Contraception 101 (2020) 342–349

Contents lists available at ScienceDirect

Contraception

journal homepage: www.elsevier.com/locate/con

Original Research Article

Risk of vasectomy failure by ligation and excision with fascial interposition: A prospective descriptive study ☆,☆☆

Silvia Juliana Miranda Claro [a,*], Jonathan Vargas Laverde [a,b,1], Elsa Mariño Samper [a], Milcíades Ibáñez Pinilla [a,c], Diana Soraya Torres Quiroz [b], Michel Labrecque [d]

[a] Universidad El Bosque, Avenida Kr. 9 No. 131 A – 02, Bogotá, Colombia
[b] Profamilia, Teusaquillo Calle 34 No. 14 – 52, Bogotá, Colombia
[c] Universidad del Rosario, Hospital Universitario Mayor-Méderi, Bogotá, Colombia
[d] CHU de Québec-Université Laval Research Centre, Population Health and Optimal Health Practices, 1050 Chemin Sainte-Foy, local K0-03, Québec (Qc) G1S 4L8, Canada

ARTICLE INFO

Article history:
Received 29 May 2019
Received in revised form 26 January 2020
Accepted 5 February 2020

Keywords:
Vasectomy
Ligation
Excision
Fascial interposition
Effectiveness
Failure risk

ABSTRACT

Objective: To evaluate the occlusive failure risk of ligation and excision with fascial interposition vasectomy technique. There are doubts about the effectiveness of this technique largely used in Asia and Latin America.

Study design: We conducted a prospective longitudinal observational descriptive study among men who underwent a vasectomy performed under local anesthesia in a clinic specializing in sexual and reproductive health services in Bogotá, Colombia. Three urologists used the Percutaneous No-Scalpel Vasectomy technique to isolate the vas deferens. They then ligated the vas, excised a 1 cm segment between ligations, and ligated the fascia on the prostatic end to cover the testicular end. We requested all patients to submit a semen sample three months after the vasectomy. We defined probable and confirmed vasectomy failure as 1–4.9 million sperm/ml and 5 million sperm/ml or more or any number of motile sperm observed on the last semen sample available, respectively.

Results: Among 1149 participants, 581 (51%) had at least one post-vasectomy semen analysis. The overall failure risk was 5.2% (30/581; 95% confidence interval [CI] 3.6%–7.3%) with probable and confirmed failure risk of 1.9% (11/581; 95% CI 1.1%–3.4%) and 3.3% (19/581; 95% CI 2.1%–5.1%), respectively. Older men and one urologist had statistically significant higher risk of overall failure.

Conclusion: Our study confirmed that the ligation and excision with fascial interposition vasectomy technique is associated with an unacceptable risk of failure.

Implications: Surgeons who use the ligation and excision with fascial interposition vasectomy technique and countries with large vasectomy programs in Asia and Latin America that still recommend this technique should consider adopting alternatives to reduce the failure risk to below 1% as recommended by the American Urological Association.

1. Introduction

Vasectomy consists of two specific surgical steps: (1) isolating and exposing the vas deferens outside of the scrotum and (2) occluding the vas. The No-Scalpel Vasectomy technique to expose the vas was developed in China by Dr. Li Shunquiang in 1974 [1] and promoted internationally by EngenderHealth since at least 1992 [2]. This minimally invasive technique to expose the vas is the most extensively studied approach to expose the vas [3]. There is high-quality evidence demonstrating that it reduces the risk of hematoma and infections [3–5].

For occluding the vas, EngenderHealth recommends putting two silk ligatures on the vas, excising about a 1-cm vas segment

☆ Funding: This research benefited from a small grant from Universidad El Bosque, Bogota, Colombia. The Michel-Labrecque Fund for Male Reproductive Health (4476) from the Laval University Foundation supported travel to Colombia for investigator meetings. We did not receive specific grants from funding agencies in the public, commercial, or not-for-profit sectors.
☆☆ Declarations of interest: none.
* Corresponding author.
E-mail addresses: smiranda@unbosque.edu.co (S.J. Miranda Claro), jvargasla@unbosque.edu.co (J. Vargas Laverde), marinoelsa@unbosque.edu.co (E. Mariño Samper), mibanezpi@unbosque.edu.co (M. Ibáñez Pinilla), dianasorayatorres@gmail.com (D.S. Torres Quiroz), michel.labrecque@mfa.ulaval.ca (M. Labrecque).
[1] Present address: Profamilia, Calle 59 # 50 – 17, Barranquilla – Atlántico, Colombia.

https://doi.org/10.1016/j.contraception.2020.02.001
0010-7824/

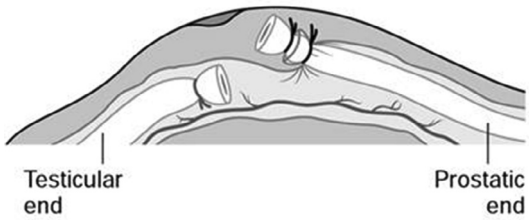

Fig. 1. Vasectomy occlusion technique by ligation and excision with fascial interposition on testicular end [2]. Reproduction of the figure authorized by EngenderHealth.

between the ligatures, and interposing the vas sheath (fascia) on the testicular end of the divided vas with a silk suture tied on the abdominal end (Fig. 1) [2]. However, the failure risk of this technique, based on the post-vasectomy semen analysis, seems to be greater than 1%, which is the highest acceptable failure risk recommended by experts [3]. Risks of occlusion failure of 0% [6], 2.1% [7] 2.5% [8], 2.6% [9], and 7.6% [10] have been reported for the aforementioned occlusion technique, with the most robust result from a high-quality randomized clinical trial reported at 5.9% [11].

Nevertheless, this technique is still the recommended standard in large vasectomy programs in countries with limited resources such as India, Nepal, Mexico, and Colombia [12]. The American Urology Association recommends using this technique if experienced surgeons consistently obtain satisfactory results [3]. However, due to the doubts about the effectiveness of this occlusion technique, we evaluated its failure risk in a large cohort of men vasectomized by experienced surgeons in Colombia.

2. Material and methods

2.1. Study design

We conducted a prospective longitudinal observational descriptive study of a cohort of adult men who voluntarily underwent a vasectomy under local anesthesia between April 7, 2017 and January 15, 2018, at a private clinic specializing in sexual and reproductive health services in Bogotá, Colombia.

2.2. Recruitment of participants

Men requesting a vasectomy at the clinic routinely have a pre-vasectomy visit with general practitioners. They provide counselling on vasectomy, perform a medical history and physical exam, and complete an electronic medical record. They also request that men sign a form describing all information needed to make an informed consent to voluntary sterilization. The clinic usually schedules the vasectomy within a week. Men did not receive any information about the study at this time.

Trained nurses screened and informed men about the study on the day of the surgical procedure. Those who agreed signed an informed consent form to participate in the study. We did not offer any incentive for participating. Both the research ethics board from the clinic and the Universidad El Bosque, Bogotá, Colombia, approved the study.

We intended to recruit all participants consecutively. However, there were some interruptions in the recruitment process due to the unavailability of trained personnel assigned to other clinical tasks during the study recruitment period (Fig. 2). Accounting for the difficulty to estimate *a priori* the excepted failure risk and compliance to post-vasectomy semen analysis, we aimed to recruit 1200 participants to ensure sufficient precision of our results. For estimating failure risks with absolute precision and 95% confidence of 2% ± 1% and 5% ± 2%, the study required compliance rate of 75% (753 subjects) and 46% (457 subjects), respectively [13].

2.3. Vasectomy technique

Three urologists performed the vasectomies. Each had performed more than 10,000 cases using the percutaneous no-scalpel vasectomy technique [14], a minimally invasive technique [3] which involves a slight modification of the original technique described by Li [1], and the ligation and excision with fascial interposition occlusion technique illustrated in Fig. 1. At the time of study, two urologists were practicing full time while the other was only working part-time at the clinic, performing more vasectomies in other settings. The doctors standardized their technique before the study. All three performed the same technique in all vasectomized men. A video of the occlusion technique performed by each surgeon is available at https://youtu.be/HQwQx4oQ8sg. All three surgeons signed an informed consent form allowing the collection of their professional and clinical information.

2.4. Semen analysis

We had the following procedures in place to encourage men to comply with the post-vasectomy semen analysis. First, at the time of the pre-vasectomy visit, men signed a form specifying, among other information, that vasectomized men have to do a post-vasectomy semen analysis three months after vasectomy and only results of this test can confirm sterility. Second, on the day of the vasectomy, nurses informed participants verbally and in writing about the importance of undergoing a post-vasectomy semen analysis at three months after the vasectomy at the institution laboratory, and, meanwhile, to have as many ejaculations as possible. The standard post-vasectomy instructions sheet given routinely to all vasectomized men in the clinic and the informed consent form to participate in the study provided these instructions. Third, we reminded participants who did not comply with the post-vasectomy semen analysis at three months by phone. We attempted up to three times to contact each participant. We contacted 941 men (81.9%) at least once. Participants had at least six months of follow-up after the vasectomy, as the study data collection ended on July 15, 2018.

The following customary pre-analytic and analytic procedures for post-vasectomy semen analysis were in place at the time of the study. We did not modified them. According to written instructions, patients needed to bring the first semen sample produced by masturbation in a condom with no time limit for delivering the sample at the clinic laboratory after its collection. The laboratory technicians did not centrifuge the semen samples. They did not assess motility at the first post-vasectomy semen analysis. They reported sperm counts of less than 100,000 sperm/ml as "0", meaning "no significant number of sperm detected". We did not request further samples in this case. If the first post-vasectomy semen analysis showed 100,000 sperm/ml or more, we contacted the participant by phone to schedule an appointment for a second test. We asked men to submit additional samples, produced by masturbation preferably in the laboratory facilities, every six weeks until confirmed success or failure of vasectomy. The laboratory technicians analyzed samples within 2 hours of delivery. We requested sperm count per ml and motility for additional post-vasectomy semen analyses.

We defined success/failure of vasectomy on the following criteria: Confirmed success: <100,000 sperm/ml; Probable success: 100,000 sperm/ml; Indeterminate: 100,000 sperm/ml to <1 million sperm/ml; Probable failure: 1 million sperm/ml to 4.9 million sperm/ml; Confirmed failure: 5 million sperm/ml or more, or any

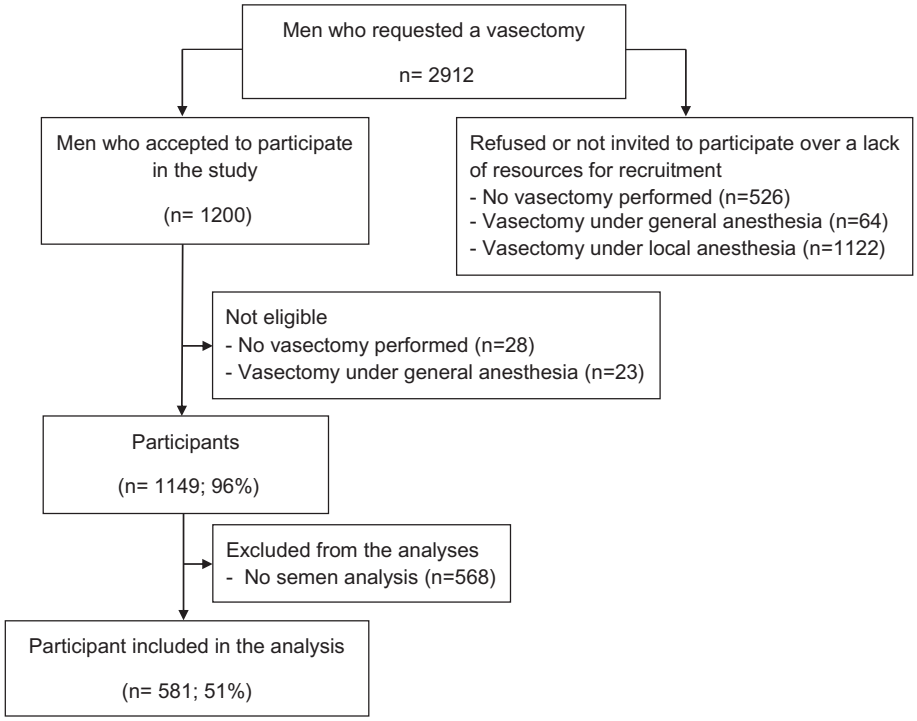

Fig. 2. Study flow chart.

number of sperm with motility, or pregnancy with a post-vasectomy semen analysis showing any number of motile or non-motile sperm, or any patient who, according to the urologist, should have a repeat vasectomy.

2.5. Data collection

We extracted data on the following variables potentially associated with vasectomy failure from the electronic medical record: age, height, weight, urologist who performed the vasectomy, anatomical alteration found at the time of the surgical procedure, and failing to perform fascial interposition on either side. The laboratory sent daily paper reports of post-vasectomy semen analysis to the study team. We entered data in an Excel datasheet.

To reduce the risk of information bias, two independent study team members performed a double data entry of the results of the post-vasectomy semen analysis. In addition, at the end of the study, we compared all data in the Excel datasheet to those from the electronic medical record database. We verified and corrected discrepancies for each variable, varying between 0% and 0.3%.

2.6. Data analysis

We excluded from the analysis participants who did not provide at least one semen sample. We compared participants with and without post-vasectomy semen analysis for each variable potentially associated with vasectomy failure using Student's *t*-test and Chi-square test or Fisher's exact test where applicable.

The effectiveness of the vas occlusion technique (confirmed success, probable success, indeterminate, probable failure, and confirmed failure) was determined using the results of the last post-vasectomy semen analysis available for each patient. The overall risk of failure, combining probable and confirmed failure, was the main outcome of the study. The 95% confidence interval (CI) of the estimates were calculated using the Wilson procedure with no continuity correction [15].

We evaluated the influence of the following variables on the risk of overall failure: age (<35, 35–39, 40+ years old), body mass index (<18.5, 18.5–24.9, 25–29.9, 30+), urologist who performed the vasectomy (1, 2, and 3), anatomical alteration found at the time of the surgical procedure (yes/no), failing to perform fascial interposition on either side (yes/no), and timing of the first post-vasectomy semen analysis (<90 days/90 days or more). We assessed differences in risk failure with relative risk (RR) and 95% CI calculated with Cox regression models with constant time at risk [16]. We performed statistical analyses with STATA 15.

3. Results

Among 2358 men who had a vasectomy at the clinic during the study period, 1149 eligible men participated in the study and 581 (51%) participants produced at least one sample for post-vasectomy semen analysis (Fig. 2). Among these, 482 (83%) were recommended to stop other contraceptive methods based on the results of the first post-vasectomy semen analysis. In the remaining 99 men, 55 (56%) provided a second semen sample. The status related to success or failure of vasectomy remained unchanged, improved, and worsen in 9 (16%), 42 (76%), and 4 (7%) men after the last test available, respectively Table Appendix A. Forty-one (41%) men fully complied with all post-vasectomy semen analysis requests.

We present the demographic and clinical characteristics potentially associated with vasectomy failure of men with and without at least one post-vasectomy semen analysis in Table 1. Men without post-vasectomy semen analysis were significantly younger on average. Significantly more had anatomical alterations reported by urologists at the time of the surgery and more tended to have their surgery performed by urologist 1 and 3.

Table 2 presents the effectiveness of the occlusion technique studied. The overall (probable and confirmed) vasectomy failure risk was 5.2% (30/581) with a 95% CI ranging from 3.6% to 7.3%. Men with vasectomy failure provided their last semen sample at

Table 1
Variables potentially associated with vasectomy failure risk according to the provision of at least one post-vasectomy semen analysis.

Variables	All participants n = 1149	With PVSA n = 581	Without PVSA n = 568	P-value
Mean age (±sd); years	37.1 ± 7.6	37.6 ± 7.7	36.6 ± 7.4	0.02[a]
Mean body mass index (±sd)	22.0 ± 2.9	22.0 ± 3.0	22.0 ± 2.9	0.96[a]
Urologist who did the vasectomy; n (%)				
1	419 (36.5)	207 (35.6)	212 (37.3)	0.05[b]
2	661 (57.5)	348 (59.9)	313 (55.1)	
3	69 (6.0)	26 (4.5)	43 (7.6)	
Failing to perform FI; n (%)	7 (0.6)	3 (0.5)	4 (0.7)	0.73[c]
Anatomical alterations; n (%)	21 (1.8)	6 (1.0)	15 (2.6)	0.04[b]

Sd = standard deviation; PVSA = post-vasectomy semen analysis; FI = fascial interposition.
[a] Student's t-test.
[b] Chi-square test.
[c] Fisher's exact test.

Table 2
Vas occlusion effectiveness in the 581 participants with post-vasectomy semen analysis.

Outcome based on the last PVSA available[a]	n	% (95% CI)
Overall success	545	93.8 (91.5–95.5)
Confirmed success	519	89.3 (86.6–91.6)
Probable success	26	4.5 (3.1–6.5)
Indeterminate	6	1.0 (0.5–2.2)
Overall failure	30	5.2 (3.6–7.3)
Probable failure	11	1.9 (1.1–3.4)
Confirmed failure	19	3.3 (2.1–5.1)
Total	581	100

PVSA = post-vasectomy semen analysis; CI = Confidence interval.
[a] Confirmed success: <100,000 sperm/ml; Probable success: 100,000 sperm/ml; Indeterminate: 100,000 sperm/ml–<1 million sperm/ml; Probable failure: 1 million sperm/ml–4.9 million sperm/ml; Confirmed failure: 5 million sperm/ml or more, or any number of sperm with motility, or pregnancy with a post-vasectomy semen analysis showing any number of motile or non-motile sperm, or any patient who, according to the urologist, should have a repeat vasectomy.

mean of 195 ± 102 days and a median of 160 days after the vasectomy ranging from 70 to 381 days. We present in Table Appendix B the semen analysis results and the time interval between vasectomy and semen analyses for each probable and confirmed failure. Neither vasectomized men nor urologists reported a pregnancy. Urologists did not repeat any vasectomy not based on the post-vasectomy semen analysis failure criteria.

Table 3 presents the overall (probable and confirmed) failure risk according to variables that may influence that risk. The overall failure risk was significantly higher in men aged 40 and older compared to men aged less than 35 (RR 2.8, 95% CI 1.1–7.0) and in those who had their surgery performed by urologist 3 vs. 2 (RR 0.3, 95% CI 0.1–0.9).

Table 3
Overall (probable and confirmed) failure risk of vasectomy according to potentially modifying variables.

Variables	Failure risk		Relative risk
	n/N (%)	% (95% CI)	(95% CI)
Age			
<35	6/220	2.7 (1.3–5.8)	1[a]
35–39	7/143	4.9 (2.4–9.8)	1.7 (0.6–5.0)
40+	17/218	7.8 (4.9–12.1)	2.8 (1.1–7.0)
Body mass index			
<18.5	2/42	4.8 (1.3–15.8)	1[b]
18.5–24.9	23/455	5.1 (3.4–7.5)	1.1 (0.3–4.5)
25–29.9	5/76	6.6 (2.8–14.5)	1.4 (0.3–7.1)
30+	0/8	0	–[c]
Urologist			
1	11/207	5.3 (3.0–9.3)	0.4 (0.1–1.1)
2	15/348	4.3 (2.6–7.0)	0.3 (0.1–0.9)
3	4/26	15.4 (6.2–33.5)	1[a]
Anatomical alteration			
yes	0/6	0	
no	30/575	5.2 (3.7–7.4)	–[c]
Failing to perform FI			
yes	0/3	0	
no	30/578	5.2 (3.7–7.3)	–[c]
Timing of the first PVSA			
<90 days[d]	2/28	7.1 (2.0–22.6)	1.4 (0.3–5.9)
90 days or more	28/553	5.1 (3.5–7.2)	1[b]

CI = Confidence interval; FI = fascial interposition; PVSA = post-vasectomy semen analysis.
[a] Cox regression model with constant time at risk [16] adjusted for age and urologist.
[b] Unadjusted Cox regression model with constant time at risk [16].
[c] The relative risk was not possible to calculate because of the 0 value in the model.
[d] Range 32–90 days. One man had a confirmed failure (35 million sperm/ml at 84 days) and another had a probable failure (4 million sperm/ ml at 70 days).

4. Discussion

We observed that vasectomy occlusion performed with ligation and excision with fascial interposition is associated with a high risk of failure based on the post-vasectomy semen analysis results. Our study confirms the results of five out of six previously published studies showing that the failure risk of this technique is unacceptable [10–15]. The acceptable failure risk of a vasectomy occlusion technique should be under 1% [3]. Even in younger men and men vasectomized by the urologist who had the lowest risk of failure, the lower bound of the 95% confidence interval is higher than 1%.

These results have important implications. Many low-resource countries with large vasectomy programs are still recommending this technique [12]. Although most vasectomy failures can be identified with post-vasectomy semen analysis, in low-resource countries, vasectomized men have limited access to this test and rely on the number of months or/and number of ejaculations after vasectomy before discontinuing other contraceptive methods. Furthermore, even when post-vasectomy semen analysis is available, compliance is low, as observed in our study. The risk of unexpected pregnancies despite the use of vasectomy as a contraceptive method may then be significant if the ligation and excision with fascial interposition is used. In addition, in countries where fascial interposition is indicated within national standards, it is often omitted because of time constraints and insufficient surgical skills [17], resulting in an even higher failure risk [18,19].

Uptake of vasectomy is low in most low-resource countries [20], and unexpected pregnancies after vasectomy may limit efforts to increase its use [20]. It is essential that vasectomy providers perform the most effective vas occlusion techniques. Most recent clinical practice guidelines from United States of America [3], United Kingdom [21], Europe [22], and Canada [23] recommend that cautery of the mucosa of the vas lumen, prefer-

ably combined with interposing the fascia between the divided ends of the vas should be used to occlude the vas. Combining mucosal cauterization of the vas deferens with fascial interposition results in the lowest risk of occlusive failure (well below 1 % based on post-vasectomy semen analysis) [4,18,19]. This technique has been successfully integrated into vasectomy programs in Rwanda [24], Haiti, Kenya, and, more recently, in Colombia after we made the results of our study available locally [12].

4.1. Limitations

This study has some limitations. First, as indicated in Fig. 2, we could not invite about half of the 2358 men who had a vasectomy at the clinic to participate in the study. This was due to the lack of available human resources and not to a purposely-differential selection of participants. Ultimately, we extended the recruitment period to attain our targeted sample size.

Second, about half of the participants did not provide a first post-vasectomy semen analysis despite all efforts to maximize compliance as described in Section 2. There were statistically significant differences in some clinical characteristics of participants with and without post-vasectomy semen analysis due to our large sample size. However, this self-selection of participants performing a post-vasectomy semen analysis does not bias the results. A selection bias would have occurred only if the loss to follow-up (non-compliance) had been associated with the exposure (vasectomy technique) and the outcome of interest (vasectomy failure). It is unlikely that the urologists modified the vasectomy technique according to prior knowledge of who would comply with the test or not in the future. Furthermore, there is no reason to believe that non-compliance is associated with failure risk. The high attrition rate however decreases the precision of our results evaluated with 95% CIs. Nevertheless, the number of participants remaining for analyses yielded 95% CIs precise enough to show that the risk of failure is unacceptable, well above the 1% cut-off recommended by the American Urological Association [3].

Third, non-compliance with additional post-vasectomy semen analysis after the first test may have led to both overestimation and underestimation of the failure risk. On one hand, based on the number of sperm on the initial post-vasectomy semen analysis, participants with a probable (1–4.9 million sperm /ml) or confirmed (5 million or more sperm/ml) failure may have been declared a success with additional post-vasectomy semen analyses. About half of vasectomized men with 1–19 million sperm / ml and one-third with 20 million or more /ml at the initial post-vasectomy semen analysis are known to have a delayed vasectomy success within six months post-vasectomy [25]. However, such quantities of sperm at three months are highly suggestive of recanalization, and despite the possibility of delayed success in several cases, we may considered most as occlusive failures. This can be avoided with better occlusion techniques [26].

On the other hand, classifying men who had 100,000 sperm/ml or less at their initial post-vasectomy semen analysis as successes without assessment of motility could have led to an underestimation of the failure risk. The sperm count cut-off recommended to stop other methods of contraception after a vasectomy (indicating a successful vas occlusion) is currently 100,000 non-motile sperm/ml or less [3,21–23,27]. However, assessing motility would not have changed our conclusions. Among post-vasectomy semen analysis showing rare sperm (less than 1 million/ml), only 9% [28] to 11% [29] displayed some motile sperm and up to three-quarters of additional post-vasectomy semen analysis were negative [25].

Fourth, the aim of the study was to determine the failure risk based on post-vasectomy semen analysis. As such, it is not possible to draw conclusions about the contraceptive effectiveness of the studied vasectomy technique. Considering the high occlusive failure risk, we were however expecting to observe a few pregnancies, especially in men who did not comply with post-vasectomy semen analysis, even over the relatively short - year and a half - duration of the study. In a cohort of 1263 men from rural Nepal who had a vasectomy mostly performed by simple ligation and excision, 2.3% still had 500,000 sperm/mL or more in their semen 1–3 years after the procedure; pregnancy rates were 0.7%, 1.7% and 4.2% at 3, 12 and 36 months, respectively [30]. Our participants spontaneously reported no pregnancies and none of the three urologists interviewed in March 2019 remembered hearing about a case from the studied cohort.

4.2. Generalizability

Our results apply to the ligation and excision with fascial interposition technique recommended by EngenderHealth [2]. This was precisely the occlusion technique studied by Sokal et al. in their randomized trial conducted in seven countries and showing a failure risk of 5.9% (95% CI 3.8%–8.6%) [11].

We restricted study eligibility to men who had their vasectomy under local anesthesia. Among the 2358 men who had their vasectomy during the study period (participants and non-participants), 87 (3.7%) had their vasectomy performed under general anesthesia. This was unexpected. A survey of 100 members of the Vasectomy Network, an international Google discussion group, showed that on average vasectomists consider that less than 1% of men should have their vasectomy done under general anesthesia (unpublished data). The institution is currently addressing the issue.

In conclusion, our study confirmed that the ligation and excision with fascial interposition vasectomy technique is associated with an unacceptably high risk of failure, even when performed by experienced surgeons. Vasectomy programs in low-resource countries should consider adopting alternatives to this technique. Combining thermal cautery with fascial interposition can reduce the failure risk to below 1% [3]. Although cautery can be implemented in low-resource countries, more research is needed to identify a vasectomy occlusion method that could be highly effective, safe and not require any equipment beyond no-scalpel vasectomy instruments and suture material [31].

Appendix

Appendix A
Results of the first and last post-vasectomy semen analyses (PVSA) in men with sperm at the first PVSA, according to status related to success or failure of vasectomy.

No	Time interval vasectomy – 1st PVSA (days)	Sperm concentration ($n \times 10^6$/ml)	Status at the first PVSA	Time interval vasectomy – last PVSA (days)	Rank of PVSA	Sperm concentration ($n \times 10^6$ /ml)	Status at the last PVSA
Unchanged status							
1	102	40	Confirmed failure	381	4th	0.6[a]	Confirmed failure
2	147	15	Confirmed failure	370	3rd	0.1[a]	Confirmed failure
3	108	48	Confirmed failure	309	2nd	20	Confirmed failure
4	150	20	Confirmed failure	280	2nd	200	Confirmed failure
5	180	20	Confirmed failure	360	2nd	11[a]	Confirmed failure
6	145	25	Confirmed failure	272	2nd	20	Confirmed failure
7	97	15	Confirmed failure	293	2nd	40	Confirmed failure
8	103	0.1	Probable success	189	2nd	0.1	Probable success
9	91	0.1	Probable success	179	2nd	0.1	Probable success
Better status							
1	93	31	Confirmed failure	211	2nd	1	Probable failure
2	119	10	Confirmed failure	224	2nd	0.2	Indeterminate
3	97	8	Confirmed failure	205	3rd	0.1	Probable success
4	98	47	Confirmed failure	271	2nd	0	Confirmed success
5	108	20	Confirmed failure	191	2nd	0	Confirmed success
6	91	1	Probable failure	185	2nd	0.5	Indeterminate
7	162	4	Probable failure	261	2nd	0.1	Probable success
8	92	1	Probable failure	229	2nd	0.1	Probable success
9	92	2	Probable failure	279	2nd	0	Confirmed success
10	105	2	Probable failure	251	2nd	0	Confirmed success
11	91	1	Probable failure	217	2nd	0	Confirmed success
12	100	1	Probable failure	227	2nd	0	Confirmed success
13	98	1	Probable failure	226	3rd	0	Confirmed success
14	110	1	Probable failure	231	2nd	0	Confirmed success
15	97	0.5	Indeterminate	203	2nd	0	Confirmed success
16	103	0.5	Indeterminate	329	4th	0	Confirmed success
17	105	0.3	Indeterminate	231	2nd	0	Confirmed success
18	96	0.2	Indeterminate	216	2nd	0	Confirmed success
19	77	0.2	Indeterminate	359	4th	0	Confirmed success
20	98	0.2	Indeterminate	182	2nd	0	Confirmed success
21	118	0.2	Indeterminate	239	2nd	0	Confirmed success
22	117	0.2	Indeterminate	214	2nd	0	Confirmed success
23	112	0.1	Probable success	232	2nd	0	Confirmed success
24	178	0.1	Probable success	255	2nd	0	Confirmed success
25	111	0.1	Probable success	223	2nd	0	Confirmed success
26	92	0.1	Probable success	280	2nd	0	Confirmed success
27	97	0.1	Probable success	202	2nd	0	Confirmed success
28	92	0.1	Probable success	202	2nd	0	Confirmed success
29	119	0.1	Probable success	215	2nd	0	Confirmed success
30	92	0.1	Probable success	199	3rd	0	Confirmed success
31	105	0.1	Probable success	199	2nd	0	Confirmed success
32	140	0.1	Probable success	249	2nd	0	Confirmed success
33	225	0,1	Probable success	362	2nd	0	Confirmed success
34	97	0,1	Probable success	191	2nd	0	Confirmed success
35	99	0,1	Probable success	245	2nd	0	Confirmed success
36	98	0,1	Probable success	244	2nd	0	Confirmed success
37	98	0,1	Probable success	224	2nd	0	Confirmed success
38	119	0,1	Probable success	330	2nd	0	Confirmed success
39	95	0,1	Probable success	230	2nd	0	Confirmed success
40	120	0,1	Probable success	176	2nd	0	Confirmed success
41	92	0,1	Probable success	199	2nd	0	Confirmed success
42	105	0,1	Probable success	191	2nd	0	Confirmed success
Worst status							
1	108	1	Probable failure	356	3rd	0.3[a]	Confirmed failure
2	99	0.2	Indeterminate	313	2nd	3[a]	Confirmed failure
3	100	0.1	Probable success	236	2nd	0.5	Probable failure[b]
4	95	0.1	Probable success	189	2nd	0.2	Indeterminate

PVSA = post-vasectomy semen analysis.
[a] Presence of motile sperm.
[b] Because the number of sperm increased from 100,000 sperm/ml to 500,000 sperm/ml 236 days after the vasectomy, we classified this vasectomy as a probable failure although the number of sperm was under 1 million/ml.

Appendix B

Results of the post-vasectomy semen analyses (PVSA) of men with probable and confirmed vasectomy failure.

No	Time interval vasectomy – 1st PVSA (days)	Sperm concentration ($n \times 10^6$/ml)	Motility	Time interval vasectomy – 2nd PVSA (days)	Sperm concentration ($n \times 10^6$/ml)	Motility	Time interval vasectomy – 3rd PVSA (days)	Sperm concentration ($n \times 10^6$/ml)	Motility	Time interval vasectomy – 4rd PVSA (days)	Sperm concentration ($n \times 10^6$/ml)	Motility
Probable failure (Time interval between vasectomy and last PVSA: mean ± standard deviation = 143 ± 50 days and median = 144 days)												
1	93	31	-	211	1	–						
2[a]	100	0.1	–	236	0.5	–						
3	174	2	–									
4	150	3	–									
5	164	2.5	–									
6	144	1	–									
7	84	4	–									
8	101	3	–									
9	92	1	–									
10	118	1	–									
11	95	1	–									
Confirmed failure (Time interval between vasectomy and last PVSA: mean ± standard deviation = 225 ± 113 days and median = 272 days)												
1	102	40	–	191	1	–	259	0.5	–	381	0.6	Yes
2	147	15	–	217	0.1	–	370	0.1	Yes			
3	108	1	–	154	0.3	No	356	0.3	Yes			
4	108	48	–	309	20	–						
5	150	20	–	280	200	–						
6	180	20	–	360	11	Yes						
7	145	25	–	272	20	–						
8	97	15	–	293	40	Yes						
9	99	0.2	–	313	3	Yes						
10	104	20	–									
11	176	40	–									
12	155	20	–									
13	297	45	–									
14	94	20	–									
15	97	20	–									
16	118	6	–									
17	70	35	–									
18	132	80	–									
19	91	70	–									

[a] Because the number of sperm increased from 100,000 sperm/ml to 500,000 sperm/ml 236 days after the vasectomy, we classified this vasectomy as a probable failure although the number of sperm was under 1 million/ml.

References

[1] Li SQ, Goldstein M, Zhu J, Huber D. The no-scalpel vasectomy. J Urol 1991;145:341–4.
[2] No-Scalpel Vasectomy. An illustrated guide for surgeons. 3rd ed, New York, NY: EngenderHealth; 2003. https://www.engenderhealth.org/files/pubs/family-planning/no-scalpel.pdf (accessed January 16, 2020).
[3] Sharlip ID, Belker AM, Honig S, Labrecque M, Marmar JL, Ross LS, et al. Vasectomy: AUA guideline. J Urol 2012;188:2482–91.
[4] Labrecque M, Dufresne C, Barone MA, St-Hilaire K. Vasectomy surgical techniques: a systematic review. BMC Med 2004;2:21.
[5] Cook LA, Pun A, van Vliet H, Gallo MF, Lopez LM. Scalpel versus no-scalpel incision for vasectomy. Cochrane Database Syst Rev 2006::CD004112.
[6] Kumar V, Kaza RM. A combination of check tug and fascial interposition with no-scalpel vasectomy. J Fam Plann Reprod Health Care 2001;27:100.
[7] Farrokh-Eslamlou HR, Eslami M, Abdi-Rad I, Eilkhanizadeh B. Evaluating success of no-scalpel vasectomy by ligation and excision with fascial interposition in a large prospective study in Islamic Republic of Iran. East Mediterr Health J 2011;17:517–22.
[8] De los Rios Osorio J, Angelo Castro Alvarez E. Analysis of 5000 vasectomies in a family planning centre in Medellin-Colombia. Archivos Españoles de Urología 2003;56:53–60.
[9] Li SQ, Xu B, Hou YH, Li CH, Pan QR, Cheng DS. Relationship between vas occlusion techniques and recanalization. Adv Contracept Deliv Syst 1994;10:153–9.
[10] Altok M, Şahin AF, Divrik RT, Yildirim Ü, Zorlu F. Prospective comparison of ligation and bipolar cautery technique in non-scalpel vasectomy. Int Braz J Urol 2015;41:1172–7.
[11] 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.
[12] Labrecque M. Are evidence-based vasectomy surgical techniques performed in low-resource countries?. Gates Open Res 2019;3:1462.
[13] Dhand NK, Khatkar MS. Statulator: an online statistical calculator. Sample size calculator for estimating a single proportion 2014. http://statulator.com/SampleSize/ss1P.html (Accessed January 14, 2020).
[14] Chen K-C, Peng C-C, Hsieh H-M, Chiang H-S. Simply modified no-scalpel vasectomy (percutaneous vasectomy)—a comparative study against the standard no-scalpel vasectomy. Contraception 2005;71:153–6.
[15] Newcombe RG. Two-sided confidence intervals for the single proportion: comparison of seven methods. Stat Med 1998;17:857–72.
[16] Barros AJD, Hirakata VN. Alternatives for logistic regression in cross-sectional studies: an empirical comparison of models that directly estimate the prevalence ratio. BMC Med Res Methodol 2003;3:21.
[17] Labrecque M, Pile J, Sokal D, Kaza RCM, Rahman M, Bodh SS, et al. Vasectomy surgical techniques in South and South East Asia. BMC Urol 2005;5:10.
[18] Sokal DC, Labrecque M. Effectiveness of vasectomy techniques. Urol Clin North Am 2009;36:317–29.
[19] Sokal D, Irsula B, Chen-Mok M, Labrecque M, Barone MA. A comparison of vas occlusion techniques: cautery more effective than ligation and excision with fascial interposition. BMC Urol 2004;4:12.
[20] Shattuck D, Perry B, Packer C, Chin Quee D. A review of 10 years of vasectomy programming and research in low-resource settings. Glob Health Sci Pract 2016;4:647–60.
[21] Faculty of Sexual & Reproductive Healthcare (FSRH). Male and female sterilisation. https://www.fsrh.org/documents/cec-ceu-guidance-sterilisation-cpd-sep-2014. 2014 (accessed January 16, 2020).
[22] Dohle GR, Diemer T, Kopa Z, Krausz C, Giwercman A, Jungwirth A, et al. European association of urology guidelines on vasectomy. Eur Urol 2012;61:159–63.
[23] Zini A, Grantmyre J, Chan P. CUA guideline: vasectomy. Can Urol Assoc J 2016;10:E274–8.
[24] Labrecque M, Kagabo L, Shattuck D, Wesson J, Rushanika C, Tshibanbe D, et al. Strengthening vasectomy services in Rwanda: introduction of thermal cautery with fascial interposition. Contraception 2013;87:375–9.
[25] Labrecque M, St-Hilaire K, Turcot L. Delayed vasectomy success in men with a first postvasectomy semen analysis showing motile sperm. Fertil Steril 2005;83:1435–41.
[26] Labrecque M, Hays M, Chen-Mok M, Barone MA, Sokal D. Frequency and patterns of early recanalization after vasectomy. BMC Urol 2006;6:25.
[27] 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.
[28] Chawla A, Bowles B, Zini A. Vasectomy follow-up: clinical significance of rare nonmotile sperm in postoperative semen analysis. Urology 2004;64:1212–5.
[29] Labrecque M, Nazerali H, Mondor M, Fortin V, Nasution M. Effectiveness and complications associated with 2 vasectomy occlusion techniques. J Urol 2002;168:2495–8. discussion 2498.
[30] Nazerali H, Thapa S, Hays M, Pathak LR, Pandey KR, Sokal DC. Vasectomy effectiveness in Nepal: a retrospective study. Contraception 2003;67:397–401.
[31] Sokal DC. Vasectomy techniques—need for better occlusion methods. Asian J Androl 2010;12:442–3.