Evidence Essential

Veress needle laparoscopic entry technique

ASERNIP-S REPORT NO. 76

September 2010

Australian Safety & Efficacy Register of New Interventional Procedures - Surgical

The Royal Australasian College of Surgeons
Veress needle laparoscopic entry technique

ISBN 978-0-9806299-8-9
Published September 2010

This report should be cited in the following manner:

Copies of these reports can be obtained from:
ASERNIP-S
PO Box 553,
Stepney, SA 5069
AUSTRALIA
Ph: 61-8-8363 7513
Fax: 61-8-8362 2077
E-Mail: asernips@surgeons.org
http://www.surgeons.org/asernip-s
The Evidence Essential of
Veress needle laparoscopic entry technique
Was ratified by the ASERNIP-S Advisory Committee on 18 June 2010
Approved by the Research Audit and Academic Surgery Board on 5 July 2010
Received by the Professional Development and Standards Board on 4 August 2010
Noted by the Council of the Royal Australasian College of Surgeons on 27 August 2010
ASERNIP-S Evidence Essentials

PURPOSE AND SCOPE
The ASERNIP-S Evidence Essentials document is a structured literature review on a given health technology (procedure or device). It may be produced where current published systematic review evidence is available on a procedure nominated for ASERNIP-S assessment.

The Evidence Essentials is designed to inform on the existence and findings of high-level evidence such as systematic reviews and health technology assessments. In this way it reduces duplication of endeavour and provides rapid and timely information to interested end-users, particularly those who have approached ASERNIP-S to investigate the given topic. Evidence Essentials intends to provide a summary of the high-level evidence base, including an appraisal of the quality and appropriateness of the published evidence; a commentary on the appropriateness of the data to the Australian locality (if possible); and a summary of the overall conclusions of the published evidence.

METHODOLOGY
Evidence Essentials presents summary high-level evidence arising from current, English language systematic reviews (published within two years as either a full systematic review/health technology assessment or a peer-reviewed publication). For this purpose, systematic reviews are defined as those studies that meet all the following criteria as defined by Cook et al (1997) (focused clinical question, explicit search strategy, use of explicit, reproducible and uniformly applied criteria for article selection, critical appraisal of the included studies, qualitative or quantitative data synthesis). Evidence Essentials does not encompass any new synthesis of primary data.

Evidence Essentials also provides a comment on any clinical trials in progress, to provide an indication of the current status of research, and also presents available clinical practice guidelines.

Where necessary, recent non-systematic clinical reviews are used to provide background information on the indications and technology. These papers are cited at the end of the document. Evidence Essentials provides a summary on available high-level evidence on a given topic, but does not include direct input from clinical experts as it is anticipated that the included studies have incorporated clinical input as part of their methodology.

INTRODUCTION

DEVICE/PROCEDURE

Veress needle laparoscopic entry.

Laparoscopy allows direct visualisation of the abdomen or pelvis and enables minimally invasive surgery to be performed (Ahmed et al 2008). Most complications in laparoscopic procedures relate to the initial step of entry into the abdomen, with complications such as injury to blood vessels or viscera in the abdomen rare but potentially life-threatening (Middlesbrough Consensus 1999). The Veress needle laparoscopic entry technique is a common entry method used to insert a laparoscope into the abdomen, via creation of a pneumoperitoneum (inflation of the abdomen with gas) (Azevedo et al 2009). The Veress needle technique involves the blind insertion of a spring loaded disposable or reusable Veress needle through a small skin incision into the
peritoneal cavity, to allow gas insufflation. This is followed by blind insertion of the first trocar, through which the laparoscope is introduced (Ahmed et al 2008).

**INDICATION**
Laparoscopy is regularly used in gynaecology, general surgery and urology, and can also be used in other specialties such as cardiovascular and orthopaedic surgery. Common laparoscopic procedures include laparoscopic cholecystectomy, gynaecological laparoscopy, and laparoscopic sterilisation (Merlin et al 2001). In gynaecology, laparoscopy can be used to examine the outside of the uterus, the fallopian tubes, and the ovaries, for diagnosis and/or treatment of conditions such as endometriosis, ectopic pregnancy, ovarian cysts, infertility and cancer. Laparoscopy is used in general surgery to examine the abdominal organs, including the intestines, gallbladder, bile ducts, liver, pancreas and appendix. Examples of general or urological laparoscopic procedures include cholecystectomy, bile duct exploration, appendicectomy, hernia repair, gastric bypass surgery, bowel resection, liver resection, adrenalectomy, nephrectomy and prostatectomy. The Veress needle technique can generally be used at the commencement of any laparoscopic procedure, although additional caution is required for patients with scarring from previous abdominal surgery, and in very thin or morbidly obese patients (RCOG 2008).

**ALTERNATIVE TREATMENTS**
Laparoscopy is used as a minimally invasive alternative to open surgery. Methods available for creating a pneumoperitoneum and inserting the laparoscope at the beginning of a laparoscopic procedure can be divided into open or closed entry techniques. Closed techniques include the Veress needle technique and the direct trocar technique, which involves the blind insertion of a trocar directly into the peritoneal cavity, followed by laparoscopic inspection and subsequent gas insufflation (Ahmed et al 2008). The open (Hasson) technique consists of an initial incision into the peritoneum allowing direct visualisation of the insertion of a blunt trocar, before gas insufflation and laparoscope introduction (Ahmed et al 2008). Other entry options include hybrid visual/closed techniques (such as optical Veress needles or optical trocars), and radially expanding access trocars (Ahmed et al 2008, Merlin et al 2001).

**CURRENT FUNDING STATUS IN AUSTRALIA**
The Veress needle laparoscopic entry technique is not listed as an individual Medicare Benefits Schedule (MBS) item number. Rather, the relevant MBS item numbers refer to entire laparoscopic procedures, which could include entry using the Veress needle.

**AVAILABLE HIGH LEVEL EVIDENCE**
A systematic search of the literature was carried out to identify available, current, English-language systematic reviews and health technology assessments. The databases searched and terminologies used are included at Appendix A.

**RELEVANT UNIQUE CITATIONS IDENTIFIED**
- Laparoscopic entry techniques (Ahmad et al, *Cochrane Database of Systematic Reviews* 2008).
- Other reviews of interest, guidelines and clinical trials are summarised in Appendix B.
EVIDENCE APPRAISAL

The quality of the identified systematic reviews was assessed using key items from the QUOROM statement (Moher et al 1999).

Ahmed et al (2008) included randomised controlled trials (RCTs) to compare a number of different interventions in diverse patient populations. Study methodology was adequately described, and included RCTs were assessed for quality and risk of bias. Study outcomes were reported narratively and quantitatively using meta-analyses.

Azevedo et al (2009) used broad inclusion criteria, with no restrictions regarding the type of study included, the characteristics of patients, or the surgical details of the intervention. The study methodology was only briefly described, and no detail was provided for study characteristics, making it difficult to determine if the grouping of studies was valid. The review did not make comparisons between the intervention of interest and alternative techniques, thereby limiting the conclusions that could be made.

<table>
<thead>
<tr>
<th>Domain</th>
<th>Ahmad et al 2008</th>
<th>Azevedo et al 2009</th>
</tr>
</thead>
<tbody>
<tr>
<td>Question</td>
<td>To compare different laparoscopic entry techniques in terms of their influence on intra-operative and post-operative complications</td>
<td>To assess the prevalence, risks, and outcomes of injuries caused by the Veress needle described in the literature</td>
</tr>
<tr>
<td>Selecting</td>
<td>Inclusion criteria sufficient. Exclusion criteria not reported.</td>
<td>Brief inclusion and exclusion criteria</td>
</tr>
<tr>
<td>Study flow</td>
<td>Not reported</td>
<td>Not reported</td>
</tr>
<tr>
<td>Validity assessment</td>
<td>Comprehensive</td>
<td>Not reported</td>
</tr>
<tr>
<td>Data abstraction</td>
<td>Processes described</td>
<td>Not described</td>
</tr>
<tr>
<td>Study characteristics</td>
<td>Comprehensive</td>
<td>Brief</td>
</tr>
<tr>
<td>Data synthesis</td>
<td>Narrative description of selected studies and statistical analysis (meta-analyses with odds ratios and 95% confidence intervals, with tests for heterogeneity)</td>
<td>Narrative description with quantification of injury prevalence</td>
</tr>
</tbody>
</table>

SUMMARY OF FINDINGS

In both reviews, the main outcomes examined related to safety and the occurrence of complications during laparoscopic entry.

Ahmed et al (2008) included 17 RCTs of 3040 participants undergoing laparoscopy, and found no evidence of advantage using any single laparoscopic entry technique in terms of preventing major complications. Specifically, the review identified two RCTs which compared the closed entry Veress needle technique with the open entry technique, with a total of 212 participants. A meta-analysis did not demonstrate an advantage of using...
either an open entry or closed Veress needle entry in terms of vascular injury and visceral injury, with odds ratios of 0.14 (95% confidence interval (CI) 0.00 to 6.82; P=0.32) and 1.00 (95%CI 0.06 to 16.14; P=1.0) respectively. One study reported no complications for either technique. Six RCTs were included which compared the Veress needle technique with direct trocar access, with a total of 1909 participants. Meta-analysis demonstrated an advantage of using direct trocar entry in terms of reduced extraperitoneal insufflation and decreased failed entry into the abdomen compared to Veress needle entry, with odds ratios of 0.06 (95%CI 0.02 to 0.23; P<0.00001) and 0.22 (95%CI 0.08 to 0.56; P=0.00031) respectively. There was no evidence of an advantage for either technique in terms of avoiding solid organ entry. No RCTs were identified which compared the Veress needle technique with direct vision entry. Regarding variations to the Veress needle technique, a single RCT found no advantage of either trans-fundal or infra-umbilical insertion of the Veress Needle. Another RCT identified an advantage of not lifting the abdominal wall before Veress needle insertion compared to lifting, in terms of successful entry without an increase in the complication rate (Ahmed et al 2008).

Azevedo et al (2009) included 39 studies that reported iatrogenic injury from the Veress needle during diagnostic or therapeutic laparoscopy. No comparative analysis of outcomes with alternative approaches was undertaken. A total of 1,575 injuries were caused by the Veress needle in 696,502 procedures (0.23% of procedures). Of these, 126 (8% of injuries, 0.018% of procedures) were injuries to blood vessels or hollow viscera, including 42 major vascular injuries and 17 major hollow viscera injuries. The remaining 1,449 injuries were minor injuries (neither vascular nor to hollow viscera). The authors suggested further studies which investigate alternative sites for insertion of the Veress needle (Azevedo et al 2009).

OTHER CONSIDERATIONS

A number of recent clinical guidelines on laparoscopic entry techniques are available, some of which are evidence-based (Appendix B). In the same way as the systematic reviews, these clinical guidelines are limited by the quality of evidence on the comparative safety of the different entry techniques. While the review by Ahmed et al (2008) found no existing RCT evidence that the open technique is safer than the closed Veress needle technique, the available RCTs either excluded patient groups which may be more at risk of injury during the closed technique (i.e. those with an existing abdominal scar or low body weight) or did not clearly state exclusion criteria (Ahmed et al 2008). RCTs are often undertaken to strict criteria in large teaching hospitals, which may not always be reflective of standard care. Another limitation noted by Ahmed et al (2008) was that available RCTs were small and had insufficient power to demonstrate an advantage for any entry technique in terms of reduced major complication rates. RCTs with sufficient power to detect a significant reduction in risk of major complications require very large numbers of participants in each intervention group. The review suggested that an alternative to RCTs may be the maintenance of large databases of reported major complications (Ahmed et al 2008). The review did not include lower level evidence, but highlighted that some retrospective studies had reported that an open technique to establish pneumoperitoneum is safer than the closed technique, in terms of avoiding major visceral and vascular injury (Ahmed et al 2008).
CONCLUSIONS

Two recent systematic reviews on Veress needle laparoscopic entry were identified. The main outcome examined in both reviews was complications caused by the entry technique. As demonstrated in the recent review by Ahmed et al (2008), there is insufficient high level evidence regarding the safety of the Veress needle and other entry techniques to determine a benefit of one over another. At this time a further full systematic review is unlikely to reach a different conclusion, although the inclusion of lower level studies may add value to the assessment, especially in terms of adverse events.

A commentary has been provided by the Royal Australian and New Zealand College of Obstetricians and Gynaecologists (RANZCOG) regarding their experience in the use of the Veress needle. This is shown in full in Appendix C.

Please note that this Evidence Essentials document is not a comprehensive systematic review of the safety and effectiveness of the Veress needle laparoscopic entry technique, and should not be used for this purpose. This document presents a summary of the current, available high-level evidence.

REFERENCES

SYSTEMATIC REVIEW EVIDENCE USED TO PRODUCE THIS EVIDENCE ESSENTIALS DOCUMENT


FURTHER REFERENCES USED


Royal Australian & New Zealand College of Obstetricians & Gynaecologists (RANZCOG) and the Australian Gynaecological Endoscopy Society (AGES). Use of the Veress needle to obtain pneumoperitoneum prior to laparoscopy. RANZCOG College Statement: C-Gyn 7, 2008.


### DATABASES SEARCHED AND SEARCH TERMS USED

<table>
<thead>
<tr>
<th>Database</th>
<th>Search terms</th>
<th>Date searched</th>
</tr>
</thead>
<tbody>
<tr>
<td>Systematic reviews/health technology assessments</td>
<td>York CRD (<a href="http://www.crd.york.ac.uk/crdweb/">http://www.crd.york.ac.uk/crdweb/</a>) Veress needle OR verres needle</td>
<td>10 March 2010</td>
</tr>
<tr>
<td>Systematic reviews/health technology assessments</td>
<td>The Cochrane Library (<a href="http://www.cochrane.org/">http://www.cochrane.org/</a>) Veress needle OR verres needle</td>
<td>10 March 2010</td>
</tr>
<tr>
<td>Current trials</td>
<td>Current Controlled Trials (<a href="http://www.controlled-trials.com/">http://www.controlled-trials.com/</a>) Veress needle OR verres needle</td>
<td>23 March 2010</td>
</tr>
<tr>
<td>Current trials</td>
<td>Clinical Trials.gov (<a href="http://www.clinicaltrials.gov/">http://www.clinicaltrials.gov/</a>) Veress needle OR verres needle</td>
<td>23 March 2010</td>
</tr>
<tr>
<td>Clinical practice guidelines</td>
<td>Trip database (<a href="http://www.tripdatabase.com/index.html">http://www.tripdatabase.com/index.html</a>) Veress needle OR verres needle</td>
<td>10 March 2010</td>
</tr>
</tbody>
</table>

**NOTES:** CRD Centre for Reviews and Dissemination
CLINICAL PRACTICE GUIDELINES AND CURRENT CLINICAL TRIALS

CLINICAL GUIDELINES
• The European Association for Endoscopic Surgery clinical practice guideline on the pneumoperitoneum for laparoscopic surgery (Neudecker et al, Surgical Endoscopy 2002)
• Preventing entry-related gynaecological laparoscopic injuries (The Royal College of Obstetricians and Gynaecologists (RCOG) Green-top Guideline no. 49, 2008)
• Use of the Veress needle to obtain pneumoperitoneum prior to laparoscopy (Royal Australian & New Zealand College of Obstetricians & Gynaecologists (RANZCOG) and the Australian Gynaecological Endoscopy Society (AGES), 2008).

CURRENT CLINICAL TRIALS IDENTIFIED
• XCEL Bladeless Trocar Versus Veress Needle: A Randomised Controlled Trial Comparing These Two Entry Techniques in Gynaecological Laparoscopic Surgery.

OTHER REVIEWS
• Open versus closed laparoscopy entry – Which are the evidences? (Opilka et al, Hepato-Gastroenterology 2009). This additional recent review was excluded as it did not state whether systematic methodology was applied. It reached the conclusion that the open technique for laparoscopic entry was associated with fewer surgical complications than the closed Veress needle technique, but acknowledged that this finding was supported by a low level of evidence.
COMMENTARY BY THE ROYAL AUSTRALIAN AND NEW ZEALAND COLLEGE OF OBSTETRICIANS AND GYNAECOLOGISTS (RANZCOG) REGARDING THE USE OF THE VERESS NEEDLE.

The Veress needle was invented by respiratory physician Janos Veress in 1938 (1) for the creation of pneumothoraces in the treatment of pulmonary tuberculosis. It was later popularized in the 1960s by Professor Kurt Semm for the production of pneumoperitoneum in gynaecological laparoscopy. The technique of open laparoscopy was first described by Harrith Hasson in 1971 (2). While open entry has become more widely used in recent years, the Veress needle is still very commonly used by gynaecologists for laparoscopic entry. This is in contrast to surgeons, who have adopted laparoscopy at a much later point in its evolution, and who almost exclusively use open laparoscopy. It should be noted that all entry techniques have an incidence of visceral and vascular complications. Randomised trials show no particular advantage of open laparoscopy over Veress needle in this respect. Furthermore evaluation of newly developed techniques for entry are limited by the need for large numbers in each arm of a randomised trial to be able to show any difference in complication rates between any two methods of entry.

An important point is that the Veress needle should be used with the recommended technique. RANZCOG and AGES have published a joint statement (C-Gyn7) outlining the correct use of the Veress needle. This statement is available from the RANZCOG website on the publications / college statements page of the website. It should also be noted that if there are peri-umbilical or lower abdominal adhesions “Palmers Point”, may be a safer location for entry with the Veress needle.

References
1. Veress J. neues instrument sur Ausfuhrung von Brustoder Deutsche Medizinische Wochenschrift 1938; 64: 1480-1