Comparison of macroscopic one-layer over number 1 nylon suture vasovasostomy with the standard two-layer microsurgical procedure

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Abstract
Objective: To compare the outcomes of macroscopic one-layer vasovasostomy (MOLVV) with those of two-layer microsurgical vasovasostomy (TLMVV).
Methods: Standard TLMVV was performed in 112 men (Group 1), while MOLVV was performed in 94 patients. All of the MOLVVs were performed with number 1 nylon suture as a temporary stent. The outcome measures were as follows: patency rate, pregnancy rate, operation time, total procedure cost, and complications.
Results: The mean operation duration was 114 ± 10 min for the TLMVV technique, and 74 ± 5 min for the MOLVV procedure (P = 0.024). In patients who underwent vasal patency at 6-month postoperative period, the median sperm density (10^6/mL) was 28.3 and 27.7 in Groups 1 and 2, respectively (P = 0.62). At the same time, the median total motile sperm count (10^6) was 39.4 and 32.6 in two-layer microsurgical and one-layer macroscopic groups, respectively (P = 0.47). Patency rates were 82.1% in Group 1 and 77.7% in Group 2, which were not significantly different (P = 0.21). The pregnancy rate was 28.4% for patients in Group 1 and 26.7% for patients in Group 2 (P = 0.38). Conclusions: There were no significant differences in terms of patency and pregnancy rates between MOLVV and TLMVV methods, but the MOLVV technique offers a decreased cost and operative time, and a simplified procedure.

Keywords: Vasectomy reversal, vasovasostomy, microscopic, patency, pregnancy, operation time, postoperative vasal stricture

Introduction
Vasectomy is widely practised as a method of male contraception in Iran. An increase in divorce/remarriage has become a major cause of vasectomy reversal; of men who have undergone vasectomy, up to 6% will eventually seek vasectomy reversal (Potts et al., 1999). Bilateral vasovasostomy (VV) is the most cost-effective method for contraception after vasectomy. This holds true in the era of advanced assisted reproduction technologies (ARTs) such as intracytoplasmic sperm injection (ICSI) (Meng et al., 2005). In the past, most vasovasostomies were done using a macroscopic technique over an indwelling stent. Microsurgical VV was first introduced in 1975 by Silber (1975) who then demonstrated the superiority of this technique (Silber, 1978). Following this, many surgeons using the microsurgical VV considered it as the procedure of choice for the reversal of vasectomy. The overall patency and pregnancy rates reported by the vasovasostomy study group were 86% and 52%, respectively (Belker et al., 1991). There are pro and con studies in the literature regarding the microsurgical VV. Lee and McLoughlin (1980) reported a 90% return of sperm and a 46% pregnancy rate for macroscopic VV and a 96% return of sperm and a 54% pregnancy rate for TLMVV. However, the presence of sperm in the ejaculate may be transient after VV. In the long term, 3–12% of men will develop secondary azoospermia after an initial presence of motile sperm in the ejaculate (Matthews et al., 1995). Jee et al. compared microsurgical and loupe-assisted techniques for MOLVV (Jee & Hong, 2010). There was no statistically significant difference in pregnancy rates between the two
groups; however, microscopic technique groups showed a higher patency rate than the loupe-assisted technique. In another study, Hsieh et al. (2005) reported that there was no significant difference in patency and pregnancy rates between microscopic surgery and loupe-assisted one. In this regard, despite two decades of experience with microsurgical VV, we were never able to achieve a 50% pregnancy rate; our overall pregnancy rate is between 25% and 30% with the standard TLMVV. The TLMVV is an expensive, technically demanding, and time-consuming procedure. Over the last 20 years, several methods of VV have been devised to simplify the procedure, to reduce the operative time and cost, and achieve favourable pregnancy rates (Hsieh et al., 2005; Schiff et al., 2004; Fischer & Grantmyre, 2000). In an attempt to simplify the procedure, reduce the cost, decrease the operating time, and obtain a comparable result regarding pregnancy rate, we have therefore examined prospectively the results of MOLVV. We have tested whether MOLVV over a number 1 nylon suture material yields results similar to those of the TLMVV with the aim of introducing a safe, simple, and cost-effective method for VV with favourable outcomes. Our main target was general urologists.

Materials and methods

Study population

In a pilot study, an initial group of 10 patients underwent MOLVV over a number 1 nylon suture. After the data from the pilot study showing acceptable results, we proceeded to perform this method in further patients. From January 2002 to January 2008, a total of 248 vasectomized men underwent vasectomy reversal using TLMVV (n = 136, Group 1) or MOLVV (n = 112, Group 2) in a randomized manner, based on the availability of the surgical microscope. The average interval from vasectomy was 6.4 (range, 2.7–16.4) years for the TLMVV group, and 6.7 (range, 2.6–17.1) years for the MOLVV group. All the patients gave their informed consent, and the study was carried out in accordance with the International Conference on Harmonisation-Good Clinical Practice (ICH-GCP) guidelines and the principles of the Declaration of Helsinki.

Evaluations

The patient demographics, obstructive interval, operation method, intraoperative surgical findings, operative time, complications, female fertility status, and results of the postoperative semen analyses were recorded. Semen analysis was carried out at the first, third, and sixth months postoperative appointment, and thereafter at 12-week intervals until pregnancy was achieved or the patient was lost to follow-up. At each follow-up visit, two semen analyses were performed 1 week apart, and the mean of the two was used for the analysis. Vasal patency was defined as the presence of sperm (motile or non-motile) with tails in at least one postoperative semen analysis. Disappearance of motile sperm that had been reported on semen analysis at the first 3 months after vasovasostomy was considered to be postoperative vasal stricture. Pregnancy was determined at least 2 years after vasectomy reversal. The female partners were diagnosed as fertile after meticulous clinical and laboratory examinations including physical examination; haematological and biochemical assays; baseline body temperature; serum progesterone concentrations on Days 21 and 25 of the cycle; karyotyping; serum hormonal profile, including follicle-stimulating hormone, luteinizing hormone, prolactin, thyroid-stimulating hormone, and thyroxine; antiphospholipid and anticardiolipin antibodies; immobilizing antibodies in serum; lupus anticoagulant; hysterosalpingography; and cervical cultures for Mycoplasma, Ureaplasma, Chlamydia, and bacterial vaginosis as needed. Female partners with abnormal findings on hysterosalpingography underwent laparoscopy and/or hysteroscopy.

The primary outcome measure was vassal patency, and the secondary outcome measures were pregnancy rate, operation time, total procedure cost, and complication. The cost-effectiveness of the two procedures was calculated as the sum of each procedure. Only naturally conceived pregnancies were reported, and none of the female partners used ART. Pregnancy was determined by using a pregnancy test and confirmed by the presence of foetal heartbeats at 6–7 weeks. Exclusion criteria were patients undergoing unilateral VV, vasoepididymostomy, and all those with a prior reversal of vasectomy.

Surgical techniques

All vasovasostomies were performed under general anaesthesia by a single surgeon (MRS). All patients underwent bilateral VV. The standard TLMVV was performed as described by Belker (1995). The standard TLMVV technique was a 10-0 nylon mucosal (four sutures) and a 9-0 outer layer (four sutures).

For MOLVV, both testicles were delivered from the scrotum via a 5- to 7-cm midline incision in an extravaginal fashion. The vasal defect was identified, and the previous vasectomy site removed. The transaction of the vas deferens was at a 90-degree angle. The testicular and abdominal ends of the vas deferens were carefully dissected with meticulous attention to preserve perivasal tissue. Before vasal anastomosis, intravasal fluid was tested and the gross and microscopic appearance (using 400 x wet mount light microscopy) was assessed. Gross appearance of vasal fluid was considered favourable when sperm or copious amounts of clear fluid with thin consistency were observed in the fluid exuded from the testicular end of the vas deferens. Thick, water-insoluble and toothpaste-like fluids were regarded as unfavourable. A stay suture was then placed through the serosa of the vas at both ends for re-approximation of vasal ends. A piece of number 1-nylon suture material (# 5 cm)
was inserted into both ends of the vas simultaneously as a temporary stent to support the anastomosis and to allow for mucosal alignment. Four equally spaced full-thickness sutures were placed over the stent using slowly absorbable 6-0 polyglactin sutures and ×4 magnification. The nylon stent was removed before tying the last suture (Figure 1). The stay sutures were removed and the testes returned to their respective hemiscrotum. The incision was closed in two layers with 3-0 monocryl suture, and a sterile athletic supporter filled with dressing was applied.

Vasovasostomy was carried out only if sperm were found in the intravasal fluid. If no fluid was observed, the fluid was creamy and toothpaste-like without sperm parts, or the fluid with sperm heads only was expressed, then we proceeded to perform vasoepididymostomy. Patients were instructed to avoid heavy exercise for 1 month after discharge and ejaculation was not allowed for 1 month postoperatively. Of 248 recruited patients, 206 (112 from TLMVV group, and 94 from MOLVV group) met the study criteria (Figure 2). Of patients in the TLMVV and MOLVV groups, 6 (4.4%) and four (3.6%) were lost to follow-up. Of 18 excluded patients in the MOLVV group, 6 needed vasoepididymostomy, which has been done under a ×4 magnification Loup.

Statistical methods

An a priori power analysis was carried out. Given the sample size, the power of the study was 85% (β = 0.15) at a P level of 0.05 to detect a 15% difference in patency rates. The normality of data was checked using Kolmogorov test. The cube root transformation was applied for non-normally distributed data (sperm density, total sperm count, and total motile sperm). Univariate analyses were performed using Student’s t-test for continuous variables, and the chi-square test or Fischer’s exact test for dichotomous variables when appropriate. A multivariate logistic regression model was applied to determine the probability of a successful vasectomy.

Figure 1. Technique of one-layer vasovasostomy over number one nylon. A: A No. 1 nylon suture is placed into the two ends of vas deferens as a guide. B, C, and D: 12, 6, and 9 o’clock sutures are placed. E: After placing 3 o’clock suture, No. 1 nylon suture guide is removed, and the sutures are tied (F).

Figure 2. Flowchart of recruited subjects. Key: TLMVV = two-layer microsurgical vasovasostomy, MOLVV = macroscopic one-layer vasovasostomy.
Macroscopic one-layer vasovasostomy for vasectomy reversal

The patient characteristics are presented in the Table I. Patient's and partner's age were similar between the two groups. In addition, there were no significant differences in factors affecting the presence of sperm in the ejaculate, such as the time from vasectomy, the presence and the extent of sperm granuloma, and degree of vasal dilation (data not shown). The mean operation time was 114 ± 10 min for Group 1 and 74 ± 5 min for Group 2, which was significantly different ($P = 0.024$) (Table II). Patency rate did not differ significantly between the two groups. Following the VV, 105 (93.8%) and 80 (85.1%) of patients exhibited sperm in the ejaculate with densities ranging from 1 to 65 million sperm/ml in Groups 1 and 2, respectively ($P = 0.28$). However, the long-term patency rates were 82.1% and 77.7% in Groups 1 and 2, respectively ($P = 0.21$). In patients with postoperative semen analysis, no significant difference was found in semen volume, total sperm count, sperm concentration, motility, or total motile count between the two groups (Table II). For example, at 6 months post-operative, semen analysis showed median sperm densities of 28.3 million/mL and 27.7 million/mL, and mean sperm motilities of 40.6% and 38.7% in Groups 1 and 2, respectively ($P = 0.62$ and $P = 0.44$) (for details, see Table II). Pregnancy rates in Group 1 (28.4%) and Group 2 (26.7%) were similar ($P = 0.38$). There were no significant differences in complications including haematoma or wound infection among the groups. The mean cost for performing bilateral TLMVV was 24 000 000 Rials (median, 22 600 00 Rials [11000 Rials = 1 USD]), which was significantly below the mean cost of MOLVV (146 000 000 Rials: median, 13 400 000 Rials; $P = 0.004$).

Table II. Outcome of standard microsurgical two-layer vasovasostomy versus macroscopic one-layer over number 1 nylon vasovasostomy.

<table>
<thead>
<tr>
<th>Measures</th>
<th>Microsurgical (n = 112)</th>
<th>Macroscopic (n = 94)</th>
<th>P value*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean operation time (min)</td>
<td>114 ± 10</td>
<td>74 ± 5</td>
<td>0.024</td>
</tr>
<tr>
<td>Semen parameters*</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mean volume (ml)</td>
<td>3.1</td>
<td>3.2</td>
<td>0.62</td>
</tr>
<tr>
<td>Median sperm density (10⁶/mL)</td>
<td>28.3</td>
<td>27.7</td>
<td>0.62</td>
</tr>
<tr>
<td>Mean sperm motility</td>
<td>40.6%</td>
<td>38.7%</td>
<td>0.44</td>
</tr>
<tr>
<td>Median total count (× 10⁵)</td>
<td>84.7</td>
<td>78.8</td>
<td>0.74</td>
</tr>
<tr>
<td>Median total motile count (× 10⁶)</td>
<td>39.4</td>
<td>32.6</td>
<td>0.47</td>
</tr>
<tr>
<td>Patency rate, n (%)</td>
<td>92 (82.1)</td>
<td>79 (84.0)</td>
<td>0.21</td>
</tr>
<tr>
<td>Pregnancy rate, n (%)</td>
<td>29 (28.4)</td>
<td>23 (26.7)</td>
<td>0.08</td>
</tr>
<tr>
<td>Postoperative stricture, n (%)</td>
<td>6 (5.4)</td>
<td>4 (4.4)</td>
<td>0.38</td>
</tr>
<tr>
<td>Median cost, USD</td>
<td>2054.4</td>
<td>1218.2</td>
<td>0.004</td>
</tr>
</tbody>
</table>

*All p values are two-sided chi-squared test.
*Based on the semen analysis performed at 6 months postoperatively.
*Minimum follow-up of 2 years.
*Defined as disappearance of any sperm that had been found on ejaculated semen previously.

Discussion

MOLVV provides some advantages over standard TLMVV. Operative time is much shorter, the cost is.
much lower, performing the procedure is considerably easier, and there is no need for sophisticated equipments such as surgical microscope. Moreover, VV outcomes were not compromised with those of this technique.

Microsurgical VV is time-consuming, expensive, and technically challenging. To decrease the operative time and cost, obtain comparable operative outcomes, and make the procedure easy, various investigators have proposed alternative techniques. A temporary number 1 nylon suture stent can facilitate and accelerate vasovasostomy and resulted in easier and faster operations, since it held the lumens of both vas ends accurately in line during suturing. A disadvantage of the TLMVV is that the knots of suture are left near the outside of the mucosa, which may provoke fibrosis and result in stricture at the anastomotic site. In the present study, the long-term patency rate was 82.1% and 84.0% for TLMVV and MOLVV techniques, respectively. In addition to one layer suture, we used slowly absorbable suture material. All suture materials used in male infertility are made from non-absorbable materials, usually either nylon or polypropylene. Despite up to 99% initial patency rate for TLMVV using non-absorbable suture materials (Goldstein et al., 1998), a late obstruction rate of 12% (Matthews et al., 1995) remains a challenge. Local tissue reaction to the suture because of the presence of foreign material at the anastomotic site may have a negative effect on the long-term patency after VV (Fallick et al., 1997). Absorbable polyglyconate sutures have some advantages. They retain their strength throughout the absorption time, and cause less tissue reaction and damage than braided sutures; their breakdown is not via phagocytosis but take places through pure hydrolysis (Huang et al., 1995). We used 6-0 polyglyconate sutures with the MOLVV technique. Additionally, more perimucosal sutures can lead to the formation of a suture granuloma and fibrosis of the vas lumen (Fischer & Grantmyre, 2000). In the present study, only four full-thickness sutures were placed.

In most studies, the results of microsurgical techniques are better than those of macrosurgical anastomosis. The reported patency is more than 80% in most microsurgical series, with some studies achieving 100% long-term patency rate (Schiff et al., 2004; Sigman, 2004; Fox, 1994). Despite two decades of experience with TLMVV, we never achieved this high long-term patency rate. In the present study the patency rate was similar in the two groups of patients undergoing MOLVV or TLMVV. This agrees with the findings of Fischer and Grantmyre (2000). In another study, Hsieh et al. (2005) compared the results of loupe-assisted modified MOLVV and conventional TLMVV for vasectomy reversal. They concluded that due to the shorter operation time and less-expensive equipments required, the loupe-assisted one-layer VV should be regarded as the best method for simple vasectomy reversal. Several other studies have also demonstrated that the one-layer VV is comparable with the two-layer anastomosis in terms of patency and pregnancy rates (Fuse et al., 1995; Lee, 1986). In the present study, although the patency rates are similar to many other published series, the pregnancy rates seemed low, possibly due to the factors such as partner fertility status, especially age, epidiymal dysfunction, the presence of anti-sperm antibodies, and other unidentified factors.

Our study has some limitations. First, we reported pregnancy rates rather than live births largely because the former have been used more widely in vasectomy reversal studies. However, live birth rate is the 'gold standard' outcome to which publications should aspire. Second, it is important to recognize the possibility of patient selection bias. Of the men recruited initially, 17% were excluded from the analysis and it is unclear how this influenced our study outcome measures. Finally, the true incidence of vasal obstruction with longer follow-up is not known.

Most investigators advocate that vasovasostomy should be performed by urologists trained in microsurgery or carried out in dedicated centres. However, with the growing number of vasectomy reversal requests and deterioration of economic status in most societies, we need simple, cost-effective methods with favourable outcomes for vasectomy reversal as the approach we have described provides.

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