TITLE: Evaluation of the New Veress Needle+ Mechanism; A Pre-clinical Study on Thiel-embalmed Bodies.

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Date/Version: 29-3-2021 Vs. 2

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1. Background and significance

Complications that occur in laparoscopic surgery are often associated with the initial entry into the peritoneal cavity. The literature reported incidences of Veress Needle (VN) injuries of e.g. 0.31% and 0.23% . In a 2010 national survey of laparoscopic entry techniques in the Canadian General Surgical practice, 57.3% of respondents had either experienced or witnessed a serious laparoscopic entry complication like bowel perforation and vascular injury. As those complications are potentially life threatening and should be avoided at all costs, improving safety of this initial action is paramount.
Based on a bare minimum design approach with focus on function expansion of existing components, a new Safety mechanism was developed for the VN that decreases the risks of VN overshooting. The mechanism works by preventing the puncturing acceleration of the tip of the VN by decoupling the surgeon's hand from the VN immediately after entering the abdomen.
A first prototype of our so called VN**+** with force decoupling mechanism proved very reliable in reducing overshooting in an ex-vivo model.

2. Study objective(s):

The purpose of the study is to repeat our previous ex-vivo experiments in a real-life laparoscopic set up in a human/cadaveric model.
The primary objective will be to establish what the amount of benefit will be in using the VN**+** as compared to a standard VN. We need to measure in a life-like situation what the reduction of the overshoot will be while in the hands of novices, junior residents and experts to validate the learning curve. Other secondary objectives are establishing the amount of haptic feedback of the VN+ compared to the standard VN and potential safety issues. All the practical investigations will need to take place in the ASC. Data study and technical alterations on the instruments will take place at the TU Delft.

3. Methods

3.1 Study design, population and procedures

Study design: open randomized controlled prospective cross over cohort study
Study population: A) group of 10 novices, B) group of 10 surgical, urological or gynaecological residents, C) group of 10 experts consisting of surgeons, urologists or gynaecologists.
Study procedure: After information is given on the purpose and set up of the experiment all participants will be asked to sign an informed consent form.
A video will be shown of the working of a normal VN and of the VN+. After this a detailed video will be shown wherein all basic steps of the procedure are outlined. Then after randomization half of the group will start with a VN and the other half with the VN+. After 5 attempts the groups will switch device and repeat the procedure.

3.2 Procedure and anatomical considerations

After making a small skin incision the insertion of the Veress needles will be:
- at Palmer's point which is 2-3 cm below the left costal margin in the midclavicular line.
- right below the umbilicus after lifting the skin with a clamp

A "grid" will be drawn on the skin. Guided by the grid each attempt will be in a new and unused part of the abdominal wall.
As in total 300 VN(+) insertions have to be performed we will probably need three cadavers

The anatomical region to be used will thus be the abdomen.
In order to see what depth the different needles reach and the possible anatomical structures that will be injured, we will first introduce a laparoscope in the left (or depending on the cadaver the right) lower abdominal quadrant via an open technique and establish pneumoperitoneum through this laparoscope trocar with a pressure that is as low as possible.
Then measurements will take place through recording the number of marks on the needle (previously laser engraved) that are to be seen in the abdomen. The actions will all be filmed and photographed.

4. Data collection and analysis

In all three groups the measured maximum insertion depths will be calculated in Excel and then any differences between the conventional (VN) and the modified (VN+) groups will be determined with a Mann-Whitney test (SPSS v16, SPSS inc. Chicago, IL) as the data will not be normally distributed. A p-value<0.05 will be considered significant.
All inadvertent tissue or organ damage will be determined and compared between the two types of needles and the groups using a Student T-test (SPSS v16, SPSS inc. Chicago, IL).
A questionnaire (with a Likert scale) will be used to establish the amount of haptic feedback the subjects experience with either the VN or the VN+ at the two different entry sites.

5. Data and study record management

Data and video footage will be stored on a secured TU Delft laptop and designated secured part of the 3ME faculty TU Delft server. All personal information of individuals taking part in this study will be anonymized.

6. Study Limitations

Limitations:
- different tissue volume and elasticity compared to living tissue
- intraabdominal organs will not react the same way as in living human being
- to be able to determine depth of insertion a small pneumoperitoneum has to be created which in real life situations will not be the case

7. Ethical Considerations

If the VN+ really does make a significant difference in safety of VN insertion its use will lead to a worldwide reduction in morbidity and mortality caused by VN insertion. A pilot study in an ex-vivo animal (pig) model showed significant positive results. In order to take the step to clinical implementation experiments on human tissue are paramount.

8. Plans for dissemination of findings

The results of this study will be disseminated to a clinical scientific audience through publishing in peer reviewed clinical surgical journals and participation in relevant international congresses and symposia.
Adequate references to our use of the specimens and associated anatomy departments will be given.

Amsterdam Skills Centre – Research Request Protocol – Template 2021

The following protocol will be presented to an ethics committee. This committee comprises of a professor in medical ethics, a professor in anatomy, two legal councils and two surgeons. Based on your answers provided, a decision will be made as to whether the proposed research can take place on human specimens, derived from the Dutch body donation program, within the Amsterdam Skills Centre. Once a decision has been reached, we will notify you of the outcome and provide you with a cost estimate.