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Original Article

Surgery Section

Effect of Incisional Negative Pressure Wound Therapy Following Incisional Hernia Repair- A Randomised Controlled Trial

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ABSTRACT

Introduction: Incisional hernia is one of the common complications following abdominal surgery in patients undergoing laparotomy. Various surgical procedures are performed by creating a potential space and placing a foreign body (mesh), which may render the wound susceptible for many postoperative complications. It is clinically important to evaluate the efficacy of Incisional Negative Pressure Wound Therapy (INPWT) in reducing wound complications.

Aim: To compare the efficacy of INPWT dressing with traditional gauze dressing in reducing postoperative complications following meshplasty in incisional hernia repair.

Materials and Methods: This was a hospital-based randomised controlled trial, conducted in the Department of General Surgery, Jawaharlal Institute of Postgraduate Medical Education and Research (JIPMER), Pondicherry, India, from October 2013 to July 2015. Total 64 consenting patients with incisional hernias undergoing meshplasty were included in this study. After being randomised into the two study groups, they had their postoperative wounds dressed with either INPWT (group A) for five days, or traditional gauze (group B) based dressings. Operative parameters like duration of surgery, type of dissection and type of skin sutures used were studied and analysed. Also, postoperative outcomes like Surgical Site Infection (SSI), seroma, duration of drain, hospital stay were analysed using Chi-square or Fisher's-exact test.

Results: Group A and B had the mean age of 47±11.61 years and 43±10.53 years respectively. Out of total 64 patients, there was a statistically significant reduction in the volume of drain (p=0.004) and duration of wound drainage (p=0.029) with the use of INPWT. There was also a reduction in the incidence of SSI (6.7% vs 17.6%) and seroma (6.7% vs 11.8%) and the duration of postoperative hospital stay (6.03±1.99 days vs 7.09±2.31 days) in the INPWT group, which were however not statistically significant. Age, co-morbidities, Body Mass Index (BMI), duration of surgery, type of dissection and type of skin sutures were not found to have any effect on the parameters assessed.

Conclusion: Incisional negative pressure wound therapy in postoperative wounds, following meshplasty for incisional hernia significantly reduces the volume and duration of wound drainage. It also reduces the incidence of SSI, seroma and the duration of hospital stay.

Keywords: Drains, Mesh repair, Surgical site infection, Vacuum therapy

INTRODUCTION

Incisional hernia is one of the common complications of abdominal surgery with an incidence of 11-20% in patients undergoing laparotomy [1]. About 30% of these hernia patients, develop symptoms of pain, obstruction and strangulation requiring repair [2]. Various surgical procedures have been described among which, open onlay and sublay are commonly used techniques to treat incisional hernias. Abdominal wall reconstruction involves creation of a subcutaneous space surrounding the hernial defect for the placement of the mesh. This potential subcutaneous space and the presence of a foreign body (mesh) render the wound prone to prolonged drainage and SSIs. The reported rates of SSIs after these types of mesh repair are 29-66% [3]. SSIs and other wound complications are associated with increased morbidity, mortality, hospital stay and cost [4].

Negative Pressure Wound Therapy (NPWT) is a novel method of wound management first introduced in 1995, with proven efficacy in improving the rate of wound healing in open bone fractures, diabetic ulcers and open abdomen [5-7]. INPWT consists of a closed drainage system connected to vacuum pump which maintains a negative pressure on the wound. The exact mechanism of NPWT is not known though many hypotheses have been put forth. In recent years, it has also been used for postoperative closed wounds and it has been named as INPWT. Most of the studies highlighting this efficacy concentrated on postoperative orthopaedic wounds like lower limb traumatic fractures, total hip or knee arthroplasty and spinal surgery [5]. INPWT has been found to decrease the volume of wound drain as well as the rate of SSI in other surgeries, which include caesarean section, abdomino-perineal resection, reconstructive flap surgeries, sternotomy for cardiac surgeries [7-10].

However, in the present literature, the role of INPWT in postincisional hernia repair wounds is inadequate and contradicting. The few related studies available are mostly retrospective cohort studies or case series. Hence, this randomised controlled study was undertaken to evaluate the effects of this new method of wound treatment in reducing the incidence of various wound complications like seroma, SSI and the duration of drain output and hospital stay following meshplasty for incisional hernias. The primary outcome of the study was to assess the role of INPWT in incisional hernia in the immediate postoperative phase. Secondary outcome was to assess its efficacy as compared to conventional gauze dressing and whether other parameters like age, co-morbidities, surgical parameters like suture materials used, type of dissection, duration of surgery have any significant bearing on the outcomes.

MATERIALS AND METHODS

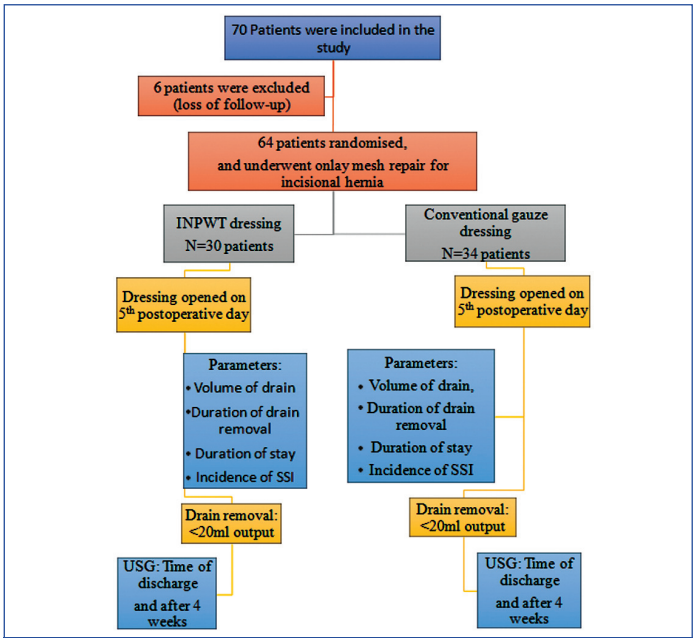
This study was a hospital-based randomised controlled trial, conducted in the Department of General Surgery, JIPMER, Pondicherry during the study period extending from October 2013 to July 2015. The study was undertaken after obtaining clearance from the Institute Research Committee and the Institute Ethics Committee (JIP/IEC/2014/1/234).

Inclusion criteria: All patients with age more than 18 years with incisional hernia following abdominal or gynaecological surgeries were included in the study.

Exclusion criteria: Diabetics with HbA1c (Glycosylated haemoglobin) >9%, patients on anticoagulation, previous meshplasty/radiotherapy to abdomen, immunocompromised patients and inadvertent intraoperative bowel injury were excluded from the study.

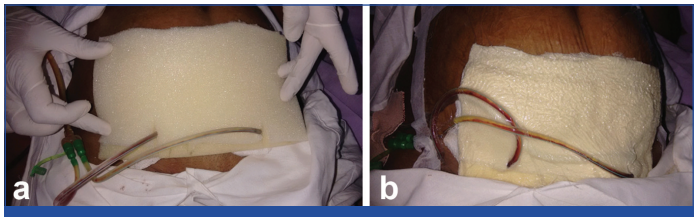
Seventy consecutive consenting patients with incisional hernia who underwent meshplasty in JIPMER, satisfying the inclusion criteria were included in the study. Six patients were lost to follow-up for the ultrasound scan after a month of surgery. Therefore, the final analysis included the remaining 64 patients. Sample size was decided based on the number of cases being done in this centre over a period of 2 years. These patients were divided into two groups, group A: study group (n=30), who received INPWT postoperatively and group B: control group (n=34), who received gauze dressings.

Method of randomisation: Randomisation was carried out using the Sequentially Numbered Opaque Sealed Envelope (SNOSE) method, with the envelope opened at the end of surgery for a given patient. Thereby, either traditional gauze dressing (control group) or INPWT (study group) dressing was applied in the immediate postoperative period [Table/Fig-1-3].



[Table/Fig-1]: CONSORT flowchart.

[Table/Fig-2]: Postoperative wound following meshplasty with subcutaneous wound drains.



[Table/Fig-3]: a) White foam used above postoperative wound, b) Air-tight polyurethane dressing with suction pressure applied between layers of foam.

Surgical Techniques

Written informed consent for participation in the study was taken from the patients before the day of surgery. Perioperative antibiotics (Inj. Cefazolin, 1 gm dose at induction of anaesthesia, and two doses postoperatively) were given to all the patients. Onlay mesh repair was performed in all patients. Absorbable polypropelene mesh or a composite poliglecaprone-polypropylene mesh was used for meshplasty. Skin incision was closed with interrupted (simple/mattress) sutures using either silk or polypropylene sutures. After the surgery, the closed incision wound was covered using either INPWT dressing (study group) or gauze dressing (control group). In the INPWT group, after the skin closure, a double layer of white foam and a tube drain (a plastic gastric tube) in between the layers of foam was placed covering the incision and the area of subcutaneous dissection. The entire dressing was then covered with an adhesive transparent surgical drape, making the system air-tight. The tube drain was connected to a wall suction and the pressure calibrated to 125mmHg. In the control group, a tube drain was placed between the mesh and the flap and connected to sterile bag.

In both the groups, the dressing was kept undisturbed for five days. However, if there were any signs of SSI such as fever, pain over operated site or dressing soakage, the dressing was removed and the wound was inspected. If SSI was found, in either group the wound was dressed with gauze dressings daily, any fluid collection was drained and the patient was started on appropriate antibiotics. The cumulative daily wound drain output was monitored, and the drains were removed once the output became less than 20 mL/day. Patients were discharged after removal of subcutaneous drains and once the wound was healthy. Ultrasound examinations were performed to look for local haematoma or seroma at the time of discharge from hospital and during a follow-up visit after four weeks from the date of surgery.

Parameters studied: The parameters studied included demographic data, BMI, co-morbidities, total volume of wound drain, duration of wound drainage, duration of postoperative hospital stay and incidence of SSI or seroma. SSI was classified according to the Centre for Disease Control (CDC) [4], as superficial, deep and organ space infection.

STATISTICAL ANALYSIS

Statistical analysis was analysed using Statistical Package for the Social Sciences (SPSS) version 16.0. (Chicago, IL. USA). The study group and the control group were compared using Chi-square or Fisher's-exact test for categorical variables such as gender, co-morbidities, dissection type, skin suture material and incidence of SSI. The p-value of 0.05 was considered statistically significant. For analysing continuous variables like age, BMI, volume of drain, duration of surgery, duration of wound drain and duration of postoperative hospital stay, either Student t-test or Mann-Whitney U test was used, based on whether the data distribution was normal or not. Finally, multivariate regression analysis was used to assess the impact of multiple variables on the studied parameters. Correlation analysis was done for normally (Pearson's) or abnormally (Spearman's) distributed variables to look for association between variables.

RESULTS

In terms of patients' profile such as age, sex, BMI and co-morbidities both groups were comparable [Table/Fig-4]. In group A, the age range was 27 to 70 years with a mean±SD of 47±11.61 years and in group B, it was 27 to 67 years with mean±SD of 43±10.53 years (p-value=0.239). Total males were 10 (15.6%) and females were 54 (84.4%) (p-value=0.495). All the surgical site infections in the present study were superficial. Operative parameters including type of dissection, duration of surgery and suture material used, when compared did not show any statistical significance [Table/Fig-5].

Demographic parameters	Group A N=30	Group B N=34	p-value
Age (years)			
Range	27-70	27-67	0.239
Mean±SD	47±11.61	43±10.53	
Sex			
Male	6	4	0.495
Female	24	30	
Body Mass Index (body mass divided by the square of body weight: kg/m^2)			
Normal (18.5-24.9)	19	25	0.799
Over Weight (25-29.9)	10	8	
Obese (30 or >30)	1	1	
Mean±SD	23.93±2.68	23.76±2.61	
Co-morbidities			
Diabetes mellitus	4 (13.3%)	4 (11.7%)	1.00
Hypertension	5 (16.7%)	3 (8.8%)	0.45

[Table/Fig-4]: Demographic parameters in both the groups.

Surgical parameters	Group A N=30	Group B N=34	p-value
Type of dissection			
Electrocautery	18	22	0.897*
Sharp dissection	12	12	
Suture material for skin			
Silk	22	27	0.78*
Polypropylene	8	7	
Duration of surgery (mins)	92.50±14.89	97.21±11.63	0.16†

[Table/Fig-5]: Comparison of surgical parameters in both the groups.
†: student unpaired t-test; *: Chi-square test

Outcome parameters: In the INPWT group, two patients (6.7%) and in control group, six patients (17.6%) developed SSI (p-value=0.265). In both the groups, superficial SSI was observed. Postoperative seroma was observed in two patients (6.7%) in INPWT group and four patients (11.8%) in the control group. There was no statistically significant difference in the seroma formation between the two groups (p-value=0.676).

The mean±SD drain output in the INPWT group was 158±90 mL and 218±119 mL for the control group. Analysis of the drain volumes using Mann-Whitney U test revealed, a statistically significant reduction in the drain volume in the INPWT group compared to the control group (p-value=0.004) [Table/Fig-6].

Outcome parameters	Group A N=30	Group B N=34	p-value
SSI			
Present	2 (6.7%)	6 (17.6%)	0.265§
Absent	28 (93.3%)	28 (82.4%)	
Seroma			
Present	2 (6.7%)	4 (11.8%)	0.676§
Absent	28 (93.3%)	30 (88.2%)	
Wound drain (mL)	158±90	218±119	0.004‡
Duration of drain (days)	5.6±1.48	6.5±1.71	0.029†
Hospital stay (days)	6.03±1.99	7.09±2.31	0.057†

[Table/Fig-6]: Comparison of postoperative outcome.
§Fischer's-exact test; †Student unpaired t-test; ‡Mann-whitney test

The mean±SD duration of wound drainage for the INPWT group was 5.6±1.48 days and 6.5±1.71 days for the control group, the difference was statistically significant (p-value=0.02). Analysis of postoperative hospital stay revealed no statistical difference [Table/Fig-6].

The mean±SD duration of postoperative hospital stay for the two groups were 6.03±1.99 days for the INPWT group and 7.09±2.31 days for the control group. Analysis of duration of postoperative hospital stay between the two groups by an unpaired t-test revealed no statistically significant difference (p-value=0.057) [Table/Fig-6].

DISCUSSION

Incisional hernia is a common complication of laparotomy and require reconstruction often combined with placement of mesh. During surgery, wide separation of flaps and implantation of foreign body increases wound complications. Prophylactic NPWT has been tried as a new method to prevent wound complications. It is named as INPWT. The exact mechanism of INPWT is not known. However, the suggested hypothesis is, NPWT in general, creates a moist wound environment, drains exudates, reduces oedema, contracts the wound, stimulates the wound bed and angiogenesis and formation of granulation tissue by increasing the blood flow [11]. In this study, it was found that due to negative pressure therapy, there was obliteration of dead space leading to reduced seroma formation, thereby reducing the drain output. However, contracture of wound, angiogenesis and granulation tissue formation were not assessed since, it was a closed wound.

In a study by de Vries FEE et al., 66 patients undergoing abdominal wall repair with NPWT as prophylaxis, showed significant decrease in wound infection rate [12]. Two controlled observational studies found significant reduction in SSI. One study included clean hernias repair and the other both clean and clean-contaminated hernias [13,14]. In the study, INPWT group had two patients (6.7%) of SSI and control group had six patients (17.6%) of SSI. Though the number of SSIs was less in the study group, there was no statistically significant difference found in the rate of SSI in the two groups, probably due to small number of patients in the groups.

Stannard JP et al., conducted a prospective randomised controlled trial in which they studied the effects of NPWT on postoperative wounds of tibial plateau, pilon and calcaneus fracture repair following lower extremity trauma [15]. They applied INPWT at a pressure of 125mmHg, to their study group (n=141), for a mean period of 2.5 days, and standard dressings for the control group (n=122). During an interim analysis, they demonstrated a significant reduction in the volume of wound drain (p-value=0.03) in INPWT group. A retrospective study by Hansen E et al., have demonstrated a reduction in the volume of wound drain with INPWT, in patients having high drain volumes after undergoing total hip arthroplasty [16]. Though both these studies were on orthopaedic surgery, present study compared with the above studies showed significant reduction in the volume of wound drainage (p-value=0.004).

Pachowsky M et al., studied the effect of NPWT on wound healing and seroma formation in patients undergoing total hip arthroplasty. This was a randomised trial in which 19 patients were divided into the two study groups, 10 in the control group and 9 in the INPWT group. NPWT was delivered using a commercial system marketed by PREVENA. It was applied for duration of five postoperative days. Wound secretion was measured in terms of drain volume and repeated ultrasound examinations were performed to detect any seroma and measure its volume, if present. The study showed the presence of a seroma (detected by USG), in 90% of the controls and 44% of the INPWT patients. There was a significant difference in the volume of seroma between the groups at the tenth postoperative day (p-value=0.021). However, the drain volume, though lesser in the INPWT group, did not attain statistically significant difference [17]. In contrast, in this study there was no statistically significant difference in seroma formation, but the drain volume was statistically significant.

On comparing the duration of wound drainage in both the groups, it was found that number of days were less in INPWT group, when compared to the control group and was statistically significant (p-value= 0.029). However, in both the groups duration of postoperative hospital stay was not statistically significant (p-value=0.057).

The materials used for INPWT device in this study was different from commercial device, as negative pressure was achieved by utilisation of wall suctions, which were easily available in our hospital and are expected to be available in any hospital especially in postoperative wards, making a low cost way of delivering effective INPWT.

Limitation(s)

The present study has small sample size, higher sample size would have backed the results to ascertain the effect of INPWT in reducing the incidence of SSI and seroma.

CONCLUSION(S)

Use of INPWT in postoperative wounds for incisional hernia repair (meshplasty) significantly reduces the volume and duration of wound drainage. The incidence of SSI and seroma in such wounds were also found to be less with INPWT. INPWT can be used routinely in wounds after incisional hernia repair as it is economical and effective.

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Declaration: This study was done as a part of postgraduation thesis by the authors when they were in JIPMER.

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