

NEW INDIAN JOURNAL OF SURGERY

(PEER-REVIEWED AND REFEREED JOURNAL)

VOLUME 15 NUMBER 3 JULY - SEPTEMBER 2024



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New Indian Journal of Surgery

NIJS

Volume 15 Number 3

July - September 2024

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Miracle Negative Pressure Wound Therapy (NPWT) or Vacuum Assisted Closure (VAC): For Difficult and Complicated Wounds: An Observational Study

Abhishek Sharma

How to cite this article:

Abhishek Sharma. Miracle Negative Pressure Wound Therapy (NPWT) or Vacuum Assisted Closure (VAC): For difficult and Complicated Wounds: An Observational Study. *New Indian J Surg.* 2024; 15(3):95-100.

Abstract

In complicated wounds, healing is a challenge, particularly for the elderly with co-morbidities, which is a major concern. It can lead to prolonged treatment, pain, and morbidity and require major reconstructive procedures, which foist enormous financial and social burdens. Negative pressure wound therapy (NPWT) or vacuum-assisted closure (VAC) is a miracle and more acceptable method as an alternative in wound management that relies on sub atmospheric pressure and encourages the wound for spontaneous healing or by reducing the burden of reconstructive procedures. VAC application methods include thorough debridement, haemostasis, and the application of sterile sponge or foam dressing. A tube with fenestrations is submerged in the sponge, and the wound is wrapped to make it airtight or watertight with adhesive tape. The vacuum pump with fluid collection container is connected to the fenestrate tube. The pump delivers intermittent or continuous suction with pressure ranging from 50-55 to 120-125 mmHg. The NPW dressings are replaced on the third day. Negative pressure therapy reduces wound oedema and bacterial load, stabilizes the wound environment, improves perfusion, and stimulates angiogenesis and granulation tissue. All these mechanisms facilitate the possibility of primary wound closure and reduce the need for other reconstructive procedures. VAC therapy seems to be more effective and simpler

than traditional dressings for wound care management in reduction in wound size and volume, depth, treatment duration, and cost.

Keywords: VAC (vacuum-assisted closure); Negative pressure wound therapy (NPWT); Complicated and difficult wounds; Low cost; Sub-atmospheric pressure dressing.

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Received on: 07-10-2024

Accepted on: 12-11-2024



INTRODUCTION

In complicated wounds, healing is a challenge, particularly for the elderly with co-morbidities, which is a major concern. It can lead to prolonged treatment, pain, and morbidity and need major reconstructive surgical procedures, which foist enormous financial and social burdens. Negative pressure wound therapy (NPWT) is a miracle and more acceptable method of management of wounds alternatively that relies on negative pressure to prepare the wound for healing spontaneously or by reducing reconstructive procedures. The vacuum-assisted closure is a non-surgical and non-pharmacological means for modulating wound healing; it was first suggested by Argenta and Morykwas in 1997.^{1,2} The application of vacuum-assisted therapy reduces infection and oedema and improves local blood flow, which promotes healing.³ It is used as an alternate or adjunct to surgery for a wide range of wounds, with the target of decreasing the duration of hospitalisation, morbidity, cost, and patient comfort.⁴⁻⁶

MATERIALS AND METHODS

VAC application method

The debridement and cleaning of the wound are done thoroughly, irrigated with normal saline, and haemostasis is achieved, and the skin surrounding the wound is made dry. To facilitate an equal distribution of negative pressure, sterile sponges are required for dressing, as they cover an over-the-whole wound bed. Two different types of foams or sponges are commonly used: white (polyvinyl alcohol), which is dense, hydrophilic, and has a hole size of 250 μm .⁸ Black (polyurethane ether is a lighter, porous, 400–600 μm of size and hydrophobic in nature) is used for abdominal and thoracic cavity wounds. A fenestrated evacuation tube is buried in the sponge, which is attached to a container and a vacuum pump. The adhesive drape was used to seal the wound. Drapes should cover tubing beyond the foam at least 4–5 cm of neighbouring skin to make it airtight or watertight seal. The VAC dressing is recommended to change on the third day. There are two modes of negative pressure, intermittent or continuous, ranging from 50 to 125 mmHg. Higher pressures (150 mmHg plus) are used for exudative and large cavity wounds. Intermittent mode consists of a 5-minute on and 2-minute off phase. In painful and chronic

wounds, the setting of pressure can be kept low (40–75 mmHg).

RESULT

In this study, we compared our results of vacuum-assisted wound closure technique in different wound scenarios and compared the efficacy and economy of commercialised VAC and indigenously made VAC therapy. A total of 24 patients were included in this study, in whom VAC wound closure treatment was given in our institute between January 2022 and December 2023. The distribution of the patients was as per aetiology as follows: 12 traumatic, 3 pressure sores, 8 diabetic foot ulcers, and 1 post-CABG wound dehiscence. All cases were assessed in terms of wound size, aetiology, gender, age, and treatment period. In the patients studied, 20 were men (83.33%) and 4 were women (16.66%). The age of patients ranged 18–69 years, and the mean age of the patients was 42.6 years. Most of our patients suffered from trauma and diabetic ulcers. After the indigenous vacuum-assisted wound closure application, wound size reduced by 38.8%, and the mean surface area of the wound was 95.7 cm^2 (12.8–218.3 cm^2) on average. Once the wounds

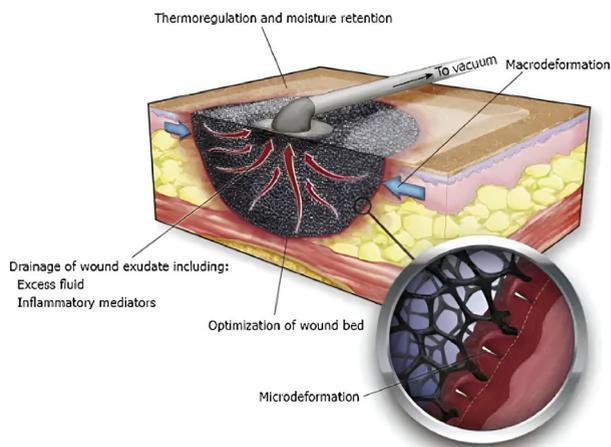


Fig. 1: Physiological changes during VAC therapy

became primed for surgery, split-thickness grafting was used in 8 patients. 5 of them needed secondary sutures; full-thickness grafting was used in 8 of them; 2 of them required flaps; and 1 healed itself by secondary intention. The average period of the application of vacuum-assisted wound closure was 11.4 days (8–16 days). In the long term, the overall cost of treatment is further lower with indigenously made VAC. Our study results were comparable to commercial systems, and indigenously made vacuum-assisted wound closure can be considered

satisfactory, economical, and without complications when cases are selected properly.



Fig. 2: Locally available material or device to assemble VAC therapy

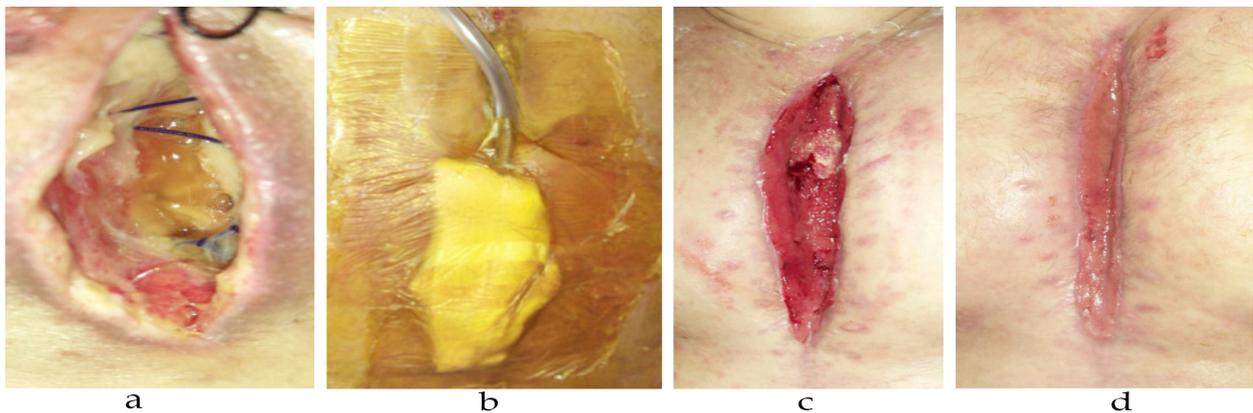


Fig. 3: (a) Wound over chest following CABG; (b) Indigenously prepared VAC in place; (c) Post-VAC therapy wound after two sessions; (d) Same wound after 2 weeks

DISCUSSION

In the beginning, NPWT-negative pressure wound therapy was used to hasten the preparation of wounds bedside. To evaluate the negative pressure therapy effect of topical on bacterial clearance, local blood flow, the formation of granulation tissue, and flap survival Morykwas *et al.*^{1,2} observed in a series of experiments in animals. Subsequently, they decided to use a sponge dressing with a vacuum suction for wound management, with an adjusting vacuum pressure of intermittent and continuous modes. **Indications** of vacuum-assisted closure include bed sores, diabetic foot ulcers, flap salvage, skin graft fixation, crush injuries, burns, abdominal or sternal dehiscence of wounds, wounds after fasciotomy, animal bites, or frostbite extravasation wounds. VAC is not recommended in patients with unmanaged osteomyelitis, body cavities, fistulae, or malignant wounds, with wounds with exposed

arteries, nerves, anastomotic sites, or organs showing up necrotic tissue.^{8,9} VAC is relatively contraindicated in patients actively bleeding, on anticoagulant therapy, or with wound dyscrasia.⁹ **Alarming signs** during VAC therapy include surrounding invasive sepsis, active or excessive bleeding, signs of infection, increased pain, such as fever, foul-smelling drainage, or pus, and an allergy to the adhesive material.⁹ **VAC therapy complications** include VAC system failure (power failure, loss of seal, and drainage system blockage), pain, wound infection, bleeding, skin excoriation, limited mobility, being allergic to drape, adhesion of the tissues to the foam, skin necrosis, and a lack of patient compliance. VAC therapy gives rise to reduced hospital stays by reducing the bacterial load, number of dressing changes, improving skin perfusion, reducing patient comfort, reducing oedema, and providing a moist, optimum wound healing environment.

Mechanism of action

Animal and human studies have indicated VAC therapy causes reduction of the area of wound, increased blood flow, granulation tissue growth, and regulation of the inflammatory response.^{1,10} VAC causes optimisation of the wound environment, wound contraction, removal of wound exudates, micro-deformation of cells, and decreased oedema. These effects allow VAC to improve wound healing by virtue of reduced bacterial load, increased blood flow, and improved wound size reduction for subsequent coverage.^{1,12} The tissue hypoxia induced by negative pressure causes wound compression, which leads to decreased perfusion beneath the sponge, which stimulates angiogenesis and local vasodilatation due to the release of nitric oxide.^{13,14,15} This happens during the "suction off" periods of therapy. Therefore, the intermittent VAC mode is relatively proven to be more efficient as compared to the continuous mode. Interstitial hypobaric pressure and increased vessel permeability following injury lead to the development of oedema.¹⁶ VAC application leads to increased pressure inside tissue, which causes vessel compression of and increased acceleration of the intravascular fluid, which decreases the intravascular fluid pressure (Bernoulli's principle).

Both of these factors cause decreased oedema due to less efflux of intravascular fluid. In addition, increased blood velocity shifts extracellular fluid into the vessel. In addition, negative-pressure wound therapy reduces injured tissue oedema away by compressive forces. All these processes result in improved oxygenation of cells and less interstitial fluid pressure. VAC therapy causes the immobilisation of wounds, which also favours ealing.^{17,18}

The release of growth factors occurs due to micro-deformation of cells caused by VAC, which causes tissue expansion.^{19,20-21} After negative pressure application, the expansion effect on the tissue occurs due to the differential pressure changes. The pressure beneath the dressing and outside the cells is negative, whereas the pressure inside the cells is positive. This causes the wound edges closer to a further, decreasing size of the wound, the expansion of cells, and granulation tissue growth. A recent study has shown that the paradoxically increased pressure that occurs in the basic wound is (hyperbaric)²² In the capillaries, perfusion pressure in normal tissue ranges 10-35 mmHg.²³ If the vascular anatomy is normal, there are no chances that hyperbaric pressure causes capillary occlusion. Whereas, in vascularly compromised tissue, hyperbaric pressure may lead to ischaemia

and necrosis. Therefore, VAC should be used with caution on tissue with less vascularity or ischaemia, especially if it is circumferential.

Optimum negative pressure required

Various controversies exist regarding the optimal pressure application in negative pressure therapy. Some studies on animal models have shown formation of granulation tissue occurs with 125-mmHg negative pressure compared with elevated (500 mmHg) vacuum suction and low (25 mmHg) vacuum suction. The low pressure during VAC (25 mmHg) leads to less removal of toxins and fluid drainage from the wound and decreased cell deformation. This results in a reduced rate of formation of granulation tissue. The suction pressure high (500 mmHg) during VAC causes enhanced mechanical distortion of tissues, which causes a decrease in perfusion locally and reduced formation of granulation tissue. Therefore, a 125 mm Hg of negative pressure is considered an optimal pressure.^{7,24} Results of various levels of negative pressure in different wounds (10-175 mmHg) reveal that the negative pressure changes should be adjusted according to the types of the wound. For chronic non-healing venous ulcers, the 50 mm Hg at intermittent cycles optimum pressure is required. In acute traumatic wounds, 125 mm Hg is the optimum negative pressure required.^{25,26}

Continuous vs. Intermittent VAC

Negative pressure intermittently is recommended as it improves more blood flowing during the vacuum "off" phase. Studies have revealed that granulation tissue formation rate is doubled with negative pressure intermittently than with continuous pressure. (104% with intermittent vs. 64% with continuous).²⁷ **Leakage of air** in the dressing should be avoided, as they can lead to a continual flow of air over the wound, leading to tissue desiccation and the formation of eschar. This eschar formation covers the wound with retained exudate and leads to deterioration of wound condition.²⁸ **The** pressure in a vacuum-assisted dressing gradually reduces over 48 hours; therefore, dressings should be changed after 2 days.²⁹ Caution should be taken during VAC therapy; rebound phenomenon and worsening of the wound condition are seen if it is terminated abruptly after one session. Therefore, at least two to three sessions of VAC should always be considered. There is one randomised control trial that provides objective evidence regarding the use of VAC in different situations. There is a strong recommendation that grade "A" is suggested only for the skin grafting procedure management; grade

“B” is the use of VAC as a span therapy between multiple debridements; and grade “C” is considered for traumatic wounds.³⁰

Cost

There are studies on various wounds that suggest that vacuum assisted closure is to a great extent more economical as compared to traditional wound care management techniques, as it requires a lesser number of dressings and fewer reconstructive procedures for wound healing. Wound healing becomes faster, and the duration of the overall hospital stay and treatment are reduced. Even though commercial VAC dressings are more costly than conventional dressings, in the long term, the overall cost of treatment is lower with VAC.^{31,32}

The San Antonio, TX, Kinetic Concepts, Inc. (KCI) wound VAC system and non-availability of other commercial vendors everywhere, and these devices are expensive too. Without buying costly dressing material, we have used off-the-shelf components in our patients for cost-effective negative pressure therapy or borrowed the KCI system, which may cost Rs. 8,000/day approximately. We have utilised locally available materials like abdominal drains, cling drapes, bactigras, sponges, and foams to congregate a dressing (Fig. 2). To generate pressure (75–125mmHg) negatively, this indigenously prepared dressing is connected to wall-mounted suction. This dressing is extremely cost-effective. The all-component cost is only Rs 400-500. This indigenously made VAC dressing system was used in many cases without complications and with results that are comparable to the commercial system^{31,32} (Fig. 2, Fig. 3). The lack of ability to use mounted suction intermittently is one of the limitations of this indigenous dressing because mounted suction devices have only a continuous mode.

Key points

- In complicated wounds, VAC is a better alternative or adjunct to standard wound management.
- It reduces the burden of reconstructive procedures.
- The 125 mm of mercury is optimum recommended pressure setting.
- Intermittent suction mode has an advantage over continuous suction mode.
- Over the conventional wound care methods, VAC has logistical benefits.
- The cost wise VAC in the long term has a cost-benefit ratio. It's results are too parallel to standard wound-care methods.

CONCLUSIONS

VAC/NPWT is a miracle in the field of surgery. It decreases the bacterial load, reduces oedema, stabilises the wound, improves tissue perfusion, and stimulates granulation tissue. It reduces the requirement for major reconstructive surgical procedures and improves the chances of voluntary wound healing. Vacuum assisted closure is an effective and simpler substitute for the management of various wounds than conventional dressing methods in terms of reduction in wound size, duration, and treatment cost.

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Clinical Presentation and Outcome of Adult Groin Hernia

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How to cite this article:

Sumit Salve, Anitha Kandi, Avinash Surwade, *et al.* Clinical Presentation and Outcome of Adult Groin Hernia. New Indian J Surg. 2024; 15(3):101-105.

Abstract

Aims & Objectives: To study the groin hernias in adult and its outcome in terms of clinical presentation, precipitating factors, intra-operative findings & complications.

Materials and Methods: This prospective clinical observational study was carried out in 400 patients with complaints related to the groin region to the department of general surgery in a tertiary care center over a period of 2 years after ethical committee approval.

Observation & Results: In this study inguinal swelling was the most common presentation in (77.25%), followed by localized pain in swelling (12%), localized pain in swelling with vomiting (2.25%) localized pain, vomiting And constipation in (5.75%) and distention in (1.25%) patients. The male-to-female ratio of groin hernia was 13.3, indicating a male preponderance. Unilateral groin hernias (83.5%) with right sided preponderance (49.75%) were more common than bilateral cases (16.5%) Uncomplicated groin hernias were seen in 86.75% patients while complications were seen in 12.25% patients as irreducible (6.75%), obstructed (4.25%) and strangulated (2.25%) In emergency operated case 1 patient had anastomotic leak in post-operative period and patient later succumbed. In 2.25% emergency and 1.5% elective patients had surgical site infection.

Conclusion: In this study we found an association between groin hernias & various precipitating factors, comorbidities and occupation. Both complicated and uncomplicated groin hernias are most common in males. Uncomplicated groin hernias are more prevalent than complicated ones. Uncomplicated groin hernias are posted for elective hernia repair & are managed by Lichtenstein's tension free mesh repair while incidence

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Received on: 29-08-2024

Accepted on: 16-10-2024

of complicated groin hernias is low and requires emergency surgical management & is associated with high morbidity and mortality.

Keywords: Groin hernias; hernia repair.



INTRODUCTION

Hernia is defined as a protrusion of a viscus or part of viscus through an opening in the wall of the cavity in which it is contained. Groin hernias are the most common types of hernia and account of 75% of all abdominal wall hernia. Inguinal hernias account for 95% of these and femoral hernias the rest.¹ Groin hernias are a very common problem in surgical practice.

Longer duration of symptoms, late presentation, concomitant diseases and high ASA class are found to be significant factors linked with unfavorable outcomes.^{1,2}

Groin hernia has varied presentation and treatment depends upon duration and type of presentation.^{3,4} Irreducibility, obstruction and strangulation are its commonest complications which presents as acute emergencies. The treatment of hernia is surgery. Different techniques such as Bassini's, Stopa's, Shouldice's, Darning, Lichtenstein and Laparoscopic repair have been evolved for repair of inguinal hernias.⁵ The mainstay of surgery is tension free repair of posterior wall of inguinal canal.^{2,3}

Strangulation, the most common serious complication of a hernia, occurs in only 1% to 3% of groins and is more common at the extreme of age.^{4,6,7} Most strangulated hernias are indirect inguinal hernias, however femoral hernias have the highest rate of strangulation.^{2,3,4} Emergency repair of complicated hernias is associated with poor prognosis and a high rate of post-operative complications even with better care and improved anaesthetic management.^{6,7} Co-morbid conditions, short duration of symptomatology and old age group are the major risk factors which predict complications in elder adults with groin hernia.^{3,4,5}

Thus, the purpose of this research was to study the various modes of presentation, clinical and operative findings and post operative outcome in adult groin hernia in tertiary care centre.

MATERIALS AND METHODS

Present prospective clinical observational study was carried out in 400 patients admitted with groin hernia to department of general surgery in a tertiary care center from 1 November, 2018 to 31 March, 2020 after ethical committee approval.

AIM AND OBJECTIVES

Aim: To study the clinical presentation of groin hernia in adult and its outcome.

Objectives

- To study the clinical presentations of groin hernia in terms of:
 1. Site and side
 2. Precipitating factors
 3. Type of hernia
 4. Clinical features
- To study the intra-operative diagnosis and surgical intervention for each hernia
- To study the outcomes in terms of intra-operative and post-operative complications

Inclusion Criteria

- All patients of groin hernia above 18 years age.

Exclusion Criteria

- All patients of groin hernia below 18 years age.
- Those who are not willing to enroll in study.

Data Collection and Clinical Evaluation

This was a prospective clinical observational study carried out in 400 patients with complaints of groin swelling. On presentation history was taken & a detailed examination was performed. If the patient had irreducible swelling & an absent cough impulse patient was admitted immediately & was posted of emergency surgery after adequate resuscitation & laboratory investigation. Other patients with reducible swelling were sent for routine blood (CBC, KFT, LFT, HHH, etc.) & radiological (Ultrasonography was done to rule out BPH & X-ray abdomen erect) investigations & followed up. Per rectal examination was done in all cases to rule out prostate enlargement. These patients were admitted after complete anaesthetic evaluation & were posted for routine hernia repair surgery.

Any underlying risk factor or medication if any were enquired.

Almost all patients were operated under spinal anaesthesia. Occasionally general anaesthesia was given.

An appropriate incision was taken for the type of hernia, sac was dissected out and was opened. The

site of constriction was noted and the contents of the sac were seen. The bowels were examined for viability. When doubtful or nonviable bowel was seen, oxygen was administered for 3-4 minutes and a warm saline mop was placed on the intestinal loops. If the color returned, peristaltic waves seen on stimulation and mesenteric pulsations felt, the bowel was returned to the abdomen. When the bowel was non-viable, it was resected and end to end anastomosis was done. Appropriate repair of the hernia was done. The resected specimen was sent for histopathologic examination. Hernia repair was done with mesh placement whenever possible. Sutures were removed on the 7th or 8th day and were discharged. Patients were advised for follow-up and also advised against lifting heavy objects for 3 months.

RESULTS

Table 1: Distribution of patients according to side of hernia

Side	Type of hernia		No. of patients
	Inguinal	Femoral	
Right	197	2	199
Left	135	0	135
Bilateral	66	0	66
Total	398	2	400

Table 2: Distribution according to precipitating factors

Precipitating factor	Type of hernia		No. of patients
	Inguinal	Femoral	
COPD	34	0	34
Urethral stricture	21	0	21
TB	26	0	26
BPH	50	0	50
COPD+BPH	12	0	12
None	255	2	257
Total	398	2	400

Table 3: Distribution according to clinical presentation

Symptom	Type of hernia		Total
	Inguinal	Femoral	
Swelling alone	309	0	309
Localized pain in swelling	52	0	52
Localized pain in swelling with vomiting	9	2	11
Localized pain in swelling with vomiting and constipation	23	0	23
Localized pain in swelling with vomiting, constipation and abdominal distension	5	0	5
Total	398	2	400

Table 4: Distribution according to type of hernia on clinical examination

Type of hernia	Type of hernia		No. of patient
	Inguinal	Femoral	
Reducible	347	0	347
Irreducible	27	0	27
Obstructed	15	2	17
Strangulated	9	0	9
Total	398	2	400

Table 5: Distribution according to type of hernia on Intra-operative Diagnosis

Intra-operative diagnosis	Management		Total
	Emergency	Elective	
Direct hernia	0	128	128
Indirect hernia	33	213	246
Pantaloon hernia	4	20	24
Femoral hernia	2	0	2
	39	261	400

Table 6: Distribution according to intervention

Surgery done	Management		Total no of patients
	Emergency	Elective	
Lichtenstein Tension free mesh repair	0	345	345
Hernia contents repositioned in abdomen with herniorraphy	3	8	11
Release of adhesion with reposition of Saccotentin abdomen with herniorraphy	15	6	21
Omentectomy and herniorraphy	10	0	10
Omentectomy, bowel resection, end to end anastomosis and herniorraphy	9	0	9
Laparoscopic hernia repair	0	2	2
Femoral hernia repair	2	0	2
Total	39	361	400

Table 7: Distribution of cases according to complications

A	Complication	Management		Total
		Emergency	Elective	
1.	Bleeding	10	14	24
2.	Spermatic cord injury	0	1	01
3.	Bowel perforation	1	0	01
4.	None	28	346	374
	Total	39	361	400

Table cont...

B Post-operative				
1.	Surgical site infection	13	6	19
2.	Cord oedema	8	8	16
3.	Anastomotic leak	1	0	1
4.	Death	1	0	1
5.	None	16	347	353
		39	361	400

DISCUSSION

Demography

In the present study out of 400 patients, the youngest patient was 19 year old and eldest patient was 89 years old and the mean age was 56.85 years. Maximum patients were found in age group 61-70 years in uncomplicated as well as complicated cases of operated for groin hernias. Present study correlates with Ratan *et al.* and Sushanta *et al.*⁸ and Agrawal S N *et al.*⁹

The male to female ratio was 13:1 showing male preponderance. Present study correlates with Rao SS *et al.*¹⁰, and Sushanta and Ratan R, Singh S *et al.*¹¹

There was right sided preponderance 49.75% in groin hernia and 16.5%. (Table 1). Present study correlates with Rao SS *et al.*¹⁰ and Singh S *et al.*¹¹ and Sushanta Tripathy and Ratan *et al.*⁸

Precipitating factors: (Table no.2)

Benign Prostatic Hyperplasia (12.5%) was the most common precipitating factor in groin hernia followed by COPD (8.5%). Present study correlates with M ceresoli *et al.*, Rao SS *et al.*¹⁰ and Susanta Tripathy and Ratan R study.⁸

Clinical presentation: (Table 3)

In the present study swelling was present in 309 (77.25%) cases of inguinal Hernia. Localized Pain in hernia swelling was present in 52 (13%) cases of inguinal hernia. Localized Pain in hernia swelling with vomiting was present in 9 (2.25%) cases of inguinal and 2 (0.50%) cases of femoral hernia. Localized Pain in hernia swelling, vomiting and constipation was present in 23 (5.75%) cases of inguinal. Localized Pain in hernia swelling, vomiting and constipation, abdomen distention was present in 5 (1.25%) cases of inguinal hernia. Present study correlates with Singh *et al.*¹¹ sushanta and Ratan⁸ and Dr Vinaykumar Teradal *et al.*¹² study.

Type of hernia on clinical examination and intra-operative evidence (Table no. 4 and 5 respectively)

In the present study of Groin hernia 347 (86.75%) were uncomplicated and 53 (13.25%) were complicated groin hernia. Out of 400 groin hernia cases 347 (86.75%) cases were reducible type, 27 (6.75%) were irreducible type, 17 (4.25%) were obstructed groin hernia in which 15 (3.75%) was inguinal hernia and 2(0.50%) had femoral hernia, and rest of the 9 (2.25%) cases were of strangulated hernia. Present study correlate with Rao *et al.*¹⁰ and Dr. Devalik chowlek shyam *et al.* Susanta Tripathy and Ratan R *et al.*⁸

In both uncomplicated and complicated cases of inguinal hernias, indirect inguinal hernia (61.5%) was the most common finding where as Pantaloon hernia was seen in 20 cases (5%) of uncomplicated hernias. Both the cases of femoral hernias presented as complicated groin hernia and were seen in females.

In the present study, 213 (53.25%) indirect inguinal hernia, 128 (32%) direct inguinal hernia and 20 (5%) pantaloon hernia were managed electively. the remaining 33 (8.25%) indirect inguinal hernia and 4 (1%) pantaloon hernia, 2(0.50%) femoral hernia were managed by emergency intervention. The above results correlate with Singh S *et al.*¹¹ and Susanta Tripathy and Ratan R⁸, Joseph B mabula *et al.*⁴

Type of intervention

In the present study in elective cases Lichtenstein tension free mesh repair was done in 345 (86.25%) cases and 2 (0.50%) cases were managed by laparoscopic hernia repair. Electively, hernia contents reposition in abdomen with herniorrhaphy was considered in 3 (0.75%) cases and release of adhesion with reposition of sac content in abdomen with herniorrhaphy was performed in 6 (1.5%) cases .In emergency management, hernia contents reposition in abdomen with herniorrhaphy was performed in 8 (2%) cases, release of adhesion with reposition of sac content in abdomen with herniorrhaphy was performed in 15 (3.75%) cases. Omentectomy and herniorrhaphy was performed in 10 (2.5%) cases .Omentectomy, bowel resection, end to end anastomosis and herniorrhaphy was performed in 9 (2.25%). Two patients with obstructed femoral hernia were managed by high inguinal approach with femoral hernia repair in emergency. Present study correlates with Rao SS *et al.*

*al.*¹⁰ and Makio Mike al and Milivoje Vukovic *et al.*

Intra-operative complications (Table 7A)

In the present study Intra-operative bleeding present in 8 (2%) cases of emergency and 12 (3%) cases of elective management. Spermatic cord injury in 1 (0.25%) cases of uncomplicated case of inguinal hernia surgery. Iatrogenic bowel perforation seen in 1 (0.25%) case of complicated presentation of groin hernia. While rest of the uncomplicated 346 (86.5%) and complicated 28 (7%) groin hernia there was no Intra-operative complications present. Present study correlates with Rao SS *et al.*¹⁰ study

Post-operative complications: (Table 7 B)

In the present study surgical site Infection was present in 13 cases (3.25%) of emergency and 6 cases (1.5%) of elective surgical management. Cord oedema was present in 8 cases (2%) of emergency and 8 cases (2%) of elective surgical management. Mortality due to septicaemia secondary to anastomotic leak was seen in 1 operated case of strangulated inguinal hernia who underwent emergency surgical treatment. Of the 400 cases, 347 (86.75%) cases of uncomplicated groin hernias and 16 cases (4%) of complicated hernias had no post operative complications. Present study correlates Susanta Tiwari and Ratan R⁸, Goddam padmasree *et al.*

Conflicts of Interest

The authors declare that there were no conflicts of interest regarding the publication of this paper.

CONCLUSION

In this study we found an association between groin hernias & various precipitating factors, comorbidities and occupation. Both complicated and uncomplicated groin hernias are most common in males. Uncomplicated groin hernias are more prevalent than complicated ones. Uncomplicated groin hernias are posted for elective hernia repair & are managed by Lichtenstein's tension free mesh repair while incidence of complicated groin hernias is low and requires emergency surgical management & is associated with high morbidity and mortality.

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Role of Non cultured Keratinocyte Graft with Sucralfate in Second Degree Scald Burns

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How to cite this article:

Siva Subramaniyan S, Ravi Kumar Chittoria, Amrutha J S. Role of Non cultured Keratinocyte Graft with Sucralfate in Second Degree Scald Burns. *New Indian J Surg.* 2024; 15(3):107-110.

Abstract

Normal wound healing is a complex process involving three phases namely inflammatory, proliferating, and remodeling. Studies have shown that sucralfate has a beneficial effect on ulcers, skin lesions, and burn wounds by promoting healthy granulation thereby preparing the wound bed. Whereas non cultured keratinocyte graft has proven to promote epithelialization of the wound. In this study, we used non cultured keratinocyte graft with sucralfate in a pediatric patient with burn wounds on the face.

Keywords: Sucralfate, Keratinocyte, Wound bed, Wound healing.

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Received on: 20-09-2024

Accepted on: 12-11-2024

INTRODUCTION

Wound healing is a physiological response of a living being to physical, chemical, mechanical or thermal injury. The wound healing process consists of several phases: homeostasis, inflammation, proliferation/granulation, and remodeling/maturation. Still, when the healing course deviates from the normal path, the healing does not advance past the inflammatory phase and becomes a chronic healing wound. This impairment is due to changes in one or more of the Components that aid in wound healing like growth factors, cytokines, and associated comorbidities like diabetes, infection, etc.,¹ In the case of burns, there will be a deficiency in normal healing. Therefore to aid the process of wound healing we used sucralfate



to promote healthy granulation so that the wound bed is prepared²⁻⁴ for grafting with noncultured keratinocytes which promotes epithelialization of the wound.⁵ Therefore a synchronized beneficial effect towards better wound healing is provided.

MATERIALS AND METHODS

This study was conducted in the Tertiary Care Centre in the Department of Plastic Surgery after getting the department's ethical committee approval. Informed consent was obtained. The subject was a 1-year-old female child who had an accidental second-degree scald burn injury that involved the left side of the face, pinna, and retro auricular region, left arm, and forearm (Fig. 1). She was taken to a nearby hospital within 30 minutes- inadequate initial resuscitation. The child developed blistering

and swelling around the left eye the next day and presented to our center after a delay of 12 hours. She was admitted to the tertiary burn care unit and initial resuscitation with intravenous fluids, analgesics, and prophylactic antibiotics started. After tangential excision on post-burn day 5, a Noncultured keratinocyte graft with sucralfate ointment is applied over the deeper areas of burn over the side of the face and scalp. A 3cm x 1cm area of the scalp region adjacent to the burn wound was marked (Fig. 2). The donor area was dermabraded (Fig. 3) after the application of sucralfate ointment. The paste, containing dermabraded cells, was collected, homogenized, and applied along with sucralfate ointment over the wound (Fig. 4). A non-adherent dressing was placed on it followed by a gauze dressing. The wound was inspected on the 7th day and thereafter weekly. Remnant raw area was calculated on each dressing.



Fig. 1: 2nd degree scald burns over left side of face and left arm



Fig. 2: wound wash with silver stream



Fig. 3: Dermabrasion and harvest of non cultured keratinocyte graft



Fig. 4: Application of non cultured keratinocyte suspension with sucralfate over the wound

RESULTS

Intraoperative and postoperative periods were uneventful for the patient. On post-operative day 7, the dressing was opened and it showed significant areas of re-epithelialization and healing (Fig. 5). All second-degree superficial burn wounds healed completely and islands of re-epithelization appeared in deep second-degree burns areas. No complications or side effects were noted during the entire procedure.



Fig. 5: Partially healed wound after 7 days

DISCUSSION

The normal pace of wound healing and epithelialization is at the rate of 1mm/day. Optimum recovery requires the wound bed and the patient to be fit. To assist with implementing the concept of wound bed preparation, the TIME acronym was developed in 2002 by a group of wound care experts, as a practical guide for use when managing patients with wounds.⁶ The Time table summarizes the four main components of wound bed preparation:

1. Tissue management
2. Control infection and inflammation
3. Moisture imbalance
4. Advancement of the epithelial edge of the wound

Advanced wound healing therapies aim to hasten the process of wound healing by expediting the advancement of the epithelial edge of the wound. Many growth factors have been used to advance

epithelialization. As sucralfate promotes healthy granulation in the wound bed and noncultured keratinocytes provide epithelialization of the wound, a synchronized beneficial effect is achieved in the wound healing process.

The application of cultured keratinocytes appears to promote healthy granulation tissue formation within the wound bed. The graft, when applied as a sheet, acts as an occlusive dressing, preventing wound dehydration and maintaining a moist environment. The majority of evidence suggests that cultured epidermal allografts do not survive indefinitely after transplantation.⁷ Their brief contact with the wound, however, seems sufficient to stimulate reepithelialization, particularly when dermal tissue is present in the wound bed. This may be due to the release of growth factors by keratinocytes which may favourably influence wound healing. In addition to this, there is a release of several growth factors by keratinocytes that promote wound healing. It is known that cultured keratinocytes release various factors that enhance the growth of other cells in vitro including keratinocytes, fibroblasts, and melanocytes. Identified factors include interleukin-1, other interleukins, and transforming growth factor-alpha.

These keratinocytes may be autologous or allogenic in origin. These cells are separated from skin graft by using trypsin or other methods. After separation, these are cultured in appropriate media to form a sheet. These sheets are used as grafts to cover the wound. In our case, we have used autologous non-cultured, non-trypsinised keratinocytes cells to promote the healing. We observed favourable results in terms of the formation of healthy granulation tissue and rapid epithelialization of the wound from the margins.

The mechanism of action by which sucralfate helps in wound healing is multifaceted. Sucralfate increases growth factors bioavailability and prostaglandins and decreases the production of oxygen free radicals synthesis, thus potentiating angiogenesis, granulation tissue, and re-epithelialization. It increases the bioavailability of growth factors, particularly of FGF. It increases the production of prostaglandins and inhibits oxygen-free radicals⁸.

In our case, we have used sucralfate cream locally and noncultured keratinocyte graft over second-degree scald burns. We have observed rapid healing in terms of reduction in necrotic tissue and faster appearance of granulation tissue along with epithelialization of the wound. The commercially

available sucralfate cream also contains xylocaine, which helps in pain relief. No adverse effect was noted with its application.

Due to the small sample size statistical analysis could not be done. A randomized control study with an adequate sample size with wounds of different etiology is desirable to substantiate the results.

CONCLUSION

The application of non cultured keratinocyte graft with sucralfate in the treatment of second-degree scald burns has been proven effective in this study. It hastens the overall healing time of second-degree superficial and deep wounds to within a week. Thus minimizing the total hospital stay and infection rates.

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Medical Management of Benign Prostate Hyperplasia and its Outcome

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How to cite this article:

Varun Gawda, Anitha Kandi, Suyash Deshmukh, *et al.* Medical Management of Benign Prostate Hyperplasia and Its Outcome. New Indian J Surg. 2024; 15(3):111-116.

Abstract

Introduction: Benign prostatic hyperplasia, one of the most common diseases among ageing men. BPH prevalence increases from approximately 50% at 60 years to 90% in men older than 85 years. Lower urinary tract system significant impact on the overall quality of life. The treatment options include: **1.** Watchful waiting: if the symptoms are mild and not causing any change. **2.** Medical treatment - Alfa-receptor antagonists, 5 alfa-reductase antagonists, antimuscarinics, phosphodiesterase 5 inhibitors and their combinations. **3.** Surgical management is preferred in patients with an IPSS score more than 19-traditional monopolar Transurethral resection of the prostate (TURP), Prostatic Urethral Lift.

Aims and Objectives

Aim of the study: To study the outcomes of medical management of BPH based on the IPSS. **Objectives of the study:** *Primary Objective:* To study the outcomes of medical management of BPH in terms of reduction of IPSS, change in prostate size, post-void residual volume as assessed by USG with medical management. *Secondary Objectives:* 1. To study the age distribution in BPH 2. To study the symptomatology of BPH.

This prospective observational study was carried out. A total of 55 patients presenting with lower urinary tract symptoms secondary to BPH were enrolled for the study. International Prostate Symptom Score was assessed on presentation and patient was started on either monotherapy or combination therapy depending on the prostate

volume and then reassessed at 3 and 6 months after starting drug therapy.

Conclusion: Medical treatment for LUTS/BPH aims to produce rapid, sustained, and safety improvements in the lower urinary tract symptoms associated with benign prostatic hyperplasia that affect the quality of life in the majority of men over the age of 45. Combined therapy of an α 1-adrenergic receptor antagonist (tamsulosin) plus a 5-alpha reductase inhibitor (dutasteride) is a good approach

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Received on: 21-08-2024

Accepted on: 23-09-2024



for meeting these objectives.

Keywords: Benign prostate hyperplasia, Medical management, Tamsulosin, Dutasteride, Lower urinary tract symptoms, Acute retention of urine, Prostate volume, Postvoid residual volume.

INTRODUCTION

Benign prostatic hyperplasia (BPH) is the non-malignant enlargement of the prostate gland. It refers to stromal and glandular epithelial hyperplasia that occurs in the periurethral transition zone of the prostate that surrounds the urethra resulting in compression of the urethral canal to cause partial, or sometimes virtually complete, obstruction of the urethra, interfering with the normal flow of urine and leads to the symptoms of urinary obstruction and irritation, collectively referred to as lower urinary tract symptoms (LUTS).^{1,2}

Male LUTS can be classified into three categories, voiding (hesitancy, slow stream, intermittency, incomplete emptying), storage (frequency, urgency, nocturia, urge urinary incontinence) and postmicturition (Postvoid dribbling).^{1,2}

Medical therapy for BPH attempts to shrink or stop the growth of the prostate or open the urethral channel within the prostate, without using surgery. The FDA has currently approved multiple drugs to relieve the symptoms associated with an enlarged prostate. Medications in the class known as 5-alpha-reductase inhibitors (5-ARIs) result in decreased production of the hormone dihydrotestosterone (DHT), which is responsible for the growth of the acinar glands of the prostate. These include Finasteride, FDA-approved in 1992, and dutasteride, FDA approved in 2001. The 5-ARIs may either prevent the progression of growth of the prostate or shrink the prostate in some men. Another class of drugs used for treating BPH is the alpha-1-adrenergic receptor blockers (alpha-blockers), which act by relaxing the smooth muscle of the prostate and bladder neck to improve urine flow and reduce bladder outlet obstruction. This class includes terazosin, doxazosin, tamsulosin, and alfuzosin. Terazosin and doxazosin were developed as blood pressure pills, but tamsulosin and alfuzosin were developed specifically to treat BPH. There is excellent clinical trial data that shows that combination therapy with a 5-ARI and an alpha-blocker (finasteride and doxazosin)

together is more effective than using either drug alone to relieve symptoms and prevent BPH progression. The dual-drug regimen reduced the risk of BPH progression by 67 percent, compared with 39 percent for doxazosin alone and 34 percent for finasteride alone.^{2,3}

The major goals in the treatment of BPH include improvement in symptom scores, quality of life, patient satisfaction and lowering the risk of disease progression and the need for further surgical interventions.^{3,4}

The American Urologists Association have given Symptom Index (AUASI) and International Prostate Symptom Score (IPSS) which are now 2 considered the gold standard measurement tools for the assessment of BPH symptoms and response to treatment in clinical practice.⁴

Medical treatment is offered to men who have bothersome LUTS using Alfa-receptor antagonists, 5 alpha-reductase antagonists, antimuscarinics, phosphodiesterase 5 inhibitors and their combinations.^{5,6}

The purpose of our study was to see the outcome of medical management in benign prostatic hyperplasia in the department of general surgery at the tertiary care centre.

AIMS AND OBJECTIVES

Aim of the study: To study the outcomes of medical management of Benign prostate hyperplasia based on the International Prostate Symptom Score.

Objectives of the study

Primary Objective: To study the outcomes of medical management of BPH in terms of reduction of IPSS, change in prostate size, post-void residual volume as assessed by USG with medical management.

Secondary Objectives: 1. To study the age distribution in BPH, 2. To study the symptomatology of BPH.

MATERIALS AND METHODS

This prospective observational study was carried out at a Tertiary care centre in a government set up over two years from September 2019 to September 2021 after approval by the Institutional Ethical committee.

A total of 55 patients presenting with lower urinary tract symptoms secondary to BPH were enrolled for the study. Due to the Covid-19 Pandemic, there was reduced patient input in both Outpatient and In-patient departments in this period of time. The effort was taken to contact patients using a mobile survey and during follow up the patient was examined by taking Pandemic precautions. A detailed clinical history was taken from all patients followed by thorough clinical examination, urine routine examination, ultrasonography and PSA. The drug was given based on International Prostate Symptom Score (IPSS) and prostate volume. Based on IPSS and prostate volume; monotherapy in the form of Tamsulosin 0.4mg was given to 35 patients with Moderate to Severe IPSS and Prostate Volume less than 40cc while a combination of tamsulosin with dutasteride was given to patients with moderate to severe IPSS and prostate volume more than 40 cc. Patients were also informed about the possible Side-effects. Patients were asked to follow up after 3 months and 6 months and their IPSS, prostate volume and pre and Postvoid volume were measured. Data was analysed and the efficacy of the medical management was studied.

Study design: Prospective observational study

Inclusion criteria: 1. Age more than 45 years; 2. All patients with IPSS more than 8; 3. Patients with a post-void volume less than 100ml; 4. Patients with LUTS persistent secondary to BPH after treatment of Urinary tract infections.

Exclusion criteria: 1. Non-ambulatory patients; 2. Age less than 45 years; 3. All patients with IPSS less than 8 ;4. Postvoid volume of more than 100ml; 5. Supine BP less than 90/60; 6. Patient with previous surgery intervention for BPH; 7. Patients with Neurogenic bladder, Prostate Carcinoma, stricture urethra, Vesical calculi, recent gross hematuria, acute urine retention, history of prostate surgery were excluded from this study; 8. LUTS secondary to urinary tract infection which resolved after a course of antibiotics and no abnormality in Urine routine and Urine Culture and Sensitivity.

RESULTS

The most common age group in the present study was 51-80 years of age (84.9%).

Sensation of incomplete bladder emptying was the most common voiding symptom seen in 50 of the patients (90.9%).

Frequency of micturition was the commonest storage symptom in all of the patients (100%).

Moderate IPSS score was found in 34 patients (61.8%) and 21 patients (38.2%) had severe IPSS scores before starting drug therapy. After 3 months IPSS decreased from 18 ± 3.17 to 13.9 ± 3.1 . At 6 months follow up IPSS decreased to 6.27 ± 3.4 .

Grade 1 Prostate volume (20-40cc) was seen in 47.3% which did not show significant change after 6 months of treatment.

There was a significant decrease in the post-void residual volume at the end of treatment. The baseline PVR was 36ml decreased to 8ml after 6 months of treatment.

Improvement in IPSS $\geq 25\%$ was observed in 39.6% of cases and ≥ 3 points improvement was seen in 81.8% of cases.

Of 55 patients 45 patients were responders.¹⁰ were non-responders. Tamsulosin responders were 74.3% (26 patients out of 35). The combination of Tamsulosin and Dutasteride responders was 95% (19 out of 20 patients).

The total incidence of individuals experiencing adverse effects in our study was 12.6% (7/55).

DISCUSSION

A total of 55 patients presenting with lower urinary tract symptoms secondary to BPH were screened and enrolled for observational study in our government set up Tertiary care centre from 1st September 2019 to 31st September 2021.

Age Distribution: studies conducted by Singh *et al.*, Pande *et al.*, Casabe *et al.* it was observed that the mean age of patients with BPH causing LUTS was 68.4 ± 11.8 years, 61 ± 7.88 years, 63.7 years and 66.42 ± 9.84 years respectively.⁵⁻⁷

The most common age group in the present study was 51-80 years of age and the youngest patient was 45 years while the eldest patient was 85 years. The mean age of patients was 64.38 years which is similar to the abovementioned studies.

Voiding Symptoms: The sensation of incomplete bladder emptying was the most common voiding symptom seen in 50 of the patients (90.9%) while straining to urinate was the least voiding symptom seen in 4 patients (7.3%).

Storage Symptoms: Frequency of micturition was the commonest Storage symptom in all of the patients N=55 (100%) while 38 patients (69.1%) had urgency.

International Prostate Symptom Score: In the present study baseline, IPSS is 18.58 ± 3.17 , of which Moderate IPSS score was found in 34 patients (61.8%) and 21 patients (38.2%) had severe IPSS score before starting drug therapy. After 3 months IPSS decreased from 18 ± 3.17 to 13.9 ± 3.1 . At 6 months follow up IPSS decreased to 6.27 ± 3.4 .

Prostate Volume: In the present study, Grade 1 Prostate volume was seen in 47.3% which did not show significant change after 3 months of therapy. Pande *et al.*, in 2014, reported that there was no significant reduction in prostate volume after 12-week of therapy in either group of silodosin or tamsulosin while Singh *et al.* 2014 also observed no significant change in the prostate volume after 12 weeks. Other studies like those by Djavan *et al.* in 2011 and Drake *et al.* in 2015 showed no change in prostate volume even after 2 and 1 year of drug therapy respectively.^{5,6,8,9}

Postvoid Residual Volume: In the present study, there was a significant decrease in the post-void residual volume at the end of treatment compared to baseline and improvement was seen by the three months after starting medical therapy. The median baseline PVR was 36ml decreased to 8ml at the end of the treatment at the end of 6 months. Studies like Garg *et al.* (Baseline PVR of 76.98 ± 17.10 ml reduced to 45.12 ± 8 ml by the end of 6 months), showed a significant decrease in Postvoid volume similar to the present study.¹⁰ However, studies by Pande *et al.*, and Manohar *et al.* showed no significant decrease in Postvoid residue.^{6,11}

Responders based on IPSS Change In the present study, we observed that out of 55 patients the improvement in IPSS $\geq 25\%$ was observed in 39.6% of cases (42.8% on Tamsulosin and 35% on Tamsulosin and Dutasteride) and ≥ 3 points improvement was seen in 81.8% of cases (74.3% of cases on Tamsulosin alone and 95% of cases on combination therapy) at the end of 3 months. A similar study by Roehrborn *et al.* 2008 in their CombAT study, which was a multicentre (446 investigators in 35 countries), randomized, double-blind, parallel-group study of 4844 subjects over

2 years, and recognized responders based on IPSS change.⁽¹²⁾ They were 72% on Combination therapy, 65% on Dutasteride, 62% on Tamsulosin. This study showed a greater improvement in IPSS after drug therapy, more with combination therapy than monotherapy. Another similar study Garg *et al.* in 2017 studied 110 subjects, who received a once-daily dose of the combination of silodosin 8 mg and dutasteride 0.5 mg for a period 62 of six months there was improvement of IPSS is seen by 27.75% compared to baseline.¹⁰ Yu *et al.* in 2011 conducted a study whereof 170 (81.3%) patients who completed the study, 86.2% in the silodosin group and 81.9% in the tamsulosin group achieved a $\geq 25\%$ decrease in IPSS ($P = 0.53$). This study goes in contrast to our study.¹³ This variation of results from our study could be probably because of having a smaller number of patients, shorter follow up period and inclusion of patients of older age group in our study and IPSS is a subjective score.

Adverse Events: The total incidence of individuals experiencing adverse effects in our study was 12.6% (7/55). Four patients had giddiness, two had features of decreased libido. Ejaculation disorder was seen in one each while none complained of impotence, liver or renal dysfunction before or after treatment. Reassurance was given to those with giddiness and as the elderly patients had decreased libido and ejaculation disorder they were also counselled and reassured. Yu *et al.* reported that 1% of patients receiving tamsulosin complained of abnormal ejaculation.¹³ Pande *et al.* 2014 found dizziness or postural hypotension in 3 subjects out of 27 in the tamsulosin group.⁶ Drake *et al.* observed that of 1066 patients receiving treatment in NEPTUNE II 499 patients (46%) experienced treatment adverse events.⁹ Most common were dry mouth (12.4%), constipation (5.2%), dyspepsia (2.7%), urinary retention (1.1%), Erectile dysfunction (1%). Manohar *et al.* observed adverse effects in 54 out of 269 patients (20.07%).¹¹ Dizziness was the most common side effect in all of the 3 groups.

CONCLUSION

The primary objectives of the medical treatment for LUTS/BPH are to produce rapid, sustained, and safety improvements in the lower urinary tract symptoms associated with benign prostatic hyperplasia that affect the quality of life in the majority of men over the age of 45. Although this study is short term and limited in the number of patients, it provides evidence that the combined

therapy of an α 1-adrenergic receptor antagonist (tamsulosin) plus a 5-alpha reductase inhibitor (dutasteride) is a good approach for meeting these objectives. Additional studies on a greater number of patients for a longer period are needed to substantiate the preliminary evidence of this study.

Limitation: **1.** Sample size was less due to Covid-19 Pandemic. **2.** PSA was not done in patients aged >75 years as there was no family history of prostate carcinoma and Digital Rectal Examination was not evident of malignant signs. **3.** Lack of long term follow up owing to a limited study period of 2 years.

Table 1: Age Distribution

Age (years)	Number of patients	%	Responders	%
45-50	5	9.1	5	100
51-60	15	27.3	12	80
61-70	17	30.9	16	94.1
71-80	15	27.3	10	66.6
>80	3	5.5	2	66.6

Table 2: Voiding Symptoms

Voiding symptoms	Patients	Percentage
Hesitancy	23	41.8
Decreased force and calibre of stream	23	41.8
The sensation of incomplete bladder emptying	50	90.9
Straining to Urinate	4	7.3
Postvoid dribbling	13	23.6

Table 3: Storage Symptoms

Storage symptoms	Pre drug	Percentage
Frequency	55	100
Urgency	38	69.1
Nocturia	50	90.9

Table 4: International Prostate Symptom Score

IPSS	Pre drug	After 3 months of drug therapy	After 6 months of drug therapy
<7	0%	0%	49.1
8-19	34(61.8%)	94.4%	50.9
20-35	21(38.2%)	5.6%	0
Mean±SD	18.58±3.17	13.9±3.1	6.27±3.4

Table 5: comparison of pre and post drug therapy Prostate Volume

Prostate volume (cc)	Pre drug	After 3 months	After 6 months
Normal: < 20 cc	7 (12.6%)	11 (19.8%)	9 (16.4%)
Grade 1: 20-40 cc	29 (52.7%)	26 (47.3%)	26 (47.3%)

Grade 2: 40-60 cc	18 (32.7%)	17 (30.9%)	19 (34.5%)
Grade 3: 60-80 cc	0 (0%)	0 (0%)	0 (0%)
Grade 4: > 80cc	1 (1.8%)	1 (1.8%)	1 (1.8%)

Table 6: comparison of pre and post drug therapy Postvoid residual volume

Postvoid residual volume (ml)	Pre drug	After 3 months	After 6 months
< 10	2 (3.6%)	13 (23.6%)	72.7%
11-25	16 (29.1%)	21 (38.2%)	12 (21.8%)
26-50	19(34.5%)	14 (25.4%)	0 (0%)
51-75	6 (10.9%)	5 (9.1%)	1 (1.8%)
76-100	12 (21.9%)	1 (1.8%)	1 (1.8%)
Mean	38.9±25.2	20.6±16.9	8.3±12.7

Table 7: Responders based on IPSS Change

IPSS change	Tamsulosin Responders	(Tamsulosin + Dutasteride) responders	Total Responders
>25% reduction after 3 months	15(42.8%)	7(35%)	22(39.6%)
>3 points reduction after 3 months	26(74.3%)	19(95%)	45(81.8%)

Table 8: Side effects

Side effects	No. of patients
Decreased Libido	2
Giddiness	4
Ejaculation disorder	1
Impotence	0

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Use of Three Layered Regenerative Scaffold Dressing in the Wound Bed Preparation of Second Degree Scald Burns

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How to cite this article:

Viswak M, Ravi Kumar Chittoria, Amrutha J S. Use of Three Layered Regenerative Scaffold Dressing in the Wound Bed Preparation of Second Degree Scald Burns. *New Indian J Surg.* 2024; 15(3):119-121.

Abstract

Burns are one of the most common injuries among the children, which are due to thermal, scald, electrical burn injuries. Scald injuries tend to be the most common type of burn injury under the age of five, accounting for over 65% of the cases. In current scenario, various scaffolds are used to improve the quality of healing process and reduce the scar formation. Collagen acts as a scaffold through which regeneration of tissues occurs and also helps in new vessel formation. Other scaffolds like amniotic membrane which has unique antiinflammatory, bacteriostatic property helps in proper epithelization and reduces scarring and silicone gel sheets has hydrophobic property, which reduces scarring and provides analgesia. In this study we attempted three layered scaffold dressing for an second degree scald burn pediatric patient.

Keywords: Three layer scaffold; Regenerative; Pediatric; Second degree scald burns.

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Received on: 23-09-2024

Accepted on: 12-11-2024

INTRODUCTION

Wound healing is a physiological response of a living being to physical, chemical, mechanical or thermal injury. The wound healing process consists of several phases: homeostasis, inflammation, proliferation/granulation, and remodeling/maturation. Still, when the healing course deviates from the normal path, the healing does not advance past the inflammatory phase. In case of burns, there will be deficiency in normal healing. In modern medicine, usage of scaffolds either natural or synthetic has become popular and been recognized.

An ideal scaffold should consist of these key features: fitting physical, mechanical properties,



physiological background to enable cell adhesion, proliferation and differentiation, a high porosity, a large surface area to volume ratio and to be flexible enough to accommodate the shape of the wound and preferably biocompatible and biodegradable.

Collagen, synthetic or natural acts as a substitute for the dermal matrix through which epithelialization occur.¹ In the process of wound healing, degradation of collagen aids in the formation of new vessels, thereby it also helps in angiogenesis.

Amniotic membrane which is a natural scaffold has its own properties which includes its anti inflammatory, bacteriostatic, anti fibrotic, anti scarring and promotion of epithelization as well.² Since it has low immunogenicity and has its own progenitor cells, it can be an ideal choice in terms of usage of scaffolds for healing of wounds.

Silicon act as a barrier by reducing mechanical friction and transepidermal water loss which have been shown to be associated with the severity of a subsequent infection.³ In vitro study shows silicone may regulate the inflammatory growth factors that cause fibrosis and promote acute wound healing. Important elements in this process include inflammatory markers such as TNF- α , TGF- β , IL-1, and IL-6 that are also implicated in acute inflammation.

MATERIALS AND METHODS

This study was conducted in Tertiary Care Centre in Department of Plastic Surgery after getting the department ethical committee approval. Informed consent was obtained. The subject was a 18-month - old female child who had accidental second degree scald burn injury which involves her left upper limb, left side of her face and postauricular region. She was admitted in tertiary burn care unit



Fig. 1: Second degree scalds burn

and initial resuscitation with intravenous fluids, analgesics and prophylactic antibiotics started. On postburn day 3, the three layered scaffold dressing was made and applied over deeper burn areas after dermabrasion assisted tangential excision. The three layers of scaffold is made by sterile amniotic membrane, dry collagen sheet and silicone sheet. The layer of amniotic membrane comes directly over the wound. The dressing was kept intact for 5 days.

RESULTS

Intraoperative and post-operative periods were uneventful for the patient. On post operative day 5, dressing was opened and it showed significant areas of re-epithelialization and healing. All second degree superficial burn wound healed completely and islands of re-epithelization appeared in deep second degree burns areas. The future plan is to proceed with skin grafting of deep areas. No complications and side effects were noted during entire procedure.



Fig. 2: Three layered scaffold with amnion, dry collagen sheet and silicone sheet applied over the burn wound



Fig. 3: Burn wound 5 days after application of regenerative scaffold- all superficial burns completely healed and islands of re-epithelization formed in deep burn areas

DISCUSSION

Partial-thickness burn wounds can heal spontaneously, whereas full-thickness burn wounds require skin grafting for definitive wound closure. Historically, the gold standard for closure of excised full-thickness burn wounds is split-thickness skin autograft. Patients with very large burn wounds have limited donor sites for harvesting of autograft and may benefit from the use of skin substitutes. Engineered skin substitutes that may provide temporary wound coverage until donor sites are ready to be reharvested for autograft, or if they contain autologous cells, may provide permanent wound closure. Relatively few permanent skin substitutes are currently available, but developments in tissue engineering of human skin are expected to soon provide improved models for increased availability and enhanced healing of burn wounds.⁴ Commercially available Dermal Regeneration Template is a two-layered skin regeneration system.⁵ The outer layer of this system is made of thin silicone film act as the epidermis of skin. This layer helps in protecting wound from infection and controls in loss of both heat and moisture. The outer collagen glycosaminoglycan (GAG) thermal layer functions as a biodegradable template that helps in regeneration of dermal tissue neodermis by the body. The inner layer of dermal regeneration template is made of complex matrix of cross-linked fibers. The porous material of the template helps in regeneration of skin. The cross-linked fiber material of dermal regeneration template acts a scaffold for the regrowth of skin layer. Once the dermal skin layer is regenerated, the outer layer of template is removed and is replaced with a thin epidermal skin graft. This procedure leaves the wound to a flexible, growing and allows permanent regeneration of skin. It allows faster healing of wound with minimum scarring. Here we have tried to replicate the same mechanism in our indigenously made dermal regeneration

scaffold. One of the main drawbacks is the cost of the template. The indigenous dermal regeneration scaffold prepared from silicone sheet, dry collagen sheets and amnion is cost-effective and can be easily prepared and used on wounds. Thus, it can be used in hospital settings in developing countries where the affordability of commercial regeneration template is doubtful.

CONCLUSION

The adoption of this cost effective three layered scaffold dressing in second degree scald burns has been proven effective in this study. It hastens the overall healing time of second degree superficial and deep wound to within a week. Thus minimizing the total hospital stay and infection rates. However a large multicentric, double-blinded control research with statistical analysis is needed.

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