

HOME COPY

- 1 -

TRANSVAGINAL TUBE AS AN AID TO LAPAROSCOPIC SURGERY

THIS INVENTION relates to a transvaginal tube which is particularly useful in laparoscopic surgery, and also to a procedure for the use of such a tube.

Modern advances in laparoscopic surgical equipments have meant that surgeons are able to remove the uterus and/or ovaries laparoscopically, removing the need for a long abdominal incision.

A laparoscopic radical hysterectomy for cancer has evolved from the efforts of a few oncology centres with an interest in minimising invasive surgery. The operative technique is analogous to a modification of the operation originally described by Wertheim and Meigs. The laparoscope surgeon passes a 10mm laparoscope trans-abdominally through a sub-umbilical incision after establishing a pneumoperitoneum. Using two lateral portals the ovarian pedicles are divided down to the level of the uterine arteries. The ureter is isolated and protected and the uterine vessels and parametrium are divided after mobilising the bladder. The next stage is to remove the uterus and close the vaginal vault so the pneumoperitoneum can be re-established for the lymphadenectomy. The lymph nodes are removed by plucking them from their bed and dragging them out of the abdomen through the trans-abdominal wall port used for the grasping forceps.

Various medical commentators suggest that laparoscopically assisted radical hysterectomy (colloquially known as

This Sheet Has Been Replaced



REPLACED SHEETS SG

- ☒ Description : paged to paged13.....
- ☒ Claim(s) : paged14..... to paged15.....
- ☒ Drawing(s) : paged16..... to paged17.....
- ☒ Abstract : paged18..... to paged19.....

DATE OF RECEIPT

- 2 -

"keyhole Wertheims") offers many advantages. Patients go home earlier and the convalescence period is shorter. The disadvantage is that the additional laparoscopic surgery increases operative time.

Plastic bags have been used to harvest ovaries in an attempt to minimise the contamination of metastatic material through the ports. However, these are fiddly to use and can be difficult to drag out of the abdominal port. Nonetheless, one study has demonstrated that ordinary plastic bags are just as effective as commercially available customised bags and ovaries and omentum can be placed in a bag and delivered through the vagina. This is an excellent refinement for ovarian surgery but it is difficult to place multiple small nodes in several bags and be sure of their origin.

The present invention provides a transvaginal tube, and a procedure for using that tube, which is suitable for use in laparoscopic surgical techniques.

According to one aspect, the present invention provides a transvaginal tube adapted for insertion into the vaginal tract for the exteriorization of intra-abdominal tissue, the tube having a diameter greater than the cervix opening and having a distal end and a proximal end, the proximal end being cut in a plane non-normal to the tubular axis and being adapted to define a cervico-vaginal junction.

Preferably, the proximal end of the transvaginal tube is bevelled so that the leading or anterior edge of the tube protrudes beyond the posterior edge. In this respect, the anterior edge is, for example, 1 to 2 cm longer than the posterior edge. To avoid tissue damage in use, the edge of the tube surrounding the open bevelled end may be adapted



- 3 -

to have a smooth edge. This may, for example, be achieved by moulding or shaping the tube with smooth convex edges or by attaching a cover means to the proximal end of the tube walls which blankets and provides a smooth surface over the wall of the bevelled open end of the tube.

The transvaginal tube may be formed of any material. However, the tube is preferably made of a plastic material which provides a degree of flexibility.

Preferably, the tube is also substantially transparent. It will be appreciated that the tube may also be formed of opaque material but may contain one or more transparent portals along the length of the tube.

The tube may be of any length and diameter. Preferably the tube is of a greater length than 5 cm and has a diameter of from 10 to 100 mm. More preferably, the tube is 25 to 50 cm in length and has a diameter of from 30 to 50 mm.

To facilitate use in a sterile environment, the transvaginal tube is preferably capable of withstanding sterilization and the distal end of the tube may be sealed or open. Any means known in the art which is capable of sealing the distal end of the tube may be employed in the invention. For example, the distal end may be capped or plugged. Preferably the sealing means is capable of effecting a fluid tight closure of the distal end of the tube to approximately 5 to 30 cm of water pressure but most preferably 15 cm of water pressure.

Alternatively, the distal end of the tube may be in a releasable sealing engagement with at least a valve means which when closed is capable of forming a fluid tight enclosure at the distal end of the tube to approximately 5 to 30 cm of water pressure, and most preferably to 15 cm

This Sheet Has Been Replaced



- 4 -

of water pressure. Any valve means known in the art which is capable of achieving this may be employed in the invention. To facilitate use in a sterile environment, the valve means is preferably capable of withstanding sterilization.

When the distal end of the transvaginal tube is open, one or more smaller bore tubes may be inserted into the transvaginal tube. For example, a smaller bore tube may be fitted into the end of the transvaginal tube to promote washing of body fluids and tissue specimens from the proximal end of the interior of the transvaginal tube into a plastic collection bowl with or without the aid of suction when the transvaginal tube is fitted within a subject. Alternatively there may be passed into the transvaginal tube an intra-uterine manipulator which is longer than the internal length of the tube and which may be fixed by aids to the inside of the tube. The distal end of this manipulator may be used to enter the cervix to allow manipulation of the cervix throughout the surgical procedure of hysterectomy or adnexal surgery.

In another embodiment of the invention there is fixed in a concentric arrangement within the transvaginal tube a fluid tight channel through which a telescope or light sources may be inserted while maintaining fluid pressure within the tube. Preferably that channel extends from the distal end to the proximal end of the tube. The channel may be sealed at the distal end of the tube. Alternatively, the distal end of the tube may be adapted to house a portal which is capable of forming a releasable sealing engagement with the circumferential rim of the distal open end of the channel providing the interior of the channel with a means of communication with the exterior of the tube. The proximal end of the tube is sealed.



- 5 -

Desirably the releasable sealing engagement between the tube and the channel should be capable of withstanding approximately 5 to 30cm of water pressure but most preferably 15cm of water pressure. While such a channel may be suitable for telescopes and light sources it will be appreciated that other surgical instruments may be inserted in the channel.

In a further embodiment, when the interior of the channel is in communication with the exterior of the tube there is preferably provided at least a valve means inserted in the longitudinal wall of the tube. The valve means should be capable of withstanding 5 to 30 cm of water pressure but most preferably 15 cm of water pressure.

In yet a further embodiment of the invention there is releasably engaged to the longitudinal wall of the tube at least a valve means and there is passed in concentric arrangement through the distal end or longitudinal wall of the transvaginal tube and extending the length of the tube, smaller bore tubes which may, for example, provide passage for intra-uterine manipulators, tubes to promote irrigation of tissue, laparoscopic grasping forceps, laparoscopically directed stapling devices or laparoscopically directed electro-coagulation diathermy, laser or ultrasonic scalpel devices. To facilitate use in a sterile environment the tube is preferably sealed at the distal end and is preferably capable of withstanding sterilization. Any means known in the art for sealing the valve means and the smaller bore tubes may be employed with the invention. Preferably the tube comprises at least a valve means and one or more narrow diameter tubes, and when sealed at its distal end, is capable of withstanding approximately 5 to 30 cm of water pressure but most preferably 15cm of water pressure.

This Sheet Has Been Replaced



- 6 -

The present invention may be employed in laparoscopic surgery for exposure of the vaginal fornices, as an aid to separation of the bladder from the vagina, for division of the vagina by electro-coagulation diathermy, laser or ultrasonic scalpel, and as a conduit for exteriorising tissue from the abdominal pelvic cavity (see Tables 1 and 2). In this respect, the tissue may be the uterus and/or its adnexal, ovarian cysts, and particular pelvic lymph nodes. The present invention may also be employed as an exit for fluid such as blood and irrigation fluid and smoke or vapour from the abdominal pelvic cavity, as a splinting device to present and expose the dividing edges of the vagina, to facilitate suture closure as a splinting device in the vagina, to expose the vaginal fornices and lateral edge at bladder neck surgery, for insertion of sling devices and as a portal for telescopes or light tubes into the vagina while keeping them separate from the vaginal wall and exposing the vaginal mucosa through the substantially transparent walls of or transparent portals in the tube.

The tube may be used to outline the vagina at open surgery. In these cases the valved end (distal) is not required.

According to a second aspect of the invention there is provided a method for laparoscopic hysterectomy treatment comprising the steps of:

- (i) introducing a tube according to any one of claims 1 to 18 into the vagina of a patient so that the proximal end of the tube circumscribes the cervico-vaginal junction;
- (ii) separating the cervix from the vagina; and
- (iii) mobilizing a surgical specimen and inserting it into the proximal end of the tube.

This Sheet Has Been Replaced



- 7 -

Preferably the cervix is separated from the vagina by the steps of:

- (i) exposing and holding the cervix with laparoscopic grasping manipulators;
- (ii) inserting a knife or diathermy knife to the proximal end of the tube;
- (iii) rotating the tube so the plane non-normal to the tubular axis stretches the vagina and at the same time cutting the cervico-vaginal junction as the tube is rotated.

As well as being most commonly used for simple laparoscopic hysterectomy, the present invention may also be used in laparoscopic radical hysterectomy and pelvic lymph node dissection.

The present invention will now be described in relation to various examples, which in turn refer to the embodiment to the transvaginal tube as illustrated in the Figures 1 to 3. However, it must be appreciated that the following description is not to limit the generality of the above description.

The invention will be more fully understood in the light of the following description of one specific embodiment. The description is made with reference to the accompanying drawings of which:-

Figure 1 is an isometric view of a transvaginal tube;
Figures 2 and 3 are sectional view of the proximal end of the transvaginal tube; and
Figure 4 is a sectional view of the proximal end of the transvaginal tube in situ.



- 8 -

The embodiment (Figure 1) relates to a transvaginal tube which has a body defined by a tube 10 which has a proximal end 12 and a distal end 14. The distal end 14 engages a valve means 16 at a junction 18. The tube 10 is a relatively stiff yet flexible plastic material such as polypropylene. The junction 18 is provided by the resilience of the plastic material allowing for a force fit engagement of the distal end 14 of the tube 10 with one end of the valve means 16 so as to provide a substantially fluid tight engagement.

Figures 2 and 3 show sectional side views of the proximal end 12 of the tube 10 including an anterior edge 20 and a posterior edge 22. It will thus be apparent that the proximal end 12 is cut at an angle non-normal to the longitudinal axis of the tube. This provides the bevelled appearance that is apparent in Figures 2 and 3 and results in the anterior edge 20 being 1.5cm beyond the posterior edge 22.

Figure 4 shows the proximal end 12 of the tube 10 located insitu at the cervico-vaginal junction 24. When located in this position, the vaginal walls 26 envelope the tube 10 forming a seal around the tube. The cervix 28 protrudes into the proximal end 12 of the tube 10 and the uterus 30 lies above and exterior to the anterior edge 20. Thus it will be apparent that the posterior end 12 is adapted to circumscribe to the cervico-vaginal junction.

Example 1

A tube made of firm or flexible smooth transparent plastic, with a valve mounted at one end is sterilised in preparation for gynaecological laparoscopic surgery. When the patient is anaesthetized, positioned, cleansed and



- 9 -

draped according to local custom, the tube is passed through the female vagina. The proximal end of the tube circumscribes the cervix from the vagina. The tube is removed to allow the uterus and appendages to be exteriorised, following which the tube is replaced and the proximal end of the tube is intraperitoneal. The distal end is closed with a valve and the pneumoperitoneum is maintained. No other device is needed to maintain the pneumoperitoneum but the tube is secured in place. Any fixation is acceptable but it is usually held by an assistant surgeon or one end is rested on a table. The tube is positioned according to need.

The proximal end of the tube when located intra-abdominally lies distal above the exteriorised end to allow surgical specimens to pass down the tube by gravity. The proximal end is placed close to the vaginal edges pointing slightly to the appropriate pelvic side wall during a pelvic lymphadenectomy but is placed further through the vagina for a cholecystectomy. The surgical specimen is mobilised and placed in the mouth of the tube. It is exteriorised as it slides down the tube. In this respect tissue may be encouraged to pass down the tube by washing it with irrigation fluid.

Blood and irrigation fluid that has collected in the cul de sac may also be exteriorised through the tube. As an additional aid the valve engaged to the distal end of the tube may be opened, releasing the pneumoperitoneum and the high intra-abdominal pressure relative to the environment would further expel free intra-abdominal and intratube contents. At the completion of the laparoscopic surgery the tube would be removed and the vagina closed.

This Sheet Has Been Replaced



- 10 -

Example 2

The tube was sterilised with ethylene oxide gas. However, it will be appreciated that any method of sterilization may be employed to sterilise the apparatus.

The first steps of a true laparoscopic hysterectomy are to secure and divide the ovarian, uterine and cervical branch of the uterine artery and reflect the bladder. The uterus is separated from the vagina and its uterosacral ligaments using the tube. The tube diameter depends on the patient. A 5cm diameter tube is ideal for multiparous and overweight women but a smaller 4 or 3.5cm diameter tube is needed for postmenopausal and nulliparous women to make it fit the vagina. It is inserted through the introitus and advanced to the cervix. This elevates and defines the cervicovaginal junction and further bladder mobilisation can be performed at this stage if more vagina exposure is necessary.

Once the vaginal epithelium is exposed the diathermy knife/scissors follows the rim of the tube circumcising the vagina and dividing the uterosacral ligaments. Holding the exposed cervix with laparoscopic grasping forceps and rotating the tube so that the longer bevelled end is beneath the knife puts the vagina under further local stretch. This reduces local blood flow and makes uni-polar electrocoagulation particularly efficient.

After the cervix has been separated from the vagina it is held with laparoscopic grasping forceps and fed in the open end of the vaginal tube. When the tube is slowly removed vaginally the cervix follows. The gas is then temporarily released from the peritoneal cavity to prevent any explosive spray of body fluids from the introitus as the

This Sheet Has Been Replaced



- 11 -

tube and specimen are removed. If the uterus is too large to be totally inserted into the tube, just the cervix is inserted and the specimen is steered to the introitus where it can be grasped by a vulsellum and removed.

Another advantage of the tube is that the vault can be sutured laparoscopically without resorting to intracorporal knots. Replacing the tube in the vagina supports and exposes the vaginal edges. The edges can be sutured by placing a needle, preferably taper-cut with a monofilament absorbable suture, in the tube so the trailing end remains intravaginal. The needle is recovered from the tube and the first stitch passes through the inside of the vagina to the peritoneal surface. The vault is closed with a purse string or a linear closure from one end to the other and back again. When the suturing is complete the needle is returned to the transvaginal tube so that both ends of the suture are in the vagina. The tube is withdrawn leaving the needle and trailing end of the suture at the introitus so the operator can lean over and tie the ends intravaginally. Other intracorporeal or extracorporeal techniques of knot tying may be employed.

Results

The tube was used to separate the vagina from the cervix in forty cases by five different surgeons, thirty-four of these were simple laparoscopic hysterectomies for benign diseases in women with limited vaginal access, three were hysterectomies plus pelvic lymphadenectomy for endometrial cancer and three were modified radial hysterectomies for early cervical cancer. In twenty cases the vault was closed laparoscopically. There were no intraoperative complications attributable to the tube.

This Sheet Has Been Replaced



Example 3

Use of the transvaginal tube as an aid to bladder neck surgery.

At either open or laparoscopic surgery, designed to elevate the bladder neck for treatment of stress incontinence of urine in the female, by either the Birch, Cato-Murray or similar procedure, the transvaginal tube previously described can also be used without the valve at the distal end to enhance bladder neck surgery. The tube may be any length from 5cms to 35cms in length, made of the same clear, rigid or semi-rigid plastic as previously described.

At that time in the procedure when the para-vesical area is being prepared to expose the lateral vaginal fornices, the tube is inserted with a telescope, either a direct (0 degrees) or a forward oblique type for example, with a 30 degree angle.

The tube acts to expand the vaginal walls, particularly the vaginal fornices so that they are made more prominent and fixed so that definite identification from either the open procedure or the retro-peritoneal laparoscopic or trans-peritoneal laparoscopic approach, is enhanced. The view of the vaginal fornix on the left and right is further enhanced by trans-illumination from the vaginal aspect by the telescope light. This enables improved exposure and ability to see and reflect the bladder wall from the vaginal fornices from above because of the trans-illumination effect. It also allows enhanced identification of the para vaginal venous plexus so that the large veins can be more easily avoided by the needle and suture placed from above into the vaginal wall. Placing of the Birch or Cato-Murray type suture through the



- 13 -

sub-mucosal layers of the vagina is made easier as the large veins of the para-vaginal wall are made more identifiable by trans-illumination. With the vaginal telescope within the tube, connected to a camera and a screen, the appropriate site selected for insertion of the suture can be seen through the wall of the tube merely by compressing the wall with the outer part of the needle before insertion of the suture. The tube allows a broader and more secure bite of the wall to be taken and puncture of the mucosal or epidermal layer by the needle can be immediately recognised on the vaginal telescope screen. This supersedes the current practise of an assistant placing a thimble covered finger in the right and left vaginal fornices while the operator places the suture in the area of the vagina over the assistant's finger. With the vaginal fornices secured, tension can then be placed on the securing sutures and an appreciation of symmetrical bladder neck elevation can be made on the screen. At present, other than by the assistant's palpation as an assessment of the elevating effect, the surgeon has no idea of the degree of elevation or the right or left symmetry that is being obtained by the procedure.

In that case, full thickness penetration by the non-absorbable suture can only be discerned by the operator or the assistant feeling contact with the metal needle with the metal thimble or noting bleeding on the assistant's glove which would indicate full thickness puncture. In that case, the needle has to be withdrawn and re-inserted into the sub-mucosal dermis of the vagina.

It should be appreciated that the scope of the present invention need not be limited to the particular scope of the embodiment described above.





- 14 -

THE CLAIMS defining the invention are as follows.

1. A transvaginal tube adapted for insertion into the vaginal tract of a patient, the tube having a diameter greater than the patients cervix opening and having a distal end and a proximal end, the proximal end being cut in a plane non-normal to the tubular axis and being adapted to define the patient's cervico-vaginal junction.
2. A tube according to claim 1 wherein the proximal end of the tube is bevelled.
3. A tube according to claim 1 or 2 wherein the proximal end is adapted to have a smooth edge.
4. A tube according to any one of claims 1 to 3, wherein the tube is substantially transparent.
5. A tube according to any one of claims 1 to 3, wherein the tube is substantially opaque, and has one or more transparent portals along the length of the tube.
6. A tube according to any one of claims 1 to 5, wherein the distal end is sealed effecting a fluid tight closure of the end to approximately 5 to 30cm of water pressure.
7. A tube according to claim 6 wherein at least a valve means is releasably engagement with the longitudinal wall of the tube.
8. A tube according to any one of claims 1 to 5, wherein the distal end is in releasable sealing engagement with at least a valve means which when closed is capable of forming a fluid tight closure of the end of the tube to approximately 5 to 30cm of water pressure.



* C L M S *



- 15 -

9. A tube according to any one of claims 1 to 5, wherein the distal end of the tube remains open and there is inserted in and releasably attached to the interior of the tube one or more bore tubes of smaller diameter than the tube.

10. A tube according to claim 9 wherein the smaller bore tubes are capable of facilitating washing of body fluids and tissue specimens from the proximal end of the anterior of the tube.

11. A tube according to claim 9 wherein at least a smaller bore tube is capable of providing suction with the tube.

12. A tube according to any one of claims 1 to 5 or claims 9 to 11 wherein the distal end of the tube remains open and there is inserted in and releasably attached to the interior of the tube at least a surgical manipulator.

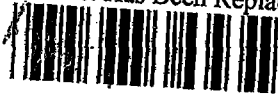
13. A tube according to any one of claims 1 to 5, wherein there is supported in concentric arrangement within the tube a fluid tight channel, said channel being sealed at its proximal end and open at its distal end and wherein the circumferential rim of the distal end of the channel is in sealing engagement with a portal formed in the distal end of the tube therein providing a means of communication between the interior of the channel and the exterior of the tube.

14. A tube according to claim 13 wherein the engagement between the channel and the tube is capable of withstanding approximately 5 to 30cms of water pressure.

15. A tube according to claims 13 or 14, wherein the channel is adapted to receive a telescope.



This Sheet Has Been Replaced



- 16 -

16. A tube according to claims 13 to 15 wherein the channel is adapted to receive at least a light source.

17. A tube according to any one of claims 13 to 16 wherein at least a valve means is releasably engaged to the longitudinal wall of the tube.

18. A tube according to any one of claims 6 or 7 or 13 to 17 wherein at least a bore tube of smaller diameter than the tube is inserted through and releasably engaged to the longitudinal wall or distal end of the tube.

19. A method for laparoscopic hysterectomy treatment comprising the steps of:

- (i) introducing a tube according to any one of claims 1 to 18 into the vagina of a patient so that the proximal end of the tube circumscribes the cervico-vaginal junction;
- (ii) separating the cervix from the vagina; and
- (iii) mobilizing a surgical specimen and inserting it into the proximal end of the tube.

20. A method according to claim 19 wherein the cervix is separated from the vagina by the steps of:

- (i) exposing and holding the cervix with laparoscopic grasping manipulators;
- (ii) inserting a knife or diathermy knife to the proximal end of the tube;
- (iii) rotating the tube so the plane non-normal to the tubular axis stretches the vagina and at the same time cutting the cervico-vaginal junction as the tube is rotated.



* C L M S *