The incidence of chronic post-vasectomy scrotal pain – a prospective cohort study with a mean of five years follow-up

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ABSTRACT

BACKGROUND:
Chronic post-vasectomy scrotal pain (CPVSP) remains a poorly quantified and significant clinical problem; quoted figures for severe CPVSP vary from 0.9% to 6%. The first prospective assessment of CPVSP to assess the extent of scrotal pain in men before and after vasectomy was published by the authors reporting a 0.9% rate of new onset scrotal pain that was quite severe and noticeably affects their quality of life at a mean follow up of 7 months. This paper goes on to report the outcomes of this prospective audit at a mean follow up of 5.1 years.

METHODS:
Between November 2004 and January 2006 nine surgeons performed vasectomies on 625 men under local anaesthesia. A questionnaire was devised to establish the presence of any scrotal pain, and to characterise any discomfort prior to their vasectomy. At six months and five years following the procedure a modified version of the same questionnaire was sent to all patients who responded to the pre-op questionnaire.

FINDINGS:
593 (94.7%) men returned the pre-operative questionnaires and were entered into the study. Of these men, 58 described scrotal pain prior to the procedure (9.8%). The mean age of men undergoing vasectomy was 39.9 years (SD 5.6). 336 men (57%) completed the follow-up questionnaire at a mean follow up time of 5.1 years (SD 0.9). 30 men (10%) then reported new-onset post vasectomy scrotal pain with a mean pain score on the visual analogue scale of 3.6. One man described the pain after vasectomy as ‘quite severe and noticeably affecting his quality of life’.

INTERPRETATION:
In this prospective audit of vasectomy in a high volume centre, 5 years following vasectomy, 2 in 300 or 0.6% of previously asymptomatic men currently have scrotal discomfort that is severe enough to cause the patient to seek medical attention and/or to interfere with quality of life. Overall, 10% of previously asymptomatic men have some degree of scrotal discomfort. The authors discuss reasons why the true rates are likely to be lower and unlikely to be higher than these estimates.

INTRODUCTION

Vasectomy is a popular and reliable method of contraception, used by about 31 million couples worldwide(1). In a physician survey, an estimated 526,501 vasectomies were performed in the US in 2002 (2), the prevalence of vasectomy in the UK is 16%, and can reach up to 23% in countries such as New Zealand (3). Indeed, since opening in 1970, over 40,000 vasectomy operations have been performed by our group alone at the Elliot Smith Clinic, Oxford, UK. Despite this high prevalence, it was only in 2012, that the American Urological Association (AUA) and the European Association of Urology (EAU) published guideline documents for the first time (4, 5).

The risks of intraoperative and early postoperative pain, bleeding and infection are related mainly to the method of vas isolation. Methods of vas isolation include Conventional Vasectomy (CV), No-Scalpel Vasectomy (NSV) and Minimally- Invasive Vasectomy (MIV) – see Table 1 for definitions (4). It has been demonstrated that the NSV technique carries with it a reduced risk of short-term complications when compared to the scalpel vasectomy (6-8). The AUA guidelines recommend the use of MIV(4) and this is supported in the UK by the Royal College of Obstetricians and Gynaecologists (RCOG) who have recommended in their 'Male and Female Sterilisation Evidence-based Clinical Guidelines' (9) that NSV should be used, as this results in a lower rate of early complications.

Persistent pain after vasectomy has been reported by several authors with pain that is severe enough to cause the patient to seek medical attention ranging from 0.9-6% (10-16). To further investigate this, our group initiated a prospective audit of scrotal discomfort following vasectomy. At seven months following surgery, we reported a 14.7% incidence of pain but only 0.9% rate that was severe enough to cause the patient to seek medical attention and/or to interfere with quality of life (16). We have continued this prospective study and now report the results of patient reported outcomes at a mean of five years following vasectomy.

METHODS

The study population comprised all men undergoing vasectomy at The Elliot Smith Clinic, Oxford, UK between November 2004 and January 2006. Nine surgeons performed the operations: four Urologists, three General Practitioners, and two Gynaecologists.

Prior to the procedure, an information pack was sent to the patients regarding the operation and included in this was a dedicated questionnaire to assess pre-operative scrotal discomfort. At the time of the procedure, patients gave written informed consent in the normal manner.

Seven surgeons used a MIV technique, while a CV technique was used by two. The procedure has been described previously (17) but in essence all patients had intra-luminal electrocautery applied to both ends of the divided vas deferens after removal of a 1-2cm segment. Fascial interposition was not routinely performed, nor were clips or ligatures applied. The vas was not sent for histology.

Six months following the procedure a follow-up questionnaire was sent out. These results have been reported (16).

Five years following the vasectomy procedure, a similar follow-up questionnaire was sent out. If there was no response, then an attempt was made to contact the patient by telephone (usually no more than two attempts). Data were recorded on a standard proforma and compared statistically.

RESULTS

Between November 2004 and January 2006, 626 men attended the clinic with 593 men completing the pre-operative questionnaire and thus agreeing to take part in the prospective audit (94.7%). The mean age of men undergoing vasectomy in this study was 39.9 years (SD 5.6). Following vasectomy, 488 (82.2%) of these men completed the follow-up questionnaire at 6 months resulting in a mean follow up time of 6.8 months (range 4.4 – 10.6 months, SD 1.6). (16)

A further questionnaire was completed by 336 men in a mean follow up time of 5.1 years (range 3.8 – 7.4 years, SD 0.9). This represents 54% of original sample and 69% of those who had returned questionnaires at 6 months. Figure 1 shows the breakdown of men who answered the questionnaires, in terms of non-responders and responders and their reports of pre-operative and post-operative pain. Interestingly, as we previously reported (16), 36 men in this second audit had described scrotal pain prior to vasectomy on the initial questionnaire: thus omitting these gives the relevant denominator of 300 men for the five year study analysis and of these 270 describing no pain at 5.1 years.

At 5.1 years follow-up, 30 men described scrotal discomfort following vasectomy, a rate of 10% at that time-point. Figure 2 shows the extent of the problem in those men that reported any chronic post-operative pain. Of these 30, five men described pain or swelling or complications of some kind in the weeks after the procedure. Two men took antibiotics for an infection and three had more pain than they expected.

Figure 3 shows the timing of onset of pain with 53% saying that the pain started more than 6 months following the procedure. Five men had bilateral pain, 11 men felt pain on the right, 11 men felt pain on the left and 3 men complained of prostatic or perineal pain. Half the men described a tender spot that they could pinpoint.

Qualitatively, 22 out of 30 men (73%) described the pain as a dull ache, three described a sharp pain, three men described throbbing, one a burning sensation and one did not respond. 17 men might go for weeks or more without pain, 9 might go for days without pain, 2 men experienced pain every day and two men described continuous pain. Figure 4 shows the durations of pain episodes. Five men described the pain occurring during sex. Overall 16 men (53%) had at some time sought advice from their doctor regarding the pain.

Figure 5 shows the pain score attributed to the discomfort using a visual analogue scale. One man described the pain as 9 out of 10, in terms of severity. He also described ongoing pain that was severe enough to cause him to seek medical attention and to interfere with quality of life, the only man in this follow-up cohort to report this. This man had not described any pain in the six month questionnaire and he commented that the pain started between 6 and 12 months following the vasectomy. Three men gave a score of 6 out of 10 and two further men gave a score of 7 out of 10. Of these five, all but one (described further below) were satisfied or very satisfied with the outcome..

Of note, in the six month questionnaire four men, who had not reported pre-vasectomy pain, had described pain that was severe enough to cause the patient to seek medical attention and/or to interfere with quality of life (16). All were in this follow-up and three of them now reported that they were pain-free. However the fourth described the pain as continuing: 7 out of 10 on visual analogue scale, moderate in severity, and he was dissatisfied with the procedure. None of these reported having required anything more than supportive (primarily analgesic) treatment for their pain.

Table 2 makes a comparison between the two techniques used and shows a significantly lower incidence of post-operative pain in the MIV patients at a mean of 5.1 years [OR 0.39 (95%CI 0.18-).83);p=0.015].

DISCUSSION

We have defined chronic post vasectomy scrotal pain (CPVSP) as pain that lasts for a period of more than three months that interferes with daily activities and prompts a man to seek medical advice, this can be intermittent or constant, unilateral or bilateral. (11, 16).

The current medical evidence on the subject is of poor quality due to the retrospective nature of the questionnaires used, such that: there is often an unknown true total denominator of procedures from which the men with problems have emerged; failure to use validated pain measures; the low percentage of responders; the variable follow up periods and the lack of controls. The opinion of the AUA Panel was that the most important information for patient counselling is the risk of chronic scrotal pain which is severe enough to cause the patient to seek medical attention and/or to interfere with quality of life (4). Our own previously published study appears to be the most robust study of this problem to date and indicates a 0.9% rate of such a pain after the surgery (16) – with 82% follow-up, though up to only seven months.

Three studies of chronic scrotal pain after vasectomy have reported follow-up for three years or more. In a single-group retrospective study, Choe et al. reported that at 4.8 years of follow-up, 2.2% of vasectomized men reported chronic scrotal pain sufficient to exert an adverse impact on quality of life(14). McMahon et al. reported in a prospective single-cohort design with four years of follow-up that 5% of vasectomized men sought medical attention because of testicular pain(18). In the only comparative study, Morris et al. showed that at 3.9 years of follow-up 6.0% of vasectomized men reported pain severe enough to motivate the seeking of medical care compared to 2.0% of non-vasectomised men(15).

This study is the first long-term prospective audit of post vasectomy pain to be published. The high initial uptake and response has meant that a large group of men have been followed from pre-procedure until a mean of 5.1 years of follow-up.

In this group of men, if there is no prior discomfort, and based on the denominator of responders at 5 years, the likelihood of reporting any scrotal pain after vasectomy is 10%. However, even in this group, the mean pain score on the visual analogue scale is 3.6 and, despite some degree of discomfort it is of note that 93% of these men were satisfied or very satisfied with the procedure. The likelihood of having pain at 5 years that is such as to noticeably affect quality of life is 0.3% or 1 in 300, rising to 2 in 100 (0.6%) for pain that gives rise to a man’s dissatisfaction with the procedure.

We suggest that the true rates for chronic scrotal pain are likely to be no higher and very probably lower than those just given, calculated on a denominator of the 336 responders to the second questionnaire. Having been sent at 5 years to all 488 who had responded at the 7

month stage (see Figure 1), it can be argued that the 152 non-responders would if still pain-free see little point in restating the fact; whereas men with continuing or new CPVSP would take the opportunity to report this. A future long-term audit with optimal follow-up might establish this definitively.

Due to the nature of the pre-procedure questionnaires, we have been able to exclude men from the analysis who reported pre-vasectomy pain. The pre-pain cohort represents a group of 58 men (9.8% out of 593 at presentation in our first report) and this level is higher than reported elsewhere. Two groups(13, 14) noted that pre-vasectomy pain was reported by between 2% and 3% of their responders, when that history was obtained some months post-operatively (not pre-operatively as in this study), and these patients were excluded in the final analysis in those papers. In all 45 men with pre-vasectomy pain responded at 6 months (9.2% of responders) and 36 responders at 5 years had a history of pre-vasectomy pain (10.7%). At seven months 22 men (48.9% of this sub-group) still reported pain and at five years, 10 (27.8%) of these men still reported pain. The nature of this incidental scrotal pain remains uncertain. It seems clear that care should be taken in the counselling of men who have had scrotal pain before the vasectomy and they should be warned about the higher possibility of pain postoperatively.

The cause of the post-operative pain is uncertain. There seems little doubt from our findings that technique has a part to play in this, and care must be taken at the time of the procedure to make sure the anaesthetic is working, with gentle handling of the tissues especially in the initial stages, in case the area is not fully anaesthetised. One of the surgeons (DC) who deals with all the post-operative complications at the Elliot-Smith Clinic has seen a number of patients complaining of severe post-operative pain, who share a history that the pain first started when the surgeon initially grasped the vas with forceps when the area was not fully anaesthetised. This background to the initiation of the chronic pain is suggestive of an affinity with neuropathic pain of the "phantom limb" type, as is the good response sometimes noted to drugs like amitryptiline and gabapentin. Our finding of delayed onset of the pain, more than 6 months post-surgery, both in the only man with continuing severe pain and also in 53% of the men reporting any pain at a mean of 5 years, is also congruent with neuropathic pain - which is known to be sometimes considerably delayed following the trigger event(19).

Another cause of discomfort may be back pressure in the epididymis due to build up of sperm that cannot escape, and although the sperm are reabsorbed, it often causes a pressure like effect for a time(20, 21).

This study that also validates the current understanding that using the NSV technique (or variants classifiable as MIV, Table 1) is less likely to cause CPVSP, given there was a significant

difference (p=0.015) in the incidence of pain at 5 years in those undergoing MIV vs CV in our cohort (Table 2).

The main limitation of this study is it is a prospective audit rather than a randomized controlled trial. The response rate of this study is acceptable. Of the 593 men originally included 336 responded at a mean of 5 years (57%). Importantly, of those who responded at 6 months (488 men) 69% responded at 5 years. However, with a similar occlusion technique being used by all surgeons and two different approaches to delivering the vas that could be compared, the prime aim was to provide an assessment of post-operative pain in a high turnover unit with an acceptable follow up rate. It proved impossible to evenly distribute patients between surgeons, hence certain biases may have resulted. Other limitations of this audit lay, inevitably, in the subjective nature of pain and its assessment.

Nevertheless this is the most comprehensive paper in the literature to date on post-operative pain following vasectomy, which by definition involves a group of patients who are young fit and not infrequently moving location.

CONCLUSION

This the first prospective audit of chronic scrotal pain following vasectomy with a mean follow-up of 5.1 years. Two men in 300 (0.6%) had continuing pain that was severe enough to interfere with quality of life or cause dissatisfaction with the procedure. It is important that men are counselled concerning this recognised complication of vasectomy, however also explaining that it is uncommon and over 99% of men report that it does not affect their quality of life.

Table 1 Vas Isolation Techniques
Conventional Vasectomy (CV): One midline or bilateral scrotal incisions are made with a scalpel. Incisions are usually 1.5-3.0 cm long. No special instruments are used. The vas usually is grasped with a towel clip or an Allis forceps. The area of dissection around the vas usually is larger than occurs with MIV techniques.
No-Scalpel Vasectomy (NSV): A minimally invasive method that uses specific instruments and sequential specific steps. Alteration of any of the specific steps does not allow the surgical technique to be called NSV. The NSV incision is less than 10 mm, and no skin sutures are needed. Two special instruments (vas ring clamp and vas dissector) are essential to NSV. The area of dissection around the vas is kept to a minimum.
Minimally Invasive Vasectomy (MIV): Methods with minor variations of the NSV technique are defined as MIV methods. Skin openings of ≤10 mm are typical and special instruments such as the vas ring clamp and vas dissector that are used for the NSV technique or similar special instruments are commonly used. The area of dissection around the vas is kept to a minimum.

Table 1: Definitions for Vas Isolation Techniques as defined in the American Urological Association (AUA) Vasectomy Guideline(4)

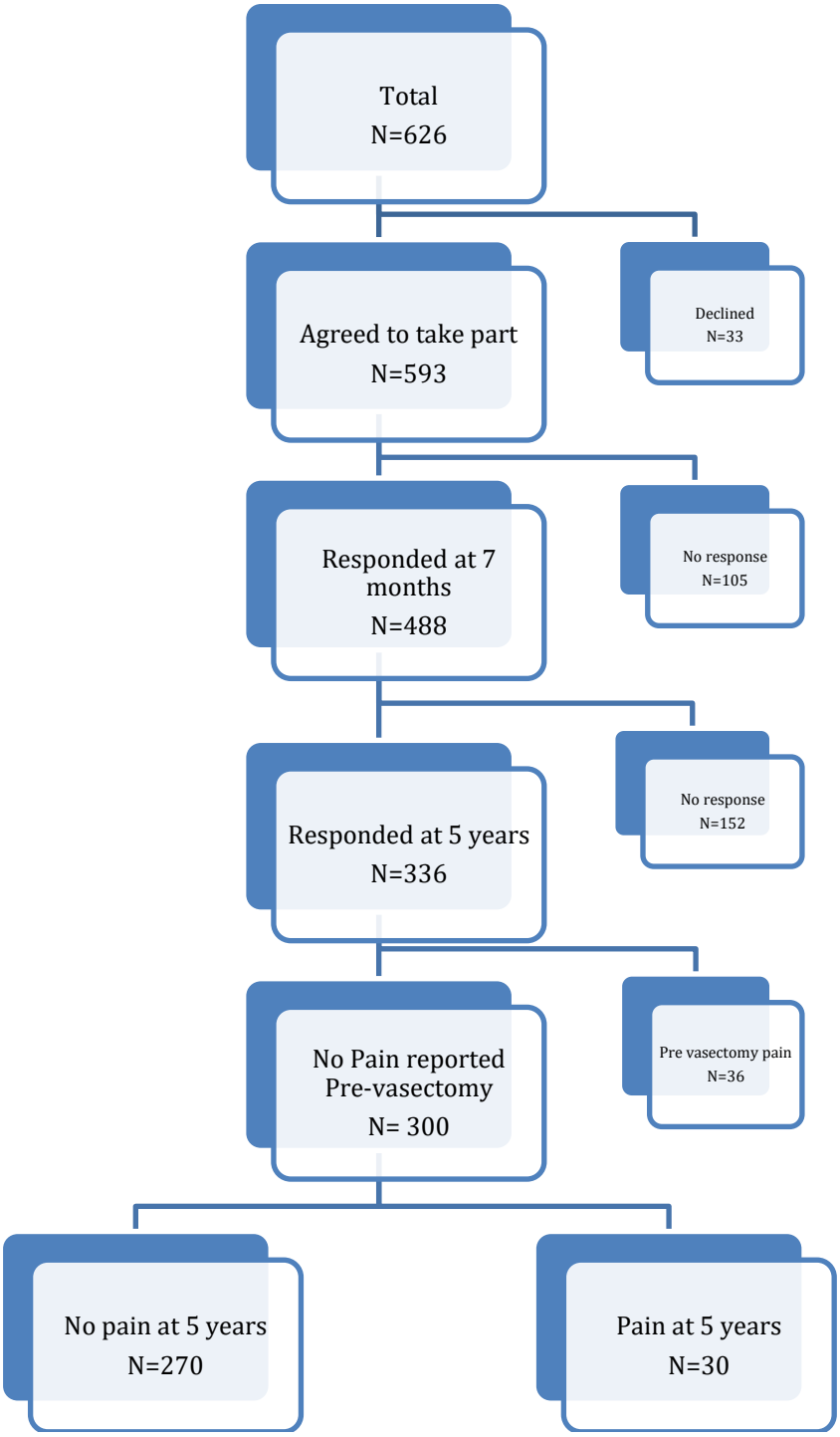

Figure 1: Responders and non-responders to the questionnaires (see text)

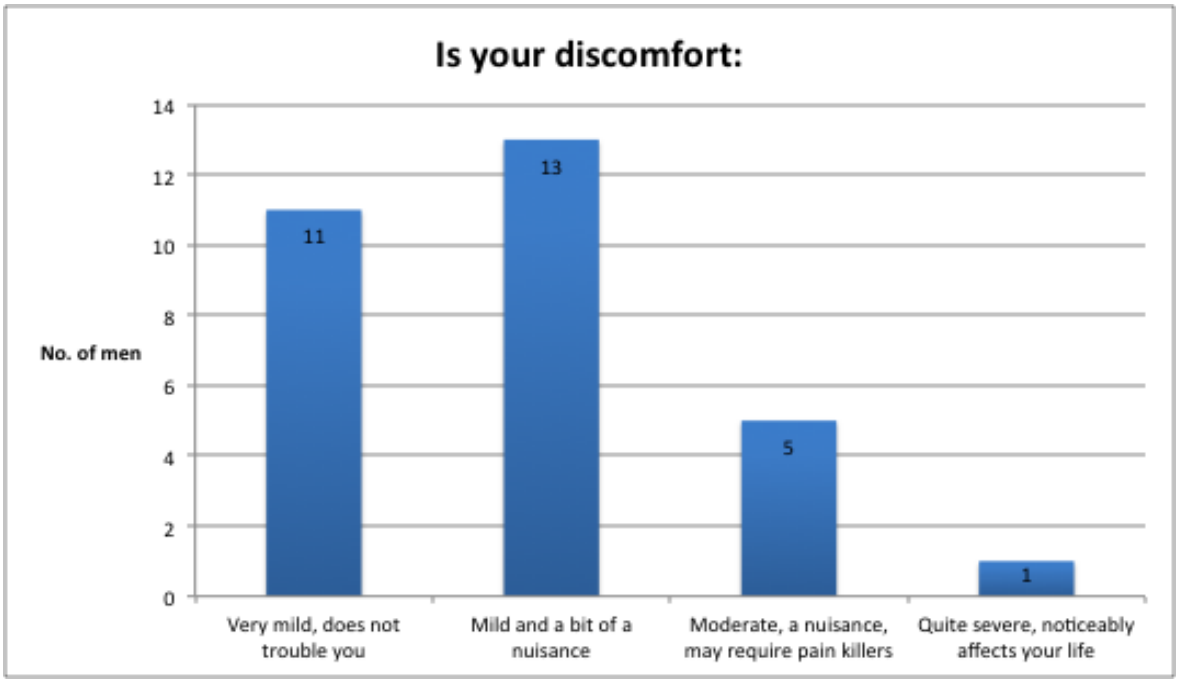

Figure 2: the extent of the problem in those men that reported new onset pain.

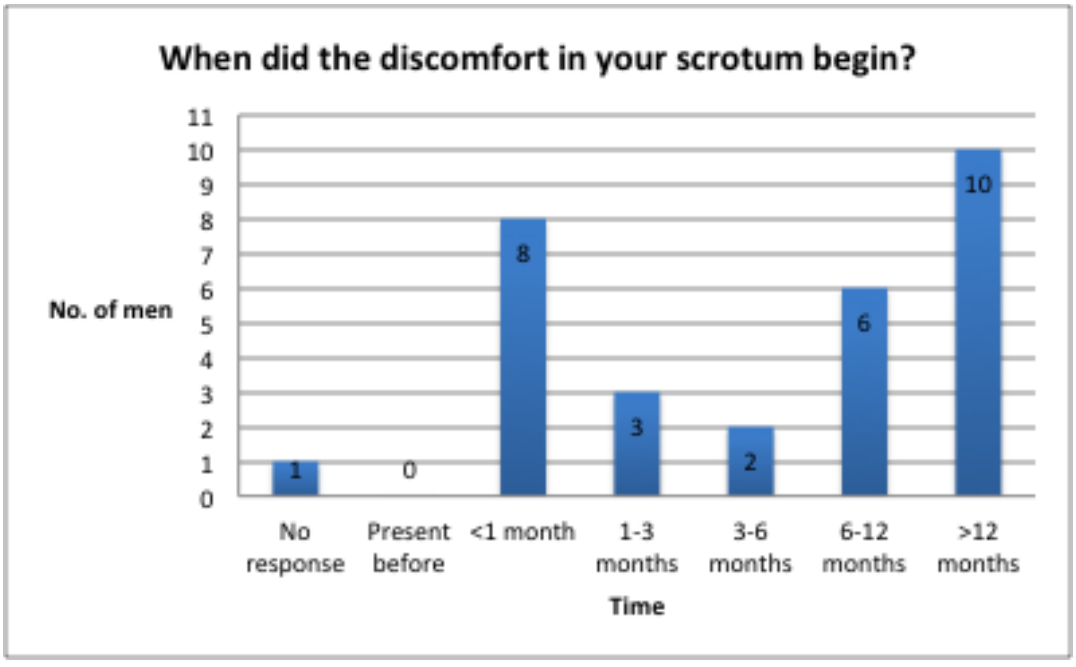

Figure 3: the timing of onset of pain.

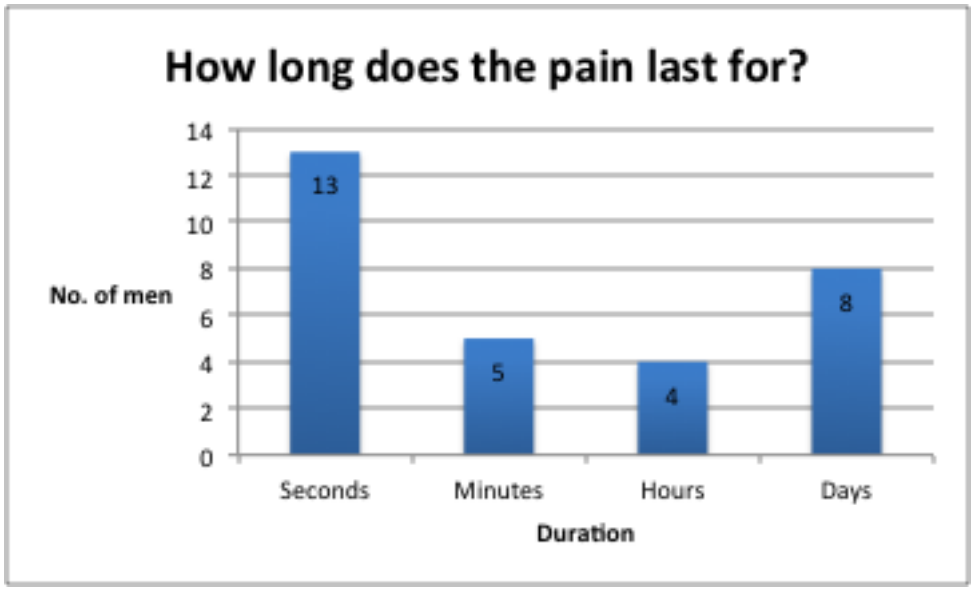

Figure 4: the duration of pain episodes.

Figure 5: the pain scores using a zero to 10 visual analogue scale.

	Patients who had no pain before vasectomy	Episodes of new post vasectomy discomfort at 5 years	% episodes of new post vasectomy discomfort
CV	**99**	**16**	**16.1**
MIV	**201**	**14**	**7.0**

Table 2 Comparison of a conventional vasectomy (CV) as compared with minimally invasive vasectomy (MIV)at the Elliot Smith Clinic. OR 0.39 (95% CI 0.18-0.83); p=0.015

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