Study Protocol

A prospective comparative Clinical Trial of Onlay Versus Sublay Mesh Repair for Treatment of Ventral Hernia

ABSTRACT

INTRODUCTION: -This prospective comparative clinical study done at Sharda Hospital on patients admitted in Surgery ward with Ventral hernias after taking an Informed consent. Patients investigated as a part of pre-operative evaluation and Hernia Repair surgery done as planned.

AIMS & OBJECTIVE: - To compare the onlay vs sublay mesh repair techniques for ventral hernias in patients coming to Sharda hospital for 1) post-operative pain (vas) 2) Duration of hospital stay, 3) Time required to return to work 4) Complications (Seroma, Hematoma, Wound Infection, Recurrence.)

MATERIAL AND METHODS: - Patients reporting to General surgery OPD of SMS&R, S. hospital, G. N. with Ventral hernia were included in the study. Patients will be randomized into two groups: -group A, patients operated upon by Onlay mesh repair and group B, patients by Sublay component separation repair. Patients followed up for- 1) post-operative pain (day 2, day 7 ,1 month and 3month) using VAS, 2) mean hospital stay (in days), 3) return to basic activity (in days) and 4) complications including Seroma, Hematoma, SSI and recurrence.

RESULT: - Data collected and entered in the proforma, tabulated and analyzed using software package for statistical analysis (SPSS2015). Seroma, hematoma, superficial skin necrosis, SSI, hospital stay, & return to normal activities was more in onlay than in sublay repair.

CONCLUSION: - Sublay mesh repair was found to be excellent in terms of short-term results with minimal morbidity. It resulted in fewer complications and no recurrence was noted. Seroma, hematoma, superficial skin necrosis, SSI, hospital stay, & return to normal activities was relatively more in onlay mesh repair than sublay mesh repair.

KEYWORDS: - Ventral hernia, Onlay, Sublay, Mesh, Seroma, Hematoma

INTRODUCTION

Ventral hernias involve abnormal protrusion of any intra-abdominal viscera or its part via an abdominal wall defect. It can be of two types, namely congenital or acquired. Abdominal wall hernias usually present at the site of potential weakness i.e., at places where aponeurosis and fascia are not covered by flat striated abdominal wall muscles namely inguinal, femoral, umbilical area, Linea alba, a lower portion of semilunar line, and incisional hernias (sites of previous incisions) [11]. Incisional and paraumbilical hernias make about 85% of total common ventral hernia [12]. Western literature quotes an incidence of 15-20% of ventral hernia and prosthetic mesh implantation remains the most preferred method of dealing with ventral hernia[10]. Surgical correction of Ventral hernia is by far one of the commonest procedures performed internationally with an estimated 300,000 procedures done in Europe and 400,000 procedures done in the United States annually[1]. Multiple Studies have reported prevalence rates ranging between 3.7%-28% in patients undergoing various abdominal surgeries[2,3]. Untreated the Ventral hernias may increase in size thereby leading to discomfort and pain or may even get complicated by incarceration, obstruction or even strangulation. Such progressive natural history leaves surgery as the only mainstay of their treatment. Ventral hernia repair is a real surgical challenge. Ventral hernia surgery has been continuously evolving. To begin with, Bassini in 1884 did the first inguinal hernia repair, first nylon prosthetic mesh was designed by Bourret in 1948, which was later replaced by prolene by Usher in 1963.Later on a great volume of work from Rives, Stoppa, and Wantz bettered the technique. Lichtenstein's tension-free Hernia repair in 1986 revolutionized the treatment[4]. Leblanc and Booth in 1993 reported the first laparoscopic ventral hernia repair [5]. Since then, Laparoscopic hernia repair is in vogue internationally. However, in many resource poor countries, open repair of ventral hernia is still regularly practised6. Multiple options for the placement of prolene mesh in the hernia repair results in availability of varied surgical techniques. They include onlay repair where in the mesh is placed in the subcutaneous plane anterior to the anterior rectus sheath or external oblique; inlay repair is the one in which the is mesh is sutured to the edges of the defect at the hernial neck; sublay repair is the one in which mesh is placed in the retro muscular layer anterior to the posterior rectus sheath, preperitoneal repair is the one in which mesh is placed between the peritoneum and posterior rectus sheath whereas intraperitoneal repair is the one in which mesh is placed from inside the peritoneal cavity and fixed to anterior abdominal wall[7]. Out of these, onlay & sublay are routinely practiced. The preperitoneal (sublay) mesh hernia repair was initially mentioned by Rene Stoopa, Jean Rives, and George Wantz. Contemporary surgeons consider this technique to be the gold standard for the open repair of ventral hernias 8. Onlay repair is believed to be easily performed and takes less time of operation, but it is associated with higher incidence of complications, whereas Sublay repair, is most efficient in terms of lower recurrence rate 10. However, it remains unclear which technique is superior. The aim of this study is to compare the outcome of the onlay versus sublay mesh repair for ventral hernia, in terms of post-operative pain, mean hospital stay, return to basic activity, complications including Seroma, Hematoma, SSI (surgical site infection), and recurrence. The results of this pilot study will help in guiding and establishing institutional evidence-based practices for our setup.

MATERIAL AND METHODS

A randomized clinical study was conducted from May 2019 to September 2020 in the Post Graduate Department of General surgery, S. Hospital, School of Medical Sciences & Research, G. N. on patients diagnosed as Ventral hernias which fulfilled the inclusion criteria after approval from institutional ethical committee. A written informed consent was taken from every patient included in the study. From previous studies and literature review the prevalence for ventral hernia was 3.7% -28%. Our institutional previous years surgery records evaluation and assessment concorded with initial value of the range of prevalence. The prevalence was therefore 3.7% ~/= 4%. Absolute error was=5% as per universal statistical standards. The sample size was calculated by using the WHO sample size calculator with Power of test (1-β) =95%, Level of significance (α)=5%, population SD (σ)=41, population variance (σ2) =

$$N= Z^2 P (1-P)/ e^2$$

Where n is the sample size, Z=1.96 (constant), P= prevalence, e=error (precision).

The sample size was calculated as was calculated as 30 ± 30 = 60 patients.

The inclusion criteria included patients of both genders with uncomplicated ventral abdominal hernias between 18-70 years of age who were fit for surgery (ASA class I to III). The exclusion criteria included patients with Pregnancy, Terminal Illness, Malignancies , Collagen Diseases, Active / Open Pulmonary Tuberculosis, Diffuse skin Disease, patients on Anti Neoplastic Therapy, patients unfit for surgery (ASA class IV & V, renal failure and coagulopathies). 60 Patients with paraumbilical, epigastric and supraumbilical, umbilical, incisional hernias were included in the study. Patients were randomly divided into two equal groups (group A and B) consisting of 30 patients each by closed envelope method. Group-A patients underwent mesh repair of ventral hernia by onlay technique while group-B patients underwent mesh repair of ventral hernia by sublay technique. The patients included were evaluated for postoperative seroma formation wound infection (SSI), postoperative hospital stay, and recurrence of symptoms. In group A, the mesh was placed above the rectus sheath. The defect was closed primarily by prolene 1'0' suture followed by placement of prolene mesh. The mesh was placed such that it extended at least 5 cm beyond the edges of the defect and is not merely stitched to the hernia edges. In group B, mesh was placed mainly under the defect in the retro muscular layer of abdominal wall posterior to the rectus muscles and anterior to the posterior rectus sheath. The mesh was placed such that it extended at least 5 cm beyond the edges of the hernial defect and is not merely stitched to the hernia edges. The contact between intestines and mesh is prevented by the posterior rectus sheath and the layer of peritoneum that lies under the mesh. All the operations were carried out under general anesthesia and prophylactic antibiotic dose of injection (Ceftriaxone) 1 grams intravenous was given at the time of induction of anesthesia. Romovac™ suction drain was placed in all patients during the surgical closure. Drain was removed if the output was less than 25 ml in 24 hours with clear or serous discharge. Post-operatively patients were discharged on 5th-7th post-operative day with removal of drain depending upon the patient's condition and they were followed in outpatient department (surgery OPD) on 14th and 28th & 120 postoperative days for -All patients were followed for wound edge necrosis, wound infection (Development of post-operative fever, incision site redness and tenderness, wound discharge and local

abscess was labelled as surgical site infection SSI), seroma formation (Collection of pockets of clear serous fluid formed post hernia repair) and hematoma formation (localized collection of blood outside the blood vessels, due to intra operative surgical trauma to blood vessels). All the patients will be followed on $2^{nd,}$ 7^{th}, 14^{th} and 28 th postoperative days for wound infection. Follow up was ensured by taking mobile numbers of patients. Data was analyzed using software package for statistical analysis (SPSS2015). Mean and SD was calculated for quantitative variables like age and operation time. Qualitative variables like wound infection, seroma formation and hematoma formation were recorded in terms of frequency percentage. Chi square test was applied for qualitative variables. Independent sample t-test was applied for quantitative variables. A *p*-value of ≤0.05 was considered as significant.

The work has been reported in line with Consolidated Standards of Reporting Trials (CONSORT) Guidelines.

RESULTS

A total of 60 patients were included in the study and were divided into two groups of 30 patients each. The patients included 42 females (70.00 %) and 18 males (30 %). Female to male ratio was 7:3. The mean age of patients was41.95 ± 9.11 years (range 28-65 years). Mean age was 40.95 ± 9.6 years (range 28-65 years) for patients in onlay mesh repair group and 42.95 ±8.6 years (range 34-64 years) for sublay mesh repair group. Out of 60 patients, had 10 epigastric hernia (16.67%), 16 had paraumbilical hernia (26.67%) ,14 cases of umbilical (23.33%) and 20 cases of incisional hernia (33.33%). Complications were observed in 12 patients (40.00%) in onlay group versus 6 patients (20.00%) in sublay group. The *p*-value about complications between the two groups was statistically significant (*p*=0.02). There were 2 cases (6.67%) of surgical site infection in group A which were managed conservatively by intravenous antibiotics. There was one case (3.33%) of SSI (wound infection) in group-B. The difference between the two groups was statistically insignificant (*p*=0.51). The commonest complication seen was seroma formation in 11 patients (18.33%) included in the study. Seroma formation occurred in 8 patients in group A (26.67%) versus 2 patients (6.67%) in group B. The difference being statistically significant (*p*=0.033). Seroma cases were managed by opening of the stitches, drainage of seroma, drain placement and secondary closure of wound. Drains were kept until the drain output became less than 25 ml in 24 hours with clear or serous only discharge. There were 3 cases (10.00%) of hematoma formation in onlay mesh repair group versus 4 cases (13.33%) in sublay mesh repair group. The hematoma formation between the two groups was statistically insignificant (*p*=0.53). The duration of hospital stay was on an average 3–4 days in group B, and average hospital stay was 3–5 days in group A. In the group B, the drain was removed after 3–4 days, and in cases with small defect, the drain was removed in 2-3 days, but in group A, the drain was removed after 2–5 days, except for patients with large incisional hernia, where drain was removed after 10 days.

DISCUSSION

Majority of our patients were females because of the previous gynecological surgeries like Caesarean section or hysterectomy or ectopic pregnancy precipitating the incisional hernias. In our randomized controlled trial, 42 (70.00%) out 60 patients were female. The mean age of patients was 41.95 ± 9.11 years. Complications were reported in 12 patients

(40.00%) in onlay group and 6 patients (20.00%) in sublay group, the difference being statistically significant with p=0.02. The seroma formation in the two groups was statistically

significant in our study with p=0.0333. Hematoma formation in both groups in our study was 10.00% and 13.33% between the two groups which was statistically insignificant (p=0.53). Finally, the wound infection in our study was statistically insignificant between the two groups with p =0.51. Duration of hospital stay was measured in both the groups. Serious complications post ventral hernia repair are uncommon. It is imperative to enquire about the detailed past surgical and medical history especially about the presence of chronic cough due to COPD, Asthmatic bronchitis, chronic constipation and urinary retention especially in elderly due to BPH, stricture to caution patients about likely chances of future recurrence. Laparoscopic hernia repair has also gained wide acceptance in current times but in a resource poor country like ours, the requisite armamentarium is not available everywhere. Although the operative time is longer in sublay repair, it has been found to be the better technique in our study and can be a plausible alternative to the routinely done onlay method for repair of ventral abdominal hernias. Hernia Recurrence in Our study mainly comprised of observing the patients in follow up for short term recurrence, if any, occurring within a month and 3 months after ventral hernia repair. Further work is required on this topic with larger sample size for longer durations follow up for predicting recurrence rates, long term morbidity and complications associated with ventral hernia repair.

CONCLUSION

Sublay mesh hernioplasty is edge over the onlay mesh hernioplasty for ventral abdominal hernia repair in terms of efficacy, safety, and reliability. The merits of lessor frequency of post-operative complications in sublay mesh hernioplasty definitively outweighs the demerit of longer operative time.

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COMPETING INTERESTS DISCLAIMER:

Authors have declared that no competing interests exist. The products used for this research are commonly and predominantly use products in our area of research and country. There is absolutely no conflict of interest between the authors and producers of the products because we do not intend to use these products as an avenue for any litigation but for the advancement of knowledge. Also, the research was not funded by the producing company rather it was funded by personal efforts of the authors.

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