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A Comparative Study of Skin Staples with Skin Sutures for Modified Radical Mastectomy Skin Closure in Agmc And GBP Hospital

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I. INTRODUCTION

Surgery is derived from the earlier name chirurgery (old French word), which means handwork. It is a science and art that shows the manner in which to work on man's body exercising all manual operations necessary to heal or as much as possible using most expedient medicines or techniques.

The goal of surgery is to achieve healing by such means with minimal edema, no serous discharge or infection, without separation of the wound edges and with minimal scar formation.

After any surgical procedure (assuming there are no tension and a good blood supply) careful approximation of the tissues will allow healing by primary intention.

Precise approximation of skin incisions and lacerations with wound closure devices is critical for a favorable cosmetic and functional surgical result. Principles of wound closure focus on relieving tension on the wound and bringing the skin edges together in an everted orientation. If sutures are tied too tight or left in too long, they may leave permanent suture tracts if sutures are removed before adequate healing, the lack of wound tensile strength may result in wound dehiscence or a widened scar.

Wound closure includes ensuring a clean wound with satisfactory vascularity and hemostasis and apposition without wound tension. Principles of wound closure focus on relieving tension on the wound and bringing the skin edges together in an everted orientation.

"Surgery is the first and the highest division of the healing art , pure in itself , perpetual in its applicability , a working product of heaven and sure of fame on earth " SUSHRUTA (400 B.C.)

Surgical site infection (SSI) is the most common nosocomial infections reported in the hospital patients. Up to 2.5% of the patients undergoing clean extra abdominal operations and upto 20% of intra abdominal operations will develop SSI.

SSI remains a complication of surgical procedures resulting in increased morbidity, mortality and cost.

Infection remains the most significant factor affecting wound healing. A closure that penetrates the epidermis and dermis only serves to auto – inoculate the wound of the patient, driving surface flora deep into the subcutaneous tissue.

Percutaneous suture closure provides an extra source of contamination through the suture canal and results in a thin perisutural cuff of dead epidermis , dermis , and subcutaneous fat. Suture closure also is a potential source of foreign body reaction within the susceptible subcutaneous tissue[1].

The type of suture material for skin closure is also reported to influence post-operative wound complications. However, several other studies have failed to demonstrate significant differences between different types of suture material.

The surgical scar remains the only visible evidence of the surgeon's skill and not infrequently , all of his efforts are judged on its final appearance.

Skin staples give a neat scar with good wound eversion and minimal cross-hatching effect. They can be placed faster than sutures and have a lower predisposition to infection because they do not penetrate entirely through the wound and do not produce a complete track from one wound to the other[2].

When the surgeon suture a clean incision, healing takes place with minimum loss of tissue and without significant bacterial infection with minimal scarring. With passage of time and availability of newer methods of skin closure, it has become an art with stress on better cosmetic results. Any method of skin closure should provide adequate approximation of the tissue to allow wound healing with minimal risk of infection and should produce an acceptable cosmetic result. The method should be simple, quick to use and cost effective.

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Since long the art of suturing is emerging continuously for the betterment of the patient in terms of cosmetic appearance, minimal scar, decreasing the risk of infection, better patient compliance,thus overall decreasing the morbidity.

So, with the application of skin staple in skin closure of modified radical mastectomy it has been found that the wound closure time was much faster which was statistically significant and also it has a great impact on post operative recovery as the patient can be weaned off from the anaesthesia faster and thereby reducing overall operating time and hence decreasing post operative morbidity and mortality. Post operative pain was significantly lesser and wound healing was better with minimal infection. As a result , the patient can be discharge early and the hospital duration of the patient was lesser with the use of skin stapler in modified radical mastectomy.

Surgical wound closure aims to move close the skin flaps to favor rapid healing and a good cosmetic outcome with low risk of complications. Infection of surgical wound is a relevant complication with an incidence of 1% to 3%; it is favored by age, underlying illness (American Society of Anesthesiologists score of three or more, diabetes, malnutrition, low serum albumin, radiotherapy, and steroid use), obesity, host immune status, smoking, site, level of wound contamination.[3,4] Further significant risk factors are related to type and complexity of the surgical procedure, duration of operation, type of surgical approach (laparotomic or laparoscopic or robotic).[5] Wound dehiscence is another complication of surgical procedures that may increase the inpatient stay, resulting in additional costs, and it has a 9.6% attributable mortality. Further surgical wound complications are the formation of hypertrophic or keloid scarring. The cosmetic appearance of the scar after healing is a relevant outcome, which affects the satisfaction of patients. A meticulous surgical technique is needed to avoid local swelling, dehiscence of the wound, and a poor cosmetic result. Different methods and materials are used for wound closure and they are highly dependent on the type of surgery, the length and anatomical site of the wound.[6] Skin closure of surgical wounds is usually achieved with sutures. Sutures can be continuous or interrupted and the material used can be natural or synthetic, absorbable or non-absorbable, single filament or braided, depending on the length and anatomic location of the wound. The principal advantages of sutures are their flexibility, strength, non-toxicity, and in vivo degradation properties. Staples are a valid alternative to sutures and are mainly made of stainless steel, although staples using absorbable materials are now available.[6] Although the sutures are the most common technique of closure, they could increase the risk of wound infection. In fact, the sutures could cause the ischemia of the wound flaps and this hinders a regular healing. The potential advantage of staples in surgical wound closure is related to their low level of tissue reactivity.[7] This generates a higher resistance to infection in contaminated wounds, given the non-introduction of exogenous material, and consequent impairment of local immune response.[8] Furthermore, it is thought that the use of staples reduces the local inflammatory response, width of the wound, time to wound closure, and residual cross marks.[9,10] Even if the skin closure is conventionally performed by sutures, staples seem to be better in terms of efficacy of fixation, good cosmetic results and rapidity of application. However, in literature, it is unclear which is the best skin closure technique between sutures and staples. While some RCTs report that there is no difference between two methods in terms of overall wounds infections,[11,12] others report higher rates of wound complications following the use of staples.[13]

II. AIMS AND OBJECTIVE

AIM

The aim of the study is to compare the outcome of stapler and conventional suturing in skin closure of Modified Radical Mastectomy.

OBJECTIVES:

1. To compare the post operative pain and operative time required for stapler and suture.
2. To compare the effect on wound healing with the use of sutures and staples.
3. To compare the duration of hospital stay with these two techniques.

III. REVIEW OF LITERATURE

Mastectomy

A mastectomy is a surgical procedure involving removal of all or part of the breast. The term originates from the Greek word mastos, meaning “woman’s breast” and the Latin term ectomia which signifies “excision of.” Mastectomy classifies into partial, simple, modified-radical, and radical. Other variations in terminology or technique include skin-sparing mastectomy and nipple-areolar sparing mastectomy, which are techniques that often accompany breast reconstruction.

Anatomy and Physiology

The breast is found on the anterior thoracic wall and overlies the pectoralis major muscle. The superior border of the mature female

breast approaches the level of the second or third rib and then extends inferiorly to the inframammary crease or fold. The medial boundary of the breast is the sternal border. Laterally, the breast extends to the mid-axillary line. Posteriorly, approximately two-thirds of the breast overlies the pectoralis major muscle, and the remaining portion overlies the serratus anterior and upper portion of the oblique abdominal muscles.[14] The portion of the upper breast that extends superior-laterally toward the axilla is often referred to as the axillary tail of Spence. The breast divides into four quadrants which allow for consistency in the documentation of findings on physical examination or breast imaging. The four quadrants are upper inner, upper outer, lower inner and lower outer. The majority of breast tissue resides in the upper outer quadrant, including the axillary tail of Spence. As a result, it is the most common location for breast cancers.[15]

The breast is composed of mammary tissue and covered by subcutaneous fat and skin and possesses superficial and deep fascial layers. The superficial layer of fascia is deep to the dermis and covers the breast anteriorly and then extends over the medial and lateral breast. The deep layer of superficial fascia covers the posterior surface of the breast and lies anterior to the pectoralis major fascia.[16] Suspensory ligaments of Cooper are fibrous bands of connective tissue that extend from the deep layer of superficial fascia and run through the breast parenchyma and insert perpendicularly to the dermis. It is the weakness of these ligaments that are responsible for breast ptosis.[16] Breast tissue includes epithelial parenchymal elements and stromal tissue. In their text, The Breast: Comprehensive Management of Benign and Malignant Disease, Bland and Copeland detail the intricate anatomy of the breast. The epithelial component comprises about 10 to 15% of the overall breast volume, and the remainder is composed of the stromal elements. The breast stroma is made up from approximately 15 to 20 lobes, and these further subdivide into nearly 20 to 40 lobules. Lobules are made up of branched tubuloalveolar glands. The intervening spaces between the individual lobes contain adipose tissue. Each lobe drains into a major lactiferous duct that extends to the nipple.

Blood supply to the breast comes from several vessels running medially and laterally, as well as several deeper penetrating vessels that must pass through chest wall muscles before reaching the breast. Medially, the internal mammary artery gives rise to various perforating branches. These two to four anterior intercostal perforating arteries pass through pectoralis major into the breast tissue as medial mammary arteries. Laterally, the arterial supply to the breast comes from the lateral branches of the posterior intercostal arteries and branches of the axillary artery, including the lateral thoracic artery and pectoral branches of the thoracoacromial artery. The lateral vessels wrap around the superior and lateral border of the pectoral muscle to reach the breast.

Venous drainage of the drainage typically follows the arterial supply, with most of the drainage extending toward the axilla. Principal venous drainage is through the perforating branches of the internal thoracic vein, tributaries of the axillary vein and perforating branches of the posterior intercostal veins. Knowledge of the venous drainage is essential, as the lymphatic channels typically follow the course of blood vessels. This lymphatic drainage is relevant as it is the pathway for potential cancer metastasis via lymphatic and venous channels.

Breast lymphatic drainage is via the axilla 95% of the time. There is some variation in the description of lymph node groups between anatomists and surgeons. Surgeons typically define axillary nodes with respect to their relationship to the pectoralis minor muscle. Lymph nodes located lateral to or below the lower border of the pectoralis minor muscle are called Level I and this typically includes the external mammary, axillary vein, and scapular lymph node groups. Level II lymph nodes are located deep to the pectoralis minor muscle and include the central lymph node group and possibly some of the subclavicular nodes. Level III axillary nodes are medial or superior to the upper border of the pectoralis minor muscle and include the subclavicular lymph nodes. Surgeons also commonly identify Rotter's or interpectoral nodes that are located between the pectoralis major and minor muscles. These Rotter's nodes may further drain into the central or subclavicular node groups representing a possible "skip pathway" for tumor cells to metastasize from the breast to level III nodes while bypassing levels I or II. Other sites of lymphatic drainage include the internal mammary chain, the lateral and medial intramammary regions, the interpectoral region, and the subclavicular lymph node basin.

Indications

The most frequent indication for mastectomy is a malignancy of the breast. In most cases, the mainstay of treatment of a breast cancer necessitates localized surgical treatment (either mastectomy or breast-conserving surgery) and can be in combination with neoadjuvant or adjuvant therapy, including radiation, chemotherapy or hormone antagonist medications, or a combination

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thereof. Tumor characteristics like size and location and patient preference are a significant part of the decision-making process; given that in many circumstances, survival rates are equivalent among patients undergoing mastectomy or lumpectomy with adjuvant radiation therapy.[17]

Briefly, cancers of the breast may include both invasive and non-invasive histologies. The most common breast cancer diagnosis is invasive ductal carcinoma, and approximately 85% of all invasive breast cancers are ductal in origin. Alternatively, invasive lobular carcinoma and other infrequently seen histologies, such as breast sarcoma or breast lymphoma, are much less common. Non-invasive carcinoma of the breast includes ductal carcinoma in situ and lobular carcinoma in situ. The latter is often regarded as a marker of increased risk of future breast cancer and may best be considered a benign precursor lesion.[18]

Patients with Paget's disease of the breast may be considered for mastectomy as well. Paget's disease is a rare manifestation of breast cancer where neoplastic cells are present in the epidermis of the nipple-areolar complex. While the disease may remain confined to this area, approximately 80 to 90% of cases will have an associated cancer elsewhere within the involved breast. Total mastectomy with axillary sentinel node biopsy has been the traditional approach to surgical management of Paget's disease. Central lumpectomy with complete removal of the nipple-areolar complex has been effective for local control in patients without an associated cancer elsewhere in the breast when followed with whole breast radiation therapy.

Mastectomy may be indicated in patients whose disease is multifocal or multicentric within the breast due to the volume and distribution of disease. Also, patients who present with advanced locoregional disease, including large primary tumors (T2 lesions greater than 5 cm) and skin or chest wall involvement may benefit from mastectomy in many situations. Patients who present with inflammatory breast cancer are also treated with mastectomy, in addition to systemic chemotherapy and radiation treatment, due to tumor burden within the dermal lymphatic channels and more diffuse involvement of the underlying breast parenchyma.

Patients who initially undergo breast-conserving surgery (i.e., lumpectomy or partial mastectomy) and have margin involvement with tumor cells may be considered for a mastectomy if margin re-excision is not successful or is not technically or cosmetically feasible. Clear or negative margins following the resection of a primary tumor is a strong factor in reducing the risk of recurrence. Mastectomy is also indicated in patients with recurrent breast cancer who underwent previous treatment with lumpectomy and radiation.

In patients who do not have a diagnosis of malignancy, mastectomy may be an option for risk-reduction or prophylaxis in certain situations. Patients who are proven to carry a deleterious BRCA genetic mutation are at increased risk of breast cancer throughout their lifetime. A BRCA1 or BRCA2 mutation carriers have a lifetime risk of breast cancer as high as 80 to 85%. Even in the absence of a diagnosis of breast cancer, the National Comprehensive Cancer Network (NCCN) supports the recommendation of risk-reducing bilateral mastectomy in patients who are BRCA1 or BRCA2, p53, PTEN, or other gene mutation carriers and adds that special high-risk screening protocols exist for this subset of patients. However, routine contralateral prophylactic mastectomy in average-risk patients with unilateral disease does not provide a survival benefit and is often discouraged.[19]

Contraindications

In most situations, mastectomy may be done safely and easily, if medically indicated. There are a few crucial factors that merit consideration as contraindications for surgery. These can often be broken down into two separate categories: systemic and locoregional. Mastectomy may be contraindicated in patients with proven distant metastatic disease. Also, frail or elderly patients with significant medical co-morbidities or systemic organ dysfunction may not be candidates for surgery due to the burden of their overall health and poor performance status. Patients who have a predicted high risk of mortality associated with surgery or anesthesia are not candidates for surgery. For patients with advanced locoregional disease, mastectomy may be relatively contraindicated at the time of diagnosis if there is skin or chest wall involvement and concerns regarding the ability to close the surgical wound or obtain a negative surgical margin. In these circumstances, neoadjuvant treatment with chemotherapy, radiation or endocrine therapy may be of benefit to reduce the volume or extent of local disease and open the door for surgery.

Equipment

Mastectomy may be performed using sharp dissection with a scalpel or scissor technique. Another alternative is to use an energy device such as electrocautery or one of the various ultrasonic devices for dissection of the breast from the superficial tissues and to release the posterior

attachments from the chest wall. Standard general surgery equipment, including retractors and suction, are often utilized. At the discretion of the surgeon, a temporary, closed suction drain (i.e., Jackson Pratt drain) may be placed in the wound bed to decrease the rate of seroma formation. Absorbable suture is the most common choice for closure of the mastectomy defect and incision.

Axillary sentinel lymph node biopsy is commonly an option for staging purposes at the time of definitive breast surgery. Most surgeons employ a dual tracer technique, which typically involves the use of technetium sulfur colloid which is injected into the breast preoperatively by the nuclear medicine department of radiology. Intra-operatively many surgeons will inject a vital blue dye, such as methylene blue or isosulfan blue, into the breast to aid in the identification of axillary sentinel lymph nodes. A gamma probe is required to detect any nuclear tracer uptake in the axilla and to guide dissection and exploration in this region for biopsy.

Personnel

Breast cancer care is complex and involves a comprehensive an interprofessional care team. A general surgeon or breast/oncologic surgeon typically performs the mastectomy. Additional personnel involved during mastectomy procedures include perioperative nursing staff, anesthesia providers, and surgical technologists or assistants in surgery. For patients who require axillary node biopsy at the time of mastectomy, a radiologist or nuclear medicine technologist is often involved for perioperative technetium sulfur colloid injection as part of sentinel lymph node mapping. In patients undergoing reconstructive procedures, a plastic surgeon typically works alongside the general or breast surgeon to perform the appropriate reconstructive surgery which has its basis in various patient factors. Additionally, most patients who undergo a mastectomy do so because of malignancy, and their postop care team includes medical oncology and possibly radiation oncology. Following mastectomy, patients may require home healthcare nursing support and even physical or occupational therapy to maximize the return of capacity for activities of daily living.

Preparation

Mastectomy is typically an elective procedure, and patients usually report to the hospital or surgical center on the day of their surgery. Pre-operative antibiotics are indicated for patients undergoing mastectomy, with or without axillary surgery or reconstruction, to reduce the risk of surgical site infection; this consensus statement came from the American Society of Breast Surgeons and updated in 2017. A first-generation cephalosporin is the antibiotic of choice for prophylaxis unless the patient is allergic or has a history of methicillin-resistant Staphylococcus aureus infection.[20]

Patient positioning is in a supine position in the operating room, and the breast, chest wall, axilla, and upper arm are exposed, after induction of anesthesia. Many surgeons may include the contralateral breast in the prepped operative field. The field is sterilely prepped with an agent to decrease the presence of skin flora and reduce the risks of surgical site infection. Alcohol-based skin preps, such as chlorhexidine gluconate are common agents chosen for surgical antisepsis.

Perioperatively, surgeons should prepare patients for their procedure and discuss anticipated postoperative course and care. Many surgeons elect to place a drain at the time of mastectomy to evacuate any fluids that may accumulate in the wound bed and to promote adherence of the flaps to the chest wall. Patients benefit from education on the aspects of drain care and recording an accurate log of output. Patients should also receive counsel regarding their postoperative restrictions regarding lifting, driving and any other limitations in the immediate recovery period.

Technique

While there is a historical reference to surgical removal of the breast dating back to the 18 century, William Halsted described his radical mastectomy technique in 1894 where "suspected tissue should be removed in one piece."[21]This radical technique involves complete en bloc resection of the breast with the pectoralis major muscle and regional lymphatics. There was a significant amount of skin sacrificed, and a skin graft was often necessary for coverage of the chest wall defect with this approach. This technique left women with significant deformities and disabilities. As a result, there have been several modifications to the technique to reduce the morbidity of the operation. In the 1940s, David Patey modified the Halsted radical mastectomy by preserving the pectoralis muscle, and his outcomes were favorable for less postoperative complications, including pain, lymphedema, and limitations in upper extremity mobility.[22]

John Madden described the current standard for a mastectomy in 1972. This technique involves making an elliptical incision circumscribing the breast and including the nipple areolar complex while keeping the site of the tumor as a central landmark.[23] The mammary tissue is separated from the skin flaps and resected along with the pectoralis major fascia while preserving

both pectoral muscles. As a result, this approach requires less disruption of surrounding neurovascular and lymphatic structures. Originally described with this modified radical mastectomy technique, Madden included level I-III axillary lymphadenectomy for staging purposes, and this was thought to offer a therapeutic benefit as well.[22] In contrast to this modified radical mastectomy technique, total mastectomy refers to surgical removal of all mammary tissue. However, no axillary node dissection is necessary.

As reconstructive techniques have evolved and become more popular, some patients who choose to have breast reconstruction may be candidates for skin-sparing and nipple-sparing mastectomy. Regardless of approach, oncologic principles take precedence over cosmetic concerns. As the name suggests, skin-sparing mastectomy is designed to preserve a healthy skin envelope for immediate breast reconstruction, provided adequate margins can be achieved. Nipple-sparing mastectomy allows removal of the mammary tissue and pectoral fascia while preserving the nipple-areolar complex and entire skin envelope of the breast. This surgical approach is done only in patients undergoing immediate breast reconstruction. With this approach, it is critical to preserve blood supply to the nipple areolar complex to prevent flap ischemia or breakdown.

With all described mastectomy techniques, uniform flaps are created by dissecting just above the superficial layer of the superficial fascia of the breast. There has been much controversy over the ideal flap thickness, with the ultimate goal of removing all possible breast tissue while preserving skin viability.[24] As noted above, mastectomy dissection should continue to the anatomic boundaries of the breast, regardless of the type or location of skin incision used. Flaps are elevated and retracted at a right angle to the chest wall while the surgeon retracts the breast tissue away from the overlying tissue. The skin flap is elevated to the level of the clavicle superiorly, the anterior border of the latissimus dorsi laterally, the sternal border medially and to just below the inframammary crease inferiorly. Once the dissection of the overlying flaps is complete, the breast is removed with the pectoralis major muscle, working from the superomedial border to the inferolateral border. A closed suction drain is usually placed beneath the skin flaps, in the wound bed, and the incision is closed in a two-layer fashion using absorbable suture.

Complications

Patients tolerate mastectomy well in most settings with low morbidity and mortality. However, several possible complications may occur. These include seroma or hematoma formation, wound infection, skin flap breakdown or necrosis and lymphedema. Seroma is a collection of fluid in a surgically created cavity that results from the transection of vessels and lymphatics. Most surgeons used closed suction drains beneath the skin flaps to decrease the rate of seroma formation. The frequency of surgical site infection in patients undergoing breast surgery is approximately 8%.[20] The most common organisms involved are Staphylococcus aureus, and Streptococcus epidermis and infections should receive treatment with an appropriate antibiotic, with or without opening of the wound. Similarly, flap necrosis occurs in about 8% of patients and is related to inadequate blood supply to the flap, wound closure under tension, obesity, and type of incision (vertical versus transverse). Necrosis is managed with debridement and skin graft coverage if indicated. Lymphedema is less commonly present since the advent of modified mastectomy techniques. Axillary lymph node dissection is the most significant risk factor for the development of lymphedema, with a reported incidence of greater than 20%. Comparatively, 3.5 to 11% of patients who have sentinel lymph node biopsy develop lymphedema.[25] In patients who develop lymphedema, early intervention with physical therapy and decompressive massage techniques can help prevent progression and, in some cases, reduce lymphedema.

Clinical Significance

There have been significant advances in the patient management of breast cancer patients since Halsted first described his radical surgery in the late 1800s. There has been a growing trend toward breast conservation, and numerous studies have looked at the efficacy of breast-conserving surgery when compared to standard mastectomy techniques. With the addition of adjuvant therapies, including radiation and systemic treatment with chemotherapy and endocrine therapy, rates of mastectomy have declined. Twenty-year follow up data from NSABP-06 shows no difference in disease-free survival or overall survival in patients randomized between modified radical mastectomy, lumpectomy with axillary dissection and radiation or lumpectomy and axillary dissection alone.[26] NSABP-06 was critical in establishing the concept of breast-conserving surgery, and the results have received validation from other clinical trial groups, including the European Milan Cancer Institute.[26]
Evolution of radical mastectomy for breast cancer

The current standard in radical mastectomy was established by John Madden in 1972 [27]. His contribution to the technique was the preservation of both pectoral muscles. Between 1894, when William Halsted performed the surgery that bears his name [28], and the modern era in the surgical treatment of breast cancer, there have been attempts to expand the scale of the intervention, but these operations, called supraradical mastectomies were associated with significant morbidity and proved to be of little therapeutic benefit. After the implementation of the Madden modified radical mastectomy, along with advances made in adjuvant therapy and radiotherapy, conservative treatment was adopted because, it was shown that that it achieved similar results to mastectomy in terms of oncological safety, but with obvious benefits in terms of aesthetics. Sentinel node technique favored the limitation of unnecessary interventions regarding axillary lymphadenectomy, and, in this way, the rate of postoperative complications (lymphedema, paresthesia, upper limb mobility limitation) was decreased considerably. The combination of plastic surgery principles in cancer surgery gave birth to oncoplastic surgery that brought a great contribution regarding the obtaining of an optimal esthetic result, with techniques such as nipple areola sparring mastectomy or skin-sparing mastectomy, to facilitate breast reconstruction. Although controversial in terms of cost and learning curve, the use of robotic surgery in breast surgery, particularly in skin sparring mastectomy can be a solution because of the advantages that robotic dissection offers.

Halsted's Mastectomy

There is no reliable data on the origin of mastectomy but it is known that it was practiced routinely in breast cancer patients since the days of the Byzantine Empire [29]. In 1882, William Halsted documented the first interventions he carried out, establishing guidelines in radical cancer surgery and using new anesthesia, aseptic and antiseptic techniques for the first time. Results in terms of survival and local recurrence reduction were exceptional, thus making the Halsted operation, described in the 19th century, be performed on more than 90% of the patients with breast cancer in the US until the 1970s of the 20th century [30]. Halsted's radical mastectomy involved large incisions and extensive tissue ablation. The mammary gland, both pectoral muscles, and the entire axillary lymphatic tissue, up to its tip, were excised. The advantage of the technique is the facilitation of access to the axillary vein, which can be completely denuded [31]. The extent of resection also led to an important associated morbidity (paraesthesia, lymphedema of the arm, rib cartilage damage, or pneumothorax by the perforation of the intercostal space). The hypothesis on the futility of such radical an intervention was initially advanced by Haagensen in 1935, but was confirmed by Bernard Fisher in 1971 with the publication of the results of the first prospective study comparing Halsted mastectomy to modified radical mastectomy that preserves pectoral muscles, with comparable results in terms of survival [32]. David H. Patey modified Halsted's operation by keeping the great pectoral muscle. The surgery is less traumatic and is followed by less postoperative complications (axillary retractable scar, painful syndrome, lymphedema, upper limb mobility limitation). Lymphedema was not constant and the postoperative outcome was better with the preservation of the great pectoral and by changing the type of incision, which was oblique or transverse, and circumscribed the breast as an ellipse with poles on the xiphoid medial breast and axillary lateral basis [33].

Madden modified radical mastectomy

The current standard for mastectomy is the surgery described by Madden in 1972. He concluded that keeping both pectoral muscles gives the best result. Madden mastectomy involves making an elliptical incision circumscribing the breast and including the nipple areola complex while having as a central landmark the site of the tumor. Thus, for a tumor located in the lower quadrants of the breast, the upper limit of the incision will be just above the areola while the lower limit will be placed towards the inframammary fold, to allow the inclusion of as much tissue close to the tumor site as possible. The mammary gland is separated from the skin flaps by cutting the Cooper's ligaments. Mammary gland ablation is done simultaneous with the pectoralis major fascia to reduce the risk of chest wall recurrence, although some authors disagree with this aspect particularly for early stage cases. Axillary lymphadenectomy is a mandatory component of radical mastectomy. The following stations are targeted: brachial lymph node group (lateral), pectoral lymph node groups (superior), subscapular lymph node groups (posterior), central nodal group, and apical lymph node group (medial or subclavicular). In need of a surgical systematization, John W. Berg divided the axillary lymph nodes into three stations according to the position they occupied in relation to the minor pectoris muscle. The first station comprised nodes located outside the external edge of the minor pectoris muscle. A second station included nodes

that were found behind it and the third station was contained in a space within the internal edge of the muscle. Lower axillary lymphadenectomy involves the ablation of the first station, while complete axillary lymphadenectomy means that all three stations are taken out [34].

A controversy on Madden's mastectomy concerned the interpectoral lymphatic group (Rotter's group). In a prospective study on a group of 172 patients, published in 2005, in Tumori, Vrdoljak concluded that up to 30% of the patients with axillary lymph node invasion need interpectoral lymph node ablation [35]. A similar proportion has been indicated by a study conducted by Gregory earlier [36]. The author recommended a routine nodal ablation because the surgical approach of this group was easy and the aesthetic result was not affected. However, the pedicle of the pectoral can produce damage at this level, which could also mean that the great pectoral muscle could develop a partial atrophy [37]. In some cases, axillary lymphadenectomy leads to a serious complication, lymphedema. Once installed, the treatment has only a palliative role. For this reason, many tried to minimize the extent of dissections without harming the surgical safety. Thus, there were authors, including Benson and Procaccini, who issued theories on the required number of lymph nodes for a correct histological examination. Thus, initially 10 nodes were thought to be enough, then 4 [38]. All these dilemmas were answered with the introduction of the sentinel node technique, the procedure that identifies the first lymph node to which the tumor drains lymph. Through high sensitivity and specificity of the method, practically unnecessary resections are excluded [39].

Madden Mastectomy – Complete axillary

The Romanian experience

Romanian physicians had their own contribution to breast cancer surgery, with names like Ion Chiricuta or Alexandru Trestioreanu. By analogy with Chimera, a character from Greek mythology composed of segments belonging to different animals, Chiricuta proposed a "chimerization" of the pectoral muscles. The intervention did not make concessions regarding radicalism, both axillary and interpectoral lymph nodes being excised. It comes instead with an artifice, which consists of removing parts of the pectoral muscles to ensure the easy access for performing extensive axillary lymphadenectomy and suturing the remaining part of the muscles afterwards, thus creating a "muscular screen" as Trestioreanu described this surgery in 1978 at a scientific session of the Oncology Institute in Cluj [40].

With the advance of imaging and radiology, the detection of suspicious breast lesions has been achieved from non-palpable stages; thus, conservative treatment has emerged as a viable alternative. In order to operate on such small

lesions, a preoperative localization is required, usually by ultrasound or mammography in case of suspicious micro calcifications. Conservative treatment for breast cancer is not only addressed in early stage cases but also for tumors that respond well to neoadjuvant therapy and have a less aggressive histopathological and immunohistochemical profile. The placement of radiopaque markers in the tumor bed when the biopsy is performed to guide the subsequent surgery is appropriate. In case of ptosis, oncoplastic surgery techniques, which can address both breasts to achieve, for example symmetrization, can produce a favorable postoperative outcome in terms of aesthetics, which may often matter for the patient's evolution. Currently, all aspects of the multimodal treatment of breast cancer are covered, from diagnosis to treatment and follow-up, at the Bucharest Institute of Oncology.

Perspectives

Breast cancer is a disease with a pronounced impact in society. A mastectomy is mutilating for a woman. The doctor who treats breast cancer is quite often put in difficulty by the disarming progression of the disease, despite all efforts. Perhaps for this reason, the approach on breast cancer was radical over time. The limits of radicalism have sometimes been pushed beyond a net benefit for the patient. The argument of this approach was the sacrificing of the quality of life to ensure survival. However, history has shown that, in many cases, this approach would have been different. Thus, conservative treatment has now reached from Halsted's mastectomy. It is possible that future clinical trials, currently in progress, will confirm the hypothesis set forth by the American College of Oncologists and Surgical Oncologists (ACOSOG Z0011), which demonstrated that the extension of axillary lymphadenectomy does not significantly influence survival [41]. Before these conclusions are implemented in daily practice, further studies are needed to confirm and validate the results obtained so far.

Suturing Techniques

As a method for closing cutaneous wounds, the technique of suturing is thousands of years old. Although suture materials and aspects of the technique have changed, the primary goals remain the same, as follows:

- Closing dead space
- Supporting and strengthening wounds until healing increases their tensile strength
- Approximating skin edges for an aesthetically pleasing and functional result
- Minimizing the risks of bleeding and infection

The postoperative appearance of a beautifully designed closure or flap can be compromised if an incorrect suture technique is chosen or if the execution is poor. Conversely, meticulous suturing technique cannot fully compensate for improper surgical technique. Poor incision placement with respect to relaxed skin tension lines, excessive removal of tissue, or inadequate undermining may limit the surgeon's options in wound closure and suture placement. Gentle handling of the tissue is also important to optimize wound healing.

The choice of suture technique depends on the following:

- Type and anatomic location of the wound
- Thickness of the skin
- Degree of tension
- Desired cosmetic result

Proper placement of sutures enhances the precise approximation of the wound edges, which helps minimize and redistribute skin tension. Wound eversion is essential to maximize the likelihood of good epidermal approximation. Eversion is desirable to minimize the risk of scar depression secondary to tissue contraction during healing. Usually, inversion is not desirable, and it probably does not decrease the risk of hypertrophic scarring in an individual with a propensity for hypertrophic scars.

The elimination of dead space, the restoration of natural anatomic contours, and the minimization of suture marks are also important to optimize the cosmetic and functional results.

The techniques of suture placement for various types of stitch are described, the rationale for choosing one suture technique over another is reviewed, and the advantages and disadvantages of each suture technique are discussed. Frequently, more than one suture technique is needed for optimal closure of a wound. After reading this article, the reader should have an understanding of how and why particular sutures are chosen and an appreciation of the basic methods of placing each type of suture. [42,43]

Simple interrupted suture

Compared with running (continuous) sutures, interrupted sutures are easy to place, have greater tensile strength, and have less potential for causing wound edema and impaired cutaneous circulation. Interrupted sutures also allow the surgeon to make adjustments as needed to properly align wound edges as the wound is sutured. A 2019 study suggested that high-density suture spacing

(approximately 5 mm apart) could improve early scar formation, but noted that placing sutures farther apart (approximately 10 mm) results in fewer puncture wounds, decreases tissue trauma, saves surgical time, and conserves suture material. [44]

Disadvantages of interrupted sutures include the length of time required for their placement and the greater risk of crosshatched marks (ie, train tracks) across the suture line. The risk of crosshatching can be minimized by removing sutures early to prevent the development of suture tracks.

Simple running suture

Running sutures are useful for long wounds in which wound tension has been minimized with properly placed deep sutures and in which approximation of the wound edges is good. This type of suture may also be used to secure a split- or full-thickness skin graft. Theoretically, less scarring occurs with running sutures than with interrupted sutures because fewer knots are made with simple running sutures; however, the number of needle insertions remains the same. Both basting sutures and tie-over bolsters have been used to help secure skin grafts. [45]In one study, no statistically significant differences in wound cosmesis or complications were noted between running cuticular sutures spaced 2 versus 5 mm apart, suggesting that the extra time involved in placing very closely spaced sutures may not be worthwhile, [46] although the personal preference of the surgeon ultimately dictates the distance he or she chooses to place between sutures.

Advantages of the simple running suture over simple interrupted sutures include quicker placement and more rapid reapproximation of wound edges. Disadvantages include possible crosshatching, the risk of dehiscence if the suture material ruptures, difficulty in making fine adjustments along the suture line, and puckering of the suture line when the stitches are placed in thin skin.

Running locked suture

Locked sutures have increased tensile strength; therefore, they are useful in wounds under moderate tension or in those requiring additional hemostasis because of oozing from the skin edges. Running locked sutures have an increased risk of impairing the microcirculation surrounding the wound, and they can cause tissue strangulation if placed too tightly. Therefore, this type of suture should be used only in areas with good vascularization. In particular, the running locked suture may be useful on the scalp or in the postauricular sulcus, especially when additional hemostasis is needed.

Vertical mattress suture

A vertical mattress suture is especially useful in maximizing wound eversion, reducing dead space, and minimizing tension across the wound. One of the disadvantages of this suture is crosshatching. The risk of crosshatching is greater because of increased tension across the wound and the four entry and exit points of the stitch in the skin.

The recommended time for removal of this suture is 5-7 days (before formation of epithelial suture tracks is complete) to reduce the risk of scarring. If the suture must be left in place longer, bolsters may be placed between the suture and the skin to minimize contact. The use of bolsters minimizes strangulation of the tissues when the wound swells in response to postoperative edema. Placing each stitch precisely and taking symmetric bites is especially important with this suture.

Half-buried vertical mattress suture

The half-buried vertical mattress suture is used in cosmetically important areas such as the face.

Pulley suture

The pulley suture facilitates greater stretching of the wound edges and is used when additional wound closure strength is desired. It has been shown to dramatically reduce defect size, simplify reconstructive techniques, and enable reconstruction of significant skin cancer defects of the head and neck to be performed in the clinic setting rather than in an operating room. [47]

Far-near near-far modified vertical mattress suture

The far-near near-far modification of the vertical mattress suture, which basically functions as a pulley suture, is useful when tissue expansion is desired, and it may be used intraoperatively for this purpose. This suture is also useful when one is beginning the closure of a wound that is under significant tension. Placing pulley stitches first allows the wound edges to be approximated, thereby facilitating the placement of buried sutures. When wound closure is complete, the pulley stitches may be either left in place or removed if wound tension has been adequately distributed after placement of the buried and surface sutures.

Horizontal mattress suture

The horizontal mattress suture is useful for wounds under high tension because it provides strength and wound eversion. This suture may also

be used as a stay stitch for temporary approximation of wound edges, allowing placement of simple interrupted or subcuticular stitches. The temporary stitches are removed after the tension is evenly distributed across the wound.

Horizontal mattress sutures may be left in place for a few days if wound tension persists after placement of the remaining stitches. In areas of extremely high tension at risk for dehiscence, horizontal mattress sutures may be left in place even after removal of the superficial skin sutures. However, they have a high risk of producing suture marks if left in place for longer than 7 days.

Horizontal mattress sutures may be placed before a proposed excision as a skin expansion technique to reduce tension. Improved eversion may be achieved with this stitch in wounds without significant tension by using small bites and a fine suture.

In addition to the risk of suture marks, horizontal sutures have a high risk of tissue strangulation and wound edge necrosis if tied too tightly. Taking generous bites, using bolsters, and cinching the suture only as tightly as necessary to approximate the wound edges may decrease the risk, as does removing the sutures as early as possible. Placing sutures at a greater distance from the wound edge facilitates their removal.

Half-buried horizontal suture

The half-buried horizontal suture (also referred as the tip stitch or three-point corner stitch) is used primarily to position the corners and tips of flaps and to perform M-plasties and V-Y closures. The corner stitch may provide increased blood flow to flap tips, lowering the risk of necrosis and improving aesthetic outcomes. [48] However, in larger flaps with greater tension, this technique has been reported to position the flap tip deeper than the surrounding tissue, often resulting in a depressed scar. [49,50]

Absorbable buried suture

Absorbable buried sutures are used as part of a layered closure in wounds under moderate-to-high tension. Buried sutures provide support to the wound and reduce tension on the wound edges, allowing better epidermal approximation of the wound. They are also used to eliminate dead space, or they are used as anchor sutures to fix the overlying tissue to the underlying structures. Wounds under significant tension may benefit from the use of a subcutaneous inverted cross-mattress stitch (SICM stitch), which can approximate such wounds relatively easily via a lateral pulley effect. [51,52]

Dermal-subdermal suture

A buried dermal-subdermal suture maximizes wound eversion. It is placed so that the suture is more superficial away from the wound edge.

Buried horizontal mattress suture

The buried horizontal mattress suture is used to eliminate dead space, reduce the size of a defect, or reduce tension across wounds. [53]

Running horizontal mattress suture

The running horizontal mattress suture is used for skin eversion. It is useful in areas with a high tendency for inversion, such as the neck. It can also be useful for reducing the spread of facial scars. If the sutures are tied too tightly, tissue strangulation is a risk. Although it is slightly more time-consuming to place, this suture appears to result in smoother and flatter scars than a simple running suture. [54] A modification of the horizontal running suture with intermittent single loops was recently reported to avoid the characteristic track marks resulting from suture tension while increasing wound eversion. [55] Other modifications include the V-shaped Victory stitch. [56]

Running subcuticular suture

The running subcuticular suture is valuable in areas where tension is minimal, dead space has been eliminated, and the best possible cosmetic result is desired. [57] Because the epidermis is penetrated only at the beginning and end of the suture line, the subcuticular suture effectively eliminates the risk of crosshatching.

The suture does not provide significant wound strength, though it does precisely approximate the wound edges. Therefore, the running subcuticular suture is best reserved for wounds in which the tension has been eliminated with deep sutures, and the wound edges are of approximately equal thicknesses.

Running subcutaneous suture

The running subcutaneous suture is used to close the deep portion of surgical defects under moderate tension. It is used in place of buried dermal sutures in large wounds when a quick closure is desired. Disadvantages of running subcutaneous sutures include the risk of suture breakage and the formation of dead space beneath the skin surface. Modifications of this suture have been recently described, which reportedly allows for consistent eversion and excellent cosmetic results in challenging high-tension areas. [58,59]

Running subcutaneous corset plication stitch

The corset plication technique is used in wounds wider than 4 cm that are under excess tension. It creates natural eversion and better wound edge approximation. This technique eases subsequent placement of intradermal sutures, in

that wound diameter and tension are significantly reduced.

The strength of the suture relies on inclusion of the septations from the fascial layer beneath the subcutaneous tissue. If tissue ruptured postoperatively, tension would be distributed more broadly. Potential problems include suture breakage and wound distortion. [60]

Modified half-buried horizontal mattress suture

The modified corner stitch allows equal eversion of the flap tip edges and improved aesthetic outcomes. Although it may increase risk of necrosis if tied too tightly, a study by Bechara et al suggested that the incidence of flap tip necrosis was comparable with that of the traditional corner stitch. [50] Modified subcutaneous buried horizontal mattress sutures relieve more wound tension and have a lower risk of dehiscence compared with vertical buried mattress sutures. [61]

Deep tip stitch

The deep tip stitch is used for M-plasty, W-plasty flaps, and V-Y closures to increase wound eversion. It provides longer-term support to the flap than the traditional corner stitch does and improves alignment of the tip with the sides of closure. This technique also avoids surface sutures, decreasing the risk of track marks. Flap tip necrosis and complications were comparable to that of standard sutures. [49]

Technical Considerations

Best practices

Effective suturing technique depends on appropriate selection of sutures, surgical gloves, needles, and needle holders.

Suture selection

Much of the process surrounding suture selection depends on surgeon training and preference. A wide variety of suture materials are available for each surgical location and surgical requirement. Generally, the surgeon selects the smallest suture that adequately holds the healing wound edges. The tensile strength of the suture should never exceed the tensile strength of the tissue. As the wound heals, the relative loss of suture strength over time should be slower than the gain of tissue tensile strength.

Certain general principles can be applied to suture selection. Sutures are no longer needed when a wound has reached maximum strength. Therefore, nonabsorbable suture should be considered in skin, fascia, and tendons (slowly healing tissues), whereas mucosal wounds (rapidly healing tissues) may be closed with absorbable sutures.

Aesthetic concerns are at a premium in regions of the head and neck such as the eyelid, periorbital area, nose, pinna, lip, and vermillion. In these areas, tensile strength requirements tend to be less, and smaller suture sizes are preferred. However, the mobility of the lip and vermillion requires a relatively higher suture tensile strength.

The activity and mobility of the face, anterior and posterior neck, scalp, superior trunk, and nasal and oral mucosa demand higher tensile strength requirements in suture selection. Additionally, major musculocutaneous flaps tend to be closed under significant tension, requiring maximal long-term tensile strength.

Because the presence of foreign bodies in contaminated tissues may facilitate infection, special consideration of suture selection in these locations (eg, a contaminated posttraumatic wound) is imperative. Multifilament sutures are more likely to harbor contaminants than monofilament sutures are; accordingly, monofilament sutures are generally preferable in potentially contaminated tissues. The smallest inert monofilament suture materials (eg, nylon or polypropylene) should be sued in this setting.

The optimal suture size is generally the smallest size that can still effectively achieve the desired tension-free closure. If wound tension is high, smaller-diameter sutures may actually injure tissues by cutting through them. Therefore, the tensile strength of the suture and that of the tissue should be closely matched.

Surgical glove selection

Surgeons who use sutures and needles should wear sterile surgical gloves without cornstarch, which has been shown to promote wound infection, cause serious peritoneal adhesions and granulomatous peritonitis, and act as a well-documented vector of the latex allergy epidemic. In 2008, 13 health professionals filed a citizen's petition to the US Food and Drug Administration (FDA) to ban cornstarch powder on medical gloves. [62]

The FDA allows 1.5% of the surgical gloves to have holes, and these holes allow the transmission of blood and thus of potentially deadly bloodborne viral infections between patient and surgeon. After surgery has begun, a major cause of glove holes is surgical needle penetration through the glove. Consequently, the double-glove Biogel Puncture Indication System should be used to detect the location and presence of holes in the gloves, allowing the surgeon to change the gloves when a hole is detected. [63]

Needle selection

No standardized sizing system or nomenclature is available for needles. The main consideration in needle selection is to minimize

trauma. A taper-point needle is sufficient for tissues that are easy to penetrate. Cutting needles are typically reserved for tough tissues. As a general rule, taper-point needles may be used for all closures except skin sutures. The length, diameter, and curvature of the needle influence the surgeon's ability to place a suture. Ideally, the needle-body diameter matches the suture size.

Needle-holderselection

No standardized sizing system or nomenclature is available for needle holders. Needle control and performance is affected by the stability of the needle within the needle holder; thus, for a secure needle hold and prevention of rocking, turning, and twisting, the jaws of the needle holder must be appropriate to the needle size. Often, the surface contact with the needle-holder jaws and the bending moment of the needle are maximized with an ovoid cross-section of the needle body.

In addition, the handle of the needle holder must be appropriate for the depth needed for the suture placement. A mechanical advantage for exerting force through the needle point is created by the difference between the length of the handle and the jaw.

The needle-holder clamping moment is a measure of the force applied to a suture needle by the needle holder, and the needle-yield moment is the amount of deformation that can occur before a needle is permanently deformed. Thus, when the needle-holder clamping moment is greater than the needle-yield moment, the needle is likely to be permanently deformed, which may lead to complications.

Outcomes

A study by Lin et al found the handling characteristics of Polysorb sutures to be superior to those of polyglactin 910 (Vicryl) sutures. [64] With comparable knot construction and suture sizes, the knot-breaking strength of Polysorb sutures was significantly greater than that of polyglactin 910 sutures. In addition, the mean maximum knot rundown force noted with Polysorb sutures was significantly lower than that noted with polyglactin 910 sutures, facilitating knot construction.

Drake et al used a miniature swine model to study the determinants of suture extrusion after subcuticular closure by synthetic braided absorbable sutures in dermal skin wounds. [65] Standard, full-thickness skin incisions were made on each leg and abdomen. The wounds were closed with either Polysorb or polyglactin 910 sutures.

Each of the skin incisions was closed with five interrupted subcuticular vertical, loops secured with a surgeon's knot. [65] The loops were secured with three-throw knots in one pig, four-throw knots in the second pig, and five-throw knots in the third pig. Suture extrusion, wound dehiscence, stitch abscess, and granuloma formation were all observed.

The cumulative incidence of suture extrusion over 5 weeks ranged from 10% to 33%. Polyglactin 910 sutures had a higher cumulative incidence of suture extrusion than Polysorb sutures did (31% vs 19%). [65] With Polysorb sutures, the five-throw surgeon's knot had a higher cumulative incidence of suture extrusion than the three-throw or four-throw surgeon's knot (30% vs 17% and 10%, respectively).

When Sanz et al randomly assigned 210 rats into one of five study groups to compare polytrimethylene carbonate (Maxon) with three absorbable sutures (polyglactin 910, chromic catgut, and polydioxanone [PDS II]) with respect to tissue inflammatory reaction, knot security, suture tensile strength, and suture absorption, Maxon and PDS II elicited a lower degree of chronic inflammation than polyglactin 910 and chromic catgut did. [66]

In addition, the tensile strengths of Maxon and polyglactin 910 significantly exceeded those of PDS II and chromic catgut during the critical period of wound healing. [66] Maxon and PDS II retained a larger percentage of tensile strength during the long postoperative period, whereas polyglactin 910 and chromic catgut were mostly absorbed. The investigators concluded that Maxon was an excellent addition to the armamentarium of the surgeon.

A randomized control study of the barbed suture (V-Loc) confirmed the unique performance of this suture for gastrointestinal (GI) wound closure. [67] The V-Loc wound closure device appeared to offer GI closure comparable to that achieved with 3-0 Maxon while being significantly faster. However, further studies with V-Loc are required to evaluate its use in laparoscopic surgery.

When Pineros-Fernandez et al compared the biomechanical performance of polyglytone 621 (Caprosyn) suture with that of chromic gut suture, both suture types provided comparable resistance to wound disruption. [68] The biomechanical performance studies included quantitative measurements of wound security, strength loss, mass loss, potentiation of infection, tissue drag, knot security, and knot rundown, as well as suture stiffness.

Before implantation, suture loops of Caprosyn had significantly greater mean breaking strength than suture loops of chromic gut did [68] ; 3 weeks after implantation of these absorbable suture

loops, the sutures had no appreciable strength. The rate loss of suture mass of these two sutures was similar.

As expected, chromic gut sutures potentiated significantly more infection than Caprosyn sutures did. [68] However, the handling properties of Caprosyn sutures were far superior to those of chromic gut sutures, and the smooth surface of the Caprosyn sutures encountered lower drag forces than the chromic gut sutures did. Furthermore, it was much easier to reposition the Caprosyn knotted sutures than the knotted chromic gut sutures. In the case of chromic gut sutures, it was not possible to reposition a two-throw granny knot.

These biomechanical performance studies demonstrated the superior performance of the synthetic Caprosyn sutures compared with chromic gut sutures and provided compelling evidence of why Caprosyn sutures are an excellent alternative to chromic gut sutures.

Chauhan A et al [69] (2018) found that to compare the merits and demerits of stapled skin closure when compared to conventional sutures skin closure in elective general surgical cases. Total of 100 patients (50 in stapler and 50 in suture group) were selected. They underwent closure of skin incision after general surgical procedures (Like open cholecystectomy, appendectomy, modified radical mastectomy, inguinal hernia repair). According to their assigned growth with either nylon (in suture group) or stainless skin staples (in stapler group). Both the groups were compared and analysed for speed of closure, pain on removal, patient comfort, wound related complications and aesthetic outcome i.e. resulting scar. The mean incision length in suture group was 7.2±1.2 cm while in stapler group was 7.4±1.1 cm which was statistically insignificant. The mean time of closure was 48 seconds in suture group while in stapler group was 295 seconds which was statistically highly significant ($p<0.001$). It was concluded that skin staples are better alternative to conventional sutures in general surgical procedure as they lead to faster wound closure with better aesthetic outcome and patient comfort with low wound complication rates.

Brickman KR et al [70] (1989) found that Automatic skin staplers have been commonly used for surgical wound closure for many years. The efficiency and ease of placement of skin staplers make them an attractive alternative to suture repair of selected lacerations in the emergency department. Emergency physicians, however, have been reluctant to use staplers in the ED. We evaluated skin staples in 76 patients presenting with 87 lacerations to the scalp, trunk, or extremities, excluding hands and feet. Patients returned to the ED in two and seven to ten days for wound check and staple removal. Skin stapling was assessed for efficiency, cosmetic results, complications, and cost-effectiveness. Only one significant complication was noted in our study group — a dehiscence of a scalp laceration secondary to hematoma collection. There was also a minor dehiscence of a superficial laceration of the leg due to inadquate primary closure, which did not result in any cosmetic deformity. No infectious complications, delayed wound healing, or cosmetics problems were seen. Skin stapling was easier and quicker than suture repair at a lower overall cost in most circumstances. Our study shows skin stapling to be an efficient and cost-effective alternative method to suture wound closure for selected laceration in patients presenting to the ED, without compromising wound healing or cosmetic results.

Cochetti G et al [71] (2020) showed that to compare the effects of sutures and staples for skin closure of surgical wounds. We included published and unpublished randomized controlled trials (RCTs) and cluster-randomized trials comparing staples with sutures. Patients were adults (aged 18 years or over) who had undergone any type of surgery. The primary outcomes were risk of overall and severe wound infection. Secondary outcomes included length of hospital stay, readmission rate, adverse events, patient satisfaction with cosmetic results, postoperative pain. Forty-two very low to low quality RCTs with a total of 11,067 patients were included. Sutures resulted in slightly fewer overall wound infections (4.90%) compared to staples (6.75%) but it is uncertain whether there is a difference between the groups (risk ratio [RR] 1.20, 95% confidence intervals [CI] 0.80–1.79; patients=9864; studies=34; I2=70%). The evidence was also insufficient to state a difference in terms of severe wound infection (staples 1.4% vs sutures 1.3%; RR 1.08, 95% CI 0.61–1.89; patients=3036; studies=17; I2=0%), grade of satisfaction (RR 0.99, 95% CI 0.91–1.07; patients=3243; studies=14; I2=67%) and hospital stay. Staples may increase the risk of adverse events (7.3% for staples vs 3.5% for sutures; RR 2.00, 95% CI 1.44–2.79; patients=6246; studies=21; I2=33%), readmission rate (RR 1.28, 95% CI 0.18–9.05; patients=2466; studies=5; I2=66%) and postoperative pain (standardized mean difference [SMD] 0.41,95%CI −0.35 to 1.16; I2=88%, patients=390 patients, studies=5). Due to

the lack of high quality evidence, we could not state if sutures are better than staples in terms of wound infection, readmission rate, adverse events, and postoperative pain. With a low quality of evidence, sutures reduce postoperative pain and improve grade of satisfaction with the cosmetic outcome.

Batra J et al [72] (2016) found that to investigate the merits and demerits of stapled skin closure when compared to conventional sutures in head and neck cancer surgery. A total of 80 patients (40 patients each in control and study group) were enrolled. The patients underwent closure of incision wounds following head and neck cancer surgical procedures. Skin incisions were closed with sutures using 3-0 silk in control group and with stainless steel staples in study group. Both the groups were compared for speed of closure, cost effectiveness, pain on removal, patient comfort, aesthetic outcome on day of removal, 15 and 30 days after day of removal and complications. The mean incision length in control group was 54 ± 16.3 cm while in study group was 53.7 ± 15.4 cm which was statistically not significant (P = 0.95). The mean time of closure in control group was 34.2 ± 12 min while in study group was 3.3 ± 1.2 min which was statistically highly significant (P < 0.001). The mean cost of material for skin closure in control group was Rs. 270.0 ± 46.4 and in study group was Rs. 517.5 ± 135.7 which was also statistically highly significant (P < 0.001). It was concluded that skin staples are better alternatives to conventional sutures in head and neck cancer surgery as they offer ten times faster wound closure, cost effectiveness, and similar results to sutures in terms of patient comfort, aesthetic outcome and complication rate.

Varghese F et al [73] (2017) showed that Wound closure is as important as any other action performed by the surgeon. Apart from the need forproducing a healthy and strong scar, it is the surgeon's responsibility to ensure its aesthetically pleasing physicalappearance. Skin staples are an alternative to regular sutures in offering this advantage. The present study has helpedto highlight the benefits of skin stapler. Out of the 120 participants, 60 underwent skin closure with Stainless steel skin staples and the remaining60 with non-absorbable Polyamide mattress sutures randomly. They all received one mandatory dose of pre-operativeparenteral antibiotic 1 hour prior to the incision. On the 3rd postoperative day, the wound was evaluated forinflammation, infection and wound gape. Participants were re-evaluated for infection/gape/inflammation duringfollow-up on 7th day. The wounds were evaluated at 1 months follow up which were rated for cosmesis by VisualAnalogue Score. The data was coded and entered in Microsoft excel and then analysed using statistical softwareSSPS.Results: Study population consisted of 79 males (65.8%) and 41 females (34.2%). Mean age of the study populationwas 49.35 with an SD 16.739. Wound infection was found to be higher in stapler group (30%) when compared toconventional suture group (11.7%)which was found to be statistically significant with chi-square value 6.114 and pvalue 0.013. Mean time for closure was significantly shorter in stapler group 4.55 minutes, when compared to suture group (11.22 minutes). Better cosmetic outcome was observed in conventional suture group. Preventing wound infection, especially in abdominal wounds, is of importance as it may lead to wound gaping. Incidence of post-operative wound infection was more with skin staples. Cosmesis is essential and important aspect in this day and age. A cosmetic scar not only gives satisfaction to the patient but also mental ease to the surgeon. Conventional sutures provided better cosmetic result when compared with skin staplers.

Kathare SS et al [74] (2019) showed that the objectives of the study were to study the operative time, the effect on wound healing, cosmetic results, patients acceptance and total cost with the use of sutures and staples. The study was conducted on 100 patients who were undergoing elective surgery from January 2016 to July 2017 in our institute. The patients were randomly selected to receive either suture or staple. The study group included 50 patients who underwent wound closure by staplers and 50 patients underwent suturing. The commonest region of the surgical wounds was Mc Burneys site. The time taken for wound closure using staplers showed statistically significance difference over closure with suture, it took the stapler 4 times less duration to perform wound closure. The average cost of using stapler was higher than suturing. The appearance of the scar among the staple group was good in 90% of those who returned for follow-up at 1 month, 10% had average scar. The patients acceptance was better in staple group with less pain during removal as compared to suture group. P-value calculated using students unpaired T-test. P<0.0001 which was highly significant. Staples did not cause excess wound pain and allows saving in time with better cosmetic results.

Iavazzo C et al [75] (2011) found that Surgical sutures are conventionally used in skin closure of surgical wounds. Alternative wound closure techniques include staples and adhesive strips. We

aimed to evaluate sutures versus staples as methods of surgical wound closure by performing a meta-analysis. We searched PubMed, Scopus, and Cochrane Central Register of Controlled Trials for randomized controlled trials that compared sutures with staples for surgical wound closure. Trials referring to orthopedic operations were excluded. Twenty studies (involving a total of 2111 patients) were included. Five studies referred to obstetrics/gynecological operations, seven to general surgery, four to emergency care treatment, three to head/neck operations, and one to vascular surgery. Regarding the time needed for wound closure, staples were superior to sutures; the mean difference observed between the sutures and staples groups was 5.56 minutes per wound (95% confidence intervals [CI], 0.05 to 11.07). Wound infections were significantly fewer in the staples group compared with the sutures group(s) (12 studies, 1529 patients; odds ratio, 2.06; 95% CI, 1.20 to 3.51). In five studies, the use of staples was associated with significantly more pain compared with sutures. The majority of studies with available relevant data reported nonsignificant differences regarding the cosmetic result and patient's satisfaction. Our findings suggest that staples are associated with fewer wound infections compared with sutures in the evaluated types of surgery. However, in a rather limited number of studies, the use of staples was associated with more pain. Further studies incorporating more objective methods for assessment cosmetic and patient satisfaction are required to clarify this issue.

Freitas Júnior RD et al [76] (2019) found that to evaluate the safety profile and aesthetic results of 2-octyl-cyanoacrylate versus intradermal nylon suture in breast surgeries.An open-label, randomized, clinical trial evaluating the occurrence of complications, such as dehiscence, hematoma, infection, and allergic reactions after the use of 2-octyl-cyanoacrylate or nylon thread. The size of the incisions, skin closure time, and total surgical time were also analyzed. The aesthetic outcome was evaluated at 40 and 180 days after surgery, by means of the average width of the surgical wound and by subjective conceptual assessment (optimal, good, reasonable, or poor). 79 patients were included: 37 in the 2-octyl-cyanoacrylate group and 42 in the nylon suture group. The study was stopped before the end of patient recruitment due to the occurrence of a greater number of dehiscences in the adhesive group (OR: 11.42; 95%CI: 1.36-96.02; p=0.007). Regarding the other analyzed complications, the surgical duration and postoperative aesthetic result, no significant differences were observed between the groups. The mean operative wound size was greater in the adhesive group than in the suture group, but there was no correlation between wound size and the largest number of dehiscences. While the cosmetic outcomes with the two techniques were similar, there was a greater risk of dehiscence with the use of 2-octyl-cyanoacrylate compared to intradermal suturing.

Stockley I et al [77](1987) found that a disposable skin stapler (Elite®: Auto Suture UK Ltd) and Nylon vertical mattress sutures have been used for skin closure. The complications related to each method were evalued in 129 wounds. There was a higher incidence of inflammation, discomfort on removal and spreading of the healing scar associated with staples. The only advantage ofstaples was speed ofwound closure.

Kanegaye JT et al [78] (1997) found that to compare the total costs and the physician time requirements for suture and staple repair of pediatric scalp lacerations. Eighty-eight children, 13 months to 16 years of age, coming to a children's hospital emergency department with simple scalp lacerations were prospectively randomly selected to receive staple or suture repair. Wound lengths, times required for initial wound care and closure, and equipment use were recorded. Patients returned in 1 week for suture or staple removal and wound reevaluation. The two methods were compared in terms of both time expended and costs of equipment and physician compensation. Forty-five children underwent staple repair and 43 underwent suture repair. There were no differences in age, sex, wound length, number of sutures or staples per centimeter, or physician experience. Stapling resulted in shorter wound closure times (65 vs 397 seconds; $p < 0.0001$) and shorter overall times for wound care and closure (395 vs 752 seconds; $p < 0.0001$). Staple repair was less expensive in terms of equipment ($12.55 vs $17.59; $p < 0.0001$) and total cost based on equipment and physician time ($23.55 vs $38.51; $p < 0.0001$). The follow-up rate was 91%, with no cosmetic or infectious complications in either group. Stapling is faster and less expensive than suturing in the repair of uncomplicated pediatric scalp lacerations, with no additional complications. Physicians who treat children with scalp lacerations should consider the use of stapling devices.

Orlinsky M et al [79] (1995) found that a prospective study was performed to test the null hypothesis that there is no difference between the cost of stapling and suturing for skin closure of selected linear lacerations. Appropriate wounds were randomly assigned to be closed by staples or sutures. Wound lengths, skin closure times, and the number of

staples or the number and types of sutures used were recorded. Costs for materials and labor were calculated. The average total cost per case was $17.69 (with suture kit) and $7.84 (without suture kit) for the staple Group compared with $21.58 for the suture Group (P = .0001 for each). It is concluded that stapling is less costly than suturing and that the advantage appears to increase as laceration length increases.

Eldrup J et al [80] (1981) found that the Proximate stapler was compared with usual skin closure in a randomized trial, with 137 patients having elective abdominal and breast surgery. The median duration of skin closure with the Proximate stapler was 80 seconds, which was significantly shorter than the median of 242 seconds with conventional closure. No difference was found with regard to wound infection, but pain was more frequent after stapling.

Maurer E et al [81] (2019) showed that superficial wound infections after gastrointestinal surgery markedly impair the affected patients' quality of life. As it is still unknown which method of skin closure is best for the reduction of wound infections in elective gastrointestinal sur- gery, we compared the frequency of wound infections after intracutaneous suturing versus skin stapling. In a prospective, randomized, single-center study, patients undergoing elective gastrointestinal surgery were intraoperatively randomized to skin closure either with an intracutaneous suture or with staples. The primary endpoint-the occurrence of a grade A1 wound infection within 30 days of surgery-was evaluated according to the intention-to-treat principle. Out of a total of 280 patients, 141 were randomized to intracutaneous suturing and 139 to stapling. The groups did not differ significantly with respect to age, sex, or ASA classification. 19 of the 141 patients in the intracutaneous suturing group (13.5%) had a grade A1 wound infection, compared with 23 of 139 in the stapling group (16.6%) (odds ratio [OR]: 0.79; 95% confidence interval: [0.41; 1.52]; p = 0.47). A multiple regression analysis revealed that the type of surgery (colorectal vs. other), the approach, and the incision length were independent risk factors for a grade A1 wound infection. When wound dehiscences were additionally considered, wound complications were found to have arisen significantly more often in the stapling group than in the intracutaneous suturing group (16.3% [23/141] versus 30.2% [42/139], OR: 0.45 [0.25; 0.80]; p = 0.006). In elective gastrointestinal surgery, intracutaneous suturing was not found to be associated with a lower rate of superficial wound infections than skin stapling, but fewer wound dehiscences occurred in the intracutaneous suturing group.

Karthikeyan S et al [82] (2018) found that tissue repair following skin incisions should be with good strength with least tissue damage and less inflammation with aesthetically acceptable scar. So we compared the conventional and stapler suturing in terms of the above parameters. 100 sequentially admitted patients were divided into 2 groups and one underwent stapler suturing and the other underwent conventional suturing. We measured the length of the incision sutured per minute, pain score, scar type, expenses and wound infections. The mean age of people is 44.56 + 14.9 years with males 62% and Females 38%. The complication rates between two groups are stapler group 4% and conventional group 17%. The number of centimeters covered per minute in stapler method 4.2 + 0.9 cm and conventional suturing method 1.9 +1 cm. Pain scoring using Visual Analog Scale for stapler method 0.46 + 5.7 conventional suturing method 1.38 + 5.6. Regarding the cost effectiveness, there is only a marginal difference with both methods. The incidence of Wound infection, pain score, time taken for suturing are lesser in stapler group compared to Conventional group. Cost wise the Conventional type of suturing is cheaper than the Stapler method.

Krishnan R et al [83] (2016) showed that to determine whether there still remains a significant advantage in the use of sutures to staples for orthopaedic skin closure in adult patients. MEDLINE-OVID, EMBASE-OVID, CINAHL and Cochrane Library. Grey and unpublished literature was also explored by searching: International Clinical Trial Registry, Grey Matters BIOSIS Previews, Networked Digital Library of Theses and Dissertations, ClinicalTrials.gov, UK Clinical Trials Gateway, UK Clinical Research Network Study Portfolio, Open Grey, Grey Literature Report, and Web of Science. Articles were from any country, written in English and published after 1950. We included all randomised control trials and observational studies comparing adults (≥18 years) undergoing orthopaedic surgery who either received staples or sutures for skin closure. The primary outcome was the incidence of surgical site infection. Secondary outcomes included closure time, inflammation, length of stay, pain, abscess formation, necrosis, discharge, wound dehiscence, allergic reaction and health-related quality of life. 13 studies were included in our cumulative meta-analysis conducted using Review Manager V.5.0. The risk ratio was computed as a measure of the treatment effect taking into account heterogeneity. Random-effect models were applied. There was no

significant difference in infection comparing sutures to staples. The cumulative relative risk was 1.06 (0.46 to 2.44). In addition, there was no difference in infection comparing sutures to staples in hip and knee surgery, respectively. Lastly, except for closure time, there was no significant difference in secondary outcomes comparing sutures to staples. Except for closure time, there was no significant difference in superficial infection and secondary outcomes comparing sutures to staples was found. Given that there may in fact be no difference in effect between the two skin closure and the methodological limitations of included studies, authors should begin to consider the economic and logistic implications of using staples or sutures for skin closure.

Gohiya A et al [84] (2015) found that surgical site wound closure plays a vital role in post-operative success. The use of either sutures or staples for skin approximation is a vital and frequently debated issue. We compared the outcome, using staples versus sutures, in open elective orthopedic surgical procedures. Material and Methods: This study was done over a period of 2 years at Department of Orthopedics Gandhi Medical College Bhopal. Patients aged between 18 to 80 years undergoing elective open surgeries were included. Computer generated random number randomized them in two groups. Skin closure was done by either monofilament nylon or metallic staples. The wounds were assessed in terms of discharge and if discharge showed bacterial growth than it was considered as wound infection. Wound dehiscence, pain during removal on the basis of VAS pain scale was also noted. Follow up was done in the 6th week in terms of patient satisfaction using visual analogue scale (VAS) and validated cosmesis scoring system Hollander Wound Evaluation Score (HWES). Results : Total 503 wounds were included in this study (262 in suture and 241 in staple groups), 14 (5.3%) wounds were culture positive in the suture group within 8th postoperative day as compared to 36(14.9%) in staples group with $\chi 2$ 9.65 and (p=0.002) which is significant. 320 wounds with >10cms incision were analyzed (166 in suture and 154 in staple group) out of which 12 (7.22%) were infected in suture group and 24 (15.5%) in staple group with $\chi 2$ was 7.6 and (p=0.006) that statistically significant. Conclusion: We found a statistically significant higher incidence of superficial wound infection following skin closure by metallic staples as compared to monofilament nylon. This incidence of wound infection is detrimental to patient safety and also increases hospital stay and cost.

Naireen N et al [85] (2016) showed that the objectives of this study were to compare the two techniques, skin staplers and conventional sutures in abdominal skin wound closure with respect to the total cost, operative time required, incidence of wound infection, postoperative pain and cosmetic outcome. The study was conducted on 100 patients undergoing elective surgery for GI malignancies from December 2013 to May 2015 in the Department of General Surgery, Government Medical College, Kozhikode. The patients were randomly assigned to closure by suture or staple. The study groups included 50 patients who underwent wound closure by staplers and 50 patients who underwent closure by non-absorbable ethilon sutures. The time taken for wound closure was found to be statistically significant, with staplers requiring five times less duration than conventional sutures. The average cost of using stapler was found to be significantly more expensive than suture. There was no significant difference in post-operative pain between the two groups. The incidence of wound infection was more in stapler group than in suture group although statistically non-significant. The cosmetic outcome with stapler closure was found to be significantly superior to that with sutures.

Ghosh A et al [86] (2015) found that comparison between stainless steel staples and silk sutures for primary closure of skin in patients undergoing neck dissection, in context of rapid application, approximation of the skin edges, economy and aesthetics of the resultant scar. (1) To compare surgical stainless steel staples and silk sutures for primary wound closure, with respect to presence/absence of wound infection and dehiscence (2) To compare the resultant scar following the two different methods of the closure at 3 rd month postoperatively with the help of visual analog scale and analyze the result statistically This study was designed to compare skin closure using staples and silk sutures in patients undergoing neck dissection, using both methods in one-half of the same wound; thus each wound affording its own control. The study was conducted on patients requiring collar line incision (high submandibular incision) with or without a cephalad extension of midline lower lip split incision for surgical access, who presented to the Department of Oral and Maxillo-Facial Surgery. (1) Sample size: 10 (2) Study design: Prospective Comparative study (3) Study duration: One and half years (4) Surgical stainless steel staples: Proximate Plus MD 35 W, Ethicon Endo Surgery (5) Sutures: 3-0 Ethiprime NW 5003, Non-Absorbable Surgical Suture, Mersilk-90 cm,

Ethicon, (16 mm 3/8 circle cutting needle). It was concluded that there is no significant difference between the scars observed in the regions of incision which underwent primary closure by two different methods, that is surgical stainless steel staples and 3-0 Mersilk Sutures.

Chandrashekar N et al [87] (2013) found that the skin stapling devices have revolutionized surgery for the purpose of rapid closure of abdominal wounds. However, staples have their own drawbacks. In view of this, this prospective study has been undertaken to highlight the outcomes of closure by staples and sutures with respect to speed of closure, cost effectiveness and post operative wound dehiscence, acceptance of scar and post operative pain. This is a prospective hospital based study conducted in our hospital from October 2009 to September 2011 involving a total of 200 patients who underwent abdominal surgery both on an emergency and elective basis. Results were analyzed and compared with previous studies. It has been found that the use of staples in abdominal surgical wound closure gives faster speed of closure, less postoperative pain, and better cosmetic results. Staples, however, are costlier, and when used in emergency cases, associated with higher rates of wound dehiscence and a less acceptable scar.

Sundresh NJ et al [88] (2018) showed that wound closure biomaterials were of three types sutures, staplers/ ligating clips and tissue adhesives. The consensus of either suture or stapler is better for wound closure in case of laparotomy is yet to be arrived. This was a non randomised controlled trial done among the patients admitted for laparotomy in tertiary care hospital. 50 patients were recruited into experimental group (wound closure with staples) and 50 recruited as controls (wound closure with sutures), after obtaining informed consent. After the surgery the investigator evaluated the study participants and recorded various variables like wound infection, wound dehiscence etc. The time for wound closure was significantly lesser in the staples group than the suture group. Wound infection was present in 36% of cases in the staples group and in 74% of cases in the suture group. Good cosmetic appearance was present in 82% of the staples group and 54% of the sutures group Discomfort in suture removal was present only in 6% of the cases when staples were used against 96% when sutures were used. 88% of the patients were satisfied in staples group against 38% in the control group. All the above mentioned variables were found to statistically significant. Staples were superior to sutures with respect to time for closure of the wound, occurrence of lesser complications namely lesser wound infections, better cosmesis, less discomfort during suture removal. All the above led to a satisfied patient.

Gatt D et al [89] (1985) showed that skin staples were compared with two conventional suture methods for speed, convenience, effectiveness and cost. One hundred and ninety-five patients having linear abdominal incisions were randomly allocated to one of three methods of interrupted skin closure--polypropylene sutures, polyglactin sutures or stainless steel staples and the wounds were assessed over 30 days. The mean rate of wound closure using sutures was 4.2 cm per minute while staples were faster at 22.5 cm per minute and saved an average of three minutes per wound. The time saved was considerably greater with long incisions. Staples cost 50p more per 15 cm wound than either suture. In other respects the three methods were comparable except that polyglactin caused the least wound pain. We believe the advantages of speed and convenience of skin staples outweigh the extra cost, provided the disposable instruments are reused until empty.

Smith TO et al [90] (2010) found that to compare the clinical outcomes of staples versus sutures in wound closure after orthopaedic surgery.Medline, CINAHL, AMED, Embase, Scopus, and the Cochrane Library databases were searched, in addition to the grey literature, in all languages from 1950 to September 2009. Additional studies were identified from cited references. Two authors independently assessed papers for eligibility. Included studies were randomised and non-randomised controlled trials that compared the use of staples with suture material for wound closure after orthopaedic surgery procedures. All studies were included, and publications were not excluded because of poor methodological quality. Two authors independently reviewed studies for methodological quality and extracted data from each paper. Final data for analysis were collated through consensus. The primary outcome measure was the assessment of superficial wound infection after wound closure with staples compared with sutures. Relative risk and mean difference with 95% confidence intervals were calculated and pooled with a random effects model. Heterogeneity was assessed with I2 and $\chi 2$ statistical test. Six papers, which included 683 wounds, were identified; 332 patients underwent suture closure and 351 staple closure. The risk of developing a superficial wound infection after orthopaedic procedures was over three times greater after staple closure than suture closure (relative risk 3.83, 95% confidence interval 1.38 to 10.68; P=0.01). On subgroup analysis of hip surgery alone, the risk of

developing a wound infection was four times greater after staple closure than suture closure (4.79, 1.24 to 18.47; P=0.02). There was no significant difference between sutures and staples in the development of inflammation, discharge, dehiscence, necrosis, and allergic reaction. The included studies had several major methodological limitations, including the recruitment of small, underpowered cohorts, poorly randomising patients, and not blinding assessors to the allocated methods of wound closure. Only one study had acceptable methodological quality. After orthopaedic surgery, there is a significantly higher risk of developing a wound infection when the wound is closed with staples rather than sutures. This risk is specifically greater in patients who undergo hip surgery. The use of staples for closing hip or knee surgery wounds after orthopaedic procedures cannot be recommended, though the evidence comes from studies with substantial methodological limitations. Though we advise orthopaedic surgeons to reconsider their use of staples for wound closure, definitive randomised trials are still needed to assess this research question.

Oswal S et al [91] (2017) found that to evaluate the efficacy of staples in skin closure after neck dissection in patients with oral squamous cell carcinoma. The authors hypothesized that the use of staples would result in better wound closure compared with the use of nonabsorbable monofilament sutures. A prospective single-blinded randomized clinical trial was performed to compare various parameters, including time for wound closure, inflammatory changes, pain, cost efficacy, complications, and esthetic outcome of skin closure with surgical staples versus nonabsorbable monofilament sutures and to determine their statistical relevance using $\chi 2$ and Mann-Whitney U tests. In a study of 124 patients, the mean skin closure time was 29.2 ± 4 minutes with sutures (n = 61) and 5.3 ± 1.29 minutes with staples (n = 63), which was significant (P = .01). Mean pain scores during removal using the visual analog scale were 5.08 ± 1.29 and 3.15 ± 0.89 with sutures and staples, respectively. Postoperative complications, such as gapping and stitch abscess with purulent discharge, were noted. Staples provided better esthetics with fewer complications, faster closure, minimal pain at removal, and faster healing compared with sutures. The slowest closure time in the staples group was 4 times faster than the fastest closure time in the sutures group. However, staples cost 5 times more than sutures.

Hlubek R et al [92] (2014) showed that surgical incision closure, as well as total joint replacement itself, plays a key role in the overall outcome of an arthroplasty procedure. Uncomplicated wound healing is the essential condition of successful rehabilitation and the patient's return to normal activities. Although there are many innovative suturing techniques which offer advantages, their safety is still being discussed. The aim of this prospective non-blind randomised study was to evaluate wound healing and complications in relation to skin incision closure with either conventional suture or metal staples. A total of 72 patients, 21 men and 51 women, who underwent a standard primary total knee arthroplasty (TKA) at our department in the period from January till June 2013, were evaluated. They were allocated to two groups by random assignment based on the patient's date of birth (even or odd day of birth). In group 1 (n=39) skin was closed using metal staples (Leukosan Skin Stapler), in group 2 (n=33), conventional continuous Donati suture was used. The groups, previously assessed as independent and comparable in terms of age, gender and BMI, were compared in the following criteria: suturing time, duration of wound drainage, wound healing, complications, resuturing when necessary, and their relation to the body mass index, skin plica thickness and co-morbidities potentially complicating soft tissue healing. The differences were statistically evaluated by parametric and non-parametric tests, i.e., the median test, $\chi(2)$-test, Student's t-test, Fisher's exact test and Pearson's correlation coefficient. The statistical significance of differences was set at a level of 0.05. A significant difference ($p<0.005$) between the groups was found in suturing time; the median time for staples was 81 sec in comparison with 290 sec for conventional suture. In both groups, staples or sutures were removed on the 12 th postoperative day and there was no difference in wound drainage (median time, 5 days; p=0.891 for both). Treatment for late discharge was required in two sutured wounds (6.1%) and in three stapled wounds (7.7%). One of the latter was due to early deep wound infection, which later resulted in revision TKA. The groups did not differ in the values of either BMI or plica thickness (Pearson's r). Views on alternative suture techniques for skin closure in orthopaedic surgery vary. In this study, the use of metal staples or conventional suture is compared between two groups of patients undergoing TKA, i.e., the same type of procedure. The advantage of staples involves a quick and simple application but, as reported, removal may be more painful with staples than with stitches, and much depends on the technique of staple application. The continuous suture technique may produce skin strangulation at

wound margins, which will complicate healing. Staples minimise this risk and are therefore commonly used in TKA surgery. However, only very few studies comparing these two suture techniques in TKA patients have been published. Correctly performed skin suturing by means of metal staples is not associated with a higher complication rate and is therefore a simple, rapid, efficient and economical alternative to the conventional suture technique.

Bhatia R et al [93] (2002) showed that this prospective, randomized controlled trial assessed the use of staples for closure of the palmar skin following Dupuytren's surgery. Although staples were significantly quicker to insert than sutures, patients experienced significantly more pain on removal of staples. There was no difference in the cosmetic appearance of the wound in the two groups. We recommend use of staples for palmar wound closure following long procedures.

Hiremath S et al [94] (2016) found that the type of suture material for skin closure is also reported to influence post-operative wound complications. However, several other studies have failed to demonstrate significant differences between different types of suture material. Materials and Methods: This study was conducted at M. S. Ramaiah hospitals, Bengaluru - 560 054, Karnataka, India, where 100 patients underwent abdominal skin closure with either staples or conventional vertical mattress suturing with Ethilon. Results: The present 1 year observational study was conducted in the Department of Surgery, M. S. Ramaiah Hospitals, Bengaluru - 560 054, Karnataka, during the year December 2014-November 2015. Data obtained was tabulated and analyzed in tables. Conclusion: The use of skin staples in low tension incision is easy, associated with low incidence of wound complications, provides good cosmetic outcome and also takes considerably less time for skin closure and thus recommend its use more frequently especially for closure of long and multiple incisions.

Kumar S et al [95] (2019) showed that tissue repair following skin incisions should be with good strength with least tissue damage and less inflammation with aesthetically acceptable scar. The aim of this study is to compare two skin closure techniques – suture and stapler in open abdominal surgeries. 160 sequentially admitted patients were divided into 2 groups and one underwent stapler suturing and the other underwent conventional suturing. We measured the length of the incision sutured per minute, pain score, scar type, expenses and wound infections. The incidence of Wound infection, pain score, time taken for suturing are lesser in stapler group compared to Conventional group. Cost wise the Conventional type of suturing is cheaper than the Stapler method. Conclusion: Wound closure with staples is almost three times faster thus time saving.

KHAN AN et al [96] (2002) showed that the purpose of this study is to compare the cosmetic outcome of scalp wound closure with staples to traditional skin sutures. A prospective, randomized trial was conducted using a convenience sample of children (aged 1–16 y) with simple scalp lacerations admitted to the pediatric emergency department. After parental consent was obtained, patients were randomly assigned to either a stapling or suturing procedure. A trained attending physician completed the procedure following a standard protocol. Based on previously published data, a sample size of 18 patients per group was calculated to give 85% power to detect a 10% difference on a visual analogue scale (VAS) score (two-sided alpha 0.05). Initial outcome of wound healing at 7 to 10 days and final cosmetic outcome after 6 to 18 months were estimated using a VAS. Cosmetic outcome was assessed by a physician blinded to the procedure. Data were analyzed using SPSS (Version 8.02; SPSS Inc., Chicago, IL). The VAS scores for the two treatment groups were compared using the two-tailed Student t test. Analysis of age, race, mode of injury, time interval, and size of the wound were performed to estimate the strength of the association of VAS score with the treatment, adjusted for the covariates. A total of 42 patients were enrolled. Of the 42, 38 (90.5%) finished the initial follow-up and 31 of those 38 (81.6%) finished the final follow-up. There were no significant demographic differences between groups at recruitment and first follow-up. Among those patients who completed the final follow-up, 15 underwent stapling, and 16 underwent suturing. There were no significant demographic or baseline differences between the groups. Procedure time was significantly lower in the stapling group ($P = 0.001$). Final follow-up evaluations were completed in 12 ± 4 months. The mean VAS scores at first and final follow-up were 78.75 ± 16.16 and 96.31 ± 8.06 for the suturing group and 86.67 ± 9.76 and 97 ± 7.02 for the stapling group ($P = 0.17$). There remained no significant difference in the final follow-up VAS score between groups when adjusted for covariates. Stapling appears to be a fast and cosmetically acceptable alternative to suturing for simple scalp lacerations.

Yuenyongviwat V et al [97] (2016) found that nylon sutures and skin staples are used commonly in total knee arthroplasty (TKA) surgical wound closure. However, there is no study that compares the

wound healing efficacy and patient satisfaction scores of both techniques in the same knee. We randomised 70 patients who underwent primary TKA into two groups. In one group of 34 patients, the skin at the upper half of the wound was closed with skin staples and the lower half of the wound was closed with simple interrupted nylon sutures. In the other group of 36 patients, the skin at the upper half of the wound was closed with nylon stitches and the lower half of the wound was closed with skin staples. We recorded the wound closure time, pain score at the time of stitch removal, wound complication rate, patient satisfaction score, and the Hollander wound evaluation score at the post-operative periods of five days, 14 days, six weeks, three months, and six months. Each half wound was analysed separately. The mean patient body mass index was 26.8 kg/m2 (standard deviation 6.3). A total of 70 nylon stitched wounds and 70 skin stapled wounds were analysed. There were no significant differences in wound complication rates, patient satisfaction score, and the Hollander wound evaluation score between both types of wounds ($p > 0.05$). The wound closure time for skin stapled wounds was significantly lower than the nylon stitched wounds ($p < 0.001$). However, the skin stapled wounds had a significantly higher pain score at the time of stitch removal ($p < 0.001$). Skin staples and nylon stitches had comparable results with respect to wound healing and patient satisfaction in TKA wound closure in non-obese patients. The benefit of skin staples over nylon stitches was a decrease in operative time, but was more painful upon removal. **Harvey CF et al [98] (1986)** found that comparison between stainless steel staples and silk sutures for primary closure of skin in patients undergoing neck dissection, in context of rapid application, approximation of the skin edges, economy and aesthetics of the resultant scar. (1) To compare surgical stainless steel staples and silk sutures for primary wound closure, with respect to presence/absence of wound infection and dehiscence (2) To compare the resultant scar following the two different methods of the closure at 3rd month postoperatively with the help of visual analog scale and analyze the result statistically Design: This study was designed to compare skin closure using staples and silk sutures in patients undergoing neck dissection, using both methods in one-half of the same wound; thus each wound affording its own control. The study was conducted on patients requiring collar line incision (high submandibular incision) with or without a cephalad extension of midline lower lip split incision for surgical access, who presented to the Department of Oral and Maxillo-Facial Surgery. (1) Sample size: 10 (2) Study design: Prospective Comparative study (3) Study duration: One and half years (4) Surgical stainless steel staples: Proximate Plus MD 35 W, Ethicon Endo Surgery (5) Sutures: 3–0 Ethiprime NW 5003, Non-Absorbable Surgical Suture, Mersilk-90 cm, Ethicon, (16 mm 3/8 circle cutting needle). It was concluded that there is no significant difference between the scars observed in the regions of incision which underwent primary closure by two different methods, that is surgical stainless steel staples and 3–0 Mersilk Sutures.

IV. MATERIALS AND METHODS:

This study was conducted in the female patients attending the Breast clinic , Department of General surgery in Agartala Government Medical College and G.B Pant Hospital , which is a tertiary referral hospital of Tripura State. The department and hospital has good patient inflow and is adequately equipped for the conduction of this study.

STUDY DESIGN: Prospective study.

TYPE OF STUDY: Hospital based prospective study

STUDY SETTING: This study was conducted in the Dept. of General Surgery, AGMC & GBP Hospital

DURATION OF THE STUDY: 1 and ½ years (October 2018 – May 2020)

STUDY POPULATION: All diagnosed patients of Ca breast who was underwent MRM.

SAMPLE SIZE: As per previous records available, the no. of patients who underwent Modified Radical Mastectomy are :

2015 = 24 patients
2016 = 28 patients
2017 = 30 patients
Mean = 24 +28+ 30 = 82/3 = 27.3 per year
No. of patients in one and half year = 40 patients

SAMPLING DESIGN: Census sampling and patients were selected consecutively.

INCLUSION CRITERIA:

All female patients with diagnosed Ca Breast, in whom modified radical mastectomy was perform.

EXCLUSION CRITERIA:

1. Psychiatric patients
2. Immuno compromised states like TB , HIV
3. Patients having uncontrolled diabetes
4. Patients who refused to cooperate for the entire study period.

MATERIALS:

A) The materials used for study include:

- Sterile disposable skin stapler in which each Stapler contains 35 stainless steel staples 6.9mm * 3.6 mm
- Non absorbable suture material like 1-0 or 2-0 ethilon material
- Betadine 10 % solution
- Dressing with sterile gauze and adhesive tape.

B) The parameters which shall be compared :

- Operative time taken for closure
- Post operative wound healing
- Post operative pain
- Duration of hospital stay.

METHODS:

Patients with diagnosed Ca breast and plan for Modified Radical Mastectomy were subjected for this study. Informed consent was obtained after informing the study subjects the details of the procedure. With tossing a coin, the patientswere divided into two groups for skin staple and skin suture. If head appears, patients were go to suture group and if tail appears the patient were go for staple group.

A detailed history of each patient was obtained, starting with a history of presenting symptoms and any coexisting , comorbid conditions such as DM , TB and HIV .

Preoperatively all patients were undergo following investigations:

- Complete blood count , urine examination
- Bleeding time , Clotting time
- Blood sugar , blood urea , serum creatinine
- Liver function test
- Chest X ray , ECG
- Viral markers

The cases were only elective surgeries and the mode of anesthesia was general anesthesia. All patients were received one mandatory dose of pre-operative parenteral antibiotic before surgery. Painting was done with 10 % povidone iodine solution for all cases. For all patients sub cutaneous sutures were put to relieve tension , dead space was closed and wound edges apposed. Then the wound was closed by skin staples or skin sutures. Wound was evaluated for one week, then at one month.

Wound was evaluated for erythema , infection , swelling , serous discharge, over lap of edges, separation of edges , wound dehiscence, hypertrophic scar.

Wound appearance was determined by 4 item ordinal scale. Wound was assigned 0 or 1 point for each for the presence or absence of the following:

1- Step of borders (0 for yes , 1 for no)
2- Contour irregularities-puckering (0 for yes, 1 for no)
3- Wound margin separation (0 for yes , 1 for no)
4- Good overall appearance (0 for poor , 1 for acceptable)

Wound with a score of 4 is considered to have an optimal cosmetic appearance , others sub optimal appearance

Visual analogue scale was used for examining post operative pain.

Statistical Analysis:

For statistical analysis data were entered into a Microsoft excel spreadsheet and then analyzed by SPSS (version 27.0; SPSS Inc., Chicago, IL, USA) and GraphPad Prism version 5. Data had been summarized as meanand standard deviation for numerical variables and count and percentages for categorical variables. Two-sample t-tests for a difference in mean involved independent samples or unpaired samples. Paired t-tests were a form of blocking and had greater power than unpaired tests. A chi-squared test ($\chi 2$ test) was any statistical hypothesis test wherein the sampling distribution of the test statistic is a chi-squared distribution when the null hypothesis is true. Without other qualification, 'chi-squared test' often is used as short for Pearson's chi-squared test. Unpaired proportions were compared by Chi-square test or Fischer's exact test, as appropriate.

Explicit expressions that can be used to carry out various t-tests are given below. In each case, the formula for a test statistic that either exactly follows or closely approximates a t-distribution under the null hypothesis is given. Also, the appropriate degrees of freedom are given in each case. Each of these statistics can be used to carry out either a one-tailed test or a two-tailed test.

Once a t value is determined, a p-value can be found using a table of values from Student's t-distribution. If the calculated p-value is below the threshold chosen for statistical significance (usually the 0.10, the 0.05, or 0.01 level), then the null hypothesis is rejected in favour of the alternative hypothesis.

p-value $\leq$ 0.05 was considered for statistically significant.

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V. RESULT AND ANALYSIS

Table: Association between Age in Years: Group

	GROUP		
Age in Years	**Stapler**	**Suture**	**TOTAL**
40-50	11	8	19
Row %	57.9	42.1	100.0
Col %	55.0	40.0	47.5
51-60	8	9	17
Row %	47.1	52.9	100.0
Col %	40.0	45.0	42.5
>61	1	3	4
Row %	25.0	75.0	100.0
Col %	5.0	15.0	10.0
TOTAL	20	20	40
Row %	50.0	50.0	100.0
Col %	100.0	100.0	100.0

Chi-square value: 1.5325; **p-value:**0.4648

In Stapler, 11(55.0%) patients were 41-50 years old, 8(40.0%) patients were 51-60 years old and 1(5.0%) patients were >61 years old.

In Suture, 8(40.0%) patients were 41-50 years old, 9(45.0%) patients were 51-60 years old and 3(15.0%) patients were >61 years old.

Association of Age in years vs. group was not statistically significant (p=0.4648).

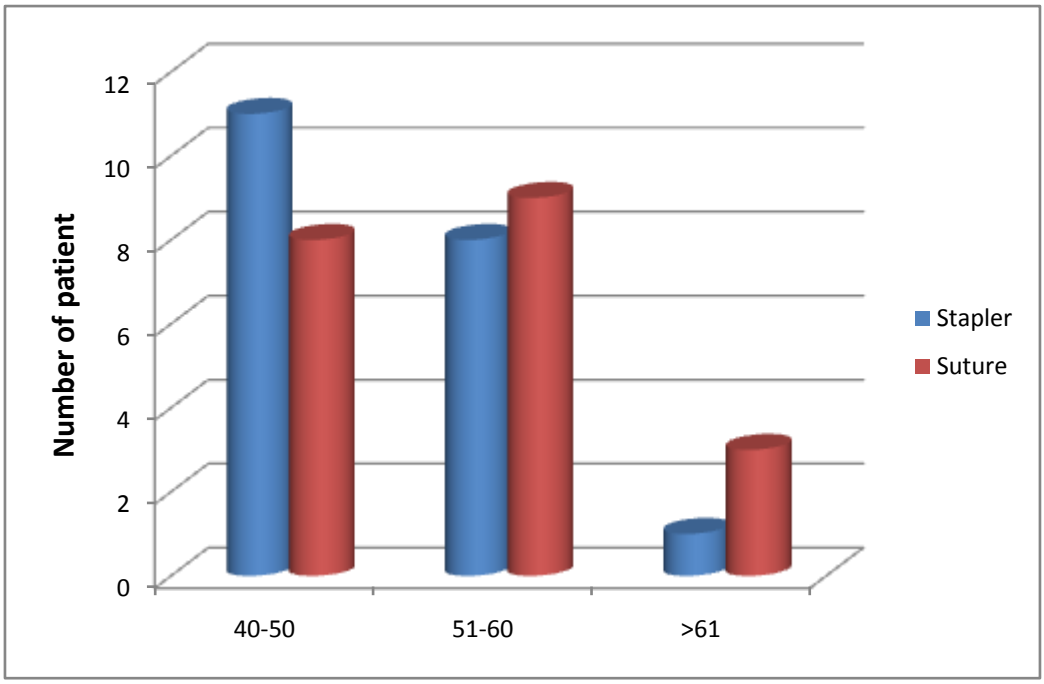

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Table: Association between Religion: Group

	GROUP		
Religion	**Stapler**	**Suture**	**TOTAL**
Hindu	12	17	29
Row %	41.4	58.6	100.0
Col %	60.0	85.0	72.5
Muslim	8	3	11
Row %	72.7	27.3	100.0
Col %	40.0	15.0	27.5
TOTAL	20	20	40
Row %	50.0	50.0	100.0
Col %	100.0	100.0	100.0

Chi-square value: 3.1348; **p-value:**0.0766
Odds Ratio:0.2647 (0.0580, 1.2089)
In Stapler, 12(60.0%) patients were Hindu and 8(40.0%) patients were Muslim.
In Suture, 17(85.0%) patients were Hindu and 3(15.0%) patients were Muslim.
Association of Religion vs. group was not statistically significant (p=0.0766).

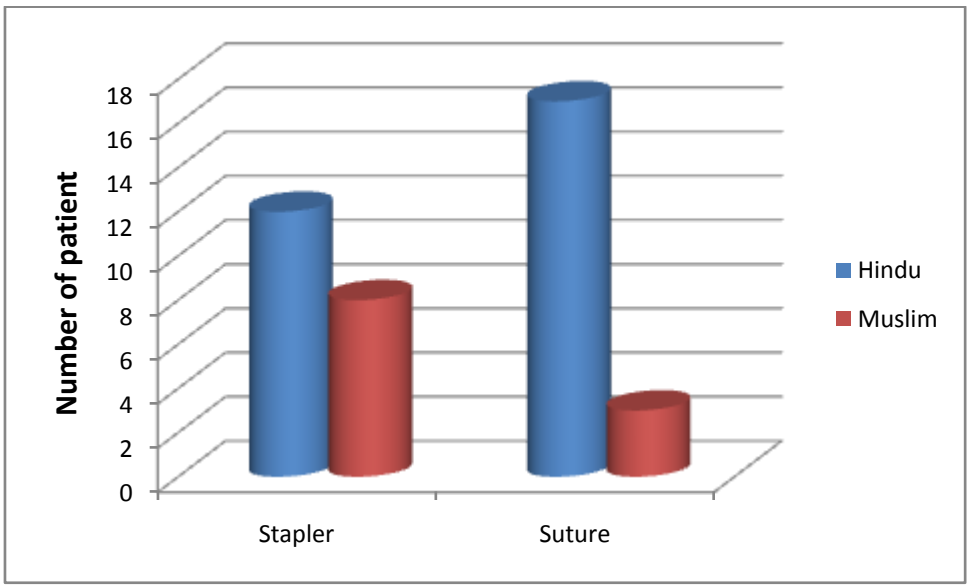

Table: Association between Occupation: Group

	GROUP		
Occupation	**Stapler**	**Suture**	**TOTAL**
Employee	6	5	11
Row %	54.5	45.5	100.0
Col %	30.0	25.0	27.5
House Wife	14	15	29
Row %	48.3	51.7	100.0
Col %	70.0	75.0	72.5
TOTAL	20	20	40
Row %	50.0	50.0	100.0
Col %	100.0	100.0	100.0

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Chi-square value: 0.1254; **p-value:**0.7232
Odds Ratio:1.2857 (0.3194, 5.1749)
In Stapler, 6(30.0%) patients were Employee and 14(70.0%) patients were House Wife.
In Suture, 5(25.0%) patients were Employee and 15(75.0%) patients were House Wife.
Association of Occupation vs. group was not statistically significant (p=0.7232).

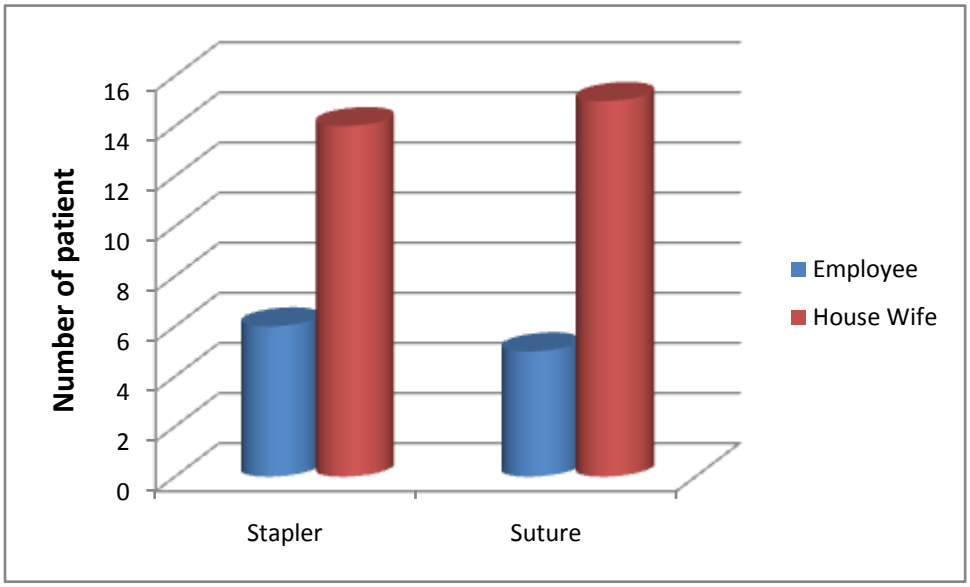

Table: Association between Socio- Economic status: Group

GROUP			
Socio- Economic status	**Stapler**	**Suture**	**TOTAL**
APL	6	8	14
Row %	42.9	57.1	100.0
Col %	30.0	40.0	35.0
BPL	14	12	26
Row %	53.8	46.2	100.0
Col %	70.0	60.0	65.0
TOTAL	20	20	40
Row %	50.0	50.0	100.0
Col %	100.0	100.0	100.0

Chi-square value: 0.4396; **p-value:**0.5073
Odds Ratio:0.6429 (0.1735, 2.3815)
In Stapler, 6(30.0%) patients were APL status and 14(70.0%) patients were BPL status.
In Suture, 8(40.0%) patients were APL status and 12(60.0%) patients were BPL status.
Association of Socio- Economic status vs. group was not statistically significant (p=0.5073).

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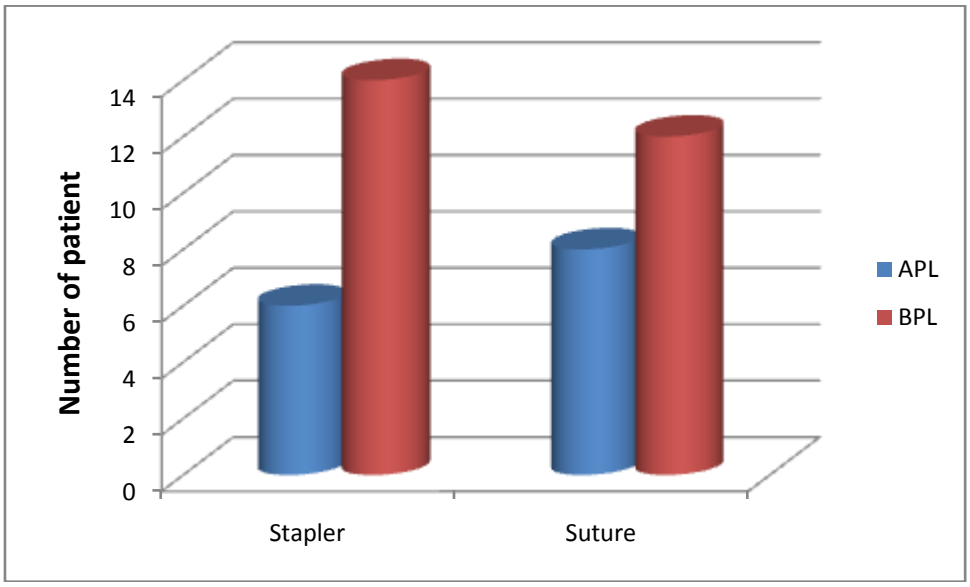

Table: Association between Diet: Group

	GROUP		
Diet	**Stapler**	**Suture**	**TOTAL**
Non veg	20	20	40
Row %	50.0	50.0	100.0
Col %	100.0	100.0	100.0
TOTAL	20	20	40
Row %	50.0	50.0	100.0
Col %	100.0	100.0	100.0

In Stapler, 20(100.0%) patients were Non veg.
In Suture, 20(100.0%) patients were Non veg.

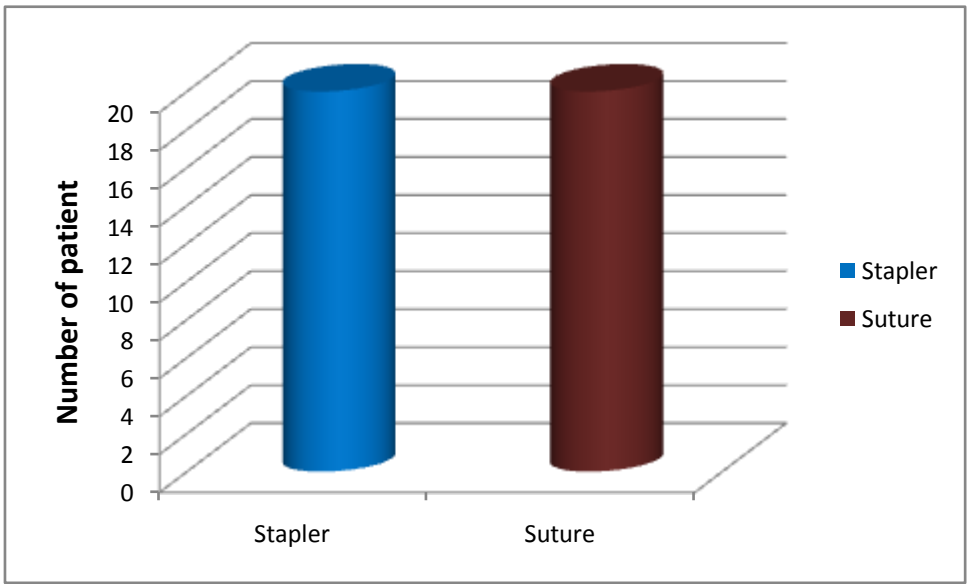

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Table: Association between USG/ Mammon: Group

GROUP			
USG/ Mammon	**Stapler**	**Suture**	**TOTAL**
Done	20	20	40
Row %	50.0	50.0	100.0
Col %	100.0	100.0	100.0
TOTAL	20	20	40
Row %	50.0	50.0	100.0
Col %	100.0	100.0	100.0

In Stapler, 20(100.0%) patients were done USG/ Mammon.
In Suture, 20(100.0%) patients were done USG/ Mammon.

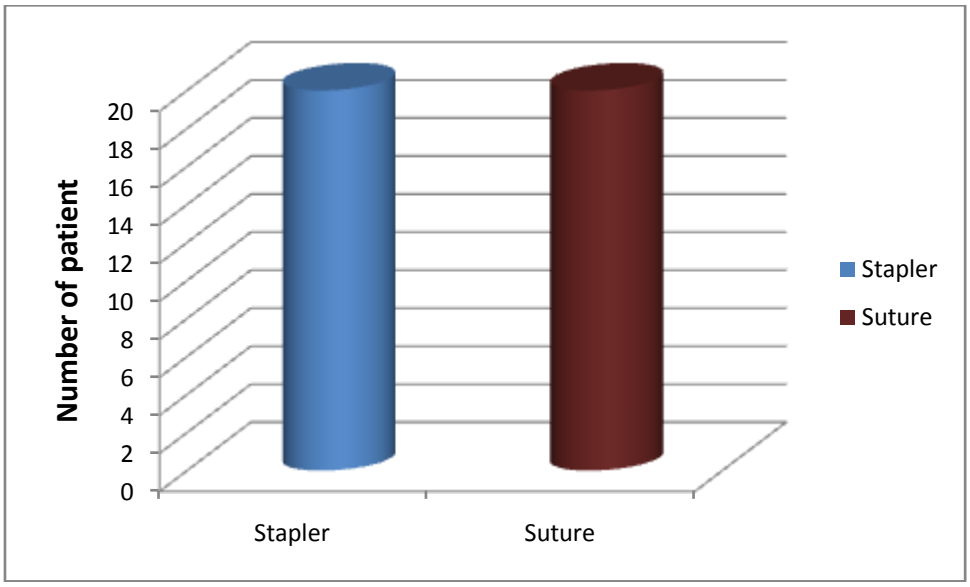

Table: Association between FNAC/ True cut: Group

GROUP			
FNAC/ True cut	**Stapler**	**Suture**	**TOTAL**
Done	20	20	40
Row %	50.0	50.0	100.0
Col %	100.0	100.0	100.0
TOTAL	20	20	40
Row %	50.0	50.0	100.0
Col %	100.0	100.0	100.0

In Stapler, 20(100.0%) patients were done FNAC/ True cut.
In Suture, 20(100.0%) patients were done FNAC/ True cut.

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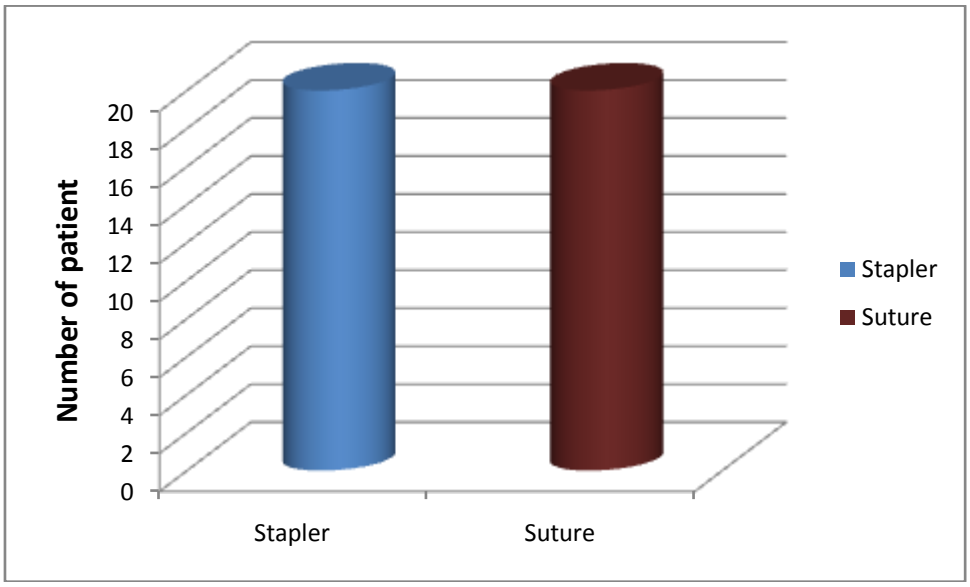

Table: Association between Surgical Procedure done: Group

GROUP			
Surgical Procedure done	**Stapler**	**Suture**	**TOTAL**
MRM	20	20	40
Row %	50.0	50.0	100.0
Col %	100.0	100.0	100.0
TOTAL	20	20	40
Row %	50.0	50.0	100.0
Col %	100.0	100.0	100.0

In Stapler, 20(100.0%) patients had MRM Surgical Procedure done.
In Suture, 20(100.0%) patients had MRM Surgical Procedure done.

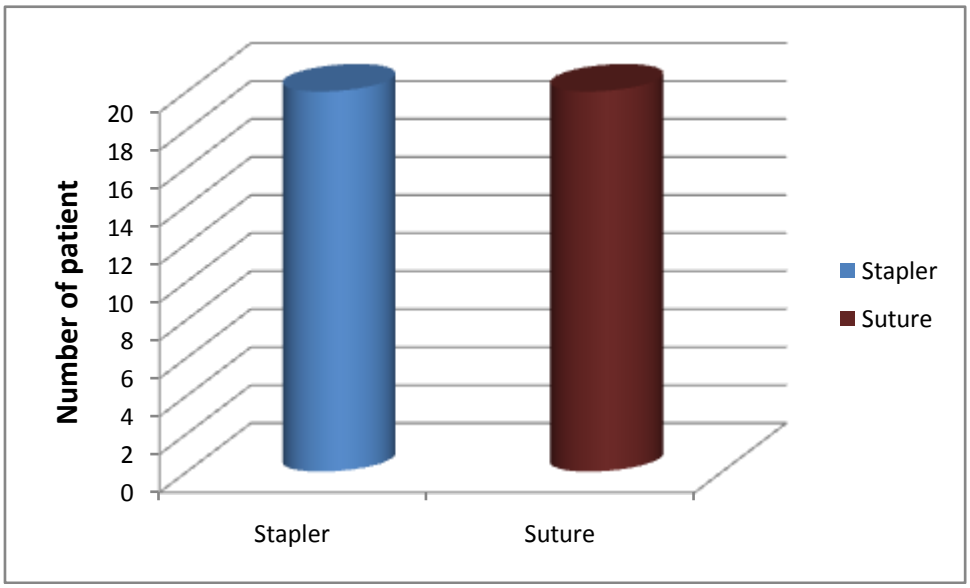

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Table: Association between Post operative pain: Group

GROUP			
Post operative pain	**Stapler**	**Suture**	**TOTAL**
Moderate	19	16	35
Row %	54.3	45.7	100.0
Col %	95.0	80.0	87.5
Severe	1	4	5
Row %	20.0	80.0	100.0
Col %	5.0	20.0	12.5
TOTAL	20	20	40
Row %	50.0	50.0	100.0
Col %	100.0	100.0	100.0

Chi-square value: 2.0571; **p-value:**0.1514
Odds Ratio:4.7500 (0.4810, 46.9079)

In Stapler, 19(95.0%) patients were Moderate and 1(5.0%) patients were Severe.
In Suture, 16(80.0%) patients were Moderate and 4(20.0%) patients were Severe.
Association of Post operative pain vs. group was not statistically significant (p=0.1514).

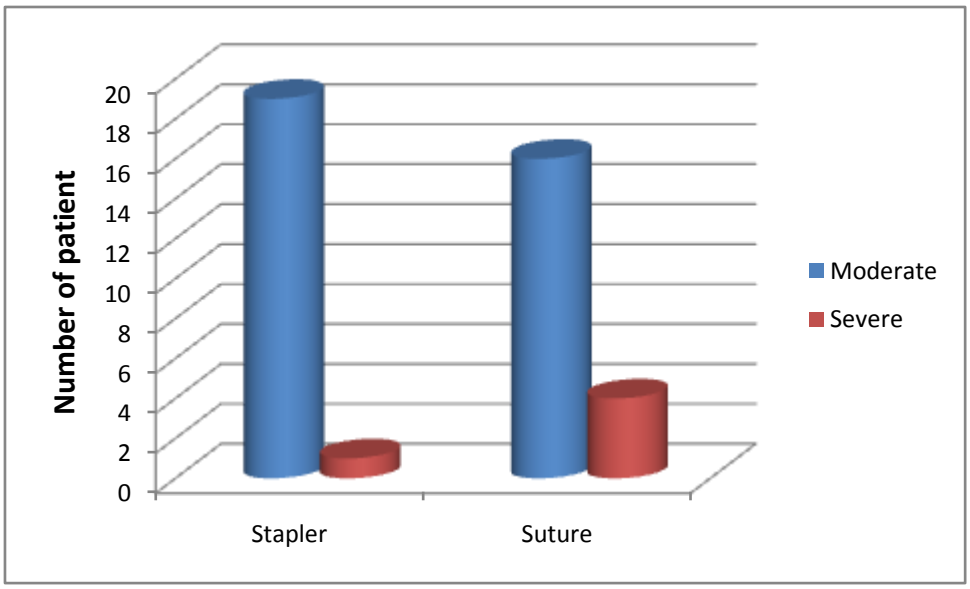

Table: Association between Wound healing: Group

GROUP			
Wound healing	**Stapler**	**Suture**	**TOTAL**
Score = 2	0	3	3
Row %	0.0	100.0	100.0
Col %	0.0	15.0	7.5
Score = 3	2	13	15
Row %	13.3	86.7	100.0
Col %	10.0	65.0	37.5
Score = 4	18	4	22
Row %	81.8	18.2	100.0

Col %	90.0	20.0	55.0
TOTAL Row % Col %	20 50.0 100.0	20 50.0 100.0	40 100.0 100.0

Chi-square value: 19.9758; **p-value:**<0.0001

In Stapler, 2(10.0%) patients had Score = 3and 18(90.0%) patients had Score = 4.
In Suture, 3(15.0%) patients had Score = 2,13(65.0%) patients had Score = 3and 4(20.0%) patients had Score = 4.
Association of Wound healing vs. group was statistically significant (p<0.0001).

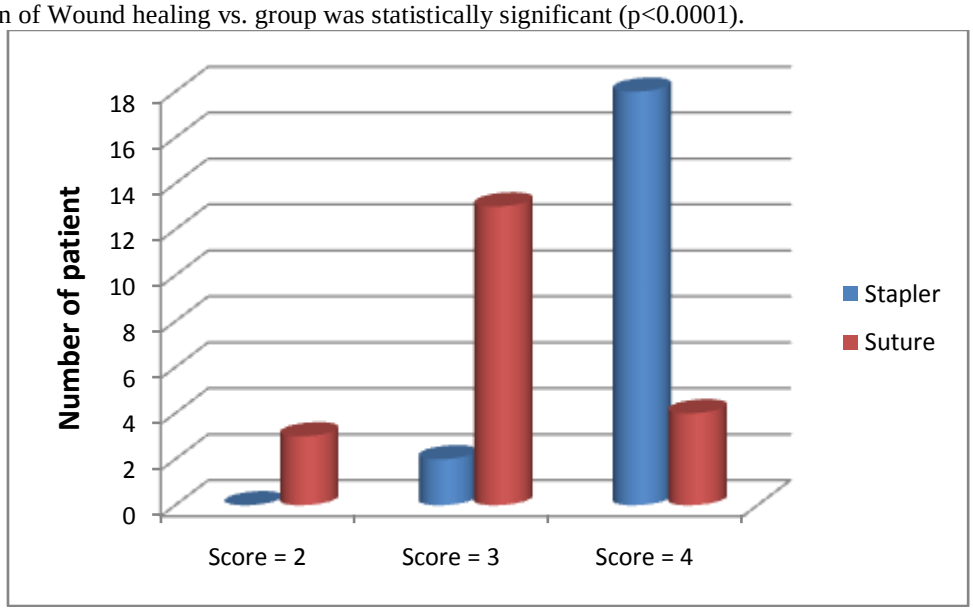

Table: Distribution of mean Age: Group

		Number	Mean	SD	Minimum	Maximum	Median	p-value
Age	Stapler	20	51.6000	5.9771	43.0000	67.0000	50.0000	0.4376
	Suture	20	53.1500	6.5073	40.0000	66.0000	53.0000	

In Stapler, the mean Age (mean± s.d.) of patients was 51.6000± 5.9771.
In Suture, the mean Age (mean± s.d.) of patients was 53.1500± 6.5073.
Difference of mean Age with both Group was not statistically significant (p=0.4376).

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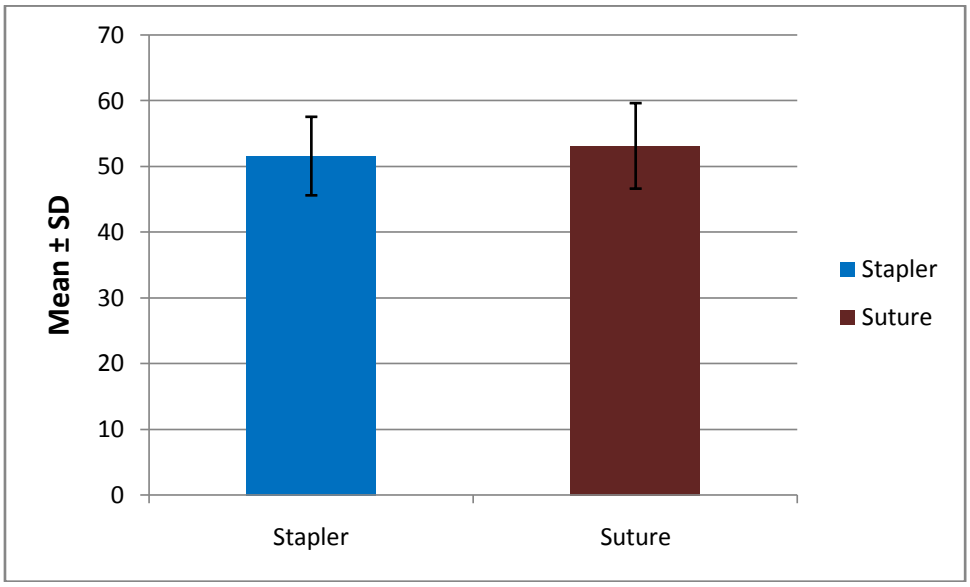

Table: Distribution of mean Weight: Group

		Number	Mean	SD	Minimum	Maximum	Median	p-value
Weight	Stapler	20	57.8500	4.8262	49.0000	67.0000	57.5000	0.5626
	Suture	20	58.7500	4.9191	51.0000	69.0000	59.0000	

In Stapler, the mean Weight (mean± s.d.) of patients was 57.8500± 4.8262.
In Suture, the mean Weight (mean± s.d.) of patients was 58.7500± 4.9191.
Difference of mean Weight with both Group was not statistically significant (p=0.5626).

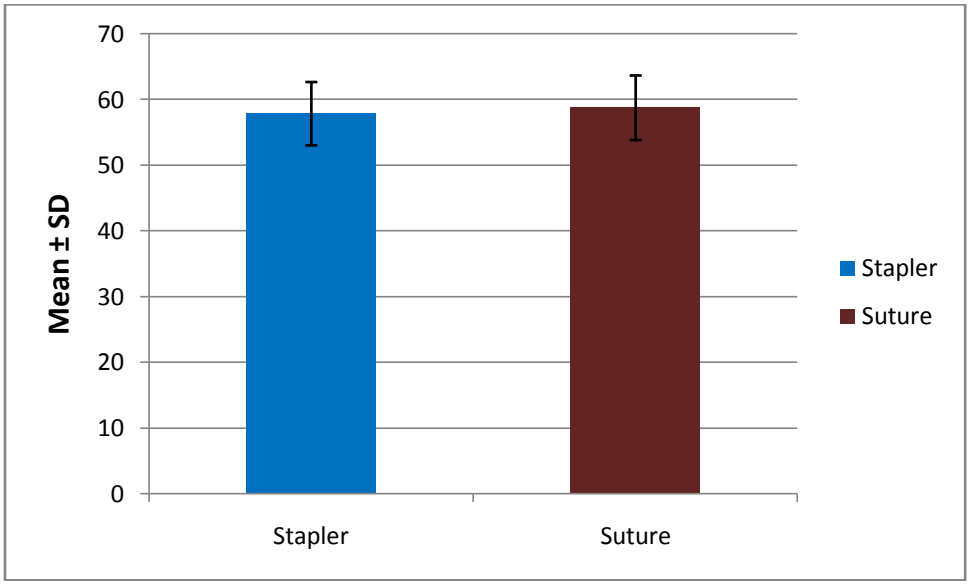

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Table: Distribution of mean Height: Group

		Number	Mean	SD	Minimum	Maximum	Median	p-value
Height	Stapler	20	1.4850	.0366	1.4000	1.5000	1.5000	0.7636
	Suture	20	1.4900	.0641	1.4000	1.6000	1.5000	

In Stapler, the mean Height (mean± s.d.) of patients was 1.4850± .0366.
In Suture, the mean Height (mean± s.d.) of patients was 1.4900± .0641.
Difference of mean Height with both Group was not statistically significant (p=0.7636).

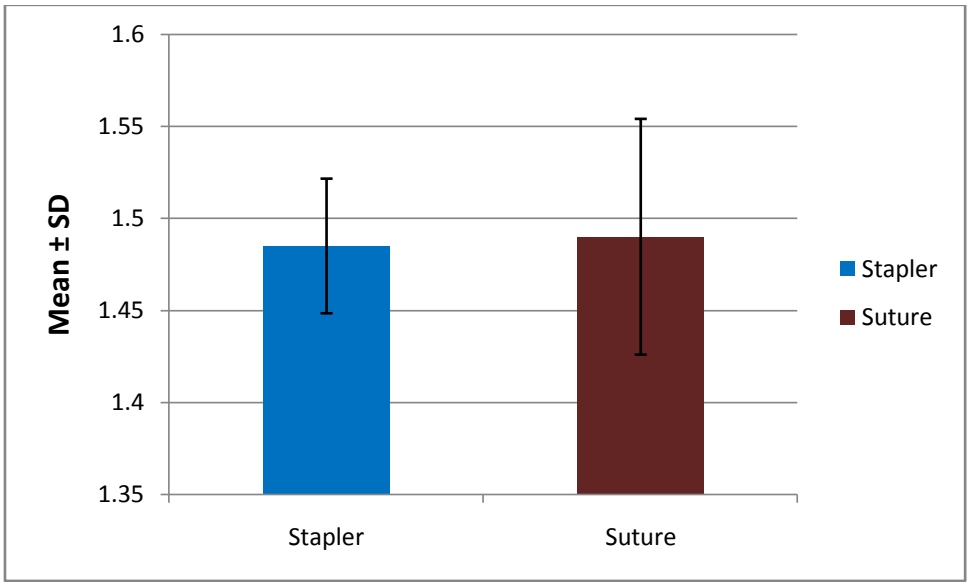

Table: Distribution of mean BMI: Group

		Number	Mean	SD	Minimum	Maximum	Median	p-value
BMI	Stapler	20	26.2350	2.8996	21.7000	33.1000	25.5000	0.7315
	Suture	20	26.5800	3.3931	21.8000	34.6000	26.1500	

In Stapler, the mean BMI (mean± s.d.) of patients was 26.2350± 2.8996.
In Suture, the mean BMI (mean± s.d.) of patients was 26.5800± 3.3931.
Difference of mean BMI with both Group was not statistically significant (p=0.7315).

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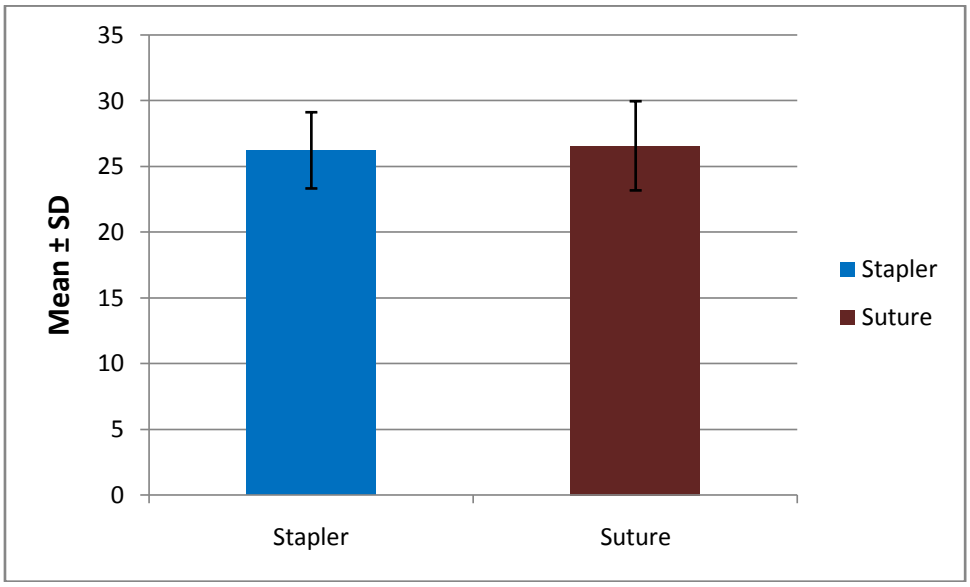

Table: Distribution of mean Closing time Required: Group

		Number	Mean	SD	Minimum	Maximum	Median	p-value
Closing time Required	Stapler	20	72.1500	5.8154	63.0000	82.0000	72.0000	<0.0001
	Suture	20	285.0500	88.0290	72.0000	340.0000	319.0000	

In Stapler, the mean Closing time Required (mean± s.d.) of patients was 72.1500± 5.8154.
In Suture, the mean Closing time Required (mean± s.d.) of patients was 285.0500± 88.0290.
Difference of mean Closing time Required with both Group was statistically significant (p<0.0001).

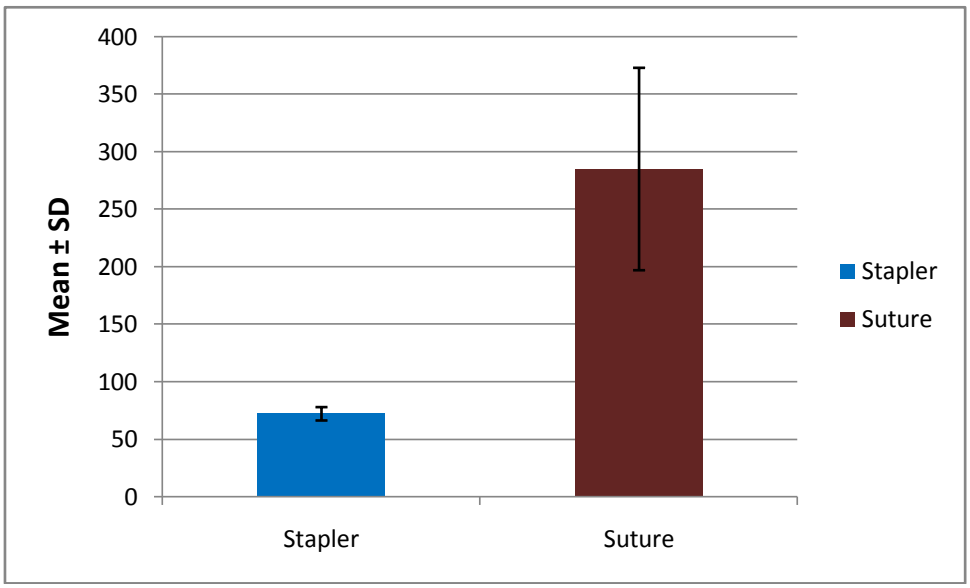

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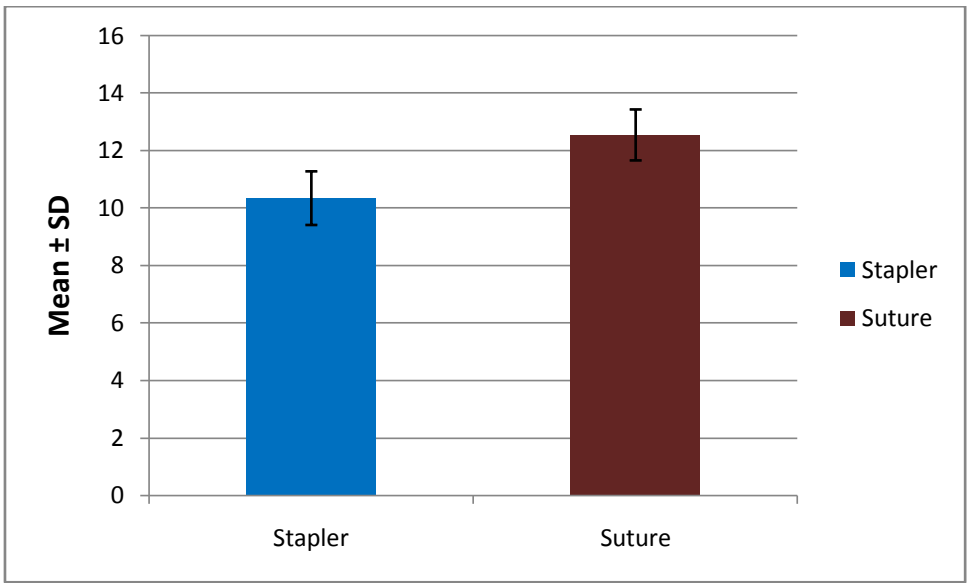
Table: Distribution of mean Duration of hospital stays: Group

		Number	Mean	SD	Minimum	Maximum	Median	p-value
Duration of hospital stays	Stapler	20	10.3500	.9333	9.0000	12.0000	10.0000	<0.0001
	Suture	20	12.5500	.8870	11.0000	14.0000	12.5000	

In Stapler, the mean Duration of hospital stays (mean± s.d.) of patients was 10.3500± .9333.
In Suture, the mean Duration of hospital stays (mean± s.d.) of patients was 12.5500± .8870.
Difference of mean Duration of hospital stays with both Group was statistically significant (p<0.0001).



VI. DISCUSSION

Our study showed that in Stapler, 11(55.0%) patients were 41-50 years old, 8(40.0%) patients were 51-60 years old and 1(5.0%) patients were >61 years old. In Suture, 8(40.0%) patients were 41-50 years old, 9(45.0%) patients were 51-60 years old and 3(15.0%) patients were >61 years old. Association of Age in years vs. group was not statistically significant (p=0.4648). In Stapler, 12(60.0%) patients were Hindu and 8(40.0%) patients were Muslim. In Suture, 17(85.0%) patients were Hindu and 3(15.0%) patients were Muslim. Association of Religion vs. group was not statistically significant (p=0.0766). In Stapler, the mean Age (mean± s.d.) of patients was 51.6000± 5.9771. In Suture, the mean Age (mean± s.d.) of patients was 53.1500± 6.5073. Difference of mean Age with both Group was not statistically significant (p=0.4376).In Stapler, the mean Weight (mean± s.d.) of patients was 57.8500± 4.8262. In Suture, the mean Weight (mean± s.d.) of patients was 58.7500± 4.9191. Difference of mean Weight with both Group was not statistically significant (p=0.5626).

In our study in Stapler, the mean Height (mean± s.d.) of patients was 1.4850± .0366. In Suture, the mean Height (mean± s.d.) of patients was 1.4900± .0641. Difference of mean Height with both Group was not statistically significant (p=0.7636). In Stapler, the mean BMI (mean± s.d.) of patients was 26.2350± 2.8996. In Suture, the mean BMI (mean± s.d.) of patients was 26.5800± 3.3931. Difference of mean BMI with both Group was not statistically significant (p=0.7315).

Varghese F et al [73] (2017) showed that Mean age of the study population was 49.35 with an SD 16.739. Wound infection was found to be higher in stapler group (30%) when compared to conventional suture group (11.7%)which was found to be statistically significant with chi-square value 6.114 and p value 0.013. Mean time for closure was significantly shorter in stapler group 4.55 minutes, when compared to suture group (11.22 minutes). Better cosmetic outcome was observed in conventional suture group. Preventing

wound infection, especially in abdominal wounds, is of importance as it may lead to wound gaping. Incidence of post-operative wound infection was more with skin staples.

Chauhan A et al [69] (2018) found that the mean incision length in suture group was 7.2±1.2 cm while in stapler group was 7.4±1.1 cm which was statistically insignificant. The mean time of closure was 48 seconds in suture group while in stapler group was 295 seconds which was statistically highly significant (p<0.001). It was concluded that skin staples are better alternative to conventional sutures in general surgical procedure as they lead to faster wound closure with better aesthetic outcome and patient comfort with low wound complication rates.

Brickman KR et al [70] (1989) found that no infectious complications, delayed wound healing, or cosmetics problems were seen. Skin stapling was easier and quicker than suture repair at a lower overall cost in most circumstances. Our study shows skin stapling to be an efficient and cost-effective alternative method to suture wound closure for selected laceration in patients presenting to the ED, without compromising wound healing or cosmetic results.

Batra J et al [72] (2016) found that the mean incision length in control group was 54 ± 16.3 cm while in study group was 53.7 ± 15.4 cm which was statistically not significant (P = 0.95). The mean time of closure in control group was 34.2 ± 12 min while in study group was 3.3 ± 1.2 min which was statistically highly significant (P < 0.001). The mean cost of material for skin closure in control group was Rs. 270.0 ± 46.4 and in study group was Rs. 517.5 ± 135.7 which was also statistically highly significant (P < 0.001). It was concluded that skin staples are better alternatives to conventional sutures in head and neck cancer surgery as they offer ten times faster wound closure, cost effectiveness, and similar results to sutures in terms of patient comfort, aesthetic outcome and complication rate.

Iavazzo C et al [75] (2011) suggest that staples are associated with fewer wound infections compared with sutures in the evaluated types of surgery. However, in a rather limited number of studies, the use of staples was associated with more pain. Further studies incorporating more objective methods for assessment cosmetic and patient satisfaction are required to clarify this issue.

Stockley I et al [77](1987) found that there was a higher incidence of inflammation, discomfort on removal and spreading of the healing scar associated with staples. The only advantage of staples was speed of wound closure.

Kanegaye JT et al [78] (1997) found that Stapling is faster and less expensive than suturing in the repair of uncomplicated pediatric scalp lacerations, with no additional complications.

Eldrup J et al [80] (1981) found that the no difference was found with regard to wound infection, but pain was more frequent after stapling.

Naireen N et al [85] (2016) showed that there was no significant difference in post-operative pain between the two groups. The incidence of wound infection was more in stapler group than in suture group although statistically non-significant. The cosmetic outcome with stapler closure was found to be significantly superior to that with sutures.

In Stapler, 6(30.0%) patients were Employee and 14(70.0%) patients were House Wife. In Suture, 5(25.0%) patients were Employee and 15(75.0%) patients were House Wife. Association of Occupation vs. group was not statistically significant (p=0.7232). In Stapler, 6(30.0%) patients were APL status and 14(70.0%) patients were BPL status. In Suture, 8(40.0%) patients were APL status and 12(60.0%) patients were BPL status. Association of Socio- Economic status vs. group was not statistically significant (p=0.5073).In Stapler, 20(100.0%) patients were Non veg. In Suture, 20(100.0%) patients were Non veg. In Stapler, 20(100.0%) patients were done USG/ Mammon. In Suture, 20(100.0%) patients were done USG/ Mammon.In Stapler, 20(100.0%) patients were done FNAC/ True cut. In Suture, 20(100.0%) patients were done FNAC/ True cut.

We found that in Stapler, 20(100.0%) patients had MRM Surgical Procedure done. In Suture, 20(100.0%) patients had MRM Surgical Procedure done.

Karthikeyan S et al [82] (2018) found that the complication rates between two groups are stapler group 4% and conventional group 17%. The number of centimeters covered per minute in stapler method 4.2 + 0.9 cm and conventional suturing method 1.9 +1 cm. Pain scoring using Visual Analog Scale for stapler method 0.46 + 5.7 conventional suturing method 1.38 + 5.6. Regarding the cost effectiveness, there is only a marginal difference with both methods. The incidence of Wound infection, pain score, time taken for suturing are lesser in stapler group compared to Conventional group. Cost wise the Conventional type of suturing is cheaper than the Stapler method.

KHAN AN et al [96] (2002) showed that there were no significant demographic or baseline differences between the groups. Procedure time was significantly lower in the stapling group (P =

0.001). Final follow-up evaluations were completed in 12 ± 4 months. The mean VAS scores at first and final follow-up were 78.75 ± 16.16 and 96.31 ± 8.06 for the suturing group and 86.67 ± 9.76 and 97 ± 7.02 for the stapling group (P = 0.17). There remained no significant difference in the final follow-up VAS score between groups when adjusted for covariates. Stapling appears to be a fast and cosmetically acceptable alternative to suturing for simple scalp lacerations.

It was found that in Stapler, 19(95.0%) patients were Moderate and 1(5.0%) patients were Severe. In Suture, 16(80.0%) patients were Moderate and 4(20.0%) patients were Severe. Association of Post operative pain vs. group was not statistically significant (p=0.1514). In Stapler, 2(10.0%) patients had Score = 3and 18(90.0%) patients had Score = 4. In Suture, 3(15.0%) patients had Score = 2,13(65.0%) patients had Score = 3and 4(20.0%) patients had Score = 4. Association of Wound healing vs. group was statistically significant (p<0.0001).

Cochetti G et al [71] (2020) showed that Sutures resulted in slightly fewer overall wound infections (4.90%) compared to staples (6.75%) but it is uncertain whether there is a difference between the groups (risk ratio [RR] 1.20, 95% confidence intervals [CI] 0.80–1.79; patients=9864; studies=34; I2=70%). The evidence was also insufficient to state a difference in terms of severe wound infection (staples 1.4% vs sutures 1.3%; RR 1.08, 95% CI 0.61–1.89; patients=3036; studies=17; I2=0%), grade of satisfaction (RR 0.99, 95% CI 0.91–1.07; patients=3243; studies=14; I2=67%) and hospital stay. Staples may increase the risk of adverse events (7.3% for staples vs 3.5% for sutures; RR 2.00, 95% CI 1.44–2.79; patients=6246; studies=21; I2=33%), readmission rate (RR 1.28, 95% CI 0.18–9.05; patients=2466; studies=5; I2=66%) and postoperative pain (standardized mean difference [SMD] 0.41,95%CI −0.35 to 1.16; I2=88%, patients=390 patients, studies=5). Chandrashekar N et al [87] (2013) found that the use of staples in abdominal surgical wound closure gives faster speed of closure, less postoperative pain, and better cosmetic results. Staples, however, are costlier, and when used in emergency cases, associated with higher rates of wound dehiscence and a less acceptable scar.

Sundresh NJ et al [88] (2018) showed that Staples were superior to sutures with respect to time for closure of the wound, occurrence of lesser complications namely lesser wound infections, better cosmesis, less discomfort during suture removal. All the above led to a satisfied patient.

Oswal S et al [91] (2017) found that the mean skin closure time was 29.2 ± 4 minutes with sutures (n = 61) and 5.3 ± 1.29 minutes with staples (n = 63), which was significant (P = .01). Mean pain scores during removal using the visual analog scale were 5.08 ± 1.29 and 3.15 ± 0.89 with sutures and staples, respectively. Postoperative complications, such as gapping and stitch abscess with purulent discharge, were noted. Staples provided better esthetics with fewer complications, faster closure, minimal pain at removal, and faster healing compared with sutures. The slowest closure time in the staples group was 4 times faster than the fastest closure time in the sutures group. However, staples cost 5 times more than sutures.

Hiremath S et al [94] (2016) found that the use of skin staples in low tension incision is easy, associated with low incidence of wound complications, provides good cosmetic outcome and also takes considerably less time for skin closure and thus recommend its use more frequently especially for closure of long and multiple incisions.

Kumar S et al [95] (2019) showed that the length of the incision sutured per minute, pain score, scar type, expenses and wound infections. The incidence of Wound infection, pain score, time taken for suturing are lesser in stapler group compared to Conventional group. Cost wise the Conventional type of suturing is cheaper than the Stapler method. Wound closure with staples is almost three times faster thus time saving.

We found that in Stapler, the mean Closing time Required (mean± s.d.) of patients was 72.1500± 5.8154. In Suture, the mean Closing time Required (mean± s.d.) of patients was 285.0500± 88.0290. Difference of mean Closing time Required with both Group was statistically significant (p<0.0001).In Stapler, the mean Duration of hospital stays (mean± s.d.) of patients was 10.3500± .9333. In Suture, the mean Duration of hospital stays (mean± s.d.) of patients was 12.5500± .8870. Difference of mean Duration of hospital stays with both Group was statistically significant (p<0.0001).

VII. SUMMARY AND CONCLUSION

Our study found that Post operative pain was more Suture procedure compared to Stapler procedure though it was not statistically significant.

Higher Wound healing score was observed in Stapler procedure compared to Suture procedure which was statistically significant.

We found that age in years and Religion were not statistically significant in two groups.
It was found that Occupation and Socio- Economic status were not statistically significant in two groups.
All patients had done MRM in Stapler and Suture technique.
In Stapler, the mean Closing time Required (mean± s.d.) of patients was 72.1500± 5.8154. In Suture, the mean Closing time Required (mean± s.d.) of patients was 285.0500± 88.0290. The mean Closing time was more Suture procedure compared to Stapler procedure which was statistically significant.
We found that duration of hospital stay was higher in Suture procedure compared to Stapler procedure which was statistically significant.
We concluded that Stapleris better than Suture in terms of Closing time, Wound healing, hospital stay and postoperative pain.

LIMITATIONS OF THE STUDY

In spite of every sincere effort my study has lacunae.
The notable short comings of this study are:

1. The sample size was very small. Only 40 cases are not sufficient for this kind of study.
2. The study has been done in a single centre.
3. The study was carried out in a tertiary care hospital, so hospital bias cannot be ruled out.

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