Original Article
Male reproductive health and infertility

pISSN: 2287-4208 / eISSN: 2287-4690
World J Mens Health Published online Jan 2, 2022
https://doi.org/10.5534/wjmh.210191

The World Journal of MEN's HEALTH

Post-Vasectomy Semen Analysis: Optimizing Laboratory Procedures and Test Interpretation through a Clinical Audit and Global Survey of Practices

Ashok Agarwal[1], Sajal Gupta[1], Rakesh K. Sharma[1], Renata Finelli[1], Shinnosuke Kuroda[1], Sarah C. Vij[2], Florence Boitrelle[3,4], Parviz Kavoussi[5], Amarnath Rambhatla[6], Ramadan Saleh[7], Eric Chung[8], Taymour Mostafa[9], Armand Zini[10], Edmund Ko[11], Neel Parekh[2], Marlon Martinez[12], Mohamed Arafa[1,13,14], Nicholas Tadros[15], Jean de la Rosette[16], Tan V. Le[17,18], Osvaldo Rajmil[19], Hussein Kandil[20], Gideon Blecher[21], Giovanni Liguori[22], Ettore Caroppo[23], Christopher C.K. Ho[24], Andrew Altman[2], Petar Bajic[2], David Goldfarb[2], Bradley Gill[2], Daniel Suslik Zylbersztejn[25], Juan Manuel Corral Molina[26], Marcello M. Gava[27,28], Joao Paulo Greco Cardoso[29], Raghavender Kosgi[30], Gökhan Çeker[31], Birute Zilaitiene[32], Edoardo Pescatori[33], Edson Borges Jr[34], Gede Wirya Kusuma Duarsa[35], Germar-Michael Pinggera[36], Gian Maria Busetto[37], Giancarlo Balercia[38], Giorgio Franco[39], Gökhan Çalik[40], Hassan N. Sallam[41], Hyun Jun Park[42,43], Jonathan Ramsay[44], Juan Alvarez[45], Kareim Khalafalla[13], Kasonde Bowa[46], Lukman Hakim[47], Mara Simopoulou[48], Marcelo Gabriel Rodriguez[49], Marjan Sabbaghian[50], Haitham Elbardisi[13,14], Massimiliano Timpano[51], Mesut Altan[52], Mohamed Elkhouly[53], Mohamed S. Al-Marhoon[54], Mohammad Ali Sadighi Gilani[50], Mohammad Ayodhia Soebadi[47], Mohammad Hossein Nasr-Esfahani[55], Nicolas Garrido[56], Paraskevi Vogiatzi[57], Ponco Birowo[58], Premal Patel[59], Qaisar Javed[60], Rafael F. Ambar[28,61], Ricky Adriansjah[62], Sami AlSaid[13], Sava Micic[63], Sheena E. Lewis[64], Shingai Mutambirwa[65], Shinichiro Fukuhara[66], Sijo Parekattil[67], Sun Tae Ahn[68], Sunil Jindal[69], Teppei Takeshima[70], Ana Puigvert[71], Toshiyasu Amano[72], Trenton Barrett[73], Tuncay Toprak[74], Vineet Malhotra[75], Widi Atmoko[58], Yasushi Yumura[70], Yoshiharu Morimoto[76], Thiago Fernandes Negris Lima[77], Yannic Kunz[36], Yuki Kato[78], Yukihiro Umemoto[79], Giovanni M. Colpi[80], Damayanthi Durairajanayagam[81], Rupin Shah[82]

[1]American Center for Reproductive Medicine, Cleveland, OH, USA, [2]Department of Urology, Glickman Urological and Kidney Institute, Cleveland Clinic, Cleveland, OH, USA, [3]Reproductive Biology, Fertility Preservation, Andrology, CECOS, Poissy Hospital, Poissy, France, [4]Paris Saclay University, UVSQ, INRAE, BREED, Jouy-en-Josas, France, [5]Austin Fertility and Reproductive Medicine/Westlake IVF, Department of Urology, University of Texas Health Science Center at San Antonio, San Antonio, TX, USA, [6]Vattikuti Urology Institute, Henry Ford Health System, Detroit, MI, USA, [7]Department of Dermatology, Venereology and Andrology, Faculty of Medicine, Sohag University, Sohag, Egypt, [8]Department of Urology, Princess Alexandra Hospital, University of Queensland, Brisbane, Australia, [9]Department of Andrology, Sexology & STIs, Faculty of Medicina, Cairo University, Cairo, Egypt, [10]Department of Surgery, McGill University, Montreal, QC, Canada, [11]Department of Urology, Loma Linda University Health, Loma Linda, CA, USA, [12]Section of Urology, University of Santo Tomas Hospital, Manila, Philippines, [13]Department of Urology, Hamad Medical Corporation, Doha, Qatar, [14]Department of Urology, Weill Cornell Medical-Qatar, Doha, Qatar, [15]Division of Urology, Southern Illinois University School of Medicine, Springfield, IL, USA, [16]Department

Received: Aug 30, 2021 **Revised:** Sep 16, 2021 **Accepted:** Sep 23, 2021 **Published online** Jan 2, 2022
Correspondence to: Ashok Agarwal https://orcid.org/0000-0003-0585-1026
Andrology Center and American Center for Reproductive Medicine, Cleveland Clinic, Mail Code X-11, 10681 Carnegie Avenue, Cleveland, OH 44195, USA.
Tel: +1-216-444-9485, **Fax:** +1-216-445-6049, **E-mail:** agarwaa@ccf.org, **Website:** www.Clevelandclinic.org/ReproductiveResearchCenter

of Urology, Medipol Mega University Hospital, Istanbul, Turkey, [17]Department of Andrology, Binh Dan Hospital, Ho Chi Minh City, Vietnam, [18]Department of Urology and Andrology, Pham Ngoc Thach University of Medicine, Ho Chi Minh City, Vietnam, [19]Department of Andrology, Fundacio Puigvert, Barcelona, Spain, [20]Fakih IVF Fertility Center, Abu Dhabi, UAE, [21]Department of Surgery, School of Clinical Sciences, Monash University, Melbourne, Australia, [22]Department of Urology, University of Trieste, Trieste, Italy, [23]Reproductive and IVF Unit, Asl Bari, Bari, Italy, [24]Department of Surgery, School of Medicine, Faculty of Health and Medical Sciences, Taylor's University, Subang Jaya, Malaysia, [25]Department of Reproductive Medicine and Urology, Hospital Israelita Albert Einstein, São Paulo, Brazil, [26]Servicio de Urología, Hospital Clínico de Barcelona, Barcelona, Spain, [27]Sexual and Reproductive Medicine, Department of Urology, Faculdade de Medicina do ABC, Santo André, Brazil, [28]Andrology Group at Ideia Fertil Institute of Human Reproduction, Santo André, Brazil, [29]Divisao de Urologia, Hospital das Clínicas HCFMUSP, Universidade de Sao Paulo, São Paulo, Brazil, [30]Department of Urology and Andrology, AIG Hospitals, Gachibowli, Hyderabad, India, [31]Department of Urology, Samsun Vezirköprü State Hospital, Samsun, Turkey, [32]Institute of Endocrinology, Lithuanian University of Health Sciences, Kaunas, Lithuania, [33]Andrology and Reproductive Medicine Unit, Gynepro Medical, Bologna, Italy, [34]Fertility Medical Group, São Paulo, Brazil, [35]Department of Urology, Faculty of Medicine, Sanglah General Academic Hospital, Udayana University, Denpasar, Indonesia, [36]Department of Urology, Innsbruck Medical University, Innsbruck, Austria, [37]Department of Urology and Organ Transplantation, University of Foggia, Ospedali Riuniti of Foggia, Foggia, Italy, [38]Department of Endocrinology and Metabolic Diseases, Polytechnic University of Marche, Ancona, Italy, [39]UOC Urologia, Department Materno-Infantile e Scienze Urologiche, AOU Policlinico Umberto I, Sapienza University of Rome, Rome, Italy, [40]Department of Urology, Faculty of Medicine, Istanbul Medipol University, Istanbul, Turkey, [41]Department of Obstetrics and Gynaecology, Alexandria University Faculty of Medicine, Alexandria, Egypt, [42]Department of Urology, Pusan National University School of Medicine, Busan, Korea, [43]Medical Research Institute of Pusan National University Hospital, Busan, Korea, [44]Department of Andrology, Hammersmith Hospital, London, UK, [45]Centro ANDROGEN, La Coruña, Spain, [46]Department of Urology, School of Medicine and Health Sciences, University of Lusaka, Lusaka, Zambia, [47]Department of Urology, Universitas Airlangga/Rumah Sakit Universitas Airlangga Teaching Hospital, Surabaya, Indonesia, [48]Department of Experimental Physiology, School of Health Sciences, Faculty of Medicine, National and Kapodistrian University of Athens, Athens, Greece, [49]Departamento Docencia e Investigación, Hospital Militar Campo de Mayo, Universidad Barcelo, Buenos Aires, Argentina, [50]Department of Andrology, Reproductive Biomedicine Research Center, Royan Institute for Reproductive Biomedicine, ACECR, Tehran, Iran, [51]A.O.U. Città della Salute e della Scienza di Torino, Molinette, Italy, [52]Department of Urology, Hacettepe University, Ankara, Turkey, [53]Bourne Hall Fertility Center, Dubai, UAE, [54]Department of Surgery, Urology Division, Sultan Qaboos University, Muscat, Oman, [55]Department of Animal Biotechnology, Reproductive Biomedicine Research Center, Royan Institute for Biotechnology, ACECR, Isfahan, Iran, [56]IVI Foundation, Instituto de Investigación Sanitaria La Fe (IIS La Fe), Valencia, Spain, [57]Andromed Health & Reproduction, Fertility Diagnostics Laboratory, Maroussi, Greece, [58]Department of Urology, Cipto Mangunkusumo General Hospital, Faculty of Medicine, Universitas Indonesia, Jakarta, Indonesia, [59]Section of Urology, University of Manitoba, Winnipeg, MB, Canada, [60]Department of Urology, Ahalia Hospital, Hamdan Street Branch, Abu Dhabi, UAE, [61]Department of Urology, Centro Universitario em Saude do ABC, Santo André, Brazil, [62]Department of Urology, Faculty of Medicine, Universitas Padjadjaran, Hasan Sadikin General Hospital, Bandung, Indonesia, [63]Department of Andrology, Uromedica Polyclinic, Belgrade, Serbia, [64]Examenlab Ltd., Weavers Court Business Park, Linfield Road, Belfast, Northern Ireland, UK, [65]Division of Urology, Safeko Makgatho Health Scienses University and Dr George Mukhari Academic Hospital, Pretoria, South Africa, [66]Department of Urology, Graduate School of Medicine, Osaka University, Osaka, Japan, [67]Avant Concierge Urology & University of Central Florida, Winter Garden, FL, USA, [68]Department of Urology, Korea University Guro Hospital, Korea University College of Medicine, Seoul, Korea, [69]Department of Andrology and Reproductive Medicine, Jindal Hospital, Meerut, India, [70]Department of Urology, Reproduction Center, Yokohama City University Medical Center, Yokohama, Japan, [71]Fundació Puigvert, Hospital de la Santa Cruz y San Pablo, Universidad Autonoma de Barcelona, Barcelona, Spain, [72]Department of Urology, Nagano Red Cross Hospital, Nagano, Japan, [73]Perth Urology Clinic, Perth, WA, Australia, [74]Department of Urology, University of Health Sciences, Fatih Sultan Mehmet Training and Research Hospital, Istanbul, Turkey, [75]Department of Andrology and Urology, Diyos Hospital, New Delhi, India, [76]HORAC Grand Front Osaka Clinic, Osaka, Japan, [77]Department of Urology, Veredas Hospital, Maceió, Brazil, [78]Department of Integrative Cancer Therapy and Urology, Kanazawa University Graduate School of Medical Science, Kanazawa, Japan, [79]Department of Nephro-Urology, Nagoya City West Medical Center, Nagoya, Japan, [80]Andrology Unit, Procrea Institute, Lugano, Switzerland, [81]Department of Physiology, Faculty of Medicine, Universiti Teknologi MARA, Sungai Buloh Campus, Selangor, Malaysia, [82]Division of Andrology, Department of Urology, Lilavati Hospital and Research Centre, Mumbai, India

Purpose: The success of vasectomy is determined by the outcome of a post-vasectomy semen analysis (PVSA). This article describes a step-by-step procedure to perform PVSA accurately, report data from patients who underwent post vasectomy semen analysis between 2015 and 2021 experience, along with results from an international online survey on clinical practice.
Materials and Methods: We present a detailed step-by-step protocol for performing and interpretating PVSA testing, along with recommendations for proficiency testing, competency assessment for performing PVSA, and clinical and laboratory scenarios. Moreover, we conducted an analysis of 1,114 PVSA performed at the Cleveland Clinic's Andrology Laboratory and an online survey to understand clinician responses to the PVSA results in various countries.
Results: Results from our clinical experience showed that 92.1% of patients passed PVSA, with 7.9% being further tested. A total of 78 experts from 19 countries participated in the survey, and the majority reported to use time from vasectomy rather than the number of ejaculations as criterion to request PVSA. A high percentage of responders reported permitting unprotected intercourse only if PVSA samples show azoospermia while, in the presence of few non-motile sperm, the majority of

responders suggested using alternative contraception, followed by another PVSA. In the presence of motile sperm, the majority of participants asked for further PVSA testing. Repeat vasectomy was mainly recommended if motile sperm were observed after multiple PVSA's. A large percentage reported to recommend a second PVSA due to the possibility of legal actions.
Conclusions: Our results highlighted varying clinical practices around the globe, with controversy over the significance of non-motile sperm in the PVSA sample. Our data suggest that less stringent AUA guidelines would help improve test compliance. A large longitudinal multi-center study would clarify various doubts related to timing and interpretation of PVSA and would also help us to understand, and perhaps predict, recanalization and the potential for future failure of a vasectomy.

Keywords: Male contraception; Semen; Sperm; Survey; Vasectomy

INTRODUCTION

Vasectomy is a surgical technique where the vasa deferentia are divided and ligated with sutures or clips and/or electrocautery, with or without tissue interposition, thereby preventing the delivery of sperm through the vas into the ejaculate. Since 1830, when it was first performed, and through its progressive modifications as a procedure, vasectomy has become the most effective method of male contraception [1]. In many countries, it is the most common male contraception other than the use of condoms [2,3], and vasectomy has been reported to account for 5% to 10% of all contraceptive approaches used by couples worldwide [3-5]. In the United States, 11% of couples utilize vasectomy as a primary method of contraception, with 527,476 vasectomies performed in 2015 [6].

The procedure is intended to be permanent, but sterility is not achieved immediately [7] as there are sperm in the distal vas that need to be expelled, and other forms of contraception must be utilized until the success of the vasectomy is confirmed. Rare failures due to recanalization can occur. Hence, correct post-vasectomy monitoring to document the success of the procedure is very important. Between January 1990 and December 2017, the Westlaw database identified 67 lawsuits related to vasectomy in the United States, of which pregnancy/wrongful birth was the most common reason for suing [8].

According to the American Urological Association (AUA) vasectomy guidelines, the success of the vasectomy procedure is confirmed when a post-vasectomy semen analysis (PVSA) (Fig. 1) demonstrates either complete absence of sperm (azoospermia) or the presence of only rare non-motile sperm (RNMS, ≤100,000 non-motile sperm/mL) in one well-mixed, fresh, uncentrifuged post-vasectomy semen sample [7,9,10] (Fig. 2).

Azoospermia signifies that the distal segment of the vas, seminal vesicles, and ejaculatory ducts have shown clearance of the spermatozoa and that no technical failure or recanalization has occurred. However, some patients will demonstrate RNMS (≤100,000 non-motile sperm/mL) on PVSA, and according to the AUA guidelines they are still considered sterile. The timing of PVSA recommended by the AUA is at least 8 to 16 weeks post-procedure and varies by surgeon [7,11]. An additional PVSA should be performed in cases where the first screening fails and these evaluations need to be repeated until the PVSA sample passes the AUA criteria for success. Any motile sperm on PVSA at 6 months is considered a failure and a repeat vasectomy should be considered [7]. The presence of >100,000 non-

Fig. 1. The success of a vasectomy procedure is confirmed by semen analysis. (A) Semen sample is collected, (B) loaded into a micro-chamber, and (C) analyzed microscopically or through automatic analyzers.

The World Journal of MEN's HEALTH

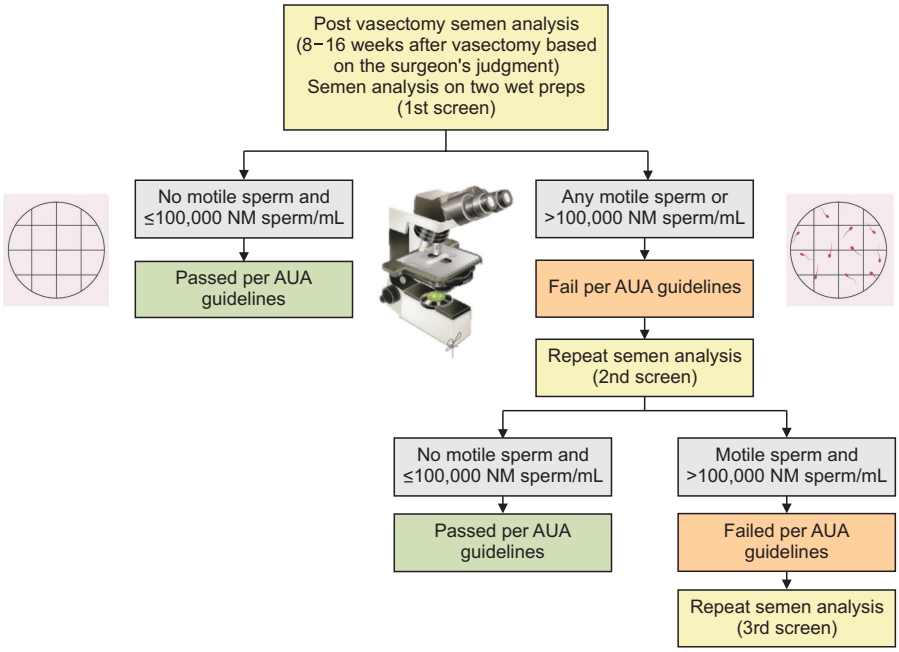

Fig. 2. Workflow summarizing the steps for post-vasectomy screen as per the American Urological Association (AUA) guidelines. NM: non-motile.

motile sperm/mL at 6 months is considered a potential failure and requires the surgeon to assess the trends of the PVSA results and use clinical judgment for further management of the patient [7]. However, guidelines from other professional societies differ on some of these points (Table 1) and hence this study was carried out to provide much-needed clarity on PVSA testing and its clinical interpretation.

The aims of this study are three-fold as follows:

(1) To present a detailed step-by-step protocol for PVSA testing together with a guide for reporting and interpretation of test results, and recommendations for proficiency testing and competency assessment for performing PVSA.

(2) To understand clinician responses to the first PVSA result and outcomes of further PVSA testing *via* a clinical audit of PVSA testing performed in the Cleveland Clinic's Andrology Laboratory.

(3) To review global attitudes of clinicians towards PVSA testing through an online survey of PVSA testing practices amongst experts in various countries and comparing these results with the guidelines from various professional societies.

MATERIALS AND METHODS

1. Step-by-step protocol for post-vasectomy semen analysis

1) Specimen collection

Patients should be provided with clear instructions on the proper collection technique of the post-vasectomy semen sample, which can be collected either at home or onsite. Based on the World Health Organization (WHO) guidelines [12,13], patients must adhere to 2 to 7 days of abstinence before the sample collection either by masturbation into a sterile container or through collection into a special semen collection condom designed for semen analysis. Only specific non-spermicidal lubricants, such as Surgilube, which can be provided by the laboratory should be used to aid collection, without using saliva or any other lubricants such as oils. The ejaculate sample is brought to the laboratory at a scheduled appointment time within one hour of collection (see Table 1 for different collection time recommendations from various bodies). The sample must be kept at 20°C to 37°C when in transit. The PVSA should include evaluation of the semen volume and wet preparation for the presence of sperm and its motility [14].

Table 1. Comparative study of society guidelines for PVSA screen outcomes

Society name guidelines/year	Abstinence/ejaculations	Specimen collection and examination	Pass/fail criteria for PVSA	Comments
AUA/2012 (amended 2015) [7,10,11]	Recommended at 8–16 weeks post procedure.	A fresh single, uncentrifuged semen sample should be examined within two hours after ejaculation.	1. Pass: azoospermia 2. Pass: RNMS ≤100,000 non-motile sperm per mL 3. Fail: if any motile sperm are seen on PVSA 4. Fail: >100,000 non-motile sperm/mL	Clinical judgment is needed if serial PVSA of >100,000 non-motile sperm/mL persist beyond six months after vasectomy. Vasectomy is considered a failure if motile sperm are found after 6 months.
ABA, BAS, BAUS/2016 [17,18]	12 weeks after surgery and after a minimum of 20 ejaculations.	Samples should be routinely evaluated within 4 hours of production if assessing for the presence of sperm. If non-motile sperm are seen, then further samples must be examined within 1 hour of collection.	1. Pass: single sample shows azoospermia 2. Pass: special clearance level is defined as <100,000 non-motile sperm/mL 3. Special clearance cannot be given if any motile sperm are observed	If any motile are seen, special clearance is given only after examination of two samples meeting the passing criteria.
EAU/2012 [15,16]	The screen should be performed at 3 months after the procedure and at least 20 ejaculations.	Semen analysis was performed as per the WHO 2010 guidelines.	1. Pass: azoospermia 2. Pass: if <100,000 non-motile sperm/mL	The persistent presence of motile sperm at >6 months of follow-up is an indication to perform a repeat vasectomy.
CUA/2016 [23]	Semen analysis should be done 3 months after the procedure after 2–7 days of abstinence.	Semen analysis should be performed on whole unprocessed semen and centrifuged semen with reporting of sperm concentration at 400× magnification.	1. Pass: one sample with azoospermia 2. Pass: two samples with severe oligospermia (<100,000 immotile sperm per sample) 3. Fail: any motile sperm 4. Fail: >100,000 immotile sperm/mL	The evaluation of two samples after the procedure is a better predictor of success than one sample.
ASERNIP-S/2014 [24]	Semen analysis 3 months after the procedure with at least 20 ejaculations.	No specific conditions mentioned.	1. Pass: azoospermia 2. Pass: special clearance–2 consecutive tests with <100,000 immotile sperm/mL at least 7 months after the procedure 3. Fail: motile sperm–confirm with a repeat test after 1 month	The presence of immotile sperm is inconclusive–repeat test every month until azoospermia or special clearance given.

PVSA: post-vasectomy semen analysis, AUA: American Urological Association, ABA: Association of Biomedical Andrologists, BAS: British Andrology Society, BAUS: British Association of Urological Surgeons, EAU: European Association of Urology, CUA: Canadian Urological Association, ASERNIP-S: Australian Safety and Efficacy Register of New Interventional Procedures–Surgical, RNMS: rare non-motile sperm, WHO: World Health Organization.

2) Specimen rejection criteria

Criteria for sample rejection include: samples received after 2 hours of collection, or following improper storage, such as frozen or refrigerated samples, or overall transportation of sample at a lower or higher temperature than the recommended range of 20°C to 37°C.

3) Macroscopic examination of the sample

After complete liquefaction, the sample pH, volume, color, and viscosity are examined. If the sample is viscous, it can be enzymatically treated with trypsin enzyme, by incubating the sample for an additional 10 minutes at 37°C [14] or it can be mechanically treated to reduce viscosity by techniques such as pipetting.

4) Microscopic examination of the sample

This step includes the examination of the sample for the presence of sperm. Six μL of the sample are loaded on a fixed cell counting chamber. At least two wet preparations must be scanned thoroughly for the presence of sperm under high power magnification (200×). If sperm are present, an estimation of the sperm concentration is performed. The sperm concentration is calculated manually to check whether it is greater or equivalent to/less than 100,000 non-motile sperm/mL. Sperm are also examined for motility and, if present, sperm motility is estimated and reported as percent motility [12].

5) Definition of vasectomy success

The international guidelines for vasectomy success vary slightly as reported by the European Association of Urology (EAU) [15,16], British Association of Urological Surgeons (BAUS) [17,18], and the AUA [10] (Table 1). The EAU recommends that clearance can be given if the PVSA demonstrates azoospermia or RNMS (<100,000 non-motile sperm/mL) in the ejaculate at least 3 months post-procedure. The BAUS guidelines allow clearance if two centrifuged semen samples document azoospermia or RNMS, at 12 weeks after the procedure and after a minimum of 20 ejaculations. The 2012 AUA vasectomy guidelines denote procedural success with azoospermia or RNMS in a single uncentrifuged sample.

6) Reporting and interpretation of post-vasectomy semen analysis results

A PVSA result may be reported as the "absence of sperm in wet preparations from an uncentrifuged sample" if there are no sperm observed [14]. If sperm are present, it must be reported whether they are motile or immotile on wet preparation, and if motile sperm are seen this should be reported as percentage motile sperm. If there are enough sperm to be quantitated, then the concentration should be reported (Table 2). If there are are not enough sperm to be quantitated in M/mL, the use of the following codes is recommended:

(1) ≤100K NMS: less than or equal to 100,000/mL non-motile sperm; result passes AUA criteria for vasectomy success.

(2) >100K NMS: greater than 100,000/mL non-motile sperm; result fails AUA criteria for vasectomy success.

(3) RMS: rare motile sperm; result fails AUA criteria for vasectomy success.

2. Clinical audit of post-vasectomy semen analysis

All records of PVSA performed at the Andrology Laboratory, Cleveland Clinic's, from March 2015 to August 2021 were retrospectively collected. The data were analyzed and recorded as "passed" or " failed" on the first, second and third PVSA, so that repeat tests and their further outcomes could be charted. Data is presented descriptively, and no statistical analysis was conducted.

3. Online global survey

An online survey was carried out by the Andrology Team (AA, RKS, SG, RF, and SK), to investigate the use of PVSA in the monitoring of vasectomized patients (Supplement File 1). Questions were framed by a team of experts composed of urologists, andrologists, and researchers in male infertility focusing on the timing of PVSA, its interpretation, and the subsequent

Table 2. Clinical utility of the PVSA test based on AUA criteria

Results	AUA criteria
Absence of sperm in uncentrifuged wet preparation	Pass
Non-motile sperm count less than or equal to 100,000/mL	Pass
Non-motile sperm count greater than 100,000/mL	Fail
Sperm motility greater than 0%	Fail

PVSA: post-vasectomy semen analysis, AUA: American Urological Association.

clinical actions. The survey was written in English and included questions about demographic data (n=7 questions), and PVSA practice (n=14 questions). The SelectSurvey (https://www.classapps.com/product_ssv5.aspx) platform was used to populate the survey, and the link was sent by e-mail to a targeted audience of urologists performing vasectomy, selected among 93 collaborators. These experts further shared the link through their personal network worldwide. The link was open from August 13, 2021, to August 23, 2021, to allow the participants to provide their responses. Results were downloaded as a comma-separated values (CSV) file format and analyzed using Excel after the exclusion of incomplete answers. Data are reported as the number of participants and the percentage was calculated based on the total number of participants.

4. Ethics statement

The present study protocol was reviewed and approved by the Institutional Review Board of the Cleveland Clinic (IRB no. 21-839).

RESULTS

1. Clinical audit of post-vasectomy semen analysis

The PVSA results of 1,114 patients were examined. At the first PVSA examination, 1,026/1,114 patients (92.1%) passed as per the AUA guidelines. Out of 88 patients who reported failed PVSA, 57 (64.8%) showed the presence of greater than 100,000 non-motile sperm/mL, while motile sperm were observed in 6 patients (6.8%) (Fig. 3). A total of 25 patients (28.4%) failed PVSA due to both the presence of greater than 100,000 sperm/mL and motility >0%. Failure of the first PVSA screen was an indication for performing a second PVSA (Fig. 4). Out of 1,026 men who had passed the first test, 80 were

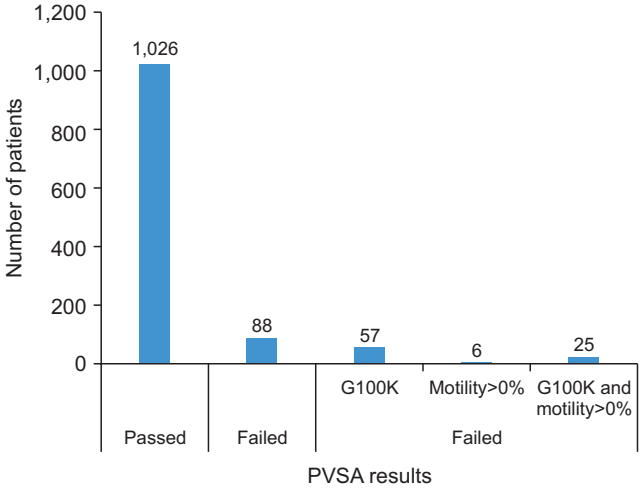

Fig. 3. First post-vasectomy semen analysis (PVSA) results of patients (n=1,114) who underwent vasectomy at the Cleveland Clinic's Andrology Laboratory. G100K: greater than 100,000 non-motile sperm.

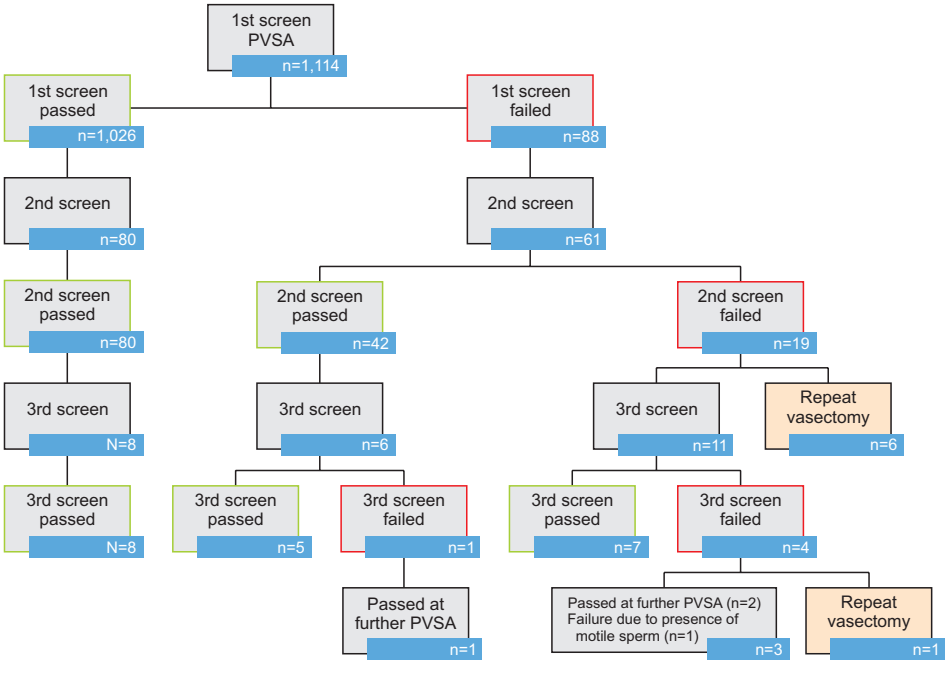

Fig. 4. Detailed post-vasectomy semen analysis (PVSA) results of 1,114 patients who had their post-vasectomy screen at the Cleveland Clinic's Andrology Laboratory between March 2015 to August 2021.

retested based on surgeon preference and all of them passed the second PVSA. Of these, 7 were retested for the third PVSA due to physician or patient's preference and all passed the test. A total of 88 men failed the first PVSA, however, only 61 men underwent the second PVSA; of these, 42 (69%) passed the repeat test, however, 6 men were tested for the third time. One man who had passed the second PVSA failed the third test due to the presence of non-motile sperm (>100,000/mL) but passed the 4th PVSA. A total of 19 men failed the second PVSA (31%). Of these, 6 underwent repeat vasectomy, while 11 (58%) were retested for a third PVSA. As shown in Fig. 4, 7 passed the test at their third attempt, while 4 failed. Of these four, 2 passed at 4th or 5th test, 1 underwent repeat vasectomy, while 1 showed motile sperm and was considering a repeat vasectomy.

2. Online global survey

After removing incomplete answers, we analyzed the responses provided by 78 out of 93 (83.9%) participants who confirmed that they perform vasectomies in their respective clinics. Participants were from 19 countries (Fig. 5); demographic data are reported in Supplement File 2. Responses to the survey are listed in Table 3. The experience level of the participants was uniformly distributed with 39% being lower volume surgeons (<20 vasectomies per year), while 38% were higher volume surgeons (>50 vasectomies per year) (Fig. 6). The majority of surgeons used time from vasectomy, rather than the number of ejaculations, as the criterion for requesting the first PVSA. The presence of motile sperm in PVSA was checked primarly within 1 hour (Fig. 7). A high percentage of participants (42.3%) reported permitting unprotected intercourse only if PVSA samples show azoospermia (Fig. 8). In cases where a few non-motile sperm are found in the first PVSA, the majority of participants (60.3%, n=47) suggested using alternative contraception, followed by another semen analysis after 1 month (Fig. 9).

If motile sperm were found in the first PVSA, the majority (56.4%, n=44) opted to wait for another 1 to 3 months and repeat the PVSA before taking any decision, but 12 participants (15.4%) advocated immediate repeat vasectomy (Fig. 10). In the presence of persistent motile sperm, confirmed by multiple PVSA

Fig. 5. Geographical distribution of participants to the survey from 19 countries (created by using Tableau Public, https://public.tableau.com/en-us/s/).

Table 3. Participants' responses to survey questions

Question	n	%
In your clinic, how many vasectomies do you perform annually?		
1–10	21	26.9
11–20	9	11.5
21–50	18	23.1
51–100	16	20.5
>100	14	17.9
When do you perform the first semen analysis after vasectomy?		
1 month	3	3.8
2 months	24	30.8
3 months	34	43.6
After 12 ejaculations post vasectomy	10	12.8
Other	7	9.0
How do you check the post-vasectomy semen sample for the presence of motile sperm?		
Analysis of fresh semen within 1 hour	45	57.7
Analysis of semen sample after centrifugation	24	30.8
Analysis of fresh semen within two hours	8	10.3
Presence of sperm in a mail-in PVSA test kit followed by an examination of fresh sample	1	1.3
As per PVSA, when do you permit unprotected intercourse?		
Azoospermia or <10,000 non-motile sperm/mL	3	3.8
Azoospermia or <100,000 non-motile sperm/mL	20	25.6
Azoospermia or <50,000 non-motile sperm/mL	1	1.3
Azoospermia or any number of immotile sperm	3	3.8
Only after 2 PVSA samples show azoospermia	18	23.1
Only if PVSA shows azoospermia	33	42.3
What is your next step if a few nonmotile sperm are found in the first PVSA?		
Continue use of alternative contraception, repeat semen analysis after 1 month	47	60.3
Allow unprotected intercourse, no need for repeat semen analysis	13	16.7
Continue use of alternative contraception, repeat semen analysis after 3 months	12	15.4
Allow unprotected intercourse, repeat semen analysis after 1–2 months	4	5.1
Allow unprotected intercourse, repeat semen analysis after 3 months	2	2.6
What is your next step if motile sperm are found in the first PVSA?		
Continue use of alternative contraception, repeat semen analysis after 1 month	44	56.4
Continue use of alternative contraception, repeat semen analysis after 2–3 months	22	28.2
Recommend repeat vasectomy	12	15.4
When do you recommend repeat vasectomy?		
Only if multiple PVSA over several months show motile sperm	40	51.3
If the first and second PVSA show motile sperm	31	39.7
If the first PVSA shows motile sperm	7	9.0
If there are more than 100,000 non-motile sperm present on PVSA at 6 months, what do you do?		
Repeat vasectomy	37	47.4
Continue alternative contraception and obtain another PVSA in 3 months	33	42.3
Give clearance to stop using other forms of contraception	8	10.3
How many cases of failed vasectomy have you seen in your practice?		
None	29	37.2
1–2	39	50.0
3–5	6	7.7
>5	4	5.1
If the first PVSA shows no sperm, do you still recommend another test after a few months to check for late recanalization?		
No	56	71.8
Usually yes	14	17.9
Occasionally	8	10.3
Does the possibility of legal actions influence the recommendation for second semen analysis?		
No	32	41.0
Yes	32	41.0
It depends on the patient	14	17.9
What is the risk of failure in pregnancy despite no sperm in one PVSA?		
May happen rarely	51	65.4
May occur in >0.5% of cases	18	23.1
No risk	9	11.5
Do you inform the patient about the risk of recanalization?		
Always	72	92.3
In selected cases	4	5.1
Never	2	2.6
Is there a need for a vasectomy consent form based on expert consensus to protect the surgeon regarding legal liability?		
Highly recommended	64	82.1
May be useful	9	11.5
Not needed, current consent forms are adequate	5	6.4

Data is reported as number of participants (n) and percentage (%) out of the total (n=78).
PVSA: post-vasectomy semen analysis.

over several months, the majority (n=40, 51.3%) recommended repeat vasectomy. On the other hand, 39.7% (n=31) of participants recommended repeat vasectomy if the first and second PVSA show motile sperm, and only 9.0% (n=7) in case of motile sperm in the first PVSA. The participants' opinions were divided when it came to persistent non-motile sperm. In the event of >100,000 non-motile sperm/mL on PVSA at 6 months,

The World Journal of MEN's HEALTH

47.4% (n=37) of the participants recommended repeat vasectomy, while 42.3% (n=33) chose to continue alternative contraception and obtain another PVSA in 3 months. If the first PVSA showed no sperm, most participants (n=56, 71.8%) did not recommend another test to check for late recanalization. A large percentage of participants stated that the possibility of legal action influenced their recommendation for a second semen analysis and that it was common practice (n=72, 92.3%) to inform the patient about the risk of recanalization. The majority (n=51, 65.4%) acknowledged that there could be a failure despite a successful PVSA, but most (n=39, 50.0%) had seen only 1 to 2 cases of failed vasectomy in their clinical practice (Fig. 11). The overwhelming majority of participants (n=64, 82.1%) felt the need for a consent form based on, and validated by, expert consensus.

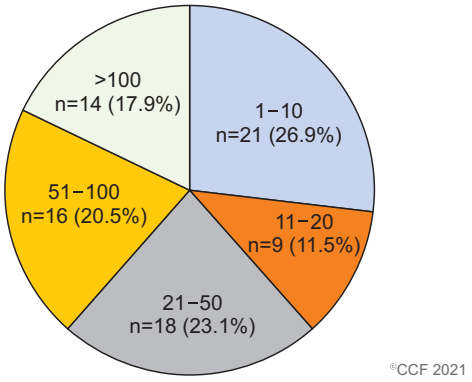

Fig. 6. Number of vasectomies performed annually. Data are reported as the number of participants (n) and percentage (%) out of the total (n=78).

DISCUSSION

1. Post-vasectomy semen analysis: laboratory aspects

The PVSA is an important test with significant clinical ramifications and needs to be performed and interpreted carefully as advised in relevant guidelines. The various guidelines vary (Table 1) in technical aspects (*e.g.*, timing of sample collection and the need for centrifugation of the sample) and in the interpretation

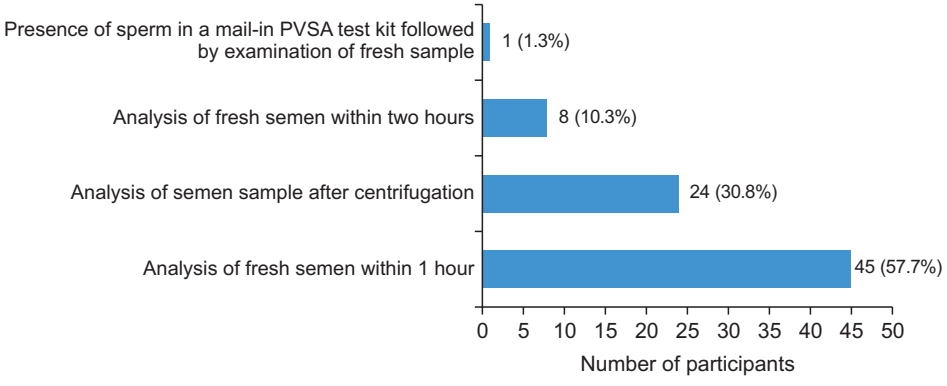

Fig. 7. Type of sample analyzed after vasectomy to check for the presence of motile sperm. Data are reported as number of participants (n) and percentage (%) out of the total (n=78). PVSA: post-vasectomy semen analysis.

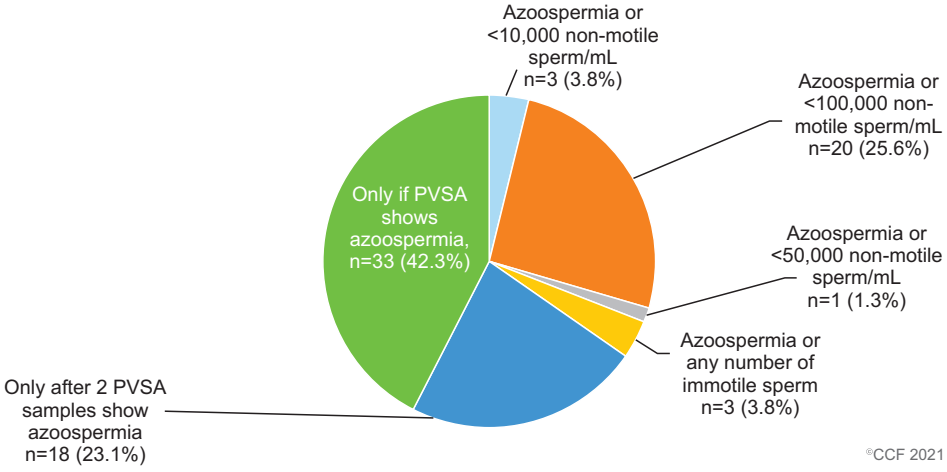

Fig. 8. Pie chart illustrating the condition when participants to the survey permit unprotected intercourse. Data are reported as number of participants (n) and percentage (%) out of the total (n=78). PVSA: post-vasectomy semen analysis.

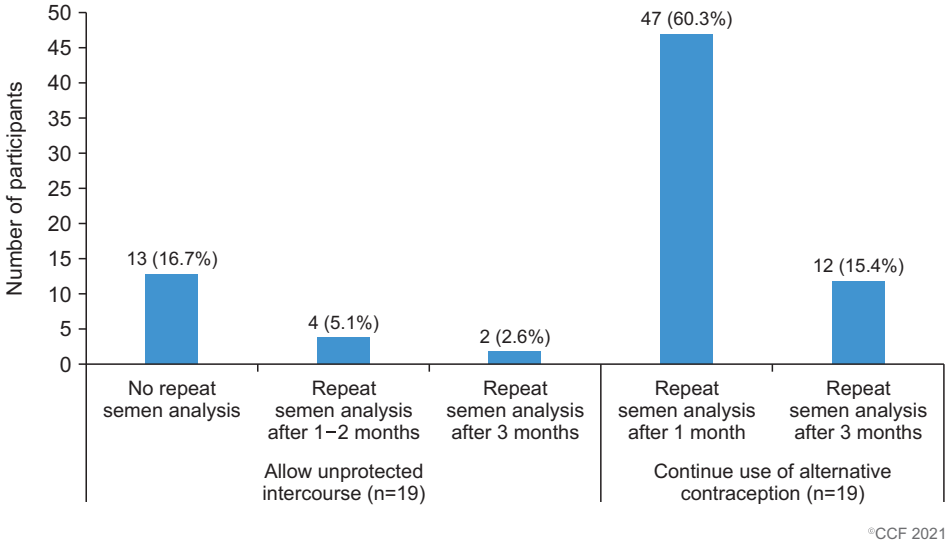

Fig. 9. Next step in clinical management when a few non-motile sperm are found in the first post-vasectomy semen analysis. Data are reported as number of participants (n) with a total number of 78.

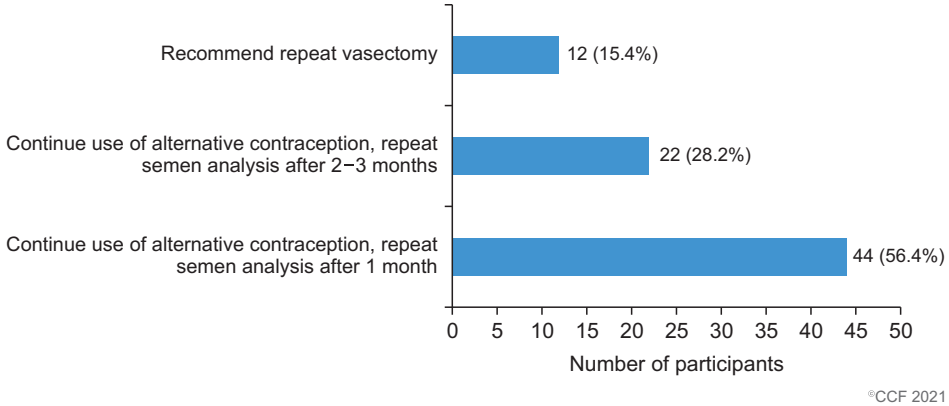

Fig. 10. Next step in clinical management in case motile sperm are found in the first post-vasectomy semen analysis. Data is reported as number of participants (n) with a total number of 78.

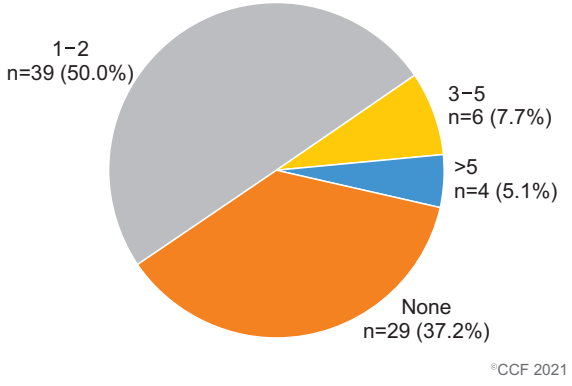

Fig. 11. Number of failed vasectomy cases observed in participants' clinical practice. Data reported as the number of participants (n) and percentage (%) out of the total (n=78).

of test results. Clinicians need to be aware of the official guidelines for the region/country they are working in. Proficiency testing and competency assessment for PVSA and quality control are important and are discussed below. Proficiency testing should be performed biannually by the referral laboratory for PVSA. The accreditation agency sends two analytes (samples) semi-annually, and the presence or absence of sperm is evaluated and noted in the results. If sperm are present, then the sperm concentration is calculated and reported as M/mL. Results are classified as normal if the sperm concentration is ≤100,000 non-motile sperm/mL and abnormal if it is >100,000 non-motile sperm/mL (Fig. 12). Laboratory results must be within ±2 standard deviations of the mean for all laboratories. This criterion is applicable when there is a test failure and the reported sperm concentration or motility is within the mean ±2 standard deviation of all laboratories as reported by the proficiency test agency. Competency assessment is performed for the medical technologists annually to ensure accurate performance of the PVSA test using a competency checklist. Medical technologists are assessed for their knowledge of the PVSA test

Post Vasectomy Sperm Count – Proficiency Test Results

Procedure	Method	Exception Code	PVR-03	PVR-04
Qualitative Sperm Present/Absent	010 3433	020 ○11 ○33	030 ◉113 Present ○112 Absent	040 ○113 Present ◉112 Absent
Quantitative Sperm Count* x 10E9/L or million/mL	050 3433	060 ○11 ○22 ○33	070 2.30 080 ☐ (4) Fill if less than	090 0.00 100 ☐ (4) Fill if less than

* Perform a count and indicate your result. If no sperm are present, enter zero for the count. If you do not perform sperm count, leave the boxes blank.

©CCF 2021

Fig. 12. Example of proficiency test results for post-vasectomy sperm count as per the accreditation agency.

and the AUA criteria in the form of a quiz. The technologists have to pass the aforementioned competency tests to be approved to perform the PVSA evaluation. Quality control is performed daily for sperm count and motility assessment. Quality control passes when manual evaluation of sperm concentration and motility is within 20% of the values obtained by a computer-assisted semen analyzer in a normal sample.

2. Clinical audit of post-vasectomy semen analysis: the Cleveland Clinic's experience

The first PVSA examination was successful in 92.1% of men which is comparable to other published literature reports [19]. Eighty men from this successful group underwent a second PVSA and 7 had a third test and all tested "passed" confirming that there is no need for a second test, if the first one is clear. In a recent report, Manka et al [20] highlighted the ongoing discordance between vasectomy guidelines and practice patterns, with 72% of repeat PVSA obtained unnecessarily based on AUA guidelines. This redundant testing and unnecessary financial burden probably reflects the desire on the part of the doctor and patient to be very sure of the success of the vasectomy and is mirrored in some guidelines that recommend 2 PVSA routinely (Table 1). Of the men who failed the first PVSA, two-thirds passed the second PVSA, and of those who failed the second PVSA, almost half (9/19) passed on the third, fourth, or fifth PVSA (Fig. 4). This delayed clearance of sperm suggests that when a man fails the initial PVSA, there is no need to rush to repeat vasectomy, and waiting may prove the procedure successful in the majority of patients. Our data showed that 7 cases (out of 1,114, 0.63%) needed repeat vasectomy, which is in agreement with previous reports in the literature [21], since the reported failure rate with vasectomy varies from 0.01% to 5% [3].

3. Online global survey

The recommendations of various societies differ on a variety of points (Table 1) and this is reflected in the varying clinical practices of various experts around the globe. In our online global survey on the use of PVSA for monitoring the outcome of vasectomy, the same heterogeneity in clinical practice was found amongst 78 clinicians from 19 different countries. The majority of surgeons used duration since vasectomy, rather than the number of ejaculations, as the criterion for requesting the first PVSA. Clearance of sperm from the distal end of the vas deferens after vasectomy is a time-dependent process with longer periods associated with higher clearance rates [22]. The guidelines of professional societies also recommend obtaining PVSA based on time after vasectomy but two (EAU and BAUS) of those include both times after vasectomy and number of ejaculations. None of the societies recommend checking a PVSA based on the number of ejaculations alone.

Forty-five percent of the clinicians ask for the sample to be submitted within 1 hour. The AUA guidelines suggest that a PVSA can be examined within 2 hours to provide ample time for men to travel after performing a home collection. They suggest that this is acceptable since during a PVSA, the only concern is the presence of motility and not necessarily the quality of the motility [7]. The BAUS guidelines suggest that PVSA samples should be evaluated within 1 hour when assessing for motility [17].

A total of 30% of participants asked for examination of the centrifuged sample. British Andrology Society (BAS) guidelines suggest PVSA should be checked after centrifugation, while AUA guidelines do not recommend centrifugation, and EAU guidelines do not make any references to the centrifugation status [7,15,17]. Centrifugation will help detect rare sperm; it is not clear whether this will have clinical predictive value or

will merely result in more false labels of failures leading to unnecessary repeat testing and anxiety.

As per AUA guidelines, the presence of a few non-motile sperm in the first PVSA is considered a successful result and unprotected intercourse can be permitted if there is azoospermia or ≤100,000 non-motile sperm/mL. Yet there is considerable disagreement on this subject amongst the clinicians who participated in the survey. Only one-fourth of the participants permitted unprotected intercourse if <100,000 non-motile sperm/mL were present. Forty-two percent of participants stated that the sample should show total azoospermia, and an additional 23% insisted on 2 PVSA samples showing azoospermia before they allowed unprotected intercourse. As a result, more than half (59%) of the participants said they would advise continuing the use of alternative contraception if a few non-motile sperm were present in the ejaculate. This cautious approach may result in unnecessary testing and a delay in freeing the couple from the need for alternative contraception. Also, there may be a greater chance/higher probablity of non-compliance/failure to comply when multiple tests are asked for.

If motile sperm were found in the first PVSA, the

Table 4. Literature review reports of recanalization following vasectomy

Year	Author	Article title	Journal	Main finding
1974	Esho et al [33]	Recanalization following vasectomy.	*Urology*	After 1 year, 215 patients who were negative for PVSA were analyzed again: 3 reported high sperm concentration.
1984	Philp et al [34]	Late failure of vasectomy after two documented analyses showing azoospermic semen.	*British Medical Journal*	2 PVSA confirmed azoospermia in 14,047 men. After 3 years, the partners of 6 of them were pregnant; this confirmed recanalization of the vasa (incidence=1:2,300).
1990	Davies et al [39]	The long-term outcome following "special clearance" after vasectomy.	*British Journal of Urology*	After 3 years, 1 out of 50 patients reported <5,000 sperm/mL.
1994	Smith et al [27]	Fatherhood without apparent spermatozoa after vasectomy.	*Lancet*	They described 6 cases in which fatherhood was proved by DNA analysis but was associated with persistently negative semen analyses. In each case, 2 negative sperm counts were obtained. Pregnancy occurred after 1–5 years post vasectomy depending on the patient.
1997	De Knijff et al [35]	Persistence or reappearance of nonmotile sperm after vasectomy: does it have clinical consequences?	*Fertility and Sterility*	The reappearance of non-motile sperm after initial azoospermia (at 12 weeks) was found in 6 of 65 men (9.2%). The five patients with the reappearance of non-motile sperm (longest follow-up 22 months) did not report any pregnancies.
2000	Haldar et al [36]	How reliable is a vasectomy? Long-term follow-up of vasectomised men.	*Lancet*	2,250 men had been followed up for at least 1 year after vasectomy clearance. 1,400 of these men had reached 2 years follow-up and 1,000 had reached 3 years follow-up. Of these, 20 men had a positive semen analysis, 15 at the first year, four at the second year, and one at the third year. In those men with a positive test at either the second or third year, none had had a positive test the previous years. The sperm count, however, was less than 10,000 sperm/mL in 17 men, and semen samples of 14 were negative 1 month later (three patients did not provide follow-up samples). No pregnancy was reported.
2004	Deneux-Tharaux et al [37]	Pregnancy rates after vasectomy: a survey of US urologists.	*Contraception*	Among the 511 urologists who had been doing vasectomies for at least 5 years, the estimated incidence of pregnancy 2.5 years after vasectomy was 1/1,000 procedures. The estimate was 0.51/1,000 procedures for early pregnancies attributed to non-adherence, and 0.49/1,000 for pregnancies attributed to vasectomy failure.
2005	Griffin et al [38]	How little is enough? The evidence for post-vasectomy testing.	*Journal of Urology*	This literature review reported the reappearance of non-motile sperm in 7 studies, occurring up to 22 months after vasectomy.
2020	Michaelides and Ghani [25]	Paternity seven years after a negative post-vasectomy semen analysis: a case report.	*Journal of Medical Case Reports*	After negative PVSA, his wife conceived seven years after the procedure, and semen analysis confirmed a total of 0.5 million sperm per milliliter of semen in a total semen sample of 6.3 mL.

PVSA: post-vasectomy semen analysis.

majority of participants advised continuation of alternative contraception and required further PVSA tests, in accordance with the guidelines. This approach is also validated by our study results, in which 47% of those who had failed 2 PVSA tests eventually passed the test. However, 12% of participants did advocate immediate repeat vasectomy without the need for further testing.

When the PVSA showed more than 100,000 non-motile sperm/mL at 6 months, the participants were almost equally divided between proceeding to repeat vasectomy (as recommended by Canadian guidelines [23]) *versus* further observation with another PVSA at a later date, reflecting the uncertainty about the relevance of non-motile sperm in the post-vasectomy ejaculate (AUA guidelines recommend clinical judgement). Relevant factors such as number of ejaculations before PVSA and number of PVSA done are important considerations to take into account, and the Australian guidelines [24] suggest special clearance when 2 ejaculates show <100,000 non-motile sperm/mL and at least 7 months have passed since vasectomy.

There is a very small but real risk of pregnancy following vasectomy. Vasectomy failure is the occurrence of pregnancy or failure to achieve azoospermia or RNMS after 6 months following vasectomy [7,15]. The reasons may be technical failure or recanalization at the vasectomy site [7]. Technical failure is defined by the AUA guidelines as the presence of "normal or nearly normal motile sperm counts" post vasectomy. On the other hand, recanalization is considered when motile sperm or rising sperm concentrations are seen after achieving azoospermia or RNMS [7]. Pregnancy due to recanalization may result from early or late failure, which occurs in 1 in 250 patients and 1 in 2,000 patients, respectively [7,25].

Failure of vasectomy is every surgeon's concern and two-thirds of the particpants reported having had at least one failure. In a study conducted by Jamieson et al (2004) [26], the cumulative probability of failure per 1,000 procedures (95% confidence interval) was 7.4 (0.2–14.6) 1 year post vasectomy and 11.3 (2.3–20.3) at 2, 3, and 5 years. In a case report, a pregnancy was reported 7 years after vasectomy and this was attributed to late recanalization [25]. In another study, paternity was reported despite negative semen analysis reports and the births occurred 1 to 5 years after vasectomy [27]. Alderman [28,29], who used ligation and excision for vas occlusion, reported four pregnancies among 5,331 men who completed the recommended PVSA regimen, giving a rate of about 1 in 1,300. A few cases confirmed paternity based on genetic testing even though the men had had PVSA previously showing azoospermia [25,27,30,31]. The true incidence of late recanalization is difficult to estimate, as PVSA is rarely repeated after a test showing azoospermia or RNMS [7,15].

Spermatozoa may reappear in the ejaculate as a result of spontaneous recanalization and do not depend on the surgical procedure [30,31]. Therefore for the physicians, counseling is prudent to ensure that the patient and the partner fully understand the implications of non-compliance and the possibility of recanalization and pregnancy (Table 4) [25,27,32-39]. This was strongly reflected in the survey with 90.3% counseling their patients about the risk of recanalization and 82% highly recommending the need for a vasectomy consent form based on expert consensus.

This is not surprising since complications or failure of a vasectomy can have unfortunate consequences leading to litigation. A study reviewing malpractice suits related to vasectomies found that 37% alleged negligence in post-operative care, 35% claimed negligence in surgical performance, and 28% stemmed from negligence in informed consent [8]. The study further detailed the most common reasons for filed damages, which were pregnancy/wrongful birth, chronic pain, hematoma, and loss of testicle.

4. Laboratory scenarios

1) Case 1

(1) Scenario

A patient presents to the andrology laboratory for a scheduled PVSA test 12 weeks after vasectomy procedure. The semen analysis results are: sperm concentration of 0.34 M/mL with RMS.

(2) Response

The PVSA has failed the AUA, EAU, and BAUS criteria for passing the test.

2) Case 2

(1) Scenario

A patient fails the first PVSA at 12 weeks, with

sperm concentration of 2.40 M/mL and sperm motility of 5%. He has a second PVSA 4 weeks after the first PVSA. Second PVSA results are reported as sperm concentration of 0.50 M/mL and RMS seen.

(2) Response

The second PVSA has failed as per the AUA, EUA, and BAUS guidelines. However, there is a significant fall in count and motility that may progress to azoospermia in future. The results are communicated to the physician to counsel the patient appropriately.

5. Clinical scenarios

1) Case 1

(1) Scenario

A patient had a vasectomy 6 months ago. PVSA reports the presence of >100,000 non-motile sperm/mL at 6 months. How will you manage this patient?

(2) Response

Patients may stop using other methods of contraception only when examination of PVSA shows either azoospermia or only RNMS (≤100,000 non-motile sperm/mL). Since the report shows >100,000 non-motile sperm, alternative contraception should be continued. Trends of further PVSA tests and clinical judgment should be used to decide whether the vasectomy has failed and whether a repeat vasectomy is indicated.

2) Case 2

(1) Scenario

A patient had a vasectomy 3 months ago. His PVSA demonstrated the presence of RMS. How will you manage this patient?

(2) Response

This is a failed PVSA and the patient needs to use another form of contraception until negative PVSA. The PVSA should be repeated at the clinician's discretion and patient's convenience. The vasectomy should be considered unsuccessful if any motile sperm are seen on PVSA at 6 months after vasectomy.

3) Case 3

(1) Scenario

A patient had a vasectomy 1 year ago. PVSA at 6 months showed <100,000 non-motile sperm/mL. However, PVSA at 1 year shows >100,000 sperm/mL with 5% sperm motility. What is your advice for the patient?

(2) Response

This is a case of failed vasectomy. A repeat vasectomy may be offered to the patient after counseling.

4) Case 4

(1) Scenario

A patient underwent a vasectomy procedure two years ago. He states that his wife is 8 weeks pregnant. What is the next step in the management of this patient?

(2) Solution

A fresh semen test should done and the clinician should also check if the patient had obtained an initial PVSA. The reported compliance rate for a PVSA is roughly 78% [7]. If the PVSA had not been done, then there is the possibility of a technical failure that was not detected. If the current report shows motile sperm but the PVSA had shown azoospermia or RNMS, then the physician should inform him that the pregnancy could be due to spontaneous recanalization. Even if the current report shows no sperm, there is the possibility of transient recanalization [27,31]. Hence, before vasectomy, the patient should always be counseled about a 1 in 2,000 risk of pregnancy after vasectomy even after the PVSA test is clear. Finally, the patient can be counseled about the option to perform genetic testing on the offspring to document paternity.

CONCLUSIONS

Vasectomy is one of the most common forms of male contraception. The PVSA plays an important role in determining when the vasectomy is considered successful and the couple can stop using contraception. Hence, proper methodology and correct interpretation are crucial. However, there is controversy over the significance of non-motile sperm in the PVSA sample and this has resulted in discrepancies between the different vasec-

tomy guidelines from various professional societies and is also reflected in varying clinical practices around the globe. Our data suggest that the less stringent AUA guidelines are adequate. Simplifying the PVSA test procedure would help improve test compliance. There is the need for a large multi-center study that would assess serial PVSA over an extended period of time in a larger number of men. This would clarify various doubts related to timing and interpretation of PVSA and would also help us understand, and perhaps predict, recanalization and the potential for future failure of a vasectomy.

Conflict of Interest

The authors have nothing to disclose.

Funding

None.

Acknowledgements

Authors are thankful to the artist, Bernastine Buchanan, from the Cleveland Clinic's Center for Medical Art & Photography for her help with the illustrations. The study was supported by the American Center for Reproductive Medicine.

Author Contribution

Conceptualization: AA, RKS, SG, RF, SK. Writing – original draft: All the authors. Writing – review & editing: All the authors.

Supplementary Materials

Supplementary materials can be found *via* https://doi.org/10.5534/wjmh.210191.

Data Sharing Statement

The data analyzed for this study have been deposited in HARVARD Dataverse and are available at https://doi.org/10.7910/DVN/NDPCI6.

REFERENCES

1. Drake MJ, Mills IW, Cranston D. On the chequered history of vasectomy. BJU Int 1999;84:475-81.
2. Sheynkin YR. History of vasectomy. Urol Clin North Am 2009;36:285-94.
3. Eisenberg ML, Lipshultz LI. Estimating the number of vasectomies performed annually in the United States: data from the National Survey of Family Growth. J Urol 2010;184:2068-72.
4. Schwingl PJ, Guess HA. Safety and effectiveness of vasectomy. Fertil Steril 2000;73:923-36.
5. Weiske WH. Vasectomy. Andrologia 2001;33:125-34.
6. Ostrowski KA, Holt SK, Haynes B, Davies BJ, Fuchs EF, Walsh TJ. Evaluation of vasectomy trends in the United States. Urology 2018;118:76-9.
7. Sharlip ID, Belker AM, Honig S, Labrecque M, Marmar JL, Ross LS, et al. Vasectomy guideline [Internet]. Linthicum (MD): American Urological Association; c2015 [cited 2021 Nov 10]. Available from: https://www.auanet.org/guidelines/guidelines/vasectomy-guideline.
8. Blazek AJ, Belle JD, Deibert MP, Deibert CM. Legal review of vasectomy litigation and the variables impacting trial outcomes. Urology 2019;131:120-4.
9. Velez D, Pagani R, Mima M, Ohlander S. Vasectomy: a guidelines-based approach to male surgical contraception. Fertil Steril 2021;115:1365-8.
10. Sharlip ID, Belker AM, Honig S, Labrecque M, Marmar JL, Ross LS, et al.; American Urological Association. Vasectomy: AUA guideline. J Urol 2012;188(6 Suppl):2482-91.
11. Coward RM, Badhiwala NG, Kovac JR, Smith RP, Lamb DJ, Lipshultz LI. Impact of the 2012 American Urological Association vasectomy guidelines on post-vasectomy outcomes. J Urol 2014;191:169-74.
12. World Health Organization (WHO). WHO laboratory manual for the examination and processing of human semen. 5th ed. Geneva: WHO; 2010.
13. World Health Organization (WHO). WHO laboratory manual for the examination and processing of human semen. 6th ed. Geneva: WHO; 2021.
14. Agarwal A, Gupta S, Sharma R. Andrological evaluation of male infertility: a laboratory guide. Cham: Springer; 2016.
15. Dohle GR, Diemer T, Kopa Z, Krausz C, Giwercman A, Jungwirth A; European Association of Urology Working Group on Male Infertility. European Association of Urology guidelines on vasectomy. Eur Urol 2012;61:159-63.
16. Niederberger C. Re: European Association of Urology guidelines on vasectomy. J Urol 2012;188:557-8.
17. Hancock P, Woodward BJ, Muneer A, Kirkman-Brown JC. 2016 Laboratory guidelines for postvasectomy semen analysis: Association of Biomedical Andrologists, the British

Andrology Society and the British Association of Urological Surgeons. J Clin Pathol 2016;69:655-60.
18. Beder D, Chitale S. The clinical impact of British guidelines on post-vasectomy semen analysis. Cent European J Urol 2020;73:558-62.
19. DeRosa R, Lustik MB, Stackhouse DA, McMann LP. Impact of the 2012 American Urological Association vasectomy guidelines on postvasectomy outcomes in a military population. Urology 2015;85:505-10.
20. Manka MG, Miller A, Sharma V, Butaney M, Trost L, Ziegelmann M. Discrepancy between post-vasectomy semen analysis recommendation and practice patterns in the post-2012 American Urological Association guideline era. J Urol 2020;204:1312-7.
21. Denniston GC. Vasectomy by electrocautery: outcomes in a series of 2,500 patients. J Fam Pract 1985;21:35-40.
22. Sokal D, Irsula B, Hays M, Chen-Mok M, Barone MA; Investigator Study Group. Vasectomy by ligation and excision, with or without fascial interposition: a randomized controlled trial [ISRCTN77781689]. BMC Med 2004;2:6.
23. Zini A, Grantmyre J, Chan P. CUA guideline: vasectomy. Can Urol Assoc J 2016;10:E274-8.
24. Australian Safety and Efficacy Register of New Interventional Procedures. Post-vasectomy testing to confirm sterility [Internet]. Stepney (SA): ASERNIP-S; c2003 [cited 2021 Nov 16]. Available from: https://nsva.org.au/wp-content/uploads/2020/02/ASERNIP-Post-Vasectomy-Semen-Analysis.pdf.
25. Michaelides A, Ghani M. Paternity seven years after a negative post-vasectomy semen analysis: a case report. J Med Case Rep 2020;14:53.
26. Jamieson DJ, Costello C, Trussell J, Hillis SD, Marchbanks PA, Peterson HB; US Collaborative Review of Sterilization Working Group. The risk of pregnancy after vasectomy. Obstet Gynecol 2004;103(5 Pt 1):848-50.
27. Smith JC, Cranston D, O'Brien T, Guillebaud J, Hindmarsh J, Turner AG. Fatherhood without apparent spermatozoa after vasectomy. Lancet 1994;344:30.
28. Alderman PM. General and anomalous sperm disappearance characteristics found in a large vasectomy series. Fertil Steril 1989;51:859-62.
29. Alderman PM. The lurking sperm. A review of failures in 8879 vasectomies performed by one physician. JAMA 1988;259:3142-4.
30. Verhulst AP, Hoekstra JW. Paternity after bilateral vasectomy. BJU Int 1999;83:280-2.
31. Lucon M, Lucon AM, Pasqualoto FF, Srougi M. Paternity after vasectomy with two previous semen analyses without spermatozoa. Sao Paulo Med J 2007;125:122-3.
32. Belker AM, Sexter MS, Sweitzer SJ, Raff MJ. The high rate of noncompliance for post-vasectomy semen examination: medical and legal considerations. J Urol 1990;144(2 Pt 1):284-6.
33. Esho JO, Ireland GW, Cass AS. Recanalization following vasectomy. Urology 1974;3:211-4.
34. Philp T, Guillebaud J, Budd D. Late failure of vasectomy after two documented analyses showing azoospermic semen. Br Med J (Clin Res Ed) 1984;289:77-9.
35. De Knijff DW, Vrijhof HJ, Arends J, Janknegt RA. Persistence or reappearance of nonmotile sperm after vasectomy: does it have clinical consequences? Fertil Steril 1997;67:332-5.
36. Haldar N, Cranston D, Turner E, MacKenzie I, Guillebaud J. How reliable is a vasectomy? Long-term follow-up of vasectomised men. Lancet 2000;356:43-4.
37. Deneux-Tharaux C, Kahn E, Nazerali H, Sokal DC. Pregnancy rates after vasectomy: a survey of US urologists. Contraception 2004;69:401-6.
38. Griffin T, Tooher R, Nowakowski K, Lloyd M, Maddern G. How little is enough? The evidence for post-vasectomy testing. J Urol 2005;174:29-36.
39. Davies AH, Sharp RJ, Cranston D, Mitchell RG. The long-term outcome following "special clearance" after vasectomy. Br J Urol 1990;66:211-2.