

Original Article

Complications of vasectomy: results from a prospective audit of 105 393 procedures

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Objectives

To provide up-to-date complication rates for vasectomy in the UK using 15 years of data collected by the Association of Surgeons in Primary Care (ASPC).

Patients and Methods

Data were collected between 2007 and March 2022. A patient questionnaire was completed on the day of surgery and at 4 months postoperatively. Rates of early and late failure, infection, hospital admission or re-admission, haematoma and post-vasectomy pain syndrome (PVPS) were recorded. There were no specific exclusion criteria. Complication rates were compared to those published by major urological organisations. Descriptive statistics were utilised, without formal statistical analysis.

Results

Over the 15-year study period, data from 105 393 vasectomies were collected, performed by >150 surgeons. In 2022, 94.4% of surgeons used one test to prove sterility. In all, 65% of patients used a postal sperm test after vasectomy to confirm sterility. Early failure rates were available for 69 500 patients. Early failure occurred in 648 patients (0.93%). Of 99 124 patients, late failure occurred in 41 (0.04%). Of 102 549 vasectomies, postoperative infection was reported in 1250 patients (1.22%), haematoma in 1599 patients (1.56%), and PVPS was reported in 139 patients (0.14%).

Conclusions

Vasectomy remains a safe and reliable contraceptive method. The rates of complication were generally lower than those published by major urological organisations. This large, prospective audit provides accurate, contemporaneous complication rates that can form the basis for pre-vasectomy counselling.

Keywords

vasectomy, complications, early failure, late failure, infections, haematomas, pain

Introduction

Vasectomy is an effective and safe form of male contraception and is considered the most reliable form of male contraception. Worldwide, it is estimated that 40–60 million men have undergone a vasectomy [1].

It is important to counsel men thoroughly about possible complications of a vasectomy; however, up-to-date data are scarce [2–4]. Vasectomy complications are a frequent cause of litigation [5]. The rate of troublesome chronic scrotal pain quoted in the BAUS patient information leaflet is ‘up to 5%’, which may discourage some patients. Similarly, the European Association of Urology (EAU) quotes a rate of chronic scrotal pain of up to 14% [1].

Vasectomy is predominantly performed in a Primary Care setting [6]. The Association of Surgeons in Primary Care (ASPC), composed mainly of GPs, has been collecting a large dataset on vasectomy over the past 15 years. The aim of this review is to provide up-to-date complication rates for vasectomy, capturing the majority of procedures performed in the UK.

Patients and Methods

Clinics participating in the study collected data prospectively through two questionnaires: an immediate post-vasectomy questionnaire (Appendix S1), and a 4-month postoperative questionnaire (Appendix S1). These were offered to all patients undergoing vasectomy surgery in a community

setting. The immediate questionnaire, completed prior to discharge, focussed on patient experience of the operation, doctor's competence and manner, together with the operative environment.

The 4-month questionnaire, typically sent with a letter reminding the patient to submit a semen sample for post-vasectomy semen analysis (PVSA), focussed on patient recovery. This included questions regarding pain, infection, haematoma formation, attendance at hospital and overall patient experience. Data on early and late failure were collected by individual clinics.

All surgeons were members of the ASPC, who regularly performed minimally invasive vasectomies, of which the non-scalpel technique is the most common, and who choose to submit their data for annual audit.

Clinics submitted their results using the ASPC vasectomy audit sheet (Appendix S2). Rates of early and late failure, infection, haematoma and post-vasectomy pain syndrome (PVPS) were recorded in Microsoft Excel. A formal ASPC vasectomy glossary helps support individual clinics in collecting data [7] (Appendix S3). Key definitions are summarised below:

- Early failure – early failure has been said to have occurred if any motile sperm are observed in a fresh sample 7 months after vasectomy.
- Late failure – this is the discovery of vasectomy failure, irrespective of time frame, after the patient has been informed the vasectomy was successful and advised it was safe to abandon contraception.
- Haematoma – this is a swelling of a certain size (roughly a golf ball and larger) that develops in the scrotal sac resulting from the vasectomy.
- Postoperative infection – any case where any clinician has deemed it appropriate to give antibiotics for a presumed post-vasectomy infection.
- Post-vasectomy pain syndrome – this is defined as chronic scrotal pain, severe enough to cause the patient to seek medical attention and/or to interfere with quality of life, occurring any time after the surgery and persisting for >6 months despite non-surgical treatments.

Results

Data collection took place for vasectomies undertaken between January 2007 and March 2022 from 99 different clinics based throughout England, Wales, Scotland and Ireland, with data from >150 vasectomy surgeons. The number of clinics who submitted data ranged from 22 to 44 per year. All surgeons were members of the ASPC who regularly performed vasectomies and chose to submit their data to the ASPC for annual audit. Data from 105 393 vasectomies were collected.

Response Rates for the Immediate and 4-Month Surveys

Since 2011, the majority of clinics who collected data did so using official ASPC questionnaires. However, the return rates of the immediate postoperative questionnaire and the 4-month postoperative questionnaire were not collected prior to 2016 and 2014, respectively.

In regard to the immediate postoperative questionnaire (Appendix S1), since 1 April 2014, 230 of 286 clinics submitted data using the official questionnaire (74.07%). The remaining clinics collected data with their own form of questionnaire. Of the clinics that reported using the official ASPC questionnaire, there was an average 71% return rate of questionnaires (34 834/50 676 vasectomies), falling to 52% when all data (i.e., not just that collected through ASPC questionnaires) was included.

Since 1 January 2012, 218 of 379 clinics (58.92%) submitted data using the official ASPC 4-month postoperative questionnaire (Appendix S1). The return rate for clinics that used the ASPC 4-month postoperative questionnaire was an average 32% (14 604/45 015 vasectomies). The figure was lower (17%) when data not submitted through the ASPC questionnaire were included.

Data for the 4-month ASPC postoperative questionnaire were further stratified into groups depending on the return rate of questionnaires (>33%, <33%, and those that did not use the questionnaire). Centres that had audit returns of <33% were still included in the analysis.

Sterility Rates

For the 2021/2022 audit cycle, 94.4% of clinics required one test to prove sterility, typically performed a minimum of 12 weeks after vasectomy and after a minimum of 20 ejaculations, in accordance with the 2016 Laboratory guidelines for PVSA recommended by the British Andrological Society (BAS) and the BAUS [8]. The postal method for PVSA was used in the majority of patients, as recommended by the Faculty of Sexual and Reproductive Healthcare (FSRH) [7]. For the 2021/2022 audit cycle, 65% of clinics used the postal method.

Sterility rates are outlined in Table 1, with an average sterility rate of 99.07% for those who undertook a PVSA to confirm sterility.

Early/Late Failure

Early failure data were available for 99 124 vasectomies. Of these vasectomies 69 500 men submitted samples for PVSA to confirm sterility and 648 early failures were reported during this time period (0.93%).

Table 1 Sterility, early and late failure rates.

Audit cycle	Vasectomies performed, <i>n</i>	Vasectomies with data submitted, <i>n</i>	Men who undertook PVSA, <i>n</i>	Compliance of PVSA, %	Sterility rates of men who undertook PVSA, %	Early failures, <i>n</i>	Late failures, <i>n</i>
2007/2008	4380	4052	3311	81.71	99.28	24	0
2008/2009	2406	2326	1515	65.13	98.94	16	5
2009/2010	3411	3411	1816	53.24	98.90	20	4
2010/2011	6116	6116	4128	67.50	99.47	22	6
2011/2012	5583	5364	3575	66.65	99.52	17	3
2012/2013	7363	7230	4752	65.73	99.39	29	2
2013/2014	6774	6080	4274	70.30	99.32	29	0
2014/2015	6581	6023	4345	72.14	99.22	34	2
2015/2016	7663	6743	4872	72.25	98.87	55	3
2016/2017	7832	7832	5994	76.53	99.32	41	3
2017/2018	7779	7537	5039	66.86	98.93	54	1
2018/2019	9604	8447	5988	70.89	98.81	71	3
2019/2020	11 335	11 005	7841	71.25	98.53	115	3
2020/2021	6620	6332	4643	73.33	99.10	42	2
2021/2022	11 946	10 626	7409	69.73	98.93	79	4
Total	105 393	99 124	69 502	70.12	99.07	648	36

Early failure rate, 0.93%; late failure rate, 0.04%.

Late failure data were available for 99 124 vasectomies and 41 late failures were recorded during this time period (0.04%). Figures for early and late failure are outlined in Table 1.

Complications

Infection data were collected for 102 549 vasectomies. Infection was reported in 1250 patients (1.22%). Each year an average of 66% of surgeons had at least one reported infection, with 37% of the antibiotics known to have been prescribed being provided by the surgeon themselves.

Haematoma data were available for 102 549 patients. Postoperative haematoma was reported in 1599 vasectomies (1.56%). Of the 1599 haematomas, 206 (13%) were described as being larger than a cricket ball (diameter >7.5 cm). On average, 60% of surgeons reported that at least one patient had a haematoma.

Post-vasectomy pain syndrome data were available for 102 549 patients. PVPS was reported in 139 patients (0.14%). When PVPS was reported in a different audit cycle year (as post-vasectomy pain would not necessarily start in the same audit cycle as the vasectomy), an additional 38 patients reported PVPS (0.17%; *n* = 177). In all, 14% of the surgeons reported at least one PVPS patient.

Table 2 Complication rates excluding early and late failures.

Audit cycle	2008	2009	2010	2011	2012	2013	2014	2015	2016	2017	2018	2019	2020	2021	2022	Overall
Infections, %	1.35	1.75	1.03	1.34	1.18	1.34	1.36	1.44	1.04	1.46	1.16	1.00	0.79	1.57	1.13	1.22
Haematomas, %	0.78	0.71	0.41	0.69	0.84	1.36	2.40	1.26	1.88	1.56	1.43	2.33	1.95	2.83	1.11	1.56
PVPS, %	0.09	0.04	0.12	0.11	0.05	0.15	0.03	0.08	0.16	0.19	0.13	0.08	0.23	0.09	0.26	0.14
Total Complications, %	2.21	2.49	1.58	2.17	2.17	2.85	3.80	2.78	3.08	3.21	2.73	3.42	2.97	4.49	2.50	2.91
<i>N</i>	97	60	53	131	116	210	256	183	195	251	213	328	329	300	266	2988

Requirement for hospital admission occurred in 62 patients out of 85 120 (0.07%). In all, 44% of these patients had infections requiring either oral or intravenous antibiotics. Most common reasons include haematomas requiring drainage, ongoing bleeding and concerns regarding sepsis. A table summarising complication rates per year (excluding failures and admissions) is outlined in Table 2.

The overall complication rate was 2.91%. A patient can have more than one complication, and this would have been recorded as such. There were no other complications recorded other than those reported above.

Discussion

Vasectomy is a form of permanent male contraception that is safer, quicker, associated with less morbidity, and more effective than female sterilisation [7,9].

This is the largest ever dataset on the complications of vasectomy. Data were collected over a 15-year study period. All clinics that submitted data were members of the ASPC who regularly perform non-scalpel/minimally invasive vasectomies and chose to submit their data to the ASPC for annual audit. Annual membership to the ASPC varies from around 90–150 members. The ASPC exist to provide support,

training, education, and professional development for all providers of surgical procedures in Primary Care, and its members, who by the very fact that they have joined the organisation, are keen to be at the forefront of changes in providing high-quality, readily available vasectomy provision throughout the UK. Over half of the members perform vasectomies (others perform procedures such as carpal tunnel release). Members are asked to audit their practice annually and are encouraged to undergo peer review.

The large sample size is the major strength of this study. Data collection occurs on a continuous basis through the ASPC, with annual review, allowing surgeons to compare their data over time, and against other surgeons [9]. Hospital Episode Statistics (HES) data are available on Sexual and Reproductive Health Services between 2012 and 2022 [10]. During this period the ASPC captured data on 89 080 vasectomies. During this time period 121 164 vasectomies were recorded on the HES database. It is unclear from the HES data what proportion of the vasectomies included in their database were performed by community surgeons, more specifically by ASPC members. Nevertheless, it is reasonable to state that the ASPC was able to capture data on a large proportion of the vasectomies carried out in the UK during this time period.

Data on complications may be collected by several means but were predominantly reported via the ASPC 4-month postoperative questionnaire. Data may also have been collected through patients directly contacting the surgeon, or the surgeon receiving a discharge letter from the hospital if admission was required. There is the possibility of under-reporting for this reason and we accept this as a limitation.

The ASPC have recommended a minimally invasive technique (of which the non-scalpel technique is the most common) since the mid-1990s, with current evidence supporting this as the safest surgical approach [11]. All vasectomies performed in this study were of a non-scalpel technique.

In the UK, it is recommended men who have had a vasectomy undertake a PVSA prior to being given 'clearance' to stop other forms of contraception. PVSA should take place at least 12 weeks after the vasectomy and after 20 ejaculations [1,8,12]. Samples showing sperm may require further testing, as demonstrated in the current clinical pathway recommended by the ASPC for PVSA submission and interpretation (Appendix S4). There are two typical ways of semen testing. Firstly the 'non-postal' method, whereby patients submit a fresh semen sample, produced either at the laboratory facility, or at home which they deliver to the laboratory. Most UK and international guidelines recommend this approach. However, the compliance of men when asked to provide a fresh sample for PVSA is generally poor, with only around two-thirds of men submitting a semen specimen

[9]. Many factors can compromise compliance with the 'non-postal' method, including embarrassment producing specimens, expense of transport, and loss of earnings [13–15]. To reduce non-compliance, a 'postal' testing strategy may be used, whereby a semen sample is produced at home and sent through the post to a laboratory for analysis [9]. Postal testing has become more common in recent years—59% of patients between 2014 and 2019 compared with earlier years, 49% between 2009 and 2013 [9]. It has been shown year on year that by using postal service, sterility rates are higher [10]. Nevertheless the 2021/2022 audit revealed that out of 10 626 vasectomies undertaken only 7409 submitted semen for PVSA (70%), reflecting that well over a quarter of patients do not submit semen samples to prove sterility. Compliance figures are summarised in Table 1.

Early and Late Failure

Data have been collected regarding complications for 15 years. For early failure, data were available for 99 124 vasectomies. Of these vasectomies 69 500 men submitted samples for PVSA to confirm sterility. During this period 648 early failures were reported or 0.93% (one in 108). This is double the figure reported on the BAUS consent form of 0.4% (one in 250) but compares favourably with the EAU guidelines, which quote a figure of 0.2–5.3% for early failure [1]. Early failure is usually related to inadequate occlusion of one or both vasa, or early re-canalisation [5]. In these circumstances a patient would be informed that their vasectomy had been unsuccessful and offered re-vasectomy or alternative ongoing contraception. The authors acknowledge the limitation that the number of men available to calculate early failure rates on is reduced due to the PVSA submission rate, and this may have resulted in the higher figure compared to the BAUS. If all vasectomies are included irrespective of whether or not a PVSA sample was submitted, the early failure rate falls to 0.65%. Routine histopathological analysis of a segment of vas, taken at the time of the vasectomy, is not recommended in current guidelines [7]. It was beyond the scope of this paper to evaluate the management of early failure patients identified, e.g., how many patients underwent re-vasectomy.

Late failure is a rare event. Often, late failure of vasectomy only becomes apparent when the partner of a sterilised man becomes pregnant [9]. The main theory of causation is late re-canalisation of the vas deferens. Data were available for 99 124 vasectomies. During this period 41 late failures were recorded or 0.04% (one in 2418). This figure is slightly lower than the BAUS figure of 0.05% (one in 2000) [4,16]. The EAU guidelines report a figure of 0.03–1.2% [1]. The notification and recording of late failures are potentially underestimated due to non-reporting by patients. This is well

covered in the literature [2,9,11,17]. We have no data on the exact timing of when late failures were reported. Pregnancies may occur many years subsequent to vasectomy and the surgeon may never be informed. In addition, the data cannot confirm that the reported late failures were indeed true late failures as confirmed by a fresh PVSA or DNA testing. It should be appreciated that with no paternity data available, the late failure figure could even be an overestimation. An additional layer of complexity arises with the knowledge that there are patients of DNA-confirmed fatherhood after vasectomy in association with persistently negative semen analysis [18]. As the numbers of late failures are small, any misdiagnosis could greatly affect the figures [9]. Nevertheless, it is well appreciated that late failure is a frequent cause for litigation, and with this in mind preoperative counselling must be thorough [19].

Further Complications

Infection data were collected for 102 549 vasectomies. Postoperative infection was reported in 1250 patients (1.22%), or one in 82 patients. The criteria for infection was pragmatic, defined as any case where any clinician has deemed it appropriate to give antibiotics for a presumed post-vasectomy infection. Wound, epididymal and/or orchitis infections were all included in the analysis, with no distinction made. Early studies suggested the incidence of infection varies between 12% and 38%, with an average of 3.4%. The BAUS guidelines quote a higher infection rate than reported in this study, of 2–10% (between one in 10 and one in 50 patients). Likewise, the EAU guidelines report a similar risk of postoperative infection to that identified in this study of 0.2–1.5% [1]. There are some limitations to these data. In some cases it is difficult to be sure whether this was a real infection, and in a significant proportion of cases the antibiotics were prescribed by a non-vasectomy surgeon. In the UK, the majority of patients with issues after vasectomy will be reviewed by their GP, not their vasectomy surgeon. Those performing the operation may have a different threshold to prescribe antibiotics than someone in primary care. Since January 2009, only 37% of the known first courses of antibiotics were prescribed by the vasectomy surgeon themselves. Those clinics with a higher return rate of postoperative questionnaires also had double the rate of infection, once again demonstrating that the higher the engagement with postoperative audit the higher the reported rate of complications. There is also potential under-reporting of data knowing that 68% of all infections were diagnosed by the GP, and that GPs are unlikely to inform the surgeon that they have given antibiotics to a patient.

Postoperative haematoma, defined by the ASPC as a painful swelling of diameter ≥ 4 cm (roughly a golf ball size) that develops in the scrotal sac resulting from the vasectomy. The

data reflects haematomas that were diagnosed clinically, although some patients would have had an ultrasound diagnosis too, especially those which required admission to hospital. Data were available for 102 549 patients, with a postoperative haematoma reported in 1599 vasectomies (1.56%), or one in 64 patients. Similar to infection, this is lower than the risk quoted in the BAUS consent form of 2–10%. The EAU guidelines report a risk of 4–22%. Haematomas are a risk factor for infection [20]; between 6% and 20% of patients with a haematoma also receive antibiotics for a presumed infected haematoma. It has been shown that the incidence of haematoma formation correlates with surgeon experience, with a rate of 4.6% for those performing 1–10 vasectomies a year, compared to 1.6% for those performing 11–50 vasectomies per year [21]. No data were available regarding the proportion of patients on anticoagulation and whether this influenced haematoma occurrence.

Post-vasectomy pain syndrome has various definitions. The ASPC describe it as taking place any time after the surgery and chronic, lasting for >6 months. They state it should be debilitating, severe enough to cause the patient to seek medical attention and/or interfere with quality of life. The FSRH Clinical Guidance define PVPS as persistent pain >3 months after the procedure (Appendix S3). The BAUS do not specify a time frame. A cause is often difficult to identify, although potential causes include congestive epididymitis or the development of sperm granuloma [5].

Of 102 549 vasectomies, PVPS was reported in 139 patients (0.14%), or one in 714 patients. When PVPS was reported in a different audit year (as post-vasectomy pain would not necessarily start in the same audit cycle as the vasectomy), an additional 38 patients were identified (0.17%, or one in 588). This is a similar figure to that reported by Leslie et al. [22] from the high-volume Elliot Smith Clinic, Oxford, which reported a rate of one in 300 patients (0.3%) of scrotal discomfort that is severe enough to seek medical attention and/or to interfere with quality of life at 5 years after surgery.

The BAUS report a much higher figure of up to 5%. The EAU guidelines provide a figure of 1–14%, adding it is usually mild but sometimes requires pain management or surgery. The AUA guidelines report a 1–2% risk of life-changing pain [1,12,23]. The ASPC have updated their definition of PVPS to reflect the AUA definition of a life-changing pain in 1–2% after vasectomy. This reflects the findings of Leslie et al. [24] who performed a prospective audit of the incidence of chronic scrotal pain after vasectomy in 625 men. At 7 months after vasectomy, 15% of men had some degree of scrotal discomfort; however, only 0.9% (four men) had 'severe pain that noticeably affected their quality of life'.

Table 3 Summary of complication rates of vasectomy compared to major European organisations [1,12].

Complication	Complication rates, %		
	ASPC	BAUS	EAU
Early failure	0.93	0.4	0.2–5.3
Late failure	0.04	0.05	0.03–1.2
Infection	1.22	2–10	0.2–1.5
Haematoma	1.56	2–10	4–22
PVPS	0.14	5	1–14

Focussing on the 2021 audit, six patients with PVPS were reported. Of these six patients, treatments included: counselling, monitoring, simple analgesia, and unknown management. Although reassurance and simple analgesia are the mainstay of treatment, there are reports of treatment options such as excision of sperm granuloma, epididymovasostomy, and vasectomy reversal [5]. Interestingly, rates of chronic pain have been shown to be decreased by the injection of local anaesthetic into the vas deferens at the time of vasectomy [24]. This audit did not factor in patients with preoperative orchialgia, and the potential impact this may have on postoperative orchialgia. The authors would recommend additional counselling when offering a vasectomy to patients with pre-existing orchialgia. This would be an interesting topic for further investigation.

Requirement for hospital admission occurred in 62 patients out of 85 120 (0.07%). Most common reasons for admission included haematomas requiring drainage, ongoing bleeding, and concerns over infection. In all, 44% of these patients had infections requiring either oral or intravenous antibiotics. A summary of all the complication rates and comparisons with the major European organisations is given in Table 3 [1,12].

Further Limitations

A limitation of these data is the return rate of questionnaires. Over the last decade, 80% of clinics who submitted audit data utilised the ASPC immediate postoperative and 59% the 4-month postoperative questionnaires as their primary source of feedback on complications and patient feedback.

Other clinics collected their complication rates (and patient feedback) through a variety of other methods, including direct patient follow-up, utilising alternative questionnaires, or providing contact details for any postoperative concern.

For this reason, the return rate for the ASPC 4-month postoperative questionnaire, when compared to the total number of vasectomies undertaken appears initially low. Whilst patient postoperative feedback is notoriously hard to collect the return rate of the questionnaire rises to 32% for

those clinics who collect their audit data (wholly or partially) using the ASPC 4-month postoperative questionnaire. The accuracy of these results can also be shown from the average complication rate every year, which have been consistent over the 15 years of data collection (Table 2).

Conclusions

Vasectomy is a safe and reliable contraceptive method. This large, prospective audit provides accurate, contemporaneous complication rates that can form the basis for pre-vasectomy counselling, during which time risks must be discussed appropriately. The rates of complications reported were generally lower than those published by major urological organisations, and it is to be hoped that these can be used to inform new guidelines.

The ASPC has been working closely with the FSRH in regard to the new FSRH Vasectomy Standards, due to be published 2024, and hope to be heavily involved when the next FSRH vasectomy guidelines are reviewed (last review 2014). The FSRH currently recommend that the ASPC immediate and 4-month postoperative questionnaires should be the audit tool of choice for all vasectomy surgeons.

Disclosure of Interests

None declared.

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Abbreviations: ASPC, Association of Surgeons in Primary Care; EAU, European Association of Urology; FSRH, Faculty of Sexual and Reproductive Healthcare; HES, Hospital Episode Statistics; PVSA, post-vasectomy semen analysis; PVPS, post-vasectomy pain syndrome.

Supporting Information

Additional Supporting Information may be found in the online version of this article:

Appendix S1. The ASPC 4-month postoperative questionnaire 2021–2022.

Appendix S2. The ASPC Conference 2023 Vasectomy Audit return for vasectomies performed between 1 April 2021 and 31 March 22.

Appendix S3. Vasectomy definition glossary 2023.

Appendix S4. Current clinical pathway suggested by the ASPC for PVSA submission and interpretation.