Med. J. Cairo Univ., Vol. 90, No. 8, December: 2565-2572, 2022
www.medicaljournalofcairouniversity.net

Evaluation of the Impact of Vacuum-Assisted Closure Therapy in Post-Operative Patients with Entero-Cutaneous Fistulae

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Abstract

Background: Enterocutaneous fistulae is a result of a wide variety of conditions and circumstances. Care of these patients can be quite challenging, frustrating, and, ultimately, rewarding.

Aim of Study: Assessment of role of vacuum assisted closure in management of patients with post-operative entero-cutaneous fistulae.

Patients and Methods: This is a prospective cohort study that will be conducted on fifteen (15) patients presenting to Ain Shams University Hospital and Cairo Fatemic Hospital (CFH) suffering from Enterocutaneous fistulae. Patients will be assessed according to inclusion and exclusion criteria. All patients sharing in the study will be fully informed about the procedure they will have, its possible squeal, and its complication with a written and informed consent will be taken from all patients who will accept to participate.

Results: In our study we found that 80% of patients had complete cure. Also vac system improve general condition and decrease skin excoriation. Vac system is a promising technic in management of ECF.

Conclusion: Enterocutaneous fistulae is a common surgical problem result of a wide variety of conditions and circumstances. Fistula management can be quite challenging, frustrating, and, ultimately, rewarding. Different methods of management are found with different results and outcomes Vac therapy is a new technique with promising results in management of fistula Vac therapy improve fistula condition, decrease soiling, improve general condition and better financially than ordinary dressing.

Key Words: *Entero-Cutaneous Fistulae – Vacuum-Assisted Closure Therapy.*

Introduction

ENTEROCUTANEOUS fistulae are an uncommon surgical problem characterized by a difficult management and healing with a mortality rate ranging between 6% and 33% Rahbour et al. **[1]** due to the development of malnutrition, electrolytic abnormalities and sepsis **[2]**.

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Enterocutaneous fistulae can be classified on the output volume, ranging from low to moderate to high output fistulae. Low output is classified as <200cc/day, moderate output as 200-500cc/day, and high output as >500cc/day **[3]**.

Furthermore, Enterocutaneous fistulae can be distinguished in simple or complex. Simple fistulae have a short, direct tract, no associated abscesses or other organ involvement.

Complex fistulae are divided into: Type 1: Associated with an abscess or involving multiple organs. Type 2: That opens into the base of a disrupted wound and is often known as entero-atmospheric fistula (EAF). EAF fistula is defined as: "An exposed fistula occurring in the midst of an open abdomen with no overlying soft tissue" **[4]**.

By nature, complex fistulae have higher morbidity and mortality rates, as well as a lower rate of spontaneous closure **[5]**.

Vacuum-Assisted Closure (VAC) Therapy is a widely acknowledged method for second intention wound closure. At first, VAC therapy was contraindicated in the treatment of intestinal fistulae **[6,7]**, as it was reported to delay their closure and cause internal organ damage **[8]**.

But as time went by, this method revealed itself to be a "Swiss knife multi-tool" **[9]**, a single device with multiple functions, like a pocket knife with many blades. Several reports are now available on the efficacy of VAC treatment in the case of many kinds of fistulae **[10]**.

Aim of the work:

Assessment of role of vacuum assisted closure in management of patients with post-operative entero-cutaneous fistulae.

Patients and Methods

This is a prospective cohort study that will be conducted on fifteen (15) patients presenting to Ain Shams University hospital and Cairo Fatemic hospital from April 2021 – October 2021 (CFH) suffering from Enterocutaneous fistulae.

Patients will be assessed according to inclusion and exclusion criteria.

All patients sharing in the study will be fully informed about the procedure they will have, its possible squeal, and its complication with a written and informed consent will be taken from all patients who will accept to participate.

Inclusion criteria:

Adult patients between 18 and 65 years of age. Male and female patients. Post-operative patients with enterocutaneous fistulae. Elective and emergency patients.

Exclusion criteria:

Pregnant females. Chrons disease. Patients above 65 or below 18 years. Immune-compromised patients. Patients on immunosuppressive therapy or corticosteroids. Patients with distal intestinal obstruction. Duration of the study: Six months (starting April 2021 and ended October 2021).

Methods:

Our study includes 15 patients of different age groups and both sexes presenting with enterocutaneous fistulae, our Sampling Method is convenient sampling. After good assessment and evaluation, the patients will be put on VAC with regular dressings every 3 days to assess healing process for a duration of two months. Avacuum system has several parts. A foam or gauze dressing is put directly on the wound. An adhesive film covers and seals the dressing and wound. A drainage tube leads from under the adhesive film and connects to a portable vacuum pump, the aspiration system must be set at a low pressure (-50/-75mmHg) so that the sponge cells do not close. If greater than -75mmHg, cells are closed and does not allow the aspiration of the secretions. After each dressing photos of the fistula will be taken for assessment of the progress of healing and degree of excoriation of skin. Vital signs of patients and amount of effluent will be recorded. After complete healing and recovery or two months results will be recorded to evaluate the efficiency of VAC therapy in management of enterocutaneous fistulae, skin protection and prevention of excoriation instead of ordinary regular dressings.

The aim of the present study is to:

Assess The Role of Vacuum Assisted Closure in Management of Post-Operative Entero-Cutaneous Fistula.

Place of work:

"Ain-Shams University Hospital" and "Cairo Fatemic Hospital" Cairo, Egypt.

Number and selection of participants:

This is a prospective cohort study that will be conducted on fifteen (15) patients presenting to "Ain Shams University hospital" and "Cairo Fatemic Hospital" developed Enterocutaneous fistulae. Patients will be assessed according to inclusion and exclusion criteria.

Plan of work:

After consent achievement and full explanation about the steps of the procedure, all patients will be subjected to VAC procedure.

Primary outcome of the study:

To Evaluate the efficiency of VAC therapy in management of Entero-cutaneous fistulae, skin protection and prevention of excoriation instead of ordinary regular dressings.

Risks and complications:

The most significant complications include: Failure, Perforation or Hemorrhage. The following photos represent a case of colo cutaneous fistula of female pt 30 years old post resection and anastomosis of iatrogenic colonic injury during laparoscopic ovarian cystectomy.

Statistical analysis:

Data are presented (in tables) either as mean ± standard deviation and range or the number of cases (percentage of the total count of the respective group) [n (%)] in case of continuous and categorical variables respectively. In the case of 2-group comparison; continuous data were compared using student *t*-test, while categorical data were analyzed using chi-square. The association of the candidate variables with esophageal varices was assessed using univariate analysis. All variables that were found to be significant in the univariate analysis were included as candidate variables in step-wise regression analysis to identify independent predictors for the presence of esophageal varices. Reported results significance level was set to ($p<0.05$). Statistical testing was performed using IBM SPSS statistics software (version 25).

Fig. (1): Before vac application.

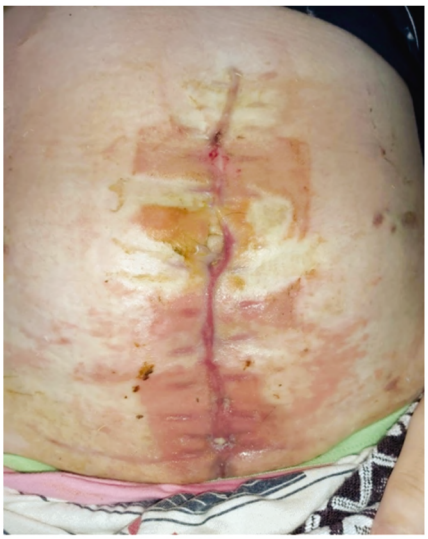

Fig. (2): Skin excoriation.

Fig. (3): After couplet colusre (10 days).

Results

Table (1): Demographics, medical and surgical history of the study patients.

Variable	Total (N=15)	Range
Age (years) (mean±SD)	39.73±12.787	25-65
Male, n (%)	11	73.3%
Female, n (%)	4	26.7%
Medical and surgical history		
Smoker, n (%)	8	53.3%
Past Medical history, n (%)	7	46.7%
DM, n (%)	4	26.7%
HTN, n (%)	4	26.7%
IHD, n (%)	2	13.3%
DM and HTN, n (%)	1	6.7%
DM and IHD, n (%)	1	6.7%
Past surgical history, n (%)	5	33.5%
Appendectomy, n (%)	1	6.7%
Cholecystectomy, n (%)	2	13.3%
Perforated D U, n (%)	1	6.7%
Ventral hernia repair, n (%)	1	6.7%

Table (2): Operations of the study patients.

Variable	Value	Range
Distal gastrostomy for cancer stomach	1	6.7%
Ovarian cystectomy	1	6.7%
Cholecystectomy	1	6.7%
Exploration for traumatic injury to the colon	1	6.7%
Exploration for blunt truma injury to jejunum	2	13.3%
Exploration for perforated duodenum	1	6.7%
Exploration for volvulus	1	6.7%
Open butterfly gastrostomy	1	6.7%
Post exploration for stap wound	3	20%
Resection and anastomosis for cancer colon	1	6.7%
Resection and anastomosis for small intestinal malignant masses	2	13.3%

Table (3): Anatomical origin of fistula of the study patients.

Variable	Value	Range
Colon	3	20%
Duodenum	2	13.3%
Ileum	3	20.0%
Jeujonum	5	33.3%
Stomach	2	13.3%

Table (4): Pathological origin of fistula of study patients.

Variable	Value	Range
Traumatic	6	40%
Iatrogenic	3	20%
Pathological	6	40%

Table (5): Outcome after vac of the study patients.

Finding	Frequency
Good general condition after vac, n (%)	13 (86.7%)
Skin excoriation, n (%)	11 (73.3%)
Complete closure, n (%)	12 (80%)

Table (6): Time on vac of the study patients.

Variable	Value	Range
1 week	1	6.7%
2 weeks	2	13.3%
3 weeks	2	13.3%
4 weeks	2	13.3%
5 weeks	3	20.0%
6 weeks	2	13.3%
More than 8 weeks	3	20%

Table (7): Complication and its type of the study patients.

Variable	Value	Range
Complicated patient	10	66.7%
Minor wound bleeding	2	13.4%
Pain	5	33.3%
Pain + minor wound bleeding	3	20%

Table (8): Univariate analysis of Operations in differentiating group I from group II.

Variable	Group 1 No. 12 (80%)	Group 2 No. 3 (20%)	*p*-value*
Age (years):			
Mean ± SD	38.08±13.2	46.3±10	0.336
Range	25-65	35-54	
Male, n (%)	9 (75%)	2 (66.6%)	0.77
Female, n (%)	3 (25%)	1 (33.3%)	0.77
Medical and surgical history:			
Smoker, n (%)	6 (50%)	2 (66.7%)	0.605
DM, n (%)	1 (8.3%)	3 (100%)	0.001 *
HTN, n (%)	3 (25%)	1 (33.3%)	0.770
IHD, n (%)	1 (8.3%)	1 (33.3%)	0.255
Past surgical history, n (%)	2 (16.7%)	3 (100%)	0.006*

p-value >0.05: Non significant.
p-value <0.05: Significant.
p-value <0.01: Highly significant.
*: Chi-square test.
•: Independent *t*-test.

Table (9): Univariate analysis of Anatomical origin of fistula in differentiating group I from group II.

Variable	Group 1 No. 12 (80%)	Group 2 No. 3 (20%)	*p*-value*
Colon	2 (16.7%)	1 (33.3%)	0.519
Duodenum	2 (16.7%)	0 (0%)	0.448
Ileum	3 (25%)	0 (0%)	0.333
Jejunum	5 (41.7%)	0 (0%)	0.171
Stomach	0 (0%)	2 (66.7%)	0.002*

p-value >0.05: Non significant.
p-value <0.05: Significant.
p-value <0.01: Highly significant.
*: Chi-square test.

Table (10): Univariate analysis of Pathological origin of fistula in differentiating group I from group II.

Variable	Group 1 No. 12 (80%)	Group 2 No. 3 (20%)	*p*-value*
Traumatic	6 (50%)	0 (0%)	0.114
Iatrogenic	2 (16.7%)	1 (33.3%)	0.519
Pathological	4 (33.3%)	2 (66.7%)	0.292

p-value >0.05: Non significant.
p-value <0.05: Significant.
p-value <0.01: Highly significant.
*: Chi-square test.

Table (11): Univariate analysis of Outcome after vac in differentiating group I from group II.

Variable	Group 1 No. 12 (80%)	Group 2 No. 3 (20%)	*p*-value*
Good general condition after vac, n (%)	12 (100%)	1 (33.3%)	0.002*
Skin excoriation, n (%)	10 (83.3%)	1 (33.3%)	0.08

p-value >0.05: Non significant.
p-value <0.05: Significant.
p-value <0.01: Highly significant.
*: Chi-square test.

Table (12): Univariate analysis of Time on vac in differentiating group I from group II.

Variable	Group 1 No. 12 (80%)	Group 2 No. 3 (20%)	*p*-value*
Time on vac:			
Mean ± SD	3.83±1.6	9±0	0.015*
Range	1-6	9	

p-value >0.05: Non significant.
p-value <0.05: Significant.
p-value <0.01: Highly significant.
•: Independent *t*-test.

Table (13): Univariate analysis of Complication and its type in differentiating group I from group II.

Variable	Group 1 No. 12 (80%)	Group 2 No. 3 (20%)	*p*-value*
Complicated patient	8 (66.7%)	2 (66.7%)	1
Minor wound bleeding	4 (33.3%)	1 (33.3%)	1
Pain	6 (50%)	2 (66.7%)	0.605

p-value >0.05: Non significant.
p-value <0.05: Significant.
p-value <0.01: Highly significant.
*: Chi-square test.

Discussion

A systematic literature review on the use of vacuum assisted closure for enterocutaneous fistula agree with our study found that VAC therapy may be considered a safe treatment for ECF. The fistula closure rate using VAC ranged from 7.7% to 100% with a median closure rate of 64.6%. Fistula output where Fourteen patients were explicitly stated to have a low output fistula of which 12 (85.7%) closed with VAC therapy. Thirty-one patients had a moderate or high output fistula of which 16 (51.6%) closed. Of these, 19 were explicitly stated to have high output fistulae of which eight (42.1%) closed with VAC. The results of this review also showed that success of VAC depends on the output of the fistula. The higher the output was, the less likely it was to close, with the proportion of fistulae closing halving from 85.7% in the low output group to 42.1 % in the high output group.

In this study we aimed to evaluate vac role as anew technique in management of ECF.

As regard demographic data in this study, the mean age was 40 years old, while The mean of age in Samak et al. **[11]** was 47.93±13.78 years, it was 60 years in Ortiz and colleagues **[12]** study and in Stremitzer et al. **[13]** the median age of the patients was 48 (range, 37-67) years.

The difference can be explained by the restricted inclusion criteria in our study to postoperative fistula patients against the wider inclusion criteria in the other studies and the healing of tissue in old age is more difficult than in young age so we can't judge on VAC.

As regards sex of the pt 11 patients were males with a percent of 73.3%, while 4 patients were females with a percent of 26.7%.

Samak et al. **[11]** had 44 patients were male 73% and 16 patients were female 27%, in Stremitzer et al. **[13]** was made on nine patients, six (67%) were male and three (33%) were female.

In our study we found 8 patients having other co morbidities with a percentage of (53.3%), while the rest 7 pt have no medical history (46.7%).

And we found that presence of co morbidities has agreat impact on healing process, general condition, hospital stay and occurance of complication and also we found that good control of other co morbidities has direct role in rapid healing, improvement of general condition, decrease hospital stay or icu need and prevent major complications.

There was no statistically significant relation between fistula closure as regard sex, age, IHD and HTN while there was statistically significant relation with DM that 75% of patients with DM failure of closure and past surgical history that 60% of patients with past medical history failure to close the fistula. In harmony with our study, Samak et al. **[11]** found in 42 patients (70%) had past medical history, so we noted that previous abdominal surgeries lead to presence of adhesions so increasing the difficulty of the operation leading to risk of injury compared to those with no negative past surgical history.

As regards the anatomical origin of the fistula our study included 2 patients with fistula originated from the stomach, while 2 other patients had fistula originated from duodenum, 5 from jejunum, 3 from ileum and 3 from colon.

In agreement with our study, Samak et al. **[11]** found that the origin of the fistula was stomach in 12 pt, Duodenum in 16 pt, Jejunum in 20 pt and Ileum in 12 pts. and also, Noori **[14]** had 5 pts their fistulae originated from Duodenum, while 4 pts their fitula originated from Jejunum,10 from Ileum, 1 from appendix and 3 pts from colon. Also, Wainstein et al. **[15]** study found that Gastroduodenal fistula occurred in 24 pts, while Colorectal fistula occurred in 17 pts, Small bowel fistula occurred in 19 pts and appendicular fistula occurred in 5 pts.

We noticed that previlance of fistula originating from small bowl is the highest among all types this is due to wide varity of small insestinal intervention and high output which may lead to leackage and fistula formation, also we found that high output fistulae impare the general condition of the pt worsening the nutritional status of the pt leading to impared healing power so high output fistula takes much more time for healing requiring a longer hospital stay and accompanied by higher lever of complications.

In our study according to pathological origin, 3 pt (20%) had fistulae due to iatrogenic injuries, while 6 pt (40%) due to pathological causes and 6 pt (40%) due to traumatic injuries.

We found that pathlogical causes come in the top priority this can be explaned by the wide variety in pathological conditions that may affect small and large intestine causing in some cases (espicialy those having adhisions) fistula formation due to adhesions betweed intestinal loops and abdominal wall.

Trumatic conditions come as second priority due to damge effect of truma in intestinal loops and presence of abdominal wounds in penetrating truma and this leads to fistula formation due to formation of atrack between intestinal loops and abdominal wound in case of penetrating trauma.

Iatrogenic show the least prevalence because iatrogentic injuries are not very common and in most cases discovered and managed intra operative.

While in Wainstein et al. [15] study the pathological origin of fistulae were abdominal truma in 20 pts (21.9%), while pathological causes in 56 pts (61.5%) this due to the different country that study conducted in that Wainstein study made in Department of General Surgery, E. Tornu´ Hospital, and the Intensive Care Unit, Churruca Hospital, Buenos Aires, Argentina.

In our study after application of vac general condition of the pts started to improve as regards vital stability. Improve of anorexia and tolerating of oral feeding and absence of toxic facies.

Nutritional status of the pts improved in the form of good apitite, increase albumin and haemoglobin.

Improvement of physical activity after application of vac comparison to period before vac.

Psychological status improvement due to stoppage of soiling and improvement of general condition.

This is explaind by decrease fistula output so improvement in dehydration and electrolites imbalance leading to positive impact on general condition.

In harmony with our result, Samak et al. [11] reported that 24 pts their general condition had improved while 16 pts had a stationary general condition mean while 12 pts had a worsened general condition.

Also, Waintstein et al. [15] found that Nutritional improvement and mobility recovery Per oral or enteral nutritional support was reintroduced after 3.4 days (mean; range: 1-20 days) in 89 patients, without a significant increase in fistula output. After 4 weeks, 39 (82.9%) of 47 severely malnourished patients regained 84% of their mean weight loss, During stage 2 of the treatment protocol, 58 (69%) of 84 patients began to walk within the first 20 days of treatment.

Only two pts had poor general condition and did not improved because they had terminal cancer and underwent neoadjuvante chemo therapy.

As regard skin excoriation, in our study 11 pt had skin excoriation before vac appling, we observed gradual improvement of skin condition during vac therapy while the rest of pts had no excoriation from the start.

The effect of vac application on excoriated skin is benifitial in that it prevent soling and so prevent excoriation and improve its condition.

In aggrement with our study, Samak et al. [11] reported improvement in skin condition in 52 pt, while 8 pts had a stationary condition of the skin. Also, Waintstein et al. [15] done on 91 pts reported Dermatitis improved in all cases. Similarly, all superficial infections were cured and a number of deep infections in close contact with the fistula also improved. Also, Cro et al. [8] done on 3 cases reported improvement in skin condition in all pts.

In our study the complication we had were pain, discomcort and bleeding.

In our study 8 pts suffered from pain during the first days, all pts encountered discomfort from noises of the device and sensation of suction, 5 pts had minor wound bleeding during dressing.

Occurrence of pain in some pts may be due to suction effect of the device, while bleeding during dressing may be due to injury of micro capillaries during dressing.

In agreement with our study, Samak et al. [11] reported Complications occurred in 40 pts 66.67%, including pain, new fistula, pulmonary embolism and ongoing sepsis, while 20 pts had no complication 33%.

A regard time of VAC, in our study we had we have 12 patients spent 6 weeks or less on vac (80%) and other 3 patients spent more than 9 weeks on vac (20%) they didn't reach full recovery nor complete fistula closure.

This can be explained as following, first pt had cancer stomach with poor general condition, cachexia and also two co morbidities leading to poor healing power and resistant fistula.

The second pt had cancer colon with poor general condition, cachexia and also two co morbidities leading to poor healing power and resistant fistula.

The third pt was morbidly obese and diabetic underwent metabolic surgery all these factors lead to poor healing power and fistula resistant to heal.

There are factors affecting closure of fistula and so time spent on vac, like general conditions, nutritional status, fistula output and origin of fistula, this factors explain the discrepancy in time spend on vac therapy between our pts.

In harmony with our result, Samak et al. **[11]** reported Regarding wound healing among the survived 48 pts, spontaneous complete closure occurred in 32 pts (66.67%). The mean time to complete closure of fistula was $8^{\pm 3}$ Wks.

Also, Wainstein and colleague study **[15]** found that in 42 cases (46%) the fistula healed without surgery within 90.11 days mean (range 8-370 days) of starting vacuumassisted treatment.

According to fisula out put our study found that all patients are suppressed at 1 st week one pt, before 2 wks 2pts, before 3 wks 2 pts, before 4 wks 2pts, before 5 wks 2 pts, before 6 wks 3 pts

Also the three pts who spent more than 9 weeks on vac although they didn't reach full recovery, the fistula output decreased by significant values.

In harmony with our result, Waintstein et al. **[15]** found that in 37 (40.7%) patients output was suppressed within 7 days of starting treatment, and in 52 (57.1%) patients it was reduced to less than 500ml/day, with a 90% mean reduction (138ml/day) within the first 72h.

Conclusion:

Enterocutaneous fistulae is a comman surgical problem result of a wide variety of conditions and circumstances. Fistula management can be quite challenging, frustrating, and, ultimately, rewarding. Different methods of management are found with different results and outcomes Vac therapy is a new technique with promising results in management of fistula Vac therapy improve fistula condition, decrease soiling, improve general condition and better financialy than ordinary dressing.

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تقييم تأثير علاج الإغلاق بمساعدة الافراغ في مرضى الناسور المعوى الجلدى ما بعد الجراحة

الناصور المعوى الجلدى هو نتيجة لمجموعة مختلفة من الحالات المرضية، العناية بالمريض الذى يعانى من هذه الحالة المرضية قد تكون مليئة بالكثير من التحديات والمصاعب والتى تجعلها مخيبة للأمال فى بعض الأحيان.

علاج الجروح باستخدام جهاز التفريغ الهوائى الفاك هو نظام للغيار على الجروح والذى يعتمد على وضع ضغط سلبى وقوة شفط متصلة أو متقطعة على سطح الجروح التى قد تكون حديثه أو مزمنة أو مركبة أو صعبة الالتام.

دراسات عديدة وصفت استخدام جهاز الفاك فى علاج الناسور المعوى الجلدى بنجاح.

جهاز الفاك تبين من خلال الدراسات أنه أمن ومفيد فى علاج الناسور المعوى الجلدى.

فى هذه الدراسة وجدنا أنه أكثر من ٨٠٪ من المرضى قد وصلوا إلى مرحلة الشفاء التام كما أن جهاز الفاك يحسن من الحالة العامة للمريض ويقلل من التهابات وتسلخات الجلد المصاحبة للناسور. جهاز الفاك هو تقنية جديدة واعدة فى علاج الناسور المعوى الجلدى.