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Vasectomy and vasectomy reversal : development of newly designed nonabsorbable polymeric stent for reconstructing the vas deferens

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Chapter 1

The impact of vasectomy technique on spontaneous early recanalization

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Introduction

The aim of this review article is to explore from the literature what method of vasectomy produces the lowest risk of early recanalization and which vasectomy technique has the preference in an era where reversal of vasectomy is increasing. It is important to establish what is considered spontaneous recanalization. Early failure, defined as the presence of motile spermatozoa in the ejaculate four months after surgery [1], is usually attributed to technical error or to early recanalization of the vas. Early failure occurs in about one out of 300 vasectomies[2,3]. Late recanalization is described as the situation, were initially azoospermia is achieved and pregnancy is recorded afterwards, regardless of the time interval between azoospermia and pregnancy [4,5]. Late recanalization is thought to be rare 0.04-0.08% [1,3] although in one study the rate of recanalization was 0.6 percent one year after vasectomy [2]. In general, success after vasectomy is assessed after two consecutive azoospermic specimens [6-8]. Persistence of non-motile sperm after two semen analyses does not mean that success is not achieved. Most of the men become azoospermic within 1 year after vasectomy [7,9] .

Growing popularity of vasectomy

Vasectomy is a safe and effective method of permanent contraception. In 1995 approximately 494.000 vasectomies were performed in the US (Haws et al) [10]. Vasectomy is less expensive and is associated with lower morbidity and mortality than tuba ligation [11,12]. Hendrix et al. [13] compared two methods of sterilization: bilateral tuba ligation and vasectomy. Compared were preoperative counseling, operative procedures, post-operative complications, procedure related costs, psychosocial consequences and feasibility of reversal. The complication rate in bilateral tuba ligation is 20 times higher and the mortality rate 12 times higher than in bilateral vasectomy. Tuba ligation is much more expensive compared to vasectomy. In 1987 in the USA a total of 976.000 sterilizations were performed (65% tubal ligation and 35% vasectomies) with an overall cost of $ 1.8 billion dollars. More than $ 800 million dollars could have been saved if 80 percent of sterilizations would have been vasectomies, as was the case in 1971. Hendrix et al. concluded that the preferred method of sterilization is vasectomy because it is safe, most efficacious and least expensive. The decline in popularity of tuba ligation is pointed out in a British study by Rowlands and Hannaford [14]. They estimated the incidence rates for tuba ligation and vasectomy and how these rates varied with age, geographical area and time. During the studied period from 1992-1999 there was a statistically significant 30% decrease in incidence of tuba ligation. The vasectomy rates did not change in time.

Chinese made vasectomy a very popular form of contraception, illustrated by a complete reversal of the ratio male-to-female sterilizations in favor of vasectomy (3: 1) [15]. Refining the technique of vasectomy, minimizing trauma, pain and complications, paved the way for the final breakthrough in the popularity of vasectomy. Nevertheless, the success of the vasectomy procedure can be endangered by the markedly increased incidence of postoperative complications in the hands of surgeons that infrequently perform the procedure [16].

Early recanalization or successful vasectomy?

The goal of each vasectomy is to obtain azoospermia. It is generally accepted that one or two azoospermic semen samples, taken 3-6 month after vasectomy, are sufficient for this statement [17,18,19]. But what if this azoospermia is not achieved and non-motile sperm persist? At what time and at which criteria do we state that recanalization has occurred? Do patients with persistent non-motile sperm have a greater risk for late recanalization then those who had initial azoospermia? In other words, is special clearance (unprotected cohabitation with the presence of non-motile sperm) after one year of follow-up justified? Answering these question is difficult because only a limited number of studies have been published referring to these issues. In a study by Benger[20] a survey was obtained from British urologist how they managed persistent quantities of motile and non-motile spermatozoa after vasectomy. There was a 56% response rate and from those responding, 23% never performed a revasectomy in case of persistent non-motile spermatozoa. They concluded from their study that the estimated risk of pregnancy occurring from the presence of non-motile sperm (sperm concentrations of one in 50 to one in 100 high-power fields) is less than the established risk of late recanalization (< 0.04-0.1%). In a more recent (2001) survey[17] among British general surgeons and urologist in the North-West region, protocols for post vasectomy semen follow-up were evaluated. Despite the fact that the majority of the protocols were not evidenced-based, the authors of this survey recommended a guideline that re-emphasized that the presence of non-motile sperm was not an indication for further sperm samples. The British Andrology Society[18] set up a guideline (2002) for the assessment of post vasectomy semen samples. They evaluated seven studies on the subject of non-motile sperm after vasectomy. In their guideline they stated that when non-motile sperm (<10.000/ml) was persistently seen after at least 24 ejaculations, the patient should be advised to discontinue contraception. The Australian Safety and Efficacy Register of

New Interventional Procedures-Surgical (ASERNIP)[19] presented a 187 pages numbered report on post-vasectomy testing to confirm sterility. They recommended that special clearance should be given to patients with two consecutive samples of non-motile sperm <10.000/ml and not earlier then 7 month after vasectomy.

Whether special clearance or even "normal" clearance in patient with non-motile sperm is justified, depends on the fact whether these patients have an increased risk on pregnancy compared to the patients with initial azoospermia and late recanalization. Philp et al.[21] reported a late recanalization rate of 0.03% (6 from 16.796 men) and described no pregnancies after special clearance of 310 (2%) men with non-motile sperm (<10.000/ml) after vasectomy. Edwards and Farlow [22] reported similar results in 200 patients with non-motile sperm. From these 200 men, 190 were followed-up 12 to 15 months after vasectomy and no pregnancies occurred. Davies et al.[23] reported no pregnancies after special clearance of 151 (2.5%) men with non-motile sperm (<10.000/ml) with a minimum follow-up of 3 years (3-8 years). There is no clear evidence in the literature (pub med search 1970-2005) proving that pregnancies rates are higher in patients with special clearance after two or more non-motile sperm samples (<10.000/ml) compared to pregnancy rates resulting from late recanalization after initial azoospermia. Despite the absence of well designed randomized comparative trials there seems to be a tendency in literature to accept and justify special clearance in case of non-motile sperm and therefore to accept this finding as an appropriate end-point after vasectomy and not as early recanalization[24].

The different vasectomy techniques and early recanalization

Author's technique: standing on the right side of the patient, the left vas is trapped between the thumb, index finger and middle finger, the right vas between only thumb and index finger. The left vas is located on top of the thumb, the right vas on the index finger. Lidocaine 2% (2cc) is infiltrated around the vas. A mid-scrotal localization is probably most convenient because in this area the vas is more straight and superficial. A 1 cm longitudinal incision is made and carried down through the vas-sheath until bare vas is exposed. The vas is delivered with a forceps or a clamp. The perivasal artery and veins are dissected from the vas. Preservation of these structures prevents possible complications like bleeding and thus hematoma. A segment of 2-3 cm is then excised, the stumps are occluded using suture material (Vicryl 2.0) and fascial sheath is interposed. The small cutaneous wounds are closed using 4.0 Vicryl Rapide. This technique is one of the many modifications of the conventional technique.

No-scalpel technique

Li [25] presented a no-scalpel technique. This method eliminates the scalpel and results in fewer hematomas and infections. A ring tipped vas deferens clamp is used and placed over the vas deferens after digital fixation of the vas under the median raphe. The skin in the clamp is tightly stretched over the most prominent portion of the vas and a sharp pointed mosquito is punctured through the overlying skin, into the vas sheath and vas wall. The clamp is gently opened until the bare vas wall can be visualized. The blades are turned 180 degrees and the vas is luxated through the puncture opening, divided and occluded.

Several studies compared the no-scalpel technique with the conventional technique and concluded that the no-scalpel technique resulted in a markedly reduced incidence of infection, hematoma and pain [26,27,28]. The time needed for the no-scalpel technique was 40 percent less. The technique is more difficult and requires intensive hands-on training. Sokal et al.[29] presented a multicenter, randomized partially masked controlled study and found no difference in success rates between the conventional and the no-scalpel technique. The no-scalpel

technique had the advantage of shorter operating time with fewer complications and reduced perioperative discomfort. However, Alderman and Morrison[30] who reviewed the records of 619 consecutive vasectomies, could not confirm these advantageous claims.

Percutaneous vasectomy

Percutaneous vasectomies have been performed by Li [31] and Ban[32] using a combination of cyanoacrylate and phenol. The vas lumen was punctured with a 22 gauge needle and the position was confirmed injecting methylene blue into the left vas as well as Congo red into the right vas. Injection of 20 micro liters of two parts phenol mixed with one part n-butyl 2-cyanoacrylate mixture via the 22-gauge blunt-tipped needle occluded the lumen. Brown coloring of urine (blue and red) confirmed that both sides were occluded. Chen and co-workers [33] performed vas occlusion in 53 men, using injection of 0.16-0.22 ml polyurethane elastomer. They reported azoospermia rates of 85% after one year and 96% after two years. They stressed the fact that the shape of the intravasal plug was of great importance for successful vasectomy rates. Zambon et al.[34] investigated the efficacy of a percutaneous vas occlusion using silicone plugs. Significantly fewer men were azoospermic after vas occlusion than after conventional vasectomy. They concluded that the reliability of percutaneous vas occlusion is poor and should be rejected. In general, using techniques of percutaneous injection of an erosive agent in quite a length of the vas deferens has the disadvantage of permanent irreversibility.

Suture ligatures, clips and cautery

Suture ligatures, still the most common method employed worldwide may result in necrosis and sloughing of the cut end distal to the ligature. On the testicular side a sperm granuloma may develop. If both ends slough, recanalization is more likely to occur [35] vasectomy failure rates due to recanalization vary from 1-5 % when only ligatures are applied for occlusion.
When using hemoclips, failure rates are less than 1% [36,37]. The more equal distributed pressure on the vas wall results in less necrosis and sloughing. Intraluminal cautery, destroying mucosa over at least one cm length, reduces recanalization rates to less then 0.5 %[38]. Labrecque et al.[39] investigated 3761 men who underwent initial vasectomy. The vasectomy failure rates in the clipping and excision group were much higher than in the cautery, interposition and open testicular end group (8.7% versus 0.3%). A prospective, non-comparative multicenter observational study was conducted by Barone et.al [40]. A total of 364 men completed follow-up in this study and were followed for 6 months. Each site used their usual cautery vasectomy technique. The overall failure rate based on semen analysis was 0.8% (95% confidence interval 0.2, 2.3). By 12 weeks 96.4% of participants showed azoospermia or severe oligozoospermia (< 100,000 sperm/mL). The predictive value of a single severely oligozoospermia sample at 12 weeks for vasectomy success at the end of the study was 99.7%. Sokal et.al [41] compared semen analysis data from men following vasectomy using two occlusion techniques. Data on intraluminal cautery came from a prospective observational study conducted at four sites. Data on ligation and excision with fascial interposition came from a multicenter randomized controlled trial that evaluated the efficacy of ligation and excision with versus without fascial interposition. Ninety-seven percent of the men in the cautery study had reached success by 12 weeks, while only 91% in the fascial interposition study had reached success by 14 weeks. The difference in the observed failure rates suggests that vas occlusion techniques that include

cautery are significantly more effective than ligation and excision plus fascial interposition, at least based on semen analysis.

Importance of vas length removed

The length of the vas removed has an impact on the failure rate. Removal of quite long parts, reduces the chance of recanalization [16], but is associated with more complications like hematomas and it impairs successful vasectomy reversal in the future. Hallan and May [42] studied 30 bilateral vasectomized men. After excision of the vas segment, X-rays were taken to assess the actual radiologic separation of the vas ends. After a median excision of 22.5 mm of vas, the median radiological gap took about 7 mm. They concluded that a very long segment (>7cm) should be excised to achieve a gap greater than that of sperm granulomas associated with vasectomy failures. Therefore they suggested that only short segments can be excised but that additional procedures, like interposition and/or fulguration, are necessary to prevent possible recanalization. In a more recent study by Labrecque et al.[43], the length of the vas resected during vasectomy had no influence on the risk of postvasectomy recanalization. They compared a group of spontaneous recanalizations with a group of azoospermic patients and a group of patient with non-motile sperm ($<1x10^6$ /mL). In cases of spontaneous recanalization versus azoospermic patients, the risk ratio (95% confidence interval) of recanalization with an average of segments of <10mm and 10-14mm was 0.6(0.1-2.0) and 0.6 (0.2-1.6) when compared to 15mm or more, respectively. In cases of spontaneous recanalization versus non-motile sperm group the risk ratio was 1.6(0.4-7.7) and 0.6 (0.2-1.7), respectively.

Clenny and Higgins[35] evaluated several vasectomy techniques and concluded that removal of at least 15 mm vas is recommended although plain cutting of the vas without removal is effective

as well in combination with adjusted techniques for handling the vas ends like folding, luminal fulguration and proximal fascial interposition.

Role of fascia interposition and/or folding back of vas ends

Interposition of fascia between the cut ends, folding back of the vasal ends and securing one end within Dartos muscle have all been advocated to reduce failure rates. In 1995 Schmidt [44] presented a series of 6248 vasectomies, all performed by one surgeon. No vasal segment was resected and the intraluminal mucosa of the cut ends was destroyed by fulguration after which the vas sheath was interposed preventing possible recanalization. In a period of 38 years he documented no persistence of sperm and post-vasectomy pregnancies. In 1994 Li et al. [45] published the results of a series of 2713 vasectomies using 7 different occlusion techniques. Especially the two techniques that used fascia interposition provided the best results.

Sokal et.al [46] performed a well conducted randomized trial to compare the probability of the success of ligation and excision vasectomy with, versus without, fascial interposition. All surgeons performed the vasectomies using the no-scalpel approach to the vas. Participants had a semen analysis two weeks after vasectomy and then every four weeks up to 34 weeks. The primary outcome measure was time to azoospermia. Additional outcome measures were time to severe oligozoospermia (<100 000 sperm/mL) and vasectomy failure based on semen analyses. Recruitment after the planned interim analysis was halted, when 841 men had been enrolled (interim analyses was separately published by Chen-Mok [47]). Fascial interposition decreased time to azoospermia (hazard ratio [HR], 1.35; $P < 0.0001$) and time to severe oligozoospermia (HR, 1.32; $P < 0.0001$) and reduced failures based on semen analysis by about half, from 12.7% (95% confidence interval [CI], 9.7 to 16.3) to 5.9% (95% CI, 3.8 to 8.6) ($P < 0.0001$).

Further recruitment was terminated prematurely. This study was one the first providing data from a randomized prospective trial showing the significant benefit of fascial interposition. Open ended vasectomies have been advocated in the 70'ties. Sperm granuloma development at the testicular open end had the advantage of preventing irreversible damage to the testis, improving the chances of successful reversal, but they provided unacceptable vasectomy failure rates varying from 7-50 percent [48,49]. In a larger series by Errey and Edwards [50] the risk of spontaneous recanalization was much less. They compared 4330 open-ended vasectomies with 3867 standard vasectomies and spontaneous recanalization was rare in both groups.

Haws et al.[10] provided nation wide data on the numbers of vasectomies, various occlusion techniques, fascial interposition and on protocols for semen follow-up in the United States. About one third of vasectomies in 1995 were no-scalpel vasectomies. The most common occlusion method was ligation and cautery. Less than half of the physicians (48%) interposed fascial sheath over one end [51].

Discussion

From these studies we conclude that the risk of pregnancy resulting from recanalization in patients with non-motile sperm is no greater than in those with two consecutive azoospermic semen samples [52,46,9,20,21,22] . Therefore persistence of non-motile sperm after one year of follow-up should not automatically be diagnosed as recanalization but rather as residual sperm higher up in the urogenital tract [53]. In our practice we perform a semen check-up after 3 months, if this indicates azoospermia or non-motile sperm in a concentration of < 100.000 non-motile sperm; no further semen specimens are analyzed. This is in accordance with the recently published guideline vasectomy of the Dutch Urological Society [54]. The only absolute proof for recanalization is undoubtedly histological investigation of a patent section at the time of the revasectomy. In daily practice this investigation is not applied. We do believe that recurrence of motile sperm during follow-up is evident proof of recanalization. In case of only several motile sperm cells in the ejaculate a repeated semen specimen can be taken 4 weeks later to confirm the persistency of this recurrent and probably enhanced motility of sperm. In such a case revasectomy is indicated.

There seems to be a relationship between the kind of vasectomy procedure and the risk of recanalization. Simple suture ligatures, resulting in necrosis and sloughing of both ends, provides the highest risk of recanalization and should therefore in our opinion be abandoned. The length of the vas resected during vasectomy is still under discussion, fascial interposition and/or folding back of vasal ends are probably of much greater importance. Those who perform vasectomies at regular bases are familiar with the fact that despite excision of a 2 cm vas segment the cut ends are still in close contact with each other. Therefore many surgeons will fall back to additional techniques like interposition or folding back to assure them that these ends will not meet and possibly recanalize. We are convinced that resection of a vas segment

<2cm provides limited contribution in preventing recanalization. Taking in account the studies with greater series it seems that cautery of the abdominal end, over a length of at least 1cm, in combination with interposition of vas sheath and an open-ended testicular side, is the preferred method of choice. These open ended vasectomies have several advantages. Leaving the testicular side open has the possible advantage of less post vasectomy chronic pain due to sperm granuloma formation [55,56]. Due to the development of sperm granuloma formation at the open testicular end, a pressure release valve can develop, reducing damage to the epididymis resulting in more successful vasectomy reversals. In an era with so many divorces and restored child wish with a new partner, long resection of vas should be carried out with restraint. Although there are from the literature only a limited number of well designed randomized comparative studies in this review, we are convinced that we have to modify our current, previously described, vasectomy technique.

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