## [Title] Evolving role of techniques of transabdominal cervical cerclage in modern maternity care

## [Running Title]Techniques in transabdominal cervical cerclage

Donald Gibb MD MRCP FRCOG,[a,*] Ertan Saridogan PhD FRCOG[b]
[a] The Birth Company, 137 Harley Street, London W1G 6BF, UK
[b] University College London Hospitals, Institute for Womens Health, 2nd Floor, North Wing, 250 Euston Road, London NW1 2PG, UK
[*] *Correspondence*: Donald Gibb. Email: Donald@thebirthcompany.co.uk

## [**Abstract**]

### Key content

- Principles of cervical anatomy, cervical weakness and strengthening, and indications for cervical cerclage
- History of the transabdominal cervical cerclage technique, literature review, results and current situation
- The surgical technique of open transabdominal cervical cerclage
- The surgical technique of laparoscopic transabdominal cervical cerclage
- Potential complications

### Learning objectives

- To better understand the role of the cervix in miscarriage.
- To understand the indications for referral for transabdominal cervical cerclage.
- To understand the ideal follow-up care of women after this procedure.

### Ethical issues

- To consider the place of this invasive procedure, with its consequent possible complications, in the management of women, who often have poor reproductive histories.
- To consider the lack of national and international availability of this potentially valuable procedure.
- To consider an effective system of assessment of this procedure in a referral context, and the future of this procedure.

**Keywords**: antenatal care / cervical suture / gynaecological surgery / laparoscopy / miscarriage

# Techniques in transabdominal cervical cerclage

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# [Main body of text]

## [Heading 1] Introduction

There has been some confusion about the role of cervical cerclage in modern perinatal care. Weakness (also called incompetence) of the uterine cervix, which is sometimes over-diagnosed, can cause pregnancy loss, and this can often be repetitive. A study by the Medical Research Council (MRC) and the Royal College of Obstetricians and Gynaecologists (RCOG)[1] prompted critical thinking as to which indications should be considered for cervical cerclage but may have resulted in some women not having a cervical suture when it was needed. The advent of cervical imaging by ultrasound scanning and further critical analysis should contribute to a better understanding. A particular challenge is presented in cases of women with repetitive midtrimester pregnancy loss, and for whom no vaginal cervix can be seen (or sometimes even felt because of previous cervical conisation or other trauma). Benson and Durfee[2] addressed this as long ago as 1965 in their report of the transabdominal open procedure for cervical cerclage. With more recent developments in minimal access surgery a new approach has been suggested for this operation. We seek to clarify any lack of understanding in this area and make the case for a national database and audit of this unusual but valuable procedure for women having difficulty carrying a pregnancy to term.

## [Heading 1] Late miscarriage and extreme premature birth

The term miscarriage is preferred to abortion and cervical weakness is preferred to incompetence. Incompetence has negative connotations for women that should be avoided.

Late miscarriage and extreme premature birth are very traumatic for a couple, physically and particularly psychologically. It may lead to them delaying or even deciding against a future pregnancy. Simplistic concepts lead to these women being treated with transvaginal cervical cerclage irrespective of the cause. The MRC/RCOG study[1] indirectly addressed this by showing that with wide indications for cerclage, even following one previous pregnancy loss, cerclage made little difference to the outcome. However, when a subgroup with three late miscarriages was considered, a significant positive effect of transvaginal cerclage was observed. The conditions shown in Box 1 and Figure 1 can contribute to midtrimester pregnancy loss.

It appears that the integrity of the cervix is partly assured by its length. In normal pregnancy the cervix is more than 40 mm long at 18 weeks of gestation. This is manifested by approximately 2 cm of vaginal cervix and 2 cm of supravaginal cervix. The bladder lies anterior to the cervix and the internal os cannot easily be reached without pushing the bladder up when approached from the vaginal route. The pouch of Douglas is relatively free and the uterosacral ligaments pass into the posterolateral part of the uterus at about the level of the internal os. Logically, a cervical strengthening suture would be most effective at the internal os.[3] Use of a Shirodkar technique[4] is more likely achieve this, while use of a McDonald technique[5] may result in a lower suture.

## [Heading 1] Clinical assessment

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Ideally a patient should be assessed and receive counselling and advice before a future pregnancy. Occasionally women present without a previous pregnancy loss, but more often there is a history of repetitive midtrimester pregnancy loss. A careful history and examination should elicit the role of any of the confounding factors presented in Box 1 and Figure 1. Persistent placental bleeding after 8 weeks of gestation is associated with midtrimester membrane rupture and pregnancy loss. It is not an indication for cervical suture in the current or future pregnancies. Midtrimester pregnancy loss is not uncommon in multiple pregnancy; it is possibly caused by an overdistended uterus stretching the cervix. These patients are sometimes told that their cervix is weak and to expect to have a cervical suture in their next pregnancy. If their next pregnancy is a singleton pregnancy then this may not be necessary; they should have ultrasound assessment of cervical length at 17 weeks of gestation. Infection may be a confounding factor. Histopathological examination of midtrimester loss tissue may show chorioamnionitis, but this does not mean it was causative. There should be some basic microbiological surveillance of a future pregnancy. Fibroids rarely cause midtrimester loss unless particularly large or submucous.[6]

Visual and digital examination of the cervix is crucial. The mistake of taking a patient to the operating theatre and finding that a vaginal suture is impossible must be avoided. Visual and digital examinations will detect cervical lacerations (Figure 2) and cervical shortening (Figure 3). This may be complemented by a transvaginal scan of the cervix.

### [Heading 1] Case selection: transvaginal or transabdominal suture?

It has been said that the indications for transabdominal suture are a grossly disrupted cervix (Figure 2) or an absent vaginal cervix (Figure 3), and previous failed elective vaginal cerclage. The first two are the most obvious indications. Questions must be asked about how the previous failed vaginal cerclage was done and whether there were other circumstances leading to its failure. If there is a good portion of vaginal cervix present, we believe that one option is a well-placed Shirodkar suture with bladder reflection, an anterior knot and short trimming of the ends, which are then buried by closure of the vaginal skin incision. There is a paucity of data concerning the relative merits of a McDonald suture compared with a Shirodkar suture.[7] A woman who has had a failed McDonald suture may not be willing to do the same again; we would offer a formal Shirodkar technique, which is higher and buried, rather than moving directly to a transabdominal approach. We think that a suture nearer to the internal os and more isolated from sources of infection may be more effective.

### [Heading 1] Transabdominal open surgical cervical cerclage

The obvious candidate for the transabdominal technique is a woman with a severely damaged cervix and midtrimester loss where a vaginal suture is impossible. Gibb and Salaria[8] used the open surgical technique in pregnancies at Kings College Hospital (Figures 4 and 5). Mersilene® tape RS22 was used, which has a smaller needle than RS21. It was done following a detailed ultrasound scan at about 11 weeks of gestation, and when the first trimester miscarriage risk had passed. In his personal experience of 98 cases, the first author found the following practical points to be useful:

1. An earlier operation (9–12 weeks of gestation) is easier, particularly when there is a multiple pregnancy.

2. Obesity and abdominal scarring from previous surgery make for a more difficult operation.
3. Regional anaesthesia may be not adequate, as experienced in one case requiring conversion to general anaesthesia. We have used general anaesthesia whereas other authors have reported satisfactory use of regional anaesthesia.

Data for the first 50 cases were published in 1995.[8] Consistent with other published studies,[9–17] these data showed a greater than 85% successful pregnancy rate, with some women having two or even three consecutive pregnancies in series, each delivered by caesarean section. In complicated cases, for example where membrane rupture or intrauterine death in the midtrimester occurred, then the suture was removed by posterior colpotomy, thus avoiding the need for a second laparotomy during pregnancy failure. A further 49 cases in a referral practice have been undertaken between 1996 and today.[18] All women except three had living children born close to or at 38 weeks of gestation. One was born at 32 weeks because of severe maternal anxiety and survived without deficit. Another was found to have a lethal fetal abnormality at 18 weeks of gestation and had a therapeutic abortion. A third pregnancy requiring hysterotomy was lost intraoperatively because of heavy revealed vaginal bleeding on account of a central low placenta. The survival rate of normally formed babies was 97.6%. This may be attributed to improved patient selection and reaching a higher point on the learning curve.

There is a limited number of published studies[9–17] with more than 12 cases in the series. These are summarised in Table 1. In summary, these indicate improved pregnancy outcomes following open transabdominal cerclage in women with previous multiple losses.

Randomised controlled trials of this technique are difficult to implement because of the small numbers of women to select from, and the fact that women would be unlikely to submit to randomisation against no cerclage. One study currently underway (www.medscinet.net/mavric) is exploring previous failed elective vaginal cerclage with a three-way randomisation to McDonald cerclage, Shirodkar cerclage and transabdominal cerclage. These may be in pregnancy or before pregnancy. This trial naturally excludes women with midtrimester losses who have no vaginal cervix on which to operate.

While the results following transabdominal cerclage are excellent, the transfer of surgical skills to younger colleagues is difficult for this relatively unusual procedure. There are not enough cases at any one centre to facilitate apprenticeship. The operation, although not technically difficult in the well-selected patient, is an open technique during pregnancy and is thus stressful for the surgeon. The threat of complications such as bleeding that is difficult to control and iatrogenic pregnancy loss, is very real, though fortunately rarely occurring. It is a particularly challenging operation in women with previous abdominopelvic surgery and in those with a significantly raised body mass index.

There have been a few reports of successful transabdominal cerclage performed as a prepregnancy open procedure.[19, 20] Dawood and Farqhuarson[21] reported on a comparison of 21 preconceptual cases and 40 first trimester cases of open transabdominal cervical cerclage, concluding that preconception cerclage yields a more favourable pregnancy outcome.

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## [Heading 1] Evolution of the technique

With the advance of laparoscopic surgery, the opportunity has arisen for collaboration between obstetricians and minimal access gynaecologists to perform the cerclage procedure laparoscopically. The required technique has been modified for the laparoscopic approach and a number of publications have been published. The authors of this article have followed a similar approach, and our preliminary results with the laparoscopic approach showed success rates similar to results published in the literature.[22]

## [Heading 1] Laparoscopic technique

The first laparoscopic transabdominal cerclages were reported by Scibetta et al.[23] and Lesser et al.[24] in 1998. Lesser et al.[24] placed their first laparoscopic suture in a pregnant woman at 11 weeks of gestation. The operation took 2 hours 20 minutes and there was some bleeding from one of the uterine arteries, which was controlled with clips and packing. The pregnancy continued and the baby was delivered by caesarean section at 35 weeks of gestation because of gestational diabetes. The suture was removed during the operation. Scibetta et al.[23] described an interval laparoscopic cerclage procedure in an infertile woman who had no visible ectocervix tissue because of two previous cone biopsies for cervical adenocarcinoma. The procedure was uncomplicated: the woman conceived following in vitro fertilisation embryo transfer (IVF-ET) 10 weeks later and the baby was delivered by caesarean section at 38.5 weeks of gestation.

Since the publication of these two cases, a number of reports have discussed the surgical and obstetric outcomes of laparoscopic cerclage, including robotic assisted procedures. A 2013 review[25] included 25 articles published until May 2012 and identified 162 laparoscopic and three robotic assisted cervical cerclage procedures. Of the 162 laparoscopic procedures, 102 were interval procedures and 60 were carried out during pregnancy. Two of the robot-assisted procedures took place during pregnancy and one was an interval procedure. Following all these groups of procedures the median gestational age at delivery was 37 weeks.

Since the cut-off date (May 2012) of the above review, three further case series have been published. One of these reported 52 interval procedures from Denmark[26] and the second article[27], from two centres in Holland and the USA, included 66 interval procedures. The third article from Australia[28] reported 64 procedures, three of which were during pregnancy. In the Danish study, of the 45 registered pregnancies, 36 progressed beyond 16 weeks; 30 (83.3%) of these were delivered by caesarean section after 36 weeks, with a mean gestational age of 37.4 weeks. In the Dutch–American study, 35 pregnancies were registered; 25 (71.4%) of these delivered at or beyond 34 weeks and the total survival rate was 90%. Three (8.6%) experienced a second trimester loss. There were no significant complications in the Danish study and the Dutch–American study reported three minor complications (uterine perforation and pelvic infection). In the Australian study, 34 out of 64 women had 35 pregnancies since the procedure. Eleven of these were early miscarriages, ectopic pregnancies, intrauterine demise due to monochorionicity or termination due to trisomy 13. The neonatal survival rate was 95.8% in the remaining 24

pregnancies. Published studies of interval and non-interval laparoscopic cerclage with more than 12 cases are summarised in Table 2.

The second author of this article has performed 32 laparoscopic interval procedures since 2005. There were no surgical complications and there was no conversion to laparotomy. An earlier audit of these cases showed one midtrimester pregnancy loss and one intrauterine death. The former was managed by removal of the suture via a posterior colpotomy; the latter was apparently managed by hysterotomy at another hospital.[22]

**[Heading 2] Surgical technique**

Laparoscopic cerclage aims to replicate the same surgical approach as the open technique except that routine bladder reflection is not carried out. The patient is placed in the lithotomy position and the bladder is catheterised with a Foley's catheter. For interval procedures, a uterine manipulator is inserted into the cervix; some groups insert an 8 mm Hegar dilator to avoid an overtight suture and obstruction of the cervical canal. For procedures during pregnancy this is obviously not possible and it makes the procedure much more difficult. While there are minor modifications to the way sutures are placed and the suture material used, the procedure usually involves placement of Mersilene® tape used for transvaginal cerclage or a No. 1 Prolene® suture around the cervix at the isthmic level. The uterovesical peritoneum is opened at the isthmic level and extended slightly laterally to expose the uterine vessels on both sides. There is usually no need to reflect the bladder downward, except in cases of previous caesarean section or other circumstances where the bladder may have been pulled up onto the anterior uterine wall. The suture may then be inserted either in the anteroposterior or posteroanterior direction. Our approach involves using the original curved blunt needle of the Mersilene® tape to place the suture in the anteroposterior direction. The needle is passed between the uterine vessels and the cervicoisthmic junction, coming out through the posterior leaf of the broad ligament, approximately 1 cm above the uterosacral ligament. The same approach is then repeated on the other side and the knot is tied posteriorly, behind the cervicoisthmic junction. Care is taken to lay the tape flat on the uterus and to cut the ends to 1–2 cm (Figures 6–10). Some groups straighten the needles so that it is easier to insert them into the peritoneal cavity through one of the ports. They then use the straightened needles to apply the suture in the posteroanterior direction, starting approximately 1 cm above the uterosacral ligaments, and tie the knot anteriorly. Some other groups use laparoscopic port closure devices (such as Endoclose®) or aneurysm needles, inserted through the anterior abdominal wall in the suprapubic region, to pull the Mersilene® tape in the posteroanterior direction at the isthmic level.

Anterior knots have the advantage of avoiding risk of adhesions in the pouch of Douglas, but may increase the risk of erosion into the bladder. Should the pregnancy fail in the second trimester, posterior knots have the advantage of possible removal via colpotomy to allow vaginal delivery. Mersilene® tape is less likely to cut through the uterine tissue in the presence of contractions but it causes fibrosis around and within the braided fibres so that it is more difficult to remove when necessary. Prolene® sutures are easier to insert and remove, but they may be more likely to cut through the uterine tissue. After the knot is tied, the uterovesical peritoneum may be closed to cover the tape, but this is not essential.

After completion of the procedure, the bladder catheter can be removed and the patient can be sent home on the same or following day.

## [Heading 1] Complications

Some of the complications of laparoscopic cerclage are the inherent risks of laparoscopic surgery, such as visceral or major blood vessel injury; others are specific to the cerclage procedure. Specific complications include bleeding from uterine vessels and loss of pregnancy for non-interval procedures. In the largest case series, which included 31 procedures during pregnancy and 34 interval procedures, there were two fetal losses (2/31, 6.4%) and seven laparotomies (7/65, 10.8%).[29] Bleeding from the uterine vessels led to five of the laparotomies, while two were because of impaired visibility caused by morbid obesity. Six of these patients were pregnant.

Preterm premature labour, midtrimester rupture of membranes and intrauterine fetal death are challenging complications after transabdominal cerclage. In this situation either the suture needs to be removed or the pregnancy is terminated via hysterotomy. The other reported complications of transabdominal cerclage, such as suture migration, rectouterine fistula some years later (one case we have seen after open transabdominal suture), uterine rupture and intrauterine growth retardation are rare and can be seen with both laparoscopic and open approaches. In cases of posterior knot, the suture may be removed via a posterior colpotomy. Laparoscopic removal of the suture has also been reported.

## [Heading 1] Discussion

The place of cervical cerclage in preventing preterm birth remains a subject of debate. A Cochrane review[30] found that vaginal cervical sutures reduced preterm birth without significantly reducing the perinatal morbidity. It was concluded that the decision on how to minimise the risk of preterm birth in at-risk women should be personalised. There are no published randomised controlled trials on the place of transabdominal cervical suture in this field. The published literature on transabdominal cerclage usually involves a very specific group of women who are at risk for midtrimester loss or preterm birth, and who are either not suitable for transvaginal cerclage (e.g. because of a lack of vaginal cervix due to previous surgery), or have tried the transvaginal approaches unsuccessfully. As discussed above, both open and laparoscopic approaches appear to offer high success rates in this group of women who usually have very poor obstetric history. The laparoscopic approach is relatively new and is carried out by a few specialists. The UK National Institute for Health and Clinical Excellence (NICE) classified the laparoscopic cerclage as a procedure with limited evidence for success and an uncertain safety record. For this reason, NICE suggested special governance and audit arrangements when this procedure is carried out.[31] We suggest setting up a UK national register to audit the outcome of transabdominal cerclage procedures.

### [Heading 2] Comparison of laparoscopic technique with the open approach

There are no prospective trials comparing the laparoscopic and open approaches. However, at least two publications have compared the outcomes of laparoscopic cerclage procedures, either with retrospective open controls or against the published results in the literature. The report by

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Whittle et al.[29] reported an 89% fetal salvage rate after laparoscopic cerclage, while a 60–100% success rate was found in the literature using the open technique. Another report by Carter et al.[32] reported 75% success after laparoscopic cerclage, compared with 71% after open cerclage. Both these reports concluded that the laparoscopic approach compared favourably to the abdominal approach. The laparoscopic approach has the advantages of shorter hospital stay, quicker recovery and better cosmesis. It may also have a lower risk of surgical complications compared with the open technique.[27]

**[Heading 2] Interval versus non-interval procedures**

As discussed above, interval procedures are easier and avoid the risk of fetal loss. If laparoscopic skills are available, then planned open interval laparotomy has no value. Laparoscopic planned procedures rarely require non-planned laparotomy, while the reported conversion rates for non-interval laparoscopic procedures are approximately 10%. The procedure requires active, and often acute, anteversion and retroversion of the uterus by an assistant with an instrument placed in the cervical canal. This is not desirable during pregnancy. For this reason it is preferable to carry out laparoscopic cerclage as an interval procedure before a woman becomes pregnant.

Two possible disadvantages of interval procedures are first trimester miscarriages and post-procedure infertility. In our experience, the women we operated on do not encounter infertility, as these are usually otherwise fertile women. Nonetheless, it would appear sensible to limit dissection of the paracervical tissues to minimise the possibility of adhesion formation on the pelvis. First trimester miscarriages are usually possible to manage expectantly or by surgical evacuation, as presence of a suture does not prevent insertion of a suction cannula large enough for this gestational age.

**[Heading 1] Conclusion**

Transabdominal cerclage, both open and laparoscopic, provides excellent outcomes in well-selected patients. Laparoscopic cerclage before pregnancy probably offers similar chances of success compared with the open approach and has the general advantages of minimal access surgery. It is likely to replace the open approach in the future. The operation is easier to perform as an interval procedure and avoids the risks of fetal loss and conversion to laparotomy. It is important that the woman be referred for assessment before she becomes pregnant. Selection criteria must be strict. A history of midtrimester pregnancy loss, the circumstances of previous failed cerclage and a seriously deficient cervix are key criteria. The alternative option of transvaginal cerclage in pregnancy should be considered. There is a problem with this in that the person with the skills to perform each procedure is likely to be different. Currently obstetricians perform transvaginal cerclage and in-pregnancy open cerclage; gynaecological surgeons – sometimes oncologists – tend to perform interval open cerclage; and minimal access surgeons perform laparoscopic cerclage. Collaboration is essential.

There is a need for a national register to monitor outcomes of this procedure, which should be relatively rarely performed.

## Disclosure of interests:

There are no conflicts of interest.

## Contribution to authorship:

DG proposed the idea. DG contributed the main part relating to the open technique and ES contributed the part related to laparoscopic technique. Both contributed to the discussion and conclusions. Both authors approved the final version.

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## [Figure legends]

Figure 1. Multifactorial aetiology of preterm birth and miscarriage.

Figure 2. Grossly disrupted cervix.

Figure 3. Absent vaginal cervix, flush vaginal vault.

Figure 4. Transabdominal cerclage: anteroposterior view.

Figure 5. Transabdominal cerclage: lateral view.

Figure 6. Opened uterovesical peritoneum.

Figure 7. Anterior view of laparoscopically placed suture.

Figure 8. Posterior view of laparoscopically placed suture before the knot is tied.

Figure 9. Posterior view of laparoscopically placed suture after the knot is tied.

Figure 10. Closed uterovesical peritoneum at the end of procedure.

[Box]Box 1: Causes of midtrimester pregnancy loss.

- Bleeding
- Uterine malformation
- Multiple pregnancy
- Polyhydramnios
- Cervical weakness (incompetence)
- Preceding chorionic villus sampling/amniocentesis (rarely)
- Preceding fibroids (very rarely)
- Maternal illness, e.g. malaria, listeriosis

[End box]

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Figure 1 – Multfactorial aetiology of preterm birth and miscarriage.

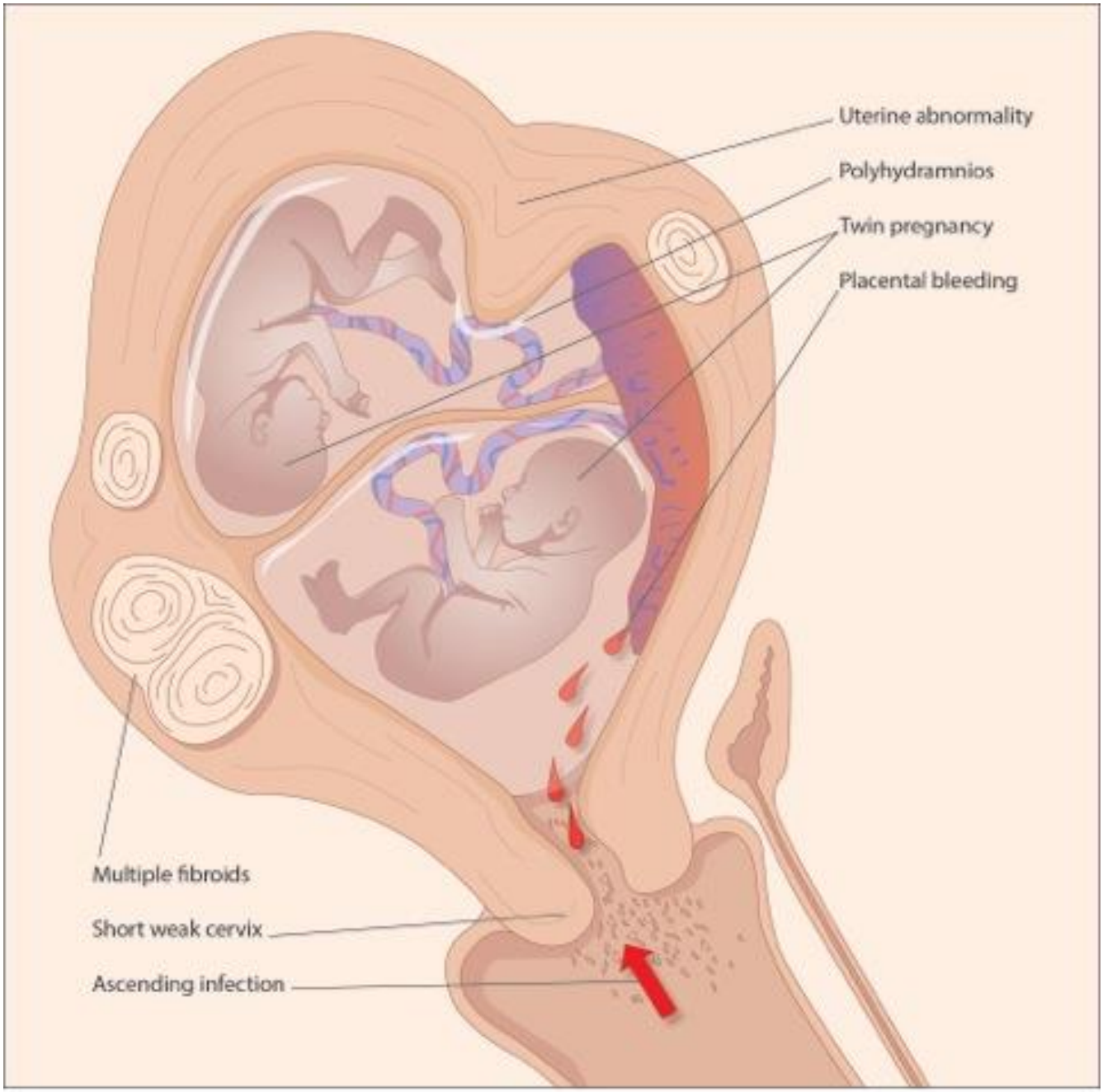

Figure 2 – Grossly disrupted cervix.

Figure 3 – Absent vaginal cervix, flush vaginal vault.

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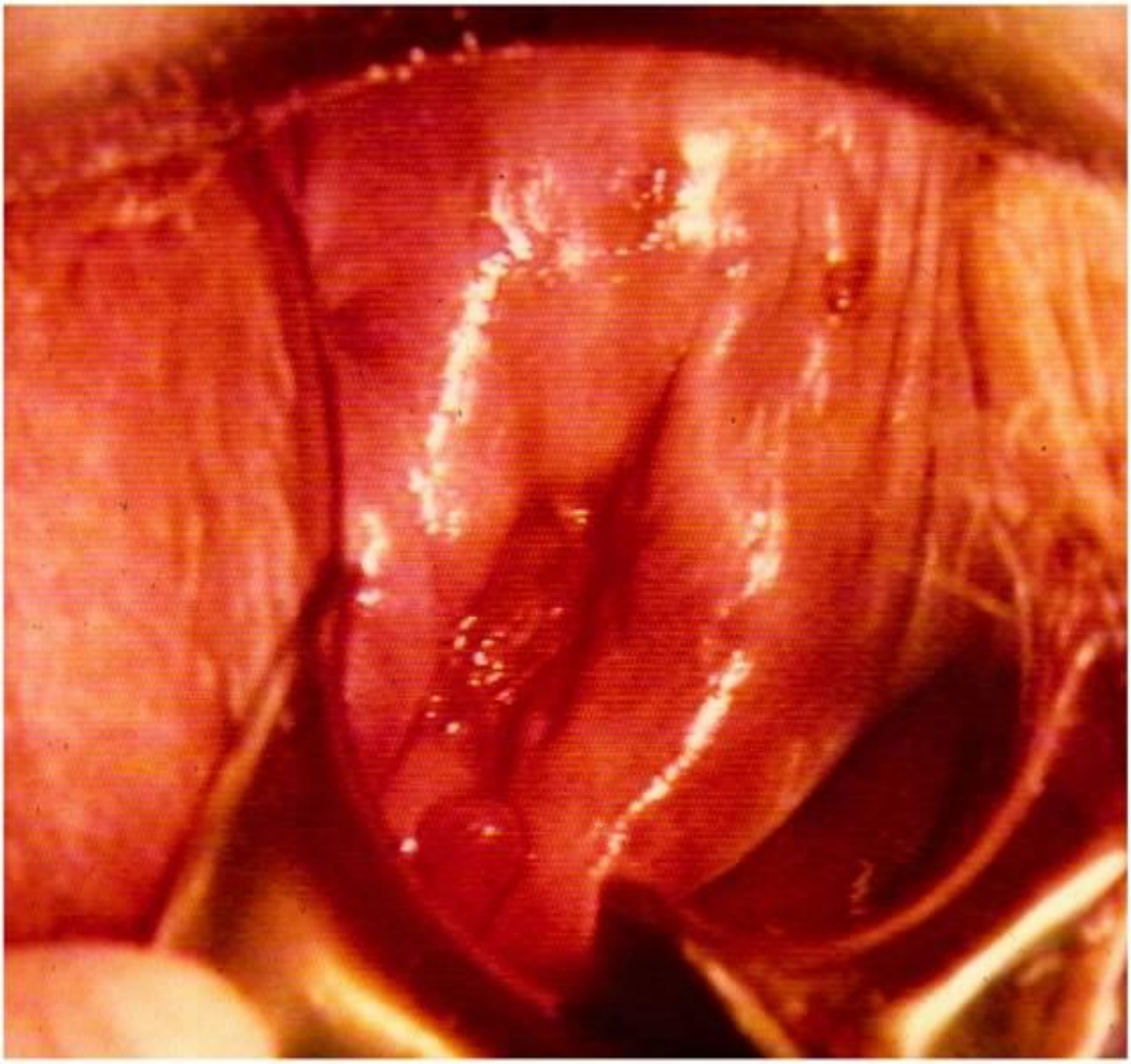

Figure 4 - Transabdominal Cerclage Antero-posterior View.

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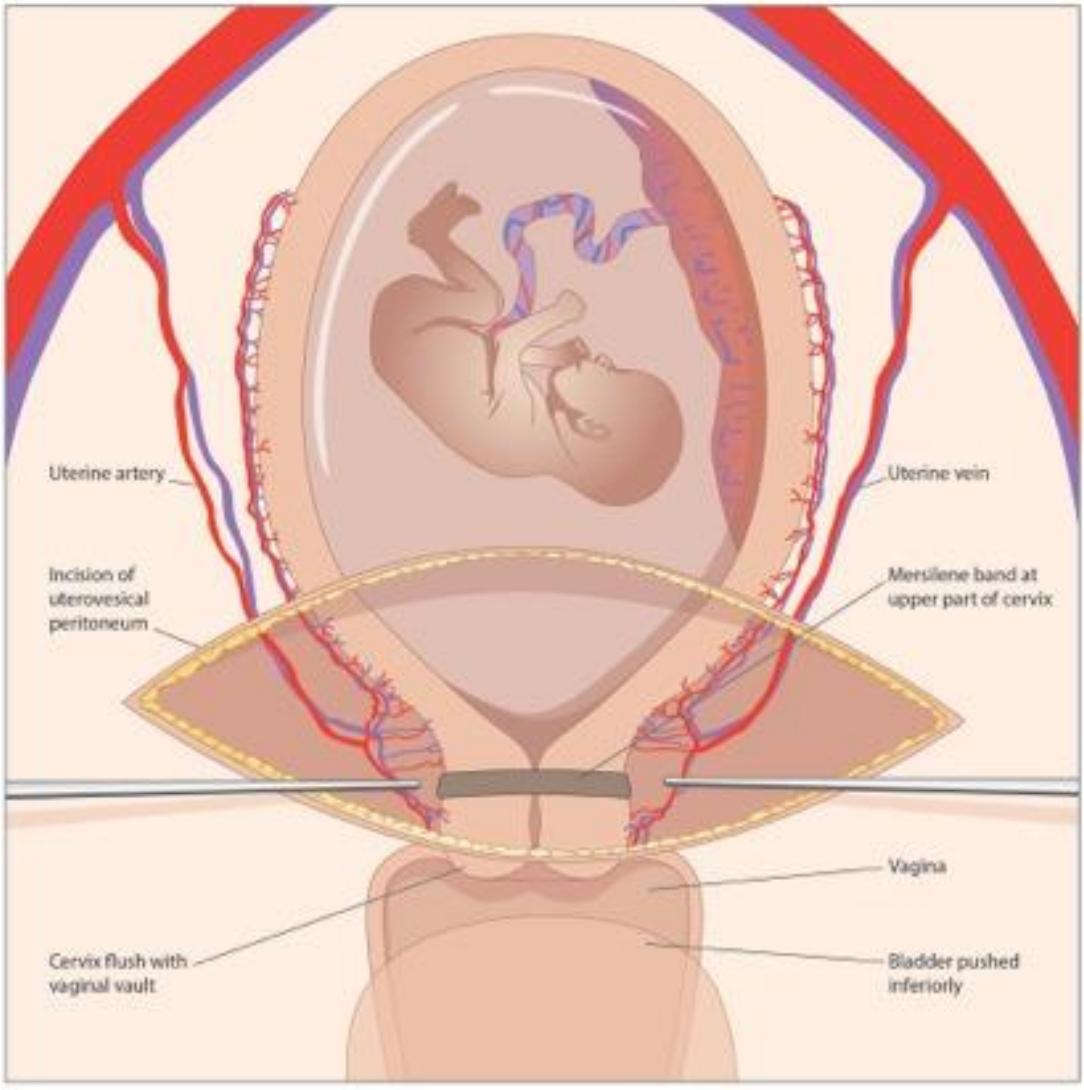

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Figure 5 – Transabdominal Cerclage Lateral View

**Techniques in transabdominal cervical cerclage**

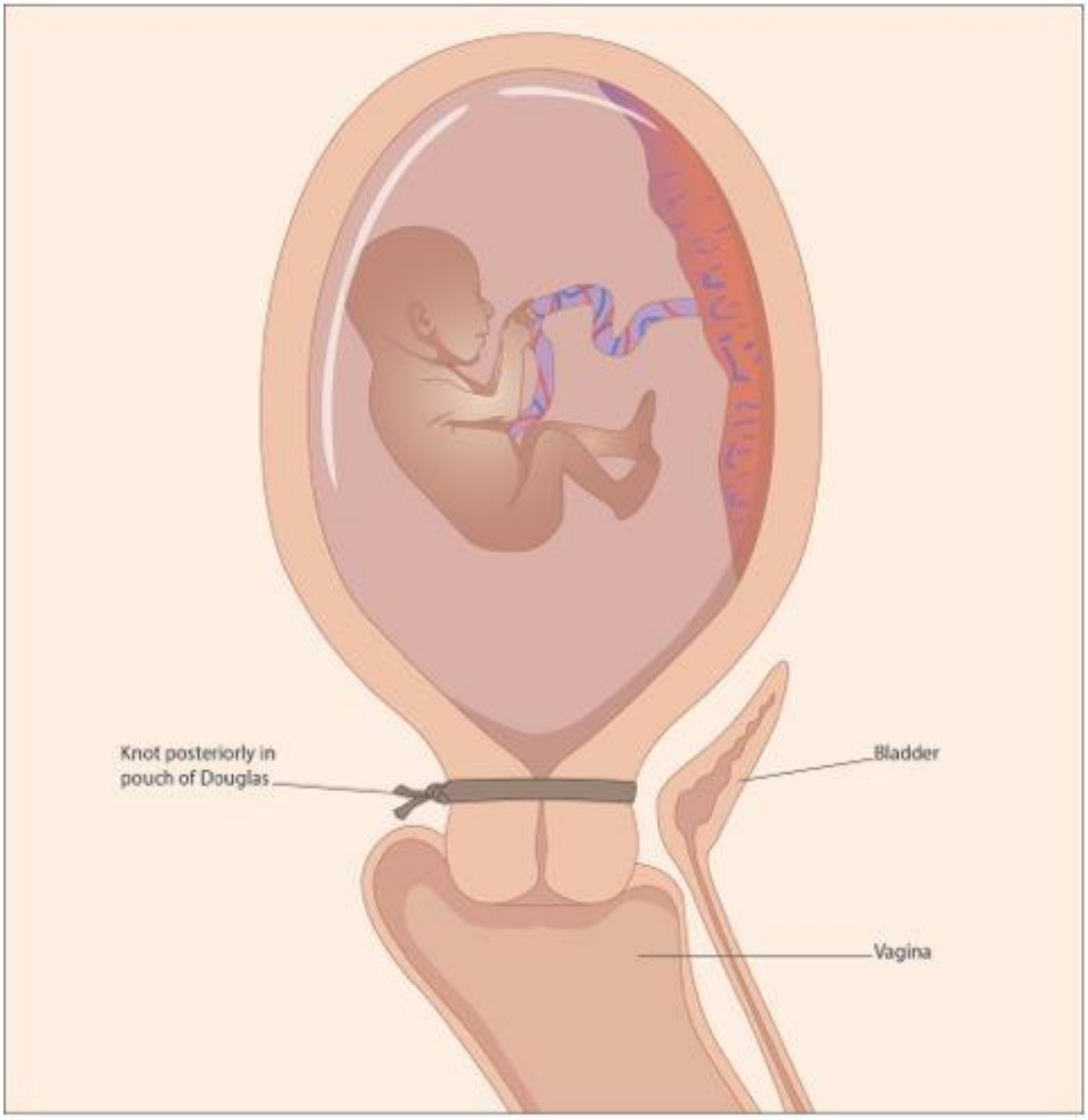
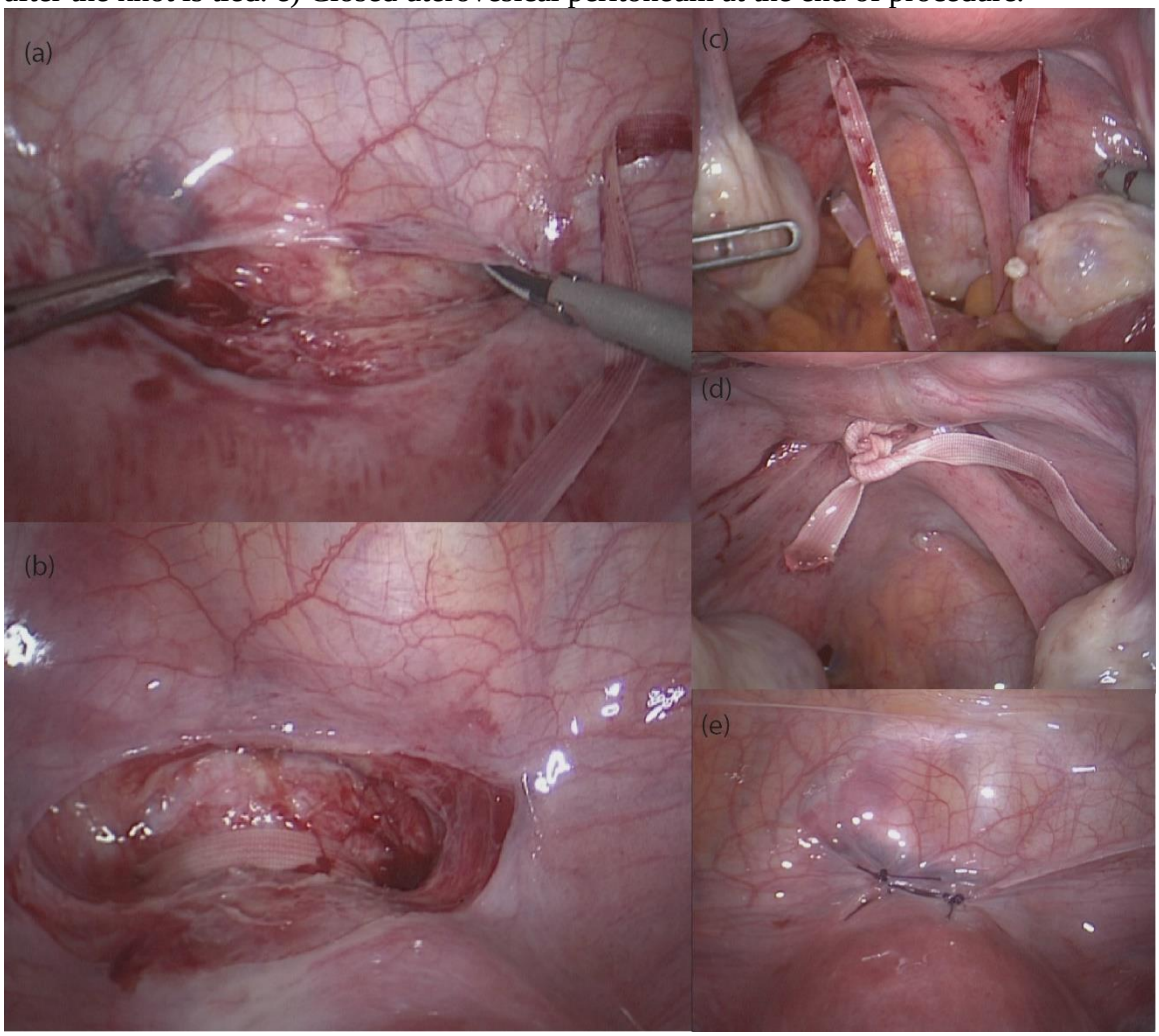


Figure 6 – Surgical steps of laparoscopic cerclage. a) Opened uterovesical peritoneum. b) Anterior view of laparoscopically placed suture. c) Posterior view of laparoscopically placed suture before the knot is tied. d) Posterior view of laparoscopically placed suture after the knot is tied. e) Closed uterovesical peritoneum at the end of procedure.




[**Tables]**

**Table 1.** Published series with more than 12 cases of open transabdominal suture in pregnancy.

| First author | Year | Cases | Country | Neonatal survival before suture (%) | Neonatal survival after suture (%) |
|---|---|---|---|---|---|

**Techniques in transabdominal cervical cerclage**

| | | | | | |
|---|---|---|---|---|---|
| Olsen | 1982 | 17 | Denmark | 12 | 88 |
| Van Dongen | 1991 | 16 | Netherlands | 36 | 96 |
| Novy | 1991 | 20 | USA | 20 | 90 |
| Cammarano | 1995 | 23 | USA | 18 | 93 |
| Gibb | 1995 | 50 | UK | 6 | 85 |
| Anthony | 1997 | 13 | Scotland | 16 | 86 |
| Lotgering | 2006 | 101 | Netherlands | 24 | 93 |
| Debbs | 2007 | 75 | USA | 3 | 96 |
| Umstad | 2010 | 58 | Australia | 22 | 100 |
| Knudtson | 2010 | 15 | USA | 7 | 73 |
| Gibb | 2012 | 43 | UK | 9 | 98 |

**Table 2.** Published series of more than 12 cases of laparoscopic transabdominal suture.

| First author | Year | Cases | Country | Neonatal survival before suture (%) | Neonatal survival after suture (%) |
|---|---|---|---|---|---|
| Cho* | 2003 | 20 | S. Korea | N/K | 95 |
| Nicolet* | 2009 | 14 | France | 7 | 83 |
| Whittle* | 2009 | 65 | Canada | 8 | 89 |
| Riiskjaer | 2012 | 52 | Denmark | N/K | 83 |
| Burger | 2012 | 66 | USA/ Netherlands | N/K | 90 |
| Ades | 2014 | 64 | Australia | N/K** | 95 |

*Included in the review by Nashar et al. (2013)[22]

**Pregnancies beyond 23 weeks of gestation; 34%