

Evaluation of subcutaneous drainage system versus tissue re-approximation alone using Pfannenstiel incision in obese females undergoing caesarean section.

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Abstract

Obesity is a growing problem and a major health problem. In 1919, Dr. Kelly described obesity by saying that "to be a storehouse for useless adipose tissue and to carry this handicap around, openly displayed wherever one goes, is one of most distressing of life's minor ailments." It has complex negative effects on the functions and procedures of various organs, and includes problems relating to wound healing .

Introduction

Obesity is a growing problem and a major health problem. In 1919, Dr. Kelly described obesity by saying that "to be a storehouse for useless adipose tissue and to carry this handicap around, openly displayed wherever one goes, is one of most distressing of life's minor ailments." It has complex negative effects on the functions and procedures of various organs, and includes problems relating to wound healing (1).

Vermillion et al; 2000 have previously demonstrated that an independent risk factor for wounds caused by a cäsarean section such as infection, seromas, dehiscence and hematoma is a subcutaneous tissue thickness of 3 cm or more (2)

David et al; 1995 conclude that subcutaneous tissue depth is the most important risk factor for abdominal wound infection after caesarean section (3)

Due to the risk of wound complications in obese women, many techniques to reduce these complications were examined. Reducing operational time, utilisation of perioperative antibiotics, irrigation of the operating site, adequate hemostasis, preventing dead space and careful surgical techniques have been demonstrated in order to reduce the risk of postoperative injury complications (4).

These techniques are based on reducing the presence of bacteria and decreasing the amount of the dead space of subcutaneous tissue. This potential area could be a focus of serous fluid or blood collection which could become infected and eventually lead to injury. (5)

A re-approximation of subcutaneous tissue should theoretically reduce the potential for complications, not just by reducing tension on tissues, but also by decreasing possible dead space for seroma and blood sucking and reducing the rate of post-operative wound complications (6).

Due to wound complications, surgical morbidity is most important when determining methods for reducing wound complications. The effectiveness of subcutaneous drainage in obese women who have c.s was not consistent between studies; these disparate findings could result from differences in design, population and sample size of studies (7).

The concurrent use of subcutaneous suture closure and drain in obese women undergoing abdominal caesarean section would significantly reduce postoperative injury complications compared to suture closure management alone (7).

AIM OF THE WORK

To compare between the efficacy of subcutaneous tissue re-approximation alone or in combination with subcutaneous drain in obese women undergoing caesarean delivery operation.

Patients And Methods

This study was Prospective randomized clinical trial study, on obese women underwent caesarean delivery operation *done in* Obstetrics and Gynaecology department, Minya Health Insurance Hospital, at the period from November 2018 to November 2020 **involved** 160 obese women underwent caesarean delivery operation.

Inclusion criteria:

All obese women underwent caesarean delivery operation, with the following criteria were included:

- Body mass index
- Hemoglobin 10gm/dl.
- Pfannestiel incision.
- Elective caesarean delivery.
- Normal laboratory investigation.

Exclusion criteria:

All women with any of the following were excluded:

- Patient receiving Immunosuppressive therapy e.g. Systemic lupus erythematosus and rheumatoid arthritis.
- Emergency laparotomy.
- Mid line incision.
- Long time range during operation.
- Associated preeclampsia.
- Associated morbidity.
- Associated mistake e.g. anesthesia allergy, shock or surgical injury.

Operational design:

Steps of performance and techniques used:

1. Explanation of study and the type of surgery for each participant after which a written consent for approval was taken

2. History taking regarding: (personal-present-past-medical) to check for inclusion and exclusion criteria according to a standardized research protocol.
3. Examination: general and abdominal for previous scar.
4. Laboratory investigations eg: CBC, random blood sugar, PT, PTT, INR, SGOT, SGPT, Serum Creatinine and Urine analysis, to exclude any associated disorders.

Surgical technique:

We recorded the entire participant operated under general or spinal anesthesia, and know the prophylactic antibiotic were used.

In all operation recruited in this study the skin was incised with (*pfannestiel abdominal incision*) while the subcutaneous tissue and rectus sheath were incised using diathermy pen electrode set on cutting mode. Parietal peritoneum opened bluntly. Hemostasis was performed using coagulation diathermy and large subcutaneous vein were sutured ligated in patients of both groups.

In 1st group, Closure was in layers, subcutaneous tissue was sutured by interrupted suture with absorbable buried polyglactin (vicryl).

In 2nd group, before suture, the drain was placed exiting the wound via a separate stab site lateral to the skin incision and the subcutaneous space was thoroughly irrigated, then the suture closed; the drain was secured with a single silk suture.

The drain used in this study composed of sterile nelton tube sized 6.7 mm in diameter (yellow color size 20FG) connected with sterile urine collecting bag.

This study was recruited in and divided into two groups according to:

- 80 patients who have subcutaneous tissue re-approximation s alone.
- 2- 80patients who have subcutaneous tissue re-approximation in combination with subcutaneous drain.

All patients of these two groups were followed:

- 1st,2nd and 3rd day of operation
- One week after operation
- One month after operation

The two groups were compared regarding these items:

- a. Wound infection, wound dehiscence, seroma, hematoma and abscess.
- b. Post-operative hospital stays (days (.
- c. Pre-and post-operative hemoglobin level (g/dl).

Statistical methods:

The collected data were recorded, tabulated, and statistically analyzed using SPSS program (statistical package for social sciences) software version 20.0.

Written sheet filled included the patient name, age, hemoglobin level before and after operation, history of medical diseases, type of operation, operator, subcutaneous tissue thickness, post-operative hospital stay, amount of drain output, time of drain removal and duration of wound closure, and obtained data as detected for statistical analysis

Results

- No significant difference was found between both group as regard to age, subcutaneous tissue thickness and BMI.
- As regard to Hemoglobin (gm/dl) before and after operation which indirectly reflect amount of blood loss our study demonstrated that no significant difference between both group.
- As regard to duration of operation patients with subcutaneous drain have needed more operative time for closure of rectus sheath, subcutaneous tissue and skin by about (1.3 minutes) (p- value < 0.001) than patients without subcutaneous drain.
- As regard to post-operative hospital stay it was significantly higher in patients with subcutaneous drain than patients without subcutaneous drain (p- value 0.040).
- As regard to composite wound complication outcome seroma 9.5%, hematoma 3.5% and abscess 6.5%. Patients with subcutaneous drain group had less frequent serous discharge (18 patient) than Patients without subcutaneous drain group (20 patients), and less hematoma formation (6 patients) than Patients without subcutaneous drain (8 patients).
- Patients without subcutaneous drain group had less frequent wound infection "abscess formation" (12 patients) than patients with subcutaneous drain (14 patients), and wound dehiscence was equal in both group (18 patients) but the difference was statistically non- significant.

Discussion

Obstetricians and gynaecologists have often experienced injury complications in obese women undergoing surgical laparotomy. Several researchers have identified obesity as a high risk factor for wound complications, e.g. (8).

In addition, an increasing subcutaneous thickness has proved to be an independent risk factor for postoperative wound complication development (9).

The increase in the incidence of obesity will increase the complication of post-operative wound, including infection, seroma or bleeding and dehiscence (2).

In our study, we evaluated the concurrent use of a drain with suture subcutaneous tissue re-approximation under the hypothesis that drainage and re-approximation of the subcutaneous space theoretically would provide further reduction in potential dead space and removal of residual fluid and blood from the wound that could serve as a medium for bacterial growth (7). (7).

No other study has assessed the role of subcutaneous tissue re-approximation in obese women who undergo caesarean treatment either alone or in combination with drain.

This study included 160 obese women undergoing caesarean section, age range from 28-50 years with BMI range (30-39) and subcutaneous tissue thickness ≥ 4 cm range (4-12), we selected women with 4 cm or more of subcutaneous tissue thickness for randomization to evaluate efficacy in a population at greatest risk for post-operative wound complications. There is a history of around 94 medical diseases such as high blood pressure, ischemic heart disease, diabetes mellitus, and liver diseases.

Results of our study demonstrated that patients with subcutaneous drain have needed more operative time for closure of rectus sheath, subcutaneous tissue and skin by about (1.3 minutes) (p-value < 0.001) than patients without subcutaneous drain.

In Blee et al's 2001 operating times in obese patients with a BMI > 30 kg/m² were significantly longer. Blee et al found that patients who were overweight (BMI, 25–29.9 kg/m²) also had significantly longer duration of the procedure. (10) (10)

In general, the risk of morbidity and postoperative stay in obese patients is significantly increased in comparison to non-obese (11) patients. Our study has shown that hospital stays are considerably higher in subcutaneous drain patients than in patients with no subcutaneous drain (p-value 0.040). Long hospitalisation associated with increasing nosocomial infections, including site infection, costly hospitalisation and prolonged therapy (12).

The process of wound healing is heavily based on oxygenation. Basically, low anemia-related oxygen levels can stop or slow the healing phase, making patients more susceptible to other complications, such as wound infection (13). Thus, our study has shown that post-operative haemoglobin has declined by 1gm percent in patients with subcutaneous drain and by 0.8 percent in those without subcutaneous drip, both before and after an operation that indirectly reflect a loss of blood and anaemia.

Our study showed that the composite wound complication results seroma 5%, hematoma 4% and abscess 29%. The serous discharge was less frequent in subcutaneous drain patients (1 patient) than in subcutaneous drain group (3 patients), and the formation of hematoma (2 patients), and more in the non-subcutaneous drain patients (1 patient), but the difference was statistically insignificant.

In patients without a subcutaneous drain group, the wound was less commonly known as "abscess formation" (10 patients), and the wound was less common than in the other group with drain (2,5 percent) than in patients with subcutaneous drain (13 patients); however, the difference was statistically

significant. Our study showed that the subcutaneous tissue thickness, drainage and drainage time in patients with subcutaneous drainage groups were directly related.

However, the use of prophylactic drainage to prevent complication of the wound is controversial; studies evaluating its efficacy have reported conflicting results in various studies (14).

Hellums et al. (2007) carried out a metanalytical study to address clinical uncertainty in women with caesarean supplies related to the use of prophylactic subcutaneous drainage that theoretically appears to be a benefit. Subcutaneous drain should reduce the potential subcutaneous dead space and eliminate the residual fluid and blood from the bacterial gross wound. In the literature, the theoretical advantages of subcutaneous drainage were not clear (5).

A prospective randomised trial of 76 women with at least two cm subcutaneous fat under the Caesarean section was conducted by Allaire et al; (2000). The patients were divided into three groups: group 1, subcutaneous tissue suture lock, group 2 subcutaneous closed suction drain, and group 3 had no suture lock or drainage, respectively. They found that the use of closed suction drainage in subcutaneous surroundings could reduce the incidence of complications of post-operative wounds. (14) (14)

Al-Inany, et al; (2002) randomised 118 pregnant obese women in two groups. Closed subcutaneous drainage system group and other non-drainage group. Both groups were routinely administered prophylactic antibiotics. The use of a subcutaneous drain as a prophylactic measure against wound collapse was not beneficial while patients were receiving prophylactic antibiotic drugs. (15) (15)

A meta-analytic study of prophylactic subcutaneous drainage after caesarean delivery was published in the Cochrane Library (2005), which concluded that the prophylactic wound drainage did not benefit caesarean women. The Cochrane meta-analysis included injury, wound complication, febrile morbidity, endometritis and blood loss, operative length and hospital stay time (16).

The recent meta-analysis in the Cochrane Library (2013) examined the effect of caesarean wound drainage. The review included ten trials that recruited 5,248 women. The meta-analysis did not find any evidence for any difference in the risk of wound infection, other wound problems or pain for women who suffered from wound drains compared to those who did not. In one trial, there was some evidence that a subcutaneous drain may increase wound infection compared to a sub-sheath drain (RR 5.42, 95 percent CI 1.28 to 22.98). No differences in results were found in the three trials which compared subcutaneous drainage with subcutaneous suture (17).

Kosins et al. (2013) conducted the greatest systematic review and meta-analysis, with the objective of determining the proven value of prophylactic drainage of surgical subcutaneous wounds. Fifty-two studies, with a total of 6,930 surgical operations, were identified as suitable to the analysis. There were 3495 drainage operations and 3435 no-drain operations. The statistical advantage of prophylactic subcutaneous drainage was only significant for:

(1) hematoma prevention during breast biopsy procedures and (2) axillary node dissection seromas prevention. Drainage did not offer an advantage in all other procedures studied. Surgeons may consider dropping after caesarea section, breast reduction, abdominal injuries, femoral injuries and replacement of the hip and knee joint. In addition, surgeons should consider not prophylactically placing drains in obese patients. Nevertheless, drainage following an operation is the choice of the surgeon and may be based on multiple factors outside the type of procedure or the body habits of the patient. (18). (19).

So the net result of our study and majority of other similar and recent study is the use of prophylactic subcutaneous drain in addition to subcutaneous tissue re-approximation in women who underwent caesarian section not significantly reduce seroma, hematoma, abscess formation and dehiscence when compared with group without drain

Our finding does not necessarily contradict the established principle that body fluid stasis increases the risk of infection. The fact that post-operative drainage of capillary bleeding provided no added benefit confirms Halsted's cited: "Drainage is a confession of imperfect surgery: the more imperfect the technique of a surgeon the greater the necessity for drainage."(19).

Conclusion

the additional use of subcutaneous drain along with a standard subcutaneous tissue re-approximation as prophylactic technique seem to be not effective for the prevention of wound complications in obese women undergoing caesarean section. Subcutaneous tissue drain placement following a surgical procedure is the surgeon's choice and can be based on multiple factors rather than subcutaneous tissue thickness and body mass index.

Declarations

Author contribution:

Safaa A. Ibrahim: (First author)

Methodology

Mena M. Abdalla: (Second & corresponding author)

collecting data

literature of review

Statistical analysis and discussion.

Rofida M. Elshafei:

introduction & references.

Conflict of interest

The authors of this manuscript declare no relevant conflicts of interest, and no relationships with any companies, whose products or services may be related to the subject matter of the article.

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Ethical approval

Institutional review boards approval was obtained.

Informed consent

Written informed consent (Consent to Participate and Consent to Publish) was obtained from all patients.

Statistics and biometry

The corresponding author has great statistical expertise

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Tables

Table (1): demographic data of both groups

	Range	Group1 (n=80) Suture with drain	Group2 (n=80) Suture without drain	t- value	p- value	Sig
		±SD	±SD			
Age (years)	21 - 44	32.3±6.9	31.6±6.5	0.4	0.6	NS
BMI (kg/m ²)	30 -39	34.6±2.5	33.5±2	2.2	0.03	S
Subcutaneous tissue thickness	4 -10.5	7.1±2.1	7.4± 1.7	0.6	0.5	NS

Table (2): comparison between patients with subcutaneous drain and patients without subcutaneous drain as regard to Hemoglobin (gm/dl) before and after operation.

	Groups			
	with drain	without drain	t- test	
	±SD	±SD	T	p
Pre-operative haemoglobin g/l	10.5±0.5	10.5±0.47	0.11	0.9 NS
Post-operative haemoglobin g/l	9.9±0.46	9.8±0.39	1.16	0.2 NS
Paired t - test p	14 0.0	11.3 0.0		

Table(3): Distribution of medical diseases of cesarean section Suture with drain group and Suture without drain group

	Studied groups		sig Test	p
	Suture with drain	Suture without drain		
	No./80	No./80		
Contour				
Symmetric	34	48	2.4	0.117
Asymmetric	46	32		
Hypertension				
Normotensive	56	50	0.5	0.4
Hypertensive	24	30		
Diabetes				
Normal	62	54	1	0.3
Diabetic	18	26		
Ischemic heart disease				
Normal	76	74	0.2	0.6
Ischemic	8	6		

Table (4): Logistic regression analysis for risk factors associated with wound infection

Variables	Odds ratio	95% confidence interval		Sig
		Lower limit	Upper limit	
Age group	7.4	0.2	205	NS
Obstetric history	0.7	.14	3.78	NS
Contour	1.2	.12	13	NS
Hypertension	1.6	.07	38	NS
Diabetes	217	9.6	4904	S
Ischemic heart disease	116	-	-	NS
Technique of wound closure	0.17	.01	2.6	NS

Table (5): Comparison between patients with subcutaneous drain and patients without subcutaneous drain as regard to post- operative complication hematoma, infection, dehiscence and seroma

Complications	With drain(n=80)		Without drain (n=80)		Test of significant	
	N	%	N	%	Fisher exact	P
Hematoma	8	5	4	2.5	-	1 NS
Infections	52	32.5	40	25	*0.5	0.4 NS
Dehiscence	0	0	2	2.5	-	1 NS
Seroma	2	2.5	6	7.5	-	0.6 NS

*Chi square test

Table(6): Association between age, contour, hypertension, diabetes and ischemic heart and wound infection

variables	Studied groups				Test of significant		
	Infection		Non-infection		X ²	p-value	Sig
	No.	%	No.	%			
Age							
≤ 35	10	9	98	91	14.2	0.0	S
>35	24	46	28	54			
Contour							
Symmetric	8	10	74	90	6.6	0.01	S
Asymmetric	26	27	72	73			
Hypertension							
Normotensive	10	9	96	91	13.1	0.0	S
Hypertensive	24	44	30	56			
Diabetes							
Normal	4	3	112	97	39	0.0	S
Diabetic	30	68	14	32			
Ischemic heart disease							
No	24	16	126	84	19	0.0	S
Yes	10	100	0	0			
Operation technique							
Suture with drain	18	22.5	62	77.5	0.07	0.7	NS
Suture only	16	20	64	80			
Obstetric history							
Primgravida	0	0	30	100		0.0	S
multigravida	34	26	96	74 ¹			

Table (7): Logistic regression analysis for risk factors associated with wound infection

Variables	Odds ratio	95% confidence interval		Sig	
		Lower limit	Upper limit		
Age group	7.4	0.2	205	.14	NS
Obstetric history	0.7	.14	3.78	.7	NS
Contour	1.2	.12	13	.8	NS
Hypertension	1.6	.07	38	.6	NS
Diabetes	217	9.6	4904	.001	S
Ischemic heart disease	116	-	-	.99	NS
Technique of wound closure	0.17	.01	2.6	.2	NS

This table shows that Diabetes is the predictor variable for occurrence of wound infection

Table(8): Incidence rate of infection among group "Suture with drain" and group "Suture only"

	Studied groups				Relative risk (95% CI)	p
	Suture with drain		Suture only			
Infection three days						
Incidence rate	8/80	10%	4/80	5%	2(0.39 -10.3)	0.6
Infection in one week						
Incidence rate	18/80	22.5%	16/80	20%	1.13(0.48 -2.62)	0.7
Infection in two week						
Incidence rate	No		no		1	

Table (9): Comparison between patients with subcutaneous drain and patients without subcutaneous drain as regard Length of hospital stay/days

	Studied groups			t test	
				t	p- value
	N	range	±SD		
Length of hospital stay/days					
With drain	80	2 -5	2.7±2.1	1.8	0.07
Without drain	80	2 -4	2.4±0.5		NS

Table(10): Correlation between skin thickness, body mass index, age and length of hospitalization

	Studied group (no.160)	length of hospitalization/day
Age (years)	r	0.53
	p	0.0
BMI (kg/m²)	r	0.33
	p	0.003
Subcutaneous tissue thickness/cm	r	.6
	p	0.0