

Original research article

A Randomized Comparative Study of Vacuum Assisted Dressing V/S Conventional Dressing in Management of Chronic Wounds In Diabetic Patients

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Abstract

Vacuum Assisted Closure therapy has been shown to be beneficial in a variety of wounds. However, evidence of its benefit in chronic wound in diabetic patients, especially in Indian population is sparse. [1] This Prospective comparative study was carried out between July 2019 to September 2020. The study enrolled 50 patients of chronic wound having diabetes, 25 Patients underwent Vacuum Assisted Dressing in group A while remaining 25 patients underwent Conventional Dressing in group B. Healing duration, Debridement session, Definitive treatment and Total Duration of Hospital stay were compared between group A and group B to conclude which type of dressing method is superior and in the best interest of patients and surgeon. Mean hospital stay was 18.12 days in group A and 36.32 days in group B. Mean debridement session 0.2 in group A and 3.16 in group B. In group A, 22 patients had skin grafting and 3 patients had secondary closure; in group B, 19 patients had skin grafting, 2 patients had secondary closure & 4 patients had amputation, which clearly signifies that Vacuum Assisted Dressing has better outcome as compared to Conventional Dressing. We conclude that, Vacuum Assisted Dressing helps in reducing rate of wound infection, formation of even uniform granulation tissue, requiring less debridement session and less burden of anesthesia associated with other surgical interventions, resulting in early definitive treatment, decreased hospital stay and less consumption of hospital resources.

Keywords: Vacuum Assisted Closure (VAC) therapy, Diabetic Patients, Conventional Dressing, Skin Grafting, Secondary Closure.

Introduction

Diabetic ulcers constitute one of the most important complications of diabetes mellitus, with a staggering 25 % lifetime risk [1, 2]. If not treated promptly, progression of infection and sepsis may necessitate a limb amputation [3, 4]. This can be attributable to several social and cultural practices such as bare foot walking, inadequate facilities of diabetic care and education, and poor socioeconomic conditions [5].

Despite recent advances in Conventional dressings, only 24 to 30 percent of Diabetic Ulcers heal within an adequate time frame of between 12 and 20 weeks [5]. Increased time required for adequate healing, increases the risk for serious complications such as hospitalization, infection, osteomyelitis and cellulitis and end stage as Limb amputation with major impact on distorting body image, loss of productivity, increasing dependency, and cost of treating foot ulcers if patient require in patient care.

During the last two decades, innovative dressings have been introduced. Vacuum Assisted closure (VAC), is a non invasive, active wound management system, which uses negative pressure in order to enhance the healing process and increase local blood flow and reduce edema and bacterial colonization rates & fluid from the extra vascular space is removed and helping to reduce the risk of wound infection and promote closure of the wound by promoting the rapid formation of granulation tissue [6]. It concurrently provides a moist wound environment and removes excess wound exudates. Topical negative pressure is said to thus aiding in the creation of the “**Ideal Wound healing environment**” thereby decreasing the period between debridement and definite surgical closure in large wounds.

Material & Methodology:

This study was carried out at Surgery Department, Sir T Hospital and Government Medical College, Bhavnagar-364001, Gujarat, India between July 2019 to September 2020. In this prospective comparative study, total 50 cases of diabetes mellitus with Chronic Wound, admitted in Surgery Department were taken. All of them were thoroughly debrided initially and then using odd/even number method patients were randomly allocated into two Groups by systemic random sampling. Group A including 25 diabetic patient of Vacuum Assisted Dressing and Group B including 25 diabetic patients of Conventional Dressing. Both Groups were compared for below mentioned Criteria. All the cases were followed for duration of 5 weeks or till the date of Definitive treatment (among both of them which was earlier) and accordingly data were collected.

Inclusion Criteria:

- All Diabetic Patients with Age between 20 to 65 year.
- All types of chronic wounds in Diabetic Patients with Wound with Size of more than 6*6cm with depth more than 2cm.
- Patients giving consent for Vacuum Assisted Dressing.

Exclusion Criteria:

- Non Diabetic Patients.
- Wounds with less than 6*6 cm size.
- Patient with underlying Osteomyelitis.
- Exposed Arteries or Veins / Varicosity and Joint capsule.
- Malignant ulcers.

Procedure:

All Diabetic patients with chronic wounds were admitted in Surgery department, underwent detailed clinical examination and recorded in standard case report form. Written and well informed consent was taken from all 50 patients. All of them were thoroughly debrided initially and then randomly divided into two groups, Group A (Vacuum Assisted Dressing) and Group B (Conventional Dressing). In Both Groups, the ulcer dimensions as well as the surface area were assessed using ruler placed beside the wound and then photographed. Initially broad-spectrum antibiotics were given and later specific antibiotics were given according to sensitivity profile.

Group A: After debridement in operation theatre, Vacuum Assisted Dressings were applied by **Surgery Residents** by following Techniques,

1. Materials Used:

- VAC Machine with Canister (Fig. 1)
- Dressing kit (foam & Drape) with ruler
- Sterile Scissors & Gloves

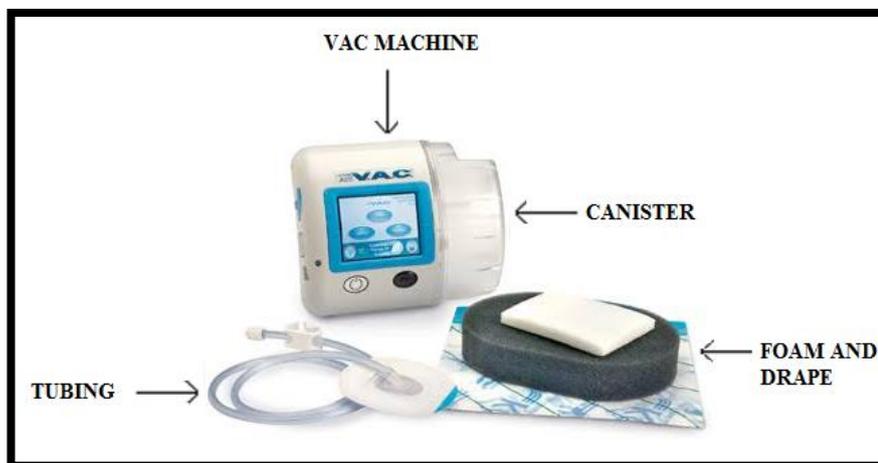


Figure 1: Vac Machine

2. Method of Application of VAC Dressing (Fig. 2)

- **Wound was cleaned thoroughly**
- **Foam was cut:** to fit the size and shape of the wound, including tunnels and undermined areas.
- **Foam was laid in the wound:** to cover the entire wound base and sides, tunneling and undermining.
- **Drape was cut:** large enough to cover the foam and 5cm of surrounding healthy

tissue with drape.

- **Drape was applied:** with beginning on one side of the foam, toward the tubing
- **A hole was cut in the drape of about 1.5 cm and tubing was applied.**
- **Canister was connected:** Dressing was connected to canister tubing, clamps were open and a negative pressure of -125 mmHg was created in an automatic intermittent manner (30 minutes on, 10 minutes off)
- **VAC dressing was covered with Gauze piece and Bandages as a supportive dressing.**

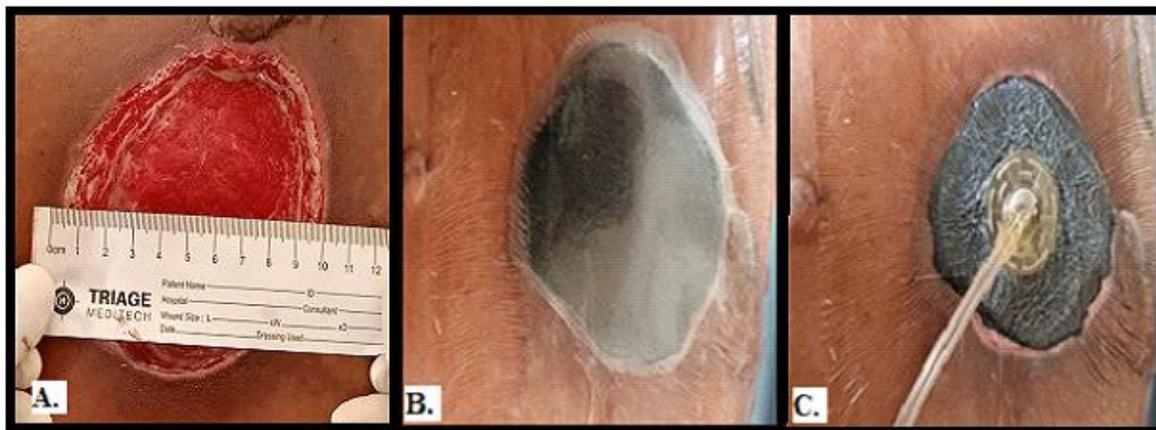


Figure 2: Image (A), (B) And (C) Showing Steps of Vacuum Assisted Dressing

After applying VAC dressing, wound was left undisturbed for 7 days and to see for skin complications by removing overlying bandage and Gauze piece twice weekly. At the time of VAC Dressing, wound was examined for Healthy Granulation tissue, ulcer dimensions as well as the surface area using ruler, Amount of exudates (collected in canister). If wound was found with slough and necrotic tissue then debridement of wound was done. Following that, again VAC dressing has been applied if needed upto 2 to 3 times after date of admission. Each of the wound with healthy granulation tissue was operated with Split thickness skin Grafting or Secondary Closure or spontaneous wound closure. All Patients were discharged from the hospital after 3 days of definitive Treatment and follow up was taken upto 5 week counting from the date of admission.

Group B: After debridement in operation theatre patients were subjected to daily dressings by Conventional methods, using 5% povidone iodine and normal saline by Surgery Residents (Fig 3). The wound's surroundings were inspected daily to check for any complication & thoroughly debrided whenever needed. At Every week, wounds were examined for Healthy Granulation tissue, ulcer dimensions as well as the surface area using ruler, Amount of exudates (Collected from soaked Gauze piece). If wound was found with slough and necrotic tissue then debridement of wound was done. Every patient was followed up every weekly up to 5 weeks or till the date of definitive treatment (among them which one was earlier). Each of the wound with healthy granulation tissue was operated with Split thickness skin Grafting or Secondary Closure or spontaneous closure but wounds with necrotic tissue at the end of 5wks, underwent amputation as definitive treatment. All Patients were discharged from the hospital after 3 days of definitive Treatment and follow up was taken upto 5 week counting from the date of admission.

The study was performed on all patients for 5 weeks from the date of admission and evaluated For Healing and Healing Rate, Granulation Tissue, Debridement Session, Definitive Outcome, Total Duration of Hospital Stay.

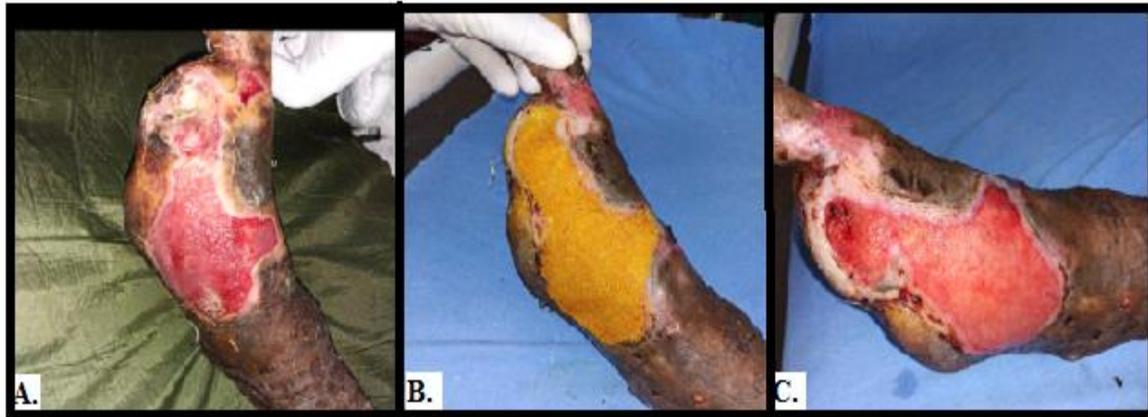


Figure 3: Image (A), (B) And (C) Showing Conventional Dressing

Statistical Methods:

Descriptive statistical analysis has been carried out in the present study. Results on continuous measurements are presented on Mean and SD (Min-Max) and results on categorical measurements are presented in Number (%). Significance is assessed at 5 % level of significance. *P* value of less than 0.05 was considered as significant.

Statistical software: The Statistical software namely SPSS 15.0, Stata 8.0, Med Calc 9.0.1 and Systat11.0, Instat were used for the analysis of the data and Microsoft word and Excel have been used to generate graphs, tables etc

Results

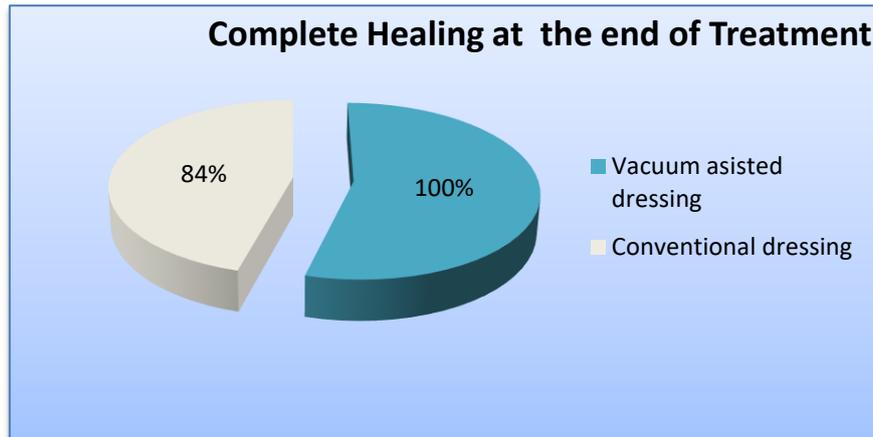
This study showing following Results,

1. Healing and Healing Rate

The overall healing rate was 2.8 cm/week and 1.6 cm/week in Vacuum Assisted Dressing and Conventional Dressing respectively (Table 1) with 100% patients showing complete healing in Vacuum Assisted Dressing while 84% showing complete healing in Conventional Dressing (Chart 1) but remaining 16% showing no healing till study duration and went for amputation as definitive treatment.

Table 1: Comparison of Healing and Healing Rates

	Vacuum assisted dressing	Conventional dressing
Complete Healing at the end of Treatment	25(100%)	21(84%)
The Overall Rate of Healing	2.8cm/week	1.6
Time of Healing in Days	15.12 SD 5.2	26.6 SD 5.34
Healing not Completed	0	04(16%)



Graph 1: Complete Healing at the End of Treatment in Both Groups

2. Granulation Tissue

In this study, in which Vacuum Assisted dressing was applied, we found that 80% patients develop granulation tissue within one week, while in Conventional Dressing 24% patients develop granulation tissue within one week.

Table 2: Comparison of Granulation Tissue

Days of Granulation tissue	Vacuum Assisted Closure cum assisted dressing (No. of Patients)	Percentage (%)	Conventional Dressing (No. of Patients)	Percentage (%)
1 st week	20	80	06	24
2 nd week	5	20	04	8
3 rd week	-	-	03	12
4 th week	-	-	07	20
5 th week	-	-	01	20
No healthy granulation tissue	-	-	04	16

3. Debridement Session

Patients of Vacuum Assisted dressing required less debridement session with mean of 0.2 (Minimum no. of Debridement is 0 and Maximum no. of Debridement is 2) and SD 0.5 as compared to conventional dressing with mean of 3.16 (Minimum. no. of Debridement is 1 and Minimum no. of Debridement is 7) and SD 1.4.(Table 3)

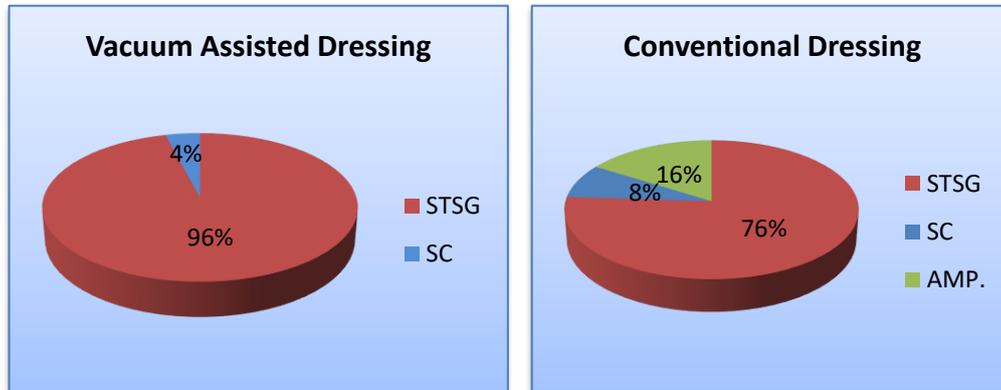
Table 3: Comparison Of Debridement Sessions

No. of debridement session	Vacuum Assisted dressing	Conventional dressing
Min. – Max. (present study)	0.0 - 2.0	1.0 - 7.0
Mean ± SD (present study)	0.2 SD 0.5	3.16 SD 1.4
Mean ± SD (Mahmoud S Shehata et al study[11])	0.2 SD 0.5	2.86 SD 2.35

4. Definitive Outcome :

In Vacuum Assisted dressing, 22 patients (88%) had STSG done and 3 patients (12%) had secondary closure while in Conventional dressing 19 patients (76%) had STSG done, 2 patients (8%) secondary closure and 4 patients (16%) had amputation (Chart 2 & 3) which clearly

signifies that Vacuum Assisted dressing has better outcome as compared to Conventional dressing.



Graph 2 & 3: Outcome in Group A And Group B

5. Total Duration Of Hospital Stay

In Vacuum Assisted dressing, mean hospital stay was less with 18.12 days and SD 5.11 days as compared to Conventional dressing with mean hospital stay 29.6 days and SD 5.34 days.

Table 4: Comparison of Total Duration Of Hospital Stay

	Mean hospital stay(Days)	
	Vacuum Assisted Dressing	Conventional Dressing
Our Present Study(p<0.0001)	18.12	29.6
Abdullah Al Sayed et all Study [6]	22.87	32.53

Discussion:

A considerable proportion of patients with diabetes mellitus develop chronic ulcers. It presents as a most common cause of non-traumatic amputation preceding as high as 85 % of the cases.[6,7] It was found that the cost of care in patients with chronic ulcer was over five times higher in the 1st year than in diabetics without chronic ulcer.[8] This is mainly due to longer duration of hospital stay needed in patients of diabetes with chronic ulcer.

Time to complete wound healing was significantly better in VAC therapy group as compared to conventional dressing, with overall healing rate was 2.8 cm/week and 1.6 cm/week in Vacuum Assisted Dressing and Conventional Dressing respectively with 100% patients showing complete healing in Vacuum Assisted Dressing while 84% showing complete healing in Conventional Dressing but remaining 16% showing no healing till study duration and went for amputation as definitive treatment. The difference was statistically significant with p value of <0.0001. It correlates with the study done by Abdelaziz A. Abdelhafez in Al-AZHAR ASSUIT MEDICAL JOURNAL on 50 patients of diabetic foot ulcer showing overall rate of healing of 96%(healing rate 2.4 cm/week) in Vacuum Assisted Dressing and 88%(healing rate 1.9cm/week) in Conventional Dressing.[8]

Chronic wounds in Diabetic are wounds that fail to heal in the normal healing phases of inflammation, proliferation, and maturation and often exhibit progressive edema, compromise

of perfusion, and elevated levels of proteolytic enzymes and cytokines that inhibit granulation tissue formation and epithelialization. It reduces the inflammatory secretion and removes wound edema, neo angiogenesis and increased perfusion helps in faster generation of granulation tissue & prepare wound bed for definitive management like STSG or Secondary Closure. Here we studied comparison of wound dressing between Vacuum Assisted Dressing and Conventional Dressing by various outcome measures such as early granulation tissue, decrease hospital stay and definitive treatments. [9]

In present study, patients of Vacuum Assisted Dressing has mean hospital stay of 18.12 days with SD 5.11 days and 80% patient having granulation tissue within 1st week, while in Conventional Dressing mean hospital stay was 29.6 days and SD 5.34 days and 24% patients have granulation tissue within 1st week. This difference was large and clinically significant with p value <0.0001. It correlates with the study done by Abdullah Al Sayed [10] on 50 patients of diabetic foot wound in which mean duration of hospital stay was 22.87 days and SD 7.62 days in Vacuum Assisted Dressing and mean duration of hospital stay was 32.53 days and SD 10.17 days in Conventional Dressing.

In present study, patients of Vacuum Assisted dressing required less no. of debridement session, resulting in mean of 0.2 with SD 0.5 while in Conventional Dressing, min. debridement session was 1 and max. Debridement session was 7, resulting in of mean 3.16 and SD 1.4. The difference was statistically significant (p value of <0.0001). It correlates with the study done by Mahmoud S. Shehata [11] on 100 patients of diabetic foot infection in which no of debridement sessions was significantly less in Vacuum Assisted Dressing with mean of 0.2 with SD 0.5 compared to Conventional Dressing with mean of 2.8 And SD 2.35.

In present study, in Vacuum Assisted dressing 22 patients(88%) had STSG done and 3 patient(12%) had secondary closure while in Conventional dressing 19 patients(76%) had STSG done ,2 patients(8%) secondary closure and 4 patients(16%) had amputation done which clearly signifies that Vacuum Assisted dressing has better outcome as compared to Conventional Dressing. The difference was statistically significant (p value of <0.0001). It correlates with the study done by Aziz Nather [12] on patients of diabetic foot infection in which total 9 patients (81%) with Vacuum Assisted dressing had STSG done and 2 patients (19%) had secondary closure.

According to our results, patients with Vacuum Assisted dressing having early healing, granulations comes early, less duration of hospital stay, with less operative procedure and better outcome, which signifies it is useful same is as study done by **Abdelaziz A. Abdelhafez et al**[8], **Abdullah Al Sayed et al** [10], **Mahmoud S Shehata et al** [11] and **Aziz Nather et al** [12] which suggest Vacuum Assisted Dressing is beneficial over conventional dressing in many ways.

Conclusion :

➤ Based on present study we conclude that, Formation of healthy uniform granulation tissue was very fast in Vacuum Assisted Dressing as compared to Conventional Dressing. The wound was fit for definitive procedures like Split Thickness Skin Grafting and secondary closure earlier in Vacuum Assisted Dressing as compared to Conventional Dressing. The number of Debridement session of the wound was less in Vacuum Assisted Dressing as compared to Conventional Dressing. No Amputation of limb in VAC Dressing.

Although cost of Vacuum Assisted Dressing Therapy is high than conventional Dressing, Hospital Stay is significantly shorter in Vacuum Assisted Dressing Therapy patient, so less consuming of hospital resources, this is finally decreasing the total budget to the hospital. As well as No Amputation of limb of patient that is best advantage to patient which overcome high cost of VAC Dressing. Overall VAC Dressing is superior and cost effective to patient than Conventional Dressing.

References

1. Lone AM, Zaroo MI, Laway BA, Pala NA, Bashir SA, Rasool A, et al. Vacuum-assisted closure versus conventional dressings in the management of diabetic foot ulcers: A prospective case-control study. *Diabetic foot Ankle* 2014;5:e23345.
2. Vishwanathan V. The Diabetic foot: Prospective from Chennai , South India. *Int J Low Wounds* 2007;6:34-6.
3. Vijay V., Narshimham DV, Seena R, Snehalatha C, Ramachandran A. Clinical profile of diabetic foot infections in South- A retrospective study. *Diabetic Med* 2000;17:215-8.
4. Hasan MY, Teo R, Nather A, Negative- pressure wound therapy for management of diabetic foot wounds: A review of the mechanism of action, clinical applications, and recent developments. *Diabetic Foot Ankle* 2015;6:27618.
5. Queen D. Orsted H, Sanada H, Sussman G: A dressing History *int Wound J* 2004; 1:59-77
6. Shojaiefard A, Khorgami Z, Larijani B. Independent risk factors for amputation in diabetic fooy. *Int J Diabetes Dev Ctries* 2008;28:32-7.
7. Robbins JM, Strauss G, Aron D, Long J, Kuba J, Kaplan Y, et al. Mortality rates and diabetic foot ulcers: Is it time to communicate mortality risk to patients with diabetic foot ulceration? *J Am Podiatr Med Assoc* 2008; 98; 489-93.
8. Al-Azhar Assiut Medical Journal, Vol 13, no 4,suppl-2 pg 289
9. Singh B, Sharma D, JaswalKS,. Comparison of negative pressure wound therapy v/s conventional dressing in management of chronic diabetic foot ulcer in a tertiary care hospital in North India. *Int J Sci Res* 2017; 6: 948-53.
10. Atef Bayoumi, Abdullah Al- Sayed et al, Abdullah Al- Mallah: *Egyptian Journal Of Hospital Medicine* Vol. 72 Page 4054-4059
11. Mahmoud S Shehata et al, Mahmoud E Nagaty, Ayman H Ebrahim, Yasser H Metwally, Ibrahim S. Bakr: *International Journal Of Multidisciplinary Research And Development* Vol. 5 Page 188-193Aziz Nather et al :*Ann Acad Med Singap* 2010 May; 39(5):353-8