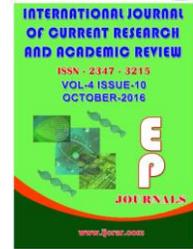




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The Outcome of Treatment of Postoperative Enterocutaneous Fistula using High Negative Pressure Vacuum and Some Modified Normal Oral Diet: A Review of 51 Cases Over a 4 - Year Period, Iraq

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KEYWORDS

Enterocutaneous fistula (ECF) and management of ECF by vacuum system and on normal oral diet.

A B S T R A C T

Enterocutaneous fistula mean connection between stomach, small or large bowel and skin with loss of gut content, about 75 - 90% are postoperative following any laparotomy especially of trauma and previous laparotomy of other procedures, may be classified depending on etiological, physiological and anatomical factors, on this classification the management of ECFs closure rate depend. The morbidity and mortality related to fluid and electrolytes losses, sepsis and malnutrition. So treatment include after diagnosis to correct fluid and electrolytes deficit with other elements by controlling fistula output by a lot of things, prevention and treatment of malnutrition by oral diet, enteral or parenteral nutrition accordingly with control of sepsis and great care and strict follow up of patients that mean conservatively, if closure of fistula not occurred after 4 - 6 weeks, so prepare for surgical closure after improvement of general condition and nutrition of patients. To assess the outcome of using high negative pressure vacuum with foley catheter and some modified normal oral diet in closure of postoperative enterocutaneous fistulas. Between a period from 2012 to 2016 in a medical city of AL-sadder teaching hospital in AL-Najaf, Iraq, treated prospectively with recently developing postoperative enterocutaneous fistulas using vacuum method with Foley catheter to close the fistula tract and change the contents daily for 14-21 days as necessary after exclusion of intra-abdominal infection, distal bowel obstruction, abdominal malignancy, abdominal irradiation and inflammatory bowel disease by abdominal imaging, all patients allowed to eat some modified normal diet with some simple drugs and IV fluid and even with home care program accordingly. A 51 patients with age 45 ± 22 years were 40 men and 11 women, all of them developed postoperatively were treated by vacuum method, the moderate and low output fistulas had the best results of 34 cases (94.4%) were closed and 13 cases (86.6 %) of high output were closed at the end of study. 35 (68.6%) cases closed after 7 days, 10 cases (10.6%) after 14 days and 2 cases (3.9%) after 21 days of this vacuum method of a successful vacuum closure rate of 47. Treatment failed in remaining 4 cases (7.8%), 2 patients of low and moderate and 2 of high outputs were subsequently did for them surgery. The prognostic factors were used are serum albumin and hemoglobin levels were showed significantly higher levels at the end of than at the beginning of this study. No patient died. The vacuum method showed best results in spontaneous fistula closure with it's simplicity, low cost, short hospital stay even at home, no skin breakdown, on normal oral diet with some modification, some simple drugs and fluid with good nutrition and usual daily activity.

Introduction

The enterocutaneous fistula (ECF) is an abnormal communication between gastrointestinal tract (GIT) and the skin mainly between stomach, small intestine and colon. The overall mortality rates in recent literature vary about 6.5% - 39%, any intra-abdominal procedure can result in ECF when some damage to GIT or interfere with its blood supply, so prevention by understanding risk factors for developing ECF is better than treatment (Hollington *et al.*, 2004; Evenson *et al.*, 2006; Lloyd *et al.*, 2006; Davis *et al.*, 2013; Kathryn *et al.*, 2006). ECF can be classified accordingly by:

- 1) Anatomical factor includes the site of fistula (F.) (gastric, small and large bowel), complex (multiple openings or within operative wound) or simple (single uncomplicated direct opening from site of drain), long or short tract, lateral bowel wall defect more or less than 1cm².
- 2) Physiological factor includes the amount of discharge (output) low if less than 200 ml \ day, moderate if 200-500 ml \ day and high output if more than 500 ml \ day.
- 3) Etiological factor includes associated diseases such as neoplastic, diverticular, irradiation, inflammatory bowel disease, appendicitis (postoperative), foreign body and postoperative complications following trauma or other procedures (like resection or previous operation, release of adhesion), this classification correlated with mortality and chance of closure (Schechter, 2011).

Following diagnosis of ECF usually at 5th–10th postoperative day by history of discharging of enteral content through drain or wound and by detecting of content, examination of operative area, following methylene blue orally intake and appearance

from F. area, ultrasound, fistula gram with water soluble contrast to give a lot of information about ECF, after stabilization and treatment of sepsis to show the configuration of tract, source of F., any abscess cavity connection with F., disease of bowel at origin, distal bowel obstruction such as stricture and show the size of bowel defect these are as effective as CAT scan with oral contrast. Most ECF are postoperative either an anastomotic leak or inadvertent enterotomy from any cause or risk factor about 75% - 90%. Risk factors include surgical and patients related, so should be prevented or treated pre, intra, and postoperatively and accordingly (Schechter, 2011; Sinha *et al.*, 2003; Evenson *et al.*, 2006). Treatment includes (1) Correction of fluid and electrolytes deficit and its maintenance with correction of anemia and malnutrition mean resuscitation (stabilization and recognition). (2) Control of sepsis either by antibiotics and/or drainage of collection under ultrasound (US) guide. (3) Control of F. output and collection to prevent or minimize skin excoriation and skin break down by negative pressure vacuum, stoma appliance, dressing or simple drain (catheter) and also by acid suppression drugs and octreotide to reduce the fistula output and its duration but of no effect on spontaneous closure rate this is only about the above drugs (Stevens *et al.*, 2011; Jamil *et al.*, 2004) but the results were best with vacuum method especially with catheter or drain as in experimental work of 7 dogs and in human beings in absence of distal intestinal obstruction (Wainstein *et al.*, 2008; Ruiz-López *et al.*, 2009; Pepe *et al.*, 2014). For prevention and treatment of malnutrition, enteral feeding is preferable than parenteral nutrition especially when taken orally because of fewer complications, improve gut absorption, immunological and hormonal function of intestine, reduce bacterial translocation and increase hepatic

protein synthesis even 20% of caloric needs are enough (Polk *et al.*, 2012; Njeze *et al.*, 2013). Other way of feeding by fistuloclysis by placing the catheter with balloon tip into the distal limb of intestine (Teubner *et al.*, 2004; Mettu, 2004). By using maximum conservative therapy spontaneous closure of ECF about 74% - 92% by 4 weeks and 9% by 12 weeks and if after 4 - 6 weeks of enteral and parenteral nutrition and with other conservative ways, not closed or markedly decreased F. output then prepare for definitive restoration of GIT continuity because within 10 days - 6 weeks there was adense fibroadhesion cause a lot of complications during reoperation which include a lot of surgical principles to look for risk factors.^(1, 4, 9, 10, 12 - 18) The incidence of recurrence of F. following reoperation in one large study about 21% especially with ECF complicated inflammatory bowel disease (crohn's disease) from uninvolved bowel (Candela *et al.*, 2007; Regueiro, 2002). Recently trial with other methods for spontaneous closure of ECF in absence of distal intestinal obstruction by injection of fibrin glue into F. tract by endoscope with a lot of side effects such as allergy, other used porcine small intestinal sub mucosa with no allergy but these are very expansive and need further studies and experience (Rabago *et al.*, 2002).

Patients and Methods

A prospective study of 51 patients (pts) with ECFs were treated by high negative pressure vacuum in a medical city of AL-Sader teaching hospital in AL-Najaf and other teaching hospitals of Iraq. Over a 4-year period from 2012 - 2016. The vacuum method of treatment started after 7 - 10 days postoperatively after the diagnosis of ECFs proved by adequate history (include age, sex, indications of surgery, some information about type of surgery, medical

history about chronic disease, timing of developing fistula, history of chronic drugs intake might affect healing and what treatment received during previous 7 - 10 days postoperatively and how the discharge developed with it's character and associated problems about fever, GIT symptoms and oral intake) and careful general and regional abdominal examination for operative and F. sites to get information about nutritional status (by weighing all pts at the end of each period with no significant changes noticed), type of F. (by daily measured the amount of output and it's character), surrounding skin and tissue for evidence of infection either of F. area or intra-abdominal and with no feature of distal intestinal obstruction. F. output measured daily to be classified low if less than 200ml \ day, moderates between 200 - 500 ml \ day and high output if more than 500ml \ day. To prove the diagnosis and it's cause by abdominal ultrasound (US), CAT scan with oral contrast and fistula gram with urograffin to show type of F. (complex or simple, single or multiple F. tract and its origin, length of tract, size of internal F. opening and connection with abscess cavity), with help of other investigations mentioned above to exclude complicated F. of inflammatory bowel disease, malignancy, radiation enteritis, ischemic one and intra-abdominal infection, also to exclude biliary and pancreatic F., mean that this vacuum study include simple fistula of 7 - 10 cm length of tract, 1 cm² or less of internal opening that developed postoperatively, once diagnosed the drainage tube or stoma appliance removed, then introduced a no, 12 Foley's catheter with stellate carefully away from internal opening and the balloon inflated gently to close the F. tract then connected with closed wound suction drainage system (SERODRAIN) of high negative pressure of about 450 mmHg and volume of 600ml that was changed the content daily with chart for

7 - day period (1st period) with measurement of amount and its character, then balloon deflated and the catheter withdrawn, if the F. still open, the catheter was immediately reinserted and the same procedure was done again for another 7 - day period (2nd period), and the same thing was done if F. still open (3rd 7- day period) used. During this period of study we checked random and fasting blood sugar and renal function test (blood urea and serum creatinine daily and 2 prognostic factors (serum albumin and hemoglobin levels) were used, measuring serum albumin and hemoglobin levels at beginning and at end of study with measuring of serum electrolytes (Na⁺, Cl⁻, K⁺ and Ca⁺⁺) with liver function test and complete blood picture twice weekly and pts were put on some modified normal oral diet with high carbohydrate to provide good energy with elements according to bowel motion and F. output and also with some simple drugs such as local zinc oxide cream, simple antibiotics and metronidazole and IV crystalloid fluid to correct electrolytes changes accordingly with usual daily activities and even we put 15 pts on home care program, 10 of low and 5 of moderate type of F. all of them were closed in 7 days with some checking in outpatient clinic. No enteral and parenteral nutrition were used in this vacuum study, lastly all those pts with spontaneous vacuum closure were followed for at least of 3 months by their surgeons and me accordingly, there was no evidence of recurrence and for those were needed surgical closure did for them operations after 6 - 8 weeks from first operation with some forms of enteral feeding to improve general condition and nutrition to support surgery later on with excision of F. and some other surgical procedures accordingly. Failure of this vacuum study mean either not closed or discharge not decreased significantly. The protocol and agreement were taken from our surgeons of general and GIT centre of same

hospital and other hospitals and of Medical Collage of Kufa University in AL-Najaf, Iraq. Statistical analysis was performed using student's t test for paired data and Fisher's exact test for comparison between proportions with respect to closure of F. Differences were considered significant when P. value < 0.05. all of them postoperative and mainly following laparotomy of trauma pts with small bowel resection or suturing of perforation and colonic injury without proximal colostomy as shown in table 1.

Results and Discussion

This is a prospective study was done for 51 pts with ECFs were 40 men and 11 women, aged 45 ± 22 years. No pt was died and no clear evidence of malnutrition. Regarding serum albumin was predominately 3.5 g \ dl or higher and for hemoglobin level was 11 g \ dl or high for both sexes so with above data and F. output in relation to number of patients with vacuum or surgical closure as shown in table 2.

The proportion of surgical closure (failure of vacuum) was significantly higher in high output F. than in moderate and low output F., P. value < 0.001, the high the normal serum albumin and hemoglobin level the higher the proportion of cured patients with vacuum system, P. value < 0.05 and < 0.03 respectively was significant. The proportion of surgical closure (failure of vacuum) was significantly higher in high output F. than in moderate and low output F., P. value < 0.001, the high the normal serum albumin and hemoglobin level the higher the proportion of cured patients with vacuum system, P. value < 0.05 and < 0.03 respectively was significant. There was a significant difference between the mean serum albumin and hemoglobin levels p. value < 0.05 and < 0.03 when compared to

the beginning of our treatment (vacuum closure) and closure of F. (end of treatment) respectively as shown in table 3.

Out of 51 cases 36 (70.6%) Fs. were classified as moderate and low output and closed at the end of study (21 days), only 2 (3.9%) cases were failed and 15 (29.4%) cases of high output, 13 (25.6) were closed with vacuum and failure rate of 2 (3.9%) cases were supplemented with some form of enteral feeding to prepare for surgical closure after 6 - 8 weeks, that mean 4 (7.8%) cases of total. With successful vacuum closure (VC) rate of 47 (92.2%) cases, 35 (68.6%) cases were closed after 7 days (end of 1st 7 - day period), 28 (80%) cases out of 35 were of moderate and low output, 10 (19.6%) cases of total were closed after 14 days (end of 2nd 7 - days period) and remaining 2 (3.9%) cases of total were closed after 21 days (end of 3rd 7 - days period) as shown in table 4.

The differences among those proportion was significant (P. value < 0.0001). 1 (1.9%) case of low output that was not closed by vacuum method due to small foreign body (shell) within the F. tract just near internal bowel opening was treated by excision of F. tract with shell and suturing of bowel defect and for remaining 3 (5.7%) cases did bowel resection with F. tract and re-anastomosis.

The main things in the management of ECFs were to be known well and to reach the diagnosis by adequate history and proper general and abdominal examination (operative site and drainage area with it's character) with an available tools in area of study, in this study we tried to know the type of F. according to anatomical, etiological and physiological factors and then prepared our treatment according to economical and political status of our country as the world know the status of Iraq now, so we thought

about this study because of an easily available instruments, low cost, and also of few complications where can be managed in our hospitals with help of other surgical ward staff and also from our followed of other articles and journals mentioned about the best results of high negative pressure vacuum system used in management of ECFs previously and recently. The treatment in general is to correct fluid and electrolytes deficit and maintain the maintenance, prevention and treatment of malnutrition by an available routes with control of sepsis. Most ECFs (75-90%) are postoperative, in general represent about 1 - 2% of complications after gastric or duodenal operations and 1% after jejunal or ileal operations according to etiology, experience of surgeons, situations of hospitals and conditions of areas where the studies were done. In this study the uncomplicated Fs involving anastomotic or suturing leakage from stomach and small bowel were 34 (66.7%) cases out of 51 cases of F., nearly similar to other studies were done by Aldo Cunha Mederion *et al.*, (2004), were in 41 (55%) cases out of 74 cases and Nubiola *et al.*, were in 43 (58%) cases, 2\3 of patients developed leakage after small bowel resection with anastomosis or suturing, this some differences were because of high incidence of trauma were treated by different surgeons and in different hospitals with their facilities. All pts in this study received adequate nutrients by some modified high protein and carbohydrate oral diet with concentration on electrolytes, vitamins and other elements rich diet with some IV fluid, antibiotics, metronidazol and other simple drugs according to general condition and nutritional status of pts with no clear evidence of malnutrition and with no sepsis or hypercatabolism development as a result there was a significant difference in serum albumin and hemoglobin levels between the beginning and the end of this

treatment. The major mortality from ECFs are because of fluid and electrolytes losses, malnutrition and complications of its treatment especially by total parenteral nutrition (TPN) and sepsis, ranges from 6.5 - 37% by early studies (Stevens *et al.*, 2011), now mortality is decreasing because of advances in care of ill pts, researches and treatment toward more simple, inexpensive, easily available with few complications like in this study with no more loss of GIT contents with improvement of general condition, nutritional and immunological status of pts. with prevention of infection, psychological support of pts, their relatives and also of surgical ward staff and of other pts because of elimination of bad odor of bowel contents especially of colonic one, in addition to that improved the operative and F. sites and even not closed spontaneously there will be of benefit for preparation of surgery later on when indicated and we need a lot of patience from pts, their relatives and surgical ward staff that is very important in management of ECFs because they need a long period of treatment and follow up as had shown in most previous reports on ECFs management that the hallmarks are of no oral intakes, control of sepsis, TPN and long periods of hospitalization between 50 - 95 days \ patient as in studies were done by Allandyce (1983), and Sitges – Serra *et al.*, (1982), but in this study, the VC rate was 92.2% of Fs. within a short period (21 days) with 35 (68.6%) cases out of 51 were closed at end of 7 days with some similarity to study was done by Mederios *et al.*, (1990), as an experimental work were 6 out of 7 dogs (out of total 14) with induced F. closed at the end of 5 days by vacuum method group and the remaining one closed at the end of 10 days when compared with control group (mean 7 dogs of each group) but without vacuum and on the same oral diet were no one closed by that period. In those closed F. clinically also confirmed

histologically when dogs killed and biopsies were taken from F. sites showed no damage in the bowels at the end of experiment was similar to study done by Aldo Cunha Medeiros *et al.*, (2004), were 48 (65%) cases of total 74 F. closed at the end of 5 days (1st 5 day period) and VC rate at the end of study (3rd 5 – day period) were 68 (92%) cases of total and failure rate of vacuum in remaining 6 (8%) were dissimilar to study done by Gune *et al.*, (2006) therapy with vacuum assisted closure (VAC) system of 15 cases 9 of low output and 6 of high output postoperative F., 11 of small bowel and 3 of colon and 1 of small and large bowel, mean period of follow 3 months, dressing were changed 3 times weekly with enteral feeding, if F. output thickened and affected the negative pressure put them on restricted oral intake, vacuum closure rate were 11 (73.3%) out of 15 range of closure 9 – 12 days, failure rate in 4 (26.7) cases all of them with visible mucosa in abdominal wall, but in this study VC rate in 47 (92.9%) cases and failure rate in 4 (7.8%) cases, 2 with high output and 1 for each low and moderate output with closure time of 21 days were dissimilar to study of 98 pts with ECFs treated successfully with mean closure time 30.9 days were 61 (56.5%) cases closed spontaneously with TPN and 25% failed were treated surgically and mortality rate of 10.5%, but in this study no one died. From above studies and others were showed a lot of differences in results of closure rates, morbidity and mortality which engorged us to use this vacuum method with this best result of those uncomplicated Fs mean with exclusion of pts. with intra-abdominal infection, inflammatory bowel disease, irradiation and neoplastic cases, these needed further treatments and studies in future to be monitored. VAC system was used for non healing wounds previously, then was tried to be used in management of moderate and high output ECFs for long

period (Karvonen *et al.*, 2011), but one study showed higher mortality rate because of subsequent new Fs development that mean recurrent with a lot of problems faced, so to be used with caution and careful follow up that showed 2 cases were closed with VAC therapy but with exposed bowel, developed new F. that required surgery similarly to that study was done recently by Rao *et al.*, of 29 patients treated with VAC,

6 of them developed new ECFs, 4 of them died, so the use of VAC therapy with exposed bowel and open abdominal wound to be with caution and may lead to new ECFs development and higher mortality, but in contrast to above 2 studies, most studies previously and recently advised to use VAC system therapy for uncomplicated and even complicated ECFs (both complex and open abdominal wounds).

Table.1 Distribution of the etiologies of post-operative fistula in the 51 patients.

Etiologies	Number of patients
Anastomotic leakage after small bowel resection (trauma).	15
Anastomotic leakage after colonic resection without proximal colostomy (on table cleaning)of trauma patients.	6
Leakage following suturing of multiple small bowel perforations (trauma).	3
Leakage following suturing and resection of multiple small bowel injuries of previous operations (iatrogenic).	3
Leakage after primary repair of colonic injury following trauma without proximal colostomy.	3
Leakage after small bowel injury with suturing following repair of obstructed recurrant incisional hernia (iatrogenic).	3
Anastomotic leakage after small bowel resection of perforated typhoid.	2
Anastomotic leakage after gastrojejunostomy and truncal vagotomy for chronic peptic ulcer.	2
Leakage following enterotomy and suturing for small bowel obstruction by Ascariasis.	2
Leakage following sleeve gastrectomy of morbid obesity.	2
Anastomotic leakage after colonic resection for sqmoid volulus without proximal colostomy (one stage).	2
Appendicular stump leakage following surgery of complicated appendicitis.	2
Leakage following mesenteric injury with suturing (iatrogenic).	1
Leakage following pyloroplasty and truncal vagotomy for treatment of severe uncontrolled bleeding duodenal ulcer.	1
Leakage following omentel patch repair of large (massive) perforated duodenal ulcer.	1
Leakage following small intestinal (distal ileum) repair of perforated typhoid.	1
Anastomotic leakage after colonic resection for diverticular disease with colonic perforation without proximal colostomy.	1
Leakage after colonic injury following repair of obstructed paraumblical hernia (latrogenic).	1
Leakage following suturing of colonic injury with repair (suturing) for foreign body (shell) within fistula tract near internal opening.	1
Total	51

As it shown in table 1, direct trauma was the more frequent indication for operation, 28/51.

Table.2 Showed the association of two prognostic factors with the number of patients of Spontaneous (vacuum) and surgical fistula closure rates in relation to fistula output and initial serum albumin and hemoglobin levels

Fistula output (ml/day)	Spontaneous(vacuum) closure	Surgical closure(failed)	Total	p-value
High output(>500)	13 (25.6%)	2 (3.9%)	15 (29.4%)	< 0.001
Moderate output(200-500)	18 (35.4%)	1 (1.9%)	19 (37.3%)	
Low output(<200)	16 (31.2%)	1 (1.9%)	17 (33.3%)	
Total	47 (92.2%)	4 (7.8%)	51 (100%)	
Base line serum albumin level, g\dl				< 0.05
≥ 3.5	30 (58.9%)	1 (1.9%)	31 (60.8%)	
3.5 –2.6	17 (33.3%)	3 (5.9%)	20 (39.2%)	
Mean	3.99	3.4		
Base line hemoglobin level, g \ dl				< 0.03
≥ 11	33 (64.7%)	1 (1.9%)	34 (66.7%)	
11 --- 8.1	14 (27.5%)	3 (5.9%)	17 (33.3%)	
Mean	11.6	10.25		

Table.3 Showed prognostic factors levels at the beginning and end of vacuum treatment (mean ± SD).

Prognostic factors	Beginning of treatment	End of treatment	P. value
Serum albumin level (g \ dl)	3.2 ± 0.6	3.5 ± 0.5	< 0.007
Hemoglobin level (g \ dl)	11 ± 2.4	12 ± 1.6	< 0.002

Table.4 Showed the successful vacuum closure (VC) rate of 47 cases in relation to the type (amount) of fistula and periods of treatment

Periods of treatment	Low output	Moderate output	High output	Total
1 st 7 - day period	20	8	7	35
2 nd 7 - day period	4	2	4	10
3 rd 7 – day period	--	--	2	2
Total	24	10	13	47

Failure rate of VC 4 cases, 2 of high output and 1 for each low and moderate output Fs.

Conclusions and Recommendations

The vacuum method of treatment using high negative pressure, had been proved of a good result of spontaneous closure of recent developed and well defined Fs. with simplicity, low cost, short hospital stay even by home care program using, no skin break down, no bad odor of especially colonic one with possibility of maintaining nutritional status by some modified normal oral diet,

with usual pt's daily activity and some IV fluid and simple commonly used drugs accordingly, were easily available and with very few side effects and can be used in any hospital even in poor areas, so we recommend to use this method of treatment for uncomplicated ECFs more and more and to be tried with all types ECFs in future because of above advantages and fewer problems might be faced with an easily to be resolved and we insist on a lot of patience to

be provided by all patients and their relatives with staff involved and even with failure of spontaneous closure, the pts were prepared and improved clinically of general condition and F. site to support surgery later on.

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