

# Surveillance of surgical site infection post vasectomy

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## Abstract

**T**he aim of this study was to determine the incidence of surgical site infection (SSI) after vasectomy and to identify associated patient and perioperative risk factors, including the operating room environment (non-ventilated treatment room or ventilated operating theatre). This study used an active 30-day surveillance follow-up programme with telephone interviews and home visits. Patients were recruited over an 18 month period. Demographics, patient details and perioperative procedures were documented on the day of surgery. Patients were telephoned 10 and 30 days post procedure. Of 1,155 patients enrolled, 994 (86%) completed the full 30-day follow-up. Of these, 25 (2.5%) developed an SSI. The mean number of days until presentation with an SSI was 13. No statistically significant difference was found in rates of SSI when vasectomies were undertaken in either ventilated operating theatres or non-ventilated treatment rooms.

## Background

Surgical site infection (SSI) has been recognised in the United Kingdom (UK) as an important preventable cause of postoperative morbidity (NICE, 2008). In England, surgical site infection surveillance is co-ordinated by the Health Protection Agency (HPA). Orthopaedic surgeries are the only category in which monitoring is mandated, but SSI surveillance on a range of other types of procedures is reported voluntarily by both National Health Service (NHS) and independent healthcare providers. However, vasectomy data is not included within this English national surveillance programme (HPA, 2006).

There are very few studies that have identified SSI rates post vasectomy and the rates vary considerably. Many of these studies do not describe their surveillance methods or use a recognised definition of SSI, or use infection as the main study outcome. As a result a recent Cochrane review (Cook et al, 2009) on the subject of vasectomy identified only two quality studies (Sokal et al, 1999; Christensen et al, 2002). These studies found SSI rates of 9.3% and 0.8%, respectively.

Specific risk factors for SSI in vasectomy patients have not been identified, but there are two procedural features which merit further investigation: technique and environment.

There are two techniques used for performing vasectomy; these are called 'scalpel' and 'non-scalpel' techniques. The two papers included in the Cochrane review (Cook et al, 2009) compared these techniques and both found non-scalpel techniques to have a lower rate of SSI.

Vasectomies are routinely undertaken in either ventilated operating theatres or non-ventilated areas such as treatment rooms. However there is no evidence as to whether the ventilated environment affects the risk of SSI in minor surgery (Humphreys et al, 2012).

The aim of this study was to implement active SSI surveillance post vasectomy, using standard definitions of infection and rigorous data collection methods. The research questions were:

1. What is the rate of SSI post vasectomy?
2. What are the significant risk factors for SSI post vasectomy?
3. Does the ventilated environment affect the risk of SSI post vasectomy?

This was one of the first studies of this kind in the UK on vasectomy patients and the aims were to provide essential information on SSI rates and risk factors to inform practice improvements within bpas, and to inform safety in vasectomy surgery more widely.

## Method

### Study setting and design

The study was carried out at bpas. bpas is an independent healthcare provider which performs over 700 scalpel or non-scalpel vasectomies per year in several operating theatre and treatment room settings across England, mostly performed under contract to the NHS. The design of the study was adapted from the HPA's mandatory SSI surveillance programme (HPA, 2006), and from the studies of Reilly et al (2005), Tanner et al (2009) and Taylor et al (2003) showing that telephone interviews and direct observation for 30 days provides the most accurate data for identifying SSIs. Our intention was to run the study until 1,000 patients had completed the surveillance.

### Inclusion criteria

As no funding was available for this study interpreters could not be used, therefore only patients that could communicate in English, and



were undergoing a vasectomy, were eligible to be included in the surveillance programme.

#### Data collection

On the day of surgery the patient's demographic details, basic medical history, risk factors and operative details were completed on a paper record by staff working at the treating unit. Precise definitions for data items were defined on the data collection form to ensure accuracy and consistency of data. The completed form was then posted to trained, but non-clinical, telephone operators who undertook follow-up calls.

1. Do you think you have a wound infection?
2. Is the area around the wound red and inflamed?
3. Is the wound very painful?
4. Is the wound hot to touch?
5. Do you have any fluid leaking from your wound?
6. Is the wound gaping open/coming apart?
7. Are the edges to the wound black?
8. Do you think have a temperature?
9. Has anyone else given you antibiotics (not us)?

Figure 1. Closed questions used by trained callers to assess the surgical wound

Each participant was followed up for 30 days postoperatively, during which they were telephoned at 10 and 30 days. During the telephone conversation the patient was asked closed questions about the characteristics of his surgical wound (see Figure 1). If the patient answered 'yes' to any of the questions, this alerted the operator to a potential infection and the operator passed the patient's details to the organisation's infection control specialist nurse. They then confirmed or rejected the presence of infection through further discussion or direct observation of the patient's operative site. The Centers for Disease Control and Prevention (CDC) definition of an SSI was used to confirm an infection (Horan et al, 2008).

#### Data analysis

Data were entered in to SPSS (Statistical Package for Social Sciences V17.0) for analysis. The rate of SSI was calculated using simple descriptive statistical analysis. Univariable analysis was used to identify factors showing a significant relationship with SSI. Due to the low numbers of infections observed it was not appropriate to undertake multivariable analysis.

Statistically significant relationships between the SSI and associated risk factors were determined using Chi-squared tests. A  $p < 0.05$  was considered to be statistically significant (Katz, 1999; Connolly, 2007).

#### Ethical considerations

This proposal was presented to the National Research Ethics Service (NRES) to determine if ethical approval was required. NRES classified the study as service evaluation and therefore did not require ethical approval. The proposal was also presented to bpa's Research and Ethics Committee and granted approval.

#### Results

A total of 1,155 patients who met the inclusion criteria were recruited into the study over the 18 month period. One hundred and sixty one patients were lost during follow-up either because they were unob-

tainable for the follow-up calls or they decided to opt out of the study after having been contacted. Therefore the findings presented are for a total of 994 patients who completed the full 30-day follow-up.

#### Surgical site infections

Twenty five patients (2.52%) developed an SSI (95% CI: 1.7-3.6). The time interval from surgery to the presentation of an SSI ranged from 4 to 30 days, with a mean time of 13 days. Two patients were admitted to hospital owing to an SSI, as they required either intravenous antibiotics and/or surgery to drain an infected abscess or haematoma.

#### Risk factors for surgical site infection

Table 1 shows the patient characteristics that were collected and analysed in relation to the development of an SSI. Following univariable analysis, none were found to be a statistically significant predictor of overall SSI.

Table 2 shows the perioperative characteristics that were analysed in relation to the development of an SSI. Following univariable analysis, the only factor identified as being statistically significant was the operating surgeon ( $p < 0.002$ ).

The analysis undertaken in Table 3 relates only to surgeon A. Surgeon A undertook 82% of the vasectomies during the study period, and operated in both treatment rooms and ventilated operating theatres. This allowed for a direct comparison between the settings. The operating room type was not a significant risk factor for SSI ( $p > 0.05$ ).

## Discussion

#### Rate and detection of SSI

We documented an SSI rate of 2.52% in this surveillance project, which is lower than the 9.4% documented by Christensen et al (2002) using a similar 30-day follow-up period, but higher than the 0.82% rate found by Sokal et al (1999). It is notable that Sokal only followed up patients for 15 days post procedure. As a result, their surveillance programme would have missed infections that occurred later, possibly contributing to their very low documented rate. Interestingly, data collected from our study identified that the time interval from surgery to the presentation of an SSI ranged from 4 to 30 days, with a mean time of 13 days. If the rate of SSI for this study were to be calculated using data collected up to only 15 days postoperatively, seven infections would have been missed. This would have given a lower overall SSI rate of 1.8%. This highlights the significance of post discharge surveillance up to 30 days, in order to accurately capture SSI prevalence after discharge.

It is also interesting to note that the rate we found was higher than the author's organisational SSI rate for the previous two years (0.64%), which had been collated from general practitioner (GP) and patient reports. This suggests that GPs and patients do not always report complications to the organisation, therefore not allowing for an accurate analysis of postoperative complications.

#### Risk factors for surgical site infection

Although specific risk factors for SSI after vasectomy have not been identified previously, they have been identified for other types of surgery. According to Gould (2012) and Kiernan (2012) these risk factors can be either patient characteristics or perioperative influences. Sangrasi et al (2008) and Neumayer et al (2007) identified patient-related SSI risk factors as age, diabetes, poor nutritional status, immunosuppression, high body mass index (BMI), current infection, and smoking. Perioperative influences include timing and method of hair removal, type of skin preparation, length of operation, and surgical expertise (Rojanapirom, 1992; Gould, 2012). It is generally thought that both categories of risk factors are applicable to all surgery (Casanova et al, 2006; Sangrasi et al, 2008; Tanner and Khan, 2008; Gould, 2012; Kiernan, 2012).



**Table 1. Univariable analysis of patient characteristics with and without surgical site infection (SSI)**

Patient characteristic	SSI	No SSI	Total	p-value
Number of SSIs	25 (2.52%)	969 (97.48%)	994	0.98
Age range	26–49	22–63	22–63	
Body mass index				
≤25	7 (2.9%)	244 (97.1%)	251	0.65
>25	18 (2.6%)	683 (97.4%)	701	
Diabetes				0.81
Yes	0 (0%)	15 (100%)	15	
No	25 (3%)	953 (97%)	978	
Smoker				0.71
Yes	5 (2%)	219 (98%)	224	
No	20 (3%)	729 (97%)	749	
Immunosuppressed				0.56
Yes	0 (0%)	21 (100%)	21	
No	25 (3%)	926 (97%)	951	

**Table 2. Univariable analysis of perioperative characteristics with and without surgical site infection (SSI)**

Perioperative characteristic	SSI	No SSI	Total	p-value
Number of SSIs	25 (2.52%)	969 (97.48%)	994	0.42
Preoperative hair removal				
Yes	19 (2%)	796 (98%)	815	
No	6 (3%)	171 (97%)	177	0.13
Operation type				
Scalpel	18 (2%)	807 (98%)	825	
Non-scalpel	7 (4%)	161 (96%)	168	0.27
Skin prep used				
Yes	19 (3%)	705 (97%)	724	
No	4 (2%)	250 (98%)	254	0.002
Surgeon				
A	15 (2%)	797 (98%)	812	
B	3 (20%)	12 (80%)	15	
C	7 (4%)	160 (96%)	167	0.57
Operation room type				
Ventilated operating room	12 (2%)	518 (98%)	530	
Treatment room no ventilation	13 (3%)	447 (97%)	460	

Recent national guidelines issued in the UK highlighted these SSI risk factors in order to ensure that organisations were aware of them (NICE, 2008). However, despite studies demonstrating that invasive surgical procedures are being undertaken in non-ventilated areas or

treatment rooms in the UK (Smyth et al, 2005; Humphreys et al, 2012), these guidelines did not address the physical conditions under which surgery should take place. We did not find that there was a difference between the rate of SSIs encountered after vasectomy



**Table 3. Univariable analysis of the operation room type with surgical site infection identified for surgeon A**

Surgeon A only		Operation room type		p-value
		Ventilated operating theatre	Treatment room no ventilation	
Wound infection identified	Yes	9 (1.8%)	6 (2.1%)	0.24
	No	504	288	
	Total count	513	294	

whether undertaken in a non-ventilated treatment room or a ventilated operating theatre ( $p>0.05$ ).

**Body mass index.** Unlike other surveillance studies, this study did not identify BMI as a predictor of postoperative SSI (Spelman et al, 2000; Arabshahi and Koohpayezade, 2006; Young et al, 2012). Previous studies were based on abdominal and gynaecological surgery where the wound is located in parts of the body with more adipose tissue, which may have made a difference.

In this study, patients who had a BMI  $\leq 25$  had an overall infection rate of 2.9% and those with a BMI  $>25$  had an overall infection rate of 2.6%, which was found not to be statistically significant ( $p>0.05$ ).

**Underlying illness.** It is interesting to note that this study did not identify diabetes or immunosuppression as a predictor of SSI, which has been identified in previous surveillance studies (Neumayer et al, 2007). The analysis, however, is limited due to the very small numbers in this subgroup. None of the 15 diabetics included in the study developed an SSI. Similarly none of the 21 patients who were identified as being immunosuppressed developed an SSI.

**Smoking.** There appears to be inconsistencies within the literature regarding the risk of smoking to the development of SSI (Spelman, 2000; Haas et al, 2005; Tanner et al, 2009). Despite including a high percentage of smokers within this study (23%), smoking was found not to be a statistically significant predictor of SSI ( $p>0.05$ ). A larger research study would help to clarify the risk.

#### Perioperative characteristics

Identifying perioperative characteristics for SSI development post vasectomy enables organisations to understand where resources should be targeted, and whether current practices should continue, stop or change. It enables organisations to make these decisions based on patient outcomes and experiences.

**Operation technique.** No statistical difference was identified in the rates of infections for scalpel and non-scalpel vasectomies ( $p>0.05$ ). However there does appear to be a trend with a higher rate of infections identified in the non-scalpel group, but this may be as a result of much lower numbers in the non-scalpel group (168 compared with 825). The actual rates of infections are slightly different, with the scalpel group being 2.2% (18/825), compared with a higher 4.2% (7/168) in the non-scalpel group. The result differs from other studies where non-scalpel vasectomies have shown a lower rate of infection, however not all of these studies found this to be statistically significant (Sokal et al, 1999; Christensen et al, 2002). It would be helpful to undertake a larger study that had equal numbers of scalpel and non-scalpel vasectomy procedures.

**Surgeon.** Three surgeons performed vasectomies at the organisation over the data collection period. As shown in Table 2 surgeon B had a considerably higher SSI rate (20%) than surgeon A and surgeon C (2% and 4% respectively). This result was statistically significant ( $p<0.05$ ), although it is important to note that surgeon B only performed a small number vasectomies during the data collection period.

It has been identified previously that the incidence of SSI varies between hospitals and surgeons, suggesting that surgical techniques and practices play an important role in the development of postoperative infection (Gould, 2012). It has also been suggested that increased surgical experience reduces rates of SSI (Ward et al, 2008). In this study surgeon B had the highest infection rate and performed the lowest number of procedures. This might appear to show that experience is related to infection rates, but as the surgeon works in other organisations simultaneously, it is not possible to draw conclusions on this relationship.

**Skin preparation.** No statistically significant difference was demonstrated when skin preparation was used or not ( $p>0.05$ ), with similar rates of infections identified for each group (see Table 2). This is a surprising result as the practice of using an antiseptic solution to prepare the surgical wound site prior to surgery to reduce SSIs is recommended in many national and international guidelines (Mangram et al, 1999; NICE, 2008).

**Hair removal.** No statistically significant difference has been demonstrated when hair was removed preoperatively or not ( $p>0.05$ ; see Table 2). National guidelines on hair removal include information about timings and methods used. It was not possible to undertake an analysis of the timings and methods of hair removal for this study due to the limited number of patients in the numerous variations of methods and timings for hair removal.

#### Ventilated operating theatres versus treatment rooms

Operating theatre ventilation standards were first formally introduced into UK hospitals in 1972 as a result of the joint working party report on Ventilation in Operation Suites from the Medical Research Council and the Department of Health and Social Security (Stacey and Humphries, 2002). The aim of introducing ventilation into operating theatres was to reduce infections caused by airborne bacteria, which can land either directly onto the operative site or onto surgical instruments (Whyte et al, 1982).

Many studies demonstrate that the introduction of ventilation in operating theatres has reduced rates of SSI (Lidwell, 1980; Meers, 1983). However most of these studies have only observed major surgery, where it is commonplace for these operations to be undertaken in ventilated premises only. It appears that there are no studies looking at whether ventilation makes a difference to minor surgical procedures, or



studies that compare SSI rates from minor surgical procedures undertaken in non-ventilated treatment rooms, compared with the same procedures undertaken in ventilated operating theatres.

In 1988 the World Health Organization (WHO) stated that vasectomies could be performed in almost any facility as long as a few minimum requirements were met. This included having a clean room for surgery equipped with a clean table for the patient and a good light source. It is not clear what research they referred to when making this recommendation, however at the time most countries were already undertaking vasectomies as an outpatient procedure performed in an office or clinic. Expert opinion deemed this to be safe (Richards, 1973; Davies and Stockton, 1997).

In 2004 the Royal College of Obstetricians and Gynaecologists (RCOG), recommended that although there are no explicit standards for the facilities required for vasectomy, existing guidance for minor surgery should be adopted where vasectomies are performed in an outpatient setting (Finn and Crook, 1998; BMA, 2001; NHS Estates, 2002).

There are also some recent guidelines produced by the Healthcare Infection Society, providing recommendations on the type of surgery that could be undertaken safely in non-ventilated areas, and they have included vasectomy (Humphreys et al, 2012). However, the authors note that due to the lack of research their recommendations are not fully evidence based.

This study did not find a statistically significant difference in the rate of SSI after vasectomy was performed in either ventilated operating theatres or non-ventilated treatment rooms ( $p>0.05$ ). These results are based on large patient numbers in each sample (530 and 460).

One surgeon in the study (surgeon A) undertook 812 vasectomies during the surveillance period – 513 were in ventilated operating theatres, 294 in treatment rooms, and the remaining 5 were not documented. As this was the same surgeon it can be assumed that the perioperative practices were the same for each group, therefore enabling a direct comparison. The results specific to surgeon A (Table 3), demonstrate no statistical difference in rates of SSI when vasectomies are undertaken in the different settings ( $p>0.05$ ).

This is an important finding as the result gives some assurance to organisations that undertake vasectomies in non-ventilated treatment rooms. This study shows no increased risk of postoperative infection when vasectomies are undertaken in that environment when compared with a ventilated operating theatre.

### Limitations

There were some limitations to this study. The study was not a randomised controlled trial, however we did not find any significant

differences in pre-identified risk factors between the groups of men who experienced an SSI as compared with those who did not.

Most of the procedures were undertaken by one surgeon who only performed scalpel vasectomies, and one of the surgeons only performed 15 vasectomies. A larger sample size may have led to the identification of some more statistically significant results.

### Summary and conclusions

Through this study, we found the rate of SSI post vasectomy at bpas to be 2.52%, which is at the lower end of reported ranges. This gives some reassurance to the organisation that their current SSI rate is within an acceptable range. However, this result is higher than previously reported rates, suggesting that if organisations wish to understand their true rate of SSIs, they should undertake active surveillance rather than relying on infections to be reported by GPs and patients.

One of the main findings is that there was no difference in the rates of SSI post vasectomy when the operation was undertaken in a ventilated operating theatre or a treatment room with no ventilation. This result was based on a large number of patients within each group. This result can be used to give not only an assurance to the organisation, but also to the wider health community where minor surgical procedures are being carried out. As previously mentioned, however, this finding is only for vasectomy procedures, although perhaps some organisations may use this result to assess the risk for other types of minor surgery.

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### Conflict of interests

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