



Comparative study between use of Buccal Mucosal Graft and Martius flap as A Second Layer in Vaginal Repair of complex Vesicovaginal Fistula: a prospective randomized trial

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ABSTRACT

Background The pathological communication that allows urine to flow into the vagina is called a vesicovaginal fistula (VVF), it is often associated with higher risks of repeated failed attempts as well the unsuccessful repair. This work aimed to compare the efficacy in addition to the safety of buccal mucosa graft and Martius flap as a second layer in vaginal repair of Vesicovaginal fistula. **Methods** we carried out this prospective randomized study on 16 cases of women with VVF, divided into two groups: The 1st group underwent trans-vaginal VVF repair with the interposition of Buccal Mucosal Graft (BMG). The 2nd group underwent trans-vaginal VVF repair with the interposition of Martius flap. Follow-up was done till 9 months after surgery for new symptoms of overactive bladder symptoms, urinary incontinence, and dysuria. CT cystogram was performed to evaluate the fistula. **Results** The mean operative time of the 2nd group was 71.37 ± 8.27 minutes which was longer than 1st group (66.25 ± 8.6 minutes) ($p=0.224$): In the 1st group: Graft pain, Perioral numbness and Opening difficulties were reported in 75%, 75% and 12.5% of the cases, respectively. The mean healing time of the donor site was 6.5 ± 2 days, the mean time of liquid tolerance was 1.62 ± 9.16 days, the mean time for catheter removal was 19.5 ± 2.77 days, the 1st group had statistically significant higher complications than the 2nd group ($p= 0.0404$). Success rate was higher in the 1st group (87.5 %) than the 2nd Group (75 %) with non-statistically significant difference between the both groups ($p<0.05$). **Conclusion** The interposition of buccal mucosa graft could be more efficient and safer as a second layer in vaginal repair of vesicovaginal fistula than Martius flap interposition. **Keywords** Buccal Mucosal Graft, Martius flap, Second Layer, Vaginal repair, Vesicovaginal Fistula.

INTRODUCTION

An estimated 50,000 to 100,000 new cases of Genital tract fistula are reported especially obstetric fistula (OF) each year, affecting over 2 million women in the Americas, Asia, and sub-Saharan Africa. Approximately five percent of

obstetric fistulas are complicated by urethral loss. About 10% of obstetric fistulae are complicated by stress incontinence, which typically occurs after injuries that involve the urethral tissue or the sphincter mechanism [1].

A vesicovaginal fistula (VVF) is a pathological track that allows urine to leak out of the bladder into the vagina. While hysterectomy is the leading cause of VVF, obstetrical trauma and pelvic surgery are the less common reasons. The spontaneous loss of vaginal urine is the most prominent sign of VVF. A cystoscopy, vaginal exam, intravenous urography, or computed tomography urography (CT) scan can confirm a diagnosis of VVF [2].

There is a higher likelihood of failure repair and more frequent failed attempts to close vesicovaginal fistulas when urethral loss (UL) is present [3]. In order to evaluate the critical features of the fistula prior to surgery, cystoscopy is necessary. All VVFs were classified by Chapple and Turner-Warwick as either simple or complex fistulas. While all other fistulas are complex, a simple VVF is often tiny, distant from orifices and the urethra, and has essential tissue boundaries. Type III per Goh's categorization includes post-radiation VVFs, fistulas involving the ureter, as well as recurrent VVFs [4].

In the event that VVF is not identified during surgery, the surgical correction will be postponed for two or three months to allow enough time for the patient to heal. For less complicated VVFs, surgical suturing of the bladder and vaginal walls is sufficient, but for more complicated fistulas, tissue grafts must be interposed. Vaginal, trans-vesical, trans-abdominal, and laparoscopic routes were commonly used in surgical procedures. In cases of relatively minor fistulas, the vaginal approach is the treatment of choice. Unlike in the past, there are very few cases requiring the trans-vesical method [5].

Within the past six years, there have been instances where neither vaginal nor bladder mucosa was acceptable for usage. The local tissue may become fibrotic and hard, making it unsuitable for use in VVF repair. This can happen following pelvic radiation therapy or several prior procedures. Free grafts harvested from non-genital regions, including skin, buccal mucosa, or bladder mucosa, can be utilized for urethral reconstruction in male patients when appropriate local tissue is not available [6].

As an alternative to skin, buccal mucosa has demonstrated its usefulness. Not only is it

tolerant of damp conditions, but it is also easy to harvest and work with. Patients with any kind of fistula or stricture have found relief with buccal mucosal grafts, which have medium-term results that are on par with skin transplants but come with less problems and reduced donor site morbidity. The ideal source for tissue replacement in management of various fistulas and fissures is buccal mucosa due to its inherent advantages [7].

The male urethra is the most typical area that BMG has been utilized for reconstruction thus far. The fact that BMG may live and thrive on the urothelium is widely recognized. When compared histologically, buccal mucosa closely resembles a normal urethra, down to the level of immunoglobulin A and cytokeratin pattern. Also, the buccal mucosa contains a thin submucosa that aids in revascularization and a dense epithelium that gives the graft its firmness [8]. So, this study aimed to compare the efficacy in addition to the safety of buccal mucosa graft and Martius flap as a second layer in vaginal repair of Vesicovaginal fistula.

METHODS

We carried out this prospective randomized study on 16 cases of women with VVF, attended to the Urology Outpatient clinic, at Zagazig University Hospital, they underwent either buccal mucosa graft and Martius flap as a second layer in vaginal repair of Vesicovaginal fistula in the duration from May 2023 to March 2024. Approval was obtained from Zagazig University Institutional Review Board (IRB #10698-16-4-2023). Consent was collected from every patient before participating in the study. The Declaration of Helsinki, the international Medical Association's guideline of ethics for studies involving humans, was followed in the conduct of this study.

We included female patients who had a confirmed imaging or clinical diagnosis of VVF. We excluded all patients with any the following conditions: patients who had malignant or irradiated fistula or fistula that was close to ureteric orifices., or severe scaring (difficult access to vagina).

The 16 included cases of women with VVF, divided into two equal groups (n=8 cases in each group): The 1st group underwent trans-vaginal

VVF repair with the interposition of Buccal Mucosal Graft (BMG). The 2nd group underwent trans-vaginal VVF repair with the interposition of Martius flap.

Preoperative Phase:

A comprehensive history was taken from patients, with analysis of their current complaints. A full physical examination, both systemic and local, was also performed. Laboratory investigations involved complete blood picture (CBC), coagulation profile, Random blood sugar, liver function tests (LFT) in addition to kidney function tests (KFT). Radiological studies included Ultrasound: to detect any upper tract hydronephrosis that may be related to concomitant ureterovaginal fistula. **CT cystogram was performed to evaluate the fistula:** the contrast material was administered through a catheter inserted into the bladder, proper timing of contrast administration was ensured to achieve optimal opacification of the urinary tract structures, the CT scan was performed, acquiring images of the pelvis in multiple phases to capture the contrast material as it filled the bladder and urinary tract.

VVF was classified according to Goh classification system [9]. Women underwent trans-vaginal VVF repair with the interposition of BMG. The operation was done under general anesthesia to facilitate harvesting an autologous BMG during dissection of the fistula. The patient was placed in the dorsal lithotomy position. The

fistula site was identified along the anterior vaginal wall. **Cystoscopy** was performed to further define the anatomical location of the fistula and its proximity to the urethra and both ureteric orifices. **Bilateral Diagnostic ureteroscopy** was done to exclude concomitant ureterovaginal fistulas with fixation of 2 ureteric catheters.

Surgical technique:

Vaginal epithelial flaps were carefully dissected laterally, proximally, and distally. Once the perivesical fascia was mobilized bilaterally and its edges could easily be brought together over the site of the fistula, the tissue layers involved in the repair could be approximated. The first layer of repair was the perivesical fascia, including the mucosa at the edges of the fistula itself. After suturing of these layers, the integrity of the repair was tested by injecting either saline or a solution of methylene blue or indigo carmine diluted in saline directly into the urethra via the urethral catheter.

The 1st group (Buccal Mucosal Graft): At the same time of dissection of the fistula, meanwhile, another team was collecting buccal mucosal graft cells from a location 1.5 cm far from Stensen's duct and 1.5 cm distant from the cheek's margin, close to the buccinator muscle. We thinned and defatted the graft. The suture lines were covered with the BMG. The last step in closing the incision was to slide a vaginal wall flap over it (Figure 1).

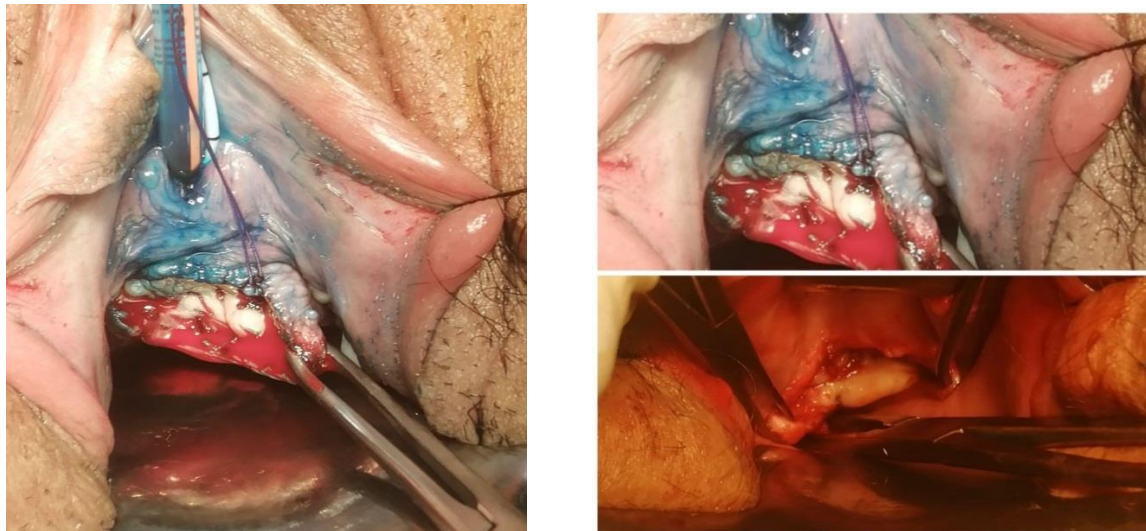


Figure 1: Buccal graft interposition as 2ry flap.

Outcome Measurements and Follow-up:

Follow-up was done at 1-3 weeks post-surgery for any new symptoms of overactive bladder symptoms, urinary incontinence, as well as dysuria. Before catheter removal, CT cystogram was done to confirm fistula closure. Additional follow up visits 3-9 months after repair.

The 2nd group (Martius flap): While in the reverse lithotomy posture, the patient's head was slightly lowered as they were put prone. After Foley was adjusted, a light tug was exerted. To further define tissue planes and stop any leakage, adrenaline was injected into the tissues. Subsequently, a 5-millimeter radius surrounding the fistula was excised from the vaginal wall. Afterwards, vicryl 3-0 was applied in two layers to the bladder wall for repair. Continuously, 2-0 vicryl suture was used to seal the vaginal wall.

Incisions were made with a 15-blade across the labium majus's midsection and thickest area, beginning at the level of the clitoral hood and continuing inferiorly to the level of the labiocrural fold, the yellow fibrofatty graft was held and drawn medially. This was done since the presence of a natural tissue plane made it easier to separate it from the labium majus that was surrounding it. The next step was to create a plane connecting the Martius graft to the bulbocavernosus muscle by retracting it laterally. A Shallcross was utilized to aid the formation of

the subepithelial defect through which the flap was passed once it was determined to be adequately mobilized. The next step was to pass the flap through the levator plate. Sewing the flap into place involves positioning it and then using interrupted 2-0 Vicryl sutures to link it to the neighboring, underlying rectovaginal fascia. So, the empty space above the fistula repair was filled up, and the devascularized, cut area received a fresh blood supply.

STATISTICAL ANALYSIS

The data was processed using SPSS version 25.0 after it had been checked, entered, and analyzed. Qualitative data was presented as numbers and percentages, quantitative data as means ± SD, and two groups.

RESULTS

The mean age of the 1st group was 34 ± 7 years. The mean number of gravidities was 4 ± 1. The mean number of parities was 3 ± 1. There were 4 cases with associated comorbidities (25%). The 2nd group mean age was 35.38 ± 7.5 years with range between 26 and 47 years. The mean number of gravidities was 4.88 ± 1.7 with range between 3 and 8. The mean number of parities was 3.13 ± 1.3 with range between 1 and 5 with non-statistically significant difference between the both groups (p= 0.709) (Table1).

Table (1): Analysis of the demographic and obstetric data in the cases of the study.

Variables		Study cases (n=16)		P Value	Statistically significant
		(1 st group n=8)	(2 nd group n=8)		
Age (years)	Mean ± SD	34 ± 7	35.38 ± 7.5	0.709	N. S
	Median (Range)	35 (22 – 47)	35 (26-47)		
Gravidity	Mean ± SD	4 ± 1	4.88 ± 1.7	0.228	N. S
	Median (Range)	3 (2 – 6)	5 (3-8)		
Parity	Mean ± SD	3 ± 1	3.13 ± 1.3	0.826	N. S
	Median (Range)	3 (2 – 4)	4 (1-5)		
		Number	Percent	P Value	Statistically significant
Associated comorbidities					
Yes		4 (25%)	12 (75%)	0.046	Sig.
No		12 (75%)	4 (25%)		

Continuous data expressed as mean ± SD and median (range)

Categorical data expressed as Number (%)

The number of the recurrent VVF in the 1st group was 1 case with percentage of 12.5%. Meanwhile the 2nd group has 2 cases with percentage of 25%. The main causes of VVF were post CS with 3 cases in the 1st group and 4 cases in the 2nd group. The number of fistulae was, in the 1st group, 1 case with one fistula and 7 cases with 2 or more fistulae. But in the 2nd group 3 cases have one fistula and 5 cases have 2 or more fistulae. The site of fistula was variable but the most common

site was supratrigonal in 3 cases of the 1st group and 4 cases of the 2nd group. Lastely, the mean size of fistula in 1st group was 2±1 and 2.44 ±1. For the 2nd group. The stress incontinence was found in only one case in the 1st group with non-statistically significant difference between both groups as regards recurrent fistulae, causes, number, sites, size or stress incontinence (p=0.5218, 0.4398, 0.2482, 0.7881, 0.768, and 0.3017 respectively) (Table 2).

Table (2): Analysis of the Vesicovaginal fistula in the cases of the study.

Variables	Study cases (n=16)				P Value	Statistically significant
	(1 st group n=8)		(2 nd group n=8)			
	No	%	No	%		
Recurrent fistula						
Yes	1	12.5 %	2	25%	0.5218	N. S
No	7	87.5%	6	75%		
Causes	No	%	No	%		
Post CS	3	37.5%	4	50%	0.4398	N. S
Post hysterectomy	5	62.5%	3	37.5%		
Post normal labor	0	0	1	12.5%		
Number of fistulae	No	%	No	%		
One	1	12.5%	3	37.5%	0.2482	N. S
Two	7	87.5%	5	62.5%		
Site	No	%	No	%		
Bladder neck	2	25%	1	12.5%	0.7881	N. S
Supratrigonal	3	37.5%	4	50%		
Trigonal	3	37.5%	3	37.5%		
Size of the fistula (cm)						
Mean ± SD	2±1		2.44 ±1		0.768	N. S
Median (Range)	2 (1-3.5)		2 (1-4)			
Stress incontinence	No	%	No	%		
Absent	7	87.5%	8	100%	0.3017	N. S
Present	1	12.5%	0	0		

Continuous data expressed as mean ± SD and median (range)

Categorical data expressed as Number (%)

The mean operative time of the 2nd group was 71.37 ± 8.27 minutes which was longer than 1st group (66.25 ± 8.6 minutes) ($p=0.224$) (Table 3).

Table (3): Analysis of the operative data in the 2 groups of the study.

Variables	1st Group N = 8		2nd Group N = 8	P Value	Statistically significant
	Number	Percent			
Operative time (min)					
Mean \pm SD	66.25 ± 8.6 minutes		71.37 ± 8.27 minutes	0.224	N. S
Median (Range)	70 (50 – 74) minutes		71 (60 – 85) minutes		
Graft pain					
Absent	6	75 %			
Present	2	25 %			
Perioral numbness					
Absent	6	75%			
Present	2	25 %			
Opening difficulties					
Absent	7	87.5 %			
Present	1	12.5 %			

Continuous data expressed as mean \pm SD and median (range)

Categorical data expressed as Number (%)

In the 1st group: The mean healing time of the donor site was 6.5 ± 2 days, the mean time of liquid tolerance was 1.62 ± 9.16 days, the mean time for catheter removal was 19.5 ± 2.77 days. In 2nd group: the mean healing time was 6.2 ± 1.7 days, the mean time for catheter removal was 18.42 ± 3.2 days with non-statistically significant difference between the both groups ($p=0.751$). The 1st group had statistically significant higher complications than the 2nd group ($p= 0.0404$). In

the 1st group bleeding was found in 2 cases (25%), in the 2nd group complications were labial infection in 1 case (12.5%), graft pain in 4 cases (50%), vaginal bleeding in 2 cases (25%), stress incontinence in 1 case (12.5%). Success rate was higher in the 1st group (87.5 %) than the 2nd Group (75 %) with non-statistically significant difference between both groups ($p<0.05$) (Table 4).

Table (4): Analysis of the postoperative data in the 2 studied groups.

Variables		1st Group N = 8		2nd Group N = 8		P Value	Statistically significant
Healing time for donor site (Days)	Mean \pm SD	6.5 ± 2		6.2 ± 1.7		0.751	N. S
	Median (Range)	7 (4 – 9)		7 (4 – 9)			
Liquid tolerance (Days)	Mean \pm SD	1.62 ± 9.16		-			
	Median (Range)	1 (1 – 3)					
Catheter removal time (Days)	Mean \pm SD	19.5 ± 2.77		6.2 ± 1.7		0.0001	Sig.
	Median (Range)	21 (15 – 21)		7 (4 – 9)			
Postoperative complications		Number	Percent	Number	Percent		
Bleeding		2	25 %	0	0%	0.0404	Sig.
Labial infection		0	0%	1	12.5 %		

Variables	1st Group N = 8		2nd Group N = 8		P Value	Statistically significant
Graft pain	0	0%	4	50%		
Stress incontinence	0	0%	1	12.5 %		
Vaginal bleeding	0	0%	2	25%		
Postoperative follow up period						
Mean ± SD	7.4 ± 1.17 months		7.4 ± 1.17 months		>0.9999	N. S
Median (Range)	7.5 (6-9) months		7.5 (6-9) months			
Success rate without recurrence	87.5 %		75 %		>0.99	N. S

Continuous data expressed as mean ± SD and median (range)

Categorical data expressed as Number (%)

DISCUSSION

In order to cure the majority VVFs, surgical intervention is necessary. For VVFs, there is yet no standard protocol for therapy. Transvaginal, transabdominal, transvesical, and various combination repair techniques are all part of the surgical repair pathway [10]. In addition to the fistula's location, size, quantity, and vaginal condition, the surgeon's clinical expertise and the patient's preference play a role in determining the surgical method [11]. However, compared to transabdominal repair, transvaginal repair is far more economical because of the shorter surgical procedures and hospital stays involved [12].

Despite the growing popularity of transvaginal repair, there has been little progress in this area of surgery due to the small vaginal opening, the difficulty of the operation, and the increased demand for separating skills [10].

Urologists like using oral mucosa because it is compatible with and shares many characteristics with urethral tract mucosa. The buccal mucosa is a nonkeratinized tissue that is able to adapt to its environment and endure shearing forces in the mouth because of its thick epithelium with vascular lamina propria [13].

For the past ninety years, vaginal VVF repair has relied on the Martius fat-pad interposition. Despite the numerous studies demonstrating the effectiveness of this method, it is not without its drawbacks. These include the possibility of surgical-area infections, bleeding of up to 20%, and hematomas of up to 6% during the treatment. Another drawback is that as we get older, the fat under the labium majus becomes less dense, and

it is not possible to remove fibrofatty flaps that are big enough, which is a problem when dealing with many tissues at once [14].

There is shortage in the studies that assess the efficacy of use of buccal mucosa graft during the repair of VVF. So, the current study was conducted to assess the efficacy of interposition of buccal mucosa graft as a second layer in vaginal repair of Vesicovaginal fistula and to compare it with the efficacy of martius flap interpositioning

The mean age of the **1st group** was 34 ± 7 years with range between 22 and 47 years. And **the 2nd group** mean age was 35.38 ± 7.5 years with range between 26 and 47 years. Similar age range was shown in the study of Nerli et al. [15] who included a total of nine women with a mean age of 38 years. This study is to demonstrate the repair of VVF guided by cystoscop using intravesical laparoscopic instruments.

In the current study, the main cause of vvf was hysterectomy with 62.5% in the 1st group and 37.5% in the 2nd group. The other most common cause of vvf was post CS by 37.5% in the 1st group and 50% in the 2nd one.

The current results agreed with Wang et al. [10] who included 37 patients with VVF and showed that Out of those six cases, one was an obstetric fistula following a vaginal delivery and five were associated with caesarean sections. There was no history of pelvic radiation in the 28 cases of gynecological fistula that occurred after hysterectomy. This was in line with the findings of Hillary et al. [16], who reported that 75% of

VVFs happened following abdominal hysterectomy in their systematic analysis.

Recurrent fistula formation, vaginal stenosis, ureteric injury or obstruction remain the major complications following VVF repairs. In the current study, 40% of the cases are recurrent, being large >1 cm and multiple. Also, With an average of 1.38 procedures per patient, Ayed et al. [17] studied 73 patients who had 97 surgeries for VVF recurrence. Recurrence was found to be statistically significant for the following factors: multiple fistulas (single vs. two or more), fistula size (>10 mm), type of fistula (Type I vs. Type II), cause of fistula (obstetrical vs. non-obstetrical), and presence of urinary tract infection before repair, according to their multivariate analysis.

In the current study, the mean size of fistula in 1st group was 2±1 and 2.44 ±1 For the 2nd group with range between 1 and 4 cm. The site of fistula was variable but the most common site was supratriangular in 3 cases of the 1st group and 4 cases of the 2nd group. In this study 37.5% of the 1st group and 50% of the 2nd group were found supratriangular and all cases were away from both UOs, so they were suitable for vaginal repair. The current study nearly approaches the results of transabdominal approach with a mucosal flap prepared from the bladder by Hazar et al. [18] in which 71% of the cases were supratriangular and 28% were trigonal.

In this study the mean operative time of the 2nd group was 71.37 ± 8.27 minutes which was longer than 1st group (66.25 ± 8.6 minutes) (p=0.224). The time needed for harvesting the BMG did not affect the total operative time because there was another team that was responsible for harvesting the graft at the same time from the beginning of operation. Regarding the outcomes after surgical repair of VVF, in developed nations, the literature reports an overall closure rate of 94.5 percent, with a range of 75.6 to 98.5 percent. Transvaginal repair of UVFs is associated with a 6.5 (1.1-51.9) percent SUI rate after successful VVF repair [5,19].

The mean healing of the oral mucosa graft site time was 6.5 ± 2 days with range between 4 and 9 days for the 1st group. The mean healing time of the 2nd group 6.2 ± 1.7 days with range between 4

and 9 days. The mean time of the liquid tolerance was 1.62 ± 9.16 days with range between 1 and 3 days. The mean time for catheter removal was 19.5 ± 2.77 days with range between 15 and 21 days for the 1st group. And 18.42 ± 3.2 days for the 2nd group with range between 15 and 21 days which nearly has no difference between both groups. The high efficacy of the technique of BMG was previously shown in 2 cases done by Hadzi-Djokic et al. [20] that included two women admitted for recurrent vaginal fibrillation; the ages of the women are 45 and 56, respectively. Transvesical extraperitoneal VVF repair with BMG interposition was performed on both women.

The 1st group had statistically significant higher complications than the 2nd group (p= 0.0404). In the 1st group bleeding was found in 2 cases (25%), in the 2nd group complications were labial infection in 1 case (12.5%), graft pain in 4 cases (50%), vaginal bleeding in 2 cases (25%), stress incontinence in 1 case (12.5%). Success rate was higher in the 1st group (87.5 %) than the 2nd Group (75 %) with non-statistically significant difference between both groups (p<0.05).

These finding coincides with recent study, in which the authors revealed that complications caused by BMGs are uncommon. The buccal donor site was associated with a 4% complication risk, with scarring and contracture being the most common complications, according to a comprehensive study. In less than 1% of cases, bleeding and the formation of hematomas did occur. Mild pain and discomfort may persist for up to four weeks following surgery. The majority of patients regain their preoperative jaw opening range within four weeks; however, some may experience temporary restrictions [21].

While the martius flap group postoperative complications included labial infection, Graft pain, Stress incontinence, Vaginal bleeding that were reported in 12.5%, 50%, 12.5%, 25% of the cases respectively.

LIMITATIONS OF THE STUDY

More patients need to be enrolled in further studies to confirm the advantages of the BMG technique specially those large complex and radiation induced fistulae. Besides long-term follow-up is required.

The transvaginal route is now the preferred route of fistula approach at our institution. Plenty of patients now prefer vaginal approach to abdominal laparotomy. One less intrusive method is the vaginal route. A variety of tissue flaps and grafts may need to be interposed in order to successfully repair a VVF, which can be a challenging surgical problem. One way to think about the excellent Martius flap is as the vaginal version of the omentum, which is utilized in transabdominal repair. The restoration of complicated VVF can also be supported by other types of harvested flaps, including as peritoneal, labial, and gluteal muscle flaps.

CONCLUSIONS

The interposition of buccal mucosa graft could be more efficient and safer as a second layer in vaginal repair of vesicovaginal fistula than Martius flap interposition.

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