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6

Controversies in the management of vesicovaginal fistula

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A B S T R A C T

Achieving 100% closure and continence rate in the management of vesicovaginal fistulas remains a challenge. There is still debate about several aspects of the care including the following:

- How successful is conservative treatment with catheter drainage, and can it be improved with newer techniques?
- When is the best time to operate?
- What is the best surgical approach?
- Are interpositional flaps helpful?
- Is there any way to reduce the risk of future stress incontinence during the initial surgery?
- How long does the bladder need to be drained after surgery?
- What is the best way to manage radiation-induced fistulas?
- Where and by whom should the patient be operated?

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Although vesicovaginal fistulas (VVFs) have been managed for many years, much of the evidence for their management is of low quality with few published trials. We therefore must rely mainly on large retrospective case series and expert opinions [1]. Two recent meta-analyses are included in this review [1,5].

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Is conservative treatment worth trying?

Diversion of urine away from the fistula may allow it to close spontaneously. Therefore, catheterization may be all that is required for a fistula to close, especially if it is small and most of the urine drains through the catheter. One should wait for 3–7 days to judge the initial response:

- If very little urine drains through the catheter, it is reasonable to remove the catheter.
- If most of the urine drains through the catheter, then it is left inside for up to 6 weeks or more.

The success rate of catheter drainage depends on several factors:

(a) The size of the defect: While conservative management is more likely to be successful if the fistula is less than 1 cm in size, sizes up to 3 cm should not preclude attempts at conservative management.

(b) The period between injury and initiation of therapy: This may be the most important factor because epithelialization of the fistulous tract prevents spontaneous healing. Therefore, the sooner a catheter is inserted, the more likely it is to be successful. In one study involving mostly postsurgical VVF patients, if a catheter was inserted less than 3 weeks following the initial insult, 22 (39%) of 57 women had spontaneous VVF closure. By contrast, when the catheter was inserted more than 6 weeks after the injury, only 1 (3%) of 32 VVFs healed [2].

(c) Duration of bladder drainage: There is no agreement on how long the catheter should be kept in situ. A good rule would be to leave the catheter inside for 2 weeks after any leakage has completely stopped and then perform a dye test to confirm the healing. In one study evaluating four VVF cases after hysterectomy, all four resolved with simple bladder drainage for periods ranging from 19 to 54 days [3]. However, some cases may require a drainage period longer than this range. For example, in an unusual case report of a 3 cm VVF following a loop electrosurgical excision procedure of the cervix, healing occurred after 11 weeks of catheterization [4].

(d) Mechanism of injury: Malignant and postradiotherapy VVFs will typically not heal with catheter treatment.

The success rates of catheter treatment vary from 5% to 11% (see Table 1).

If the diagnosis is made late and the fistula has epithelialized, there are several additional options for very small (<5 mm) fistulas. These techniques typically work when the fistulous tract is long and narrow as opposed to the tract that is short and wide. While there are no clinical trials to judge the success rates of these methods, these conservative techniques can be considered if the fistula is small and the patient wishes to avoid surgery or is not fit for surgery. One or more of the following techniques may be used:

(a) Cautery may be used to disrupt the epithelial layer, thus allowing the bladder and vaginal tissues to reseal. Typically, this is done with a monopolar electrode, which is passed within the fistula. The technique can be performed vaginally or by cystoscopic guidance. In one study, 11 of the 15 (73%) women with a VVF of diameter less than or equal to 3.5 mm had complete resolution of the fistulas with this technique [8]. In another study, four of five (80%) women undergoing fulguration had resolution of their fistula [35].

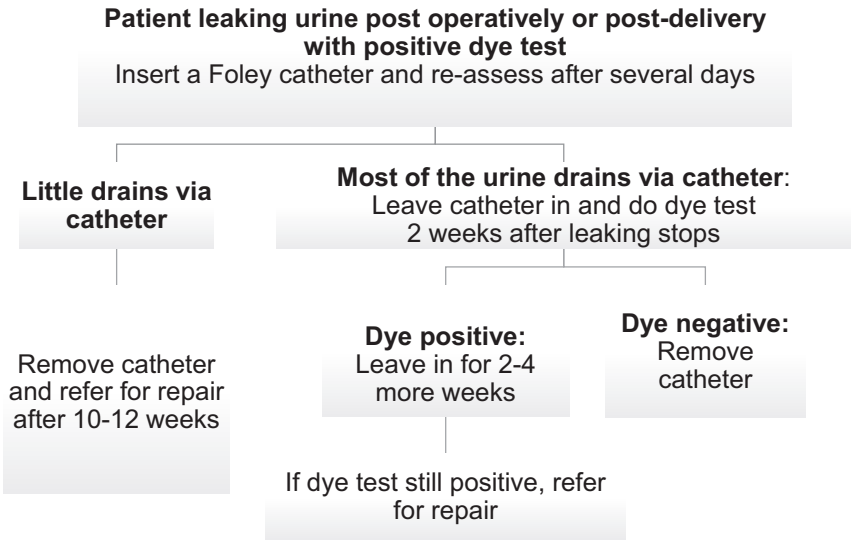
(b) Fibrin glue may be injected directly into the fistulous tract through the vagina. Once the seal is seen cystoscopically from the bladder side to fill the fistula, the injection is stopped. Some of the mixture may spill into the bladder or the vagina, but most remains in the tract. Fibrin glue forms a fibrin plug, which is approximately 10 times stronger than a physiological clot, and this plug fills the hole until tissue ingrowth occurs from the edges of the fistula. This treatment together with catheterization

Table 1
Success rates of conservative treatment for VVF.

Benign gynecological surgery	In a meta-analysis, 19 of 239 cases (8%) resolved with catheter treatment. [5].
Prolonged labor	In a series of 35 VVFs developing in the puerperium, four cases (11%) healed with catheter treatment. In all four cases, the fistula was present fewer than 3 weeks and was less than or equal to 3 cm in diameter [6]. This would suggest that attempts at catheter treatment beyond these limits are futile.
Cesarean section	With vesicouterine fistulas, the involution of the uterus should encourage the fistula to close. However, in a series of 14 cases, the success rate with conservative treatment was only 5% [7].

for 1–4 weeks may lead to closure of the fistula [9,36]. Others use fibrin glue instead of an adjuvant flap at the time of repair. In cases where there is poor tissue quality, if an intermediate layer is unavailable but desired, fibrin glue can be utilized instead of this second layer of closure [43].

(c) Autologous platelet-rich plasma (PRP) can be injected transvaginally into the tissues around the fistula. The swelling produced occludes the lumen of the fistula. In one study of patients with iatrogenic VVFs, who received PRP injections, the fistula healed in 11 of 12 cases [42]. It is thought that growth factors found in platelets stimulate tissue regeneration.



FlowChart. Flowchart for managing vesicovaginal fistula with catheter drainage.

When is the best time to operate?

Choosing the ideal time for repair is the most controversial aspect of fistula management. While some have recommended repairing the fistula as soon as the diagnosis is made, most experts agree that the best timing is when there is no edema, inflammation, tissue necrosis, or infection, i.e., when the tissues are healthy and vascularized [13]. In many patients, this will take up to 12 weeks. During this period, the quality of life may be poor; therefore, reassuring the patient and her family is of utmost importance. While there are always pressures to operate, one should never sacrifice success of surgery by operating too early, as the best chance of closure is at the first attempt. Additionally, it is worth remembering that medicolegal problems usually arise from either the development of a fistula or failure to fix it rather than for any delay in treating it.

(a) ***Postsurgical VVF:*** While there are no studies to make a strong recommendation with regard to timing of repair, we would agree that 10–12 weeks after the initial surgery is the most appropriate time for repair [10,11]. This should result in an easier operation with a better chance of success. Operating before this time period, when the tissues are friable, makes it more likely for sutures to cut through the bladder wall, thus increasing the risk of failure. In North America, patients undergoing a vaginal approach typically undergo fistula surgery earlier. This is likely a reflection of more simple pathology and anticipation of an easy repair [9]. However, even in North America, an abdominal repair is not usually performed before 12 weeks. Our view is that the same timing should be used irrespective of the route, because the absence of inflammation and infection in the bladder layer is crucial for success. Operating before 10–12 weeks, whether abdominally or vaginally, may result in an increased risk of bleeding and a higher risk of failure [14]. The risk of failure would be particularly high within 6 weeks. Exceptions to this advice are as follows:

- The unusual situation where the fistula is diagnosed within 2 days after surgery. Immediate repair may be performed either transabdominally or transvaginally, as inflammation and tissue edema are minimal during this time.
- Although up to 12% of postsurgical VVFs have an associated ureteric injury, only ureteric obstruction in the presence of sepsis, renal failure, or a unilateral kidney needs urgent intervention [12]. In these cases, a nephrostomy may be a better option than surgery as a temporary measure.
- In some cases of vesicouterine fistulas, the patient may experience significant abdominal pain that forces an early intervention. However, in addition to the repair being more difficult, this may also increase the risk of a hysterectomy being required during the repair [39].

(b) ***Fistulas following prolonged labor:*** The general rule is also to wait 12 weeks after delivery before attempting repair. This enables the slough to separate and the tissues to become less friable. Any woman who develops a fistula should have a catheter inserted. If the fistula fails to heal with catheter drainage as described previously, then surgery is performed. The nature of the tissue around the fistula and the surgeon's experience will decide the timing:

- An early repair (3–12 weeks) can be performed as soon as the fistula is clean. However, this is only appropriate for simple fistulas. There are no adequate clinical trials to support early versus later repair. Performing a repair between 3 and 12 weeks is certainly more challenging [1].
- A delayed repair (after 12 weeks) is safer, as there will be less bleeding and the success rates for most surgeons will be high.

(c) Postradiation: the general rule is to wait for 12 months after the completion of treatment.

What is the best surgical approach?

The most important principle in repair is to provide a tension-free and watertight closure, and the surgical route should be the one that provides the best possible chance of closure at the first attempt [15]. The route depends partly on the characteristics of the fistula and also on the experience of the surgeon. Although low and mid-vaginal fistulas should be repaired vaginally, high vaginal and vesicouterine fistulas can be repaired vaginally or abdominally. A meta-analysis showed that the success rates for transvaginal repairs (90.8%) were significantly higher than those for transabdominal (83.9%) repairs [1]. However, these studies were not randomized with regard to the route of repair; therefore, there is no high level evidence supporting the specific route of surgery. There are no studies comparing transvaginal repair to minimally invasive transabdominal approaches.

***Vaginal Route*:** If the access is good and the repair can be performed safely and effectively, then this is preferred for the reasons listed in Table 2 [16].

Abdominal Route: An abdominal approach is required when the fistula cannot be accessed vaginally or if one or both of the ureters needs reimplantation. The abdominal approach is more often required with postsurgical fistulas than with fistulas resulting from prolonged labor. Woo et al. concluded that most fistulas can be closed transvaginally, but abdominal access is recommended if the fistula is high in a narrow vagina [17]. There are two variations of the abdominal approach:

- *Extraperitoneal* transvesical approach: This method is usually performed through a low transverse incision, even if the primary surgery was done through a midline incision. It has the great advantage of avoiding entry into the peritoneal cavity where there are often adhesions. Because it is a less

Table 2
Advantages of vaginal approach for repair of VVF.

Avoids the morbidity of abdominal and bladder incisions with less blood loss.
Not affected by prior abdominal or pelvic surgeries.
Local interpositonal flaps are easily accessible.
Shorter operative time, less postsurgical pain, shorter hospital stay, and quicker return to normal activities.

morbid procedure, it is usually the preferred route. Either the fistula can be repaired within the bladder or, if the exposure is limited, the bladder may be split down to the fistula. The disadvantage of this route is that there are few options for an interpositional flap to be placed between the bladder and the vagina.

- *Transperitoneal* transvesical approach: This allows more options for an interpositional flap to be placed and for ureteric reimplantation when necessary.

Similar success rates are reported for both abdominal approaches [1].

Combined abdominal/vaginal: Occasionally, if the operation starts vaginally, the surgeon may need to switch to an abdominal approach if he/she fails to access the entire fistula. Therefore, fistula surgeons have to be skilled in both approaches.

Are interpositional flaps necessary?

Placing a layer of tissue between the bladder/urethra and the vagina has been used since first suggested by Martius in 1928 [20] with the aim of reducing the risk of failed repairs. This layer serves the following purposes:

(a) a mechanical barrier by separating the bladder/urethra from the vagina or uterus.

(b) a source of perfusion for previously poorly vascularized tissue. Therefore, the layer should preferably be vascular and easily mobilized with its blood supply. Muscle is an excellent layer to interpose because of its vascularity.

There is no high-level evidence to confirm the benefit of tissue interposition, particularly as the decision is usually based on specific fistula characteristics [1]. Many fistulas can be repaired adequately without an interpositional layer, thus avoiding the risks and time associated with tissue interposition [18]. This principle would apply particularly if the bladder tissues appear well vascularized [19]. The Martius flap was used almost routinely in vaginal fistula repairs until relatively recently. When many fistula surgeons stopped using it routinely, their success rates did not change [21]. Therefore, a more selective approach is used at present (see Table 3).

Interpositional tissues for vaginal repair

(1) *Pubocervical fascia:* This is the most easily accessible layer and is found, with adequate dissection, laterally beneath the vaginal epithelium except in cases where there has been a lot of tissue destruction (see Fig. 1). It can be used for many fistulas including those in the vault. This layer contains smooth muscle in addition to fascia.

(2) *Martius flap*: This is useful for mid-vaginal and distal fistulas. It is particularly useful for urethral fistulas where it is difficult to obtain other tissues.

(3) *Pubococcygeus Muscle*: This is the medial part of the levator ani muscle and has a great advantage of being easily accessible vaginally (see Fig. 2). A column of the muscle is cut posteriorly and laterally and then turned upward and medially so that its pedicle is anterior. This can
   - be sutured in place as a patch over the fistula repair [22]. While there are no studies to prove its use in this manner, our experience is that it is useful for any difficult fistula repair, especially lateral recurrent or juxta-urethral fistulas.
   - be sutured to the opposite side across the midline to form a sling under the urethra. To do this, the muscle usually must be accessed from both sides. There is weak evidence from one study where stress incontinence reduced from 33% to 18% after the introduction of this sling [38].

Table 3
Indications for interpositional flaps.

Fistulas that have failed previous repair, especially multiple repairs with significant scarring.
Radiation-induced fistulas.
A fistula associated with a difficult or tenuous closure because of poor tissue quality.
Distal fistulas involving the urethra or juxta-urethral fistulas.

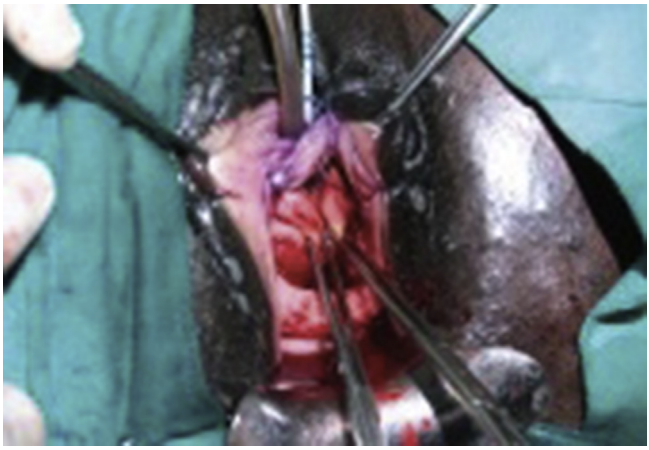


Fig. 1. Pubocervical. The figure shows the pubocervical fascia on both sides being held with Allis forceps and pulled medially toward the midline to cover the underlying fistula repair site.

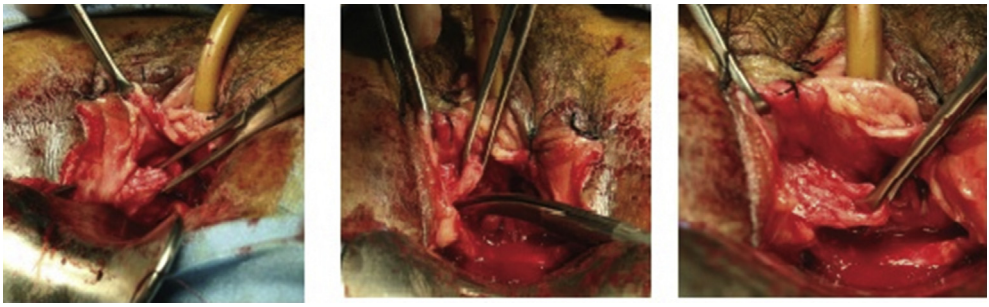


Fig. 2. Pubococcygeus. *Left:* The image shows the pubococcygeus muscle being grasped (with an Allis forceps) from the lateral vaginal wall below the ischiopubic ramus. To do this, the vaginal skin must be first dissected and retracted back to expose the underlying muscle. *Centre:* Shows a flap of this muscle being dissected out by cutting into the muscle posteriorly. It also has to be freed laterally. *Right:* Shows the freed flap of the muscle, with its pedicle based distally/anteriorly, being swung over the underlying fistula repair site.

(4) *Gracilis Muscle:* Because of its bulk and vascularity, this is an excellent intermediate layer [31] but has the disadvantage of requiring an incision in the thigh. Apart from post-radiotherapy fistulas, the Gracilis muscle can also be used in case of any difficult or recurrent fistulas.
(5) *Peritoneal flap*: This can be used for complex, high-lying vault fistulas [24]. Dissection just beyond the proximal wall of the bladder will expose the edge of the peritoneum as it reflects over the bladder. The peritoneal flap is brought forward, covering the suture line, and is secured to the bladder with interrupted sutures. The surgeon must take care to avoid accidentally dissecting into the bladder wall when mobilizing this flap.

Interpositional tissues for abdominal repair

(1) *Omentum:* This is commonly utilized, with blood supply sourced from the right or left gastro-epiploic arteries. Because creation of an omental flap is a simple procedure that results in no significant morbidity, it should be routine if a transperitoneal repair is performed. [23]. Particularly in the case of postradiation fistula, a well-vascularized omental flap can provide an adequate interpositional layer to aid in closure of this chronic type of wound [10].

(2) *Peritoneum*: In transabdominal surgery, there is typically abundant peritoneum that can be taken from several areas, but most often, it is taken as a flap from the paravesical region. In the case where an omental flap cannot be used, a well-vascularized peritoneal flap is often sufficient.
(3) *Rectus muscle:* This is the preferred layer for recurrent or radiation-induced fistulas or where the omentum is inadequate or missing [25].

What steps can reduce the risk of future stress incontinence during the initial surgery?

Stress incontinence remains the most difficult problem to manage after successful closure of a fistula involving the urethral closing or support mechanisms. Therefore, anything that can be done at the time of the initial repair to reduce this is helpful. The following steps may be considered in any fistula within 2.5 cm of the external urethral opening:

(a) Improve the urethral support: Plicate the pubocervical fascia or reattach it to the pubic bone.

(b) Placement of a fascial sling: The traditional advice has been to do this at least 6 months after the fistula repair to avoid any compromise in healing of the fistula [15]. However, performing surgery later is not without risks, partly because the space of Retzius is often very scarred and difficult to enter without causing a cystotomy. In a retrospective review by Asher-Walsh et al., there was an 18% incidence of de novo fistulas with fascia lata slings and 12% incidence with rectus fascial slings [37]. In an attempt to avoid these problems, there are two recent studies where a fascial sling was inserted at the time of the fistula repair.

- In urethrovaginal fistulas that occurred with retropubic or transobturator tapes, a fascial sling was placed at the time of repair without any tension. To help ensure this, a Foley catheter (16F) was kept in place throughout the operation to avoid urethral compression. In some cases, where extensive reconstruction was required, a Martius graft was also employed. In an update of this study, all nine fistulas had healed with no residual stress incontinence [34].
- In a randomized study of fistulas that occurred following prolonged labor (Pope R unpublished data), a rectus sling was placed at the time of the repair in 10 patients, and a pubococcygeus sling (see above) in 11 patients. In an interim safety assessment, 3 of the 10 participants who were randomized to receive a rectus sling experienced a fistula breakdown. One of the 11 pubococcygeal sling participants experienced a fistula breakdown.

While fistulas after prolonged labor are typically more scarred and therefore at greater risk of breakdown, it is likely that some of these breakdowns were due to the sling being placed too tightly or tightening occurred with closure of the fascia from where the sling was harvested. Therefore, if a sling is placed at the time of fistula repair, it must be completely free from tension. A deliberately obstructive sling, which may be required in some of these patients, can only be performed as a staged procedure. Artificial sling materials are not used, as the risk of erosion has been shown to be higher in patients with fistula [37].

(c) Vaginal closure: When closing the vagina, if there is deficiency of the skin, it is important that there is no tension on the urethral opening. If the two sides of the vagina are widely separated, it is better not to forcibly approximate them [26]. Consider using a skin graft to close the anterior vagina. Otherwise, the scarred tissue will pull open the posterior urethral wall and this tethering effect may keep the urethra constantly open even at rest. A fasciocutaneous flap (see Figs. 3, 4, and 5) can be taken from just lateral to the labia majora on one side and then tunneled under the labia into the vagina to fill the defect. This gives a very good cosmetic and functional result.

How long does the bladder need to be drained after surgery?

The catheter is left in until there is sufficient wound healing at the repair site; this timing depends on a number of factors: (a) the size and complexity of the fistula – The WHO has defined a simple fistula as being mid-vaginal with minimal scarring and with a diameter of 3 cm or less [41], (b) whether

Fig. 3. Shows a skin graft taken from the right groin lateral to the labia majora. This has then been tunneled into the vagina under the labia and then lies in the vagina to cover a fistula involving the urethra and distal bladder. The skin is taken along with the deep fascia so that the underlying muscle is exposed in the upper 2/3rds of the donor site. In the lower1/3rd the muscle is covered by the fat and fascia which contain the blood supply to the flap.

it is a first or repeat repair, (c) the repair technique, (d) skill of the surgeon, and (e) patient factors that may affect healing, such as diabetes, smoking, or immune deficiency.

The ideal duration of bladder catheterization in patients after fistula repair is unknown [11,29]. Although widely used in practice, the traditional 14 days of duration has been recently challenged.

Nardos showed that the outcome of postoperative catheterization for 10 days was not inferior to that for 14 days of drainage [27]. However, this randomized trial excluded repeat repairs and circumferential defects.

Barone, in another randomized trial, showed that 7 days of bladder catheterization was not inferior to 14 days [28]. However, this trial only included simple fistulas, and even then, no clear definition of a simple fistula was given. Considering the limitations of these two studies, fistula surgeons need more evidence to safely reduce the duration of postoperative bladder drainage, without concern for increased repair breakdown [30].

In developed countries, hospitals are encouraged to minimize the number of days patients spend in hospital. In such hospital systems, when needed, readmission can be undertaken quickly and without difficulty. By contrast, in developing countries, the pressures are different. It is extremely difficult for patients to be readmitted or to come back for another operation in the future. The journey to home itself is a hazard, as it can take many hours without the ability to void. Therefore, a more conservative approach is better in ensuring that a healed wound will remain healed.

In our experience, the benefit to the patient of having a few days less of catheterization does not outweigh the increased risk of leakage from earlier removal, and 14 days should remain as the standard.

- For simple fistulas, this can be reduced to 12 days.
- For repeat or difficult repairs, a period of 14–18 days is recommended.

Fig. 4. This is the same case as in Fig. 3 with a view within the vagina with the flap sutured in place over the defect in the vagina.

- In postradiation fistulas, a period of 28 days is recommended.
- If there is a positive dye test at the time of intended catheter removal, or if the patient starts to leak urine anytime postoperatively, an extra 2–4 weeks of catheterization may allow the fistula to heal. In addition, although there are no studies to support it, getting the patient to lie in the prone position in bed for as much time as possible improves the chance of closure. This is because it keeps the urine away from the fistula site posteriorly. If the leakage stops in this position, the fistula is likely to heal provided the patient can maintain this position for 10–14 days.

Once the catheter is removed, the patient has to be observed for several days for signs of urinary retention or infection.

What is the best way to manage radiation-induced fistulas?

There are three options for the management of the most difficult fistulas:

(a) Conventional repair: The associated devascularization in the tissues means that this has a high likelihood of failure. Mobilization of the fistula is often difficult, and the edges are more likely to slough. Repair should always be performed with an interpositional layer to bring in fresh blood supply [16]. The only radiotherapy-induced VVFs or rectovaginal fistulas that we have managed to close successfully were

Fig. 5. Shows the same case with the Singapore graft donor site healing well one week post-operatively.

performed with the help of a Gracilis or rectus muscle flap. Another more recent option is to use amniotic membrane as a patch to improve healing rates for wounds that are difficult to heal, including those in radiated tissues [32]. The membrane is placed over the repaired vaginal defect and carefully sutured in place [40].

(b) Urinary diversion is a reasonable option because the repair often fails even with a good technique.

(c) Colpocleisis is another option provided the patient and her partner are prepared to accept the loss of sexual function. By closing the lower vagina away from the irradiated area, and in tissues with better blood supply, healing becomes more likely. However, in some cases where the whole vagina has been radiated, the tissues may still fail to heal. If the vagina looks pale, then it is worth attempting colpocleisis. If the vagina appears more like slough tissue, then it is likely not worth attempting. Generally, colpocleisis is a safe and straightforward procedure and is well accepted.

Who should be operating?

Because the first attempt at repair has the best chance of success, it is important that the patient is operated on by an experienced surgeon in the right setting. Limited surgical experience makes failure of repair more likely, and an association between workload and outcome has been shown [33]. A poorly performed repair can make a fistula inoperable.

Centralization of management in areas of high prevalence/workload by an experienced multidisciplinary team is the model that has worked best. This approach is equally applicable to both well- and low-resourced settings [1].

In developing countries, fistulas from obstetric trauma have received increased attention and funding in recent years. While this has allowed more patients to be treated, it has also led to more failed repairs and complications partially because it is difficult to properly train adequate numbers of surgeons.

Summary

The great variations seen in the complexity of VVFs partly explain the differing opinions held about their management. While conservative measures generally have low success rates, attempting conservative management in the first 3 weeks after injury is reasonable, especially in smaller fistulas. If these measures fail, or the patient presents later, repair of the fistula is best left until 10–12 weeks after injury. Earlier repair may be undertaken, especially in smaller fistulas, but is both more difficult and has a higher failure rate, especially if undertaken before 6 weeks. The vaginal route is preferred, provided this gives adequate access. Experience rather than evidence suggests that interpositional flaps and newer materials are useful for difficult, repeat, or postradiotherapy repairs. If a fistula involves the urethra, additional steps can be taken to reduce the risk of stress incontinence. After repair, the duration of bladder drainage will vary with the complexity of the repair.

Practice points

- Surgical repair is best delayed until 10–12 weeks.
- The vaginal route is preferred where it is feasible.
- Interpositional flaps and newer materials are very useful in select cases.

Research agenda

- Trial of early (6 weeks) versus late (12 weeks) repair.
- Trial on the use of interpositional flaps.
- Trial on the minimum duration of bladder drainage after repair for all types of vesicovaginal fistulas.
- Trial on the use of the prone position postoperatively.

Conflicts of interest

None.

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