Randomized controlled trial of the use of drain versus no drain in open incisional hernia mesh repair.

A dissertation submitted in partial fulfilment of M.S. General Surgery Branch I Examination of the Tamil Nadu Dr M.G.R. UNIVERSITY, CHENNAI to be held in 2016.

Certificate

This is to certify that the dissertation "Randomized controlled trial of use of drain vs. no drain in open incisional hernia mesh repair." is a Bonafide work of Dr Rahul Lakshminarayanan carried out under our guidance towards the M.S. Branch I (General Surgery) Examination of the Tamil Nadu Dr M.G.R. University, Chennai to be held in 2016.

SIGNATURE:

Dr. Sukria Nayak

Professor and Head (Unit IV), Department of General Surgery,

Christian Medical College, Vellore, 632004, India

Dr John C Muthusami

Professor and Head of Department, Department of General Surgery,

Christian Medical College, Vellore, 632004, India

Dr Alfred J Daniel

Principal,

Christian Medical College, Vellore, 632004, India

Declaration Certificate

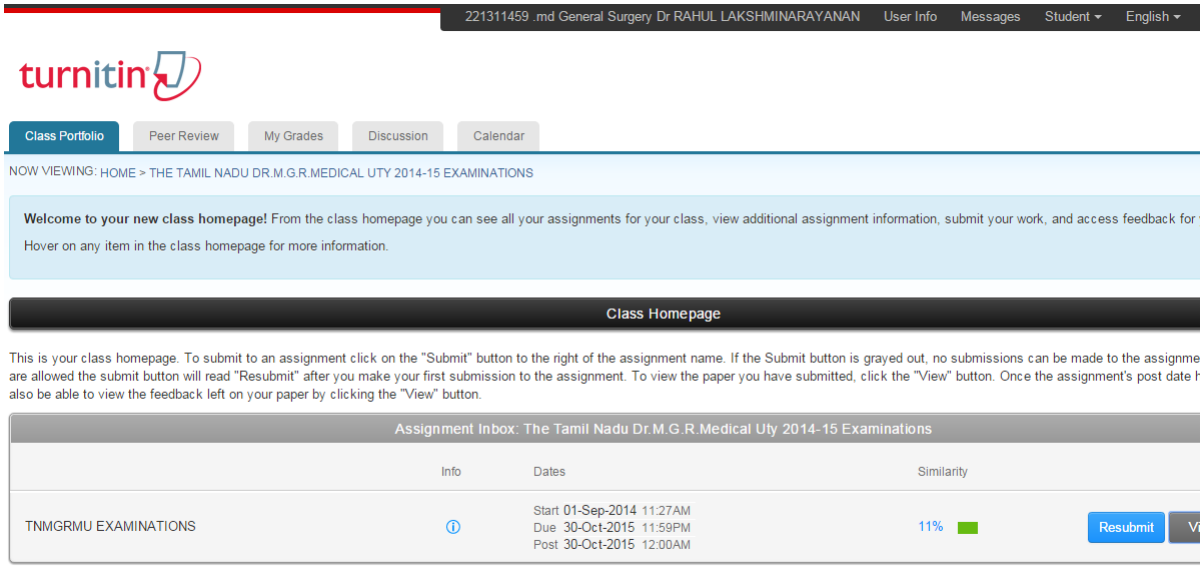
This is to certify that the dissertation titled "Randomized controlled trial of the use of drain versus no drain in open incisional hernia mesh repair." which is submitted by me in partial fulfilment towards M.S. Branch I (General Surgery) Examination of the Tamil Nadu Dr M.G.R. University, Chennai to be held in 2016 comprises only my original work and due acknowledgement has been made in text to all material used.

SIGNATURE:

Dr Rahul Lakshminarayanan

PG Registrar, Department of General Surgery

Christian Medical College, Vellore, 632004, India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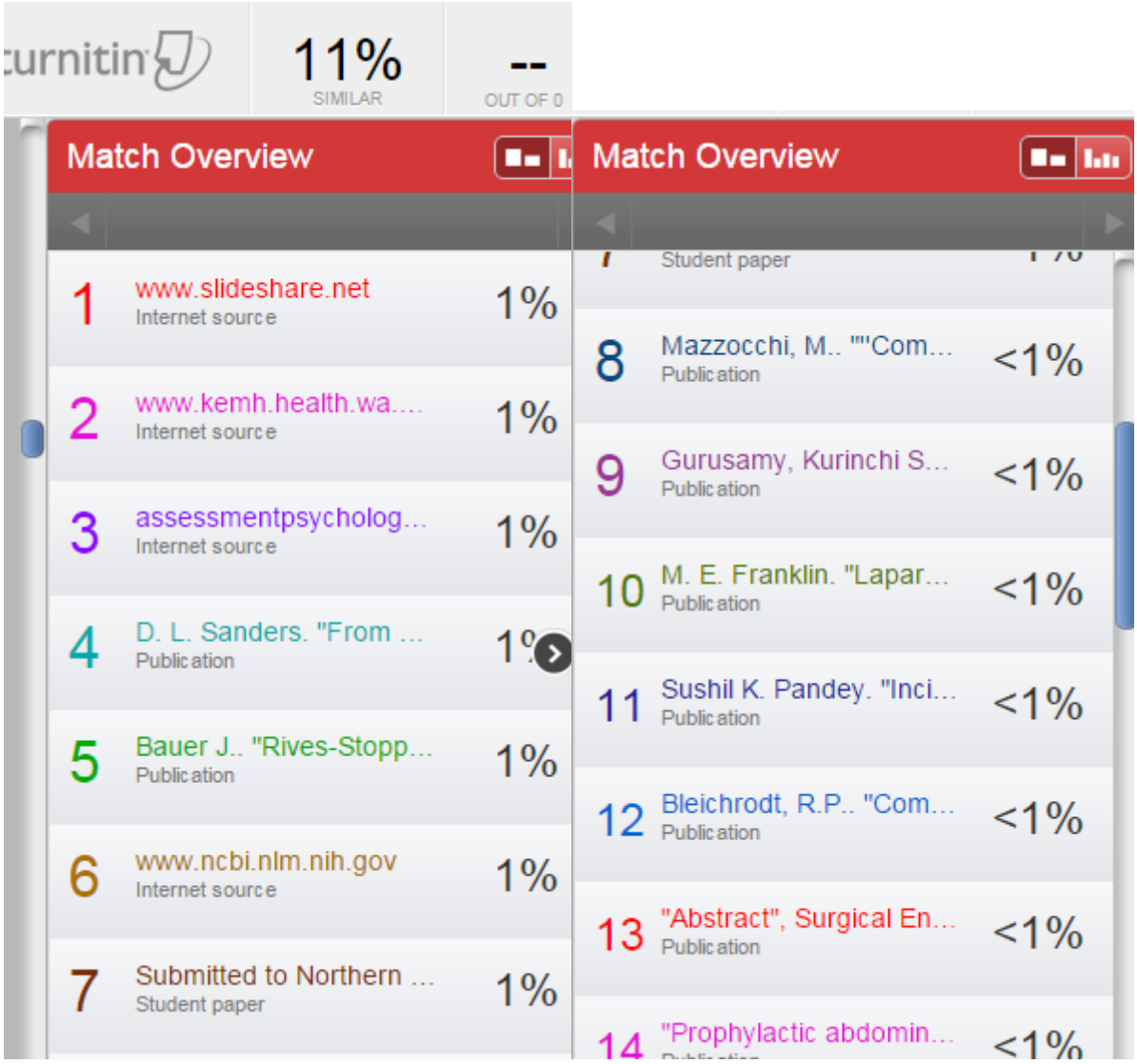
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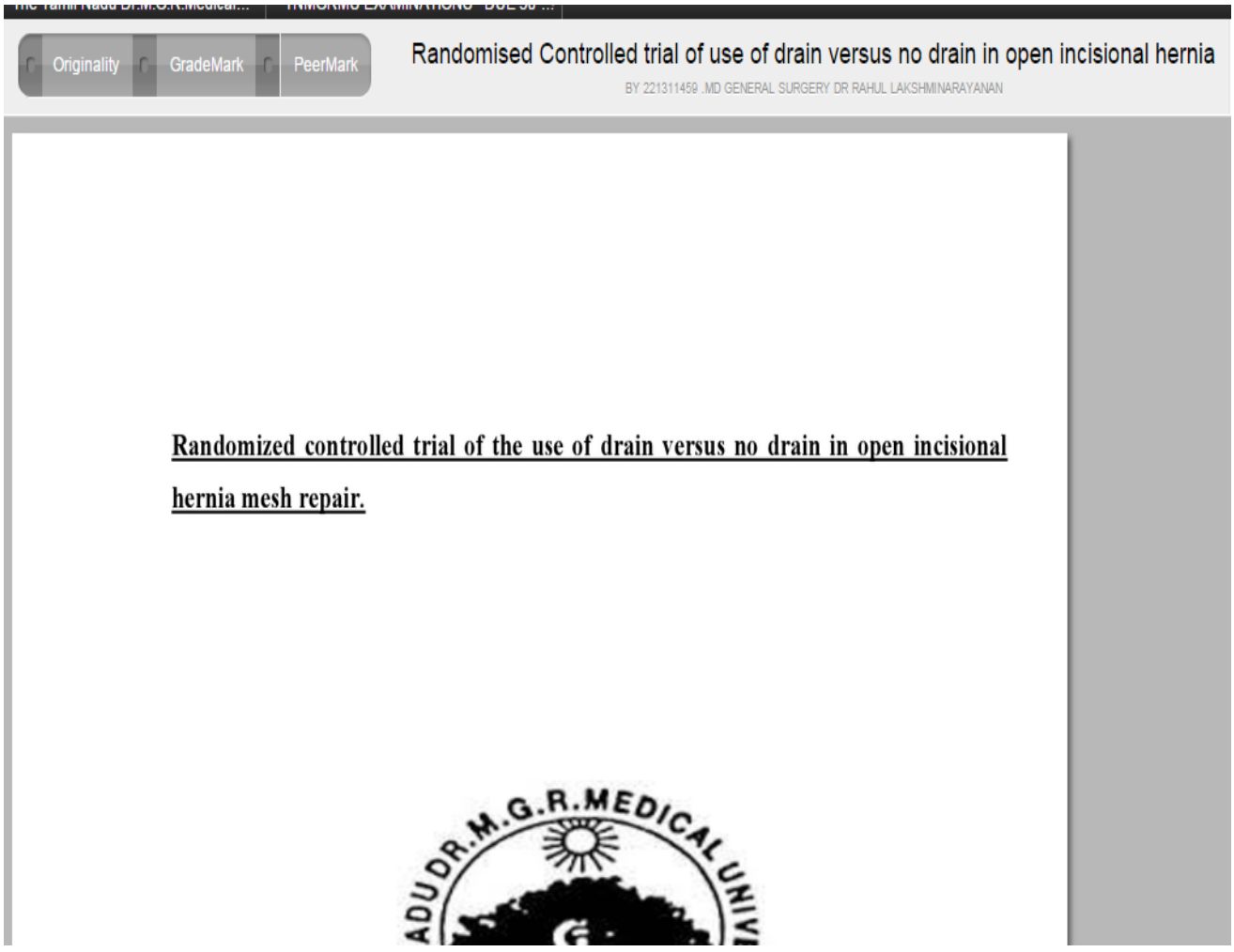
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Additional Vice Principal (Research)

February 12, 2014

Dr. Rahul Lakshminarayanan
PG Registrar
Department of Surgery
Christian Medical College
Vellore 632 004

Sub: **Fluid Research grant project:**
Randomised Controlled Trial of use of drain vs no drain in open incisional hernia mesh repair.
Dr. Rahul Lakshminarayanan, PG Registrar, Surgery, Dr. Sukria Nayak, General Surgery Unit 4, Dr. Suchita Chase, Dr. Rajesh J Selvakumar, General Surgery Unit.

Ref: IRB Min. No 8520 [INTERVEN] dated 30.10.2013

Dear Dr. Rahul Lakshminarayanan,

I enclose the following documents:-

1. Institutional Review Board approval
2. Agreement

Could you please sign the agreement and send it to Dr. Nihal Thomas, Addl. Vice Principal (Research), so that the grant money can be released.

With best wishes,

Dr. Nihal Thomas
Secretary (Ethics Committee)
Institutional Review Board

Dr. NIHAL THOMAS
MD.,MNAMS.,DNB(Endo),FRACP(Endo),FRCP(Edin),FRCP(Glasg)
SECRETARY - (ETHICS COMMITTEE)
Institutional Review Board,
Christian Medical College, Vellore - 632 002.

Cc: Dr. Sukria Nayak, General Surgery Unit 4, CMC

Ethics Committee Silver, Office of Research, 1st Floor, Carman Block, Christian Medical College, Vellore, Tamil Nadu 632 002.
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Ref: IRB Min. No 8520 [INTERVEN] dated 30.10.2013

Dear Dr. Rahul Lakshminarayanan,

The Institutional Review Board (Blue, Research and Ethics Committee) of the Christian Medical College, Vellore, reviewed and discussed your project titled "Randomised Controlled Trial of use of drain vs no drain in open incisional hernia mesh repair." on October 30th 2013.

The Committee reviewed the following documents:

1. IRB application format
2. Curriculum Vitae' Drs. Rahul Lakshminarayanan, Sukria Nayak, Suchita Chase, Rajesh J Selvakumar
3. Proforma
4. Information sheet (English, Hindi, Bengali & Tamil)
5. Letter of Consent
6. No of documents 1-5

The following Institutional Review Board (Research & Ethics Committee) members were present at the meeting held on October 30th, 2013 at 9.45 am in the CREST/SACN Conference Room, Christian Medical College, Bagayam, Vellore 632002.

Ethics Committee Silver, Office of Research, 1st Floor, Carman Block, Christian Medical College, Vellore, Tamil Nadu 632 002.
Tel : 0416 - 2284294, 2284202 Fax : 0416 - 2262788, 2284481 E-mail : research@cmcvellore.ac.in

Name	Qualification	Designation	Other Affiliations
Dr. George Thomas	MBBS, D Ortho, PhD	Orthopaedic Surgeon, St. Isabella Hospital, Chennai, Chairperson, Ethics Committee, IRB.	External, Clinician
Dr. B. Poonkuzhali	M Sc, PhD	Professor, Haematology, CMCH.	Internal, Basic Medical Scientist
Dr. Asha Mary Abraham	MBBS, MD, PhD	Professor, Virology, CMCH.	Internal, Clinician
Dr. Molly Jacob	MBBS, MD, PhD	Professor, Biochemistry, CMCH.	Internal, Clinician
Dr. B.S. Ramakrishna	MBBS, MD, DM, PhD, FAMS, FA Sc, AGAF, FNA	Retired Professor, Vellore	External, Clinician
Dr. Anuradha Bose	MBBS, DCH, MD,MRCP, FRCPCH	Professor, Child Health, CMCH.	Internal, Clinician
Dr. Biju George	MBBS, MD, DM	Professor, Haematology, CMCH.	Internal, Clinician
Dr. Vinod Joseph Abraham	MBBS, MD, MPH	Professor, Community Medicine, CMCH.	Internal, Clinician
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Rev. Dr. T. Arul Dhas	M.Sc, BD, DPC, PhD (Edin)	Chaplaincy Department, CMCH.	Internal, Social Scientist
Dr. Suresh Devasahayam	BE, MS, PhD	Professor of Bio-Engineering, CMCH.	Internal, Basic Medical Scientist

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Dr. Jayaprakash Muliyil	B. Sc, MBBS, MD, MPH, Dr PH (Epid), DMHC	Retired Professor, Vellore	External, Scientist & Epidemiologist

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Dr. Nihal Thomas	MD MNAMS DNB(Endo) FRACP(Endo) FRCP(Edin) FRCP (Glasg)	Secretary IRB (EC)& Dy. Chairperson (IRB), Prof. of Endocrinology & Addl. Vice Principal (Research), CMC.	Internal, Clinician

We approve the project to be conducted as presented.

The Institutional Ethics Committee expects to be informed about the progress of the project, any **adverse events** occurring in the course of the project, any **amendments in the protocol and the patient information / informed consent**. On completion of the study you are expected to submit a copy of the **final report**. Respective forms can be downloaded from the following link: http://172.16.11.136/Research/IRB_Polices.html in the CMC Intranet and in the CMC website link address: http://www.cmch-vellore.edu/static/research/Index.html.

Fluid Grant Allocation:

A sum of 80,000 INR (Rupees Eighty Thousand only) will be granted for 2 years.

The trial need to be registered with Clinical Trial Registry India (CTRI) http://ctri.nic.in before commencing.

The study will need to be submitted to a three monthly data-safety monitoring board (DSMB) review with duly filled in form found in the link http://172.16.11.136/Research/IRB_Polices.html

In case of adverse event, it has to be reported to the IRB Compensation Committee with duly filled in SAE format addressed to Dr. Denise Fleming, Clinical Pharmacology, CMC as a hard copy. The soft copy addressed to saeclinpharm@gmail.com and copy to research@cmcvellore.ac.in.

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To apply for Hospital Insurance, kindly contact Mr. Samuel Abraham, Senior Legal Officer, Personnel Department, CMC. The Special Contingency Insurance Policy Schedule (October 2013 – September 2014) can be downloaded from the following INTRANET LINK: http://172.16.11.136/Research/ > CMC Research > Insurance coverage scheme – Clinical Trials within CMC > October 2013 – September 2014. INTERNET link: http://www.cmch-vellore.edu/static/research/Index.html > CMC Research > Insurance coverage scheme – Clinical Trials within CMC > October 2013 – September 2014.

Yours sincerely

Dr. Nihal Thomas
Secretary (Ethics Committee)
Institutional Review Board

Dr. NIHAL THOMAS
MD.,MNAMS.,DNB(Endo),FRACP(Endo),FRCP(Edin),FRCP(Glasg)
SECRETARY - (ETHICS COMMITTEE)
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Christian Medical College, Vellore - 632 002.

Cc: Dr. Sukria Nayak, General Surgery Unit 4, CMC

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It gives me pleasure to express my gratitude to my respected teacher and guide Dr Sukria Nayak for his valuable guidance, support and encouragement in carrying out this study.

I am also indebted to my co-investigators in Surgery Unit 4, Dr Suchita Chase and Dr Rajesh Joseph Selvakumar, who have guided and helped me throughout the study.

I am also grateful to all teachers in the Department of Surgery, especially in Surgery Unit 4, for the guidance, support and suggestions I received while preparing this dissertation.

I am grateful to Dr KJ Selvaraj, who was instrumental in the initial randomisation and help with regards to the design of the study and to Mr Bijesh Yadav (both from the Department of Biostatistics) who subsequently helped me with the data analysis.

I am thankful to all my patients for their kind co-operation.

Randomized controlled trial of the use of drain versus no drain in open incisional hernia mesh repair.

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INTRODUCTION

INTRODUCTION

Incisional hernias are protrusion of abdominal contents through weakness in the scar of the abdominal wall, following any abdominal operation. They may be primary or recurrent.

They commonly occur due to pre-existing risk factors which include age, obesity, chronic obstructive pulmonary disease (especially emphysema), diabetes mellitus, smoking, drug intake around the time of surgery (like steroids), infection at the surgical incision site.

These can be repaired surgically by different methods. For incisional hernias with less than 3cm defect primary suturing can be done. For defects of more than 3 cm, mesh hernioplasty is usually done: which can be by sublay / onlay / inlay/ intraperitoneal methods. Onlay method implies placement of a mesh over the anterior rectus sheath and suturing it in place. Sublay method implies placement of mesh behind the rectus muscle (either retro rectus or preperitoneal). Inlay is used for bridging the defect with the mesh. Intraperitoneal is placement of mesh deep to the peritoneal layer, which is usually done as Laparoscopic method. Other method for inadequate anterior wall musculature includes component separation technique.

The prosthetic materials available for incisional hernia repair may be of Biological or Synthetic type. Because of various factors, like the increased cost and non- availability, the biological mesh use is very less. The synthetic materials are used more frequently. Available synthetic meshes include polypropylene (Prolene, Marlex), expanded PTFE (Gore-tex) and polyester. Prolene mesh is the most commonly used material in our institute for open repair of incisional hernias.

Regardless of the technique employed in open repair of incisional hernias the use of drains is almost universal, especially for large hernias. Insertion of drain is usually to evacuate the blood and fluid collection, which might happen in the potential space created, and to allow tissue apposition and better healing. Hence traditional teaching tells us that drains reduce the accumulation of fluid and blood, which reduce the incidence of postoperative hematoma, seroma and wound infection, and there by reduce the recurrence of incisional hernia.

However, many have found no discernable benefit of the insertion of drains, while others have in fact found a better outcome without the insertion of drains. The proponents of no-drain insertion also argue that the complications of inserting a drain can be avoided. The complications associated with insertion of drain include: drain blockage, fracture of drain, irritation, pain, decreased mobility, prolonged hospital stay, allowing a tract for introduction of wound infection, erosion into vascular or neural structures, skin flap necrosis, visceral herniation from drain tracts, loss of fluid and electrolytes, and rarely intra-coelomic migration of drain fragments.

The main purpose of the study is to assess the outcome of patients undergoing open incisional hernia mesh repair, with and without the use of drains. The patients will be randomized into 2 groups – With and without the use of drains. The patients will undergo open incisional hernia mesh repair by a standardised method. The outcome of seroma formation, hematoma formation, infection at surgical site, and duration of hospital stay will be recorded and analysed.

AIMS AND OBJECTIVES

AIMS AND OBJECTIVES

Aim of the study:

The aim of the study is to assess the outcome of drain placement Vs no drain use, in patients undergoing open mesh repair of incisional hernias in the Department of General Surgery, Unit 4.

Primary objective:

To assess and compare the occurrence of seroma, hematoma and wound infection in the two groups**.**

Secondary objective:

To assess and compare the duration of hospital stay in both the groups.

LITERATURE REVIEW

LITERATURE REVIEW

History of incisional hernia repair

Since the dawn of history hernias or ‘ruptures’ have been of interest to surgeons. More commonly groin and umbilical hernias. Only in the second half of the nineteenth century, after the advent of general anaesthesia and the practice of abdominal surgery, the incidence of incisional hernia or ‘post-operative eventration’ (as it was called then) have been documented. In response to this frequent clinical problem different techniques were being developed and employed. Historically there have been numerous mentions about the importance of the integrity of the abdominal wall and the steps advocated in preventing its disruption during abdominal operations.

Descriptive anatomy of the anterior abdominal wall has dated back to as early as the Egyptian civilisation 6000 years ago, to the Ebers papyrus , where there was a description of abdominal swellings and tumours with a description of epigastric hernias.[1]

There was only a passing mention of hernias in the Corpus Hippocraticum without any mention of treatment, although there are suggestions that the texts may be incomplete. The first mentions of incisional hernias in the Greco-roman era come from Celsus in the first century AD, who described gastrorrhaphy (from the Greek ‘gastir’ meaning the abdomen and ‘rhaphy’ meaning suture). Celsus advocated closure of abdominal wall in 2 layers. A century later Galen of Pergamon described in detail two methods of abdominal wall closure: (i) where abdominal wall was closed in a

single mass layer and (ii) where the abdominal wall closed in many layers – apposing like tissue to like. He also included a detailed description of paramedian incisions, which were less prone to incisional hernias. It is to be noted that several decades later the same methods of gastrorrhaphy were used by Antoine Vesalius and Ambrose Pare for abdominal wall closure.[2]

During the 1700s, although there were descriptions and operations being done for hernias and particularly incisional hernias, the majority of operations had adverse outcomes. In France, Le Chausse in his dissertation 'le Hernia Ventralis' classified ventral hernias based on position. There were numerous descriptions of incisional hernias in this period by de Garengeot and August Richter.

The first incisional hernia repair was described and carried out by Pierre Nichollas Gerdy in 1836. This was followed forty years later, by the first detailed treatise on hernias by Greensville Dowell titled 'A Treatise on Hernia with a New Process for Its Radical Cure'.

Since the onset of anaesthesia by Morton in 1846 and antisepsis by Joseph Lister in 1865, abdominal surgery became more survivable, and thus the incidence of incisional hernias also started increasing. In Modern times there have been more than 2000 peer reviewed articles about incisional hernia. The repair of incisional hernioplasty has evolved from suture repair to organic autoplasty or heteroplasty to the current era of using prosthetic and even biosynthetic materials. Suture repair by Keel method as proposed by Maingot in 1954 was successful for smaller hernias primarily, while auto or heteroplasty generally gave unsatisfactory results. The initial

prosthetic materials included braided silver wire and stainless steel meshes. Later tantalum gauze was also used. As these materials became scarce during World War II, manufacturers had to resort to developing plastics and polymers, which fortunately have come to be immensely useful in hernia repair.

The principles of abdominal wound closure by Jenkins have also contributed to the reduction of incisional hernia occurrence, whereby the rule of suture length to abdominal incision in a ratio of 4:1 with bites 2 cm from the fascial edge and 2 cm apart are applicable and still used for routine closure of abdominal incisions.

Irrespective of the type of abdominal closure used, the incisional hernias occurred in the past and do occur in the present era too.

Van't Riet et al. showed that any type of wound dehiscence led to an incisional hernia in 69% of patients at 10 years of follow-up[3]. They also looked at fascial closure in a similar meta-analysis which showed that the incidence of incisional hernia did not differ much whether delayed absorbable or nonabsorbable sutures were used. They also concluded that non-absorbable sutures were associated with more post-operative pain.

Incisional hernia

A hernia is classically defined as a protrusion of whole or a part of a viscus through an opening in the wall that contains it. This may apply to structures like the brain or even muscle. Most commonly the hernia as seen by a general surgeon is usually a protrusion of an abdominal viscus or omentum through the abdominal wall.

There are many varieties of hernias: the common varieties include inguinal, femoral and ventral hernias: which include para-umbilical, epigastric and incisional hernias.

Incisional hernias are out pouching of abdominal contents through weakness in the abdominal wall following surgery. over the same site [4]. The global incidence of incisional hernias has been described to be around 13-20% of all laparotomies[5]. Some studies mention the rate of 5-11 %, but the true incidence remains variable from centre to centre.

An ongoing meta-analysis by Gurusamy et al analysing the comparison of drains versus no drains in the repair of incisional hernias mentioned the incidence of incisional hernioplasties following laparotomies to be in the range of 5-11 % [6].

The Indian incidence is not known as there are no studies or long term follow up in this regard, on the incidence of incisional hernia or the outcome following their repair.

The usual incidence of incisional hernias occur around 6 months to one year after any operation, but majority of studies did not have long term follow up, thus the assumption that the incidence of incisional hernias might be grossly underestimated is not unfounded[7] .

The predisposing factors also have been reported as having significant variations according to several studies. It has been classically described that the majority of incisional hernias occur due to risk factors like elderly age, female sex, multiple laparotomies, history of previous wound infection, co morbid conditions like

diabetes mellitus, obesity, chronic obstructive pulmonary disease, malnutrition, the use of steroids, and prior history of wound infection following the initial operation. There have been studies assessing the incidence of incisional hernias following patients who have had wound dehiscence following the initial laparotomy, which showed a higher incidence of incisional hernias following abdominal aortic aneurysm surgery (84%) and following wound dehiscence with evisceration (78%)[3].

In obese patients, weight loss is very helpful prior to any subsequent repair and should strongly be considered prior to ventral hernia repair. Weight loss makes the surgery easier, because excess skin and fat can be excised, closure becomes much easier, and the eventual result is aesthetically more pleasing to the patient. As there is a decreased intra-abdominal pressure after significant weight loss, this is also thought to be a contributing factor. [8] Loss of domain after these operations is also thought to be a factor resulting in increased abdominal pressure post-operatively, thus increasing the risk of incisional hernia recurrence. [5]

Left alone the incisional hernia's natural history is such that it will grow in size and lead to complications. So with more delay in repairing the same, there is also a proportional increase in the complexity of the surgical repair, and the complications and morbidity associated with such a repair. Complications include incarceration and strangulation of viscera, atrophy of the subcutaneous tissues, thinning and ulceration of the overlying skin, and loss of domain of the viscera. In addition, the lateral abdominal muscles become atrophic, retract, thus making the hernia defect wider. All of these factors complicate any method of repair and increase the chance of repair failure, prosthetic infection, and wound problems[8].

Methods for repair

There are numerous methods of repair of incisional hernias. The classically described methods include Primary Suturing – which is described for incisional hernias which have a defect of less than 3 cm and which can be apposed with sutures.

However, recurrence of hernia after suture repair alone is high, while mesh repair in the United States gives recurrence rates usually in the 20% to 30% range. Luijendijk et al. Carried out a randomised controlled prospective trial which showed that, regardless of the size of the defect, mesh repair for incisional hernia repair was superior to suture repair. In fact, the 10-year cumulative rate of recurrence was 63% for suture repair and 32% for prosthetic repair [9].

Mesh/ prosthetic repair of incisional hernia has been recommended as the treatment of choice in incisional hernia repair following the dramatic reduction in the incidence of recurrence as reported by Burger and Luijendijk et al [9]. Available meshes include polypropylene (Prolene, Marlex), expanded polytetrafluoroethylene - PTFE (Gore-tex) and polyester. The most commonly used meshes include polypropylene and polytetrafluoroethylene. For meshes to be placed within the abdomen, PTFE is preferred as they cause a lesser degree of adhesions and fistulisation when placed in contact with the bowel. Biological mesh is another alternative to use for intraabdominal placement. However, it is not easily available and due to the high cost, it is not the preferred material for use in incisional hernia repair.

Onlay repair (also known as the pre-fascial prosthetic technique or the Chevrel technique) is done by placing a prosthetic mesh (polypropylene or PTFE) over the defect with adequate overlap all around the defect and suturing it to the anterior rectus sheath or external oblique muscle beyond the boundaries of the defect. The mesh therefore lies in a plane deep to the subcutaneous fat and superficial to the anterior rectus sheath. This was seen to have wound complication rates of 4–26%, 2.5–13% recurrence rate and mortality up to 2.7%. Avoidance of onlay methods has been recommended because of minimal tissue incorporation of the prosthesis , excessive tension on the repair , and a possible increase in the risk of seroma and infection[10].

The **Inlay** method of repair involves the use of mesh for repair of abdominal walls that are deficient or difficult to close. This involves the dissection of the sac, reduction of the contents followed by sac closure. The prosthetic mesh is sutured to the rectus sheath, end to end, to bridge the defect. This sort of repair is usually associated with tension in suture line and leads to inadequate tissue apposition, which leads to high percentage of recurrence. Hence, this type of repair has gained disrepute and has been mostly given up by the surgeons.

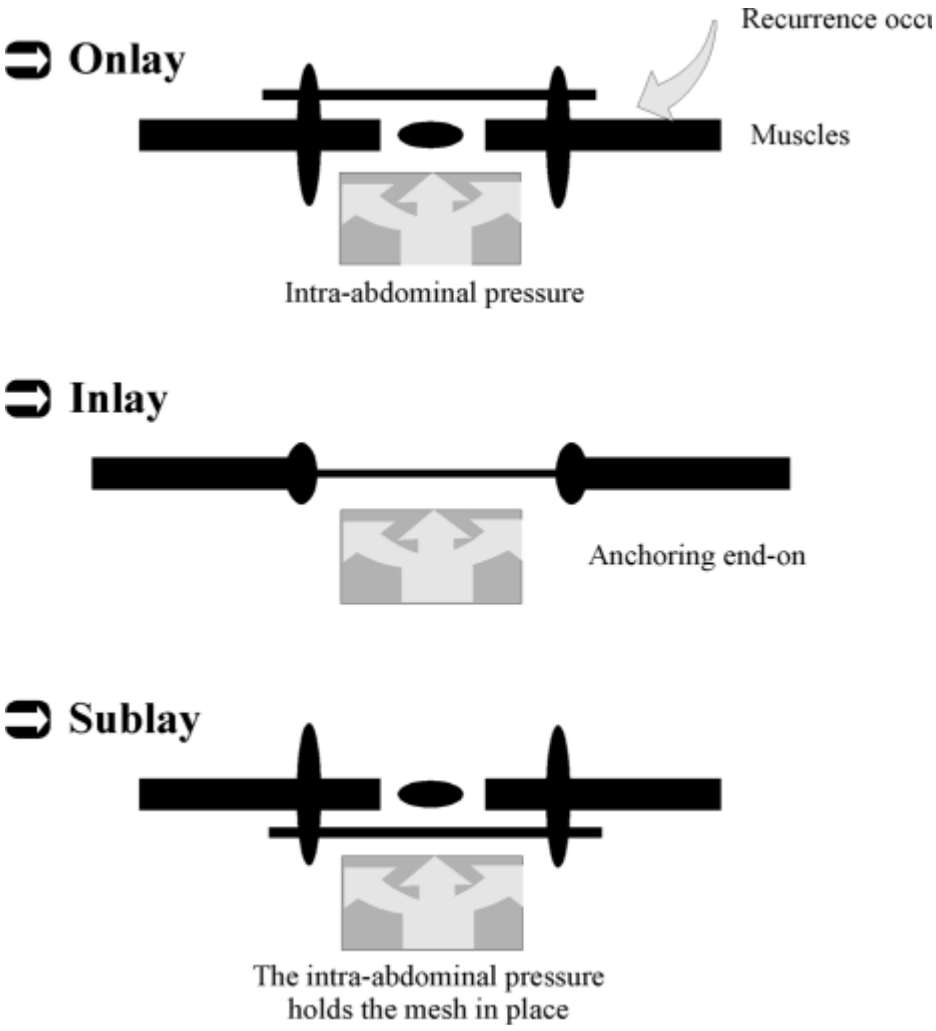


Figure 1:Methods of placement of mesh in incisional hernia repair [5]

The **Sublay** repair (also known as the subfascial prosthetic technique) involves placement of the mesh deep to the rectus sheath in one of the following three planes:

1. Between the anterior rectus sheath and the rectus muscle,
2. Between the rectus muscle and the posterior rectus sheath,
3. Between the posterior rectus sheath and the fascia transversalis, in the pre-peritoneal plane.

This is followed by closing the anterior rectus sheath over the mesh to ensure that there is no contact between the subcutaneous plane and the mesh. The sublay method of repair uses the Pascal's principle, whereby it is proposed that intra-abdominal pressure acts against the mesh to hold it in place against the anterior rectus sheath (which is the strongest layer in the anterior abdominal wall). The sublay technique gives results ranging from 1–49% wound complications, 2–23% recurrence rate and mortality up to 4.5%.[8]

The Rives-Stoppa-Wantz retro-rectus repair is a subtype of the sublay method of mesh repair and involves the placement of the mesh deep to the rectus muscle and superficial to the posterior rectus sheath (where present) or deep to the rectus muscle and superficial to the fascia transversalis (where the posterior rectus sheath is deficient)[10]. Recurrence rates in previous studies of Rives-Stoppa repairs range from zero to approximately 4%. Postoperative infections occurred in 0–18% of patients.

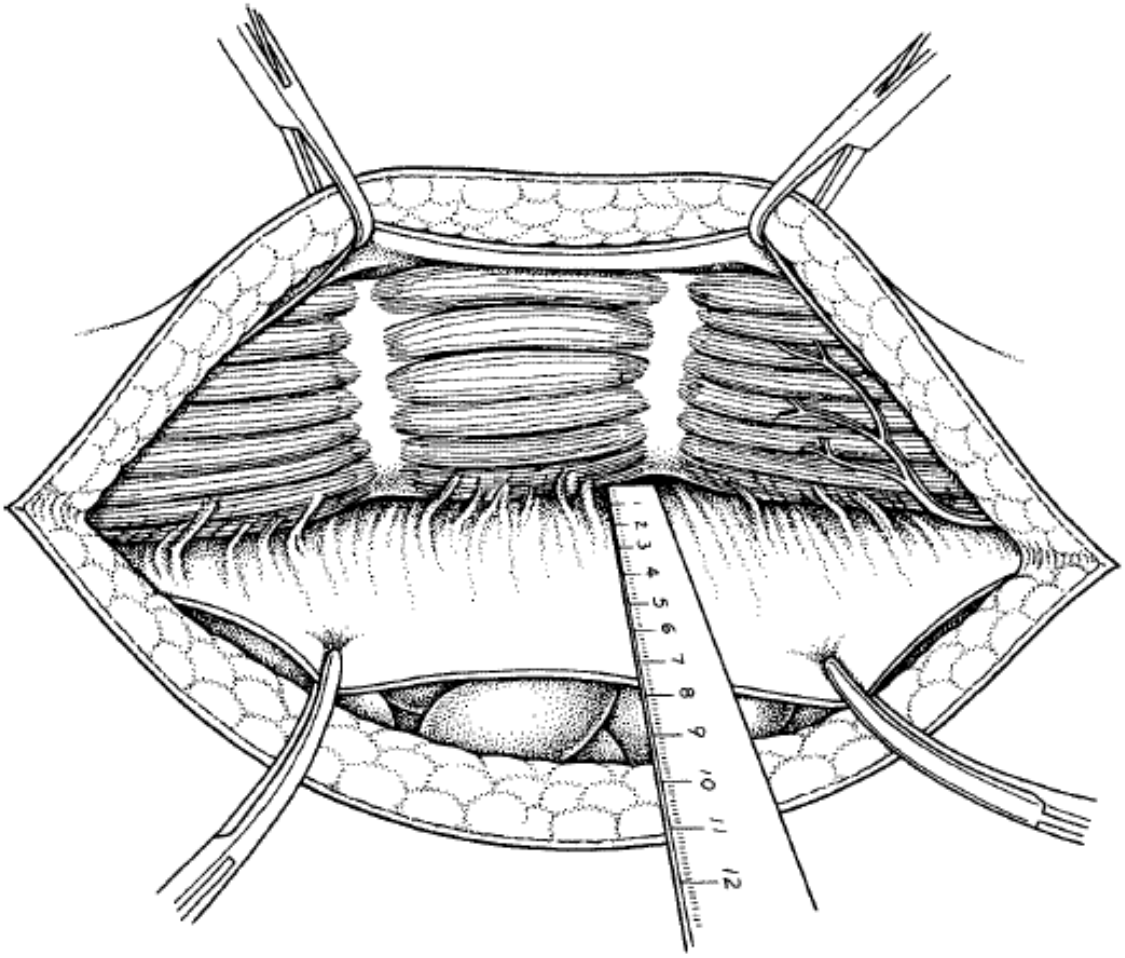


Figure 2 : Plane of mesh placement in Rives-Stoppa repair [10]

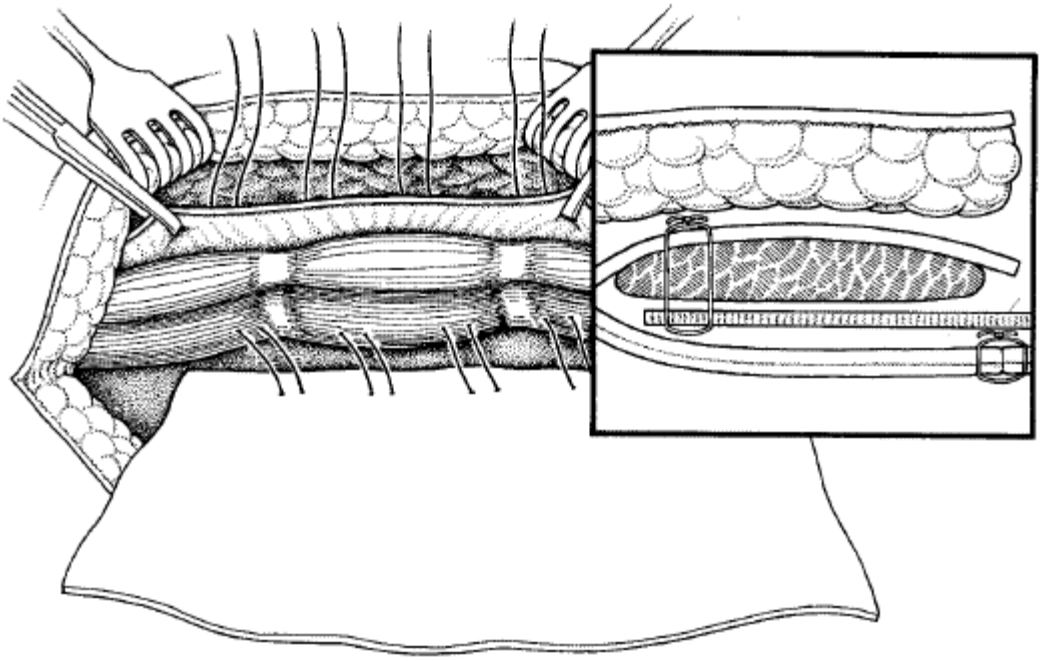


Figure 3 : After mesh placement in Rives - Stoppa repair [10]

The **Underlay** or intraperitoneal repair is done by placement of a dual sided mesh (with outer side formed by polypropylene and the inner peritoneal side formed by PTFE) intraperitoneally and fixing it to the anterior abdominal wall by using non absorbable synthetic sutures as shown in figure 3.

The **Laparoscopic approach** to ventral and incisional hernia repairs applies the underlay type of repair. Using the laparoscopic approach, a large prosthetic mesh is placed deep to posterior fascia or peritoneum), overlapping beyond the defect by several centimetres in all directions. With this technique, there is no need for the extensive soft tissue dissection seen in the open approach and its attendant complications[11]. This type of repair has gained popularity because of the advances in laparoscopic instruments and easy availability of synthetic dual side mesh and anchoring materials.

Additional methods are available as adjuncts when simple repair is inadequate or closure is not possible, because of tissue loss. The methods available include: Component separation method, and local flaps or free flaps.

The use of autologous tissue to repair abdominal wall hernias has also been described, but mainly used in the pre-mesh era. The tensor fascia lata, Sartorius and rectus femoris can be used as either free flaps or pedicled flaps to close large defects. However, the lack of sufficient tissue may require the insertion of prosthetic material or transposition of autologous material to bridge the fascial gap. These types of repairs were practised before the era of synthetic mesh use.

In 1990 Ramirez described a method of abdominal wall reconstruction without the use of a mesh. This method was initially described by a plastic surgeon and involved the enlargement of the abdominal wall by movement of the muscle layers. This method has a lot of application in the closure of a difficult abdomen. The first step is to dissect the skin and fat off of the muscles to a distance of about 5 cm lateral to the lateral border of the rectus. An incision is then made in the rectus sheath and the rectus muscle is dissected off of the posterior sheath. The next step is to incise the aponeurosis of the external oblique muscle 1 to 2 cm lateral to the lateral border of the rectus muscle for the entire length till the part extending superiorly. The external oblique muscle is separated from the internal oblique up to the midaxillary line. The rectus fascia is then closed in the midline. This allows advancement of the rectus 3 to 5 cm in the upper abdomen, 7 to 10 cm in the mid abdomen, and 1 to 3 cm in the lower abdomen. The recurrence rate following this procedure was 32% and wound

complications occurred in a similar number. Thus it is concluded that this method for ventral hernia repair may be best used in the contaminated situation where the use of a mesh may not be safe. [8]

Abdominoplasty or panniculectomy is a cosmetic procedure often used in obese patients with redundant fatty apron. This has been used along with incisional hernia repair in obese patients, in whom there is significant redundant abdominal fat. The abdominoplasty involved the use of a transverse suprapubic incision at the superior aspect of the pubic tubercle till the anterior superior iliac spines or the use of an inverted t incision with the vertical limb in the midline. Following plication of the rectus diastases or the incisional hernia repair, the sufficient flaps of skin and subcutaneous fat were excised, the umbilicus was repositioned and closure was carried out with subcutaneous vicryl and monocryl for skin closure. The main complications following these include seroma, hematoma, infection, wound-healing problems, and skin flap necrosis[12].

Complications following incisional hernia repair

The known complications following incisional hernia repair include seroma formation, hematoma formation, surgical site infections, mesh infections, recurrence , adhesions of bowel or omentum to exposed mesh, bowel injury , bowel obstruction , fistulation of bowel, and rarely, respiratory compromise following reduction of large incisional hernias with significant loss of domain.

The incidence of seroma formation following open incisional hernioplasty have been found to vary from 4-21 % [5 13 14]. It is assumed that they occur due to serum and lymph leak, but also to some extent they are contributed to by the liquefied fat following use of electrocautery as a method dissection [15]. In several cases the seroma develops due to the presence of a dead space where fluid from the raw surfaces as well as unoccluded lymphatics and blood vessels can leak and form a collection at the surgical site. In most cases, they resolve over a period of few weeks to 3 months [10]. Some studies have advocated on the placement of drains to reduce their incidence [16]. In a few instances there have been infections to pre-existing seromas, complicating the wound healing resulting in readmission and prolonged hospital stay[13]. Seromas have been found to be almost double in cases where the onlay method of mesh repair has been used [14].

The incidence of hematomas vary from 1.5-9.6 %.[7, 15] following incisional hernia repair. The incidence of hematomas were found to occur more with sublay method of mesh repair, as the risk of damage to perforators to the rectus muscle[10] and as well as the complexity of the operation was more [5].

The incidence of infections following incisional hernia repair vary from 2% to 15 % [5,13,13]). These infections varied from superficial to deep wound infections. The manifestation may vary from erythema with tenderness, discharge; wound gaping to abdominal wall dehiscence. The follow up period was in-homogenous in the various studies evaluated. This remains the more serious among the common wound complications following incisional hernia repair, as the extension of the infection to the peri-prosthetic space would entail eventual removal of the mesh and recurrence of the hernia.

Recurrence following incisional hernia repair still remains a potential problem on long term follow up of these patients. The recurrence rates vary depending on the period of follow up and are usually a late complication following incisional hernia repair. Studies have reported recurrence rates from 2.9 - 21 % [145,16].

The incidence of bowel injury, adhesions and fistulation vary depending on the method of mesh repair used, as also the mesh material used. Varying studies mention incidence of 2-4%[15,16] . They are seen more often following inlay mesh repair, as there is contact of abdominal visceras with the mesh, which act as foreign bodies.

In a study by Kingsnorth et al, who assessed the effect of loss of domain in the post-operative period, the risk of respiratory compromise was explained. When this occurs ventilatory support will be required to manage for recovery[5].

Seroma occurrence in other operations

The incidence of seroma following mastectomy and breast conservation surgery has been looked into in several studies. In summation, the cause of seroma formation has not been clearly elucidated, but is presumed to be due to exudates in response to the trauma of surgery and the acute inflammatory reaction which is a part of the process of wound healing. Some studies have described that the amount of seroma formation depends on the number and extent of lymph node involvement.[17] While other studies have found that the only statistically significant predictor of seroma formation was the type of surgery done – that is, whether a mastectomy was done or a wide local excision with Axillary lymphadenectomy. They found that the incidence of seroma following a mastectomy was more than from other surgeries. No other factors, such as age, obesity, tumour size, neo-adjuvant therapy influenced the incidence of seroma formation [18, 19]. In mastectomies, it was found that damaged blood vessels and lymphatics continually oozed blood and lymphatic fluid contributing to a seroma more in mastectomies and extensive dissections than it did for breast conserving surgeries. [20]

It was found that seroma accumulation elevated the chest flaps resulting in decreased adherence to the chest wall. The results may include wound hematoma, flap necrosis, delayed wound healing, dehiscence, prolonged hospitalisation. Some studies found a delay in initiation of adjuvant treatment while other found no associated delay. [21]

Types of drains

A drain describes any material or equipment placed in a potential space within the body and usually brought out through a narrow opening on the skin surface to allow drainage of fluids accumulating in the space, allow tissue apposition and ensure faster healing rates. Allowing unwanted fluid or blood to remain in a wound may be a potential source of infection and may also impede healing, or result in wound breakdown and dehiscence[6].

There are a variety of drains available for use in different operations. Broadly wound drains are classified as closed or open drainage system.

Closed drains are constructed so as not to expose the contents to the atmosphere. They include vacuum drains which apply negative pressure such as the Jackson-Pratt, Vario, Romovac drain, or non-vacuum systems such as the T-tube drain or the Robinson system. The use of a closed drainage system lowers the risk of infection tracking into the potential space, avoids soiling and leaves the skin surface dry, easy to manage and reduces staff contact with body fluids.

Open drains allow communication of the potential space with the atmosphere. These drains include corrugated sheet, Penrose and sump drains. Open drains are inserted directly into the wound bed through a separate opening in the body or through the incision itself. As they have an open end there is more potential for infection than in a closed drainage system. Open drains are usually secured by a suture or may have a safety pin attached close to the skin.

The use of drains in incisional hernia repair

When repairing incisional hernias, the traditional practice involved to place drains to facilitate drainage of fluids which may collect in the potential space at the site of operation[22]. Following the incisional hernia repair, usually the preferred drain of choice is a closed drain, primarily because it is a closed system and the chance of infections entering the wound are lesser compared to the use of open drains. A closed drain is an artificial conduit that is left in the wound to allow drainage of fluids into a closed container. Presently, more than 50 % of the wounds following open incisional hernia repair have drains inserted[14].

There have always been proponents for the use of drains following incisional hernioplasties and those who disagree that the routine use of drains has any additional benefit to the patients' outcome. The proponents believe that all incisional hernias require drain placement to reduce the incidence of seromas or hematomas[22]. They also state that following incisional hernia repair, the occurrence of collections like hematomas predispose to recurrence.

On the other hand there are surgeons who believe that the routine use of drains does not alter the rate of fluid collections[14], or influence in hernia recurrence[23]. The occurrence of seromas can occur from 1 week to as much as 3 months after incisional hernia repair[10] , while drains are removed usually within 3-10 days of the surgery. There is also the assumption that the longer drains are left in place, the more is the

chance of introducing infections into the wound[24],[14]. Bauer et al were very categorical in their recommendations that the routine use of subcutaneous drains at the time of surgery appears to have no effect on the complication rate. Seromas (19%) were the most common complications associated with incisional hernia repair, and virtually all seromas resorbed within weeks to 3 months following the operations.

A meta-analysis to look for previous studies comparing the use of drains in incisional hernia repair by Gurusamy et al did not find any studies comparing the outcome of drain versus no drain in incisional hernia repair. They found a study by Shafik et al which compared two types of drains – and electrified versus a corrugated drain placement following incisional hernia repair. A subgroup analysis by White et al did show that drains did not have any additional benefit or reduction in wound complications[14] .

The use of drain in other surgeries

Following face-lifts, there has been literature showing the incidence of seromas in the immediate post-operative period, which are prevented from accumulation by the placement of drains.

Following mastectomies, there have been studies assessing the outcome of drain insertion following mastectomies [16]. Somers et al assessed the use placing axillary drains following lumpectomy as part of breast conservations therapy. They found that mean volume aspirated in patients in the non-drain arm was 266.1 ml as apposed to 146.3 ml in the drain arm. Also 26 % patients in the drain arm required no

aspirations as opposed to 10.9% in the non-drain arm. They also showed a 2.8 % incidence of infection following drain placement as opposed to a 10.1% incidence in the no drain arm.[25] Overall they had concluded that drain placement helped in reducing incidence of both seroma formations and infections following Axillary dissection and lumpectomy. In addition to the above, Scevola et al showed that following reconstruction following mastectomies with TRAM or DIEP flaps , the placement of 2 drains significantly helped in the reduction of seromas compared to only one drain placement.

A study by Tabaqchali et al failed to demonstrate that drainage in thyroid and parathyroid surgery was of any benefit to the patient. Other retrospective studies and randomised trials had also not shown any advantage in draining neck wounds following thyroidectomy or parathyroidectomy. The studies showed that drains neither prevented postoperative haematoma nor facilitated their early diagnosis. The diagnosis of wound haematoma was made by observing the neck and noticing a progressive collection under the skin, as often, the neck drains became blocked with blood clots and did not function. [26] They also noted that the wound infection rate of 1% only occurred in patients who had drains placed in the neck.

The use of drains following head and neck procedures (submandibular gland excisions, parotidectomies – superficial as well as total parotidectomies, thyroidectomise) has been standard practice to reduce the incidence of seromas or hematomas post-operatively [24].

There was a meta-analysis by Peng et al to assess the outcome following drain or no drain placement following pancreatic surgery. The studies considered had a high risk of bias and had low quality of evidence, but stated that there was inadequate evidence to establish the effect of drains on mortality at 30 days, mortality at 90 days, intra-abdominal infection, wound infection, morbidity, length of hospital stay, or additional open procedures for postoperative complications. There was one drain-related complication in the drainage group [27].

The meta-analysis by Charoenkwan et al, which looked at the rate of lymphocoele after pelvic lymphadenectomy following surgeries for gynaecological malignancy, also showed no significant difference in retroperitoneal tube drain placement. In fact it showed that leaving the pelvic peritoneum open resulted in reduced risks of lymphocoele formation[28].

Wang et al in a meta-analysis for gastrectomy found that there was no difference, between the two groups of - with drain and no-drain, in mortality; re-operations; post-operative complications ; wound infection; intra-abdominal abscess:; anastomotic leak; or initiation of soft diet. However, the addition of a drain prolonged the operation time and post-operative hospital stay and led to drain-related complications[29] .

Following colorectal surgery, there has been a meta-analysis which described that pelvic drainage reduced both the post-operative leak rate and the rate and need for intervention in patient of carcinoma rectum, following anterior resections with

eextraperitoneal colorectal anastomosis. [30] It was observed in a meta-analysis by Daams et al that although the routine placement of drains following colorectal surgery did not prevent the incidence of anastomotic leaks and had thus been removed from several enhanced recovery programs, there were two studies that showed that changes of the nature of drain effluent occurred frequently and before clinical symptoms. Thus they concluded that drain placement for the first few post-operative days may be beneficial to the prediction of anastomotic leak. [31]

JUSTIFICATION

The Null Hypothesis for the study was that the insertion of drains following open incisional hernia repair reduced the incidence of wound complications like seroma and hematoma formation, wound infections, but prolonged hospital stay.

According to a recent update of a meta-analysis looking into this very question, they were unable to select any randomized controlled trial with adequate blinding comparing 2 groups having undergone incisional hernia repair, with versus without the use of drains, but was able to find one study that compared two types of drains (corrugated drain versus electric drain). Majority of studies carried out about incisional hernia repair; compare the outcomes of laparoscopic versus open method of incisional hernia repair. In addition, recent studies comparing the biochemical characteristics of drain fluid versus seroma fluid drained at a later stage following discharge were able to state that characteristics of drain fluid are unique and differ from seroma fluid. This raises questions about the efficacy of post-operative drains in reducing the incidence of seromas in the post-operative follow-up period, or even long-term. For this reason, this study was devised to compare the outcome in open incisional hernia mesh repair alone, and assess the usefulness of drain insertion during the surgery.

MATERIALS AND METHODS

MATERIALS AND METHODS

Study type: Non-inferiority, non-blinded randomised controlled trial.

Study design: Randomised controlled trial.

Setting: Surgery 4 unit, Department of General Surgery, CMC Hospital, Vellore.

Study population: Patients admitted to Surgery Unit 4 during the period of the study.

Study period: From 14th April 2014 to 26th August 2015.

Inclusion Criteria:

1. Age >18 years of age
2. Patients giving consent for participation in the trial.
3. Patients pre-operatively planned for sublay or onlay method of open incisional hernia repair

Exclusion criteria:

1. Patients not willing to participate in the study
2. Pre-operatively planned for laparoscopic or underlay method of hernioplasty
3. Patients planned for abdominoplasty, panniculectomy or components separation method of repair in association with mesh repair.
4. Patients having associated enterocutaneous fistula

Withdrawal criteria:

Patients unwilling to continue participation in the study.

Sources of information:

1. Operation notes
2. Clinical evaluation pre and post-operatively
3. OPD Medical records
4. Telephonic follow-up

Outcome measures:

PRIMARY OUTCOME:

1. Incidence of seroma / hematoma formation
2. Incidence of Surgical site infections (as described by CDC classification of Surgical site infections)

SECONDARY OUTCOME:

1. To assess the hospital stay from operation time to discharge (as measured from the date of operation and not admission)

Statistical methods:

Data entry was done using the Epidata software version 3.1. Descriptive statistics were computed with use of the SPSS software (version 14). Sample size was calculated.

Data Analysis was done using SPSS software and p values were computed with Pearson's Chi square.

Sample Size estimation:

Target sample size and rationale: 120 patients.

Sample size: Seroma formation in

- 1. Previous study with drain - 23.3 % (n=86)~ 24 % = P
- 2. Previous study without drain – 7.7 % (n=26) ~ 8% = Q
- D= 16
- Formula: $[(Z_{\alpha} + Z_{1-\beta})^2 \times P \times Q] / d^2$
- 10.4 x 24 x 8 / 16x16 = 55
- Sample Size – 55 in each study arm = 110 total
- Considering drop-outs , Sample size = 120 total

With an α error of – 5%

Power of the study – (1-β) – 90 %

Methodology:

Step 1: Recruitment

All patients fitting the inclusion criteria for the study were recruited by the primary investigator using a consent form in one of 4 suitable languages commonly spoken among patients.

Step 2: Randomisation

Method of randomization**:** Computer Generated randomization list

Method of allocation concealment**:** Allocation sheet to be kept by impartial administrator (department secretary). Envelopes were collected by the junior registrars and interns and placed in the charts of the consented patients prior to being shifted to the operation theatre. The envelopes were opened at the completion of the mesh repair and prior to abdominal wall closure or skin closure as applicable. The randomisation was followed as per the allocation in the envelopes.

Blinding and masking: Allocation to be done by Dept of Biostatistics and allotment by envelopes with Department secretary. No blinding or masking. The randomisation envelopes were sealed.

Step 3: Data collection:

Data collection was done in the ward on day 3 by the primary investigator or the concerned registrars posted in the unit on a rotatory basis. On day 7-10, corresponding roughly to the 1st visit to the outpatient clinic on follow-up, the data was entered into the electronic medical records by scanning the follow-up sheet. And the data was obtained by viewing the EMR records.

The patients were planned for an ultrasound between 7-10 days, and necessary arrangements done.

Telephone numbers were obtained at the time of consenting the patients or from the admission records and the patients were followed up at approximately 30 days from the date of the operation to assess if they had any wound complaints.

Data collected:

Name

Hospital number

Age

Sex

Residence

Occupation

Phone no

Co morbidities: T2DM/ Sys HTN/ IHD/ CKD/ COPD/ Obstructive SAS/ BPH/ TB/ Malnutrition

H/o Smoking

If yes, No. of pack years

H/o Alcohol consumption

If yes, Amount per week

H/o Wound infection at previous surgical site

H/o Steroid intake

Weight

Height

BMI

Previous surgery done

Duration of incisional hernia

Size of defect

Type of repair done: Sublay/ Onlay / Other

Randomisation allocation

Drain placed or not?

Postoperative day 3: Seroma / Hematoma: Clinical swelling? If yes, fluctuant?

Intervention done?

If drained – Nature of collection

Surgical site infection: Redness?

Tenderness

Purulent discharge

Wound Gaping

The same repeated on Post-operative Day 7

Ultrasound finding and volume of collection

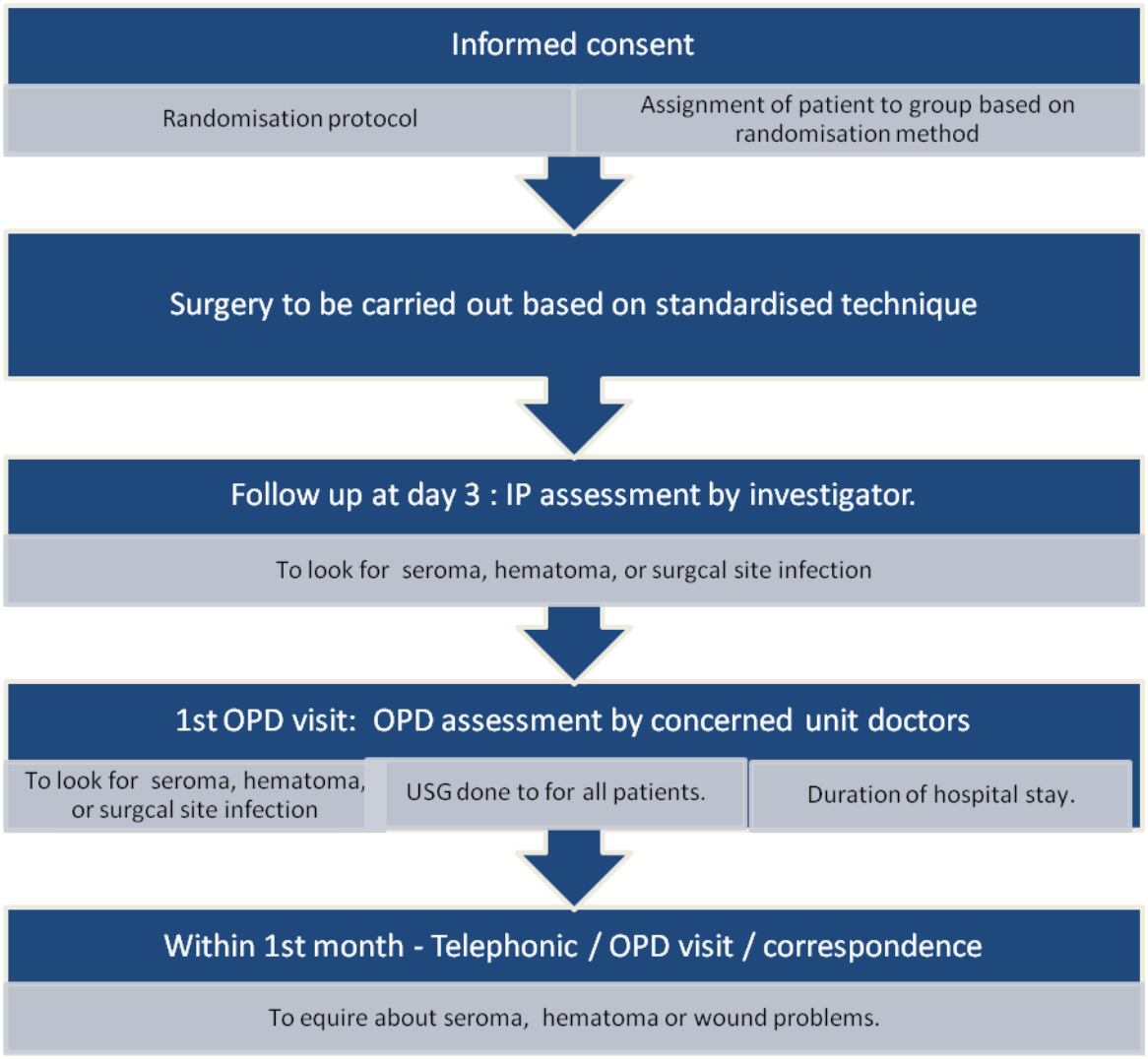
Day 30: telephonic follow up to assess the presence or absence of any wound complications.

Date of operation

Date of discharge

Duration of hospital stay

Detailed diagrammatic algorithm of the study:



Study protocol:

The study was designed to compare the outcome of drains versus no drain placement following incisional hernia repair. All eligible patients as per the inclusion and exclusion criteria were recruited. Every patient was given an information sheet which prescribed the study and its risk factors and proposed benefits. A detailed

history was taken and a physical examination done. The relevant risk factors of prior co-morbid illnesses, steroid intake and history of wound infections were taken.

They were randomised by picking an envelope which was numbered in serial order. The randomisation in the envelopes was done according to a computer generated randomisation list prepared prior to starting the study. The patients were randomised to drain placement or no drain placement.

Intraoperative procedure

- Open Incisional Hernia repair via incision over the defect.
- Plane to be created behind the rectus muscle (for sublay) and anterior to rectus sheath (for onlay).
- Polypropylene Mesh (Ethicon) to be used with a 5-6 cm extension beyond the defect.
- Linea alba to be closed by interrupted PDS.

  Vario Drain to be placed in the subcutaneous plane or above the mesh.
- Skin to be closed by 3-0 monocryl

Postoperatively, they were followed up in the ward by examination of the wound following dressing removal prior to discharge. In the out-patient department, they were reviewed at the first outpatient department visit. An ultrasound examination was done for patients who did not have wound gaping or intervention or a clinically

obvious seroma. There was telephonic follow up of any wound complications after being discharged home at post-operative day 30.

The outcomes of collection (seroma/ hematoma), surgical site infection and duration of hospital stay were recorded. The data collection was done in proformas.

Tools used:

1. BMI calculation was done using the standard Body mass Index formula [BMI = Weight (in kg) / Height^2 (in m)] and WHO approved classification of body mass index.

Table 1 : Who classification of body mass index[32]

Classification	BMI(kg/m^2)	
	Principal cut-off points	Additional cut-off points
Underweight	**<18.50**	**<18.50**
Severe thinness	<16.00	<16.00
Moderate thinness	16.00 - 16.99	16.00 - 16.99
Mild thinness	17.00 - 18.49	17.00 - 18.49
Normal range	**18.50 - 24.99**	**18.50 - 22.99**
		23.00 - 24.99
Overweight	**≥25.00**	**≥25.00**
Pre-obese	25.00 - 29.99	25.00 - 27.49
		27.50 - 29.99
Obese	**≥30.00**	**≥30.00**
Obese class I	30.00 - 34.99	30.00 - 32.49
		32.50 - 34.99
Obese class II	35.00 - 39.99	35.00 - 37.49
		37.50 - 39.99
Obese class III	≥40.00	≥40.00

2. CDC criteria for Surgical site infections

Centres for Disease Control and Prevention Criteria for Defining a Surgical Site Infection

Superficial Incisional

Infection less than 30 days after surgery

Involves skin and subcutaneous tissue only, *plus* one of the following:

- Purulent drainage
- Diagnosis of superficial surgical site infection by a surgeon
- Symptoms of erythema, pain, local oedema

Deep Incisional

Less than 30 days after surgery with no implant and soft tissue involvement

Infection less than 1 year after surgery with an implant; involves deep soft tissues (fascia and muscle), *plus* one of the following:

- Purulent drainage from the deep space but no extension into the organ space
- Abscess found in the deep space on direct or radiologic examination or on reoperation
- Diagnosis of a deep space surgical site infection by the surgeon
- Symptoms of fever, pain, and tenderness leading to dehiscence of the wound or opening by a surgeon

Organ Space

Infection less than 30 days after surgery with no implant

Infection less than 1 year after surgery with an implant and infection; involves any part of the operation opened or manipulated, *plus* one of the following:

- Purulent drainage from a drain placed in the organ space
- Cultured organisms from material aspirated from the organ space
- Abscess found on direct or radiologic examination or during reoperation
- Diagnosis of organ space infection by a surgeon

Modified from Guidelines for prevention of surgical site infection. Infect Control Hosp Epidemiol 20:252, 1999 - Mangram AJ, Horan TC, Pearson ML, et al[33].

Protocol variations: Any rules for

a. **Interim analyses:** Assessment for completeness of forms. Clarifications regarding criteria being used.
b. **For withdrawal of participants**: Patient discretion.
c. **For premature stopping of trial** : Nil

Post Trial benefits and care: Post-operative care to be provided by clinicians of the concerned unit as per pre-existing protocol. Routine follow-up and management of complications to be done on follow-up OPD visit.

Funding – The ultrasound examinations done for the patients were paid for by the Fluid research grant given for the purpose of the study.

Cost of ultrasound – Abdomen and Pelvis (C rate):- Rs.600

No of patients: 120

Patients related expenditure: 600 x 120= 72,000

Stationary: 8,000

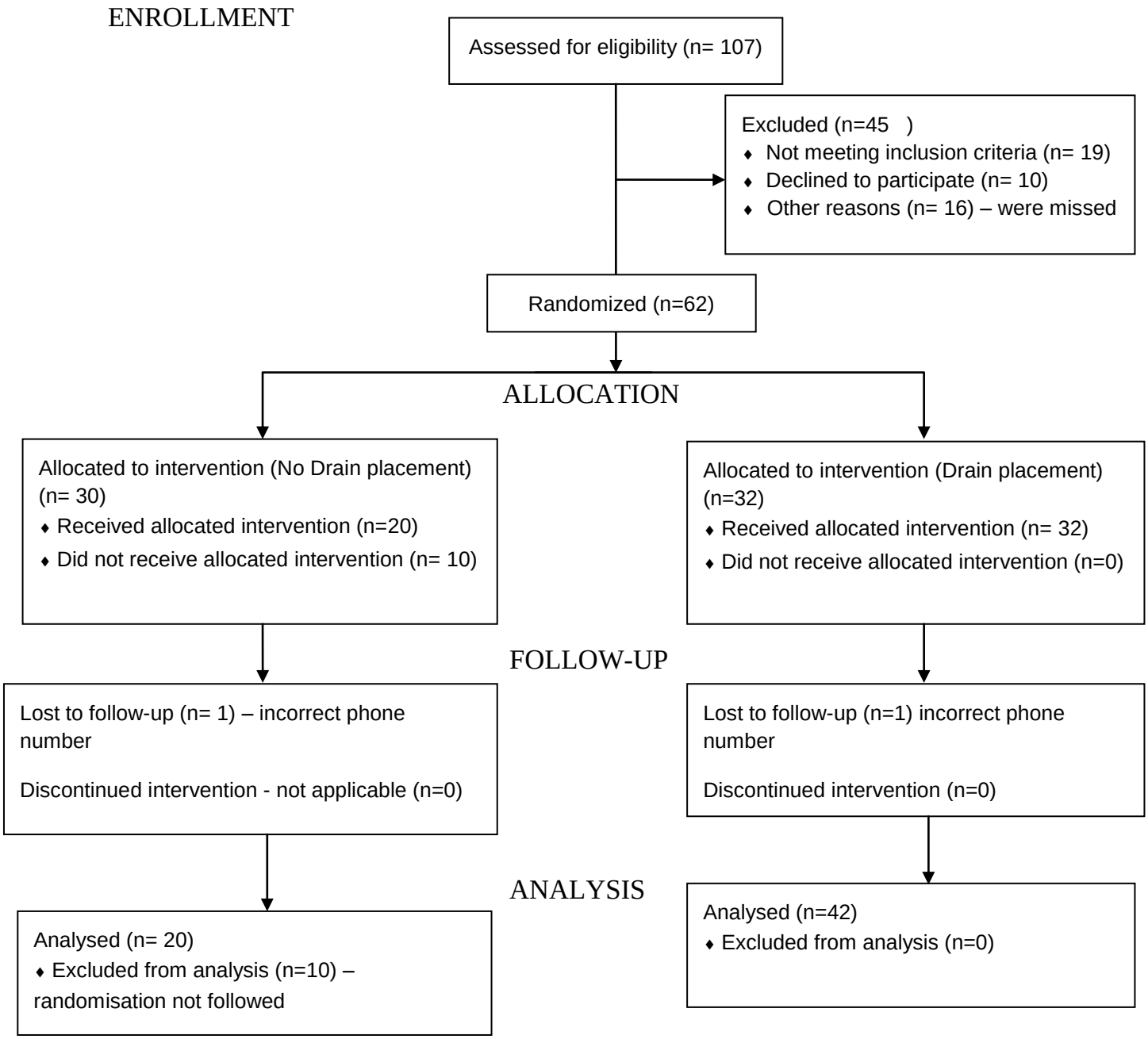
Total expenditure: 80,000.

Institutional Research Board approval and Ethical considerations:

The study proposal was presented in the IRB and Ethics Board, before commencement of the study, and was approved by both.

RESULTS

CONSORT 2010 Flow Diagram



DEMOGRAPHIC DETAILS

AGE DISTRIBUTION

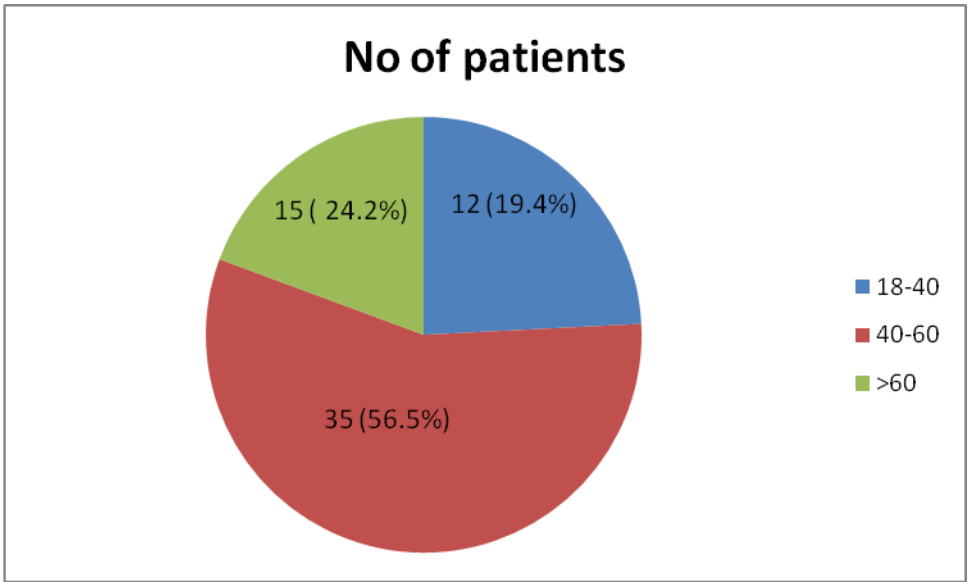


Figure 4 : Distribution of patients in age groups

The majority of patients were above the age of 40, and 56.5% were between the age group of 40- 60 years.

SEX DISTRIBUTION

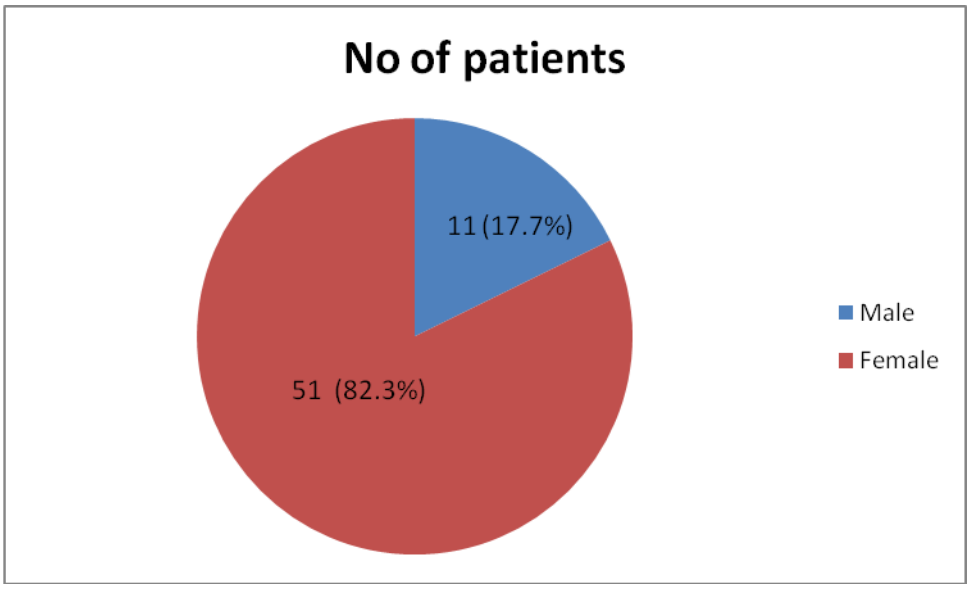


Figure 5 : Sex distribution

The majority of patients in our study were females (82.3%).

This reflects the population of patients who come here for incisional hernia repair. In literature, majority of studies have shown equal numbers of males and females.

OCCUPATION

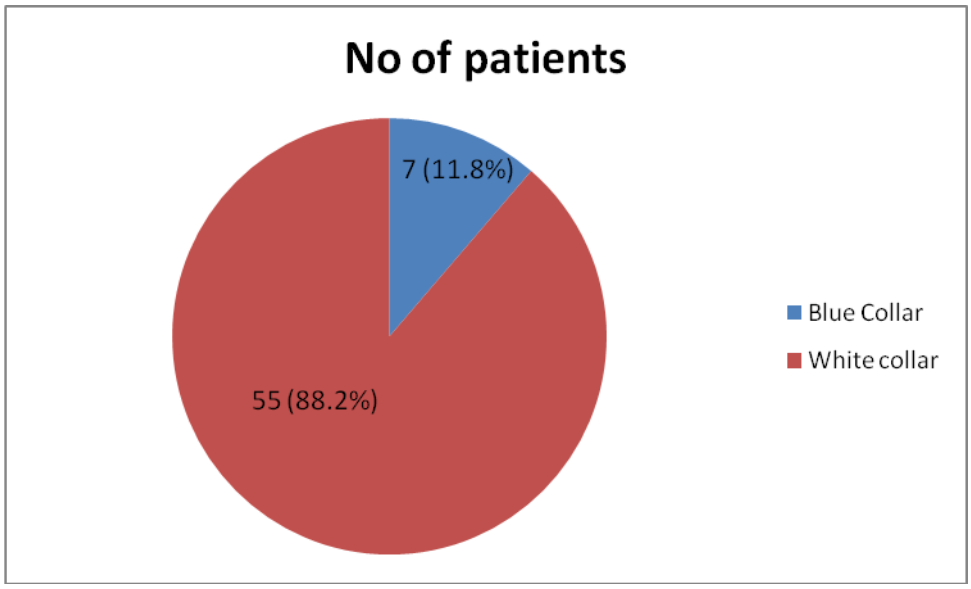


Figure 6: Type of occupation

The occupations of the patients were classified on the type of labour involved. Sedentary workers and housewives were classified as white collar and farmers and labourers were classified as blue collar workers.

Majority of patients (55 of 62) who had incisional hernias were white collar workers (88.2%)

Regional Distribution

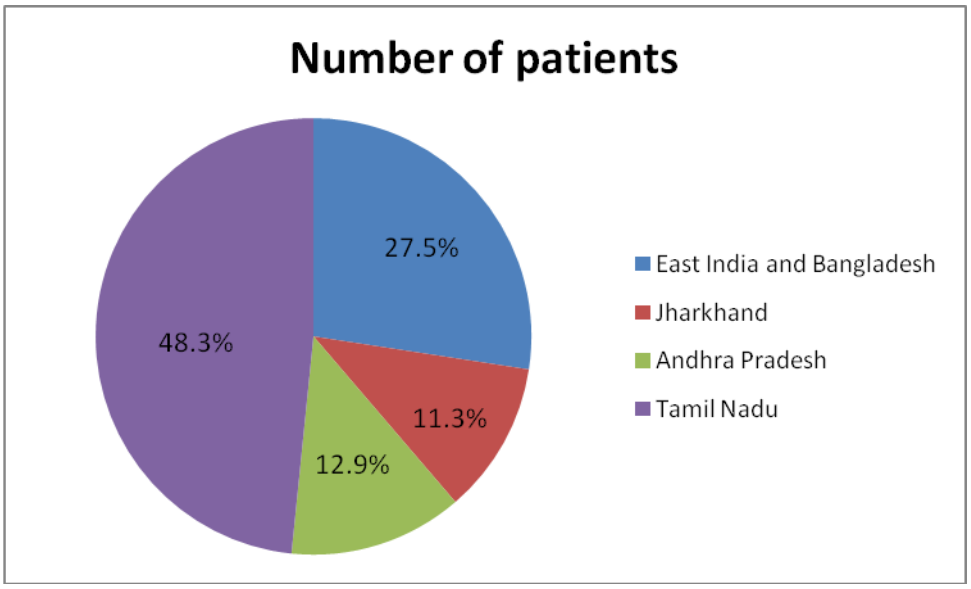


Figure 7: Regional distribution

The majority of the recruited patients were form the Tamil Nadu state, followed by Eastern and North-eastern states. 12.9% were from the neighbouring state, Andhra Pradesh.

The regional distribution of cases in our institution is because local patients are always more in number, but a number of patients – 27.5% come from East India to our institution for treatment.

COMORBID ILLNESSES

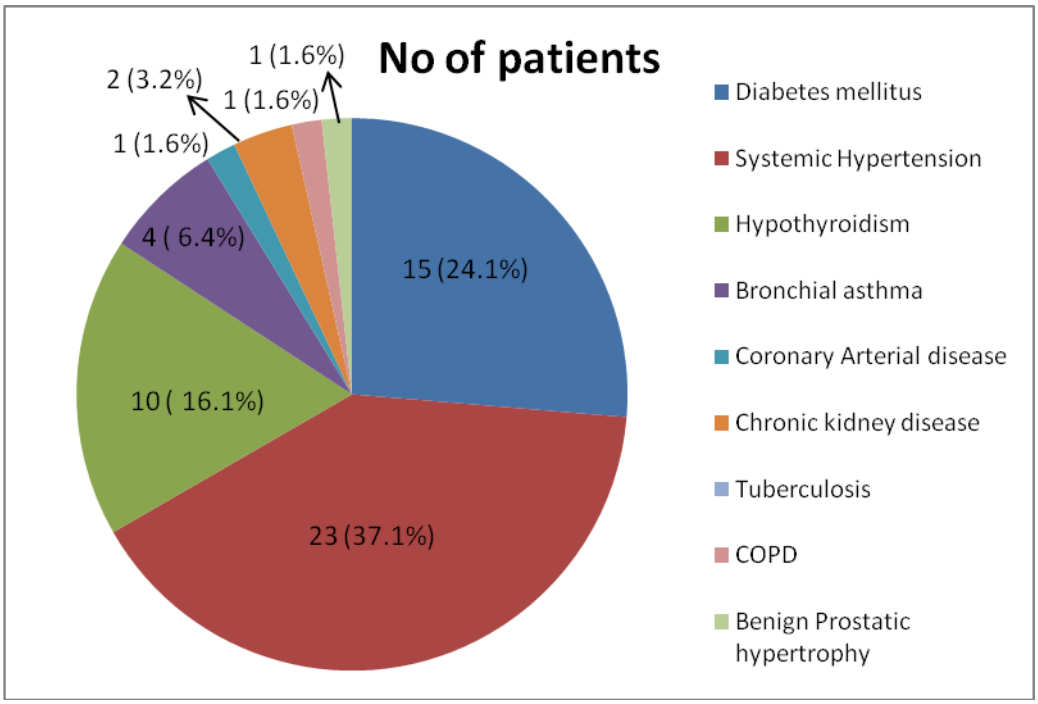


Figure 8 : Incidence of comorbid illnesses

Around 24.1% of patients in our study had Type 2 diabetes mellitus, 37.1% had systemic hypertension.

The remaining comorbid illnesses were not very high in number.

ANALYSIS

In analysing our data, several parameters were looked into and their causative association with the outcome was assessed. The outcomes were classified into Seroma / Hematoma, Infections, and having had no adverse outcome by 1st OPD visit (7-10 days)

Table 2 : Analysis of comorbid illnesses

Variable	Outcome			P value
	Infection	No adverse outcome	Total number of patients	
Ischemic heart disease	0	1	1	0.756
Chronic kidney disease	1	1	2	0.077
COPD	0	1	1	0.756
Benign prostatic hypertrophy	0	1	1	0.756
Tuberculosis	0	0	0	N/A
Asthma	0	4	4	0.309

There were no patients who had developed a seroma with any of these comorbid illnesses. The incidence of infections was also minimal. Thus as can be seen (p values in table– Pearson's Chi square), there is no correlation between the above comorbid illnesses and outcome.

Table 3 : Diabetes Mellitus

	Seroma/Hematoma	Infection	No adverse outcome	Total
DM Present	3 (20%)	3 (20%)	9 (60%)	15
DM not present	14 (29.8%)	2 (4.3%)	31 (66%)	47
Total	17	5	40	62

There were 15 patients in our study who had diabetes mellitus, of whom 40 % had adverse outcomes: 3 each had seroma / Infections.

Although the incidence of wound infections was found to be 20% versus 2.3% for non-diabetics, the p value was not significant (p value- 0.138– Pearson's Chi square). Thus although we would expect a higher incidence of wound infections in diabetics, the study could not make a positive correlation in this regard.

Table 4 : Systemic Hypertension

	Seroma/Hematoma	Infection	No adverse outcome	Total
Hypertension Present	7 (30.4%)	3 (13%)	13 (56.5%)	23 (100%)
Hypertension not present	10 (26.5%)	2 (5.1%)	27 (69.4%)	39 (100%)
Total	17	5	40	62

There were a total of 23 patients with systemic hypertension, of whom there were 7 (30.4%) patients with collections and 3 (13%) with infections, this was not found to be significant (p value – 0.448 describe– Pearson's Chi square)

Table 5 : Hypothyroidism

	Seroma/ Hematoma	Infection	No adverse outcome	Total
Hypothyroidism absent	14 (26.9%)	4 (7.7%)	34 (56.4%)	52 (100%)
Hypothyroidism present	3 (30%)	1 (10%)	6 (60%)	10 (100%)
Total	17	5	40	62

There were a total of 10 patients who had hypothyroidism in our study of whom 4 (40%) had an adverse outcome. The adverse outcome in the patients without hypothyroidism was found to be 18 (34.6%). This was not found to be significant (p value- 0.941– Pearson's Chi square)

Table 6 : Comparison of Sex Distribution and Outcome

	Outcome			
Sex	Seroma/ Hematoma	Infection	Uneventful	Total
Male	6 (54.5%)	0 (0%)	5 (45.5%)	11 (100%)
Female	11 (21.6%)	5 (9.8%)	35 (68.6%)	51 (100%)
Total	17 (27.4%)	5 (8.1%)	40 (64.5%)	62 (100%)

There were a total of 11 males among whom there were no infections noted, but a 54.5% incidence of collections. There were a total of 51 females of whom 21.6% developed a collection and 9.8% developed an infection.

There had never been a predilection to complications described. The values were not statistically significant either (p value =0.067– Pearson's Chi square)

Table 7 : Smoking

	Seroma/ Hematoma	Infection	Collection	Total
No smoking	16 (27.5%)	5 (8.4%)	38 (64.4%)	59 (100%)
Smoking present	1 (33.3%)	0	2 (66.67%)	3 (100%)
Total	17	5	40	62

There were 3 patients who were habituated to smoking among the study population of whom 1 had developed a seroma.

The numbers were too small to make a significant comparison (p value – 0.862– Pearson's Chi square)

Table 8: Comparison of alcohol consumption to outcome

	Seroma/ Hematoma	Infection	Collection	Total
No alcohol	17 (27.9%)	5 (8.2%)	39 (63.9%)	61 (100%)
Alcohol	0	0	1	1 (100%)
Total	17	5	40	62

There was only 1 patient who was habituated to alcohol consumption in the study population. This variable did not have a significant correlation to the outcome (p value – 0.756– Pearson's Chi square).

Table 9: Comparison of size of defect to outcome

	Seroma / Hematoma	Infection	No adverse outcome	Total
Size <=20 cm^2	14 (31.8%)	2 (4.5%)	28 (64.6%)	44 (100%)
Size > 20 cm^2	3 (20%)	2 (13.3%)	10 (66.7%)	15 (100%)
Total	17	4	38	59

The size of the defect was calculated based on the length and width of the defect. Area of an ellipse =π x l/2 x b/2.

By this formula, it was seen that there were15 defects more than 20 cm^2 , of which 33.3% had adverse outcomes. The correlation of area to adverse outcome was insignificant (p value- 0.400– Pearson's Chi square)

Table 10: Comparison of Width of defect to outcome

	Seroma / Hematoma	Infection	No adverse outcome	Total
Width <10cm	13	4	38	55
Width >=10cm	4	0	0	4
Total	17	4	38	59

There have been previous studies which showed the presence of more adverse outcomes following repair of incisional hernias with width > 10 cm.

There were a total of 4 such hernias, all of whom developed seromas. But the p value for the same was not significant (p value -0.28– Pearson's Chi square).

Table 11: Comparison of BMI to outcome

BMI	Seroma/Hematoma/ Infection	No adverse outcome	Total
Normal and underweight	8 (42.1%)	11 (57.9%)	19
Overweight	6 (28.6%)	15 (71.4%)	21
Obese	7 (36.8%)	12 (63.2%)	19

As there were only 2 patients who were underweight, they were analysed with the group within normal BMI as opposed to the patients who were overweight and obese. The incidence of outcomes was not significantly reduced in patients with a normal BMI. (p value – 0.665 – Pearson's Chi square)

Table 12: Comparison of number of previous operations to outcome

	Seroma / Hematoma	Infection	No adverse outcome	Total
Single operation	11 (27.5%)	2 (5%)	27 (62.5%)	40 (100%)
Multiple operations	6 (27.3%)	2 (9.1%)	14 (63.6%)	22 (100%)
Total	17	4	41	62

Of 39 patients who had had a single operation 11 developed collections (27.5%), 2 developed infections (5%). Of 22 patients who had recurrent or multiple operations 6 developed collections (27.3%), 2 developed infections (9.1%). However, the p-value (0.835 – Pearson's Chi square) was not significant. No adverse outcome percentage was similar in both groups.

Table 13 : Comparison of type of repair done versus outcome

	Seroma / Hematoma	Infection	No adverse outcome	Total
Sublay repair	12 (24.5%)	4 (8.1%)	33 (67.3%)	49 (100%)
Onlay repair	3 (50%)	0	3 (50%)	6 (100%)
Other (Underlay/ component's sep)	2 (33.3%)	1 (16.7%)	3 (50%)	6 (100%)
Total	17	5	39	61

There were a total of 6 cases in whom onlay repair was done of whom 50% developed collections. The other methods were a heterogenous group involving deviations from the preoperatively planned method of repair.

Studies have shown an increased incidence of seromas following onlay method [14] .
But despite the above percentile correlation, the value as not found to be significant.
(p value – 0.617 – Pearson's Chi square)

Table 14: Comparison of duration of incisional hernia versus outcome

	Seroma / Hematoma	Infection	No adverse outcome	Total
<=1 year	11 (28.2%)	3 (7.7%)	25 (64.1%)	39 (100%)
>1 year	6 (26.1%)	2 (8.7%)	15 (65.2%)	23 (100%)
Total	17	5	40	62

In both groups, whether incisional hernias were less than 1 year or more, there was a similar outcome of complications. Thus it was assumed that there was no relation between pre-operative duration of incisional hernia and outcome (p value – 0.978 – Pearson's Chi square)

Table 15: Comparison of drain insertion to seroma/ hematoma and infection occurrence

	Seroma/ Hematoma	Infection	No adverse outcome	Total
Drain Not placed	7 (35%)	1 (5%)	12 (60%)	20 (100%)
Drain Placed	10 (23.8%)	4 (9.5%)	28 (66.7%)	42 (100%)
Total	17 (27.4%)	5 (8.1%)	40 (64.5%)	62 (100%)

There were 20 cases in whom drain had not been placed and of them 7 (35%) had developed collections, 1(5%) had developed an infection, and 12 (60%) had had an uneventful recovery.

There was double the incidence of infection in the arm in which drain had been placed (9.5% vs. 5 %) supporting the assumption of some that drain placement had a higher incidence of infections[14].

The p value was not significant though - 0.590 – Pearson's Chi square

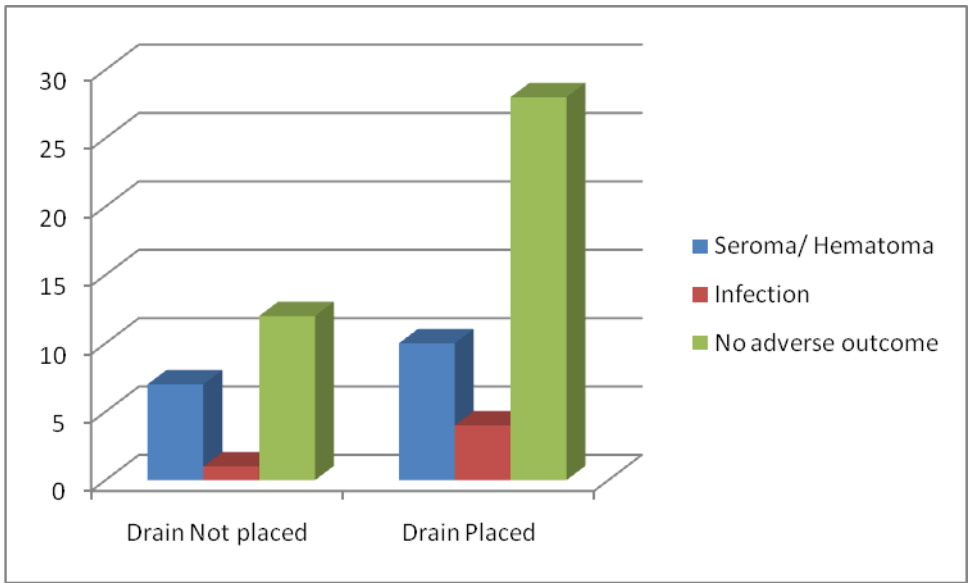


Figure 9: No drain versus drain in outcome following incisional hernia repair

Table 16: Comparison of randomisation allocation to outcome

	Seroma / hematoma	Infection	No adverse outcome	Total
Randomised to no drain	8 (26.7%)	3 (10%)	19 (63.3%)	30 (100%)
Randomised to drain	9 (28.1%)	2 (6.3%)	21 (65.6%)	32 (100%)
	17	5	40	62

There were 10 cases where randomisation had not been followed which were then analysed under the arm with drain placement.

What is significant to note is that, there is not significance seen in the outcome, had the randomisation been followed in the same 10 patients. (P value – 0.863 – Pearson's Chi square)

Thus we can assume that the analysis as per randomisation is valid.

Table 17: Comparison of Drain insertion to hospital stay

	Hospital stay <=4 days	Hospital stay >4 days	Total
No Drain Group	15 (75%)	5 (25%)	20 (100%)
With Drain Group	11 (26.2%)	31 (73.8%)	42 (100%)
Total	26	36	62

There were 20 patients in whom a drain was not placed and 75 % among them had a hospital stay < or= 4 days. Of the 42 patients in whom a drain was placed, 31 (73.8%) had a duration of hospital stay more than 4 days. Thus there was a significant correlation between the placement of a drain and the duration of hospital stay, with absence of drain placement a positive correlation of a shorter hospital stay. (p value –< 0.05 – Pearson's Chi square)

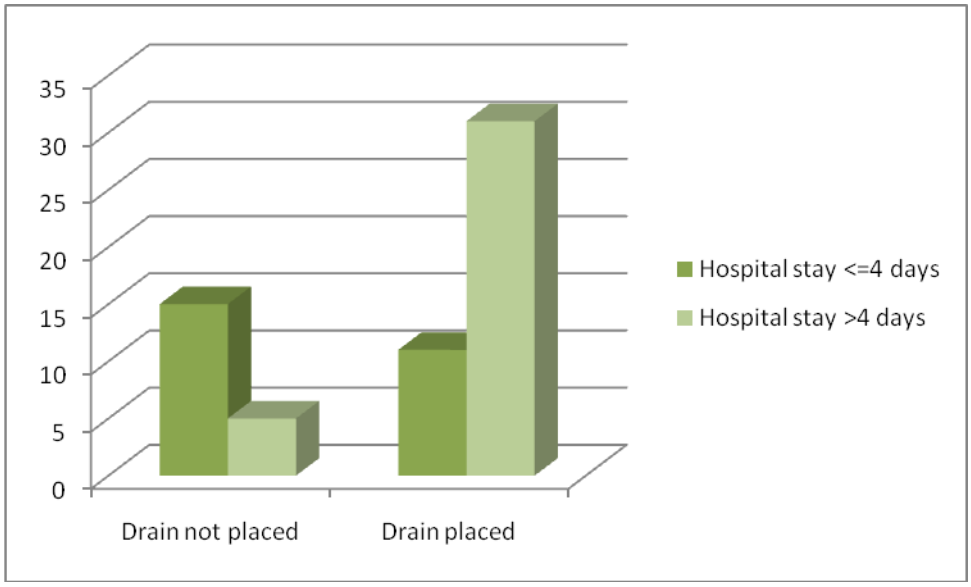


Figure 9 : Comparison of drain placement versus hospital stay

Table 18: Findings of Ultrasonography done

	Collection	Infection	No adverse outcome	Total
No collection on ultrasound	1`	1	2	4
Collection on ultrasound	10	1	4	15
	11	2	6	19

Of 62 patients in whom the study was done, 19 patients underwent an ultrasound scan.

Of the 19, there were collections seen in 15 of them of which 4 had had no associated clinical correlation → likely ultrasound detected, but not palpable clinically.

It was seen that majority of seromas (73.3%) were picked up clinically and showed a correlation with ultrasound detected collections. Thus, to assess the significance of collections detected on ultrasound, the patients followed up at day 30 were analysed to see if there was any long term morbidity associated with the seromas.

Among the 15 Collections picked up by ultrasound, the long term morbidity on follow up till 30 days post-op showed the following:

Table 19: 30 day post-operative complications among ultrasound-assessed patients

	No of patients
Seroma / Hematoma	8 (53.33%)
Infection	1 (6.67%)
Infected collection	1 (6.67%)
No adverse outcome	5 (33.33%)
Total	15 (100%)

Among 15 ultrasound-detected patients followed up till 30 days post-operatively, 53.3% had a residual collection, 13.3% developed an infection and no adverse outcome documented in 33.33% at 30 days.

Retrospectively analysing the data among the 10 patients in whom an adverse outcome was noted at day 30 post-operatively, it was found that

- 8 collections had initially been picked up clinically, while
- 1 patient who had been released from OPD follow up without an adverse outcome was found to have an adverse outcome at day 30

	No of patients
Initially picked up Collection	8
Initially picked up Infection	1
No adverse outcome	1
	10

Table 20: Comparison of outcome to the need for intervention

	Seroma/ Hematoma	Infection	No adverse outcome	Total
Intervention done	8 (47.1%)	5 (100%)	0	13
Intervention not done	9 (52.9%)	0	40 (100%)	49
Total	17 (100%)	5 (100%)	40 (100%)	62

The interventions done included aspiration, drainage, laying open of wound and/ or reoperation.

In all the patients who had infections, there was a need to lay open the sutures and allow the wound to heal secondarily.

However, in 52.9% of seroma / hematoma formation no intervention was required, and 47.1% required aspiration or drainage.

Overall 49 out of 62 did not require any intervention in 30 day observation period.

DISCUSSION

The presence of wound related complications are common following incisional hernia repair. Overall, the incidence of wound related complications came to approximately 1/3rd of the total hernia repairs (35%).

The incidence of seromas noted in our study was 24.1%. (15 / 62 patients), which is in keeping with the published literature.

The incidence of hematomas was 2 cases out of 62 (3.2%), in both of whom a drain had been placed.

As there were numerous collections for which no intervention was done and the nature of the contained fluid was not known, the seromas and hematomas were grouped for the sake of the analysis as collections (27.3%). This was comparable to several prior studies which showed wound complication rates related to seroma and hematoma formation to be between 4-21% and 1.5-9.6% respectively.

The incidence of infections in our study was 8.1% (5 cases out of a total of 62), which compared to studies by White et al and Bauer et al as between 2-15%.

As per the per-protocol analysis for the data, there were 20 cases without drain placement and 42 cases with drain placement. As per the intention to treat analysis (ITT), there were 30 cases without drain placement and 32 cases with drain placement. The comparison of outcome between both groups did not show a significant difference as neither showed a significant p-value.

There was no correlation between the obesity, co-morbid illnesses which included diabetes mellitus, systemic hypertension, hypothyroidism, asthma and the incidence of seroma, hematoma, wound infections following open incisional hernia repair. There was also no correlation between size of hernia defect [as measured by π x l/2 x b/2 (cm^2)] , duration of the presence of incisional hernia, number of previous operations or type of repair done with the presence of wound related complications.

There was a higher incidence of wound complications in patients for whom the width of the incisional hernia was more than 10 cm. This is found to be concordant with White et al.[14] The p valuefor the same was not significant though.

There was a significant reduction in the duration of hospital stay in those patients on whom no drain was placed. 75 % of patients in whom no drain was placed had a hospital stay of <= 4 days. 73.8% of patients in whom drains were placed had a hospital stay of >4 days. This was found to be statistically significant (p value <0.05)

Among the patients for whom an ultrasound was done (19/62), there were collections in 15 patients detected by ultrasound. Of these:

- 10 were detected clinically also,
- 1 was detected to have an infection,
- 4 were not found to have significant collection clinically.

Of these 15 patients with seromas, the 30 day outcome showed a morbidity in 10 (66.67%) of patients. However, 5 patients (33.33%) did not have any adverse

outcome. Of the total numbers of seroma / hematoma picked up 52.9% did not require any intervention and resolved by itself.

Among the 10 patients who showed 30 day morbidity, 9 had been picked up by clinical examination at the 1st OPD visit between 7-10 days post-operatively. This showed that routine ultrasound picked up a larger number of collections, but they did not lead to adverse outcome. Although the numbers were not sufficiently large (19/62) to assess the utility of the routine use of ultrasound, it picked up collections where clinical evaluation was negative for collections. However, clinical examination was sufficient to pick up large collections or wound infections, which would require intervention to avoid adverse outcome over a 30 day follow up period.

LIMITATIONS

Limitations noted in the study include:

1. The randomisation allocation was not followed for 12 cases, resulting in selection bias.
2. The sample size as calculated was not reached, due to a variety of causes:
    a. Cases missed.
    b. Patients not consenting to participate in a trial.
3. The ultrasound examination in incisional hernia could not be uniformly applied as patients were not compliant due to
    a. Logistical reasons – other appointments coiniciding with time slot of ultrasound.
    b. Wound complications limiting the travel of the patient to the ultrasound room.
    c. Earlier date of return prior to the date given for ultrasound.

CONCLUSIONS

Conclusion 1:

A. The incidence of seroma or hematoma with or without the use of drain did not vary significantly.

B. The incidence of infection with or without the use of drain did not vary significantly

Conclusion 2:

There was a significant reduction in the duration of hospital stay without the use of drains.

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ANNEXURES

I. INFORMATION SHEET

II. CONSENT FORM

III. DATA EXTRACTION FORM

IV. DATA SHEET

I. INFORMATION SHEET

INFORMATION SHEET

Randomised controlled trial comparing outcome following incisional hernia repair with Vs without drains

You are being requested to participate in a study to assess whether the presence or absence of drains during incisional hernia repair improves outcome. The repair of incisional hernias is usually associated with placement of drains. This study aims to assess whether drains have any measurable benefit in the outcome following surgery. We hope to include about 110 people from this hospital in the study.

Aims of study –

To assess the outcome following incisional hernia repair in the two different groups.

Reasons for this study –

Drains are traditionally placed in the plane of surgery following incisional hernia repair, presumably to drain fluids accumulating in the surgical plane – blood, serous discharge or pus. In addition, serous discharge, if localised, may predispose for infection, which may require further operation and they lead to mesh extraction. On the other hand, drains are known to have several complications including wound discomfort, prolonged hospital stay, pain, erosion into wound/ neurovascular structures, tract for introduction for infection, blockage and failure of drain, drain fracture. Studies have shown conflicting reports concerning the use of drains and there is no clear agreement among doctors, if it is useful to patients or not. The investigator wishes to study the outcomes following either the insertion of a drain or the absence of a drain.

Risk factors –

Complication in absence of drain insertion may include increased seroma or hematoma accumulation and consequent infection. Complication in presence of drain insertion may include wound discomfort, prolonged hospital stay, pain, erosion into wound/ neurovascular structures, tract for introduction for infection, blockage and failure of drain, drain fracture.

In case of development of any complications, the treatment done for the same would be done free of cost. But there would be no additional remuneration. Neither the investigator, nor the concerned unit will know in advance, if a drain will be placed for you or not after the surgery.

Do I have the right to opt out of the concerned study, at a later date, if I change my mind?

Yes. You may opt out of the study at any time and treatment would continue as per the treatment guidelines of the concerned unit.

What do I gain out of this study? –

You may be the beneficiary of a favourable outcome. Your treatment will continue as per the guidelines followed by the unit in charge, regardless of whether you are participating in the study or not.

Will my identity be revealed by this study? –

The study may be taken up for publishing in which case your identity will be preserved. However, your case notes and case information may be scrutinised and used in the future, by the principal investigator or the unit treating you, for which separate consent will not be taken at a later time.

If you have any further questions, please feel free to clarify with the following:

Dr. Rahul Lakshminarayanan, (tel: 08098951983) or email: rahulln88@cmcvellore.ac.in

Dr. Suchita Chase (tel: 8870912727)

Dr. Sukria Nayak (tel: 9487228853)

Surgery 4 office: (tel: 0416-228-2441, 228-3050), email: surgery4@cmcvellore.ac.in

II. CONSENT FORM

CONSENT FORM –

Randomised controlled trial – comparing the outcome of drains versus no drains in incisional hernia repair.

Study Number:

Participant's name:

Date of Birth / Age (in years):

I_____

_____, son/daughter of _____

Declare that I have read the information sheet provide to me regarding this study and have had adequate chances to ask questions and clarify doubts.

I also understand that my participation in this study is entirely voluntary and that I am free to withdraw permission to continue to participate at any time without affecting my usual treatment or my legal rights [ ]

I also understand that neither I, nor my doctors, will have any choice or knowledge of whether I will know whether a drain will or will not be placed, prior to admission or surgery [ ]

I also understand that during the 4 weeks of the study, the expenditure of the treatment given will be the same as for any other patient. No additional remuneration [ ]

I understand that I will receive free treatment for any study related injury or adverse event but I will not receive and other financial compensation [ ]

I understand that the study staff and institutional ethics committee members will not need my permission to look at my health records even if I withdraw from the trial. I agree to this access [ ]

I understand that my identity will not be revealed in any information released to third parties or published [ ]

I voluntarily agree to take part in this study [ ]

Name of patient :

Signature / Fingerprint:

Date:

Name of witness and relation to participant:

Signature/ Fingerprint:

Date:

Name of doctor counselling the patient:

Signature:

Date:

III. DATA EXTRACTION FORM

Proforma:

Name:

Age: Sex: Residence:

Occupation:

Email: Phone no:

Co-morbidities: T2DM/ Sys HTN/ IHD/ CKD/ COPD/ Obstructive SAS/ BPH/ TB/ Malnutrition

H/o Smoking: No. of pack years:

H/o Alcohol consumption: Amount per week:

H/o Wound infection at previous surgical site:

H/o Steroid intake:

Weight: Height: BMI:

Previous surgery done

Duration of hernia

Size of defect:

Type of repair done: Sublay/ Onlay

Date of operation:

Randomisation allocation:

Post- operative:		Day 3	1st OPD visit	Within 1 month
Seroma formation	Clinical swelling (yes/no)			
	-Fluctuant:			
	USG finding -			
	Intervention done:			
	If drained, nature of collection:			
Hematoma formation	Clinical swelling:			
	USG Finding:			
	Intervention done:			
	If drained, nature of collection:			
Surgical site infection	Redness			
	Tenderness			
	Purulent discharge			
	Abscess formed? (If yes, size of abscess – in cm):			
	Wound gaping			
Duration of hospital stay (Days)				

ORIGINAL DATA

idno	age	sex	res	occ	phno	dm	htn	ihd	ckd	copd	osas	tb	bph
1	80	0	VELLORE	LABOURER	095858882	0	0	0	0	0	0	0	1
2	62	0	vellore	LABOURER	978622616	1	0	0	0	0	0	0	0
3	66	0	SHOLINGEF	RETIRED HE	984310646	0	1	1	0	0	0	0	0
4	60	1	GUNTUR, A	PASTOR	867125958	1	1	0	1	1	0	0	0
5	30	1	MIDNAPOF	HOUSEWIF	956421569	0	0	0	0	0	0	0	0
6	32	1	VELLORE, T	HOUSEWIF	999436744	0	0	0	0	0	0	0	0
7	29	1	WB	HOUSEWIF	860916571	0	0	0	0	0	0	0	0
8	47	1	THIRUVANI	HOUSEWIF	996526211	0	0	0	0	0	0	0	0
9	45	1	TN	HOUSEWIF	960039321	1	1	0	0	0	0	0	0
10	45	1	SATHUVAC	HOUSEWIF	934530341	0	1	0	0	0	0	0	0
11	50	0	CHITTOOR,	FARMER	944147005	0	0	0	0	0	0	0	0
12	71	1	vellore	HOUSEWIF		1	0	0	0	0	0	0	0
13	67	1	vellore	HOUSEWIF		0	0	0	0	0	0	0	0
14	64	0	VELLORE	LABOURER	996554000	1	1	0	0	0	0	0	0
15	45	1	WEST BEN(	HOUSEWIF	974902486	1	1	0	0	0	0	0	0
16	48	1	HOWRAH, '	HOUSEWIF	096742181	0	1	0	0	0	0	0	0
17	65	1	RANCHI,JH/	HOUSEWIF	983550028	0	0	0	0	0	0	0	0
18	76	0	TAMIL NAD	HOUSEWIF	801578808	0	1	0	0	0	0	0	0
19	38	0	HOWRAH, '	BUSINESSM	983008146	0	0	0	0	0	0	0	0
20	27	1	THIRUVANI	HOUSEWIF	994336430	0	0	0	0	0	0	0	0
21	43	1	DHANBAD,	HOUSEWIF	829444892	1	0	0	0	0	0	0	0
22	45	1	BANJURA, '	HOUSEWIF	096094170	0	0	0	0	0	0	0	0
23	30	1	RANCHI, JH	HOUSEWIF	989478040	0	0	0	0	0	0	0	0
24	42	1	DISPUR, AS	HOUSEWIF	967825907	0	0	0	0	0	0	0	0
25	46	1	NALLAPALL	HOUSEWIF	810643821	1	0	0	0	0	0	0	0
26	52	1	BANGLADE	HOUSEWIF	980482664	1	0	0	0	0	0	0	0
27	53	1	NADIA, WB	HOUSEWIF	933338616	0	1	0	0	0	0	0	0
28	59	1	VELLORE , '	HOUSEWIF	962967243	0	0	0	0	0	0	0	0
29	52	1	GUNTUR, A	POLICE OFF	800809604	1	1	0	0	0	0	0	0
30	57	0	SOLAVARA	FARMER		1	1	0	0	0	0	0	0
31	41	1	HAZARIBAC	HOUSEWIF	983575317	0	0	0	0	0	0	0	0

32	50	1	VELLORE, T	HOUSEWIF	868294307	0	0	0	0	0	0	0	0
33	56	1	DHUBLI, AS	HOUSEWIF	995723372	1	0	0	0	0	0	0	0
34	37	1	WEST BEN(	HOUSEWIF	903867369	0	0	0	0	0	0	0	0
35	58	1	BANGLADE	HOUSEWIF	958507526	0	1	0	0	0	0	0	0
36	37	1	KADAPA, A	HOUSEWIF	988522680	0	0	0	0	0	0	0	0
37	63	1	CHITTOOR,	HOUSEWIF	918121817	0	1	0	0	0	0	0	0
38	54	1	VELLORE, T	HOUSEWIF	978964037	0	1	0	0	0	0	0	0
39	38	1	THANJAVU	HOUSEWIF	997668666	0	1	0	0	0	0	0	0
40	30	1	THIRUVANI	HOUSEWIF	887043396	0	0	0	0	0	0	0	0
41	30	1	DHAKA, BA	HOUSEWIF	017117369	0	0	0	0	0	0	0	0
42	60	1	VELLORE, T	HOUSEWIF	948693837	0	0	0	0	0	0	0	0
43	51	1	VELLORE,,T	HOUSEWIF		0	1	0	0	0	0	0	0
44	38	1	WEST BEN(	HOUSEWIF	983153218	0	0	0	0	0	0	0	0
45	51	1	VELLORE, T	HOUSEWIF	994625377	0	0	0	0	0	0	0	0
46	60	0	THORAPAD	FARMER		0	1	0	0	0	0	0	0
47	25	1	WEST BEN(	HOUSEWIF	096096285	0	0	0	0	0	0	0	0
48	63	1	WEST BEN(	HOUSEWIF	890694676	0	1	0	0	0	0	0	0
49	55	1	VELLORE	HOUSEWIF	994422654	0	1	0	0	0	0	0	0
50	58	0	CHITTOOR,	FARMER		0	0	0	0	0	0	0	0
51	45	1	VELLORE, T	HOUSEWIF	989491986	0	0	0	0	0	0	0	0
52	57	1	VELLORE, T	HOUSEWIF	960049844	0	1	0	0	0	0	0	0
53	43	0	ORISSA	BUSINESSM	943725425	0	0	0	0	0	0	0	0
54	65	1	VELLORE, T	HOUSEWIF	848960885	0	0	0	0	0	0	0	0
55	54	1	VELLORE, T	HOUSEWIF	950000453	0	0	0	0	0	0	0	0
56	49	1	VELLORE, T	HOUSEWIF	989426455	0	0	0	0	0	0	0	0
57	59	1	RANCHI, JH	HOUSEWIF	933442361	1	1	0	0	0	0	0	0
58	26	1	BOKARO, JI	HOUSEWIF	988090230	0	0	0	0	0	0	0	0
59	50	1	SINGHBJHA	HOUSEWIF	930850466	1	1	0	0	0	0	0	0
60	44	1	VELLORE	HOUSEWIF		0	0	0	0	0	0	0	0
61	66	1	HYDERABA	RETD CLERI		1	1	0	1	0	0	0	0
62	32	1	CHITTOOR,	PRINCIPAL	093943900	0	0	0	0	0	0	0	0

hypo	asth	prev	smo	pck	alc	ste	wou	wt	ht	dur	len	wid	rep
0	0		1	1	0	0	0	71	178	3	10	10	1
0	0	LAPAROTO	1	2	0	0	0	55	158	1	4	4	1
1	0	CABG WITH	1	5	1	0	1	62	161		4	5	9
0	1	CYSTECTOM	0		0	0	0	72	145	0.5	10	6	9
0	0	LSCS, LAPA	0		0	0	1	70	150	0.5	3	3	1
0	0	STERILISAT	0		0	0	0	70	153	0.5			1
0	0	OPEN APPE	0		0	0	1	55	151	0.5			
0	0	HYSTERECT	0		0	0	1	68	152		2	2	1
0	1	LSCS	0		0	0	0	65	145		1	1	2
0	0	LSCS	0		0	0	0	99	163		5	5	2
0	1	LAPAROTO	0		0	1	0	59	175	1	4	2	1
0	0	TAH	0		0	0	0	51	140	1	4	4	1
0	0	STERILISAT	0		0	0	0	65	156	1	2	2	1
0	0	OPEN CHOI	0		0	0	0	65	163	0.3	5	5	1
0	0	OPEN APPE	0		0	0	1	79	154	4	4	4	1
1	0	OVARIAN C	0		0	0	1	83	153	10	2	2	1
0	0	DEBULKING	0		0	0		65	148	0.3			1
0	0	OPEN CHOI	0		0	0	1	50	152	4	5	4	1
0	0	OPEN APPE	0		0	0	0	85	165	2	5	4	1
0	0	LSCS	0		0	0	0	73	150	0.3	2	2	1
0	0	OPEN APPE	0		0	0	0	60	152	0.7	5	8	1
0	0	LAPAROTO	0		0	0	0	55	148	0.3	8	5	1
1	0	LAP CHOLE	0		0	0	1	68	147	0.7	6	8	1
0	0	CLOSURE L	0		0	0	0	57	151	4	2	2	1
1	0	LSCS,TAH	0		0	0	1	59	144	2	7	5	
0	0	U/L SALPIN	0		0	0	0	64	155	2	8	6	1
0	0	TAH,BSO	0		0	0	1	54	156	0.3	2	2	1
0	0	OPEN APPE	0		0	0	0	62	158	0.3	3	4	1
0	0	TUBECTOM	0		0	0	0	72	152	0.1	10	15	1
0	0	RIGHT PAR	0		0	0	0	83	170	1	5	4	2
1	0	LSCS X 2 ; T	0		0	0	0	70	155	3	4	3	1

0	0	OPEN CHOI	0		0	0	0	55	154	0.3	6	4	1
1	0	LSCS X 2	0		0	0	0	59	149	1			1
0	0	LSCS, HYST	0		0	0	0	65	155	1	5	5	1
0	0	LSCS, APPE	0		0	0	0	62	141	0.5	5	5	1
1	0	LAPARPTPM	0		0	0	0	64	149	1	8	10	9
0	0	EPIGASRIC	0		0	0	0	52	150	1.5	2	2	1
0	0	TAH, BSO	0		0	0	0	50	152	0.7			1
0	0	TAH, BSO, I	0		0	0	0	86	151	1	7	4	1
0	0	STERILISAT	0		0	0	0	55	151	0.2	5	5	9
0	0	LAP CHOLE	0		0	0	1	54	155	2	5	4	1
1	0	OPEN CHOI	0		0	0	0	64	150	3	6	3	1
0	0	MYOMECT(	0		0	0	0	89	156	20	4	4	1
0	0	LSCS,TAH,I	0		0	0	1	68	151	4	5	5	1
0	0	TAH	0		0	0	0	45	156	0.5	2	3	1
0	0	LAP CONV (	0		0	0	0	66	157	3	3	2	2
0	0	LSCS, PPS, A	0		0	0	0	50	147	0.5	5	5	1
0	0	L PYELOLIT	0		0	0	0	76	157	3			2
0	0	COLOSTOM	0		0	0	0	73	150	0.3	2	2	1
0	0	LAPAROTO	0		0	0	0	80	163	0.2	2	1	2
0	0	TUBECTOM	0		0	0	0	57	138	0.2	2	3	1
0	0	TAH	0		0	0	0	61	147	0.1	1	1	1
0	0	RECCTOPEX	0		0	0	0	89	169	2	4	4	1
0	0	TAH	0		0	0	0	55	153	0.1	2	3	1
1	0	TAH, TUBE(	0		0	0	0	66	152	1	4	5	1
0	0	LSCS, INCIS	0		0	0	0	71	150	0.3	10	10	1
0	0	LAPAROTO	0		0	0	0	63	147	1	6	5	1
0	0	LSCS X 3	0		0	0	0	86	155	3	4	4	1
0	0		0		0	0	0	46	144	8	7	8	9
0	1	TAH,BSO,	0		0	0	1	65	155	0.5	3	2	1
0	0	LAPAROTO	0		0	0	0	69	159	0.5	5	6	1
1	0	COLOSTOM	0		0	0	0	64	161	0.5	8	4	9

ran	drp	out3	out7	int	nat	usg	vol	out30	doo	dod	hs
1	1	3	3	0		1	3	3	4/16/2015	4/24/2015	9
1	1	0	0	1	0	1		0	4/24/2015	4/28/2015	5
1	1	3	3	0				3	5/7/2014	5/11/2014	5
1	1	3	3	0					5/7/2014	5/24/2014	18
0	0	3	3	0		1	20	3	5/6/2014	5/9/2014	4
0	0	3	0	0		1	180	3	5/20/2014	5/22/2014	3
0	0	3	3	0		1	3	3	6/5/2014	6/8/2015	4
0	0	3	3	0		9		3	5/30/2014	6/2/2014	4
1	1	3	3	0		9		3	6/25/2015	6/29/2015	5
0	0	3	3	0		9		3	8/6/2014	8/9/2014	4
1	1		3	0		9			8/13/2014	8/18/2015	6
0	0		3	0		9		3	9/13/2014	9/18/2014	6
1	1	3	3	0		9		3	9/11/2014	9/15/2014	5
0	1	3	3	0		9		3	9/12/2014	9/16/2014	5
0	0	3	3	0		9		3	10/10/2014	10/11/2014	2
1	1	0	0	1	1	9		2	10/1/2014	10/6/2014	6
1	1	3	3	0		9		3	10/1/2014	10/6/2014	6
1	1	0	0	1	0	9		0	10/22/2014	10/30/2014	9
0	0	3	0	1	1	1	330	0	11/5/2014	11/8/2014	4
1	1	3	3	0		9		3	11/5/2014	11/7/2014	3
0	0	3	3	0		9		3	11/26/2014	12/1/2014	6
0	1		3	0		0		0	11/7/2014	11/11/2014	5
1	1	3	3	0		1	40	0	11/26/2014	11/30/2014	5
1	1	3	3	0		9		0	12/3/2014	12/6/2014	4
0	0	3	3	0		9		3	12/3/2014	12/4/2014	2
1	1	3	3	0		9		3	12/10/2014	12/13/2014	4
1	1	3	3	0		9		3	12/10/2014	12/13/2014	4
0	0	3	3	0		0		3	12/10/2014	12/11/2014	2
1	1	3	0	0		1	86	0	12/12/2014	12/16/2014	5
0	0	3	0	0		1	125	2	12/17/2014	12/20/2014	4
1	1	3	3	0		9		3	1/9/2015	1/14/2015	6

0	0	0	0	0		0		3	12/12/2014	12/17/2014	6
0	0	0	1	1		0		3	12/24/2014	12/29/2014	6
0	1	3	3	0		9		3	1/14/2015	1/17/2015	4
1	1	3	3	0		9		3	1/21/2015	1/26/2015	6
1	1	3	0	0		1		0	1/30/2015	2/10/2015	12
1	1	3	0	0		1	6	0	2/6/2015	2/13/2015	8
0	0	3	0	0		1	150	0	1/21/2015	1/23/2015	3
1	1	3	3	1	1	9		3	2/11/2015	2/20/2015	10
0	0	0	0	1	1	9		0	2/6/2015	2/16/2015	11
0	1		3	0		9		3	2/11/2015	2/18/2015	8
1	1	3	3	0		9		3	3/4/2015	3/8/2015	5
1	1	3	1	1		9		3	3/11/2015	3/15/2015	5
1	1	3	3	0		9		3	4/8/2015	4/11/2015	4
0	0	3	3	0		9		3	3/11/2015	3/14/2015	4
0	0	3	0	0		9		3	4/1/2015	4/4/2015	4
0	1	3	3	0		9		3	4/8/2015	4/11/2015	4
0	0	3	3	0		9		3	4/15/2015	4/18/2015	4
1	1	3	3	0		9		3	4/10/2015	4/13/2015	4
1	1	3	0	1	1	9		3	4/15/2015	4/19/2015	5
1	1	3	3	0		9		3	4/29/2015	5/2/2015	4
0	0	3	3	0		9		3	4/15/2015	4/17/2015	3
0	1	3	3	0		9		3	6/10/2015	6/14/2015	5
1	1	3	1	1	1	9		3	6/12/2015	6/16/2015	5
1	1	3	0	1	1	9		3	6/17/2015	6/20/2015	4
0	1	3	0	0		1	20	0	6/19/2015	6/23/2015	5
0	1	3	3	0		9		3	6/24/2015	6/28/2015	5
1	1	3	0	1	1	1	20	3	6/24/2015	6/29/2015	6
0	1	3	1	1		9		3	7/10/2015	7/16/2015	7
1	1	3	3	0		9		3	7/8/2015	7/11/2015	4
0	1	3	1	1		1		1	7/8/2015	7/18/2015	11
1	1	3	3	0		9		3	7/15/2015	7/24/2015	10

ABSTRACT

Title of the abstract: Randomized controlled trial of use of drain vs. no drain in open incisional hernia mesh repair.

Department: General Surgery, Unit IV, CMC Vellore.

Name of the candidate: Dr. Rahul Lakshminarayanan

Degree and Subject: M.S. General Surgery

Name of the guide: Dr.Sukria Nayak

Aims: The aim of the study is to assess the outcome of drain placement Vs no drain use, in patients undergoing open mesh repair of incisional hernias in the Department of General Surgery, Unit 4.

Objectives:

1. To assess and compare the occurrence of seroma, hematoma and wound infection in the two groups.
2. To assess and compare the duration of hospital stay in both the groups.

Background: Evidence in literature comparing the outcome following incisional hernia repair with or without drains is scarce. A meta-analysis comparing the same was unable to find suitable randomized controlled trials carried out in this regard. To this effect a randomized controlled trial is proposed to compare the outcome following incisional hernia repair with versus without the use of drains.

Methods: From April 2014 to August 2015, 62 patients pre-operatively planned for sublay or onlay mesh repair were randomised to drain or no drain allocation following informed consent.

Their outcomes, specifically seroma/ hematoma, wound infection and duration of hospital stay, were analysed till 30 days post-operatively.

Results: There were a total of 17 seromas and 5 infections among all the patients. The incidence of seromas, hematomas and surgical site infections was 24.1%, 3.2% and 8.1% respectively. There was no significant difference in the outcome with regard to drain placement. There was a significant reduction in the duration of hospital stay among the patients in whom no drain was placed (p value <0.05). There was no positive correlation of outcomes to co-morbid illnesses (diabetes mellitus, systemic hypertension, ischemic heart disease, chronic kidney disease, COPD or hypothyroidism). There was no correlation type of repair, BMI, duration of incisional hernia or size of the defect.

Conclusions: There was no significant reduction in the outcome of seromas, hematomas or surgical site infections with regard to drain placement. There was a significant reduction of duration of hospital stay in patients for whom drain is not placed.

Keywords: incisional hernia, mesh repair, drain, seroma, hematoma, infection, hospital stay.