



AMASI Newsletter



(Association of Minimal Access Surgeons of India)

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Dear friends,

As India slowly prises open the grip of the COVID-19 pandemic, there is a palpable atmosphere of excitement and eagerness. The past couple of years made us realise the importance of physical socialization, the joy of meeting old friends and just enjoying basic health and well-being. It was only when we were deprived of all these aspects of our lives by a miniscule organism that we learnt the significance of all things that we were taking for granted.

Last year, due to the pandemic, AMASICON2020 was a totally virtual affair. As we were also dealing with a completely new platform, we redesigned the format of the conference to make it interesting and academically satisfactory for our delegates. We were rewarded by unprecedented success as more than 12000 viewers watched and participated in the proceedings from all over the world. Moreover, the pandemic proved to be a blessing in disguise as we were compelled to develop the technology and capability to transmit surgeries from different centers in India and abroad in High Definition 4K format in real time to the screens of our delegates.

This year, AMASICON2021 aims to build on the capabilities that we already developed. To make it even more interesting, we are proposing to allow a limited number of delegates to physically participate in the conference at two or three venues in India. Depending on the government regulations, 250-300 delegates can be accommodated at each of the venues. We will soon come up with the details regarding the residential registration at these venues. Keep a track of the emails coming from AMASI in your inbox also, enroll yourself in the regional Whatsapp group. If you are not sure whether your email and whatsapp number is updated, you are requested to contact the AMASI HQ for the same.

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IN THIS ISSUE**Guideline Series**

Prof. B. S. Pathania has presented the guidelines for Laparoscopic Ventral And Incisional Hernia Repair

Gurubhashyam

Prof. Makhan Lal Saha describes his experience on Social contribution by Surgeons

Writing a Scientific paper

Prof. Vikram Kate and his team present the first part of the art of writing a scientific paper describing a Randomized Controlled Trial

Plus the regular features like:

- ◆ Upcoming events update
- ◆ Past Event

Guideline Series

The Process of Guidelines and Position Statement Formation under AMASI was envisioned in four phases:

Phase I: An expert reviews available evidence on each topic and suggests guidelines/position statement.

Phase II: The suggested guidelines/position statements are presented before a panel of experts who then critically evaluate them and suggest any amendments, if needed.

Phase III: The amended guidelines/position statements are presented before the members of AMASI through the newsletter and comments are invited, based on available evidence in published literature.

Phase IV: Once all the comments are analysed critically in light of the evidence submitted, any changes, if required are made and the final guidelines/position statements are released.

What follows is the phase 3 in the Guidelines and Position Statement Process of AMASI.

The AMASI members are requested to carefully go through them and if required, any changes can be suggest along with the evidence supporting such changes. Your suggestions along with the relevant references can be emailed to amasiguideines@gmail.com

LAPAROSCOPIC VENTRAL AND INCISIONAL HERNIA REPAIR – Part I: Preoperative Preparations and Operative Steps



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PREOPERATIVE

Smoking and obesity are known risk factors for the development of infectious complications and recurrence. Therefore cessation of smoking for at least 2 weeks before surgery is desirable. Obese patients should try to lose weight on a dietary program for 2 months before surgery. For morbidly obese individuals, a weight loss procedure is often necessary in the first stage, together with temporary closure of the hernia defect, to be completed with a definitive hernia repair 12 to 18 months later, when the patient has lost substantial weight and is less prone to infectious complications. [1][2]

References:

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ROLE OF CT OR MRI IN VENTRAL HERNIA

Preoperative use of CT OR MRI in the routine diagnosis of ventral hernias, there is not sufficient evidence. In some case series or case reports the significance of the CT scan for the diagnosis of uncommon abdominal wall hernias could be demonstrated. [1] [2] [4][7] Gough et al described the discovery of an incarcerated spiegelian hernia as the cause of an acute abdominal pain within the context of a CT scans. CT scan can also be helpful in the case of obese patients.[3][5] [8] It is recommended to use it in cases of obesity, repeated preliminary operations, large hernias with possible loss of domain, traumatic hernias and to diagnose uncommon ventral hernias. To find a recurrence or associated pathologies a CT scan should be done. In terms of the preoperative use of MRI in the diagnosis of ventral hernias there are currently no studies available. For MRI, there are currently only studies concerning the formation of adhesions following Laparoscopic hernia repair with a cine-MRI. [9][10] [11]

Suggestions

CT scan is indicated in recurrent hernia, posttraumatic hernia, and obese patients in patients having large hernias with loss of domain other locations where exact diagnosis is required. (Level of evidence 2B)

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PATIENT POSITION

Supine position with the arms tucked will offer the most versatile position when performing Laparoscopic ventral hernia repair. Hernias requiring lateral or posterior access should be performed with the patient in a full or partial lateral position. The patient should be placed during Laparoscopic ventral hernia repair in a safe and stable position to assure access to the hernia through operative exposure and an ergonomic working position for the surgeon and operating team. A supine position with the arms tucked at the patient's side is the standard position for patients with midline hernias, while hernias of the flanks or posterior abdominal wall require a lateral decubitus or modified lateral decubitus position. Maintaining the triangulation of ports procedure is carried out. Frequent tilting of the OR bed, Trendelenburg, and/or reverse Trendelenburg position may be need to optimize operative exposure by passively. Trendelenburg, and/or reverse Trendelenburg position may be need to optimize operative exposure by passively retracting the viscera out of the way, especially for large hernias or hernias located off the midline or in the subxiphoid/suprapubic location. For frequent position changes during LVHR, make the secure attachment, with appropriate padding of pressure points, of the patient to the OR bed imperative. [1]

References

1. Palanivelu C, Jani K V, Senthilnathan P, Parthasarathi R, Madhankumar M V, Malladi V K (2007) Laparoscopic sutured closure with mesh reinforcement of incisional hernias. *Hernia* 11:223-228

ANTIBIOTIC PROPHYLAXIS

Antibiotic prophylaxis in hernia surgery is controversial. The available literature does not support a recommendation for or against the routine use of antibiotic prophylaxis. The rate of infection with LVHR in specific studies can be as high as 16%, but usually much lower, ranging from 0.5 to 4%. Two studies are available at the level 2b. Rios et al [1] reported a significant difference between with and without use of prophylactic who had undergone open repair with mesh implantation, in which the two patient groups differed in numbers (140 with prophylaxis, 76 without prophylaxis) and the rate of infection (18.1%) was on the high side. The routine use of prophylactic antibiotics is commonly advocated. In a meta-analysis of Cohort studies Mavros [2] found that patient age, ASA score, smoking, and the duration and emergency setting of the operation, are associated with higher risk of development of synthetic mesh infection. Therefore, antibiotic prophylaxis in patients with personal or surgical risk factors is suggested. The most common microorganisms isolated from SSI after hernia repair are aerobic gram-positive organisms, typically *Staphylococcus* species, but aerobic streptococci and *Enterococcus* species have also been reported. MRSA is commonly found in prosthetic mesh infections {3,4} Antibiotic prophylaxis in ventral hernia is associated with significantly less local infections, and routine antibiotic use for prophylaxis is recommended [1,2].

Suggestions

A routine antibiotic prophylaxis is recommended. A single dose, first-generation cephalosporin (cefazolin) should be given preoperatively for LVHR. Vancomycin should be added in patients colonized with MRSA. Vancomycin or Clindamycin should be given to patients allergic to cephalosporins. (Level of evidence 1A)

References

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URINARY BLADDER CATHETER

Placement of a urinary bladder catheter during LVHR should be determined based on the anticipated duration of the procedure and the location of the hernia. Incisional hernias from previous lower midline incisions, particularly if the defect is near the symphysis, generally require fixation to the inferior pubic ramus. In order to properly fix the prosthetic to these structures, extraperitoneal dissection and mobilization of the bladder (similar to exposure in laparoscopic inguinal hernia repair) is necessary. Placement of a urinary bladder catheter before prepping and draping the patient allows for continuous drainage and monitoring of urine output. An empty bladder also gives additional space in the abdominal cavity, which might be essential in reducing larger hernias [1,2,3]. If a 3-way catheter is used, the bladder can be filled with sterile saline solution while clamping the outflow temporarily, which may facilitate easier identification of the urinary bladder during dissection and may help prevent injury to the bladder. In the event of a urinary bladder injury, a distended bladder may further aid in the detection and repair of the injury.

Suggestions

Placement of a urinary bladder catheter during LVHR should be determined based on the anticipated duration of the procedure and the location of the hernia. For LVHR near the symphysis that requires dissection and prosthetic fixation to the pubic bone, the placement of a 3-way catheter should be considered to allow drainage and easy instillation of sterile saline solution to distend the bladder, which may help in recognizing and avoiding bladder injuries. (Level of evidence 4)

References

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ACCESS ABDOMEN AND PLACEMENT OF TROCARS

Although a variety of techniques have been described in the published literature, all with low rates of complications and successful establishment of pneumoperitoneum [1] In the study by Sanders et al (1999) an open technique was used in all the cases. [2] One of the largest retrospective series described placement of a Veress needle at least 10 cm away from the prior scar [3] Bladeless trocars have been used in the extreme lateral position through the abdominal wall, on the side opposite the dominant bulge of the hernia. In most cases, two 5-mm bladeless trocars and a single 12-mm bladeless trocar are used. In all of these repairs, the abdomen must be entered with one of the variety of techniques that are available and may be that of the Hasson technique, the use of an “optical trocar,” or with the Veress needle. This decision can be, in and of itself, a difficult one as the subsequent steps in the operation are usually determined by the placement of the trocars themselves. After entry, the abdomen should be inspected and additional trocars should be placed under direct visualization when and where they can be done safely.

Suggestions

It is considered to choose the left or right upper quadrant subcostal area for the first access to the abdominal cavity. It is considered to use a 30 degree angled laparoscope. It is recommended that the laparoscope be inserted into each trocar after it is placed to inspect the abdominal contents from that newer perspective. Depending on the adhesions found inside as well as the size, site and number of existing wall defects the trocar entry points should be as far as possible to achieve triangulation of the site of the hernia. It is frequently necessary to place and manipulate instruments from the side of the patient in direct opposition to the viewing laparoscope to produce a mirror image for allowing a better viewing of all the adhesions. Moreover, an opposite 5mm trocar may provide a better fixation of the parts of the mesh near the optic trocar. It is very important to identify all hernia defects and include all of them. (Level of evidence 1A)

References:

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ADHESIOLYSIS

Adhesiolysis is carried out to visualize the hernial defect by using scissors / hook or by ultra scission or a combination of both. Counter pressure on the abdominal wall is used during adhesiolysis to reduce the contents. Margin of the defect is cleared of redundant fat and any other additional defect is managed. Depending on the hernia location, the falciform and umbilical ligaments may need to be taken down to identify occult hernia defects and allow adequate exposure of the abdominal wall for placement of an appropriately sized prosthetic. This might expose occult fascial defects, which occur in almost half of cases, thus allowing adequate mesh coverage of all defects and the entire old incision. [1] Adhesiolysis is performed to provide a full, clean exposure of the entire peritoneal surface of the anterior abdominal wall. A typical abdominal wall appearance is that of a dominant incisional hernia adjacent smaller hernias often accompany that. This is accomplished sharply, normally with the use of endoscopic scissors and cautery. Frequently, omentum and intestines are adherent or incarcerated within the hernia site. Adhesions between bowel or omentum and the abdominal wall should be taken down to allow complete visualization of the defect and the abdominal wall, as well as provide an adequate area for placement of the appropriate-sized prosthetic [2] The adhesions may be difficult to visualize or reach with laparoscopic instruments due to the narrow defect size or angulation required to visualize the hernia sac content through the hernia defect. Pulling on the viscera with great force can also cause injury. On the other hand, external pressure on the abdominal wall in the area of the hernia may help reduce the sac contents intra-abdominally or make them more easily visible for safe dissection and should be employed when this situation is encountered. A laparoscopic approach may be associated with a higher probability of conversion to an open approach under these circumstances. With the small defect and large sac scenario, trying to reduce acutely or chronically incarcerated viscera can result in inadvertent visceral injury. Surgeons might be able to reduce an incarcerated hernia laparoscopically by incising the neck of the hernia with a laparoscopic scissor without diathermy. Further, external pressure may prove very valuable. A laparoscopic approach may be attempted but will have a higher probability of being converted to an open or laparoscopic-assisted approach [3] Combination of scissors and ultra scission has been used for adhesiolysis [4]

Use of an energy source for hemostasis should be kept to a minimum to avoid bowel injury. It is important to recognize that as the adhesiolysis progresses, vigilance regarding the proximity of the hollow viscera, particularly in the GI tract, must be in the forefront of the surgeon's mind. In general, bleeding near the bowel should be controlled with sutures, clips or a topical hemostatic agent rather than an energy source [5] After adhesiolysis, the sac contents are gently reduced into the peritoneal cavity with atraumatic graspers, while the hernia sac is left in situ. However, it may be necessary to excise a portion of the sac if the bowel is closely adherent. If the hernia contents cannot be reduced,

conversion to an open procedure is necessary [6] At the conclusion of the adhesiolysis, it is prudent to inspect the areas of the hollow viscera involved for evidence of partial thickness, full thickness, or thermal injury.

Several maneuvers facilitate safe adhesiolysis [7][8]. Carbajo reported 8 patients who underwent laparoscopic repair of enterotomies followed by immediate Laparoscopic ventral hernia repair. Sharp dissection should always be utilized in areas of dense adhesions, particularly when the presence of bowel is suspected. Again, the use of energy sources near bowel may be a source of delayed injuries with significantly increased morbidity and mortality. Some authors advocate immediate repair of bowel injuries and completing the Laparoscopic ventral hernia repair in the same setting. [9]

Suggestions

Most challenging segment of the repair and there are significant risks of the entire operation are enterotomy, and hemorrhage. Risk of an unrecognized enterotomy is so great that the use of any energy source is avoided entirely. Use the ultrasonic scalpel, bipolar cautery, or monopolar cautery selectively. Adhesiolysis should be performed carefully with sharp and/or blunt dissection and sparing use of energy for hemostasis to avoid inadvertent delayed enterotomy clips, sutures and hemostatic agents are preferable to energy application to achieve hemostasis near the bowel. Depending on the hernia location, the falciform and umbilical ligaments may need to be taken down and the space of Retzius dissected to identify occult hernia defects and allow adequate exposure of the abdominal wall for placement of an appropriately sized prosthetic. Adhesiolysis should be limited to freeing the abdominal wall for overlapping mesh.

Sharp adhesiolysis is preferred, ultrasonic dissection or bipolar clamp is allowed, and monopolar coagulation should be avoided. (Level of evidence 3) Adhesiolysis should be done near the abdominal wall away from the adherent tissue. (Level of evidence 4) Surgeons might be able to reduce an incarcerated hernia laparoscopically by incising the neck of the hernia with a laparoscopic scissor without diathermy. Adhesiolysis should be done in a conservative way. High-energy devices can be used with caution and monopolar cautery should be avoided. The falciform and umbilical ligaments may need to be taken down for placement of appropriately sized prosthetic (Level of evidence 4) Counter pressure on the sac from abdominal wall helps in adhesiolysis & reduce contents (Level of evidence 4)

References:

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MEASUREMENT OF DEFECT AND MESH OVERLAP

Accurate measurement of the defect is a key to ensuring adequate meshes coverage and minimizing recurrence. There are two main approaches to measuring the defect – externally on the abdominal wall and internally within the peritoneal cavity [1]. This will in turn allow for selection of the most appropriately sized prosthetic, which should reduce the chance for a hernia recurrence[3].Pitfalls of performing the external measurements include (1) angling the needed (either towards or away from the defect) through the abdominal wall rather than removing and re-inserting the needle when identifying borders of the defect, and (2) performing the measurements with a fully insufflated .Because the circumference of the abdominal wall is larger on the outside compared to the inside, this technique will typically overestimate the size of the defect. It is important to note that the thicker the abdominal wall, the larger the difference will be between measured and actual size of defect. Factors increasing this discrepancy include a fully insufflated abdomen, obesity, and a large hernia sac. In the setting of obesity and a large sac, the discrepancy will be greatest., particularly if there is a large hernia sac.[4] Measuring from inside by bringing pneumoperitoneum down to 8 mm Hg and placing instrument at the margin of the defect intrabdominally and palpating it on abdominal wall and marking it by a marking pen. This method is easier and more accurate than external measurement. The external measurement exaggerates the defect size. The mesh is then tailored to overlap the defect by 5 cm wherever possible this overlap is done keeping in view the displacement of mesh in the initial stages and mesh shrinkage at a later stage.This technique was used by Sanders et al (1999)[2].

Suggestions

Size of hernia defect is a significant risk factor for recurrence in laparoscopic ventral/incisional hernia repair Bring pneumoperitoneum down to 8 mm Hg. Intracorporeal method of measurement of the size of hernial defect should be used. (Level of evidence 5)The total area encompassing all the defects should be measured.(Level of evidence 3)

Mesh should be tailored to overlap the defect by 5cms and more in obese patients keeping in view the displacement of mesh in the initial stages and mesh shrinkage at a later stage (Level of evidence 4)

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CLOSURE OF DEFECT/PRIMARY FASCIAL CLOSURE

Many authors believe that approximating the hernia defect during laparoscopic ventral hernia repair, prior to mesh fixation, provides a more physiologic and anatomic repair. Defect closure also provides more defect overlap with mesh provides a simple and reproducible way to close the hernia defect during laparoscopic ventral hernia repair. Laparoscopic ventral hernia repair has grown in popularity. Typically, this procedure is performed with a mesh bridge technique that results in high rates of seroma, eventration (bulging), and patient dissatisfaction. In an effort to avoid these complications, there is growing interest in the role of laparoscopic primary fascial closure with intraperitoneal mesh placement. This systematic review evaluated the outcomes of closure of the central defect during Laparoscopic ventral hernia repair A literature search of PubMed, Cochrane databases, and Embase was conducted. MINORS were used to assess the methodological quality. Primary outcome was hernia recurrence Secondary outcomes were surgical-site infection, seroma formation, bulging, and patient-centered items (satisfaction, chronic pain, functional status). Eleven studies were identified, eight of which were case series. rates (0-5.7 vs. 4.8-16.7 %) and seroma formation rates (5.6-11.4 vs. 4.3-27.8 %). Follow-up periods for both groups were similar (1-108 months). Only one study evaluated patient function and clinical bulging. It showed better outcomes with primary fascial closure. Closure of the defect during Laparoscopic ventral hernia repair resulted in less recurrence, bulging, and seroma than no closure. Patients with closure were more satisfied with the results and had better functional status. The quality of the data was poor, however. A randomized controlled trial to evaluate the role of closure of the central defect during Laparoscopic ventral hernia repair is warranted. The logic behind closure of defect is: restoration of abdominal wall anatomy, closing the sac enables the 5cm overlap needed in placement of mesh, it prevents mesh extrusion, post operative bulge and finally it prevents seroma formaton and gives a satisfactory body image to the patient. [1] [2]A single institution's systematic retrospective review of 1326 Laparoscopic ventral hernia repair was conducted between the years 2000 and 2014. A standardized technique of routine closure of the defect prior to the intraperitoneal on lay mesh (IPOM) reinforcement was performed in all patients Based on their experience and study, the current best indications for a successful Laparoscopic ventral hernia repair procedure should be tailored upon the limitations of

the defect's width and Some authors suggest primary fascial closure. This technique has been developed in an effort to reduce postoperative bulging and formation of seroma after laparoscopic ventral hernia repair. Given LaPlace's law, a central nonfunctional portion of the abdominal wall acts like a "sail in the wind" and is prone to bulging. Primary fascial closure restores normal anatomy by approximating the abdominal wall under physiologic tension, which may restore its function. [3] [4] The techniques for closure include intracorporeal closure, extracorporeal closure, or a mixed technique. The most commonly used technique is extracorporeal suturing, according to which small skin incisions are made after which a suture passer is used to close the defect. By eliminating the dead space, this technique decreases the incidence of seromas and wound complications. Moreover, it allows wider lateral mesh overlap that reduces the possibility of recurrence. The logic behind closure of defect is: restoration of abdominal wall anatomy, closing the sac enables the 5cm overlap needed in placement of mesh, it prevents mesh extrusion, post operative bulge and finally it prevents seroma formation and gives a satisfactory body image to the patient. [1] Some authors suggest primary fascial closure. This technique has been developed in an effort to reduce postoperative bulging and formation of seroma after laparoscopic ventral hernia repair. Given LaPlace's law, a central nonfunctional portion of the abdominal wall acts like a "sail in the wind" and is prone to bulging. Three comparative studies examined the difference between closure and nonclosure of the fascial defect during laparoscopic ventral incisional hernia repairs (level 3 and 4 data). These studies suggested that primary fascial closure (n = 138) compared to no closure (n = 255) resulted in lower recurrence

Closure of hernia defect should be undertaken at the surgeon's discretion, as theoretical advantages exist. Reasons to close the defect during Laparoscopic ventral hernia repair prior to mesh insertion include the possibility of reduced seroma rate reduced recurrence rate, improved "abdominal wall function," and improved abdominal wall contour postoperatively [5] [6][7] Suture passer techniques through a series of mini incisions through the hernia sac and/or old scar, laparoscopic techniques utilizing both intra- and extra-corporeal knot tying techniques, the use of barbed suture material, Favorable outcomes have been reported utilizing a variety of closure techniques Palanivelu C, Jani K V, Senthilnathan, Parthasarathi R, Madhankumar M V, Malladi V K (2007) Techniques of defect closure are highly variable and include a variety of suture passer techniques through a series of mini incisions through the hernia sac and/or old scar, laparoscopic techniques utilizing both intra- and extra-corporeal knot tying techniques, the use of barbed suture material, Favorable outcomes have been reported utilizing a variety of closure techniques[5][6][7][8] [9] There is advantage of closure of defect in laparoscopic repair of ventral hernia wherever possible. The logic behind closure of defect is: restoration of abdominal wall anatomy, closing the sac enables the 5cm overlap needed in placement of mesh, it prevents mesh extrusion, post operative bulge and finally it prevents seroma formation and gives a satisfactory body image to the patient. Both studies showed that a larger overlap of the prosthesis (5 vs 3 cm) was necessary if sutures were not used. If sutures were used, these studies recommended placing them no more than 5 cm apart.[10]In the suture group only 2 studies [11] The suturing concept for laparoscopic mesh fixation in ventral and incisional hernia repair: . Agarwal et al. reported on 29 patients with primary fascial closure using an overlapping repair with transfascial vertical mattress sutures, [9]

Suggestions

Specific problem associated with the laparoscopic repair of large incisional hernias and is observed in 1.6–17.4% of patients. (Level of evidence 2B) Intracorporeal facial closure of hernia defect should be undertaken in defects wherever feasible, as advantages exist. (Level of evidence 4) Reasons to close the defect during Laparoscopic ventral hernia repair prior to mesh insertion eliminates postoperative bulging, brings good body image and quality of life. There is possibility of reduced seroma and recurrence rate. (Level of evidence 3)

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MESH CHOICE AND REPAIR

When meshes are inserted intraperitoneally during laparoscopic IPOM they must meet stringent requirements because of their direct contact with the abdominal intestines. Eriksen et al (2007) formulated the following characteristics for an optimal mesh to be used for laparoscopic repair of ventral and Incisional hernias Minimal adhesion formation Excellent tissue ingrowth, Minimal shrinkage, no infection or fistula formation, minimal pain, minimal seroma formation. No change in abdominal wall compliance and Low price and Easy to manipulate.

Four main types of mesh have been used: ePTFE Polypropylene, Composite-meshes Polypropylene prosthesis has been abandoned in the laparoscopic approach, because it may create adhesions with bowel loops. It has been replaced by Mesh, which is composed of polypropylene covered with oxidized regenerated cellulose (ORC)[2] mesh for laparoscopic ventral hernia repair. Newer mesh composed of polypropylene covered by a layer of polyglactone-25 on both sides has been added recently to the surgical practice [3][4]

Suggestions

Based on today's knowledge, plain polypropylene (without a protective layer cannot be recommended for intra-abdominal use at this time. Repair for laparoscopic ventral hernia repair, only materials with permission for use in the abdominal cavity are composite meshes with protective layer on visceral side. (Level of evidence 1A) biological meshes are mainly used to reconstruct the abdominal wall in an infected field, but they are of limited use in laparoscopic ventral hernia repair in our setup. (Level of evidence 5)

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INSERTION AND ORIENTATION OF MESH

Mesh placement and orientation to overlap the hernia defect is a crucial step. The current techniques for mesh placement are time-consuming. After the selection of the appropriate sized prosthesis. One technique involves fixing the mesh with sutures circumferentially in two circles. The tackers and staplers were not used. The sutures are placed at fixed intervals, in fixed numbers and in fixed positions as mapped out with the help of circular protractors, compass and ruler. The protractors helped us in standardizing the placement intervals of sutures and in the orientation of the mesh. The orientation is maintained even for a very large mesh.[1] Another technique used is four size-0 permanent monofilament or ePTFE sutures are placed at the mid-point of each side of the mesh. Points of reference on the mesh and corresponding points on the abdominal wall are marked to aid in orienting the mesh after its introduction into the abdomen. The mesh is rolled up and pushed or pulled into the abdomen through a 5- or 10-mm trocar site. The mesh is rolled from both edges to facilitate the unfolding step. If the defect size dictates a very large prosthetic it is usually introduced in the abdominal cavity by pulling with the grasper passed through the contralateral trocar. It is important to maintain the appropriate orientation of the mesh during the insertion and unfolding of the mesh. Two Maryland graspers are best used to unfold the mesh. After the mesh is oriented

intracorporeally, the sutures are pulled through the abdominal wall with a suture passer. A 4 cm mesh/defect overlap is once again confirmed using spinal needles, as described above. The suture pulled first is usually closest to the “sensitive” border (xiphoid, pubis, iliac crest, costal margin, colostomy, etc.). We subsequently pull the suture that is adjacent (not opposite) to the first one. Once sufficient overlap is confirmed, we tie both sutures with the knots buried in subcutaneous tissues. The other two sutures are then pulled trans abdominally and tied ensuring that the overlap is sufficient and that the mesh is taut [2]

Third method is 4 sutures are placed on the axial edges of the mesh. Permanent sutures are most widely used. The suture sites are numbered with a marked corresponding on abdominal wall defect margin to ensure correct orientation of the mesh in the abdominal cavity. The mesh is rolled tightly and is inserted in the peritoneal cavity through the 10–11-mm trocar. It is unrolled inside the abdomen and spread under the defect. Assisted by a suture passer, the 4 transfascial sutures are used to fix the mesh to the interior of the abdominal wall [3] Orientation of mesh can be done by using central suture technique. Suture was introduced through the abdominal wall into the center of the defect and the suture retrieved intra -abdominally by using a needle holder/ forceps and brought out through the 10 mm trocar after removing the telescope from it under guidance of 30-degree 5mm telescope introduced through 5mm trocar. The suture was then tied to the center of the mesh, and the mesh then rolled into a cigar shape and passed through the 10 mm port into the abdomen. Then 10 mm telescope with camera attached was reintroduced through 10 mm trocar. The tail of the suture was then brought out from the abdominal wall and the mesh aligned over the center of the defect .

Suggestions

Use four-corner or center suture method for orientation of mesh which ever you are at ease. Large lightweight meshes should be tightly rolled up for safe and effective insertion through 10 – 12 mm port. (Level of evidence 4) assisted by a suture passer, the 4-transfascial sutures are used to fix the mesh to the interior of the abdominal wall (Level of evidence 4). Centre suture method (Level of evidence 5) use four corner or center suture method for orientation of mesh which ever you are at ease.

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FIXATION OF MESH

As far as the fixing mesh is concerned various fixation devices like tacks, sutures and surgical glue have been used. Heniford et al (1999) used transabdominal suture fixation using a suture passer in all cases. Secure fixation of the mesh and adequate overlap of all hernia margins with the prosthetic material are crucial to the success of Laparoscopic ventral hernia repair [1]. The two most

widely used mesh-fixation methods (the transabdominal sutures and double crown tacks fixation techniques) in Laparoscopic ventral hernia repair provide reliable results with similarly low recurrence rates. [2][3] However, fixation of the mesh to the abdominal wall also appears to be the most important source of postoperative pain. The importance of this problem was indicated by the recent study of Eriksen et al., who found that Laparoscopic ventral hernia repair was associated with considerable postoperative pain and fatigue in the first month after surgery and had significant effects on patients quality of life for up to 6 months postoperatively [4]

Currently, there are two main categories of fixation method available for use in the operating room – tacks and sutures, both of which are available in absorbable or permanent varieties. Sutures are commonly anchored to the mesh with conventional instruments in combination with a suture-passing device [5] Fixation of hernia prosthetic to the abdominal wall is required as part of Laparoscopic ventral hernia repair. Controversy exists regarding the amount, strength, [8][9]. [10] Tacks are usually deployed via a mechanical device typically referred to as a “tacker” (deploys a variety of anchoring devices collectively known as “tacks”)[11] In another study found that double-crown fixation of intra-peritoneal mesh during laparoscopic ventral hernia repair was quicker, was less painful immediately post-operative and after 3 months, and did not increase the recurrence rate at 24 months. In hernias at a distance from the bony borders of the abdomen, transfascial sutures can be omitted if a double crown of tacks [12] Summarizing the experimental and clinical data, the use of glue, especially fibrin glue, in combination with penetrating fixation devices e.g. transfascial sutures or tacks seems to be feasible in terms of biomechanical strength presupposed the appropriate type of mesh (e.g.: porosity, elasticity, coating) is selected and use of glue application is adequate. The use of additional glue fixation increases the efficacy of mechanical fixation and leads to a possible reduction of penetrating and perforating devices [13] [14].

Regarding fixation in suprapubic and subxiphoidal hernias -For Laparoscopic ventral hernia repair near the symphysis that requires dissection and prosthetic fixation to the pubic bone, the placement of a 3-way catheter should be considered to allow drainage and easy instillation of sterile saline solution to distend the bladder, which may help in recognizing and avoiding bladder injuries. [14][15] In cases of Suprapubic hernias mesh overlap of at least 5 cm and fixation of the lower margin of the mesh under direct vision to Cooper’s ligaments confers increased strength and durability and contributes to low hernia recurrence rates.[16]

Suggestions

Combination of transabdominal sutures and tacks should be considered to reduce risk of recurrence, mesh shrinkage and manageable post operative pain without compromising hernia repair (Level of evidence 1B) It is recommended to overlap the defect at least 5 cm in all directions for proper fixation and incorporation of the mesh. Removal of different anatomical structures like the falciform ligament, the ligamentum teres and the prevesical fatty tissue should be done. a larger overlap could be Currently, there are two main categories of fixation method available for use in the operating room – tacks and sutures, both of which are available in absorbable or permanent varieties necessary, minimum of 5 cm, if you fix the mesh without transfascial sutures.

Fixation in laparoscopic repair for ventral and incisional hernias performed by sutures and tacks combination of can be recommended equivalently in terms of risk of recurrence (Level of evidence 3)

Regarding the significant shorter operation time the tacker (double crown technique) fixation can be considered as technique of choice taking into account the increased risk of postoperative pain but not cost effective as number of tacks required to fix at 1 cm interval in two rows.

Suture fixation only or a combination with tacks should be performed to decrease the risk of mesh shrinkage and recurrence

It is suggested the use of absorbable penetrating fixation devices achieves sufficient tensile strength and low recurrence rates and decreased postoperative pain.

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Gurubhashyam

Social contribution by Surgeons

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Jibe prem kore jaijan seijan sebichhe ishwar - Swami Vivekananda

Most of us are very busy professionals. We have lots of commitments in life. The first and foremost is our family commitments. Once we are in some employment, our commitment is to the employer. Once we are medical practitioners, our commitment is to our patients. In our busy life schedule, we need to balance these commitments. Another important commitment for surgeons is to spend a fair amount of time for professional development, in the form of attending conferences and workshops to learn and hone new skills. In addition to this we need to think about our social commitment.

India is a vast country and celebrated its Platinum jubilee independence day on the 15th of August this year. Still all citizens do not have access to education, health, food and housing, which are considered as fundamental rights. It is true that both central and State Governments have taken several initiatives in this regard and are trying to uplift the community as far as fulfilling these basic needs are concerned. However, still the target has not been reached. Till today, we have tremendous school dropouts. Malnutrition is a widespread malady in the society. Many Indian citizens die due to inadequate health care and all do not have access to advanced health care. To aggravate the situation, the prolonged lockdown imposed by Government to control the Corona pandemic has led to an economic disaster and millions of people have lost their jobs and many have lost their near and dear ones.

We as medical professionals are extremely busy with our so many commitments and it is really impossible to find out time and energy to get involved in social activities. Over the years I started thinking about these social commitments and I am happy to share that I have been able to make some contribution for these social activities. How to get involved in these social activities is a question mark for many.

My first exposure to such social work was in the year 1978. There was a devastating flood in different parts of Bengal. Waterlogging leading to health crisis was reason for lots of deaths during flood. Cholera and typhoid were two killers during these natural disasters. The students union of college took initiative to go in batches to remote flood affected areas for relief work. We formed groups and visited remote areas in rural Bengal and were involved in mass cholera and typhoid vaccination. Although it was a very tough job we all felt satisfied at the end when we all could contribute little in controlling the epidemic of cholera.

At individual level it is difficult to reach out to the target population, both in terms of manpower and finance. There are many NGOs working in the rural areas and it is possible to reach to rural areas through them and an effective social service is possible. I feel that such activities can be accomplished either at a personal level, or through various professional bodies like the Association of Surgeons of India (ASI), Association of Minimal Access Surgeons of India (AMASI) and Indian Medical Association (IMA). Over the years, I have been fortunate enough to be able to do some social activities for the benefit of rural people. ASI and AMASI

promote social activities and it is possible to plan and execute some social activities with financial grants from ASI and AMASI.

Following the slogan of AMASI “MAS for masses” we have been able to organize rural surgical camps at various remote places in Bengal. Surgical camps were organized at Baruipur and Jhargram. Rural people could be offered the benefit of MAS at their doorstep. We have organized laparoscopic cholecystectomy camp at Baruipur. One laparoscopic hernia camp was organized at Jhargram. In both these camps, financial assistance was provided by AMASI. A group of like minded people is required to plan such programmes. Financing such activities is not difficult if we are a little proactive. e.g. AMASI provides grants for such rural surgical camps and we can also contribute in groups for such noble work.

The last one and half years has been marked by the Covid pandemic. In addition to health crisis, there has been a devastating economic crisis in large sections of population. During the initial days of Covid pandemic, there was severe scarcity of PPE kits. Through social media, I discovered that STUDD company had manufactured a face shield for doctors. I took the initiative for purchase and distribution such face shields to health care workers (HCW). With my little contribution and raising funds from friends and relatives we have distributed face shields to HCWs at Infectious Diseases Hospital, Beliaghata, M.R. Bangur Covid Hospital and Bharat Sevasram Sangha Hospital at Kolkata. During the pandemic, the HCW workers were working relentlessly and some could not even go back to their homes. I realized that if we could provide them good food on the premises, it would be a morale booster and we did so at M R Bangur Hospital. ASI head quarter had also taken initiative to stand by the side of HCW by sending the PPE Kit and sanitisers. On behalf of ASI head quarter, I personally visited the health institutions and distributed the PPE kit and sanitisers to HCW.

Consequent to prolonged lockdown, the daily wage earners from rural areas lost their jobs and they faced extreme financial crisis. Ramkrishna Mission Ashram is a NGO working in rural Bengal covering large areas of Sundarban. They were distributing food items like rice, dal, oil, soyabean, spices, salts, potatoes, soaps, masks and sanitisers to these rural people. I took an initiative and raise funds from friends, relatives and my students who contributed generously and we could distribute these food items to about 500 families in remote areas of Sundarban. Along with pandemic, there was the devastating storm AMPHAN in different areas of Sunderban. I appealed to my friend and relatives for contribution to the fund-raising drive of Ramkrishna Ashram and a significant sum of money was contributed to Ramkrishna Ashram and they have constructed new houses to replace those destroyed by the natural calamity. It was an extremely satisfying moment to see when Ramkrishna Mission Ashram has forwarded the constructed houses for these rural poor people.

Prime minister and the Chief ministers of different states have created relief funds and this is another avenue to get involved in social activities. I contributed Rs 50000 to chief minister fund for Covid related relief work. As a surgeon community, if we all come forward, this will be a great contribution to the society.

It is true that many of us want to get involved in such activities and we always face few constraints like will to do such social work, finance and the manpower. I would like to emphasise that little initiative on our part may go a long way in upliftment of distress of rural people. As I stated, there are associations which provide financial support for such activities. The social media is a strong platform and I have raised more than 10 lakhs rupees in just 3 days from friends, relatives and well wishers for a social work by appealing through facebook. The NGO's working in rural areas may be a medium through which we can do such social activities. There are lots of like minded people who want to get involved in such noble work and we have to provide leadership.



NGOs help out in relief work



Ensuring relief to the most deprived

Private enterprises can be motivated to help - distributing face shields provided by STUDD



Co-ordinating ASI efforts to provide sanitizers to HCWs

Writing a Scientific paper



Prof Vikram Kate

Randomized Controlled Trial: How to write your manuscript?

Part-1 of 2

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BACKGROUND

David Sackett, one of the pioneers of evidence-based medicine (EBM), defined EBM as "the judicious use of current best evidence in making decisions about the care of an individual patient."

(1) The practice of evidence-based medicine leads us to improved care of patients and efficient use of health resources. Randomized controlled trials (RCT) are known to be the highest quality of evidence. Shortcomings in the protocol design, practical conduct and statistical analysis and faulty reporting can be responsible for improper estimation of the effect of an intervention in a trial. In

this two-part series on randomized controlled trials, we aim to make it easy for the readers to understand the key elements of a good quality RCT and how to write one in the accepted format for successful publication.

RCTs are well planned and rigorously conducted controlled studies. Controlled trials implies that the whole experiment is carried out within controlled conditions with eligibility criteria, a priori hypothesis, primary and secondary endpoints, methods for enrollment and stopping rules. They are planned experiments designed to assess the efficacy of an intervention by comparing it to a control or another intervention (equivalence trials). Conventionally, in an RCT both the groups are matched for all the demographic details with intervention being the only difference between the two. Any differences in observation or outcome seen thus, can then be attributed to the intervention. The groups in RCTs include randomized individuals in a conventional trial. However, a cluster randomization can also be carried out when a whole community or a hospital is allocated to one of the interventional or control arm. RCTs can be performed in any setting, irrespective of the size of the institutional set-up or infrastructure and should be completed within a span of few years. Prolonged duration of RCTs is not desirable as sometimes the intervention may become obsolete or inefficacious as reported through other studies. At times, a well-planned RCTs can also be carried out as undergraduate projects and can be completed in a short period of a few months with good quality output. (2)

Types of RCTs

Individual randomized trials: Eligible individuals are randomized. Most conventional RCTs have individual randomization.

Cluster randomized trials: When randomization of individual participants is not feasible, cluster randomization of communities, hospitals or other aggregates of people are carried out. The advantage of a cluster trial is that the whole hospital can follow a surgical technique which are routinely performed in their set-up. Suppose a study is carried out on the comparison of laparoscopic versus robotic hernia repair, then in these circumstances the cluster randomized hospital can perform the routinely carried out procedure which can be either laparoscopy or robotic hernia repair in their set-up, as some of the hospitals may not be performing both types of procedures.

There are various phases of a clinical trial.

Phase 1 trial is done in a limited number of healthy volunteers. It is done to assess safety.

Phase 2 trial is done in a small number of target disease patients. It is done to assess primarily the safety in the target population and to a certain extent the efficacy.

Phase 3 trials are done in a larger number of diseased patients and are evaluated for efficacy and acceptability. Most of the conventional clinical trials fall in this category.

Phase 4 trials are long term trials with a large number of participants. They assess the long-term safety.

Trial designs for RCTs

Parallel arm design- This type of RCT has two arms- an intervention arm and a control arm. Each group of participants is exposed to only one study intervention.

Cross over design- All the participants in this study receive all the study interventions in a phased manner determined by randomization.

These studies are appropriate for chronic diseases that are stable over time and interventions that last for a short time, have a brief wash-out period and do not interfere with one another. (Fig.1)

Equivalence trial design- Head-to-head comparison of two or more groups without control arm.

- Superiority trials- When the intervention is hypothesized to be superior to the control.
- Non-inferiority trials/equivalence trials- When the intervention is hypothesized to be not-inferior or equivalent to the control arm.

Factorial design- Intervention A, intervention B, intervention A+B vs control are the various arms of the study. They provide more information than parallel arm studies but are also more complex to carry out.

Parallel arm superiority and non-inferiority trials- Parallel arm RCT is one of the most performed trials as it is done to compare a new technique or procedure to the standard of care. This type of RCTs can presume the new procedure to be superior to the existing procedure or comparable to the existing procedure. The former is referred to as superiority trial and the latter as non-inferiority trial. (3-6)

In the following parts, we will focus on formulating a research question and planning the methodology such that the manuscript of the trial can also be lucidly written by adhering to prescribed guidelines. The manuscript of a trial must be organized and presented in the standard IMRaD (Introduction, Methods, Results and Discussion) format. (7)

HOW TO WRITE A MANUSCRIPT FOR AN RCT

Introduction

Introduction is structured in a funnel-shaped manner. The reader is enlightened about the reasons for conducting the research in the light of current knowledge. Primarily the broad area of research is described following which the area of interest and the specific research question and what the investigators are looking into is focused. This can be illustrated as follows: in the overall area of research on ERAS, the area of interest could be ERAS in the emergency setting and the specific research question can be the role of ERAS in perforated duodenal ulcer or emergency small bowel surgery. (Fig 2) It is necessary in an introduction of an RCT manuscript to justify the equipoise in the literature. This means that the research question that the investigator is looking into are not answered clearly in the literature. If it has already been established that a particular procedure is superior through a control arm, carrying out an RCT becomes unethical. The a priori hypothesis must be explicit, testable, and potentially falsifiable. The objectives are the end points that must be reached to achieve the aim or address the hypothesis. They can be primary and certain secondary objectives that can add value to the clinical aim. In turn, the methodology is designed to achieve each of the end points stated in the objectives. The aims and objectives are routinely mentioned at the end of the introduction.

Methodology

The methods section in an RCT is one of the most important aspects of a manuscript as it describes in detail how the study was carried out. Any deficiency in this section can lead to rejection of the manuscript as reviewers most often focussignificantly on the methodology of the study. In most of the review reports majority of the reviewer-questions are targeted towards this section as a faulty method may make the result null and void. An explicit way of writing methodology is through adaptation of a structured format under the sub-headings: study design, study setting, study participants, study procedure, primary and secondary outcomes, and the statistical analysis. (8)

The aims and objectives must be described using the PICOT format.(Fig.3) (9)

Population: The inclusion criteria must be as broad and flexible as possible, bearing in mind the safety of the patients with diverse comorbid conditions. Exclusion criteria must be employed to not only exclude patients who will possibly be harmed due to the study intervention, but also to exclude patients with confounding factors that are likely to interfere with results. Balancing the inclusion and exclusion criteria is important, as flexible inclusion criteria leads to a good number of recruited patients and restricted exclusion criteria facilitates extrapolation of the results in the general population.

Intervention: The intervention to be studied must be previously described to benefit the clinical condition being studied. In case of novel interventions, they must be logically sound for the intended objectives of the study and approved by the ethics board. All interventions must be clearly defined in easy-to-follow steps so that blinded clinicians can carry them out without confusion. Preferably, a training session should be carried out for all those participating in the procedure prior to recruitment of patients.

Comparator/control group: This group of subjects should either undergo a standard procedure when a novel procedure is being introduced over a standard procedure (comparator arm) or serve as a placebo arm. In case of a cross-over RCT, these groups are interchanged in a blinded fashion at a predetermined time interval.

Outcome: The primary and secondary outcomes observed in both the groups must be compared using appropriate statistical analysis to determine the statistical significance. The outcomes falling short of statistical significance but of clinical significance should be made note of as future studies can be focused on verification of such findings. The primary outcome is conventionally a parameter which is the focus of the clinician. Usually in an RCT single parameter is chosen as a primary outcome, however, some studies can have more than one primary outcome. When a study has multiple primary outcomes, they can be assessed individually or as a composite outcome. The advantage of assessment as a composite outcome is the increase in the number of events in both the study and control arm, where a deficiency in the number of events in some parameters such as mortalityof the primary outcome can be compensated by other parameters occurring more frequently.

Time / follow up duration: The anticipated and feasible time frame within which patients will be recruited and the duration of follow-up, if applicable, must be planned at the protocol stage. RCTs are generally planned over a relatively brief period of time (months to a few years) so that the intervention or standard of care remains in accordance with the current practice. Sometimes interim analysis may be needed to assess the safety of the trial. Rarely, an analysis of the intervention is done few years later following the index publication to analyze results for long-term benefits and complications.

Factors need to be considered before starting RCT

- **Funding:** In addition to the above, pre-study preparation also involves applying for funding and procurement of certain special equipment or drugs which may not be routinely available at the institution. A study can be investigator-initiated or an industry-sponsored trial, especially in the latter for which the conflict of interest must be declared. A declaration of conflict of interest allows the readers to make an independent judgement about the findings of the study. This is important in an industry-sponsored drug or surgical equipment trial.
- **Consent:** The detailed explanation of what the trial involves, what are the interventions the patient will be subjected to, what are its consequences, available alternative options, side effects and other possible complications must be discussed with the patient. A written and informed consent including these details must be taken in the patient's language in simple terms. The patient must also be fully aware that they have full freedom to withdraw from the trial at any point of time. The patient is also entitled for compensation due to unforeseen complications as per the guidelines. This is specifically important in multi-centric trials.
- **Ethical clearance and trial registration:** Prior to embarking on the study, ethical clearance must be obtained from the institute ethics committee. Trial registration must be done prospectively after receiving the approval letter from the institute ethics committee and the registration number must be obtained before recruitment of the first patient into the study. Registration is now mandatory for publication in most journals of repute. The Clinical Trials Registry-India (CTRI) is the official system of the Indian Council of Medical Research (ICMR) for registration of all trials being conducted in India. (10)

Sample size: The sample size for a study should be determined based on the primary outcome and the target difference in the clinical outcome that must be achieved between the two groups for the research question to be conclusively answered. (11) Previous studies help in determining the effect size (for example, odds ratio, difference in means or proportions, relative risk or hazard ratio between the groups) and if unavailable, the study can be carried out and an interim analysis done to evaluate the statistical significance noted at that stage. (5,6) One can perform an interim analysis when a pre-decided number of patients have completed the study. The power of the study can be determined at that stage and a sufficient sample size can be arrived at. In addition, if the analysis shows clear benefit of the intervention group, it becomes unethical to continue the trial further if the control group is put at risk due to non-availability of the intervention. In case of an underpowered study, sample size adjustments can be made during an interim analysis. The interim analysis must be pre-planned during the protocol. (12) Adequately powered studies not only

provide reliable results, but also ensure reduced exposure to harm, which is more in research subjects in over-powered studies and more in the general population receiving the treatment afterwards due to an under-powered study.

The errors that must be minimized are random error (statistical/ chance error) and systematic error (bias). (13) A type 1 statistical (alpha) error is a measure of false positives, whereas a type 2 or beta error is a measure of false negatives. Both these must be minimized by adequate statistical powering. Optimal sample size calculation also helps in estimation of the grant being applied for. It is prudent to seek a statistician's guidance at this stage to determine the sample size and the statistical methods to be applied for the analysis. Random error can also occur due to fluctuations in measurement each time and can be minimized by making multiple readings. Systematic errors or bias pose a significant risk to RCTs. The Cochrane Collaboration has described a tool for assessing the risk of bias in RCTs and how they can be minimized. Six domains of bias and their sources have been enlisted. (14) Efforts must be made at every stage in advance to any type of bias.

Eligibility and Enrollment: Patients are screened with the help of a predefined eligibility criteria before enrolling them in a study which ensures that the participants meet the criteria for intervention. (15) Following enrollment, consent is obtained from the study participants. The chance of generalization becomes thinner as the eligibility criteria is narrowed down.

Allocation: The allocation of the subject to any group must be concealed. Sequentially Numbered Opaque Sealed Envelope (SNOSE) is a cheap and effective method to ensure this, and a practical technique has been elegantly described by Doig and Simpson for application in any type of randomisation. (16) Allocation concealment is done before randomisation is carried out and should not be confused with blinding as the latter is done following randomisation.

Randomisation: It is the process that ensures that each subject enrolled in the trial has an equal chance of being allocated to any of the groups, thus reducing selection bias.

There are various types of randomisations.

- **Simple randomisation:** Simple randomisation is the commonest method used wherein a patient is allocated a group manually using a random number table or using a computer-generated list. Each patient has an equal chance of getting randomised to any of the groups. However, there is a chance that an unequal number of subjects may get allocated among the groups when the number falls short in recruitment. For example, if the calculated sample size for a study is 100 patients, 50 will be randomised to each group by simple randomisation. If the recruitment stops at 80 due to logistic reasons, theoretically there is a possibility that one arm may be allotted 50 patients and the other arm 30. This is a fallacy of simple randomisation which is overcome by block randomisation.
- **Block randomisation:** Block randomisation is done to ensure a similar number of subjects in each group at any given time during the study. If we consider the above-mentioned example in simple randomisation, if the recruitment stops at 80 patients, if block randomisation is carried out with a block size of 10, 40 patients shall be allotted to each arm. A permuted block system can be employed, wherein two or more block sizes may be used to eliminate the risk that the investigator may be able to predict the allocation. (17)

- **Stratified randomisation:** Sometimes in a study there are certain factors which can strongly influence the results, the researcher would like these factors to be equally distributed in both the arms. In these situations, stratified randomisation is used where certain confounding factors get equally distributed in both the arms. For example, if the presence or absence of stoma is likely to affect the primary end point of surgical site infection, the stratification based on stoma helps in equal distribution in both arms (8)

Blinding: Whenever possible, an RCT may be blinded to remove any observer or reporting bias. (18) According to the number of stakeholder groups being masked (participants, investigators and persons analysing the results), the types of blinding are defined as single, double, triple-blinded and unblinded or open-labelled studies. (19)

- **Open-labelled trials:** Neither the investigator nor the participants are blinded. In a trial done in breast cancer patients receiving neoadjuvant chemotherapy were randomised to receive hyperbaric oxygen therapy (HBOT) and to neoadjuvant chemotherapy only with no HBOT. (20) In such a case, it is practically not possible to blind the participants or investigators. In such trials, the methodology must be strictly followed by all the personnel involved and the outcome assessment must be objective (free from the influence of participants' knowledge of the intervention received) and unambiguous. (5)
- **Single blinding:** The participants are unaware of which group they are randomised to, whether they will be receiving intervention or placebo.
- **Double blinding:** The participant and the investigator are unaware of the group the participant is allotted to. As an example, when two drugs that look identical and can be delivered via the same route of administration are being compared, double blinding is feasible and increases the quality of the study by eliminating performance and detection bias. (19,21)
- **Triple blinding:** The participant, investigator and the person analysing the data are all 'blinded.'

Withdrawals and drop-outs: Withdrawals not only provides information regarding the efforts taken to ensure adequate sampling but also regarding the care taken to ensure patient-safety before recruitment into the trial. This helps in the assessment by intention-to-treat (ITT) and per-protocol (PP) analysis.

Jadad Score: The Jadad (Oxford) scoring system (0-5) is a 3-point questionnaire that assesses the methodological quality of a clinical trial. (22) The three points in the questionnaire are randomisation, blinding and dropouts. If all these points are carried out in an RCT, 1-point is given to each component. If the randomisation and blinding are described satisfactorily, 1-point each is added to the scale. A maximum of 5 can be scored for a Jadad scale.

CONSORT (Consolidated Standards of Reporting Trials) statement and diagram: The CONSORT statement is "an evidence-based, minimum set of recommendations for reporting randomized trials." The format facilitates the transparent and complete reporting of trials so that they may be

critically analysed and interpreted appropriately. A 25-item checklist has been developed and updated (2010) and gives all the key information about the design, analysis, and interpretation of the trial to the reviewer, all at a glance. It is strongly recommended to add the CONSORT flow diagram as the first figure in the manuscript and mention it in the beginning of the results section. (6,17,19) Several journals endorse the above and insist on the inclusion of the CONSORT statement (the checklist) and the flow diagram (available for free download from <http://www.consort-statement.org/>) of the trial in the prescribed format. Adherence to this has improved the quality of reporting and reduced systematic errors. (23)

In the part II of the article, we will cover the details of results, discussion, stopping rules, trial monitoring and checklist for writing an RCT manuscript.

Some core tips have been listed in Figure 4.

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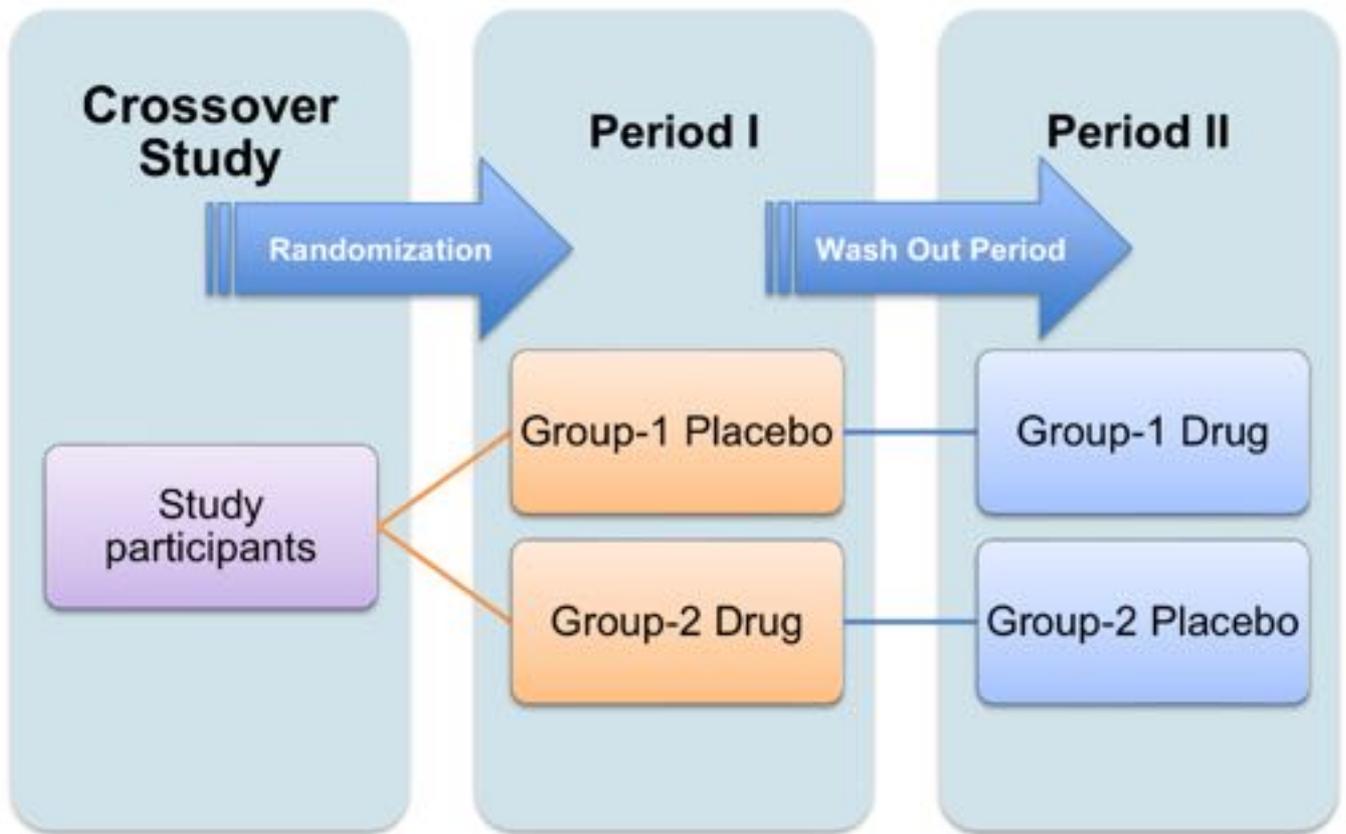


Figure 1: Crossover study design.

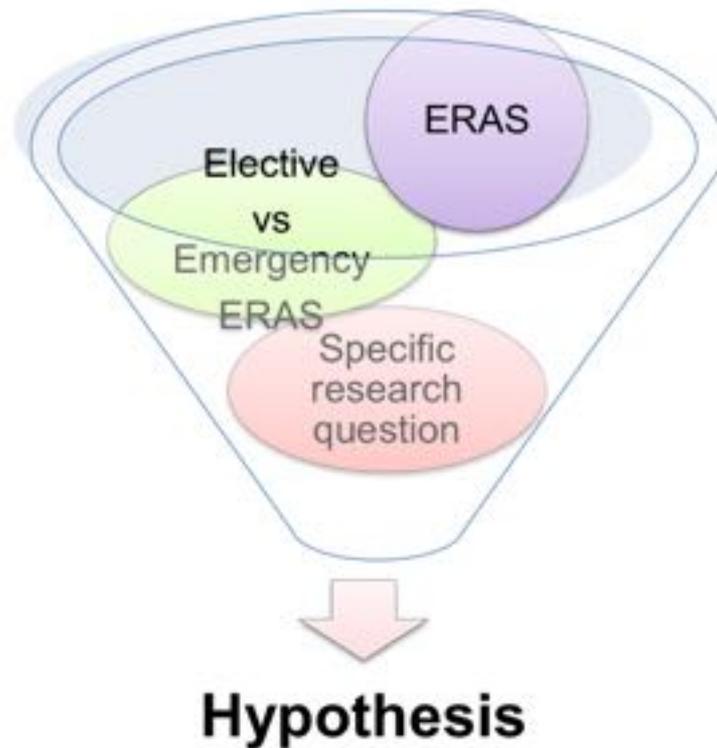


Figure-2: Illustration showing the flow of introduction in a study on emergency ERAS.

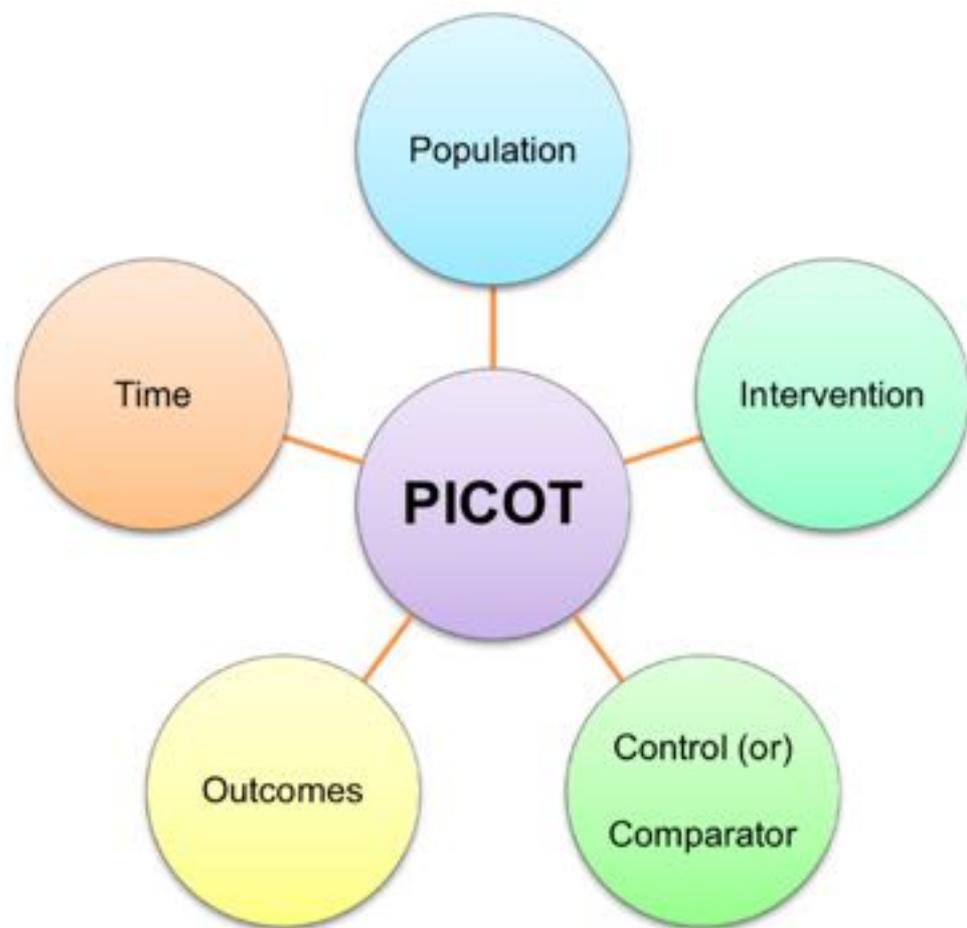


Figure 3: PICOT format for aims and objectives.

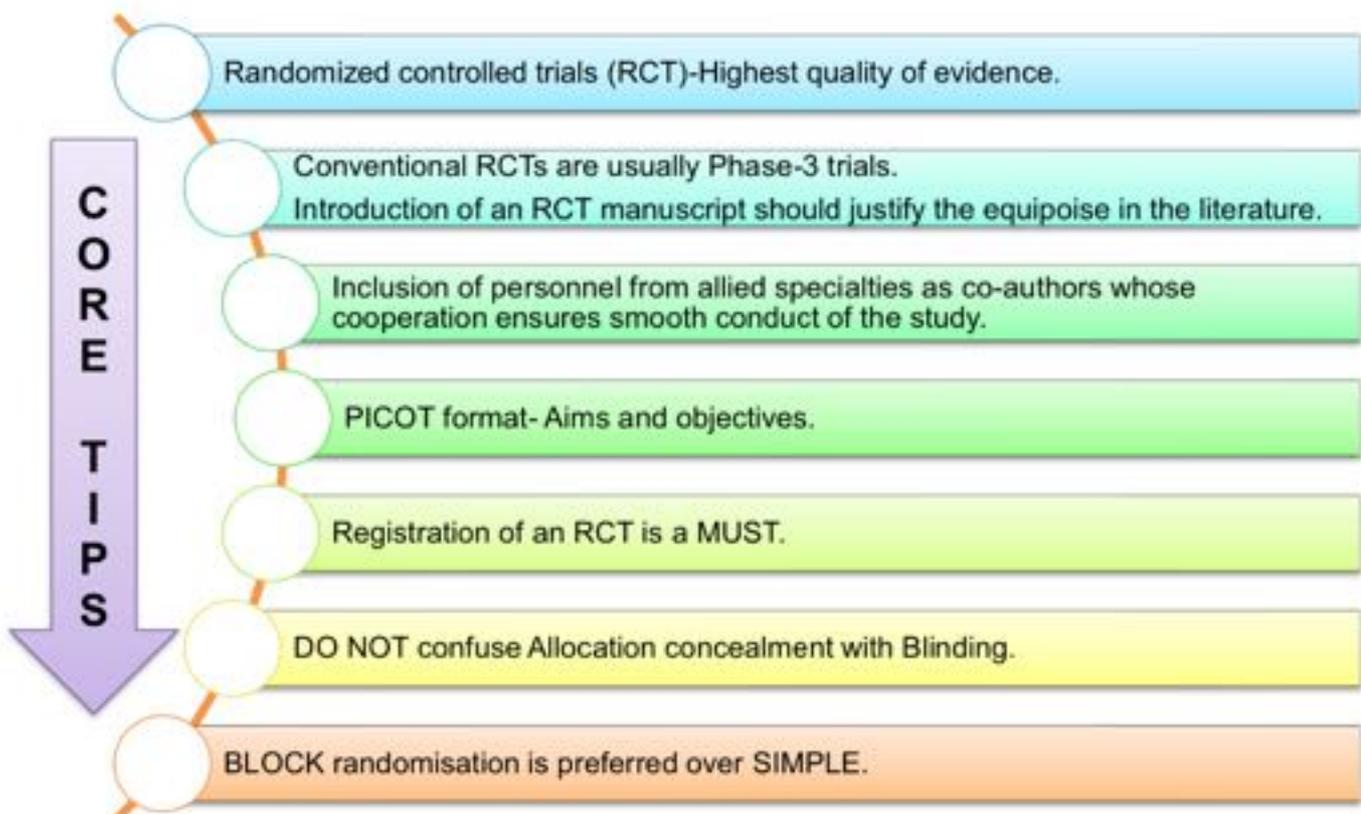


Figure 4: Core tips.

Past Events

Event	Venue	Date	Organizer
77th AMASI Skill Course and Exam	Online	JUNE 03-05, 2021	Dr. Gajendra Bhati
BARIATRICS & HERNIA ESSENTIALS	Online	31st July and 1st August	Dr Kedar Patil
78th AMASI Skill Course and Exam	Online	AUG 05 - 07, 2021	Dr Sandip Ray

Upcoming Events



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CELEBRATING 30 Years OF LAPAROSCOPIC SURGERY IN INDIA

Virtual conference & On-site Conference @ New Delhi

26th | 27th | 28th November 2021

The banner features the AMASICON logo with the tagline 'Evolution to Revolution' and 'Hybrid'. It also includes the AMASI 30th anniversary logo and a calendar icon.

AMASICON 2021



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30 Years
OF LAPAROSCOPIC SURGERY IN INDIA

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AMASICON 2021
Evolution to Revolution

Virtual conference & On-site Conference @ New Delhi



26th | 27th | 28th November 2021

Venue: India Habitat Center, Lodhi Road, New Delhi 110003
(Stein Auditorium & Theatre)



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PROPOSED LIVE SURGERIES

BILIARY

Gall stone
Simple cholecystectomy
Difficult gall bladder
Choledochal cyst
CBD stone extraction
Ca Gall bladder Radical Cholecystectomy (v)

LIVER

Hydatid cyst liver
Central hepatectomy Glissonean approach
Posterolateral segmentar Hepatectomy
Hepaticojejunostomy after hepatectomy

PANCREAS

Whipple's for ca head of pancreas
Radical distal Pancreatectomy (v)
Spleen preserving distal pancreatic resection
Pseudocyst Pancreas

ENDOCRINOLOGY & URO

Adrenalectomy- Retroperitoneoscopic / transabdominal approach
Thyroidectomy Transaxillary, post auricular / per oral technique

ESOPHAGUS

Thoracoscopic Esophagectomy in prone for cancer esophagus (McKeown's)
IVOR-LEWIS two stage Esophagogastrectomy Thoracic anastomosis.

STOMACH

Distal Gastrectomy + D2 Lymphdenectomy.
Total Gastrectomy Esophago Jejunal anastomosis

COLON & RECTAL

Right Colectomy for cancer colon CME +CVL
Subtotal / Total / Proctocolectomy
Anterior resection
Trans anal TME
Prolapse rectum Rectopexy

PROPOSED LIVE SURGERIES

GROIN HERNIA

TAPP

eTEP

Large inguinoscrotal hernia

Recurrent after TEP (v)

ABDOMINAL WALL RECONSTRUCTION (AWR) FOR VENTRAL HERNIA

IPOM plus

Plication of Divarication Recti

eTEP Retrorectus mesh repair for midline incisional hernia

Anterior Component Separation Retrorectus meshplasty for large incisional hernia ACS + RS

TAR for large abdominal wall Hernia

GERD & HIATUS HERNIA

Lap Fundoplication

Large Hiatus Hernia Fundoplication with mesh repair

Large Hiatus hernia repair without mesh

ACHALASIA CARDIA

Lap Hellers myotomy

POEM

BARIATRIC SURGERY

Sleeve gastrectomy

Roux en Y Gastric bypass

Redo Gastric bariatric surgery

ROBOTIC SURGERY

Anterior resection for cancer rectum

Esophagectomy

Whipple op

Distal Radical pancreatectomy (v)

Central pancreatectomy (v)

ANAL SURGERY

Laser haemorrhoidectomy

LIFT

GYNAECOLOGY

Fibroid excision

Hystrectomy

Wartheim's op

Paraaortic lymphdenectomy

Sacrospinous fixation of Vaginal vault

ADVANCED ENDOSCOPY

NBI

Mucosectomy ESD

Spyglass CBD exploration

Power Spiral Enteroscopy

Endoscopic pseudocyst drainage

POEM

SCIENTIFIC PROGRAM



Day 1 | Hall A

26th November 2021 | 4:00PM - 8:00PM

Time (pm)	Topic
Best Paper Competition	
4.00 - 5.00 PM	Best Paper Award - 6 papers (8 + 2 min each)
Invited Lectures	
5.00 - 5.15 PM (13 + 2)	TBA
5.15 - 5.30 PM	TBA
5.30 - 5.45PM	TBA
Panel Discussion	
5.45 - 6.30 PM	Prevention and Management of Bilio-vascular complications during laparoscopic cholecystectomy
6:30 – 7:00 PM	AMASI Oration
7:00 – 8:00 PM	Celebration of 30 years of laparoscopic Surgery and Inauguration



Day 1 | Hall B

26th November 2021 | 4:00PM - 8:00PM

Time (pm)	Topic
Video-based Lectures (15 + 5)	
Groin Hernia Series	
4.00 - 4.20 PM	Laparoscopic management of difficult groin hernias: Irreducible/Large scrotal/ Sliding
4.20 – 4.40 PM	Laparoscopic management of recurrent groin hernias
4.40 - 5.00 PM	Management of complications of laparoscopic groin hernia surgery
Debate	
5.00-5.30 PM	Intra-peritoneal vs Extraperitoneal mesh placement during LVHR
Invited lectures	
5.30-5.45 PM (12 + 3)	e-TEP approach for lateral abdominal wall hernias
5.45 – 6.00 PM (12 + 3)	Complications following e-TEP - TAR
Video based lectures (12 + 3)	
6.00-6.15 PM	Laparoscopic Management of liver cysts
6.15 – 6.30 PM	Laparoscopic CBDE: Tips & Tricks
Panel Discussion	
6.30-7.00 PM	Laparoscopic Management of GERD & Post-operative complications
7:00 – 8:00 pm	AMASI Convocation



Day 1 | Hall C

26th November 2021 | 4:00PM - 8:00PM

Time (pm)	Topic
Best Poster Presentation	
4.00 – 5.00 PM	Best Poster Award (4+2)
Scientific Papers & Posters	
5.00 -7.00 PM	



Day 2 | Hall A

27th November 2021 | 4:00PM - 6:45PM

Time (pm)	Topic
Best Video Award	
4.00-5.00 PM	Best Video Award - 6 papers (8 + 2 min each)
Invited Lectures (15 + 5)	
5.00-5.20 PM	
5.20-5.40 PM	
5.40-6.00 PM	
Video based Lecture (12 + 3)	
6.00-6.15 PM	Laparoscopic Ultra-low/interspincteric resection
6.15-6.30 PM	Transanal Procedures: TAMIS & TaTME
6.30-6.45 PM	CVL & CME in laparoscopic right hemicolectomy



Day 2 | Hall B

27th November 2021 | 4:00PM - 7:00PM

Time (pm)	Topic
Master Videos - Foregut (15 + 5)	
4.00 – 4.20 PM	Robotic lymph node clearance in esophagectomy
4.20 - 4.40 PM	Laparoscopic nodal clearance in D2 gastrectomy
4.40 - 5.00 PM	Reconstruction after laparoscopic gastrectomy/esophagectomy
Master Videos – Pancreas (15 + 5)	
5.00 – 5.20 PM	Laparoscopic distal pancreatectomy
5.20 – 5.40 PM	Laparoscopic Frey's procedure
5.40 – 6.00 PM	Laparoscopic reconstruction after pancreatoduodenectomy
New Technology series (15 + 5)	
6:00 – 6:20 PM	ICG in laparoscopic surgery: Current practice and future prospects
6.20 – 6.40 PM	Newer Robotic systems
6.40 – 7.00 PM	Laparoscopic donor hepatectomy



Day 2 | Hall C

27th November 2021 | 4:00PM - 7:00PM

Time (pm)	Topic
Young Scholar Award (8 + 2)	
4.00-5.00 PM	
Scientific Papers and Posters	
5.00 to 7.00 PM	



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