Vasectomy for the Non-Vasectomist: From Guidelines to Hands-on Practice

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Quebec City
Canada
Conflicts of Interests

• I perform vasectomy
  • 20,000+ vasectomies performed since 1986
• I had research contracts related to vasectomy
  • FHI360/EngenderHealth
  • Contravac (SpermCheck Vasectomy®)
• I was involved in the development of Clinical Practice Guidelines on vasectomy
  • American Urological Association (AUA)
  • European Association of Urology (EAU)
First World Vasectomy Day
October 18 2013

World Vasectomy Day Sites So Far ... Building the Dream
(In some cases, a single dot may represent multiple vasectomists or multiple practices.)

http://worldvasectomyday.org/
Ob-Gyn = No Vasectomy

...to remain certified by ABOG the care of male patients is prohibited except in the following circumstances:

• ...
• Family planning services, not to include vasectomy
• ...

http://www.abog.org/definition.asp
Objectives

• To adequately inform men -and women- seeking contraception about male sterilization
• To identify surgical consultants offering evidence-based vasectomy services based on current guidelines
• To experiment the No-Scalpel Vasectomy technique
AUA Vasectomy Guideline 2012

Sharlip et al. J Urol  December 2012

http://www.auanet.org/content/media/vasectomy.pdf
The Preoperative Consultation

- **Permanent** form of contraception
  - Alternatives
  - Vasectomy reversal/sperm retrieval with in vitro fertilization

- **No immediate** sterility
  - Post-vasectomy semen analysis

- **Not 100% reliable**
  - Repeat vasectomy ≤1%
  - Risk of pregnancy: 1 in 2,000 (0.05%)

- Surgical **complications**: 1-2%
- Chronic scrotal **pain**: 1-2%
Your Ideal Surgical Consultant!

- No pain
- No stitches
- No complications
- No failures
- No delayed and unneeded PVSAs
Vasectomy 101

• Step 1: Anaesthesia
  - No pain

• Step 2: Vas Isolation
  - No stitches
  - No complications

• Step 3: Vas Occlusion
  - No failures
Step 1. Anaesthesia

• Local

  AUA Expert opinion/EAU principle

• Pain can be minimized with:
  • mini-needle (#30)
  • jet gun
The Mini-Needle Technique

- 30 gauge needle 1”
- 3 cc syringe
- 2 cc lidocaine
- 0.5 cc injected in and around the vas at the level of the intended surgical site

Shih et al, J Urol 2010
The Jet Gun Technique (No Needle)
The Jet Gun Technique (No Needle)
A Good Marketing Tool!
## Pain According to the Anaesthesia Technique

<table>
<thead>
<tr>
<th>Technique</th>
<th>Expected</th>
<th>Anesthesia</th>
<th>Vasectomy</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Vasal Nerve Block</strong></td>
<td></td>
<td></td>
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</tr>
<tr>
<td><em>White 2007</em></td>
<td>2.1</td>
<td></td>
<td>1.9</td>
</tr>
<tr>
<td><strong>Local (#27)</strong></td>
<td></td>
<td></td>
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</tr>
<tr>
<td><em>Aggarwal 2009</em></td>
<td>3.3</td>
<td></td>
<td>2.7</td>
</tr>
<tr>
<td><strong>Mini-needle (#30)</strong></td>
<td>3.1</td>
<td>1.5</td>
<td>0.6</td>
</tr>
<tr>
<td><em>Shih 2010</em></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>No Needle</strong></td>
<td></td>
<td></td>
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</tr>
<tr>
<td><em>Weiss 2005</em></td>
<td>1.7</td>
<td>0.7</td>
<td>1.7</td>
</tr>
<tr>
<td><em>White 2007</em></td>
<td>1.6</td>
<td></td>
<td></td>
</tr>
<tr>
<td><em>Aggarwal 2009</em></td>
<td>2.2</td>
<td></td>
<td>2.1</td>
</tr>
</tbody>
</table>
Step 2. Vas Isolation
The “Classic” Technique
The "Classic" Technique
Recommended Vas Isolation Technique

- Minimally Invasive Vasectomy (MIV) technique
  
  *AUA Standard (Evidence Strength Grade B)*
  
  - Small (<10 mm) opening(s)
  - No skin sutures
  - Minimal dissection of the vas and perivasal tissues
This is not an MIV!
Recommended Vas Isolation Technique

- Minimally Invasive Vasectomy (MIV) technique
  - AUA Standard (Evidence Strength Grade B)
    - Small (<10 mm) opening(s)
    - No skin sutures
    - Minimal dissection of the vas and perivasal tissues

- No-scalpel vasectomy (NSV) is the best studied MIV

**NSV and MIV are vas isolation techniques, not “vasectomies”**
The No Scalpel Technique
# Surgical Complication Rates
## Classic Technique vs. NSV

<table>
<thead>
<tr>
<th>Authors</th>
<th>Hematoma (%)</th>
<th>Infections (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>C</td>
<td>NSV</td>
</tr>
<tr>
<td>Sokal 99</td>
<td>12.2</td>
<td>1.8</td>
</tr>
<tr>
<td>Christensen 02</td>
<td>15.9</td>
<td>9.5</td>
</tr>
<tr>
<td>Nirapathpongpron 90</td>
<td>1.7</td>
<td>0.3</td>
</tr>
</tbody>
</table>

All p < 0.05

*No prophylactic antibiotics

AUA Recommendation (Grade C)*

Labrecque et al, BMC Medicine 2004
Step 3. Vas Occlusion
The Most Common Vasectomy Occlusion Techniques

- Ligature
  - Suture material
  - Metal clips
- Excision
- Fascial interposition (FI)
- Intraluminal (mucosal) cautery
The “Classic” Occlusion Technique...

Histologic examination of the excised vas... not required

AUA Expert Opinion
Cautery
Fascial Interposition (FI)

Half of the vasectomies performed in USA

*Barone et al, J urol 2006*
EAU Recommendation (1a A)

- Cautery (thermal or electrocautery) and FI

...no vasectomy technique has been shown to be superior in terms of prevention of late recanalisation and spontaneous pregnancy EUA 2a
AUA Recommendation (Grade C)

- Mucosal cautery (MC) **with** or **without** fascial interposition (FI)
  - No ligatures or clips applied on the vas
  - **with FI if** testicular end left **open**
- Non-divisional method of extended electrocautery (**Marie Stopes International** technique).

... occlusive failure rates ... consistently <1% in large numbers of patients across studies conducted by different surgeons...
The “Classic” Occlusion Technique...

if ... personal training and/or experience indicate... consistently satisfactory results ...

AUA Option (Grade C)
LE Is Not Effective!

• Occlusive Failure Rates
  • Mexico: 8%
    Cortes et al Contraception 1997
  • Canada: 8%
    Labrecque et al J Urol 2002
  • Mexico: 12%
    Barone et al J Urol 2003
  • Colombia: 29%
    De los Rios Andrologia 2003
  • Seven Countries Worldwide: 13%
    Sokal et al BMC Medicine 2004
LE Is Not Effective!

- **Contraceptive Failure Rates**
  - **India:** 3% - 5%  
    *Mrhida 1979*
  - **Nepal:** 4% after 3 years  
    *Nazerali et al Contraception 2003*
  - **Vietnam:** 4% after 5 years  
    *Hieu et al Int J Gynaecol Obstet 2003*
  - **China:** 9% after 10 years  
    *Wang Contraception 2002*
Step 3. Vas Occlusion – In Summary

• Occlusion technique is crucial to achieve contraceptive and occlusive success

• Combining cauterization and FI is associated with the lowest risk of recanalization and occlusive failure

• Simple ligation and excision as an option ???
Guideline Statements on PVSA
Evidence based flow chart of post-vasectomy testing protocol

Vasectomy with cautery and FI

Single test at 3 months

≤100,000 non motile sperm/ml (95% of patients)
No further test

>100,000 sperm/ml motile or non-motile
(5% of patients)
Control 4-6 weeks

>100,000 non motile sperm/ml
Control 4-6 weeks
Possible failure
If > 6 months

≤100,000 spermato immobile/ml
No further test

8 to 16 weeks
Option (Grade C)

Labrecque et al, J Urol 2005
Your Ideal Surgical Consultant!

- No pain
- No stitches
- No complications
- No failures
- No delayed and unneeded PVSAs
NSV hands-on
http://www.vasectomie.net/vasectomiehautevitesse.wmv
Three-Finger Technique

FIGURE 6 The three-finger technique: Isolating the right vas
FIGURE 13  Holding the ringed clamp, with the palm up
FIGURE 15  Pressing the tips of the ringed clamp onto the scrotal skin overlying the right vas.
FIGURE 17  Pressing the index finger lightly downward to tighten the scrotal skin just ahead of the tips of the ringed clamp and over the anesthetized area.
FIGURE 18 Piercing the skin with the medial blade of the dissecting forceps
FIGURE 20  Spreading the tissues to make a skin opening twice the diameter of the vas
FIGURE 21  Piercing the wall of the vas with the tip of the lateral blade of the dissecting forceps
FIGURE 25 Grasping a partial thickness of the elevated vas

Groove created when the vas was punctured
FIGURE 27  Puncturing the sheath, with one tip of the dissecting forceps.
Opening the dissecting forceps to strip the sheath
There’s an App for That: An Innovative Tablet-Based Sexual Health Application

Ashley Scarborough, MPH
Linda Creegan MS, FNP
Disclosure

• We have no financial interests to disclose
Objectives

• Describe need addressed by Tablet-based Sexual Health App (TaSHA)

• Describe the process of implementing TaSHA in the clinical setting

• Outline potential routes to fund and implement an Sexual Health App in your clinical setting
The Goal, The Challenge...

• Sexual health is our **Goal** for all patients

• The **Challenge**
  – Chlamydia and gonorrhea are common in men who have sex with men (MSM)
  – Risk assessment and STD screening are not routinely done
A Solution: Technology can help!

**TaSHA**: Tablet-based Sexual Health Tool

- A self-administered Patient RA survey
- 3 Clinical Decision Supports for clinicians

Saves time
Improves patient care
Brings reimbursement for recommended testing
Towards the Goal of Sexual Health for MSM

• Routine risk assessment!!

• Routine STD screening!!
Risk Assessment Drives Screening Decisions

**STI Screening Recommendations: HIV-positive Men & Women**

<table>
<thead>
<tr>
<th>STI</th>
<th>Anatomic Site</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chlamydia</td>
<td>Genital, rectal if exposed</td>
</tr>
<tr>
<td>Gonorrhea</td>
<td>Genital, rectal &amp; oral if exposed</td>
</tr>
<tr>
<td>Syphilis</td>
<td>Serology</td>
</tr>
<tr>
<td>Trichomoniasis</td>
<td>Women only</td>
</tr>
<tr>
<td>HSV-2</td>
<td>Serology</td>
</tr>
<tr>
<td>Hep B sAg</td>
<td>Serology</td>
</tr>
<tr>
<td>Hep C</td>
<td>Serology</td>
</tr>
</tbody>
</table>

* Screen at least annually; repeat screening every 3-6 months as indicated by risk. Consider anal Pap screening for MSM.

*Primary Care Guidelines for the Management of Persons Infected with HIV: 2009 Update by the HIVMA of the IDSA. Clin Infect Dis 2009;49, 651-681.*
CT and GC infections are common among MSM.

Chlamydia

- Urethral: 5.5
- Rectal: 8.8
- Pharyngeal: 1.3

Gonorrhea

- Urethral: 6.6
- Rectal: 7.5
- Pharyngeal: 9.4

Kent, CK et al, Clin Infect Dis 2005;41:67–74
Most Rectal Infections in MSM are Asymptomatic

Rectal Infections

- Chlamydia: 86% asymptomatic, n=316
- Gonorrhea: 84% asymptomatic, n=264

Urethral Infections

- Chlamydia: 42% asymptomatic, n=315
- Gonorrhea: 10% asymptomatic, n=364

Kent, CK et al, Clin Infect Dis July 2005
Proportion of CT and GC infections missed if screening only urine/urethral site

Chlamydia
Identified 23%
MISSED 77%

Gonorrhea
MISSED 95%
Only 5% identified with urine screening
95% MISSED if no rectal and throat screening

N=3398 asymptomatic MSM
San Francisco, 2008-2009

Marcus et al, STD Oct 2011; 38: 922-4
So What are the Barriers??!!??
Risk Assessment is NOT Routine

- Primary Care Providers: Bull *STD* 1999
- Private Physicians: Tao *AIDS* 2003
- Non-ID trained Physicians: Duffus *CID* 2003
- ID trained Physicians: Duffus *CID* 2003
- HIV Care Providers: Metsch *AJPH* 2004
Providers Say:

“Other than time, what barriers are there to discussing high risk sexual risk behaviors with your MSM patients?”

8/10 providers polled said - other priorities at time of visit

5/10 providers polled said- patients uncomfortable discussing this subject
Lab Issues for Rectal and Pharyngeal Testing

- NAATs highly sensitive and specific for CT/GC

- Validation procedures must be done by labs to allow use of a non-FDA-cleared test or application

<table>
<thead>
<tr>
<th>Company-Specific Ordering Codes for Combined GC/CT Nucleic Acid Amplified Tests (NAATs)</th>
<th>Company-Specific Ordering Codes for CT test only</th>
</tr>
</thead>
<tbody>
<tr>
<td>LabCorp*</td>
<td>Quest*</td>
</tr>
<tr>
<td>Rectal</td>
<td>188672</td>
</tr>
<tr>
<td></td>
<td>188706</td>
</tr>
<tr>
<td>Pharyngeal</td>
<td>188698</td>
</tr>
</tbody>
</table>

NAATs are offered at (or from) any location in the country with these two codes.

CPT Billing Codes

- CT detection by NAAT: 87491
- GC detection by NAAT: 87591

For information on specimen collection and transportation, contact the local reference laboratory representative.

*CDC does not endorse these laboratories, however, they represent the largest laboratories nationally. There may be other private laboratories that have verified rectal and pharyngeal testing with NAATs. Many PHLs have also verified rectal and pharyngeal testing.

CLIA Verified Labs for non-genital CT and GC NAATs list on NNPTC website (www.stdhivpreventiontraining.org) under Training Resources/Clinical Practice References.
• Clinical Decision Support Systems
  • 16/21 (76%) RCT showed improved outcomes for prevention measures¹
    • screening
    • counseling
    • testing
    • vaccination rate

• ACA supports use of HIT
  – Meaningful use guidelines

¹ Garg, AX; Adhikari, NK; McDonald, H; et. al. JAMA. 2005

http://www.healthit.gov/policy-researchers-implementers/meaningful-use
General Adoption of Mobile Tech.

% of Americans over 18 yr old with Mobile Devices

Cell Phones
- 1-Apr: 73%
- Dec-07: 75%
- May-09: 82%
- Aug-11: 84%
- May-11: 87%
- Aug-12: 89%
- Sep-12: 85%
- Jan-13: 91%

Tablet Computer
- May-10: 3%
- Apr-09: 8%
- May-11: 10%
- Aug-11: 19%
- Jan-12: 18%
- Apr-12: 25%
- Aug-12: 29%
- Dec-12: 31%
- Jan-13: 34%

Pew Research Center. 2013. pewinternet.org

I hope my Doctor’s Office is smarter than my phone…
Introducing.......... TaSHA

Tablet-based Sexual Health App

• Patient Survey

• Provider Report
  – Summary of patient’s data
  – STD testing recommendations
  – Education and counseling recommendations
An Adaptable Health Assessment App from Apex Education

- Extensive experience with HIT in school-based health centers
- Existing platform for iPad tailored for our purposes
- App is available to clinics by a licensing agreement
TaSHA is HIPAA Compliant

• Apex server stores tablet data
  • Apex develops data-sharing agreements with agencies
    – Both clinic and Apex have HIPAA obligations to protect patient privacy
    – Apex stores data, and can only share with clinic
  • CAPTC can only access de-identified data via aggregate reports
• Data transmission from iPad to Apex is synched via encryption
• iPad protections
  – Password protected
  – No information is stored on iPad (automatically erases)
  – iPad are locked and tethered
## Conceptualizing TaSHA

<table>
<thead>
<tr>
<th>Desired Outcomes</th>
<th>Goals for App’s Function</th>
</tr>
</thead>
<tbody>
<tr>
<td>Increase risk assessment</td>
<td></td>
</tr>
<tr>
<td>Increase STD screening</td>
<td></td>
</tr>
<tr>
<td>Increase risk reduction discussions</td>
<td></td>
</tr>
<tr>
<td>Simple and quick</td>
<td></td>
</tr>
<tr>
<td>Clear</td>
<td></td>
</tr>
<tr>
<td>Non-judgmental</td>
<td></td>
</tr>
<tr>
<td>Yield accurate information</td>
<td></td>
</tr>
</tbody>
</table>
Content and Design for TaSHA: An Iterative Process

Patient Survey
- Formulating the questions
  - Content
  - Reading level
- Used “single click” whenever possible
- Logic and skip patterns
- Gender-neutral, non-judgmental language

Reports (Clinical Decision supports)
- CDC Recommendations for STD tests
- Language for counseling phrases
- Layout on one page
Testing TaSHA

Tested with patients at a Ryan White clinic in San Francisco, CA

Average time 2 min. 50 sec.

Q: ‘Would you use this in a real life doctor visit?’

A: “Yes”

‘I prefer it to paper. Paper is boring.’

“It was easy”
TaSHA Demo

Start a Survey
### Provider Report

#### Summary of patient’s answers

- **Practice:** Sex in last 3 months: Yes
- **Venues:** new partner(s); Mobile Apps (Grindr, Radar, etc.)
- **Disclosure:** More than 1/2 the time
- **Sexual practices:** RAS, Receives oral sex, Gives oral sex
- **Condom use:** RAS Sometimes

#### Recommendations for STD testing according to national guidelines

<table>
<thead>
<tr>
<th>Screen</th>
<th>check for last annual test</th>
<th>test today</th>
</tr>
</thead>
<tbody>
<tr>
<td>Syphilis: serology, per protocol</td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td>Rectal CT and GC: rectal swab</td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td>Urogenital CT and GC: urine</td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td>Pharyngeal GC, pharyngeal swab</td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td>Recent STD Treatment Test for Gonorrhea</td>
<td>✓</td>
<td></td>
</tr>
</tbody>
</table>

#### Counseling Messages

<table>
<thead>
<tr>
<th># of partners</th>
<th>What types of relationships do you have with your partners—steady partners/boyfriend/girlfriend?</th>
<th>Friends you see from time to time? Casual partners?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Venues</td>
<td>Tell me about where you meet partners. How do you approach safer sex and using condoms?</td>
<td></td>
</tr>
<tr>
<td>Disclosure</td>
<td>What is your approach to discussing HIV status with partners?</td>
<td></td>
</tr>
<tr>
<td>HIV Transmission</td>
<td>What has been the most difficult part of discussing HIV status with partners?</td>
<td></td>
</tr>
<tr>
<td>Condom use</td>
<td>How do you protect your negative partners from acquiring HIV?</td>
<td></td>
</tr>
<tr>
<td></td>
<td>(Unprotectedtopping; condoms, oral sex only) How do you protect yourself and your partners from sexually transmitted infections?</td>
<td></td>
</tr>
<tr>
<td>Substance Use</td>
<td>Having anal sex, particularly as a “top”, can pass HIV to negative partners. Unprotected sex can spread STDs, which are more common among HIV+ MSM. What made it difficult to use condoms?</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Using drugs like Marijuana can be harmful to your health.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Have you thought about cutting back or quitting?</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Has your drug/alcohol use been a concern to you or your loved ones?</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Has your drug/alcohol use caused tension/problems in your relationships?</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Have you missed work/school because of alcohol or drugs?</td>
<td></td>
</tr>
</tbody>
</table>
Implementation/Integration
EMR Issues for TaSHA

• EMRs won’t allow direct importation of TaSHA’s data or report

Solutions:

• Print copy of report given to provider, can be scanned into EMR media tab
• Pad-to-pad data, and provider enters data into EMR charting checklist
Our Process for Implementation into Clinical Practice

• Assess baseline
  – Current RA practices
  – Current STD screening rates
    • Urine only vs Rectal and pharyngeal testing

• Make an implementation plan
  – Involve as many staff as possible
  – Tailor to clinic’s workflow and needs

• Evaluate for increase in STD screening rates after implementation of TaSHA
What’s Next for TaSHA?

- Travel to clinics in Federal Region IX (AZ, CA, HI, NV)
- TaSHA or a similar app in your clinic setting?

Our Field-Tested Best Practices!
Funds?? $$

- Find a Partner
  - An organization charged with building clinical capacity
    - Prevention Training Center
    - Capacity Building Assistance grantees
  - A university involved in Health Information Technology and Outcomes Research

- Remember that increased screening rates=increased revenue for clinic via billing
  - Use of TaSHA will pay for itself over time
Buy-In: Find a Champion or **Be** the Champion

---

Rogers, EM. The Diffusion of Innovation. 1995
Pre-Implementation Assessment

- Survey staff about current RA practices
- Obtain baseline STD testing data
  - Urine, rectal and pharyngeal
  - Work with IT and/or lab
  - Record review if no EMR
The Nuts and Bolts

- Consider patient volume, clinic flow, staff roles
- Equipment
  - Purchasing tablets and cases for security
  - WiFi
  - Printers
- EMR/charting issues
- Make it Official! Protocols get better results*

* Myers, JJ; Steward, WT; Charlebois, E; et. al. J Acquir Immune Defic Syndr. 2004
Train All Staff

• Present the clinic’s own data about STD screening rates
• Review importance of RA and recommended STD testing for your patient populations
• ‘Role Play’—Provide an opportunity for hands-on learning with TaSHA
Build in Evaluation

FIGURE 1. Elements of the RE-AIM Framework

- How do I incorporate the intervention so it is delivered over the long-term?
- How do I ensure the intervention is delivered properly?
- How do I develop organizational support to deliver my intervention?
- How do I reach the targeted population?
- How do I know my intervention is effective?

Glasgow, RE; Kessler RS; Purcell EP; et al. Eval Health Prof. 2013.
• Thank you!
• Ask us questions!
  – We’re excited about TaSHA and want to share!