Benefit Of Vasectomy Using Cautery In Comparison With Excision And Ligation

MOUSAVI SMN, FANAIE SA, ZIAEE SA

ABSTRACT

Background: The data from a lot of comparatives analyses provided a strong hypothesis that the use of cautery is a very effective method. The main objectives of this study were to evaluate the cautery occlusion method against ligation and excision in terms of complications. The other objectives were to estimate the time of the procedure and the failures of cautery versus ligation and excision.

Methods: A prospective, comparative observational study was conducted at a referral center in Iran. One hundred men who chose vasectomy were enrolled and observed for 48 weeks. More frequent than normal semen analysis (12, 18, and 48 weeks after vasectomy) were performed. Planned outcome included early and late complication, early scrotal pain, consuming time and effectiveness (based on semen analysis).

Results: A total of 98(98%) participants in both groups completed a follow up. Significantly, the cautery technique took less time than ligation excision (7.56±1.08 min versus 9.88±1.24 min respectively). Early post-vasectomy scrotal pain based on VAS score in cautery group was significantly lower than ligation and excision (1.61±0.88 versus 2.39±1.40 respectively). Among complications, the incidence of granuloma and epididymitis in the cautery group is significantly less than ligation and excision. The overall failure rate based on semen analysis was 0.9% in the cautery group versus 4.7% in ligation and excision. (OR=4.8 CI=95%, 1.6-14.3)

Conclusions: Cautery is a very effective method for occluding the Vas deferensDespite the reduction in failure rate, it takes less time, and risk of the complications is acceptable compared to the ligation-excision technique.

Key words: vasectomy, Cautery, Ligation and Excision, complication

Introduction

Current evidence in a large systemic review supports no-scalpel vasectomy as the safest surgical approach to isolate the vas while performing vasectomy, but firm evidence to support any occlusion technique in terms of increased effectiveness or decreased risk of complications is lacking [1]. The results of 11 comparative studies, suggest that cautery of the vas lumen provides the highest level of occlusive effectiveness [1]. Apart from this, there has been little evidence to estimate early and late post vasectomy complications. In spite of the vast published literature on the

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effectiveness occlusion method, we intended to compare the cautery technique with ligation and excision especially in terms of complications. Our primary objectives were comparing early scrotal pain after vasectomy, the rate of haematoma, infection, granuloma, epididymitis, and spermatocele. Our secondary objectives were to estimate the time of procedure and the effectiveness of cautery by using standard semen analysis methods and to describe the success rate after vasectomy at 12, 18, and finally 48 weeks.

Materials and Methods
The methods of the ligation-excision and cautery have been previously described [2],[3]. This study was a prospective comparative observational study comparing two occlusion techniques. All the surgeons used the no-scalpel approach to the vas and a standard occlusion technique. The vas was occluded by using two sutures. An approximately 1-cm segment of the vas between the ligatures was excised. After that, two sutures with silk 2 O were used to contain both the ends (testicular and prostatic) of the vas. Of the 50 men who had ligation and excision in that study, 48 were included in this analysis. Two men were excluded because of lack of follow-up dates. The cautery study was designed to estimate the effectiveness and to describe the failure rate and its complication after vas occlusion by cautery versus ligation-excision. All the surgeons used the no-scalpel approach to the vas in this group and electro-cautery with both ends of the vas and with excision of a short segment of the vas. Of the 50 men enrolled, all are included in this comparative analysis.

All the patients were pre-operatively randomized by dropping coins into two groups. All the operations were performed by two surgeons. All statistic reports, such as VAS score, were prepared by research analysts who was blinded to selected cases. This study was approved by the Research Ethics Committees of the Health Care Institute for the University of Baqiyatallah.

Follow up and semen analysis methods:
Patients in both study groups had frequent semen analysis beginning at two weeks after vasectomy. However, subsequent semen analyses were conducted at weeks 12, 18, and 48 until a man who had provided two consecutive azoospermic specimens was declared a vasectomy failure and reached the end of the study follow up at 48 weeks. In both the studies, the participants were examined and asked to record their pain status according to a VAS score based on a 0-10 basis. All early and late complications were registered. Semen analyses methods for both the studies are based on World Health Organization recommendation. Freshly collected semen was examined in both the groups, and data was obtained on sperm concentration. Therefore, for this comparative analysis, we simply considered sperm concentration as an outcome measure. During both the studies, the laboratories conducted periodic quality-control tests.

Outcome measures
In both the study groups, we asked for frequent semen analysis rather than pregnancy as the vasectomy effectiveness outcome measure. This was to minimize the risk of pregnancy, sample size, and study duration. Vasectomy success is commonly defined as two azoospermic specimens. The small numbers of non-motile sperm may persist for many months in some men [4],[5]. For this reason, motility was not considered. Consequently, we used two definitions for vasectomy success for this comparative analysis. Our primary definition of a success was severe oligozoospermia defined as <100,000 sperm/ml in two consecutive specimens taken at least two weeks apart. Our alternative definition of success was the occurrence of two consecutive azoospermic specimens taken at least two weeks apart with no subsequent samples showing sperm concentrations of 100,000 sperm/ml or more[4],[5]. For early failure, we used a criterion of >10 million sperm/ml at week 12 or later, regardless of the motility [6]. The data collection form, study monitoring, and laboratory quality-control procedures were similar for both the groups.

Statistical Methods
Kaplan-Meier product-limit estimates of the probabilities of severe oligozoospermia at each scheduled week of follow up through week 48 and their 95% confidence intervals (CIs) were produced overall by the study group. The Kaplan-Meier probabilities were compared between two study groups using a two-sided log-rank test with an alpha of 0.05. The comparison of failure rates between the two study groups was based on a fisher exact test with a two-sided alternative hypothesis and an alpha of 0.05. However, the T-test was used to compare the numeric variables of complication between the groups.

Results
The baseline population characteristics, such as age distribution (41.55±5.69 in the cautery group and
40.99±5.96 in the excision and ligation group, marital status, and number of children (2.95±0.65, 2.96±0.66, respectively) was similar between groups.

**Table/Fig 1**: Comparison of Overall Incidence of post vasectomy complications and failure rate in both groups

<table>
<thead>
<tr>
<th>Complication</th>
<th>Cautery Group (50)</th>
<th>Ligation and Excision (48)</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hematoma</td>
<td>14% (7/50)</td>
<td>16.66% (8/48)</td>
<td>0.072 NS</td>
</tr>
<tr>
<td>Echymosis</td>
<td>2% (1/50)</td>
<td>6.25% (3/48)</td>
<td>0.25 NS</td>
</tr>
<tr>
<td>Infection</td>
<td>2% (1/50)</td>
<td>8.33% (4/48)</td>
<td>0.37 NS</td>
</tr>
<tr>
<td>Granuloma</td>
<td>4% (2/50)</td>
<td>16.66% (8/48)</td>
<td>0.046</td>
</tr>
<tr>
<td>Spermatocele</td>
<td>2% (1/50)</td>
<td>2.08% (1/48)</td>
<td>0.05&lt; NS</td>
</tr>
<tr>
<td>Epididymitis</td>
<td>0% (0/50)</td>
<td>10.41% (5/48)</td>
<td>0.028</td>
</tr>
<tr>
<td>Failure rate</td>
<td>0.9% (0.9%)</td>
<td>4.7% (4.7%)</td>
<td>0.0014</td>
</tr>
</tbody>
</table>

NS= Not Significant

**Analysis of complications**

We found significantly less time for operation in the cautery study than in the ligation-excision based on a prospective comparative observational study: 7.56±1.08 min versus 9.88±1.24 min respectively. (P=0.0001 by the fisher exact test). To make a precise assessment of early scrotal pain severity of these two procedures, post-operative pain in both groups was assessed by a 10-cm VAS (Visual Analogue Scale) in particular after the operation. Interestingly, there were fewer scrotal pain scores on VAS in the cautery group than in the ligation-excision group: 1.61±0.88 versus 2.39±1.40 respectively (P=0.036).

Among the complications, the overall incidence of simply granuloma and epididymitis is significantly less in the cautery group than in the ligation-excision group [Table/Fig 1].

**Analysis of Failures**

The overall failure rate was 0.9% in the cautery study versus 4.7% in the ligation and excision group (P=0.0014 by the fisher exact test). The adjusted odds ratio was 4.8 (95% CI, 1.6-14.3), indicating nearly a five-fold higher risk of early failure in the ligation and excision group than in the cautery study.

**Discussion**

Typically, short-term complications are less common with no-scalpel vasectomy [7]. V. Kumar and et al showed that hematoma was the most common complication of ligation and excision vasectomy[8]. In other studies, the range of this complication was 1-29% [8]. We should mention that hematoma in our study is defined as small and large hematoma (more and less than twice the size of normal scrotum). Because of this reason, the rate of Hematoma in our study was relatively higher. However, the role of experience is inevitable. Probably, hemostasis is one of the important issues that decrease the rate of this common complication and subsequently infection as shown in our cautery technique. The range of infection in several series varies from 0.4% to 16% [9] and up to 38% [8] (from mild erythema and stitch abscess to fulminant Fournier’s gangrene). The rate of infection in the cautery technique in our study (2%) was acceptable in comparison to some studies [Table/Fig 2]. Granuloma formation from the extruded sperm either at the vas or in the epididymis is as follows: 1% to 50% [10]. This percentage is reduced when the proximal vas is left open [11],[12]. Epididymitis and vasitis incidence is 0.1% to 8% [13]. According to the above documents, all the complication rates in both the groups approximately adjusted to the range results. Interestingly, there was a significant increase in granuloma and epididymitis in the ligation and excision group compared to the cautery group [Table/Fig 1]. The side effects of vasectomy include local pain and scrotal echymosis and swelling [14]. Scrotal pain after vasectomy is more common than is previously described, affecting almost one in seven patients[15]. All patients undergoing vasectomy must receive appropriate pre-operative counselling about this. In our study we found that early scrotal pain in the ligation-excision method is more than that in the cautery method. The other benefit of the cautery method was a shorter duration of the procedure.

Our results indicate that cautery is a highly effective and safe method to occlude the vas for...
vasectomy. In 10 published studies comparing ligation and cautery as methods of vas occlusion, the failure rates based on semen analysis ranged from 0 to 5% for cautery occlusion [1]. Surprisingly, the results of the two studies comparing ligation and excision to cautery are conflicting. One study found a higher failure risk based on semen analysis for cautery [16], and the other found a lower risk [3]. We were thus rigid in the definition of vasectomy success. A lot of comparatives analysis provides a strong hypothesis that the use of cautery is a very effective method for occluding the vas, and failure based on semen analysis is rare [2],[3],[17],[18].

Table/Fig 2: Complication Rates of No-Scalpel and Incision Vasectomy Techniques

<table>
<thead>
<tr>
<th>Study</th>
<th>Bleeding/Hematoma (%)</th>
<th>Infection (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Christensen, et al, 2002 19 (RCT)</td>
<td>9.5</td>
<td>7.1</td>
</tr>
<tr>
<td>V. Kumar, et al, 1999 12 (NRCT)</td>
<td>2</td>
<td>0.07</td>
</tr>
<tr>
<td>Nirapathpangporn, et al, 1990 7 (NRCT)</td>
<td>0.3</td>
<td>0.15</td>
</tr>
<tr>
<td>Sokal , et al, 1999 3 (RCT)</td>
<td>1.8</td>
<td>1.5</td>
</tr>
<tr>
<td>Seidl J, 1999 20 (NRCT)</td>
<td>12.4</td>
<td>2</td>
</tr>
<tr>
<td>S.M. Naini, et al, our study RCT, 2006, Cautery</td>
<td>14</td>
<td>2</td>
</tr>
<tr>
<td>S.M. Naini, et al, our study RCT, 2006, Clip-excision</td>
<td>16.6</td>
<td>8.3</td>
</tr>
</tbody>
</table>

RCT=Randomized Clinical Trial, NRCT=NonRCT

Conclusions:
Despite the lack of data from trials, we found that the use of cautery significantly reduced the vasectomy failure rates compared to the failure rates in ligation and excision. It is clear from our results that cautery takes less time and the rate of complications is less than that involved in ligation-excision. In conclusion, the cautery technique is recommended as an occlusion method in no-scalpel vasectomy, but the role of homeostasis, technical issues, and experience is inevitable in decreasing the rate of complications.

Conflict of interest: None Declared

References