European Association of Urology guidelines on vasectomy


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Vasectomy; Sterilisation; Male contraceptives; Vasectomy reversal; Pregnancy; Testis; Vasovasostomy; European Association of Urology (EAU); Guidelines

Abstract
Context: The European Association of Urology presents its guidelines for vasectomy. Vasectomy is highly effective, but problems can arise that are related to insufficient preoperative patient information, the surgical procedure, and postoperative follow-up.
Objective: These guidelines aim to provide information and recommendations for physicians who perform vasectomies and to promote the provision of adequate information to the patient before the operation to prevent unrealistic expectations and legal procedures.
Evidence acquisition: An extensive review of the literature was carried out using Medline, Embase, and the Cochrane Database of Systematic Reviews from 1980 to 2010. The focus was on randomised controlled trials (RCTs) and meta-analyses of RCTs (level 1 evidence) and on well-designed studies without randomisation (level 2 and 3 evidence). A total of 113 unique records were identified for consideration. Non-English language publications were excluded as well as studies published as abstracts only or reports from meetings.
Evidence synthesis: The guidelines discuss indications and contraindications for vasectomy, preoperative patient information and counselling, surgical techniques, postoperative care and subsequent semen analysis, and complications and late consequences.
Conclusions: Vasectomy is intended to be a permanent form of contraception. There are no absolute contraindications for vasectomy. Relative contraindications may be the absence of children, age < 30 yr, severe illness, no current relationship, and scrotal pain. Preoperative counselling should include alternative methods of contraception, complication and failure rates.

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and the need for postoperative semen analysis. Informed consent should be obtained before the operation. Although the use of mucosal cauter and fascial interposition has been shown to reduce early failure compared to simple ligation and excision of a small vas segment, no robust data show that a particular vasectomy technique is superior in terms of prevention of late recanalisation and spontaneous pregnancy after vasectomy. After semen analysis, clearance can be given in case of documented azoospermia and in case of rare nonmotile spermatozoa in the ejaculate at least 3 mo after the procedure.

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Guía clínica de la Asociación Europea de Urología sobre la vasectomía

Resumen

Contexto: La Asociación Europea de Urología presenta su guía clínica para la vasectomía. La vasectomía es muy eficaz, pero pueden surgir problemas que están relacionados con la falta de información preoperatoria del paciente, el procedimiento quirúrgico y el seguimiento postoperatorio.

Objetivo: Esta guía clínica tiene por objeto proporcionar información y recomendaciones para los médicos que realizan vasectomías y promover el suministro de información adecuada al paciente antes de la operación para evitar expectativas poco realistas y procedimientos legales.

Adquisición de la evidencia: Se llevó a cabo una revisión exhaustiva de la literatura mediante Medline, Embase, y la Base de Datos Cochrane de Revisiones Sistemáticas de 1980 a 2010. La atención se centró en los ensayos controlados aleatorizados (ECAs) y los metaanálisis de los ECAs (nivel 1 de evidencia) y en los estudios bien diseñados sin aleatorización (nivel 2 y 3 de evidencia). Un total de 113 registros únicos fueron identificados para su consideración. Se excluyeron las publicaciones que no estaban en lengua inglesa así como los estudios publicados como resúmenes solamente o informes de las reuniones.

Síntesis de la evidencia: La guía clínica debate las indicaciones y contraindicaciones de la vasectomía, la información y el asesoramiento preoperatorio del paciente, las técnicas quirúrgicas, los cuidados postoperatorios y posterior análisis de semen y las complicaciones y consecuencias finales.

Conclusiones: La vasectomía tiene la intención de ser un método anticonceptivo permanente. No hay contraindicaciones absolutas para la vasectomía. Las contraindicaciones relativas pueden ser la ausencia de hijos, edad <30 años, una enfermedad grave, ninguna relación actual y dolor en el escroto. El asesoramiento preoperatorio debe incluir métodos alternativos de anticoncepción, tasas de complicación y fracaso y la necesidad de análisis de semen postoperatorio. Se debe obtener consentimiento informado antes de la operación. Aunque el uso de cautero de la mucosa y la interposición fascial han demostrado reducir el fracaso temprano en comparación con la ligadura simple y resección de un segmento de vaso pequeño, no hay datos sólidos que muestren que una técnica de vasectomía en particular es superior en cuanto a prevención de la recanalización tardía y espontánea del embarazo después de la vasectomía. Tras el análisis de semen, se puede dar depuración en caso de azoospermia documentada y en el caso de espermatozoides inmóviles en la eyaculación por lo menos 3 meses después del procedimiento.

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Introduction

Vasectomy is the most reliable form of male contraception, and it is estimated that 40–60 million men worldwide rely on it. Although highly effective, problems can arise related to insufficient patient information before the procedure, to the actual surgical procedure, and to the process of postoperative follow-up until definitive sterility is achieved. Common long-term complications from vasectomy are scrotal pain, with about 1% reporting pain that noticeably affects quality of life, and spontaneous recanalisation of the vas deferens that occurs in 0.03–1.2% after previous clearance of spermatozoa in the semen. Furthermore, after 10 yr, about 2% of vasectomised men have a reversal operation because of a desire to have children, usually in a new relationship. The chance of a reversal request is increased in men who had a vasectomy at a young age and in those without children. It appears that the majority of men after vasectomy reversal have reduced semen quality, and sometimes additional artificial reproductive techniques are needed to achieve conception.

The aim of these guidelines is to provide information and recommendations for physicians who perform vasectomies and to emphasise the need to provide adequate information to the patient before the operation to prevent unrealistic expectations and legal procedures.
Table 1  Levels of evidence and grades of guideline recommendations, modified from the Oxford Centre for Evidence-based Medicine levels of evidence.9

<table>
<thead>
<tr>
<th>Level</th>
<th>Type of evidence</th>
</tr>
</thead>
<tbody>
<tr>
<td>1a</td>
<td>Evidence obtained from meta-analysis of randomised trials</td>
</tr>
<tr>
<td>1b</td>
<td>Evidence obtained from at least one randomised trial</td>
</tr>
<tr>
<td>2a</td>
<td>Evidence obtained from one well-designed controlled study without randomisation</td>
</tr>
<tr>
<td>2b</td>
<td>Evidence obtained from at least one other type of well-designed quasi-experimental study</td>
</tr>
<tr>
<td>3</td>
<td>Evidence obtained from well-designed nonexperimental studies, such as comparative studies, correlation studies, and case reports</td>
</tr>
<tr>
<td>4</td>
<td>Evidence obtained from expert committee reports or opinions or clinical experience of respected authorities</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Grade</th>
<th>Nature of recommendations</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>Based on clinical studies of good quality and consistency addressing the specific recommendations and including at least one randomised trial</td>
</tr>
<tr>
<td>B</td>
<td>Based on well-conducted clinical studies but without randomised clinical trials</td>
</tr>
<tr>
<td>C</td>
<td>Made despite the absence of directly applicable clinical studies of good quality</td>
</tr>
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Source: Oxford Centre for Evidence-based Medicine levels of evidence.9

Evidence acquisition

An extensive review of the literature was carried out using Medline and Embase from 1980 to 2010. Our key questions concerned indications for vasectomy, preoperative patient information, techniques of vasectomy, complications and failure rates of the procedure, postoperative follow-up, and semen analysis after vasectomy. Additionally, the Cochrane Database of Systematic Reviews was searched using the term vasectomy. The focus was on randomised controlled trials (RCTs), meta-analyses of RCTs, and well-designed studies without randomisation. A total of 113 unique records were identified for consideration. Non-English language publications were excluded as well as studies published as abstracts only or reports from meetings. Levels of evidence and grades of recommendation were added, modified from the Oxford Centre for Evidence-based Medicine levels of evidence9 (Table 1).

Indications

There are different motivations for having a vasectomy, but it is essential that the decision is made in a situation without stress or compulsion. Respect for the patient’s personal decision is essential. There are no absolute contraindications. Relative contraindications may be the absence of children, young age (<30 yr), severe illness, no current relationship, and scrotal pain.4

Essential patient information

Preoperative counselling for vasectomy must address the following items:

- The procedure should be considered irreversible.
- The procedure has a low complication rate.2,3
- The procedure has a low but existing failure rate.3,7,10
- Couples need to continue their contraceptive measures until sterility is achieved.
- All available data indicate that vasectomy is safe and is not associated with any serious, long-term side effects or disease.11

Information about contraceptive alternatives can be provided by general practitioners. The surgeon should provide additional information about the procedure; the advantages and risks associated with vasectomy; the need for postoperative semen analysis; and the chance of early failure and of late recanalisation, even if sterility is achieved, according to semen analysis.5

Vasectomy is not medically indicated, and alternatives for birth control are available. The risk of failure is not common knowledge. These arguments favour extensive preoperative patient counselling and strict documentation of the information provided. A written informed consent is recommended.

Technique

The basic principle of vasectomy is the discontinuation of the deferential ducts. This goal can be accomplished with several techniques, but some general principles apply:

- Vasectomy can be performed in an outpatient setting under local anaesthesia, but general anaesthesia might be required for specific indications.
- Both deferential ducts are exposed through one or two incisions.
- 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.12,13

For discontinuity, one of the following techniques can be applied:

- Excision of a piece of vas deferens and ligation with sutures or clips.
- Interposition of tissue to prevent recanalisation.14
- Cautery of the luminal side.15

Results of different vasectomy techniques have been reported, but comparisons of various techniques have not convincingly shown superiority of one particular approach in terms of preventing pregnancy.13 Some studies have shown that occlusion failure based on the results of postvasectomy
sperm analysis is the highest with simple excision and ligation with sutures and clips and the lowest with occlusion techniques combining cautery and fascial interposition.\(^\text{12}\)

### After the vasectomy

Usually, patients are advised not to work on the day after the operation. They are also advised to refrain from sport and exercise for a given period, which varies amongst physicians. After a short recovery period, 80% of patients return to normal activities within 1 wk.\(^\text{8}\) There is no need for routine wound consultation.

Semen analysis is an essential part of the follow-up of patients after vasectomy and is performed preferentially at 3 mo after the procedure. An adequate number of ejaculations, at least 20, should have occurred in those 3 mo.\(^\text{16}\) Semen analysis after vasectomy is best performed in a certified laboratory according to the recommendations of the World Health Organization.\(^\text{17,18}\)

There is general consensus that men can be given clearance if no spermatozoa are found in the ejaculate. At least 80% of men have no spermatozoa found in their ejaculate 3 mo after vasectomy\(^\text{19}\); in these men, no further follow-up is needed. In some men, low numbers of nonmotile spermatozoa are present and can persist for a longer period of time. These men can be given clearance,\(^\text{17,19}\) if <100,000 nonmotile spermatozoa per millilitre are present 3 mo after vasectomy.\(^\text{17,19}\) In case of persistent motile spermatozoa after 6 mo of follow-up, it is advised that the vasectomy be redone.

Reappearance of motile sperm is rare: In a study of 534 patients who had no or rare nonmotile sperm, only two patients showed motile spermatozoa at repeat examination.\(^\text{20}\) Furthermore, motile spermatozoa can be found in some cases even after two previous examinations that have shown no spermatozoa.\(^\text{21}\)

In case of rare nonmotile spermatozoa after vasectomy, a special clearance is advised.\(^\text{7}\) Special clearance suggests that contraceptive measures are no longer needed but also that no 100% guarantee can be given for permanent sterility. However, not even azoospermia can guarantee future permanent sterility.\(^\text{6,22}\) The surgeon should consider his or her national recommendations for the decision of postvasectomy semen controls and for clearance.

### Complications and late consequences

A low frequency of complications is associated with vasectomy. Different definitions of complications in the literature have resulted in different frequencies:

- Postoperative bleeding and haematoma: 4–22%\(^\text{2}\)
- Infections: 0.2–1.5%; generally, infections are mild and limited to the wound site, but Fournier’s disease has been reported.\(^\text{14,23}\)
- Chronic scrotal pain: 1–14%, usually mild but sometimes requiring pain management or surgery.\(^\text{4}\)
- Early recanalisation, persistence of motile spermatozoa in the ejaculate for which reoperation is indicated: 0.2–5.3%.\(^\text{24}\)
- Late recanalisation after previous clearance: 0.03–1.2%,\(^\text{1,7,8}\)

### Recommendations

#### Patient information

Informed consent should be obtained before the operation. Preoperative counselling must address the items concerning vasectomy that are listed in section “Essential patient information” of these guidelines.

Before the procedure, the physician should:

- Be convinced that the patient voluntarily abstains from reproduction. In case of doubt, it can be useful to introduce a period of reconsideration.
- Be informed about the health status of the patient and any contraindications or increased risk for complications.
- Discuss the vasectomy technique to be used, including the advantages and disadvantages, the chance of recanalisation, and the goal of permanent sterility after the procedure.
- Consider young patient age and absence of a relationship as relative contraindications for vasectomy.
- Discuss alternatives to vasectomy as well as potential complications, success rate, and chance of failure.
- Stress the need for contraceptive measures until sterility has been shown as well as the need for semen analyses at 3 mo after the operation.
- Provide (written) information about the procedure of semen analysis and how results are communicated.
- Inform the patient that no 100% guarantee can be given of permanent sterility and that recanalisation infrequently occurs.
- Provide additional written information and allow the patient to study the information and discuss it with his partner.
- Obtain (written) informed consent.

#### The procedure

Most surgeons will perform the vasectomy according to personal preferences; however, the following steps can be recommended:

- Use one of the three common techniques of vasectomy (see section "Technique").
- Apply safety measures for the technique used, such as interposition of tissue between both ends of the dissected vas and cautery of the vas ends.
- Describe the technique used in a standard operating room report, including precautionary measures taken to prevent recanalisation.

There is no need for routine pathological examination of the vas because usually it can be recognised easily. Not performing this examination also saves costs for the patient. In case of doubt about the nature of the tissue removed, pathological examination is advised.
The results of the semen analysis should be communicated by telephone or in writing to the patient. The results are documented in the files together with the informed consent and the report of the vasectomy.

Summary of conclusions and recommendations on vasectomy

The conclusions and recommendations on vasectomy are reflected in Table 2.

Table 2  Conclusion and recommendations on indications for vasectomy and patient information.

<table>
<thead>
<tr>
<th>LE</th>
<th>GR</th>
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<tbody>
<tr>
<td>Conclusion and recommendations on indications for vasectomy and patient information</td>
<td>4</td>
</tr>
<tr>
<td>Relative contraindications for vasectomy may be the absence of children, age &lt; 30 yr, severe illness, no current relationship, and scrotal pain.</td>
<td></td>
</tr>
<tr>
<td>Counselling of patients before vasectomy should include alternative methods of contraception, complication and failure rates, and the need for postoperative semen analysis.</td>
<td>4</td>
</tr>
<tr>
<td>Written informed consent is recommended before the operation.</td>
<td></td>
</tr>
<tr>
<td>Conclusions and recommendations on vasectomy technique</td>
<td>1a</td>
</tr>
<tr>
<td>Early recanalisation can be decreased by cautery (with either thermal or electrocautery devices) of the vas deferens and by fascial interposition.</td>
<td></td>
</tr>
<tr>
<td>To date, no vasectomy technique has been shown to be superior in terms of prevention of late recanalisation and spontaneous pregnancy after vasectomy.</td>
<td>2a -</td>
</tr>
<tr>
<td>Recommendations on semen analysis after vasectomy</td>
<td>2a</td>
</tr>
<tr>
<td>After semen analysis, clearance can be given in case no spermatozoa are found in the ejaculate.</td>
<td></td>
</tr>
<tr>
<td>Clearance can be given if &lt;100 000 nonmotile spermatozoa per millilitre are present in the ejaculate.</td>
<td>3</td>
</tr>
</tbody>
</table>

LE = level of evidence; GR = grade of recommendation.

Follow-up after the procedure

Wound examinations are not routinely needed. The patient, however, should know whom to contact in case of problems. Clear oral and written information should be provided about the need to perform semen analysis at 3 mo after vasectomy. Sterility can be concluded if no spermatozoa are found in the ejaculate. In case of the presence of <100 000 nonmotile spermatozoa per millilitre, clearance can also be given 3 mo after the procedure.

Consequences from the results of semen analysis

In case no spermatozoa are found or in the presence of rare nonmotile spermatozoa, further semen analysis is not needed. Repeat the examination at 6-wk intervals if motile spermatozoa are found or if >100 000 spermatozoa per millilitre are present. Reexamination should be continued until no more spermatozoa are found or <100 000 nonmotile spermatozoa per millilitre is obtained and clearance can be given. Redoing the vasectomy is recommended if motile spermatozoa continue to be present in the ejaculate at 6 mo after the procedure.

Summary of conclusions and recommendations on vasectomy

The conclusions and recommendations on vasectomy are reflected in Table 2.

Author contributions

Gert R. Dohle had full access to all the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.

Study concept and design: Dohle.

Acquisition of data: Dohle, Diemer, Kopa, Krausz, Giwercman, Jungwirth.

Analysis and interpretation of data: Dohle, Diemer, Kopa, Krausz, Giwercman, Jungwirth.

Drafting of the manuscript: Dohle.

Critical revision of the manuscript for important intellectual content: Dohle, Diemer, Kopa, Krausz, Giwercman, Jungwirth.

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Supervision: Dohle.

Other (specify): None.

Funding/support and role of the sponsor

None.

Conflict of interest

I certify that all conflicts of interest, including specific financial interests and relationships and affiliations relevant to the subject matter or materials discussed in the manuscript (e.g., employment/affiliation, grants or funding, consultancies, honoraria, stock ownership or options, expert testimony, royalties, or patents filed, received, or pending), are the following: Dr. Dohle has nothing to disclose. Dr. Diemer has a family member who is an employee of and has equity interests in Lilly Deutschland GmbH, Eli Lilly; has received company speaker honoraria from Bayer Vital GmbH, Bayer Healthcare, AMS American Medical Systems; and has received research grants from Takeda Pharma (as collaborator with PI Dr. V. Rohde). Dr. Kopa is a company consultant for and has received company speaker honoraria from Bayer-Schering, Pfizer, and Lilly. Dr. Krausz has received a research grant from Bioxell Milan (1-yr grant for research fellowship for year 2007). Dr. Giwercman is a company consultant for Bayer-Schering, has participated in trials for ProStrakan and Bayer-Schering, and has received research grants from Merck-Serono and Ferring. Dr. Jungwirth is a company consultant for Pfizer Austria; has received company speaker honoraria from Pfizer Austria, Eli Lilly,
Bayer Schering Healthcare, and Janssen Cilag; and has participated in trials for Janssen Cilag and Eli Lilly.

References