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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 PART 2

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The Scourge of 'Online Aggregators'



Over the last several weeks, AMASI has taken a strong stand against the predatory practices of various online companies that are involved in the business of enticing and luring patients through unethical advertising, dubious marketing techniques and popular gimmicks. These companies are known in the market as 'online aggregators'.

The internet has been a boon for several entrepreneurs. One popular model of doing business is to provide an online platform to connect the service providers with customers. Uber, Airbnb, Zomato, Swiggy, etc. are examples of these. Uber does not own a single taxi and yet it is the largest cab service provider in the world. Similarly, Airbnb does not own a single property and yet it is the biggest hotel network in the world. It was not surprising when opportunists saw an application of this business model to healthcare.

The business model of online aggregators is simple. They own neither hospital nor do they employ full-time proficient doctors. (On the latter point, the

largest online aggregator has started to employ full-time surgeons to do their bidding recently). What they have instead is a huge budget for advertising, a team of marketing professionals specialized in virtual digital marketing and readiness to exploit every loophole in the medical practice laws. Since they are a business, the normal rules of medical ethics (which were formulated when such business models were not in existence) do not apply to them. They have the funds to employ Bollywood actors as their brand ambassadors and the resources to advertise on digital platforms like Instagram, Twitter and Facebook. They are adept at manipulating search engines using SEO (Search Engine Optimization) techniques so that any Google search will show up their names first. Their teams of online marketers keep posting fake positive reviews of their services. They use terms like 'laser', 'stapler', 'latest and best' as they know that the public is a sucker for them. Unfortunately, all this is sufficient to lure the patient into their clutches.

Once the patient contacts them, they arrange a consultation with their employee doctor who may not even be MBBS, let alone a specialist surgeon/ gynecologist/ophthalmologist. A surgery is fixed up (with alacrity if the patient has mediclaim coverage), the patient is personally taken to a hospital with whom the aggregator has an MOU and a surgeon is called in to operate the patient. The hospital and the surgeon are paid a lumpsum pre-fixed amount and the rest of the amount, which is the lion's share, is taken by the aggregator as its fee or, in other words, as commission.

However, medical practice is arguably not a business but a profession, and probably the most hallowed profession that there is. When challenged, such companies typically use obfuscating languages and terms to garb their mercenary activities. They claim that they are providing 'holistic services' and 'hassle-free experience' to the patients. However, the dark underbelly is too murky to ignore. For mediclaim patients, the bills are inflated to 2-2.5 times

what is prevalent for the same surgery in that area. Yet the insurance companies and their TPAs, who are so proficient at cutting the reimbursement amount

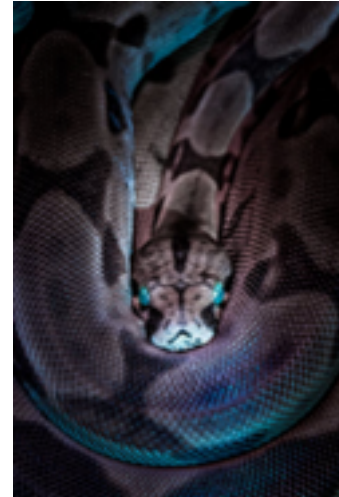
when the cashless files for the same conditions are placed by doctors, are sanctioning the full amount without any major deductions!! Is there some sort of unholy nexus between the two?

Moreover, they claim to use and charge for technology which has no proven role in surgery – like ‘laser circumcision’, ‘laser hydrocelectomy’. They claim, without any scientific evidence, that laser treatments of ‘piles’ are the best form of treatment and poor unsuspecting patient, long since attuned to obtaining his/her information on Google, is convinced by their claims.

What happens when there is a post-operative complication? The companies simply wash their hands off all responsibilities, leaving the patient to run from pillar to post.

To some extent, the fault also lies with us, as a surgical community. Our brethren, owing to whatever compulsion, agree to work for such despicable institutions, providing service for a pittance while doing a great dis-service to the medical profession. Many hospitals that tie up with such online aggregators are owned by non-medical people, but many more are owned by doctors themselves who see an added opportunity to earn some revenue. Unless we as a community decide to unite and work for the betterment of our profession, we will keep on facing such challenges in the future too.

With the support of our parent body, the Association of Surgeons of India, we appeal to all our members to refrain from signing up with such online aggregators. We request the National Medical Council to revamp the medical ethics by-laws to encompass all such business models. We urge the government to stop such unethical malpractices under the garb of providing and facilitating healthcare services. Let us practise our profession with pride, with dignity and with nobility.





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Gurubhashyam

To be a Compleat Surgeon

**Prof. Sushila Sripad
MBBS(Hons) MS(Surg) MCh(CTVS) FIACS**

In this day and age of high tech, every day, I get SMSs inviting me to join a host of seminars, master classes, Zoom conferences, webinars, workshops, skills courses etc. It is a mindboggling trend. Every trainee must be saturated with advice to the point of a grouse. Thanks to the pandemic and the varying responses of Governments, at my ripe age I am also taking online classes to my current trainees in DNB(CTVS). Technology has been a boon in multiple ways but it has also led to death of clinical medicine which is a Himalayan tragedy.

I had been passionate about Surgery from my first year first day. Prof Pasupati Bose, Vice-Principal in charge of student affairs and Head of Anatomy and Histology was a legend in his lifetime. He made the difference. He was a teacher like no one I had encountered before or since. What almost 99% of students would consider Anatomy and Embryology a dull, dry and painful subject to clear the examinations, was transformed by just this one teacher to be one of the most exciting and interesting subjects, so basic to understanding the normal as well as the deranged human body. His baritone voice, steely eyes, facile ambidextrous graphics filling a 12x10 sft blackboard and overflowing galleries are unforgettable. His teaching was the best window to the world of Surgery.

Leonardo da Vinci, a fine renaissance polymath who excelled in painting, sculpture, science and engineering, architecture and many others, revealed his exquisite knowledge and graphic display of human anatomy and used it to perfection in all other fields. Some four decades ago I happened to get two volumes on Physics and Chemistry which were prescribed for high School students in the USA. The books were full of examples from the design and engineering concepts of the human body, when explaining fluid dynamics, chemical reactions, levers,



My mentor Prof A K Basu
07.12.1912-03.12.1986
President ASI 1967
Pandalai Orator 1966

diffusion, osmosis, creating compact units with vast surface area etc. The compact oxygenator in the Heart Lung machine tries to maximise the surface area like the natural lungs (80M²) but it can achieve only a fraction (0.5-5M²) with an efficiency of a quarter of that. The design of a cable stayed bridge could be compared easily with the Mitral valve apparatus – a flimsy looking living structure that can withstand peak left ventricular systolic pressure throughout a life span of 70-80 years and prevent prolapse of the valve into the left atrium. You will find a similar disparity in efficiency and compactness of a haemodialyser and a healthy natural kidney. Nature is a perfect designer and as a surgeon one needs to grasp the intricacies of the design. Develop a habit of closely observing nature to learn of the beauty and efficiency of design. Structure determines function, so physiology and biochemistry become so very important for a surgeon. Pathology teaches you the derangement that needs to be attended to.

All living organisms are designed to protect themselves from adversity – procreation and preservation of the species being their most essential goal. The defences, we know, are a sum of the rapid and slow responses of the body in terms of disaster management and subsequent repair, reorganisation and remodelling. It is this body response that takes care of the patient after the surgeon is done with the knife.

One of the first principles of Surgery is 'primum non nocere' – first do no harm. So to be a complete surgeon one needs to understand many of the basic sciences and their applications, how and when to intervene, how to understand and evaluate to decide when not to intervene. This comes from mentors who can stimulate by example, your sense of keen observation, getting the necessary knowledge that is already available, encouraging you to dwell deeper for solutions and of course help you develop an empathy for anyone who seeks your expertise. Today, there is a surfeit of sources of information and knowledge, so you have to be analytical and selective. Surgery is at once a Science, an Art and a Craft and the training should meet all three endpoints.

In the 1960s, Surgery was the most coveted specialty. We had doyens of Surgery like L M Banerjee, A K Basu, K K Ghosh, A K Roy, R N Chatterjee, S K Chatterjee, M M Mukherjee, Anjali Mukherjee, Himadri Sarkar, K S Bose, S K Datta, Subir K. Chatterjee, Saroj K Bose and many others. They went on to pioneer the specialties of Surgery and set the stage for the meteoric expansion and sub-specializations of the 1980s to the present day.

The sixties were also a great time for hands on training. Hospitals were crammed with patients. Each on-call day in surgery, meant at least 10-12 surgical operations, closed /open reductions, Burr holes for cranial decompression, acute paediatric surgical emergencies,

burns, trauma etc. It was a great opportunity for real General Surgery. With an extremely competent Resident Surgeon available 24/7, most House Surgeons and students became skilled in the common operations of general surgery including all types of trauma care. Upon completion of five years of MBBS course and six months of unpaid rotating internships called the Pre-Registration Clinical Assistant (PRCA), the MBBS Certificate of the Calcutta University, since the British days, included the phrase 'licence to practise Medicine, Surgery and Midwifery'. That was a licence by a University that saw through the whole training. Registration with the MCI and State Medical Councils were a formality. Not so long ago a Supreme Court order put paid to this time-tested best practice and we have all powers in the MCI which did not cover itself in glory with the burgeoning of for-profit Medical Colleges. Today the simple operations that an MBBS doctor could do are done by the MS specialists. In a vast country like ours the MBBS training and skills have to be vastly improved so that MBBS practitioners become the core GPs, internet savvy and the go to person in the vast rural hinterland. Marketing managers in the garb of health camps are not the answer. The Association of Rural Surgeons of India actually does all that sub-specialists in Surgery are doing. Probably it is a misnomer given our ground reality.

From the 1980s, for about three decades, MBBS training suffered very much. Among the many reasons one stands out. Almost all students aspired to get into some postgraduate course as their goal. In a vast country like ours, many colleges/universities would have their own entrance examinations. For the students it was important to prepare for many entrance examinations, attend tutorials and cram MCQs. Thus, for the vast majority, true learning during MBBS and developing matching skills became secondary. The vast number of PGTs in every institution also meant that MBBS students did not get any opportunity for hands on skills even during their internship/Residency. Post MBBS if a doctor, worked diligently, in a general hospital in small towns, the chances of gaining hands-on skills are brighter. A few years ago, I had a DNB CTVS trainee (selected after the second counselling of NBE), who in his entire MBBS and residency could assist in only one tympanoplasty. Though a rare case, it must be an eye-opener. The so-called counselling is a gross misuse of the term. Fortunately, he was convinced that CTVS cannot be his line and found an alternative. The ASI has been running a basic skills enhancement programme this year, that features things like how to apply a bandage, how to insert a urinary catheter etc. It is a sad reflection of the standard of MBBS education and training. With one National Entrance and one National Exit examination, things may change for the better. It remains to be seen how this laudable

system unfolds. Speaking for myself, I am convinced that any system can be made to work with appropriate attention to detail, due diligence, integrity and discipline.

Minimal Access surgery needs to have a low threshold for conversion. It is important that AMASI ensures that all trainees are confident general surgeons before they can go in for minimal access. It is unfortunate, but true that hardly any open surgery exposure is available now for the vast majority of MS/DNB trainees. Perhaps every department of Surgery must have a dedicated day for Open Surgery for the trainees in their first year.

One of my favourite exhortations to new trainees, is Kipling's famous six serving men – 'their names are What and Why, and When and How, and Where and Who'. If a trainee, right from day one of MBBS through the post-graduate / doctoral course, just followed this path of enquiry, I have no doubt, we would have an army of young men and women surgeons who would be true to their profession and will be able mentors for a future generation.

Siddhartha Mukherjee is a household name after he published the "Emperor of Maladies, a biography of cancer". In a subsequent booklet he enunciated three laws of medicine:

Law One – A strong intuition is much more powerful than a weak test.

Law two – "Normals" teach us rules, "Outliers" teach us laws.

Law three – For every perfect medical experiment, there is a perfect human bias".

So be wary of all the EBMs, COEs and RCTs, and databases! Ultimately the databases are only as good as the knowledge and expertise of junior most house surgeon who writes the history and the integrity of the system! There have been several tragic reversals after millions have already suffered.

I have had an eventful roller coaster career as a Surgeon, a Cardiothoracic and Vascular surgeon, a teacher, mentor, and the privilege of continuing to mentor till now. Opportunities were very few in the sixties and seventies. There were few corporate players. For the first 17 years of my surgical career I was posted as a CTV Surgeon, in the departments of Surgery and sometimes officiated as Head of Surgery. Throughout my surgical career till date, I have remained passionate about trauma care, in particular about Life and Limb threatening emergencies. I got my first posting in a well-equipped CTVS department only in 1988 – 17 years after I trained in Brompton and Hammersmith Hospitals, London in Vascular Surgery and Cardiac Surgery and became a Magister Chirurgie in CTVS in 1973! A surgeon's life is never easy. You need passion, patience and perseverance.



Receiving Award at ASICON2005 at Jaipur.

The 40 MCh/DNB CTVS trainees and 28 perfusionists that I had the privilege of mentoring hailing from several states, and the scores of MBBS and other students in the different Medical Colleges, give some comfort that I have not lived in vain. I overcame many challenges in particular, being posted in a semiurban Medical College as a CTVS surgeon when all surgical operations were done only under open ether anaesthesia by the drip method because Nitrous Oxide was not available.

The OT was on the ground floor and a 2-bed recovery room on the first floor. There were no elevators, no pole stretchers, no special instruments, no monitors, no trained nurses, no mobiles no internet. To overcome this

challenge, get nitrous Oxide from a distance of 60km, establish endotracheal anaesthesia and perform almost all the non-open heart operations using my personal special instruments, safely for the first time in the Bankura district during the two years 1975-77, that I was posted there, was extremely satisfying and a great learning experience. It taught me to rely on my judgement based on a thorough clinical examination and do only limited investigations

necessary to confirm or exclude a diagnosis, and prevent any complications.

In 1963 ASICON was held at the Medical College. I was a student volunteer. The first paper I presented at ASI annual Conference was as an MS trainee in 1966 at the Manipal Conference. I want to share the group photograph of the delegates, that shows many of the stalwarts who have since left



us.

Individually, they had pioneered several specialties and sub specialties. I will also share a few photographs of my ASI experience. I have been associated with the ASI for 54 years.

I will end this with a quote on the clock above a spiral staircase in the hallowed Anatomy Dissection Hall of my Alma Mater and the oldest Medical College in Asia, The Medical College

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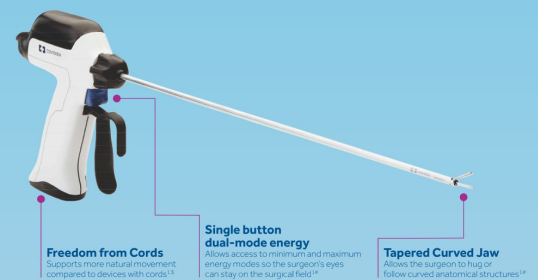
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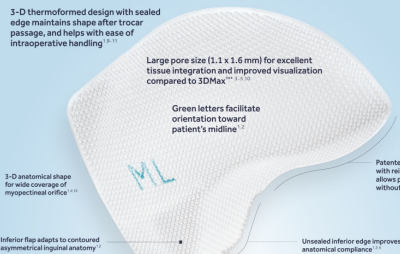
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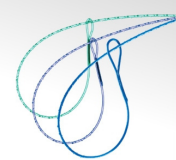
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found out it was a quote from the Bible, Ecclesiastes 9:10, “Whatsoever thy hand findeth to do, do it with all thy might”. It is pregnant with meaning and that, I think, sums up what a Surgeon needs to do throughout the professional career.



Guideline Series

AMASI GUIDELINES FOR LAPAROSCOPIC SURGERY

LAPAROSCOPIC VENTRAL AND INCISIONAL HERNIA REPAIR

Part II: Technical variations and additions, hernias at unusual sites



Dr. Bhupinder Singh Pathania

Professor

Postgraduate Department of Surgery

ASCOMS Medical College and Hospital

Jammu, Jammu And Kashmir, India

HYBRID TECHNIQUE FOR LAPAROSCOPIC VENTRAL HERNIA REPAIR

Many surgeons consider the laparoscopic method as a method of choice for incisional hernia repair. Sometimes miniinvasive repair of complicated hernia is not so easy to perform. We are convinced that selected patients may benefit from combined open and laparoscopic techniques. There are still some problems connected with complicated, large incisional hernias, including the frequency of seromas, unchanged scar appearance, and massive adhesions after previous operations (especially dangerous during placement of laparoscopic tools into the abdominal cavity). We are convinced that combining the two surgical techniques could solve these problems. The open technique ensures safe adhesiolysis, minimizing perforation of abdominal organs, the ability to place a large mesh into the abdominal cavity, and better cosmetic appearance of a single midline incision. According to initial reports of some authors, by using the combined technique, the ultimate results would be the minimal recurrence and hospital stay similar to laparoscopic mesh repair [1–4]. Hybrid techniques already combine mini-laparotomy for hernia closure and subsequent laparoscopic intraoperative onlay mesh for reinforcement, but such techniques require laparotomy.

Two hybrid techniques are used: (1) initial laparoscopic approach converted to open adhesiolysis followed by totally laparoscopic mesh fixation and (2) open repair and adhesiolysis with laparoscopic-assisted mesh fixation. In the first approach, after conversion to open adhesiolysis, mesh with four quadrant sutures is placed intraabdominally. Pneumoperitoneum is re-established, and the mesh is fixed laparoscopically with sutures and tacks in standard fashion. For the second hybrid approach, after hernia reduction and adhesiolysis, mesh is anchored with sutures placed at

3–4 cm intervals with a Reverdin needle and further secured posteriorly with a hernia tacker over 180° circumference. Prior to tying the contralateral transfascial sutures, two 5-mm laparoscopic ports are placed lateral to the mesh under direct vision on the opposite side. Once the facial sutures are tied, pneumoperitoneum is established, and the contralateral side of mesh is tacked laparoscopically.

SUGGESTIONS

In our view, the combined technique presented in this report proved to be an optimal and safe solution in cases of recurrent, complicated, large incisional or ventral hernias. The hybrid technique may be used in patients with recurrent incisional hernias.

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COMPONENT SEPARATION

The objective of abdominal wall reconstruction is to restore the structural and dynamic integrity of the abdominal wall that covers and protects the intra-abdominal viscera while minimizing complications and optimizing aesthetic body contour¹. Reconstruction of large and complicated abdominal wall hernias remains a challenging problem for surgeons.

INDICATIONS FOR COMPONENT SEPARATION

The technique is not indicated for small or average size, uncomplicated hernias since these can be repaired with the standard open or laparoscopic techniques.

Component separation should be considered in the following situations:

1. Infected abdominal wall with or without mesh.
2. Patients with hernias who are also having a colostomy reversed.
3. Very large ventral hernias.
4. Multiple defects.
5. Multiple failed attempts at previous repairs.
6. Treatment or prevention of the abdominal compartment syndrome (ACS). May avoid open wound management, which usually results in a large ventral hernia and potential skin deficit.

7. In those patients with Loss of Domain, component separation allows placement of a smaller piece of mesh, thereby minimizing eventration.

Caution should be exercised in those patients who have scarring from lateral incisions as well as those with stomas since dissection will be restricted and tedious. Also, lateral hernias prevent the use of bilateral fascial transposition and the ribs and iliac crest will limit surrounding tissue mobility.

Delaying the operation until any risk factors (obesity, smoking, COPD, malnutrition, steroids) can be eliminated will greatly improve the outcome of the operation. Primary suture repair of ventral hernias is associated with high recurrence rates^{2, 3, 4, 5}, but with the application of synthetic mesh the recurrence rates decreased significantly^{4, 5, 6, 7, 8, 9, 10}. Mesh implantation may result in adhesions (despite the use of various mesh coatings), enterocutaneous fistulae, and infection. The incidence of mesh infection after open ventral hernia repair may be up to 15 percent¹¹. Dealing with infected mesh after hernia repair is a vexing problem and is one that surgeons would like to avoid. Autogenous tissue repair that reliably restores the structural integrity of the abdominal wall without the use of synthetic material is optimal. The repair of infected ventral hernias has been successful with techniques using autogenous tissues such as the creation of myocutaneous and myofascial flaps, harvesting fascial grafts¹², and component separation techniques. However, with extensive tissue dissection or the creation of donor sites, the associated wound complications and morbidity can be high^{13, 14}.

Endoscopically-assisted component separation minimizes the lengthy subcutaneous undermining with resulting minimal blood loss, elimination of tissue ischemia, and an improved recovery time by nearly 50 percent^{15, 16, 17, 18}. 1. The patient is positioned supine on the operating table with the arms tucked at their sides. This allows freedom of movement around the patient without the arm boards interfering. In the non-infected field, resecting the cicatrix, excising the sac and reducing the hernia first approach the ventral hernia. The opening in the abdomen allows insertion of the surgeon's hand into the abdominal cavity for abdominal wall manipulation during endoscopic component separation. With infected mesh it may be more prudent to perform the ECS first to avoid cross-contamination into the lateral compartments.

When performing ECS, the most important part is entering the correct space. Making a 1.5-cm incision below the costal margin along the anterior axillary line best does this. The surgeon must be sure to be lateral to the rectus muscle to avoid entering the wrong plane. Using S-retractors and a Kelly clamp, the subcutaneous tissues are bluntly dissected to expose the external oblique aponeurosis. The external oblique aponeurosis is incised and the internal oblique muscle is identified below. An excellent option, especially for obese patients, is the use of the optical trocar for muscle dissection. This trocar allows quick and easy tissue identification and navigates the abdominal wall layers for controlled entrance between the External oblique muscle and Internal oblique muscle. Sterile lubricant is injected into the opening to facilitate balloon dissection of the space between the muscles. This is performed in a similar fashion as when creating the preperitoneal space in the inguinal TEP repair. Previous experience with the balloon dissector will make this part of the operation an easier transition. The unilateral balloon allows a more controlled dissection than the bilateral balloon; however, this is the surgeon's preference. A blunt-tip or structural balloon port is then inserted and the space is insufflated at a pressure of 10 to 12

mmHg. One 5-mm port is inserted just cephalad to the inguinal ligament and another at approximately the level of the umbilicus at the mid- to post-axillary line. This will allow adequate longitudinal and transverse dissection. A 30-degree, 10-mm scope is utilized; however, a 5-mm angled scope is also required to alternate trocars. Approximately 2 cm lateral to the linea semilunaris, using cauterizing sharp dissection; the external oblique aponeurosis is released longitudinally from the costal margin to the inguinal ligament. The same technique is performed on the contralateral side. Closed suction drains are not necessary since the space is essentially avascular³². The muscular complex is then transposed to the midline. On each side approximately 4 cm can be gained in the upper third abdomen, 8 to 10 cm in the middle, and 3 cm in the lower third¹⁸. If additional fascial translation is required, the posterior rectus sheath can be separated from the rectus muscle for 2 cm further advancement. It is possible to close very large abdominal wall defects with minimal morbidity¹¹. Reinforcement with mesh (biologic or synthetic) is at the discretion of the surgeon. Whether the mesh is placed in an overlay, underlay, open, or laparoscopic fashion is determined by the surgeon at the time of repair.

Any technical difficulty of endoscopic component separation is overcome with experience. The optical trocar permits rapid entrance between the muscle layers and the use of balloon dissection as in the preperitoneal inguinal hernia repair allows the surgeon to quickly and effectively develop the fascial plane providing an overall reduction in operative time over the open technique. The decrease in operative time overcomes the increased cost of the laparoscopic equipment.

Re-creation of the linea alba via tensionless coaptation is important to achieve wound healing³⁴ and provides an anchor for the lateral abdominal myofascial tissue, which minimizes the chance for recurrence. Adequate transection of the external oblique muscle on the thoracic wall over a 5-cm distance cephalad of the costal margin is of utmost importance to prevent undue tension on the fascia in the upper abdomen³⁵. Placing the cephalad trocar too high will impede proper dissection and restrict transection of the muscle. To achieve a tension-free closure, dissection to the posterior axillary line may be necessary for adequate midline mobilization. Further mobilization is achieved with separation of the posterior rectus sheath from the rectus muscle with attention to avoid injury to the neurovascular supply that enters the rectus muscle posteriorly. If dissection extends too deep and into the internal oblique muscle, the innervation to the rectus muscle may be injured, or the spigelian fascia may be damaged which can predispose the patient to a spigelian hernia.

The average recurrence rate for open component separation is around 6 percent³⁶. For endoscopic component separation it is as low; however, follow-up time isn't as long¹⁷. Consistent patient and disease factors must be taken into account to achieve optimal comparison.

Complications associated with Component separation Technique

Tissue necrosis

Tissue ischemia and necrosis is a complication rarely seen with endoscopic component separation. ECS preserves the blood supply and transposes innervated and vascularized tissue.

In a patient with prior lateral scarring the blood supply from the intercostal arteries may be compromised and if the musculocutaneous perforators of the epigastric arteries are transected, as in OCS, ischemia will result.

Infection

The component separation technique offers several advantages over other hernia repairs, most notably avoidance of mesh in a potentially contaminated field. Advantages of ECS versus OCS are mostly related to wound problems. Gonzalez et al³⁷ determined that the infection rate was significantly higher in OCS (33 percent) versus ECS (2 percent). In the case of abdominal wall infection, the mesh is usually removed and primary closure at the midline is the optimal treatment. ECS done in a non-contaminated space prior to manipulation of the infected field provides a major benefit over OCS and should theoretically eliminate cross-contamination into the dissected space. If an infection, hematoma, or a seroma develops postoperatively after ECS, subcutaneous progression will be minimized and a complex wound infection would be significantly reduced and more easily managed.

Stomas

The OCS is not conducive in patients with stomas since it destabilizes the outer layer of the abdominal wall allowing shifting of the skin in relation to the underlying myoaponeurotic tissue³¹. With the ECS, the dissection plane is lateral to the rectus muscle which allows a stoma to be left in position or a new stoma can be fashioned since there is no shifting of skin in relation to the rectus muscle³².

SUGGESTIONS

In large and very large ventral and incisional hernias, the endoscopic component separation can be considered in combination with laparoscopic repair if expertise is available. The search continues for reliable techniques that will provide long-term success in the repair of ventral hernias. Although there is no universal technique or algorithm for repair of complex abdominal wall hernias, the objective remains the same – minimizing recurrence and morbidity. Proper patient selection is the key to the appropriate technique. The OCS is an excellent technique that allows tension-free closure of the abdominal wall while maintaining a dynamic and stable repair without the use of mesh. The drawbacks of OCS led to the evolution of ECS, which supports the concept of decreasing wound complications by preserving tissue vascularity. The technique of ECS is relatively easy to learn for laparoscopic surgeons familiar with the use of balloon dissectors and the development of the intermuscular abdominal wall spaces and is a welcome addition to the armamentarium of hernia surgeons.

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ROBOTIC APPROACH AND FUTURE TECHNOLOGY

Advances in technology will continue to heavily influence the forward progress of surgery. Robotic innovations in the operating room have played prominent roles over the last decade and have a stable role in intra-abdominal procedures. In 2012, Allison et al. published their experience of robotically repaired ventral hernias in 13 patients with acceptable results [1]. They reported several advantages to the robot over laparoscopy including the six degree of freedom with endowrist, less abdominal trauma, the ability to perform circumferential suturing allowing for maximal mesh overlap and easier primary closure [1] Another retrospective review compared primary closure of hernias with mesh placement by robot versus traditional laparoscopic repair and IPOM. Complications profile and hernia recurrence favored the robotically repaired group with only an additional 19 minutes of operative time [2] The current discussions surrounding robotic repair in the surgical community are exciting and it appears that the advantages of this technique lend themselves to a frontier that mandates further exploration to assess their true benefits.

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PARASTOMAL HERNIAS

Parastomal hernias are the most frequent complication that occurs after a stoma is created. The exact incidence is not easy to establish because both patients and physicians underestimate this problem. The reported incidence rate ranges from 2.8 to 50 % [1] and appears to be directly related to the length of follow-up. Loop ileostomy has the lowest risk (0–6.2 %), followed by end

ileostomy and loop colostomy, which has a similar risk of 28–30 %. End colostomy carries the highest risk for parastomal hernia of more than 50 %. Even though most hernias occur within the first 2 years after stoma construction, the risk of herniation extends up to 20 years [2]. Parastomal hernia is asymptomatic most of the time, but it may be associated with serious complications such as strangulation and perforation; hence, elective repair is mandatory for carefully selected cases and surgical approaches.

The laparoscopic approach involves minimally invasive access to the abdominal cavity and intraperitoneal placement of prosthetic material with or without narrowing the defect. Similar to the open intraperitoneal mesh repair, the Sugarbaker technique, the keyhole technique, and a combination of the two described by Berger and Bientzle [3] The most important message coming from the other study with level 3b evidence, conducted by Pastor et al. [4], is that the morbidity rate of the laparoscopic approach was 15 %, while the complications after the open approach were up to 33 %. This same study showed a lower recurrence rate after the laparoscopic approach than after the open technique (33 vs. 53.8 %). In order to draw conclusions regarding recurrence, it is best to analyze the studies with level 4 evidence. Even though there are some cases series with high recurrence rates of up to 56 % [5], most of the studies report a recurrence rate below 10 % with the laparoscopic approach. This represents a much better recurrence rate than the results of the open approach. At present, none of the methods of open or laparoscopic mesh repair has proved superior. In spite of this, laparoscopic repair has gained increasing acceptance.

SUGGESTIONS

Laparoscopic repair of parastomal hernia should be considered a safe alternative to open approach

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LUMBAR AND OTHER UNUSUAL HERNIAS

We searched the PubMed and Embase databases as well as the Cochrane register using the search terms noted above for publications that appeared from 1960 to 2011. Not unexpectedly, few publications could be used for an evidence-based systematic review on the treatment of both types of hernias. The relevant publications consisted of case series that included at least five cases. Moreno-Egea et al. [1] reported on a prospective nonrandomized study of 16 patients, 15 of whom

were postnephrectomy and one after trauma. Mesh was used in all of the repairs, with seven done by the open method and nine by a laparoscopic approach. They found that the open repair was associated with a longer operative time, a longer length of stay, higher morbidity, and more recurrences. There were no recurrences in the laparoscopic group compared to three in the open group ($p = 0.4$). They concluded that the laparoscopic repair was “more efficient and profitable.” Twelve articles provided evidence at level 4. Of these, six were performed with the open technique only [2–6]. Four were performed solely laparoscopically [7–10]. One paper included patients who were treated with both open and laparoscopic method [12]. From these reports, a total of 123 patients could be evaluated. In four patients, the method of repair could not be determined from the article. The search identified only one prospective randomized trial of open versus laparoscopic repair of the spigelian hernia [13]. In this small RCT, patients were randomized to either an open or laparoscopic repair arm, with 11 patients in each arm. All meshes were placed in the preperitoneal space except for three in the laparoscopic group, where the mesh was placed in the intraperitoneal space. The laparoscopic repair was accompanied by lower postoperative morbidity ($p < 0.05$) and reduced length of hospital stay ($p < 0.001$). The authors concluded that the laparoscopic extraperitoneal repair should be the preferred treatment for these hernias.

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SUGGESTIONS

Options for repair of lumbar hernias include: open repair with or without mesh in any position and laparoscopic repair with mesh in any position. However, the laparoscopic repair is preferred due to the improvement in the postoperative morbidity

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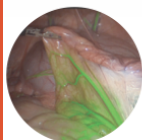
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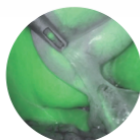
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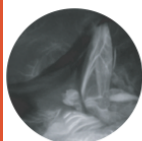
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4K fluorescence overlaid on a white light image



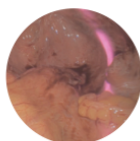
SPY ENV

4K fluorescence displayed in grayscale and green



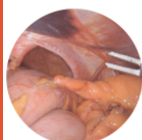
SPY Contrast

High contrast visualization of 4K fluorescence in black and white



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AutoLight

Automatic light adjustment to maintain consistent lighting throughout procedure



See beyond

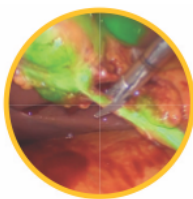


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Writing a Scientific paper

Randomized Controlled Trial: How to write youmanuscript Part-2 of 2



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In the first part of this 2-part series on randomized controlled trials (RCT), we introduced the readers to the fundamentals of RCTs, including types of RCTs, trial designs and types of randomization, blinding, sample size and types of errors and bias.¹ In the earlier part of manuscript writing we have covered the Introduction and Methodology in detail and highlighted the need to adhere to the Consolidated Standards of Reporting Trials (CONSORT) guidelines. In this segment, we shall discuss the tips for writing the following sections: statistical analysis, results, discussion, and conclusion.

Statistical analysis

Statistical analysis, along with sound methodology, forms the backbone of a well-conducted RCT and is keenly scrutinized by reviewers and knowledgeable readers. It is prudent to seek the help of a statistician familiar with clinical research right at the stage of protocol development and have the statistical methods clearly laid out. Clear communication with respect to the null hypothesis, primary and secondary objectives ensure smooth conduct of subsequent analysis of the data. A basic knowledge of the type of statistical tests relevant to the study not only improves communication with the statistician, but also helps in appropriate interpretation of the results, identification of the likely source of unexpected results and correction of errors. Likewise, one may use this knowledge to independently and critically analyze the outcomes reported in other RCTs. Hence, as a clinician it is always better to be familiar with the basic understanding of medical statistics.²

Description of the statistical analysis is usually a single paragraph in the manuscript. It includes the name of the statistical software used and how the sample size was calculated to achieve a power of at least 80%. The variables should be enumerated and categorized into numerical (discrete or continuous) and categorical (nominal or ordinal) types, the way their descriptive statistics are expressed, and the inferential statistics used to compare the groups should be mentioned. It is also customary to mention the threshold p value for statistical significance ($p < 0.05$).²

To arrive at the type of statistical tests to be used in an RCT, it is useful to follow an algorithm, starting from what the research question is trying to find out.^{2,3} Is it a comparison of two or more paired (dependent) or unpaired (independent) groups? Or are we trying to find out if there is an agreement or an association between the two groups? Next, we need to define our dependent and independent variables and see if they are categorical or numerical. The statistician will help us find out if our data is distributed normally, in which case, parametric statistical tests will be used. A normal distribution of data is described when the data follows a bell-shaped curve, and it is also known as Gaussian distribution. In a perfectly normal distribution, the mean, median and mode will be the same value which is the peak of the curve. Equivalent non-parametric tests will be applied to analyze data that is not distributed normally.⁴ The various types of statistical tests commonly used are depicted in Figure-1.

Accuracy and completeness of data: Errors during manual entry from physical proformas must be avoided. Checking the number of rows and columns, checking for duplicates, blank cells, outliers (for example, this can be done by using formulas for acceptable range in Microsoft Excel) is also important. One way of doing this is to repeatedly check the entered data for correctness by sampling 5-10% of the entries and comparing them with the original proformas until any 5-10% of the entries selected are free of errors. More than one researcher may perform such a check.

Intention to treat versus per protocol analysis:

All RCTs conventionally prefer results of intention to treat (ITT) analysis, which is least biased. In an ITT, all patients randomised are analyzed for the results. ITT will give a true estimate of the real-world applicability of the particular treatment modality since it will bring forth any issues such as need for additional treatments in that group, non-compliance due to various reasons that may need to be highlighted, or even treatment failure. In per protocol analysis (PP), the patients analyzed are those who receive the intended study intervention and only the effect of the intervention is studied.⁵ Random allocation is not respected entirely and reasons for patients not receiving the allocated intervention may not get highlighted, thus introducing bias and potentially under-reporting side effects or lack of effectiveness. However, in some situations wherein the subjects are found to be ineligible or unable to follow study protocol due to other reasons after randomizations will need to be excluded from analysis. This is termed modified ITT analysis and if applied, must be mentioned in the statistics section.⁶ Per protocol analysis is appropriate in studies such as non-inferiority trials.⁷ If no patients were lost to follow up, ITT and PP are essentially the same.

Hypothetical study:

A patient population of early breast cancer were randomized into two arms, one group underwent modified radical mastectomy (MRM) and the other group underwent some form of breast conservation surgery (BCS). They were analyzed for 5-year survival rate.

A total of 150 patients were randomized initially with 75 in each arm.

In patients who underwent BCS, 10 patients were lost to follow-up. Similarly, 15 patients from the MRM arm were lost to follow-up. In a per protocol analysis the final analysis is done with 65 in BCS arm and 60 in MRM arm. As we can see, there is an obvious bias in the per-protocol analysis, and it generates poor-quality evidence. On the contrary, in the ITT analysis the final analysis is carried out with 75 in each arm including the patients who were lost to follow-up. Thus, ITT can give reliable information regarding such data and are free from bias.

The CONSORT FLOW chart of the above description has been shown in Figure-2.

Results

The first paragraph mentions the starting and ending time points of the study (month and year) and the total duration of study. The total number of patients and number of groups are mentioned along with any significant details such as number of patients lost to follow up.

The first table in the result section is of the demographic data. As long as randomisation has been carried out correctly, any difference found between the baseline characteristics of the groups must have occurred by chance. Hence, it has been proposed that p values are not a very relevant component of the demographics table. However, stating the demographic data in numbers is essential so that any difference that may have had a bearing on the results may be available to the readers for independent judgment. Such differences, statistically significant or otherwise, may be highlighted in the section on 'Discussion' of the manuscript. When indicated, a subgroup analysis may be planned beforehand and performed if the outcome is believed to be influenced by certain demographic factors that make the study population very heterogeneous, bearing in mind certain caveats such as high rate of false-positive findings.⁹

It is also essential to choose the appropriate measure of central tendency while presenting data. Height and weight may be presented as mean values since these are generally normally distributed. Data such as length of hospital stay that is not naturally normally distributed can have a wide range or skewness. Median with interquartile range may be more suitable than mean in this case. Categorical data may be more appropriately presented as mode.¹⁰

The general characteristics of the patients from both groups and the descriptive statistics are tabulated in two separate columns with the 'n' values mentioned for each. The two groups are compared with each other to ensure randomization and mentioning the p values in the third column to show lack of significant difference is mandatory for many journals. Ideally, only the intervention must be different in the two groups. However, if there is a difference in the demographic data, the absolute numbers will help readers interpret the results keeping in mind the differences.

This is then followed by the primary and secondary outcomes. These could be separate tables or combined into one. The details in this section must include all and only the findings that were studied and already mentioned in the methods section. An a priori hypothesis is the pre-existing knowledge that has led the researcher to ask certain questions that are not answered adequately by currently available literature. The analysis should focus on testing the research question that initially led to the trial, that is, the priori hypothesis, rather than trying to 'trawl' to find the difference. Thus, this section states the comparison of outcomes clearly and only as 'facts' of the study. It must be left to the reader to interpret the data.

Usually, no references are given in the results section. Additional figures and graphs may be used to depict data in different forms. The result section must include the data in the form of numbers and comparative data must be depicted with 'p' values, especially for significant variables. It is better to avoid duplication of data from the tables. The results must be interpreted using techniques discussed in statistical analysis. It is always better to look for confidence intervals (CI) to look for precision of results. Narrow CIs are indicative of precise results while wide CIs indicate a wide range over which the values are spread. Specific data is to be depicted and implications and relevance must be straightforwardly mentioned. Interpretation and conclusions should be drawn from this section and is reserved for discussion.

The results section must also present negative findings and side effects. The reader must be able to view unbiased factual data and make his own independent judgment. Reporting bias or publication bias refers to the systematic differences caused by researchers and the journals reporting only the positive effects of intervention.

Discussion

The "discussion" section is the most interesting part of the manuscript as the results of the study are deliberated upon, in the light of evidence from existing literature. A well written discussion summarizes the results in tandem with the predefined aims and objectives, presents an objective comparison of the findings with those from other studies without being overly critical, highlights the merits of the study, acknowledges any limitations and challenges faced and highlights scope for further research on the subject. It may consist of 6-7 paragraphs and may follow an order as described below:

Paragraph 1: A quick summary of the results and the findings with respect to the aims and objectives.

Paragraph 2 and 3: Points the reader towards the lacunae in the existing literature which is why the research question was asked. A brief description of how the study has attempted to fill this gap will add to the interest with which the reader will proceed to the paragraphs that follow.

Example- In a study by Pranavi et al on adapted ERAS in patients undergoing emergency surgery for perforation peritonitis, it had a large sample of 120 patient of perforation peritonitis and had included most of the intra and postoperative component of ERAS.⁴

Most of the other studies published earlier had a relative smaller sample size and had focused on limited causes of peritonitis rather than including all causes.¹¹

This has been clearly mentioned in the discussion of the study.

Paragraph 4 and 5: Do the findings of the study agree with the previously conducted studies? How different or similar are the studies in terms of patient characteristics, other variables, and methodology? Has the current study added additional knowledge to the outcome of a particular intervention, for example, by

studying a different category of patients? If the results do not agree with previous studies, a thorough search for other negative studies and a mention of possible contributing factors are warranted.

Paragraph 6 (limitations and strengths): Despite meticulous planning and execution, certain factors may influence the outcomes. This section should list out limitations in the study design, data collection, analysis, and validity of results. An explanation on what steps were taken to minimize each limitation and how they may or may not have affected the results and the reasons for the same will allow the reader to interpret the results in the light of the limitations and consider further research with improvements. This scholarly process is essential to further deepen knowledge in the subject and gives an insight into real world conditions that interfere with study design and methodology. The author may also suggest improvements to be considered in future research projects. This will help the reviewers to understand the results in the light of certain limitations and reduces the scope for pointing out the flaws in the methodology. Strengths of the study which enables it to stand out from the rest of the pertinent literature should be highlighted to improve credibility.

Example: In a recently published study on adapted ERAS in patients undergoing emergency surgery for perforation peritonitis, minimally invasive surgery was not used due to logistic reasons. However, ERAS programme advocates the use of these. Similarly, goal-directed fluid therapy could not be tailored to the stroke volume monitoring due to logistic reasons which is again recommended for an ERAS programme. These were clearly mentioned in the study and the ways to overcome it for the readers to improvise in future studies.⁴

Paragraph 7 (conclusion): The conclusion of a study must address the reply to the objectives of the study and must be concise and precise. One may begin by restating the topic and its clinical importance. The main findings may then be summarized, followed by a brief note on how the results are likely to have an impact on clinical practice and the scope for further research to improve the current understanding. The summary of components of discussion has been depicted in Figure-3.

The formulation, conduct and publication of an RCT is a feat which can be successfully carried out with systematic planning and regular, open communication between all researchers involved, including the statistician. Writing of a good manuscript is a rewarding process and following key guidelines will make it more credible for acceptance in good peer-reviewed journals and enjoyable for the readers as well. The following checklist is a useful tool to ensure completeness of a RCT manuscript:

Checklist for an RCT:

Title: Is it appropriate? The term “Randomized controlled trial” must be mentioned in the title.

Introduction: Is the problem statement and rationale explained? The objectives to be clearly stated at the end of introduction. Are they clearly defined, and do they follow the PICOT format?

RCT study design: Is it appropriate to answer the research question of the study?

Inclusion criteria, randomisation, and blinding (if appropriate): Are they well defined and properly carried out?

Sample size calculation: Is it adequate and is the study adequately powered? A reference article must be quoted for the effect size.

Outcomes: Do they match with the aims and objectives?

Statistical tests: Are they appropriate?

CONSORT checklist: Is it adhered to?

Are the results clearly depicted without any data duplication?

The discussion is pertaining to the results in the study.

Conclusions: Are they drawn from the results of the study?

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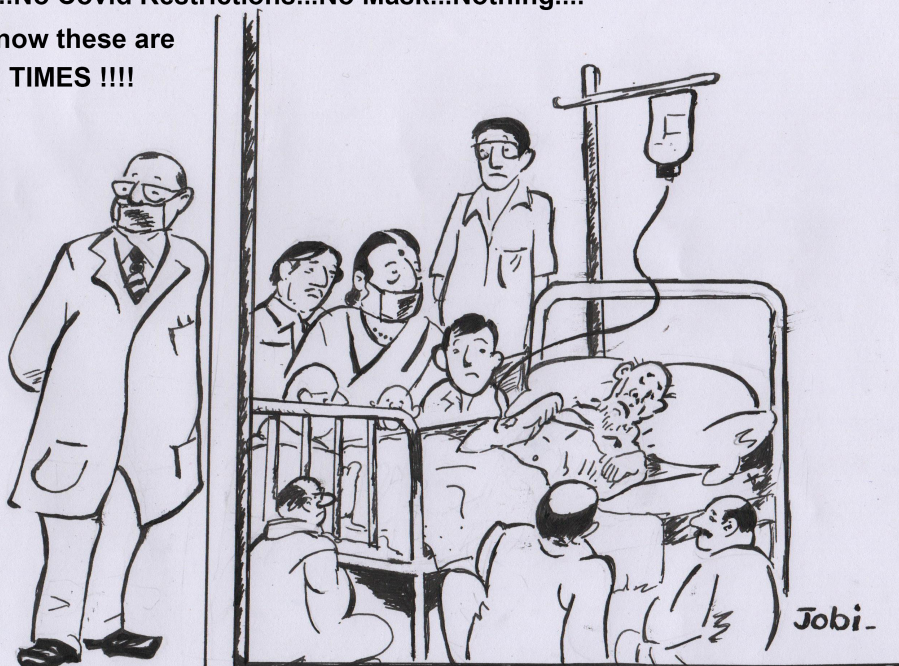
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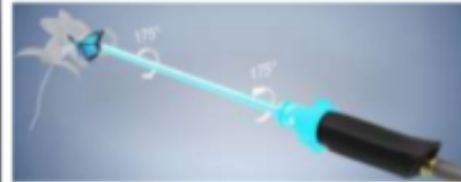
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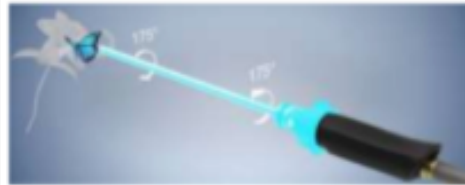


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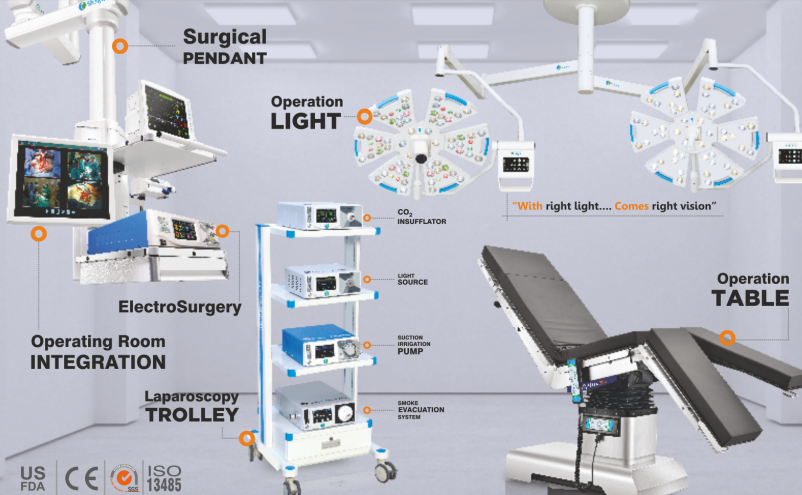
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