treated with peroral antibiotics. No unwanted pregnancies were recorded after the procedure in any patient.

In total, 298/387 (77%) patients attended the PVSA. PVSA compliance was 144/194 (74%) in group A and 154/193 (80%) in group B ($p = 0.19$). The mean time (SD) to the PVSA was 71 ($\pm$59) d for the whole group. The time from vasectomy to the PVSA in group A was 69 ($\pm$55) d and that in group B was 74 ($\pm$63) d ($p = 0.44$). All patients who attended the first PVSA were asked to deliver a sample for a second PVSA to verify azoospermia. In total, 228/298 (76.5%) attended the second PVSA. In group A, 111/144 (77.1%) men attended the

Table 1 – Patient characteristics and PVSA details

	All	Before policy change	After policy change	*p* value
Age (yr)				
Mean ± SD	39 ± 6	39 ± 6	40 ± 6	0.76
Median (range)	39 (23–64)	39 (23–64)	39 (26–64)	
Number of kids				
Mean ± SD	2.3 ± 0.9	2.3 ± 1.0	2.3 ± 0.9	0.41
Median (range)	2 (0–6)	2 (0–6)	2 (0–5)	
0, *n* (%)	13 (4)	7 (4)	6 (3)	
1, *n* (%)	33 (9)	20 (11)	13 (7)	
2, *n* (%)	204 (55)	98 (52)	106 (59)	
3, *n* (%)	91 (25)	49 (26)	42 (23)	
4, *n* (%)	20 (5)	8 (4)	12 (7)	
5, *n* (%)	5 (1)	3 (2)	2 (1)	
6, *n* (%)	2 (1)	2 (1)	0 (0)	
First PVSA				
Attended, *n* (%)	298/387 (77)	144/194 (74)	154/193 (80)	0.19
Azoospermic, *n* (%)	240/298 (80.2)	–	–	
RNMS, *n* (%)	51/298 (17.1)	–	–	
NMS >100 000, *n* (%)	7/298 (2.3)	–	–	
Second PVSA				
Attended, *n* (%)	228/298 (76)	111/144 (77)	117/154 (76)	0.82
Azoospermic, *n* (%)	218/228 (95.6)	–	–	
RNMS, *n* (%)	10/228 (4.4)	–	–	
NMS >100,000, *n* (%)	1/228 (0.4)	–	–	
Time to 1st PVSA (d)				
Mean ± SD	71 ± 59	69 ± 55	74 ± 63	0.44
Median (range)	51 (16–421)	50 (16–343)	53 (20–421)	

NMS = normal motile sperm; PVSA = postvasectomy semen analysis; RNMS = rare nonmotile sperm; SD = standard deviation.

second PVSA, and in group B 117/154 (76.0%) attended the second PVSA ($p = 0.82$).

At the first PVSA, 240/298 (80.5%) were azoospermic. Among the remaining men, 51/58 had rare sperm (RNMS) and were considered sterile, while 7/58 men had many sperm. Three of the men with many sperm found on the first PVSA were azoospermic on the second PVSA, and three were azoospermic on the third PVSA. One man continued to have sperm in his ejaculate on the third PVSA, and therefore he underwent a successful repeat vasectomy.

4. Discussion

This study found that changing PVSA protocols from "drop-in" appointments to scheduled appointments did not change significantly the number of patients who attended the PVSA. Moreover, the time between vasectomy and PVSA did not change significantly when scheduling appointments.

PVSA is an important step to ensure the success of a vasectomy before the use of other contraceptive methods can be terminated. Patients cannot be guaranteed sterility immediately after a vasectomy for several reasons. Failure to occlude the vas deferens may occur during the procedure, and there is a possibility for early recanalization between the two ends of the vas deferens [2,12]. Residual sperm might also be present in the male reproductive system, requiring a number of ejaculations to clear the system [13]. While the success rate of vasectomies is high, there is still a risk of unwanted pregnancy. This has been estimated to occur in one of 2000 vasectomies [3]. Having an unwanted pregnancy after vasectomy is frustrating for the couple and may result in medicolegal consequences for the physician performing the vasectomy [14,15].

Compliance with PVSA has historically been low, and the problem persists to this day. In a study by Bieniek et al [16], PVSA compliance was retrospectively assessed in 230 men undergoing a vasectomy between December 2009 and August 2012. Patients were instructed to deliver one semen sample 3 months after the procedure. Success was defined as a single sample showing azoospermia. For PVSA, a semen sample was delivered by 111 (48.3%) of the men at a mean (range) of 17.8 (4–45) weeks after the procedure. Another study by Duplisea and Whelan [8] retrospectively investigated PVSA compliance between January 2002 and December 2009. Patients were asked to deliver two semen samples 16 weeks after the procedure. In total, 946 patients underwent a vasectomy and 493 (52.1%) delivered either one or two samples. Multiple studies report a similar finding that only around 50% of patients attend a PVSA [7,9,17–19], while only a few studies demonstrate higher patient compliance rates of around 70–80% [20,21]. Our study presents one of the higher reported compliance rates for a PVSA. Although we did not specifically assess why we found relatively high compliance rates, it might be due to extensive communication with patients while instructing them on how to deliver a sample for PVSA. However, providing patients, both pre- and postoperatively, with written information and counseling them regarding the importance of PVSA have also been described in studies that report a low compliance rate of around 50% with PVSA [7,8,19]. To assess why compliance in our study was high

compared with other studies, a more detailed analysis of patient characteristics is needed. Only a few studies have investigated patient characteristics of men attending a PVSA. Low compliance has been associated with having four or more children and a lower educational level, while age and marital status have been demonstrated not to affect compliance [17]. Further studies are needed to elaborate the predictors of both low and high compliance with PVSA.

Before the 2012 AUA vasectomy guidelines [3], most institutions and studies requested two semen samples after the vasectomy. It has previously been debated whether the task of delivering two samples presented an overwhelming task for patients, and the necessity of determining azoospermia in two samples has also been debated [20–22]. In 2012, the guidelines of both the AUA [3] and EAU [4] were changed to recommend one PVSA 8–16 weeks after vasectomy, with the man considered sterile if the sample showed azoospermia or RNMS. While it would be intuitive that instructing patients to attend one PVSA instead of two would increase compliance, this has not been the case. Both the studies mentioned above, by Duplisea and Whelan [8] and Bieniek et al [16], found low patient compliance with PVSA, even though the first study instructed patients to deliver only one semen sample and the latter study asked patients to deliver two samples. Very few studies have investigated compliance when requesting one sample from patients for PVSA, but these studies have also found an overall low compliance rate of around 50% with PVSA [19,23,24]. Therefore, other measures should be explored to increase compliance. In a study by Dhar et al [25], 228 men undergoing vasectomy from 2003 to 2005 were evaluated; here, 114 men were asked to deliver a semen sample to the clinic as a "drop-in" appointment and the other 114 were scheduled for a follow-up appointment with a nurse when the sample was delivered. All patients were instructed to deliver the first semen sample for PVSA 2 mo after the procedure and the second one a month later. This was done until two consecutive samples showed azoospermia. Among the patients who were scheduled for an appointment, 96/114 (84%) delivered the sample and in the group, who were not scheduled for an appointment, 74/114 (65%, $p = 0.001$) delivered a semen sample. Moreover, 43/114 (48%) of the men who were scheduled for an appointment delivered the second sample, whereas for the men who did not get an appointment only 23/114 (20%, $p = 0.005$) delivered the second sample. This study demonstrated a significant effect on the number of patients attending a PVSA when appointments were scheduled instead of "drop-in" appointments. Interestingly, this was not found in our study. The major difference between the study by Dhar et al [25] and our study is that their patients were prospectively enrolled in the study, which might have affected patient compliance positively, as previously mentioned. Further, there might have been differences in study populations, and in general, it seems difficult to increase a compliance rate that is relatively high to begin with.

In general, there is a lack of literature investigating the methods of increasing compliance with PVSA. Our study is the largest study investigating different approaches for improving patient compliance with PVSA by scheduling appointments in preference to "drop-in" appointments. This study was undertaken to evaluate the effect of an institutional policy change to schedule specific appointments instead of a previous drop-in option. Although the data are from the period 2008–2010, the effect of the policy change was unknown previously. A possible limitation of this study is that data on educational level, age of children, and occupation were not reviewed, and these might influence compliance. Further, this study is retrospective with patients not knowing that the change in policy would eventually be investigated. However, this might actually be a strength as knowingly participating in a study might influence compliance.

More studies are needed to determine the effect of scheduling appointments for PVSA on patient compliance.

5. Conclusions

Scheduling appointments instead of a "drop-in" policy for PVSA did not have a significant impact on compliance rates for PVSA or on follow-up time between vasectomy and PVSA.

Author contributions: Frederik M. Jacobsen had full access to all the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.

Study concept and design: Jensen, Ohl.
Acquisition of data: Jensen, Ohl.
Analysis and interpretation of data: Jensen.
Drafting of the manuscript: Jacobsen, Jensen.
Critical revision of the manuscript for important intellectual content: All authors.
Statistical analysis: Jensen.
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Supervision: Sønksen, Ohl.
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