



A RANDOMISED PROSPECTIVE STUDY ON SHORT TERM SURGICAL SITE OCCURRENCES OF ONLAY MESH REPAIR AND SUBLAY MESH REPAIR IN VHWG GRADE 1 AND GRADE 2 VENTRAL HERNIA

Clinical Research

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ABSTRACT

Background: Ventral hernias are the defects of anterior abdominal wall most of which are incisional hernias. Mesh repair has become standardised care for ventral hernia. The Plane of placement of mesh have been widely studied out of which onlay, sublay, intraperitoneal onlay had been popularised. The short term outcomes between sublay and onlay have not been compared in a prospective randomised methods in our population.

Methods: This is randomised prospective comparative study, the patients presenting with ventral hernia after passing the inclusion and exclusion criteria had been allocated into either onlay or sublay groups using computer generated random numbers. They are followed up for two months and the preoperative, intraoperative, postoperative, follow-up data and rates of various short term surgical occurrences are identified and analysed. Student t test, confidence intervals, percentage analysis, ANNOVA are applied as statistical tests of significance using SPSS software.

Results: Most of the patients were female patients (78%) and most of the hernia were incisional hernia (90%). No difference in outcomes could be made out between ventral hernia working group Grade I and Grade II hernias. Size of the defect were not significantly associated with the surgical site outcomes. The mean operating time was significantly higher in the sublay group (difference- 17 mins, p value-0.00004). The drain output, duration of drain in situ, duration of hospital stay is significantly lower in the sublay group (p value-0.00002). The incidence of various surgical site occurrences were significantly lower in the sublay group than onlay group (24.4% vs 44.4%, p value-0.05). There were no significant changes in the pain score observed between onlay and the sublay group.

Conclusion: Standardised methods and guidelines of care should be established with respect to treatment of the ventral hernias. Sublay method should be preferred whenever possible, based on the advantages of pascal's principles and decreased rates of short term surgical occurrences derived from our study. Long term cohort follow-up studies are required to evaluate for the incidence of recurrences in both the sublay and onlay group.

KEYWORDS

ventral hernia, incisional hernia, sublay, onlay, retrorectus, mesh repair.

Aim:

To identify the rates of short term surgical occurrences in the ventral hernia repair in VHWG grade 1 and grade 2 hernias in onlay mesh repair technique and compare it with sublay mesh repair technique.

Objectives:

Primary objective: Compare the rates of short term surgical occurrences in onlay mesh repair technique and sublay mesh repair technique in our institution.

Secondary objective: identify the various factors associated with the short term surgical occurrences in both onlay and sublay mesh repair technique

MATERIALS AND METHODS:

Study design: Randomised prospective comparative study

Sample size: 90 (equally divided between sublay and onlay group). Sample size calculated based on the previous research data available in the Indian population for the short term surgical occurrences using the epi info software.

After obtaining informed consent all patients were subjected to screening ultrasonogram for identifying the defect size and the contents. After informing the details of the study and when the patient gives and informed consent for randomization into either one of the study groups inclusion criteria are analyzed and patient were given chronological serial numbers

Inclusion criteria:

1. Patient given informed written consent for study
2. Age above 18 years
3. Ventral hernia grade 1 and grade 2 requiring surgical repair
5. Patient medically fit for open hernia repair

Exclusion criteria:

1. Denial of consent
2. Age less than 18 yrs
3. Recurrent incisional hernia with at least once repaired with mesh in the past

4. Parastomal hernias
5. Obstructed, strangulated, incarcerated hernias presenting in emergencies
6. History of mesh rejection in previous hernia sites other than the presenting one
7. Pregnancy excluded.

A two set random numbers were generated by the computer and were used throughout the study for assigning the patients into the onlay group or the sublay group.

105 patients were assessed, 6 excluded. 99 patients randomly assigned to 50 onlay group out of which two deferred surgery, three lost follow up 45 included for primary outcome analyses. 49 assigned to Sublay group three lost follow up 45 included for primary outcome analyses

Pre operatively patients were collected data on preformed data collection template by the primary investigator

After collecting the pre- op data the patients were decided on the type of surgery based on preformed random numbers either into onlay or sub lay group. All patients were taken up for surgery electively under general anaesthesia. Standardized procedure were followed for the onlay and sublay repair. All patients were give parenteral antibiotics for five days post operatively. All patients had a Romovac suction drain of size 18 f placed in the subcutaneous plane and drain emptied daily. All patients were give a semisynthetic opiate – Tramadol 100 mg intramuscular twice daily for three days and changed to per oral continued for two or more days. Post-operative dressings were changed regularly. All patients were done the suture removal on 15th post-operative day.

Onlay repair – under sterile aseptic precautions a pfannenstiel incision or a sub umbilical smiley incision or a midline incision was selected based on the site of the hernia sac. Skin and subcutaneous tissue dissected and flaps raised on either side just superficial to anterior rectus sheath. Sac identified and isolated, sac opened and contents reduced. Peritoneum closed with a 2-0 vicryl round body needle and

defect delineated. The defect on the rectus or the available fascia were identified, and closed in the vertical plane in case of rectus or along the fibers in case of other fascia using a 2 – 0 polypropylene suture round bodied needle, bites of 1 cm each 1 cm apart were taken on the healthy fascia with inclusion of the fascia alone not including the muscle or the fat with in it, a suture length to wound length ratio have been maintained on 4 : 1. A poly propylene mesh PM soft quality and of size tailored to cover the defect with an overlay of 5 cm over the pre closure fascial defect. Mesh fixed in position using a 2 – 0 polypropylene suture. Wound was closed with a Romovac suction drain in placed. Herina sac retracted cephalad to visualise the pfannenstiel scar.

Sublay repair - a plane was generated in the retro muscular plane above the arcuate line or in the preperitoneal plane below the arcuate line. The adequacy of dissection was confirmed with a ruler 5 cm margin along the preclosure fascial defect.

After confirming that there is no peritoneal breach or window, A similar polypropylene mesh is tailored and taken into the plane and fixed to the fascia with four intermittent bites along the four corners of the mesh with 2-0 polypropylene suture material with sutures coming through and through the mesh and fascia and tightened appropriately without strangulating the muscle or the fascia included, adequate fat clearance was done at the sites of bites on the fascia so that no subcutaneous tissue is included in the bites.

The defect on the rectus or the available fascia were identified, and closed in the vertical plane in case of rectus or along the fibers in case of other fascia using a 2 – 0 polypropylene suture round bodied needle, a suture length to wound length ratio have been maintained on 4 : 1. Wound closed with a Romovac suction drain in place.

The short term occurrences are defined as Superficial Incisional SSI Deep incisional SSI Organ/Space SSI based on standard definitions. Pain was measured by a visual analog score. Post op follow up after discharge is carried out for the period of two months once a week in first post op month and biweekly in second post op month. During each visit the following data were noted Surgical site infections, Seroma and required intervention (USG guided aspiration), superficial infection, Deep infection, Wound gaping, Requirement of resurgery, Implant infection deeming debridement or removal, Pain score as measured in visual analog score with respect to position bending, turning and at rest, Activities of daily living, Return to occupation

The complication occurring any has been monitored and scrutinized carefully, the need for re operation has been decided on, implant infection deeming its removal, wound gaping requiring secondary suturing, deep infection which may need a secondary suturing after a thorough debridement. The complications and progress of the study and any untoward event has been thoroughly surveyed and the same has been reported to the institution scientific and ethical board and actions taken time to time. Funding for this study – no extra cost was borne by the patient. The standard costs involved was covered by government policies of health care.

RESULTS

Type of Ventral hernia

In our study the 90 % of the ventral hernias were incisional hernia, the rest of the 6 % were paraumbilical hernia, 3 % umbilical hernia and the rest 1 % was epigastric hernia.

Incisional hernia – Figure 1

Out of the incisional hernias 75.56% were done electively and rest 24.44 % as emergency procedures. Out of all the incisional hernias 33.33% of them had some form of surgical site infection in the previous surgery.

Mean operating time

Table 1

The mean operating time from the incision to the final dressing of the surgery was studied and found to be 110.40 mins (95% CI 3.10), mean operating time in onlay group was 92.76 mins (95 % CI 2.61) and in the sublay group was 110.04 mins (95% CI 4.30). There was as mean difference of 17 mins between the onlay and the sublay group with sublay requiring a higher duration than the onlay group. This difference was found to be significant with p value – 0.00004.

Quantity of drain output

Table 2

The mean Drain output on the fourth post-operative day was taken to be significant measure as the peak inflammation sets in that period and gradually weans off and was found to be 61.84 ml (95% CI 6.44), mean Drain output in onlay group was 87.91 ml (95 % CI 6.41) and in the sublay group was 35.78 ml (95% CI 2.59). There was as mean difference of 52 ml between the onlay and the sublay group with sublay showing a decreased quantity than the onlay group. This difference was found to be significant with p value – 0.00002.

The sixth Post-operative day drain output was also significantly lower in the sublay group p value – 0.00003, with a mean difference of 36 ml. many of the subjects in the sublay group had their drains removed before the sixth POD compared to their counterparts in the onlay group.

Duration of hospital stay

In order to standardise logistics and technical problems the duration of hospital stay was calculated from the day of surgery to the time of discharge.

Table 3

The mean duration of hospital stay was found to be 7.50 days (95% CI 0.42), mean duration of hospital stay in onlay group was 9.00 days (95 % CI 0.39) and in the sublay group was 6.00 days (95% CI 0.41). There was as mean difference of 3 days was observed between the onlay and the sublay group with sublay showing a more sooner discharge. This difference was found to be significant with p value – 0.00002.

Duration drain in situ

Table 4

There was as mean difference of 1.88 days was observed between the onlay and the sublay group with sublay showing a more sooner drain removal. This difference was found to be significant with p value – 0.00002.

Short term surgical occurrences

Table 5

Seroma was noted in 44.44 % (n = 20) of patients in onlay group and 24.44% (n = 11) in the sublay group with a significant difference (p value – 0.05). All patients with seroma were treated by aseptic aspiration and compression dressing, out of all patients who had seroma n=14 in onlay and n=4 in sublay group progressed to have superficial wound infection rest all were treated on outpatient basis.

Superficial infection was noted in 31.11 % (n=14) in onlay group and 8.89(n=4) % in sublay group with a significant difference (p value – 0.01). Out of which 8 in onlay and none in sublay had readmission for intravenous antibiotics and regular dressing change. Rest all patients were started on sensitive antibiotics based on the antibiogram and treated on outpatient basis.

Wound gaping followed superficial infection or seroma in 13.33% of patients in onlay group (n=6), and 2.22% (n=1) in sublay group. All needed hospital admission for sensitive intravenous antibiotics and one in onlay and one sublay progressed to deep infection, one in onlay group required a secondary suturing done rest all patients were allowed to heal by primary intention. Significant differences were observed in both onlay and the sublay group (p value – 0.05)

Deep infection was observed in one patient in each group and the patient in onlay group underwent a surgery for debridement and followed by secondary suturing, the patient in sublay had been managed by sensitive antibiotics and regular vac dressing and didn't require a resurgery. There were no significant differences in the onlay and the sublay group with respect to deep infection and resurgery (p value 1.00, 0.16)

There were no recurrences, implant infection or removal, enterocutaneous fistula, adhesive colic noted in all the patients till the end of follow up to two months.

The mean operating time was significantly higher in the sublay group than in the onlay group. The drain output and duration of drain in situ is significantly lower in the sublay group than in the onlay group. The duration of hospital stay was significantly lower in the sublay group than in the onlay group. The incidence of various surgical site occurrences were significantly lower in the sublay group than the onlay

group when observed for the duration of two months. There were no significant changes in the pain score observed between onlay and the sublay group at the time of discharge, two weeks, one month and at two months.

Literature review

The technique of mesh placement has also been variously studied and different studies suggest different opinions with no single technique has been validated best for the Indian population. The most common open techniques of prosthetic reinforcement being onlay, sublay, interposition methods. Other techniques followed includes component separation methods as advocated by Ramirez et al. [2] with or without prosthetic reinforcement.

The onlay and the sublay technique differs by the position of prosthesis with respect to the hernia defect. The onlay repair involves the primary closure of the defect with prosthesis reinforcement superficial to the defect, the interposition technique reinforces the prosthesis into the defect, while the sublay technique places it deep to the defect. Except for the interposition technique the onlay and sublay has its own advantages and disadvantages.

The recurrence of hernia have been attributed to numerous factors including immediate post-operative surgical site infection, inadequate coverage and fixation of mesh. Patient factors contributing to recurrence include obesity, BMI, improper nutrition, smoking, COPD [3]. The immediate post op infection is a major risk factor associated with recurrence rates.

Natarajan et al propose a decreased short term surgical outcome in the sublay 27.8% compared to onlay 58.3 % mesh repair technique [4]. This study was a randomised prospective study and it was done in Indian population. They also included laparoscopic intraperitoneal mesh repair in their study. The number of patients enrolled were though lower 13 in onlay group, 11 in preperitoneal group and 6 in intraperitoneal group. They concluded that out of the three groups, the sublay repair which included intraperitoneal group, was found to have better results and satisfaction with regard to Short term surgical occurrences and appearance of the abdominal wall without laxity in a single sitting.

This is supported by Lucas Timmermans et al [5]. Their study was a meta-analysis which included majority of the retrospective studies only while very few prospective studies were included in their analysis they concluded sublay was the preferred technique for the incisional hernia repair, Mohamed Leithy et al [6] also noted a decrease in short term surgical outcomes though no difference in recurrence was noted. A low-weight, large, porous mesh material was found to be favourable which represented by a reduced inflammatory part of the foreign body granuloma. There was also a theoretical benefit of Pascals law working for the reinforcement in sublay method [7]. On the contrary Dennis den Hartog et al [8] did a Cochrane review of all the trials published till the date of study and note that there is no observed difference in the recurrence rates and the short term surgical outcomes, Tim Mathes et al [9] did a meta-analysis and systematic review and note no difference and complication rates they also noted that chronic pain may be increased in sublay mesh repair group. Bess et al. [10] and Ravikumar et al also found no statistically significant difference in the complication rates of the sublay and the onlay group in their prospective study of 37 patients. [11] Shahida Parveen et al found a decreased rates of seroma in the sublay group compared to the onlay group. Their study had 100 patients with a prospective randomised design. [12]. With regards to complication rates, a long-term follow-up study of incisional hernia patients by Hawn et al [16] suggested a less recurrence rates in the sublay or the underlay technique compared to the onlay technique. One disadvantage of this study is the retrospective method and non-standardised method of hernia repair. This flaw was corrected in a study by Frederik Helgstrand et al in which they noticed a decreased recurrence rates in sublay technique [13], which was supported by Jeffrey et al in their prospective study [14]

Karl Breuing et al postulated various guidelines and treatment guidelines for the ventral hernia repair called as the Ventral Hernia Working Group guidelines which postulates the grading of ventral hernia based on the anticipated complication and contamination. Guidelines lay a strong evidence for prosthetic (Mesh) repair instead of suture repair irrespective of defect size in grade 1 and two. The choice of material synthetic, biological or biodegradable of prosthesis is

based on surgeon's decision though they suggest a light weight polypropylene mesh, for uncontaminated hernia of grade 1 and 2 and biological or biodegradable material for grade 3, 4. Both laparoscopic and open method have no significant differences. The onlay or sublay repair, as they quote, has found to have no significant differences though sublay may have a "theoretical" advantage [1].

Thus major studies identifies no difference in the complication rates while some studies project a better outcome in the sublay group, this is commented in ventral hernia working groups' guidelines as may be theoretical. Very few Indian studies are available to support this data and may prove contrary also.

Factor that plays a role in the occurrences of incisional hernia is the association of the previous surgery with surgical site infection, the same is responsible for recurrences [15] in incisional hernia surgery, and thus preventing the occurrence of incisional hernias will play a major role in this morbid condition.

CONCLUSION

Standardised methods and guidelines of care should be established with respect to treatment of the ventral hernias. The primary suture repair alone should be considered obsolete, Prosthetic repair with a soft light weight mesh should be used. The type of mesh either non absorbable or absorbable based on the grade of hernia. Grade I and II should be dealt with non-absorbable mesh only which is fixed with non-absorbable sutures. No tension closure of fascia should be followed, in case of tension, component separation should be done. Sublay method should be preferred whenever possible, based on the advantages of pascal's principles and decreased rates of short term surgical occurrences derived from our study. Long term cohort follow-up studies are required to evaluate for the incidence of recurrences in both the sublay and onlay group

Figure 1 previous surgeries in incisional hernia

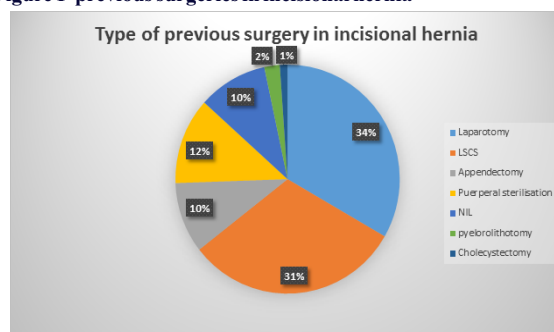


Table 1 mean operating time

Mean operating time	Total	Onlay	Sublay
Mean	110.40	92.76	110.04
Standard deviation	15.01	8.94	14.70
Confidence interval	3.10	2.61	4.30
p value		0.00004	

Table 2 drain output

Drain output	Total	Onlay	Sublay
Mean	61.84	87.91	35.78
Standard deviation	31.15	21.95	8.88
Confidence interval	6.44	6.41	2.59
p value		0.00002	

Table 3 duration of hospital stay

Duration of hospital stay	Total	Onlay	Sublay
Mean	7.50	9.00	6.00
Standard deviation	2.05	1.35	1.41
Confidence interval	0.42	0.39	0.41
p value		0.00002	

Table 4 duration of drain

Duration of drain in situ	Total	Onlay	Sublay
Mean	5.46	6.38	4.53
Standard deviation	1.62	1.23	1.39
Confidence interval	0.33	0.36	0.41
p value		0.00002	

Table 5 short term surgical occurrences

Short term surgical occurrences	Onlay percentage	Sublay percentage	P - Value
Seroma	44.44 %	24.44 %	0.05
Superficial infection	31.11 %	8.89 %	0.01
Wound gaping	13.33 %	2.22 %	0.05
Deep infection	2.22 %	2.22 %	1.00
Re-surgery	4.44 %	0.00 %	0.16

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