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The clinical impact of British guidelines on post-vasectomy semen analysis

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Introduction Following vasectomy, azoospermia may not be achieved and rare non-motile sperm (RNMS) may persist in the semen. International guidelines vary in management of this finding. Giving 'special clearance' enables vasectomy to be considered a success despite the presence of RNMS. The latest 2016 British guidelines require two centrifuged semen samples with RNMS in order to give special clearance. We investigate the impact of these latest recommendations.

Material and methods Retrospectively, patients who underwent vasectomy between 2014 and 2018 were assessed. The patient sample was divided into two groups, pre- and post-implementation of the new guidelines. The primary outcome measures were (i) total number of post-operative semen samples submitted, (ii) post-vasectomy semen analysis (PVSA) outcomes, and (iii) the numbers issued special clearance.

Results Implementation of the updated guidelines increased detection of RNMS from 18% to 27% ($p < 0.01$) and increased use of repeat testing. In the two year period prior to implementation, no patients required special clearance, however, once implemented, it was offered to 10 patients. Furthermore, there was a 5-fold increase in PVSA processing costs. The first post-vasectomy semen sample demonstrated azoospermia or RNMS in 97.5% of patients.

Conclusions British guidelines are more resource intensive, result in prolonged follow-up with increasing rates of special clearance. The European Association of Urology permits clearance, not special clearance, after a single non-centrifuged sample demonstrating azoospermia or RNMS. Bringing British recommendations in-line with European guidance would enable clearance in up to 97.5% of patients following a single sample at 12 weeks.

Key Words: vasectomy ‹› semen analysis ‹› centrifugation ‹› azoospermia

INTRODUCTION

Vasectomy was performed 9 582 times in 2017/18 by the United Kingdom's National Health Service and is the sole form of contraception for 42 million couples worldwide [1, 2]. Vasectomy involves removal of a portion of the vas deferens and procedural success is traditionally confirmed when azoospermia is demonstrated on post-vasectomy semen analysis (PVSA). Clearance of the distal vassal segment of spermatozoa occurs by ejaculation and PVSA is performed when clearance of remaining spermatozoa is likely to have been achieved. Confirmation of azoospermia permits 'clearance', allowing patients to rely on the vasectomy for contraception.

The persistence of non-motile sperm in the semen poses a challenge to the surgeon hoping to give clearance. Rare non-motile sperm (RNMS), defined as <100 000/ml of semen, traditionally precludes giving clearance, rather, 'special clearance' may be used permitting a patient to rely on vasectomy for contraception despite the presence of sperm.

More stringent methods of assessing clearance do not necessarily reduce the risk of future paternity. Indeed, the late failure rate for patients previously confirmed as having undergone a successful vasectomy is small, only 1 in 2000 [3]. There is also

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no indication that the presence of RNMS and use of special clearance increases this risk of paternity [3]. This fact is reflected in the guidelines of both the European Association of Urology (EAU) and American Urology Association (AUA) that no longer use special clearance and instead give clearance if a single semen sample demonstrates azoospermia or RNMS at 12 weeks [4, 5].

The British guidelines on PVSA have promoted centrifugation for samples demonstrating azoospermia on traditional analysis since 2002 [6]. Revisions for the 2016 guidelines recommended more stringent measures in determining vasectomy success. Clearance requires a single semen sample at 12 weeks demonstrating azoospermia, however, this sample must be centrifuged [7]. Special clearance requires two consecutive centrifuged samples demonstrating RNMS [7]. In this study, we examined the clinical implications of these newer, more stringent guidelines.

MATERIAL AND METHODS

The 2016 British guidelines were implemented in our unit in June 2016. A retrospective analysis was conducted of patients who had undergone vasectomy between January 2014 and February 2018.

The patient cohort was divided into two groups around the implementation date. Group 1 included patients from January 2014 until January 2016. Group 2 included patients who had vasectomy between July 2016 and February 2018. To avoid inconsistencies in the PVSA methods employed, patients were excluded if their vasectomy was performed between February and June 2018.

Standard PVSA utilises a 10 μl aliquot of semen placed onto a non-toxic microscope slide with a coverslip placed on top. The semen is then analysed using a systematic grid at 400x magnification. Patients within Group 1 had standard semen analysis performed; centrifugation of semen samples was never required. Whereas patients in the second group had samples examined in accordance with the more stringent 2016 guidelines.

The 2016 British guidelines advise implementing International Organisation of Standardisation (ISO 15189:2012) recommendations for further analysis of azoospermic samples to increase sperm detection. If a sample demonstrates azoospermia on standard analysis, the semen sample requires centrifugation for 15 minutes in a conical tube at 3000 g. The resulting pellet is then re-assessed after suspension in 40 μl of the supernatant [7].

Samples were required to be submitted and analysed within four hours of production. A result of azoospermia was recorded if no sperm were seen. Non-motile sperm were categorised as <100 000/ml (i.e. RNMS) or >100 000/ml. If motile sperm were noted, the referring Urologist was informed in order to arrange an urgent follow-up with the patient. A repeat vasectomy would then be offered.

In Group 1, post-operative semen samples were requested at 12 and 16 weeks for analysis. Patients were discharged with clearance if they had one azoospermic sample, or with special clearance if 2 consecutive semen samples demonstrated RNMS. In Group 2, follow-up was required at 12 weeks and patients were discharged with one sample demonstrating azoospermia following further analysis with centrifugation. If RNMS were demonstrated, then a further semen samples was required to enable patients to be discharged with special clearance.

The primary endpoints in our study were the (i) total number of post-operative semen samples submitted, (ii) PVSA outcomes, and (iii) the numbers issued special clearance.

RESULTS

A total of 215 patients were included in our study with a mean age of 41.

Two patients persistently had motile sperm in their semen and were offered repeat vasectomy. No patients subsequently demonstrated motile sperm when previously samples had demonstrated azoospermia. However, 3.5% of patients demonstrated RNMS following a previous azoospermic sample.

Table 1 demonstrates the primary outcomes for each group. The detection rate of RNMS in group 2 was 27% compared to 18% in Group 1 ($p < 0.01$). Five patients in group 2 received special clearance whereas no patients in group 1 required it ($p < 0.05$). Furthermore, an additional 5 patients in group 2 were offered special clearance if RNMS were present in their next sample, however, they did not attend for further follow-up. This most recent cohort lost 30% of patients to follow-up.

Under current guidelines, 70.8% of patients would receive clearance after one sample. However, 97.5% of the first semen samples were reported as azoospermia or as RNMS. Only 2.5% of first samples had motile sperm. Table 2 illustrates that increased testing was commonplace in Group 2 with more patients giving more semen samples.

The mean minimum length of vas removed per patient was 10.9 mm (range 3–30 mm). No association was found between the length of vas deferens removed and the persistent presence of RNMS. Compliance with these guidelines resulted in increased costs for PVSA from £8.35 to £45.

Table 1. *Primary outcomes divided by group*

	Sample size	Total samples submitted	RNMS in samples	Special Clearance
Group 1	93	55	10 (18%)	0
Group 2	122	173	47 (27%)	5

RNMS – rare non-motile sperm

Table 2. *Number of semen samples submitted, separated by group*

No. of samples	Group 1	Group 2
1	7	22
2	13	49
3	2	7
4	1	4
5	0	1
Total	43	162

DISCUSSION

Confirming procedural success is essential to permit reliance on vasectomy for contraception. However, centrifuging semen samples is associated with an increased finding of RNMS which leads clinicians to repeat semen analysis in order to give clearance or special clearance. This delays confirmation of procedural success.

The 2016 British guidelines on PVSA recommend that special clearance be given following analysis of two centrifuged semen samples showing RNMS [7]. However, many surgeons remain reticent to settle for special clearance and prefer to demonstrate azoospermia through repeat analysis, thereby delaying discharge [8]. This was highlighted in a survey of British Urologists finding that 77% would offer repeat vasectomy to patients with persistent RNMS [8]. Persistence of RNMS may continue for more than a year following vasectomy [9]. These sperm are likely to come from the ampulla of the vas or the seminal vesicles, due to previous reflux of sperm [9]. These sperm may account for up to 68% of ejaculated sperm [9]. It follows therefore that in men with increased reflux of sperm into the seminal vesicles, it will take longer to demonstrate azoospermia.

This study noted increased detection of RNMS from 18% to 27% following implementation of the 2016 guidelines. In the 2 years prior to implementing these guidelines, special clearance had not been given in our department. In the subsequent 2 years following implementation, five patients were given special clearance and a further five patients with persistent RNMS were offered special clearance. However, they did not submit a further sample and were lost to follow-up. Centrifugation of azoospermic samples was significantly associated with increased use of special clearance ($p < 0.05$). This loss to follow-up was likely because patients were going to be discharged at the next appointment with either clearance or special clearance.

A limitation of our retrospective methodology is that we cannot determine how many of the samples showing RNMS were initially reported as azoospermia on standard analysis. One prospective study has already demonstrated increased detection of RNMS in centrifuged samples, however, these patients had congenital azoospermia and had not undergone vasectomy [10].

Steward et al. prospectively centrifuged 2104 post-vasectomy semen samples reported as azoospermia following standard assessment [11]. Further analysis detected RNMS in 425 (20%) of samples and non-motile sperm >100 000/ml in only four patients. All 4 patients were subsequently able to demonstrate successful vasectomy with a PVSA showing azoospermia or RNMS.

The risk of paternity with non-motile sperm <100 000/ml has been studied and the recommendations are that men given special clearance have no increased risk of paternity compared to men demonstrating azoospermia [3, 12, 13]. Philp et al. gave 310 men special clearance for persistent RNMS and reported no subsequent pregnancies [3]. Edwards et al. in a similar study (n=200) reported no pregnancies at 15 month follow-up [12]. Another study (n = 151) reported no pregnancies after long-term follow-up (3–8 years) [13]. Although some loss to follow-up was reported in all studies, it is reasonable to assume that no pregnancies occurred as men would be quick to contact their Urologist.

If the presence of RNMS confers no increased risk of paternity compared to having confirmed azoospermia, then the findings of Steward et al. suggest that standard assessment alone is sufficient to demonstrate procedural success in 99.8% of men [11].

Complications resulting in paternity occur due to recanalization of the vas and this affects 1 in 2000 men with confirmed azoospermia, although it is not possible to predict which men will be affected [3]. Smith et al. documented six cases of DNA-proven paternity following vasectomy [14]. In all cases, procedural success had been confirmed on two successive PVSA demonstrating azoospermia. Notably, following these pregnancies, azoospermia was again demonstrated on PVSA. Therefore, azoospermia in the months following vasectomy can only be used to indicate immediate procedural success but cannot

be used to predict transient reappearance of RNMS. Transient reappearance of RNMS at 1 year (n = 1000) may occur in 0.6% of cases [15]. Five of these six men supplied further samples 1 month later and demonstrated azoospermia. This may occur at any time and one study (n = 186, mean 10.7 years) reported a finding of transient sperm reappearance in 9.7% of men [16]. The interval between vasectomy and testing did not correlate with the presence of sperm.

It would seem therefore that differentiating between men who achieve azoospermia or RNMS in the first samples post-vasectomy is unnecessary. Nonetheless, the 2016 British guidelines adopt a conservative approach in recommending clearance after 1 sample with azoospermia or special clearance after 2 samples with RNMS [7].

Differentiating between clearance and special clearance likely promotes increased testing post-vasectomy with patients submitting up to 5 samples in order to achieve clearance. This may be driven by patient wishes or Urologists keen to avoid using special clearance for fear of judicial or financial implications. Confirming azoospermia may suggest surgery was initially successful and therefore no fault lies with the surgeon in cases of future paternity. This may be the preferred option of Urologists seeking reassurance [8]. However, medico-legal studies have advised the best legal defence is thorough counselling of men and their partners with contemporaneous documentation that the risk of paternity remains 1 in 2000 irrespective of whether azoospermia has been achieved or RNMS are present [17, 18, 19]. In-lieu of changing guidelines, clear communication of this nuanced point pre- and post-operatively will offer support and reassurance to patients in the event RNMS persist in the semen.

However, guidelines provide much reassurance to professionals and laypeople alike and can reduce anxiety, worry and the inconvenience of repeat testing for all involved. Guidelines from the European Association of Urology (EAU) and the American Urology Association (AUA) recommend clearance be given following analysis of a single uncentrifuged semen sample demonstrating azoospermia or RNMS [4, 5]. Applying these standards to our patient set, would increase clearance from 70.8% to 97.5% after the first semen sample. This echoes a study assessing the impact of the latest American guidelines, which found clearance could be achieved in 97.6% of patients after one sample [20].

Improving patient compliance with follow-up is challenging and our 30% loss-to follow-up is consistent with the literature [21, 22, 23]. Efforts to improve compliance for repeated testing have shown limited success although designated appointments have shown limited benefit in some studies [24]. Inconvenience and embarrassment in providing samples are most commonly the reasons for poor compliance [25]. One survey reports 86% of men would be upset if the vasectomy failed, therefore addressing these obstacles to follow-up is imperative in order to provide patient-focussed care [25]. Making British guidelines consistent with the EAU and AUA guidelines would have avoided 114 semen samples in our cohort and avoided inconvenience for patients. In addition, by broadening the definition of 'clearance', the presence of RNMS would still confer a successful outcome. Therefore, patient confidence in the Urologist and the surgical procedure can be maintained without compromising the risk of paternity.

Fewer repeat samples would reduce the workload and pressures within the health system. The further analysis required by these guidelines resulted in a five-fold increase in PVSA processing costs in our unit. Therefore, repeat testing cost an extra £5130, with increased processing costs for Group 2 alone, being £6357. Several financial studies echo this finding that thousands of pounds in repeat testing can be potentially saved by discharging patients with clearance after a single sample showing azoospermia or RNMS and also increase clearance rates to 98.2% [20, 23, 26].

CONCLUSIONS

Compliance with the latest British guidelines is associated with greater detection of RNMS, repeat investigations, increased costs, and increased use of special clearance. Giving clearance to patients with RNMS or azoospermia, as recommended by other international guidelines, could improve clearance rates to 97.5% after a single sample.

CONFLICTS OF INTEREST

The authors declare no conflicts of interest.

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