RESEARCH ARTICLE

Are evidence-based vasectomy surgical techniques performed in low-resource countries? [version 1; peer review: 2 approved]

Michel Labrecque 1,2

1 CHU de Québec-Université Laval Research Centre, Population Health and Optimal Health Practices, 1050 Chemin Sainte-Foy, local K0-03, Quebec City, Quebec, G1S 4L8, Canada
2 Department of Family and Emergency Medicine, Laval University, Quebec City, Quebec, Canada

Abstract

Background: Research evidence published 10 to 15 years ago has shown that the type of vasectomy surgical technique performed can influence the effectiveness and the safety of the procedure. The objective of this study was to determine if evidence-based vasectomy surgical techniques are integrated in the vasectomy programs of selected low-resource countries.

Methods: The surgical techniques recommended to perform the two steps of the vasectomy procedure (isolation/exposure and occlusion of the vas deferens) were extracted from current evidence-based clinical practice guidelines. Documents describing male sterilisation standards and practice from Kenya, Rwanda, India, Nepal, Mexico, Honduras, Colombia and Haiti were reviewed to assess adequacy with international guideline recommendations.

Results: Best recommended techniques are 1) a minimally invasive technique including the no-scalpel technique (known as the no-scalpel vasectomy (NSV)) to isolate and expose the vas deferens, and 2) cautery of the mucosa of the vas preferably combined with interposition of the fascia (FI) to occlude the vas deferens. The NSV is largely adopted and performed to isolate the vas in selected low-resources countries. Ligation and excision (LE) of a small segment of the vas deferens combined with FI is the most common vas occlusion technique mentioned in the country standards. Cautery as recommended in the guidelines is seldom used in selected countries.

Conclusions: Effective and adapted vasectomy vas occlusion techniques are available, but are still underused in many low-resource countries. Providing the most effective vasectomy surgical techniques increases users’ confidence and satisfaction regarding male sterilization and may lead to higher acceptability and uptake.

Keywords
Male Sterilization, Surgical Procedure, Vasectomy, Family Planning Services, Developing Countries, Practice Guideline, Quality of Health Care, Guideline Adherence
This article is included in the International Conference on Family Planning gateway.

**Corresponding author:** Michel Labrecque (michel.labrecque@mfa.ulaval.ca)

**Author roles:** Labrecque M: Conceptualization, Data Curation, Formal Analysis, Funding Acquisition, Investigation, Methodology, Project Administration, Resources, Visualization, Writing – Original Draft Preparation, Writing – Review & Editing

**Competing interests:** No competing interests were disclosed.

**Grant information:** This study was funded by the Bill & Melinda Gates Foundation [OPP1181398] and The Michel-Labrecque Fund for Male Reproductive Health from the Laval University Fondation.

**Copyright:** © 2019 Labrecque M. This is an open access article distributed under the terms of the Creative Commons Attribution Licence, which permits unrestricted use, distribution, and reproduction in any medium, provided the original work is properly cited.

**How to cite this article:** Labrecque M. Are evidence-based vasectomy surgical techniques performed in low-resource countries? [version 1; peer review: 2 approved] Gates Open Research 2019, 3:1462 (https://doi.org/10.12688/gatesopenres.12986.1)

**First published:** 10 May 2019, 3:1462 (https://doi.org/10.12688/gatesopenres.12986.1)
Introduction

Vasectomy is generally regarded as a simple, safe, very effective, and highly cost-effective contraceptive method. In the early 2000s, randomized trials\(^1\), comparative studies\(^2\), systematic reviews\(^3\), and expert consultations\(^4\) showed that specific surgical techniques are associated with better safety and effectiveness of the procedure. More recently published North American and European practice guidelines on vasectomy based their recommendations on these findings\(^5\)-\(^12\).

Although the uptake of vasectomy is low in most low-resource countries, some have active vasectomy programs\(^11\). The objectives of this study were to determine 1) what vasectomy surgical techniques are recommended in evidence-based practice guidelines to reduce surgical complications (bleeding and infections) and to maximize occlusion and contraceptive effectiveness, and 2) if these techniques are integrated in the vasectomy norms and standards, and current practice of targeted low-resource countries.

Methodology

Recommended techniques

The recommended techniques of the two surgical steps of the vasectomy procedure (isolation/exposition and occlusion of the vas deferens) were extracted by the author from the following vasectomy practice guidelines: the European Association of Urology (2012)\(^1\), American Urological Association (2012, 2015)\(^10\), the Faculty of Sexual & Reproductive Healthcare (FSRH) of United Kingdom (2104)\(^1\), and the Canadian Urological Association (2016)\(^1\). The level of evidence, strength of recommendation and the most relevant underlying evidence from systematic reviews supporting the recommendations was also extracted.

Data from low-resource countries

A convenience sample of eight low-resource countries from Africa, Asia and America known by the author to provide vasectomy services on different scales was selected. India, Nepal, Mexico, and Colombia (through Profamilia, a non-profit governmental organisation) have large and structured vasectomy programs with thousands of men vasectomized each year while private or governmental smaller scale initiatives exist in Kenya, Rwanda, Honduras and Haiti.

For each country, the most recent document describing vasectomy techniques that should be used (national standards/norms) and/or that are performed was first identified through personal contact with individuals from or acquainted with vasectomy in selected countries. In addition, in order to validate the currency and the most relevant underlying evidence from systematic reviews supporting the recommendations was also extracted.

The surgical techniques recommended and/or commonly performed to isolate/expose (classic technique with a scalpel, NSV) and to occlude the vas (simple LE, LE+FI, cautery) in the selected countries were extracted from the retrieved documents. Additional information on the surgical techniques commonly performed as obtained by personal contact with key informants was also reported. Guideline recommendations were compared to and contextualized with vasectomy techniques performed in the selected countries.

Results

Guideline recommendations

Excerpts of recommendations from the four practice guidelines are presented in Table 1. Although the assessment of the evidence and the strength of the recommendations vary across the four guidelines, they all agree that a minimally invasive (MIV) technique including the no-scalpel technique (known as the no-scalpel vasectomy (NSV)) should be perform to isolate and expose the vas deferens. The criteria of a MIV technique are: 1) a skin opening of ≤10 mm, 2) minimal dissection of the vas and perivasal tissues, and 3) no use of skin sutures\(^10\). Among the MIV techniques, NSV is the most studied. Two systematic reviews concluded that NSV - based on high-quality evidence - is significantly associated with a lower risk of surgical complications, namely bleeding and/or hematomas\(^3\).

The guidelines also all agree that cautery of the mucosa of the vas lumen, preferably combined with interposing the fascia between the divided ends of the vas (fascial interposition (FI)), should be used to occlude the vas. Moderate-quality evidence from cohort studies showed that the “classical” ligation and excision (LE) technique consisting in putting two ligatures on the vas lumen, preferably combined with interposing the fascia at 5.9% (95% confidence interval 3.8% to 8.6%). Moderate quality evidence based on comparative cohort studies showed that combining cautery of the mucosa of the vas with either electro- or thermal-cautery, preferably combined with FI, is associated with the lowest risk of occlusion failure (<1%)\(^10,11\).

National standards and practices

National standards and practices in targeted low-resource countries are described in Table 2. All countries selected have national standards/norms\(^20\)-\(^22\); editions range from 2009 to 2018 (Table 2).

The NSV is the preferred recommended technique to expose the vas in all eight countries. Only three countries, Kenya\(^20\), India\(^2\), and Haiti\(^2\), mention that the “classical” technique, requiring a larger opening of the scrotal skin with a scalpel, is still acceptable.
<table>
<thead>
<tr>
<th>Guideline</th>
<th>Excerpts of recommendations</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Vas isolation</strong></td>
<td></td>
</tr>
<tr>
<td>EAU⁹¹</td>
<td>The no-scalpel vasectomy technique of isolation of the vas deferens is associated with fewer early complications, such as infections, haematomas, and less postoperative pain.</td>
</tr>
<tr>
<td>AUA¹⁰</td>
<td>Isolation of the vas should be performed using a minimally-invasive vasectomy (MIV) technique such as the no-scalpel vasectomy (NSV) technique or other MIV technique.</td>
</tr>
<tr>
<td>FSRH¹¹</td>
<td>A minimally invasive approach should be used to expose and isolate the vas deferens during vasectomy, as this approach results in fewer early complications in comparison to other methods.</td>
</tr>
<tr>
<td>CUA¹²</td>
<td>NSV is associated with a significantly lower risk of postoperative complications (haematoma, pain, infection) than conventional vasectomy.</td>
</tr>
<tr>
<td><strong>Vas occlusion</strong></td>
<td></td>
</tr>
<tr>
<td>EAU⁹¹</td>
<td>Early recanalisation can be decreased by cautery (with either thermal or electrocautery devices) of the vas deferens and by fascial interposition.</td>
</tr>
<tr>
<td>AUA¹⁰</td>
<td>The ends of the vas should be occluded by one of three divisional methods: Mucosal cautery (MC) with fascial interposition (FI) and without ligatures or clips applied on the vas; MC without FI and without ligatures or clips applied on the vas; Open ended vasectomy leaving the testicular end of the vas unoccluded, using MC on the abdominal end and FI; or by the non-divisional method of extended electrocautery.</td>
</tr>
<tr>
<td>FSRH¹¹</td>
<td>Cauterisation followed by division of the vas deferens, with or without excision, is associated with the lowest likelihood of early recanalisation (failure).</td>
</tr>
<tr>
<td>CUA¹²</td>
<td>Fascial interposition during vasectomy is associated with a significantly higher rate of azoospermia at three months than no interposition. Cauter of the vas should be accompanied by diathermy or ligation and fascial interposition.</td>
</tr>
</tbody>
</table>

**Recommendations** are directive statements that an action should (benefits outweigh risks/burdens) or should not (risks/burdens outweigh benefits) be undertaken based on Grade C evidence.

**Standards** are directive statements that an action should (benefits outweigh risks/burdens) or should not (risks/burdens outweigh benefits) be undertaken based on Grade A or Grade B evidence.

**FSRH nomenclature**
- Grade A - Evidence based on randomised clinical trials; no strength of recommendations specified.
- Grade B - Evidence obtained from well-conducted randomized controlled trials; at least one randomized trial. Recommendations are directive statements that an action should (benefits outweigh risks/burdens) or should not (risks/burdens outweigh benefits) be undertaken based on Grade B evidence.

**CUA nomenclature**
- Grade A - Based on clinical studies of good quality and consistency addressing the specific recommendations specified.
- Grade B - Based on well-designed studies (prospective, cohort), but without good randomized clinical trials; Grade C - Based on poorer quality studies (retrospective, case series, expert opinion). Recommendations are directive statements that an action should (benefits outweigh risks/burdens) or should not (risks/burdens outweigh benefits) be undertaken based on Grade C evidence.

**EAU nomenclature**
- Grade 1a - Evidence obtained from meta-analysis of randomised trials; Recommendation A - Based on clinical studies of good quality and consistency addressing the specific recommendations specified.
Although no vasectomy occlusion technique has been shown to be superior in term of contraceptive effectiveness in comparative trials, research evidence support the adoption of cautery over LE+FI for occluding the vas in low-resource settings. Occlusion failure risks of 2.1%, 2.5%, 2.6%, 5.9%, and 7.6% have been reported for the LE+FI technique; these are much higher than the higher acceptable risk of occlusion failure of vasectomy, which is 1%. In addition, even if FI is recommended to be combined with LE to decrease failure rate, it may not be commonly performed. In 2004, it was estimated that more than 95%, 97%, and 99% of vasectomies were done with simple LE without FI in India, Nepal, and Bangladesh despite country standards. If no FI is added to LE, the occlusive failure risk is even higher and contraceptive failure may parallel occlusion failure. In a cohort of 1263 men from rural Nepal who had a vasectomy mostly performed by simple LE, 2.3% still had 500,000 sperm/ml or more in their semen 1 to 3 years after the procedure and the pregnancy rate reported was 4.2% after 3 years. Finally, modelling the cost per couple-years of protection of LE, LE+FI, cautery, and cautery + FI in India, Kenya, and Mexico showed that cautery-based techniques are the most cost-effective methods.

This study has two main limitations. First, the sample of this convenience sample of eight countries is small. They were purposely chosen however to illustrate the situation in large and small vasectomy programs located on three continents. Second, some of the documents reviewed may be outdated. It is very only recently that Profamilia in Colombia updated their standards to include cautery combined with FI as the preferred occlusion technique of the vas. To the author’s knowledge, Haiti, Nepal, and Mexico are currently updating their male sterilization norms and standards. A future assessment of the norms and standards of the targeted countries and other low-resource countries with active vasectomy program may yield different results.

In conclusion, in low-resource countries NSV is largely adopted for vas isolation in accordance with evidence-based guidelines but recommended techniques for vas occlusion are not. Providing the most effective vasectomy surgical techniques increase users’ confidence and satisfaction regarding male sterilization and may lead to higher acceptability and increase uptake.

Table 2. National standards and practices for exposing and occluding the vas deferens in selected low-resource countries. Countries with large vasectomy programs are in italics.

<table>
<thead>
<tr>
<th>Country</th>
<th>Vas isolation</th>
<th>Vas occlusion</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Classic NSV</td>
<td>LE</td>
</tr>
<tr>
<td>Kenya 2009</td>
<td>S</td>
<td>S</td>
</tr>
<tr>
<td>Rwanda 2015</td>
<td>S</td>
<td>S</td>
</tr>
<tr>
<td>India 2013</td>
<td>S</td>
<td>S</td>
</tr>
<tr>
<td>Nepal 2010</td>
<td>S</td>
<td>S</td>
</tr>
<tr>
<td>Mexico 2009</td>
<td>S</td>
<td>S</td>
</tr>
<tr>
<td>Honduras 2010</td>
<td>S</td>
<td>S</td>
</tr>
<tr>
<td>Colombia 2010</td>
<td>S</td>
<td>S</td>
</tr>
<tr>
<td>Haiti 2009</td>
<td>S</td>
<td>S</td>
</tr>
</tbody>
</table>

NSV, no-scalpel vasectomy; LE, ligation and excision; FI, fascial interposition; S, country standards; P, Common practice but no written standards.

*personal communication with Dr. Doug Stein.

The most commonly vas occlusion technique recommended in the national standards is the LE combined with FI. Documents from India and Nepal mention that simple LE is also acceptable, Kenya only name LE, and Haiti do not mention any occlusion technique. The use of cautery is limited to four countries: Kenya, Rwanda, Haiti, and Colombia. Haiti and Kenya benefit from the support of No-Scapel Vasectomy International (NSVI), a non-governmental organisation promoting and providing free NSV services in low-resource countries. In these two countries most vasectomies are done through NSVI. Thermal cautery, using a low-cost portable thermal cautery unit, combined with FI is the vas occlusion technique recommended by NSVI (personal communication with Dr. Doug Stein, President of NSVI). In Rwanda, mucosal cautery of the vas combined with FI has been successfully introduced in 2010 and is now recommended to be used for occluding the vas. Profamilia in Colombia has recently introduced thermal cautery combined with FI as one of their recommended techniques, in addition to LE+FI. They aim to train all urologists from their family planning clinic network over year 2019 (personal communication with Dr. Diana Torres, chief urologist at Profamilia). Colombia is then the only one of the four large vasectomy programs to recommend using cautery (Table 2).

Discussion
Creating and sustaining successful vasectomy programs in low-resource countries is challenging. Demand for vasectomy, access to services, and enabling environment must all be mutually reinforced. Skillful vasectomy providers performing best practice surgical techniques is an essential component contributing to the success of vasectomy programs in countries where acceptance of vasectomy is low, follow-up of patients for complications is difficult, and access to post-vasectomy semen analysis to confirm success (or failure) of the procedure is not available.

On one hand, as recommended in the evidence-based vasectomy guidelines, NSV is uniformly adopted in the selected low-resource countries for isolating the vas deferens, minimizing the risk of bleeding and infection. On the other hand, cautery, which is recommended for occluding the vas in the guidelines, is seldom encountered in the targeted countries. In these countries, the most common standard for occluding the vas is LE+FI.
References

   PubMed Abstract | Publisher Full Text | Free Full Text

   PubMed Abstract | Publisher Full Text | Free Full Text

   PubMed Abstract

   PubMed Abstract | Publisher Full Text | Free Full Text

   PubMed Abstract | Publisher Full Text | Free Full Text

   PubMed Abstract | Publisher Full Text

   PubMed Abstract | Publisher Full Text | Free Full Text

   PubMed Abstract | Publisher Full Text | Free Full Text

   PubMed Abstract | Publisher Full Text | Free Full Text

    PubMed Abstract | Publisher Full Text

    Reference Source

    PubMed Abstract | Publisher Full Text | Free Full Text

    Reference Source

    PubMed Abstract | Publisher Full Text

    PubMed Abstract | Publisher Full Text


    PubMed Abstract | Publisher Full Text

    PubMed Abstract | Publisher Full Text

    PubMed Abstract | Publisher Full Text

    Reference Source

    Reference Source

    Reference Source

    Reference Source

    Reference Source

    Reference Source

    Reference Source

    Reference Source

    PubMed Abstract | Publisher Full Text

    PubMed Abstract | Publisher Full Text

    PubMed Abstract | Publisher Full Text

    PubMed Abstract | Publisher Full Text

    PubMed Abstract

    PubMed Abstract

    PubMed Abstract | Publisher Full Text | Free Full Text

    PubMed Abstract | Publisher Full Text | Free Full Text

    PubMed Abstract | Publisher Full Text | Free Full Text
Open Peer Review

Current Peer Review Status: ✔ ✔

Version 1

Reviewer Report 19 June 2019

https://doi.org/10.21956/gatesopenres.14093.r27324

© 2019 Li P et al. This is an open access peer review report distributed under the terms of the Creative Commons Attribution Licence, which permits unrestricted use, distribution, and reproduction in any medium, provided the original work is properly cited.

Philip S. Li
Center for Reproductive Medicine, Department of Urology, Weill Cornell Medicine, New York City, NY, USA

Omar Al Hussein Alawamleh
Department of Urology, Weill Cornell Medicine, New York City, NY, USA

General:

In this article entitled “Are evidence-based vasectomy surgical techniques performed in low-resource countries?”, the author aimed to determine if evidence-based vasectomy surgical techniques are integrated in national vasectomy programs of selected 8 low-resource countries in Asia, South America and Africa after establishing which vasectomy techniques are recommended in evidence-based practice guidelines.

This evidence-based article is well written, it clearly delineates the guidelines and data available on the techniques used for the vasectomy procedure of solation/explosion and occlusion of the vas deferens. Data indicated the preferred vasectomy technique in almost all of the select countries is the no-scalpel vasectomy (NSV), which happens to be the best surgical technique to isolate and expose the vas deferens with mucosal cautery (MC) of the vas, preferably combined with a small segment of the vas deferens along with fascial interposition (FI), and is the recommended and best surgical practice.

The information presented is valuable in informing vasectomy services in low-resource countries, and that could improve outcomes and increase demand and uptake of vasectomy in those countries.

Editorial comments:

1. Page 3, 2nd paragraph under introduction, 3rd line: “1) what vasectomy surgical techniques …” should be changed to “1) which vasectomy surgical techniques …”.

2. Page 3, 1st paragraph under results, 7th line: “(known as the no-scalpel vasectomy (NSV)) should be perform to …” should be changed to “(known as the no-scalpel vasectomy (NSV)) should be
performed to …”.

3. Page 5, 3rd paragraph under discussion, 2nd line: “has been shown to be superior in term of contraceptive effectiveness …” should be changed to “has been shown to be superior in terms of contraceptive effectiveness …”.

4. Page 5, 4th paragraph under discussion, 1st line: “the sample of this convenience sample of eight countries is small.” should be changed to “the size of this convenience sample of eight countries is small.”

**Is the work clearly and accurately presented and does it cite the current literature?**
Yes

**Is the study design appropriate and is the work technically sound?**
Yes

**Are sufficient details of methods and analysis provided to allow replication by others?**
Yes

**If applicable, is the statistical analysis and its interpretation appropriate?**
Not applicable

**Are all the source data underlying the results available to ensure full reproducibility?**
Yes

**Are the conclusions drawn adequately supported by the results?**
Yes

**Competing Interests:** No competing interests were disclosed.

**Reviewer Expertise:** I am a Professor of Urology and Reproductive Medicine in Research at Weill Cornell Medicine of Cornell University, I am an expert in no-scalpel vasectomy. Working with Dr. Marc Goldstein at Cornell, I played a key role in bringing the no-scalpel vasectomy to North America. I authored/co-authored a number of articles, videos and instructive surgical manuals on the no-scalpel vasectomy.

**We confirm that we have read this submission and believe that we have an appropriate level of expertise to confirm that it is of an acceptable scientific standard.**
David Sokal  
Male Contraception Initiative, Durham, NC, USA

General:  
- This is a very useful paper, and has implications for national vasectomy authorities, and for the World Health Organization, and for other organizations who wish to facilitate the use of best practices for vasectomy procedures. Support and training activities for vasectomy services deserve more attention.

Editorial comments: For clarity, please improve formatting and content of tables, specifically:

Table 1:  
- Put “Vas isolation” and “Vas occlusion” in bold, and/or better separate these categories in some other way(s).
- Also, what and where is FSRH? Google tells me that it is a UK standards body. That should be noted.

Table 2:  
- Italics is not sufficient to clearly identify the large and small programs, and ordering the countries by region seems less useful than ordering them by large and small, or put the large programs in bold?

Chair of the Board at the Male Contraceptive Initiative (MCI), Durham, NC, USA. This is an unpaid volunteer position. This review reflects my personal views, and not those of MCI.

Is the work clearly and accurately presented and does it cite the current literature?  
Yes

Is the study design appropriate and is the work technically sound?  
Yes

Are sufficient details of methods and analysis provided to allow replication by others?  
Yes

If applicable, is the statistical analysis and its interpretation appropriate?  
Not applicable

Are all the source data underlying the results available to ensure full reproducibility?  
Yes

Are the conclusions drawn adequately supported by the results?  
Yes

Competing Interests: I worked with Michel Labrecque on several studies about 10 to 15 years ago and we became and remain friends. A more recent connection is being co-authors on a letter to the editor in 2015. I do not believe that this affects my ability to objectively review this article.
Reviewer Expertise: Before retiring from FHI 360, I spent approximately 10 years working on clinical studies of vasectomy techniques, and authored / co-authored a number of papers on this subject.

I confirm that I have read this submission and believe that I have an appropriate level of expertise to confirm that it is of an acceptable scientific standard.