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DESARDA'S HERNIOPLASTY VERSUS MESH HERNIOPLASTY FOR STRANGULATED INGUINAL HERNIA A RANDOMIZED DOUBLE-BLIND COMPARATIVE STUDY

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Abstract
Groin hernias are the commonest abdominal wall hernias; these hernias are known to develop various complications. Strangulation is a serious and life-threatening complication. Various surgical procedures like primary tissue repair, mesh repair, keep open with secondary repair, etc. are in practice for strangulated groin hernias. Post-operative infection and recurrence are the main concerns with these procedures. The aim of conducting this study was to compare the outcomes of the mesh hernioplasty with Desarda's purely tissue hernioplasty in the treatment of strangulated inguinal hernia.
A total of one hundred and twenty-four patients were included in the study. These patients were grouped into group A (mesh hernioplasty group) and group B (Desarda's tissue repair group) and randomization was done. Results of these two techniques were compared with respect to post-operative seroma, surgical site infection, recurrence, and chronic pain.
Seroma formation was more in group A, which accounts for 35.48%(22) of patients than in group B patients accounts for 19.35%(12). Operative site infection was more in group A, which accounts for 35.48%(22) patients than in group B 9.67%(6) patients. Recurrence was more in Group A patients which accounts for 22.58%(14) than in Group B patients which accounts for 3.22%(2). More patients account for 19.35%(12) in group A experienced chronic pain than the patients 1.61%(1) in Group B.
The current study showed that Desarda's technique is a safe, effective, and single-sitting technique with a significantly reduced risk of seroma, surgical site infection, chronic pain, and recurrence than mesh hernioplasty for strangulated inguinal hernia.

Keywords: Inguinal hernia, Strangulated hernia, Desarda's repair, Mesh hernioplasty, Infection.

Introduction
Inguinal hernias constitute around 75% of all abdominal wall hernias and are considered to be one of the most common surgical problems in general surgical practice. Groin hernias may present with complications that vary from milder irreducibility to severe form of strangulation. The incidence of incarceration varies from 0.29% and 2.9% [1]. Strangulation of the contents of the hernia sac is rare, but it is a most dreaded complication of an inguinal hernia. The risk of strangulation varies with age it is 0.27% in young individuals and 0.03% in old individuals [2].
In the literature different operative procedures have been described for the management of groin hernias, which varies from simple primary tissue repair to mesh hernioplasty. Lichtenstein's "tension-free" technique with mesh is said to be the gold standard for groin hernia repair in elective cases.
Strangulation with necrosis and bowel perforation, which requires resection of the bowel with high rates of operative site Infection. Hernia repair with mesh is controversial in these circumstances [3-6].

World Society of Emergency Surgery (WSES) guidelines for the treatment of strangulated groin hernia recommends, Primary tissue repair, if the defect is small, (<3cm), otherwise either Biologi-

cal meshes or Open technique with secondary repair [7]. High rates of recurrence were reported with primary tissue repair [8]. Biological meshes are costly and readily not available [9]. Mesh hernioplasty is associated with a high incidence of infection and mesh removal [5,6,10,11]. Hence, the condition is quite challenging for surgeons and there is a continuous search for a better procedure that can take care of both issues (infection and recurrence). Desarda's technique is an effective well-accepted method that doesn't use prosthetic mesh but utilizes local fascia for tensionless inguinal hernia repair.

Outcomes of Desarda's technique (infection and recurrence) is comparable with other standard procedures in elective hernioplasty's [12,13,14].

Aim of study

This study compared the outcomes of Desarda's technique with outcomes of mesh hernioplasty and to establish better procedure for the treatment of strangulated inguinal hernias.

Patients and methods

The current study was conducted in the department of general surgery at Narayana medical college & Hospital, Nellore, Andhra Pradesh, India, between May 2012 to December 2020.

Inclusion criteria: All the patients presented to the emergency department with painful, irreducible, groin hernia swelling, with clinical features of strangulation. Patients with intraoperative findings of bowel wall ischemia, presence of hemorrhagic fluid in the sac, necrosis, and perforation of the bowel wall, requiring its resection. Patients with groin hernia above the age of eighteen years with the above features, irrespective of sex and presence or absence of comorbidities.

Exclusion criteria: Patients below eighteen years of age, recurrent hernias, hernias which got reduced pre operatively after resuscitation, intra operatively bowel without signs of ischemia, strangulation, or without hemorrhagic fluid in the sac.

Clinical signs of strangulation: Irreducibility with absent cough impulse, tender and tense swelling with erythema of the skin. Tachycardia, hyperthermia, signs of peritonitis, and signs of shock.

Based on the degree of contamination of wounds at the time of operation were classified as per the CDC classification.

Class I = clean wounds.
Class II = clean-contaminated wounds.
Class III = contaminated wounds.
Class IV = dirty or infected wounds.

Sample size calculation: Sample size calculation was don on the basis of primary outcomes (surgical site infection and recurrence) of this study, assuming the power of precision will be 95% with 5% either side. Whereas in the literature reported values ranges between 19% -21% [14], 10% - 31% [15] for infection and recurrence respectively. Average of both the values is around 20%, taken for calculation of sample size by using the softwear [https://clincalc.com/stats/samplesize.aspx].

A total of one hundred and twenty-four patients were included in the study. These patients were grouped into Group A (mesh hernioplasty group) and Group B (Desarda's tissue repair group).

Study design: Randomized double-blind comparative study.

Randomization: Randomization was done in the operative theatre by operating surgeon before starting the hernia repair. All the patients presented to emergency room with painful irreducible groin hernia swelling were admitted by emergency duty doctors, after explaining about the study and operative procedures. Consent for their willingness to participate in the study was obtained. These patients were asked to pick up a sealed envelope, with in which a slip with group allocation was placed. These envelops was opened in the operation theatre just before starting hernia repair after dealing with intestines and the patients were allocated to corresponding groups. These patients will be followed after discharge in OPD-by-OPD doctors. Neither the patient nor the admitting and follow up doctors were aware of the group allocation.

Pre-operative assessment: Patients in both groups were evaluated with regard to, duration of present complaints, fever, vomiting, treatment taken for these complaints, any previous similar attacks, associated co morbidities, and previous surgeries. Recording of vital signs, clinical examination of groin swelling and abdomen for signs of strangulation and peritonitis. Complete blood count, ultrasonography of abdomen and groin swelling, Contrast enhanced computed tomography (CECT) in case of clinical uncertainty.

Resuscitation: Resuscitation of the Patients with intravenous fluids, decompression of the stomach with ryles tube and Foley's catheterisation was

done. Injectable antibiotics, antiemetics, antacids and analgesics was administered.

Techniques: Anaesthesia: - both the procedures were performed under regional (spinal / epidural) or general anaesthesia.

Operative technique: a) Common to both procedures includes: -Skin incision, exposure and incision of the external oblique aponeurosis(EOA), dealing with contents of the sac depending on their clinical status. Closure of superficial fascia and skin incision.

Whenever condition of the hernia contents demands, abdomen was opened through midline incision. Resection of the bowel with either anastomosis or ostomy was done depending on bowel condition.

Procedure specific to each group:

Group A: Mesh hernioplasty: - one longitudinal margin of the polypropylene mesh (15x7cm) was sutured to inguinal ligament with 2o proline, starting from the pubic tubercle to 2 cm lateral to the internal ring. Then the mesh was fashioned with a lateral slit of 2 cm to accommodate the cord and to fit on to posterior wall of inguinal canal. The two lateral tails of the mesh was sutured together lateral to the internal ring to create new deep ring tight enough but not constricting spermatic card. Then mesh was fixed to posterior wall with 2o proline. EOA has been closed in front of the card.

Group B: Desarda's technique (described by Desarda) with minor modifications for study purpose: - Lower border of the upper leaf of EOA was sutured to the inguinal ligament behind the spermatic card starting from the pubic tubercle to the internal ring with continuous sutures using 2o proline. A splitting incision was made in the upper leaf of EOA separating a strip of 1.5 cm width (1-2cm) keeping the medial insertion and lateral continuity intact. Upper border of this strip was sutured to the conjoined tendon, wherever tendon was not available it was sutured to internal oblique or conjoined muscles with polydioxanone suture (PDSII)1o interrupted sutures. Now the spermatic cord lies on the newly created posterior wall by the strip of EOA. Upper border of the lower leaf of the EOA was sutured to the newly formed lower border of the upper leaf of the EOA anterior to spermatic cord, with 1o proline continuous sutures.

Outcomes: Primary out comes: - Surgical site infection, Recurrence. Secondary outcomes: - Seroma, Chronic pain.

Surgical site Infection: - presence of signs of inflammation with Purulent discharge from the wound, with fever, leucocytosis, positive culture sensitivity report [16].

Recurrence: Swelling with cough impulse at the site of operation, confirmed by ultrasonography.

Seroma: Collection of clear straw coloured fluid at the operative site without any signs of infection like fever, cellulitis, leucocytosis etc.

Chronic pain: Pain persisting 6 months or more after hernia repair [17].

Follow up: All these patients were followed up by OPD doctors who doesn't participated in the surgery, for a period of two years at 1, 3, 6, 9, 12, 18 and 24, months after discharge, for recurrence, and chronic pain.

There was no dropouts or deaths during the study period.

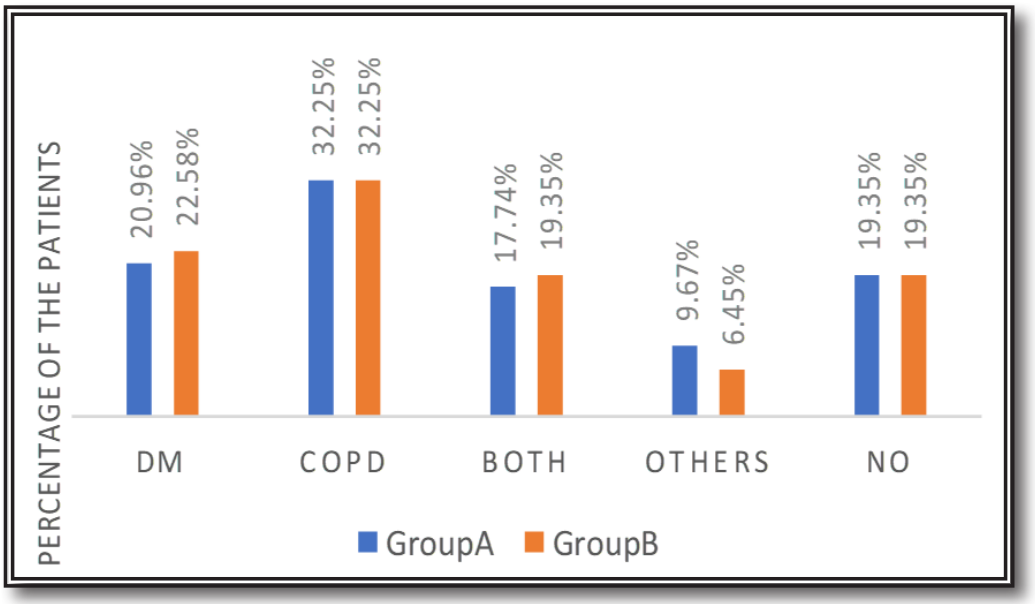
Statistics: Patient's' data between two groups was compared. Frequency's and percentages was used for representation of categorical data. The variables of both groups was compared with T test. P value of <0.05 was taken as significant.

Results

Majority of the patients 60 (96.77%) in group A and 61 (98.38%) in group B were males. Majority of the patients in both groups 41 (66.13%) in group A and 39 (62.90%) in group B were above the age of sixty years. Twenty-one (33.87%) patients in group A and 23 (37.10%) patients in group B were below the age of sixty years. Chronic Obstructive Pulmonary Disease (COPD) was the major comorbidity in both study groups 20 (32.25%) patients in each group. Thirteen (20.96%) and 14(22.58%) patients in group A&B respectively has Diabetes. Eleven (17.74%) and 12 (19.35%) patients in group A & B respectively have both Diabetes and COPD. Twelve (19.35%) patients each in both groups have no comorbidities. Six (9.67%) and 4 (6.45%) patients in group A and B respectively has multiple comorbidities like DM, COPD, Cardiac and renal problems together. Overall, statistically no significant difference between both study groups in the distribution of Sex, Age, comorbidities.

Majority of the patients in both study groups presented to emergency room between 6-12 hours after the onset of the symptoms. The other major group of patients has presented between 12-24

Figure (1) Distribution of co-morbidities (n = 6 2)



hours after the onset of the symptoms. Difference in the number of the patients (P=0.2 for 6- 12 hours and P=0.3 for 12-24 hours) between the two study groups were not significant. Majority of patients in both study groups has ischemia and gangrene as major operative findings but the difference in the number of the patients (Ischemia P= 0.07) (Gangrene P=0.1) between both the study groups was not significant [Table (1)].

Table (1) Duration of the symptoms and Operative findings

Variables	Duration of symptoms			Operative findings		
Groups	6 to <12 hours	12-24 hours	>24 hours	ischemia	gangrene	perforation
Group A n=62	33(53.23%)	19(30.65%)	10(16.12%)	33(53.22%)	22(35.48%)	7(11.29%)
Group B n=62	30(48.38%)	21(33.87%)	11(17.74%)	25(40.32%)	27(43.54%)	10(16.12%)
P value	0.2	0.3	0.4	0.07	0.1	0.2

Majority of the patients in both study groups presented to emergency room between 6-12 hours after the onset of the symptoms. The other major group of patients has presented between 12-24 hours after the onset of the symptoms. Difference in the number of the patients (P=0.2 for 6- 12 hours and P=0.3 for 12-24 hours) between the two study groups were not significant. Majority of patients in both study groups has ischemia and gangrene as major operative findings but the difference in the number of the patients (Ischemia P= 0.07) (Gangrene P=0.1) between both the study groups was not significant [Table (1)].

Table (2) Primary and secondary outcomes

Variables / Groups	Resection	Seroma	Infection	Recurrence	Chronic pain
Group A n=62	40(64.52%)	22 (35.48%)	22 (35.48%)	14 (22.58%)	12(19.35%)
Group B n=62	42 (67.74%)	12(19.35%)	6 (9.67%)	2 (3.22%)	1(1.61%)
P value	0.3	0.02	0.0002	0.0005	0.0005

Majority of the patients in both study groups has under gone resection of the bowel with either anastomosis or ostomy creation, but the difference in the number of the patients between two groups were not significant (P= 0.3). Seroma formation was significantly less in group B patients than Group A patients (P =0.02). Significantly greater number of the patients in group A has developed operative site infection than group B (P= 0.0002), eight of this patients required mesh removal. Recurrence of hernia after repair was significantly higher in group A than the group B (P=0.0005). Significantly higher number of the patients in group A has chronic pain than patients in group B (P= 0.0005) (Table 2).

Discussion

Incarcerated hernias are the irreducible hernias [18,19]. Whereas compromised blood flow to the contents of the sac results in strangulation. In the early stage of strangulation intestine develops ischemia and if it is not recognised and treated early, as the time advances ischemia may progress to necrosis and gangrene leading to perforation of the bowel. This may lead to local as well as systemic septicaemia with higher morbidity and mortality. Diagnosis of strangulation by clinical as well as by Imaging studies is quite challenging, definitive diagnosis is possible only during surgical exploration [15, 17].

Treatment of the strangulated groin hernia remains the challenging task for surgeons. Even though surgery is the treatment of choice, there is no common consensus between the surgeons regarding the type of surgical procedure for treatment of this emergency condition. Routinely practiced surgical procedures are simple primary suture repair and mesh hernioplasty. High incidence of operative site infection and recurrence are the two major concerns with these procedures. Higher recurrence rates were observed with primary tissue repair without strengthening the posterior wall of inguinal canal [8]. Strangulated groin hernias treated with mesh hernioplasty is associated with high incidence of operative site infection [10,11,20,21].

Observations in the current study showed that the strangulation is more common in elderly people than in young individuals, similar findings was reported by authors in the literature [15]. Diabetes and COPD were the major co-morbidity's present in great number of the patients of both groups. COPD is one of the major contributing factor for progression and strangulation of groin hernia and recurrence after repair. Diabetes mellitus is associated with higher rates of postoperative infection which contributes to recurrence in these patients.

Thirty-three (53.22%) patients of group A and 30 (48.38%) patients of group B in the current study presented to emergency room between 6 - 12 hours after the onset of the symptoms of strangulation. Thirty-three (53.22%) patients in group A and 25(40.32%) patients in group B had ischemia of the bowel wall, out of these, 22 (35.48%) patients of group A and 20 (32.25%) patients of group B had reversible ischemia. The Bowel has regained its viability after placing them in to abdominal cavity and with other resuscitative measures, similar findings was observed by other authors [22]. Remaining 29 (46.76%) patients of group A and 32 (51.61%) patients of group B presented late, after 12 hours either with in or more than 24 hours after the onset of the symptoms and has gangrene and/or perforation of the bowel wall. In the current study a total of 40 (64.51%) patients of group A and 42(67.74%) patients of group B had intraoperative findings of irreversible ischemia, gangrene and perforation of the bowel. All these patients required bowel resection with either anastomosis or stoma formation. The duration between the onset of the symptoms and presenting to the hospital was the important contributing factor, not only for the higher rates of advanced ischemia of bowel wall, but also influence the outcome in these patients, similar findings have been observed by other authors in their studies [23-25]. In the current study majority of the patients belongs to the villages, due to lack of adequate medical facilities, and by ignorance about the seriousness of the condition they were trying with local physicians and quacks to get relief from the symptoms, this appears to be the reason for their late presentation.

Seroma formation is one of the common postoperative complication encountered in the surgical practice, particularly in case of strangulated hernias. Seroma is one of the important factor which contributes to higher rates of operative site infection if not attended properly. The main contributing factors for seroma appears to be presence of inflammation, infection and foreign materials at surgical sight. In the current study more patients

of groupA 22 (35.48%) developed seroma than the patients of groupB 12 (19.35%). This significant difference may be attributable to the local inflammatory reaction caused by prosthetic mesh in addition to the pre-existing local inflammation and infection caused by strangulation, similar views has been expressed by other authors in their studies [26,27].

Major concerns in the management of strangulated inguinal hernia are the surgical site infection, and recurrence. In the current study both these problems were high in the mesh hernioplasty patients, than Desarda's hernioplasty patients. High incidence of the infection in the mesh group 22 (35.48%) patients than in Desarda group 6 (9.67%)patients, is not only due to mesh but it can also be attributable to irreversible ischemia and gangrene of the bowel wall. Which can lead to transmigration of the bacteria through bowel wall and contaminating the fluid in the sac. Both the mesh and these local factors acts synergistically leading to higher rates of surgical sight infection, similar views have been expressed by other authors in their studies [28-31]. Presence of irreversible ischemia, gangrene and perforation of the bowel which requires resection of the bowel, which potentially contaminates the operative field, converting the wounds in to CDC class III-IV [16], this was also contributed to the higher rates of operative site infection in the mesh hernioplasty group, similar views have been expressed by other authors in their studies [20,21,28,32].

Recurrence after hernia repair is quite depressing not only to patient but to the surgeon also. In the current study out of the 22 patients with surgical site infection in group A, 8 patients required mesh removal. This high infection rates and mesh removal were the main contributing factors for high incidence of recurrence in the group A Patients, similar observations have been noted by other authors in their studies [5,6,10,11]. Even though various other factors like surgical skills, general health of the patient, comorbidities like diabetes and COPD have been attributable for the recurrence, surgical site infection leading to mesh removal and postoperative cough seems to be major contributing factors for recurrence. Similar observations have been noted by other authors in their studies [15]. WSES guidelines updated in 2017, recommends to use biological meshes or to adopt open technique with secondary repair for the treatment of strangulated groin hernia, because of higher rates of surgical site infections associated with mesh hernioplasty in these circumstances [7]. Biological meshes are costly and readily not available particularly in emergency situation [9]. Open technique with secondary repair at later date, requires hospitalization for long period, and also associated with high recurrence rates. Lower rates of seroma, infection and recurrence observed in Desarda's repair patients of the present study may be due to utilization of local fascia for repair rather than synthetic mesh.

Various authors have showed favourable reports towards mesh use in case of incarcerated and strangulated hernias during emergency surgeries. Most of this studies were retrospective, and in other studies there was selection bias as surgical strategy has been made by surgeons [33,34].

Chronic pain is one of the debilitating complication affecting the patient's day to day activities after hernia repair. In the current study majority of the patients 12 (19.35%) in group A developed chronic pain than the group B 1(1.61%) patients. Main reasons for higher rates of chronic pain after mesh hernioplasty are nerve injury during dissection, nerve entrapment during mesh fixation, folding and wrinkling of the mesh, mesh contraction, recurrence of hernia, presence of pre- operative pain. Incidence of this chronic pain varies from 8-16% [35] to 23.48% [36]. Almost all of these reports are from the results of studies being conducted in elective surgeries, none of the authors has focused on chronic pain in their studies conducted on emergency surgery for strangulated inguinal hernia.

Conclusion

In the current study outcomes such as seroma, infection recurrence after surgery and chronic pain, of the two surgical procedures Desarda repair and mesh hernioplasty's for strangulated groin hernia were compared. It has been found that majority of patients in mesh hernioplasty group has developed seroma, operative site infection, chronic pain and recurrence than patients of Desarda repair group. It has been concluded that Desarda technique is safe and effective, single stage procedure with significantly less seroma formation, surgical site infection, chronic pain and recurrence than mesh hernioplasty, particularly in emergency conditions like strangulated groin hernia repair.

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Conflict of Interests
All authors declared no potential conflicts of interest related to the research, authorship, and publication of this article.

Ethical Approval
This protocol was approved by the institutional ethics committee

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