"A COMPARISON OF COSMETIC OUTCOME OF PERIUMBILICAL VERSUS INTRAUMBILICAL INCISION IN LAPAROSCOPIC APPENDECTOMY AND CHOLECYSTECTOMY-A ONE YEAR RANDOMISED CONTROLLED TRIAL"

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ANNONATIONS

PU	:	periumbilical incision
TU	:	Transumbilical inciosion
IU	:	Intraumbilical incision
POD	:	Post operative day
SSI	:	Surgical Site Infection
CSS	:	Cosmetic Satisfaction Score
RCT	:	Randomised Control trail
POSAS	:	Patient and observer scar assessment scale
i.m	:	intramuscular
BMI	:	Body Mass Index

ABSTRACT

Background and objective:

An issue that is important in all aspects of laparoscopic surgery is initial intraperitoneal access. In order to insert the laparoscope, an Intraumbilical or Periumbilical incision is usually performed. Very few studies have compared the cosmetic outcome between intraumbilical incision and periumbilical incision. The current literature provides limited and contradictory information about postoperative cosmetic satisfaction, incidence of Surgical site infection and operative time between intraumbilical versus periumbilical incision. The current study aimed to compare the better cosmetic outcome between transumbilical and periumbilical incision for primary port insertion in cases of Laparoscopic Appendicectomy and Laparoscopic Cholecystectomy.

METHODOLOGY:

This one year randomized control trail was done with the Department of General Surgery, KLEs Dr.Prabhakar Kore Hospital and Medical Research Centre, Belagavi, from January 2019-december 2019. A total of 100 patients operated for laparoscopic appendectomy and laparoscopic cholecystectomy were studied. The patients were divided into Group A and Group B based on type of incision taken either periumbilical or transumbilical. Postoperative cosmetic outcome was analyzed using POSAS score on post op day 3,7 and 1-month follow up.

RESULTS:

Total of 100 patients with 50 patients in each group, were followed on POD# 3,7 and 1 month follow up POSAS Score were calculated. From POSAS score

obtained at different times, POD#3 mean is 71.44 ± 7.51 in group A v/s 54.84 ±12.81 in group B, whereas mean score on POD#7 is 67.32 ± 8.11 v/s 51.36 ± 13.01 between group A and group B and 61.98 ± 7.63 v/s 47.54 ± 13.34 on 1 month follow up between group A and group B. The results are statistically significant ($P<0.05$). Between the two incisions during POD# 3 and 7 there is significant difference between variables such as induration, erythema, SSI. In our study 3 cases had SSI in both the groups.

CONCLUSION:

In conclusion, Transumbilical incision has better cosmetic satisfaction compared to Periumbilical incision.Although majority of patients give little importance to the appearance of umbilicus, but the patients who gave importance to appearance of umbilicus preoperatively had poor cosmetic satisfaction scores postoperatively.

Since the appearance of umbilicus is a major concern for a certain amount of patients undergoing laparoscopic surgery,surgeon should discuss with the patient prior to the surgery regarding the various types of incisions and its outcomes for better satisfaction.

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INTRODUCTION

In this modern era of Laparoscopic and Robotic surgeries, as we all know it, the present day first laparoscopic surgery was done in the year 1981[1]. Since then many laparoscopic surgeries are being performed for various conditions. Laparoscopic appendectomy and laparoscopic cholecystectomy are the most often performed surgical procedure worldwide.In the near future laparoscopic surgeries will be replaced by robotic surgeries.

Laparoscopic surgeries are advantageous over open surgeries in terms of minimal tissue handling, earlier return of bowel function, less postoperative pain, better cosmesis,lesser duration of hospital stay, earlier return to full activity and decreased overall cost[2].

In this laparoscopic era, the main challenge is gaining entry into peritoneal cavity, as it is a blind procedure, associated with risks such as vascular injury and bowel perforation. The incidence of bowel injuries is 0.13%, vascular injuries is 0.05-2% and abdominal wall vascularinjuries -0.2-2%[3]. Therefore, safe abdominal entry in laparoscopy is a major concern.

Considering the fact that initial entry to abdominal cavity is a blind procedure, there is no ideal entry site. Various entry points used are Umbilicus, Palmar's point, Jain point[5], Lee-Huang point[6], etc.

The umbilicus is the most preferred considering the following facts[5]:

1)Fixed Peritoneum

2)Least Vascular

3) Thin (No muscle or fat between skin and peritoneum)

4)Cosmetic

Major drawback being umbilicus is a dirty area, more prone for infection. It is shown in some studies that, after sterile preparation for surgery, umbilicus is considered as clean as any other regions in the body. Therefore, risk of infection is same as other regions.

At the umbilicus, two types of incision can be taken[7,8,9]:

1. Transumbilical / Intraumbilical

2. Periumbilical (supraumbilical or infraumbilical)

Transumbililcal incision is taken by everting umbilicus with graspers, then incising the skinvertically to reach thephysiological hernia to enlarge it. The incision is then completed with Hasson's technique.

Periumbilical incision taken by everting umbilicus with a grasper and a curvilinear or inverted 'U' shaped incision taken over superior or inferior crease followed by vertical incision over the fascia. The incision is completed with the Hasson's technique.

The type of incision to be taken can be decided by the surgeon based on the following factors:

1. Based on shape of umbilicus
2. Better ergonomics
3. Better cosmetic outcome
4. Less incidence of surgical site infection

Factors such as shape of umbilicus, ergonomics, incidence of surgical site infection has less significance between the two types of incision.

Study conducted by Audrey Bouffard- Cloutier,evaluated the preoperative 28% of population did not care about the appearance of umbilicus, but rest of them who gave importance toumbilicuspreoperatively showed poor cosmetic scores postoperatively[2].Till date, very few studies have compared the cosmetic outcome between Transumbilical and Periumbilical incision.

Therefore this study was conducted to compare the cosmetic outcome between the two types of incisions.

OBJECTIVES

To compare better cosmetic outcome between periumbilical and trans umbilical incision for primary port insertion in cases of Laparoscopic Appendectomy and Laparoscopic Cholecystectomy.

REVIEW OF LITERATURE

In 1981, first Laparoscopic appendectomy was performed and in the year 1985 first laparoscopic cholecystectomy was performed[1]. Around the globe about 6 lakhs Laparoscopic cholecystectomy [21] and 5 lakhs laparoscopic appendectomies[21] are being performed per year. Since then many developments have taken place and currently laparoscopic surgeries have become gold standard.

For every laparoscopic procedure to begin with, pneumoperitoneum is created using either veress needle or modified Hasson's method[3]. Recently, use of optical trocar helps avoiding trocar site entry complications [4].

Various entry points include Umbilicus, Palmar's point[47], Jain point[5], lee-Huang point[6] Regardless of type of access technique, Umbilicus is the most preferred site of entry in various laparoscopic surgeries [5].

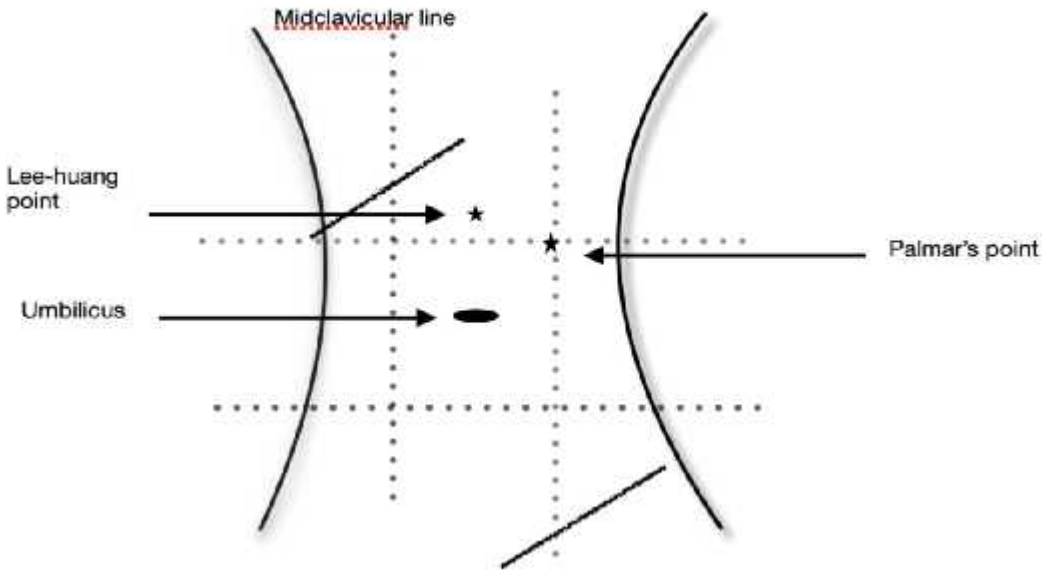


Image1: Primary trocar entry sites

Umbilicus:

Umbilicus lies in the midline between xiphisternum and pubic symphisis, represents the neonatal attachment of umbilical cord. It is a physiological scar consists of remnants of umbilical arteries, urachus, umbilical vein, peritoneum covering the umbilical region and umbilical ring and in certain cases umbilical fascia[35].

The following layers are present at the umbilicus include[35]:

1. The skin
2. The superficial fascia
3. The anterior sheath of rectus
4. The Rectus abdominis muscle
5. The posterior sheath of rectus
6. The subperitoneal connective tissue
7. The peritoneum

According to Catteau,"a typical umbilicus has a cushion and a central depression, in the bottom of which are two structures a mamelon and umbilical cicatrix."

Various shapes of umbilicus mentioned

Type1–cushion incomplete: presents a crescent or horseshoe fold below the umbilicus

Type 2 –cushion incomplete, found above the umbilicus

Type 3- Funnel shaped umbilicus, the cushion has been padded with adipose tissue

Type4-The horizontal oval umbilicus, the cushion completely surrounds a well-marked mamelon and an umbilical cicatrix.

Type 5 –the horizontal, slit like umbilicus

Type 6- the triangular slit like umbilicus

Type 7 –the perpendicular slit like umbilicus

Type 8-the perpendicular oval umbilicus

Type 9- the prominent, button like umbilicus

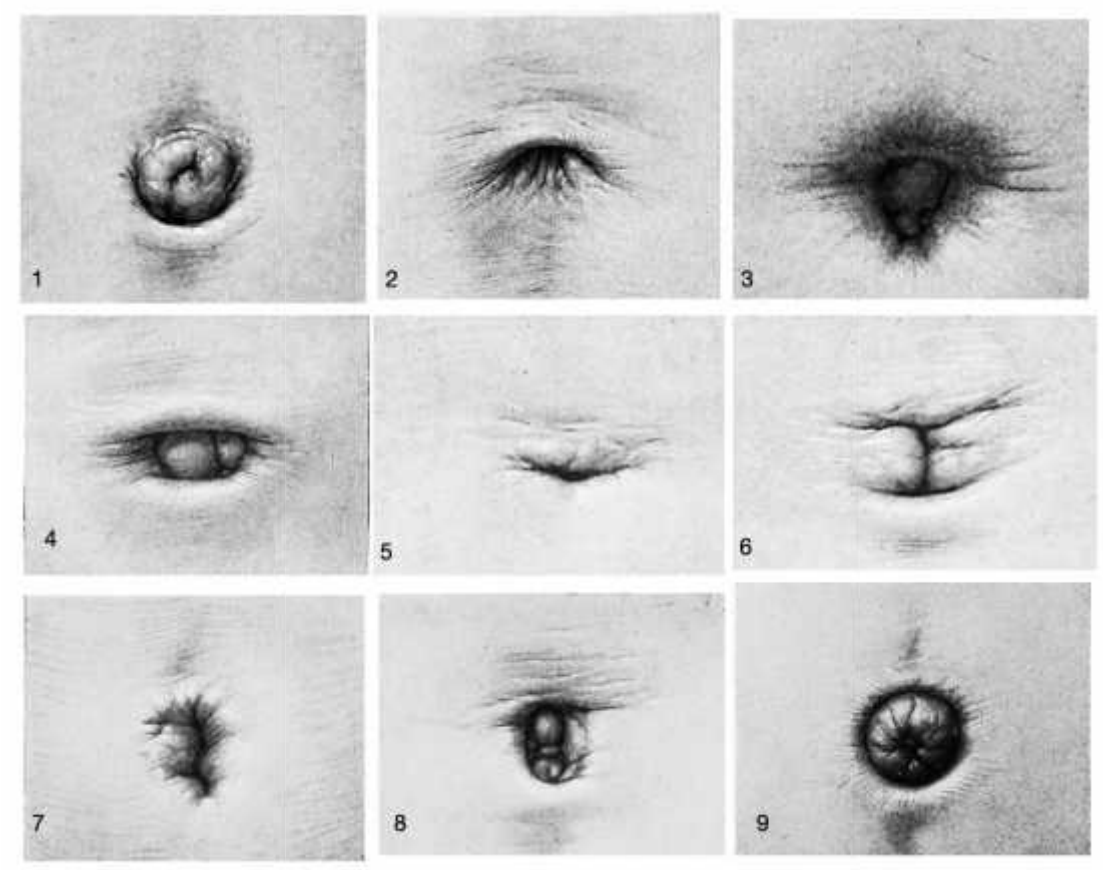


Image 2: Shows images of umbilicus according to the different types of umbilicus

Histology of umbilicus:

According to Hertz and others, umbilical pit is covered with squamous epithelium devoid of papilla, which later on replaced with normal skin epithelium without sebaceous or sweat glands.

Umbilical fascia:

It is formed from the fibres of the transversalis fascia attached to the peritoneum.

This may extend to the margin of the rectus muscle, or join with the posterior layer of aponeurosis.

As per some of the studies conducted earlier, it is shown that people give preference to appearance of umbilicus. Therefore, cosmetic outcome of the incision plays an important role in laparoscopic surgeries.

Umbilical ring:

It is an opening in the lineaalba through which passes the umbilical vessels in the foetus.

Location of umbilical ring is nearer to the pubis in young embryo, as age increases, it gradually ascends to the center of the abdomen in adult, its site being indicated by umbilicus or navel.

Embryologically, the umbilicus is a midline fusion of the medial aponeurotic borders of both rectus abdominis aponeurosis around the umbilicus.

Attachments at the umbilicus

1. Median Umbilical Fold, It lies in the midline extending from the apex of urinary bladder to the umbilicus

2.Medial umbilical folds- present on either side and lateral to median umbilical fold covering the medial umbilical ligaments, which are formed by occluded parts of umbilical arteries.

3. Lateral umbilical folds – They are present lateral to the medial umbilical folds, contsists inferiorepigastric vessels.

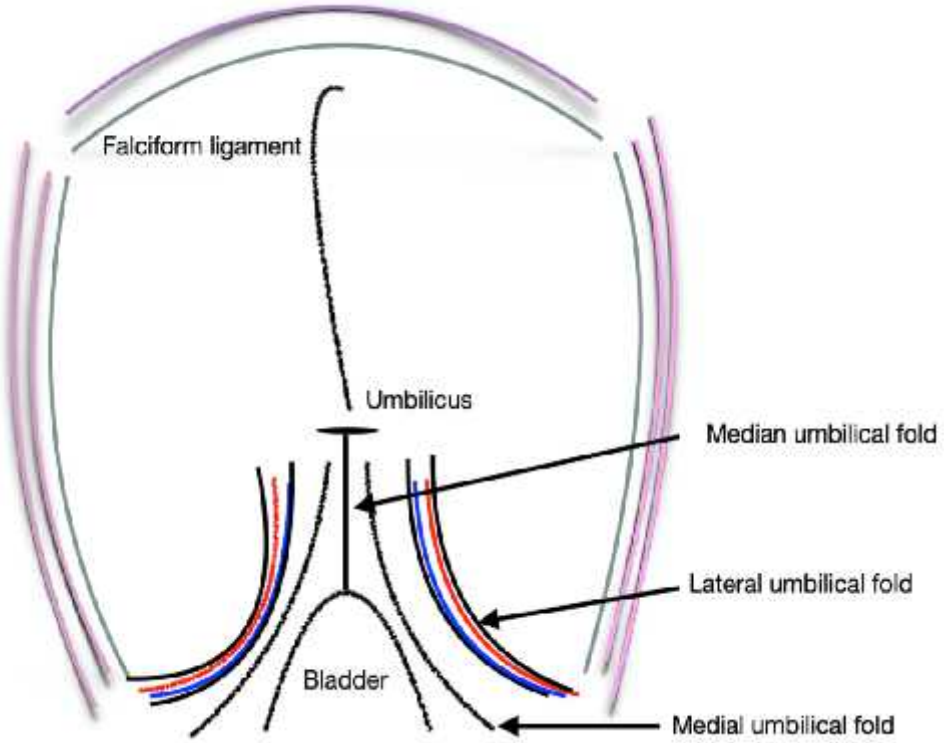


Image 3: Shows umbilical ligaments and its attachments

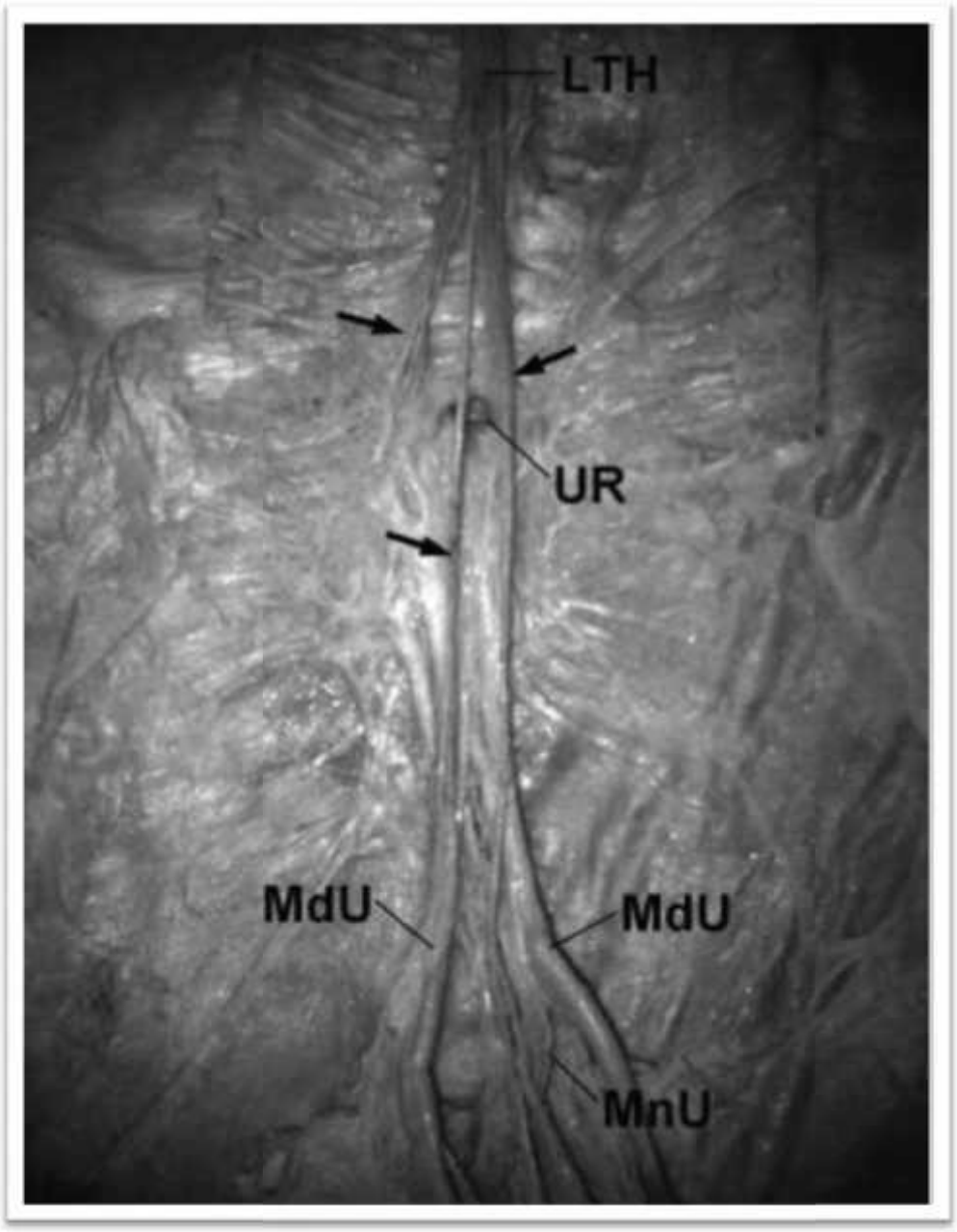


Image4: Dissected specimen shows attachment of various umbilical ligaments

VARIATIONS IN UMBILICAL RING

The variations in umbilical ring are classified in to three types[31, 32,37]:

Type A- oval or round

Type B- obliterated or slit

Type C –completely covered by connecting band between the ligamentumtereshepatis and umbilical ligaments

Image 5: Anomalies of umbilical ring

BLOOD SUPPLY

Blood supply to the umbilicus includes:

1.subdermal plexus

2.large ascending branch

3.several small branches of deep inferior epigastric arteries

4.ligamentumteres

5.median umbilical ligament

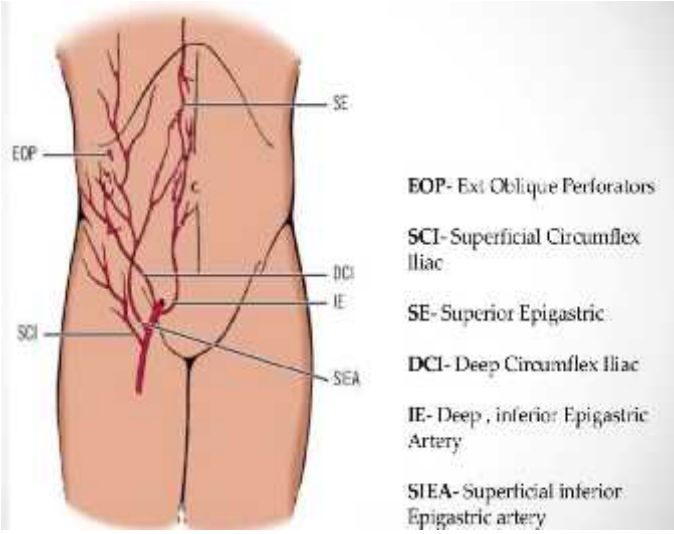


Image 6: shows Arterial supply of umbilicus

VENOUS DRAINAGE

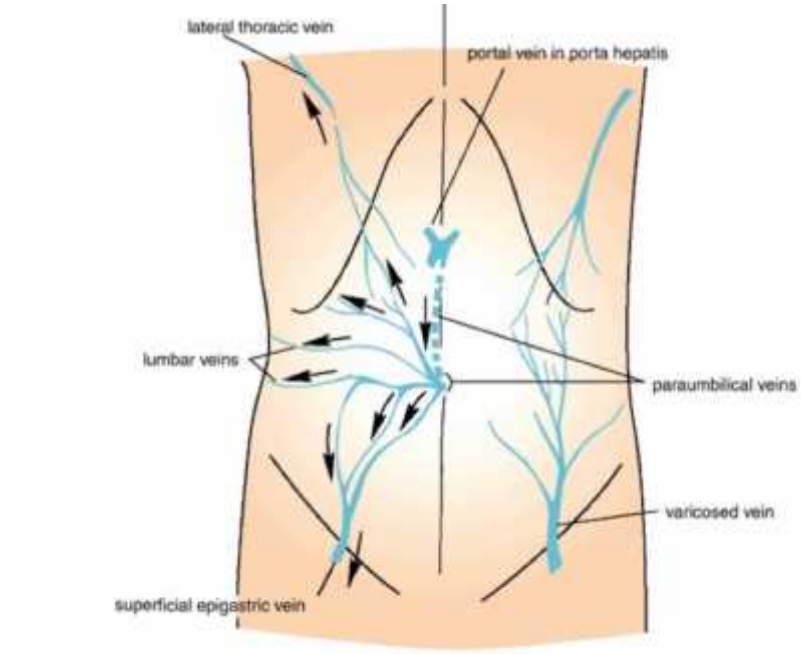


Image 7: venous drainage of umbilicus

NERVE SUPPLY

The umbilicus is supplied by tenth thoracic spinal nerve (T10)

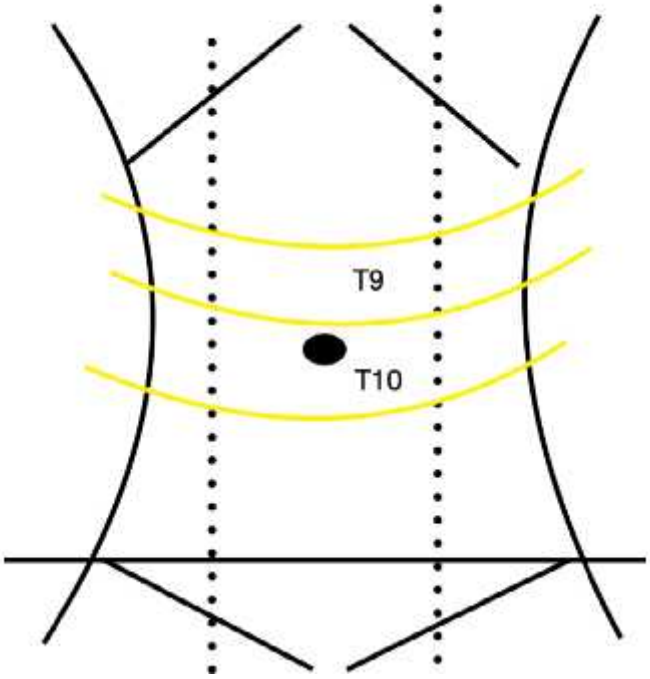


Image 8: nerve supply to the umbilicus

Various factors influencing the cosmetic outcome include:

1. Wound healing
2. Type of incision
3. Retrieval of specimen
4. Type of suture material used
5. Type of suture technique
6. Presence or absence of surgical site infection
7. Dressing
8. Suture removal day

Wound healing

The mechanism of wound healing is a combination of multiple processes to restore the structural and functional integrity of the damaged tissue.

Which involves various cells like neutrophil, macrophages and lymphocytes and fibroblast and collagen mediating various stages involved in wound healing such as haemostasis, inflammation proliferation and matrix synthesis and maturation and remodelling epithelialization and wound contracture.

Types of wound healing:

Healing by Primary intention: occur in surgically made wound and clean incised small wounds. Here epithelialization is comparatively more than the fibrosis. So wound healing enhanced with rapid healing and minimal scarring (linear and smooth)

Healing by Secondary intention: Occurs in wounds with extensive soft tissue loss conditions such as major trauma, burns and dirty contaminated wounds. Here wound healing is slower than the primary intention and it heals with the fibrosis and leaves a scar. Often it is associated with hypertrophic scar and contracture. Later re-epithelisation occurs from rest of the wound margins.

Tertiary intention: Post debridement wounds, after control of local infection wound is closed with stay sutures and it mandates a skin grafting.

Various incisions around the umbilicus

1.Transumbilical incision

2.Periumbilical incision

TRANSUMBILICAL INCISION –

Also called intraumbilical incision.

It is vertical incision taken from skin and fascia extending till umbilical ring.

PERIUMBILICAL INCISION –

It can be either supraumbilical or infraumbilical.

It passes through the skin, subcutaneous fat and fascia.

It is a 'U' shaped or semicircular incision taken over the skin, with vertical incision over the fascia.

Theoretically, since the intraumbilical incision cuts through only skin and fascia, it should take less time compared to periumbilical incision.

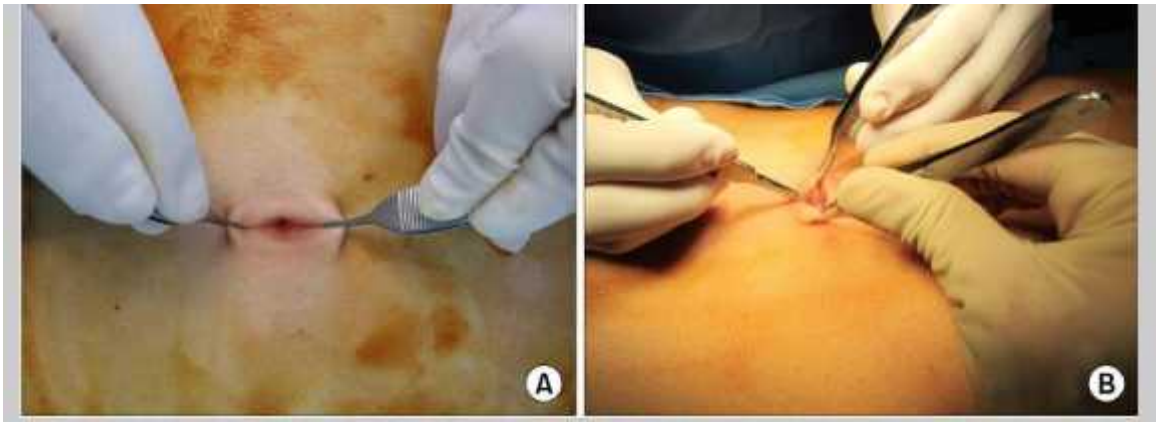
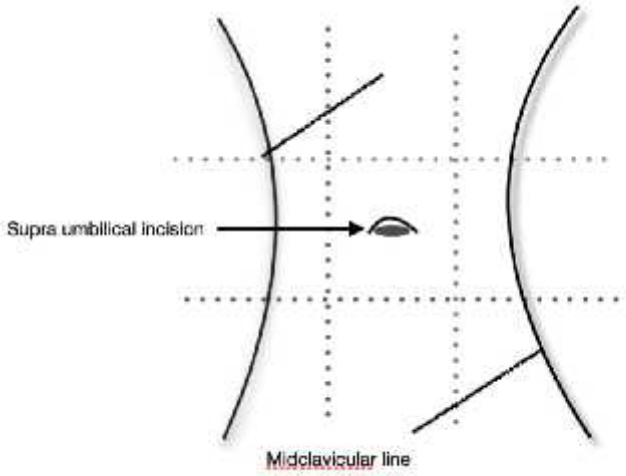


Image9A: Eversion of umbilicus with the help of graspers

Image 9B: Vertical incision taken over the skin of umbilicus till umbilical ring

A



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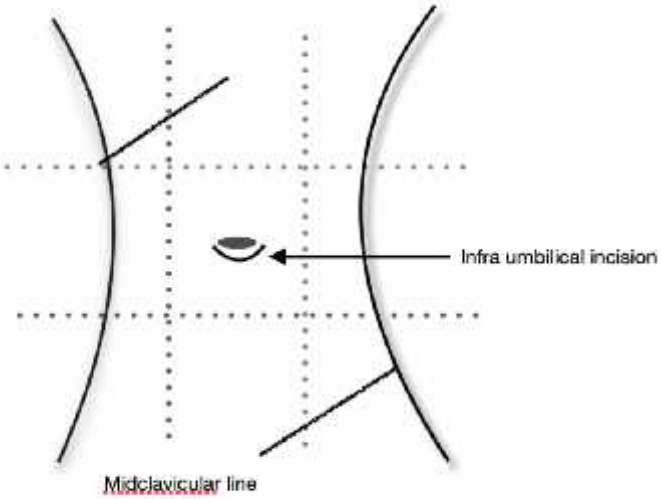


Image 10A: Supraumbilical incision

Image 10B: Infraumbilical incision

Various laparoscopic wound closure techniques include:

1. Simple sutures
2. Mattress sutures
3. Inverted mattress
4. Staples
5. Subcuticular sutures
6. Glue

Comparison between mattress and subcuticular suture:

Subcuticular sutures have good approximation, lesser skin, subcutaneous pricks, therefore better cosmetic outcome, and lesser wound infection rate.

Studies conducted by AkhilaVasudeva, et al stated "even though hypothetically subcuticular suture has better wound healing, objectively when assessed the wound with variables like induration, erythema, discharge, incidence of surgical site infections, they were equally distributed among the two groups"

Approximation of wound edges is poor with mattress suture ,but it depends on the surgeons technique ,good surgeon technique with good approximation will give better cosmetic outcome.

It is mentioned in studies "Due to more number of skin and subcutaneous tissue pricks as well as more number of suture knots during mattress skin closure, in which patients are observed with more pain in postoperative period."

Subcuticular sutures are generally put using absorbable suture material; suture removal is not required and patient need to stay till suture removal therefore decreasing length of hospital stay.

Mattress sutures are put using non-absorbable suture material, require suture removal after 7-8 days postoperatively, thus prolonging hospital stay.

Intermittent fashion of Mattress sutures provide better route for drainage of subcutaneous collection.

"Subcuticular suture requires more technical expertise, as well as longer training period, finer surgical skills and precise instruments along with more expensive suture material which have superior long term cosmetic outcome, along with better patient compliance and less duration of stay in hospital. With regard to subcuticular suture mattress suture is easier, it needs less training and less time, less surgical skills and cheaper suture material. However, mattress suturing still remains a better option [28]."

"Across studies, subcuticular sutures were observed to have decreased wound morbidity like dehiscence, discharge and better cosmetic outcome when compared to interrupted sutures, Macdeen et al observed no difference in terms of wound morbidity, pain, cosmesis and scar satisfaction [29]. Ibrahim MI et al conducted studies on obese women using subcuticular sutures, which showed significantly short-term better cosmetic outcome, but with slightly higher risk of superficial incisional surgical site infection and significantly more postoperative pain[28]."

Studies like Philip H.Zeplin,MD, Karsten Schmidt, conducted studies comparing various methods and materials for treatment of skin laceration by 3D measuring technique in which he compared between skin adhesive, continuous suture with absorbable material, continuous suture with non absorbable material, mattress suture, discontinued or single stitch suture showed similar results of wound dehiscence, continuous sutures (absorbable > nonabsorbable suture) has increased scarring. In small incision, various suture materials and techniques showed identical results.

Comparison between staples and sutures

Use of staples compared to sutures has advantages of lesser mean wound closure time, but comsesis is better with suture and cost effective.

Comparison between glue and suture and staples

Use of glue compared to sutures and staples, have the following advantages such as lesser application time, lesser postop pain due to no suture bites, and also several studies have shown better cosmetic outcome in superficial surgical wounds and less expensive.

5.Surgical site infection

Theoretically, intraumbilical incision has lesser chance of surgical site infection compared to periumbilical incision.

Several studies, which compared the incidence of SSI between the two incisions, showed similar results.

SCAR PREVENTION AND MANAGEMENT

Modifiable factors for scar formation includes

- Manner of incision
- Atruamatic tissue handling
- Proper Haemostasis
- Asepsis
- Use of tension decreasing techniques immediate postop and on long term follow up

Wound healing stages are individual; proliferative stage may even start before the inflammation stage is completed, and may continue even after remodelling phase

is started. Remodelling phase may continue for longer period even after suture removal.

Skin tension and incision design:

Langer's line and relaxed skin tension lines (RSTL) have been used as indicators of tension vectors.

High skin tension is associated with poor scar formation.

Therefore incision taken along these lines, gives better scar.

According to many authors, improper skin incision design is the main reason for hypertrophic scar.

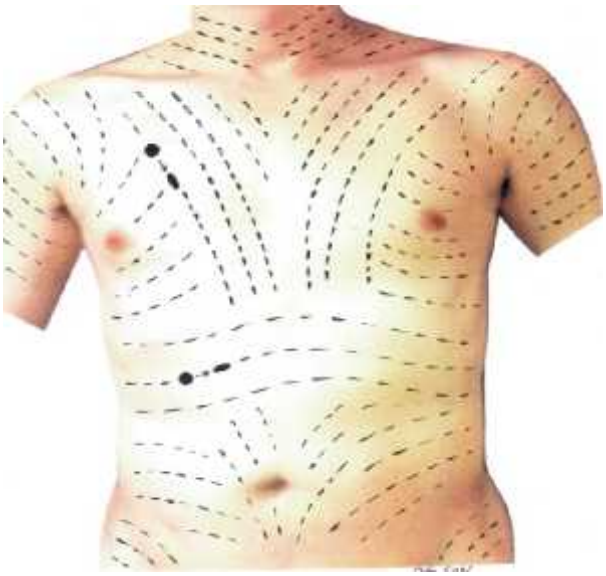


Image 11:Langer's line

Determinants of scar response:

1. Skin tension

2. Blood supply- areas with rich blood supply are known to heal with finer scars

A viable margin should receive blood supply either from the two routes, from a perforator vessel or a distant perforator by dermal plexus.

3. Patient factors –

a) Aging – decreased skin elasticity and sebaceous gland function in elderly, results in lesser chance of hypertrophic scar formation.

In children due to maximum cellular activity, longer duration for scar maturation, faster physical growth, more skin elasticity, the chance of hypertrophic scar formation is more.

b) Ethnicity – European people are tend to form fine scar

People of Africa predispose to hypertrophic or keloid scar

3) Surgeons technique – 5 A's include

- Asepsis
- Absence of tension
- Accurate approximation
- Avoidance of raw surface
- Atraumatic handling of tissue

4) Post operative care and dressing – dressing materials are well known to affect stages of wound healing and better scar formation[37].

Non-absorbable sutures can be removed once wound is able to support by itself

Postoperative follow-up should target on prevention,screening and management of hypertrophic scar**.**

REVIEW OF ARTICLES:

The Canadian Task Force classification II-1 prospective study by Mehmet BakiSenturk et al. enrolled 105 patients undergoing laparoscopic surgery. They observed that cosmetic results did not differ statistically between the patients with transumbilical, infraumbilical and supraumbilical incisions. However they noticed a significant higher incidence of vascularity, height, and total score in Vancouver scar scale in patients who had transverse incisions. Factors like gravid, age, skin thickness, body mass indices, duration of operation, time of entry had no statistical significance with cosmetic results in terms of height, vascularity and Vancouver scar scale.

A study conducted by Jun Suh Lee and Tae Ho Hong in Incheon, South Korea studied outcomes of intraumbilical versus periumbilical incisions in laparoscopic cholecystectomy. This randomized control trial included 130 patients who underwent laparoscopic cholecystectomy. These patients were further classified into those who received a periumbilical incision and those who received intraumbilical incisions. Though a significant difference in rates of complications was not observed amongst these groups, cosmetic survey score was seen to be significantly higher in the intraumbilical group. Therefore, they concluded that intraumbilical incisions prove safer, more feasible methods of intraperitoneal access with reduced operation times and superior cosmetic outcomes.

A study on periumbilical versus transumbilical laparoscopic incision: A patients' satisfaction- centered randomized trial conducted by Audrey Bouffard-Cloutier, Alex Pare and Nathalie McFadden in Canada enrolled individuals between 18-70 years of age. The operations considered for umbilical port study were laparoscopic rectopexy, laparoscopic cholecystectomy, laparoscopic appendectomy

and laparoscopic proctocolectomy. Patients were again randomized into intraumbilical and periumbilical groups. The ratio of IU: PU was 1:1. Overtly obese patients with a body mass index of >40kg/m2, patients with past history of abdominal surgeries, patients requesting a specific incision, or incisions converted to open surgeries were excluded from the study. 56 people were randomized in the study. The study found comparable results in both groups with regards to cosmetic satisfaction scores, incidence of surgical site infections and operative time. The 28% of patients who valued the appearance of their umbilicus prior to surgery has a significantly poor cosmetic satisfaction score(CSS) evolution. Preoperatively higher CSS was noticed to result in significant postoperative CSS decline. A comparison of the periumbilical incision and intraumbilical incision in laparoscopic appendectomy by Jun Suh Lee, Tae Ho Hong and Jun Gi Kim in Seoul, South Korea retrospectively reviewed 280 patients with perforated appendicitis. 159 patients received intraumbilical incision and 121 received periumbilical incision. they observed no difference in postoperative hospital stay, operation time and requirement of analgesic between the two groups. Also, there was no difference in the incidence of umbilical complications. They concluded that the intraumbilical incision is safer alternative with better cosmetic results.

MATERIALS & METHODS

One year randomized controlled trial was conducted in the Department of General Surgery, KLES Dr. Prabhakar Kore Hospital and Medical Research Centre, Belgaum over a period, from January 2019 to December 2019.

Study design: The study design was single blinded randomized controlled trial.

Study period and duration: This study was conducted for the period of one year from January 2019 to December 2019.

Place: Study was done in the Department of General Surgery, KLES Dr. Prabhakar Kore Hospital and Medical Research Centre, Belgaum attached to KLE University's Jawaharlal Nehru Medical College, Belgaum.

Sample size: A total of 100 patients divided into two groups of 50 each were studied.

Sampling procedure

Computer generated random numbers were used to assign the type of surgery to the patients that is, group A (patients undergoing periumbilical incision) and group B (patients undergoing transumbilical incision). Patients were blinded to the intervention. The sample size was taken as 100, with 50 in each group by applying the formula,

$$n = \frac{2(Z\alpha+Z\beta)2\ S2}{(x1-x2)2} = 50$$

Where, n = sample size

$Z\alpha = 1.96$

$Z\beta = 0.84$

S = Standard deviation

x1-x2 = effect size

Statistical analysis: Student's t- test if assumptions are fulfilled.

Substituting these values in the formula, N=50 and enrolment ratio is 1:1 hence, the sample size estimated will be a minimum of 100patients. Accordingly 50 patients each will be included in periumbilical incision group & 50 in transumbilical group.

Selection criteria:

Inclusion criteria:

Age - 15 to 70 yrs.

Elective and emergency lap appendectomy, lap cholecystectomy

Exclusion criteria:

Cases of extended incision for retrieval of specimen through primary port site

Operated case of umbilical hernia

Operated case of perforated appendix, gangrenous appendicitis perforated gallbladder, empyema gallbladder

Previous periumbilical scarring

Hereditary conditions - keloid, hypertrophic scar, umbilical cyst, anomalies

Burns in the umbilical region

Operative technique:

In both the groups patient presenting to KLE hospital emergency and OPD with complaints of pain abdomen with suspicion of diagnosis of acute appendicitis, perforated appendix, calculus cholecystitis, perforated gallbladder were considered for the study.

The following patients after thorough clinical and radiological evaluation planned for appropriate treatment. i.e. diagnostic laparoscopy followed by laparoscopic appendectomy or laparoscopic cholecystectomy.

Patients were explained about the study preoperatively and counselled and consent obtained for the same.

Preoperatively:

- Written informed consent taken
- Parts preparation from nipple to midthigh done
- Inj.xylocaine test dose was given in the anterior aspect of forearm intradermal
- Inj. Tetanus toxoid 0.5 ml was given deep i.m
- Patient was advice to scrub the abdomen and specifically umbilicus thoroughly
- One dose of intravenous antibiotic like ceftriaxone was given 1 hour prior to surgery

Under general anaesthesia, after catheterization, patient positioned in supine and parts painted with betadine from nipple to midthigh and draped in a standard manner.

Intraoperative:

1. Creation of pneumoperitoneum

a) **Closed method:**

By using veress needle, by inserting veress needle at palmar's point or at umbilicus.

2 mm stab incision taken along the langer's line for insertion of veress needle.

Intraperitoneal position of veress needle was confirmed by performing these two tests:

1. **Hanging drop test** – where saline from the veress needle hub is drawn to the peritoneal space when abdominal wall is lifted.

2. **Saline irrigation** in and out of peritoneal space.

Once confirmed, automated CO2 insufflator at pressure of 12-15 cm of H_20 creates pneumoperitoneum.

b) **Open modified Hasson's technique**:

In this technique 10mm trocar inserted through a transumbilical or supraumbilical or infraumbilical skin incision of approximately 10-11mm, underlying fascia identified and opened with knife and grasped with Allie's forceps and 10 mm port is negotiated in to the peritoneum.

Simultaneously the safe entry is confirmed by inserting telescope and visualization of peritoneal contents.

Pneumoperitoneum created by attaching automated CO_2 insufflator.

Respective ports are placed according to the surgery performed.

In case of laparoscopic appendectomy, two working ports are placed suprapubic and left iliac fossa.

In case of laparoscopic cholecystectomy, another 10 mm working epigastric port is placed, and two working ports are placed in mid clavicle and anterior axillary line.

Ports placed and secured.

Respective surgical dissection done.

Specimen dissected.

In case of laparoscopic appendectomy, specimen is retrieved through 10 mm umbilical port. In case of laparoscopic cholecystectomy, specimen is retrieved either from 10 mm epigastric and umbilical port.

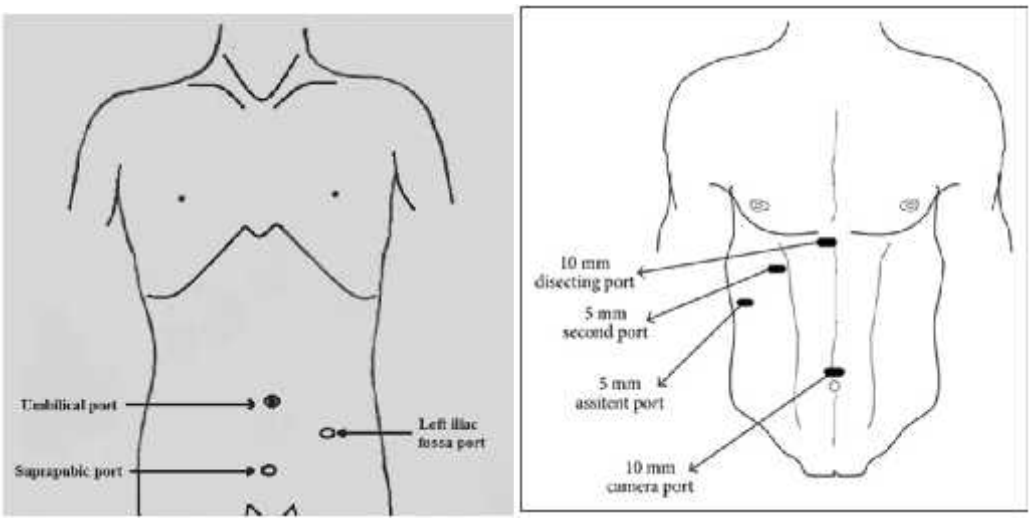


Image 12: port placement of A) Lap appendectomy B) Lap Cholecystectomy

In certain cases, specimen retrieval port incision is increase for the smooth exit of specimen.(as per size) such cases were excluded.

After retrieval of specimen, thorough irrigation given and hemostasis noted.

Trocars are removed and port site skin cleaned with betadine.

Pneumoperitoneum reduced

All cases, fascia closure done using Vicryl port closure needle.

Skin incision approximated using 3-0 Ethilon non-absorbable vertical mattress intermittent sutures.

Wound wiped with betadine and sterile gauze dressing done.

Postoperatively:

- First dressing done on post op day #3, wound is inspected for any erythema, induration, collection, discharge, wound dehiscence.
- Wound Cleaned with spirit and sterile gauze applied.
- POSAS score calculated [25].

- Then every alternate day dressing done on Post Operative day 5,7,9 using spirit and wound is inspected for any signs of infection, wound dehiscence, hypertrophic scar formation.

Outcome variables:

Thefollowing POSAS score was calculated for the patients.

It has 2 components

1. Observer scar assessment scale
2. Patient scar assessment scale

   The various components in observer scar assessment scale include:

   a) Vascularity

   b) Pigmentation

   c) Thickness

   d) Relief

   e) Pliability

Various components in patient assessment scale include:

a) Is the scar painful

b) Is the scar itching

c) Is the colour of the scar different

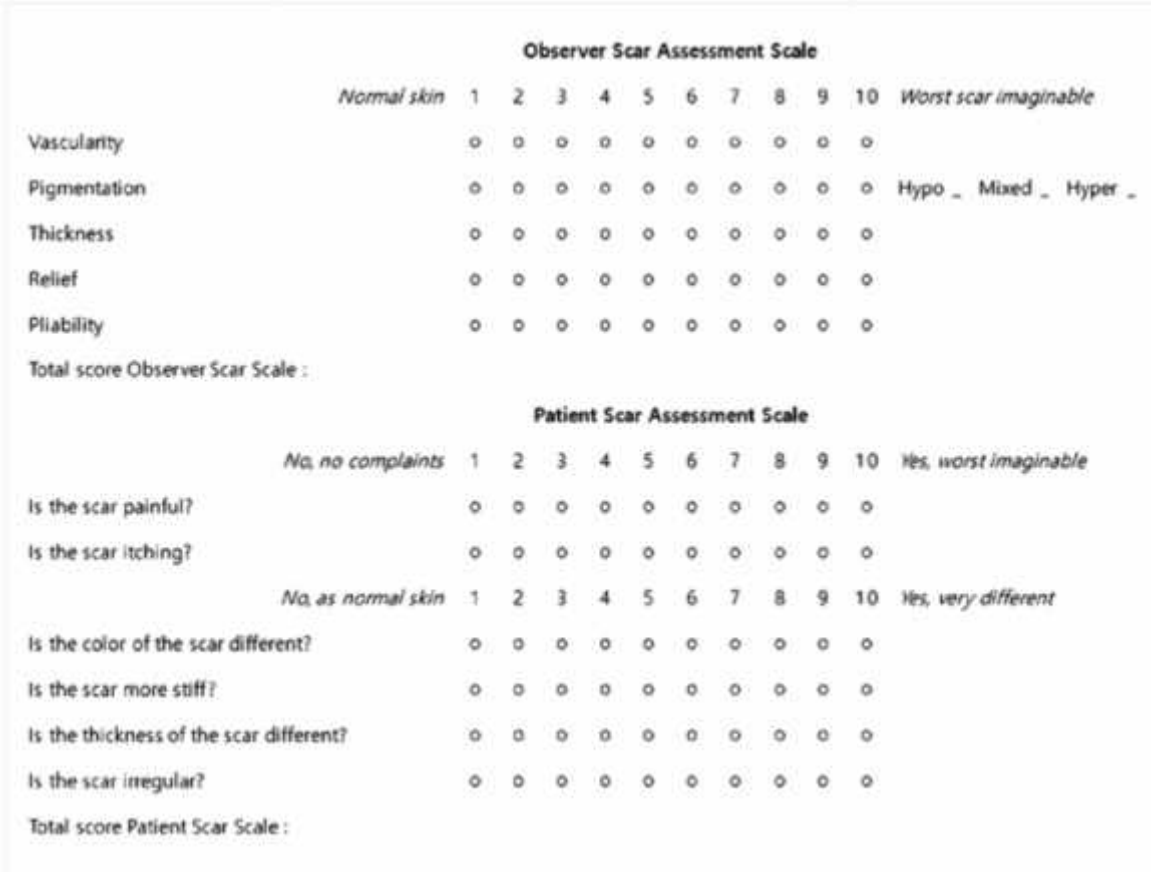
d) Is the scar more stiff

e) Is the thickness of the scar different

f) Is the scar irregular

Each variable has a score between 1- 10, the lower the score, better is the scar.

Lower the pain score, lesser pain associated with the incision.



Observer Scar Assessment Scale

	Normal skin	1	2	3	4	5	6	7	8	9	10	*Worst scar imaginable*
Vascularity		o	o	o	o	o	o	o	o	o	o	
Pigmentation		o	o	o	o	o	o	o	o	o	o	Hypo _ Mixed _ Hyper _
Thickness		o	o	o	o	o	o	o	o	o	o	
Relief		o	o	o	o	o	o	o	o	o	o	
Pliability		o	o	o	o	o	o	o	o	o	o	

Total score Observer Scar Scale :

Patient Scar Assessment Scale

	No, no complaints	1	2	3	4	5	6	7	8	9	10	*Yes, worst imaginable*
Is the scar painful?		o	o	o	o	o	o	o	o	o	o	
Is the scar itching?		o	o	o	o	o	o	o	o	o	o	
	No, as normal skin	1	2	3	4	5	6	7	8	9	10	*Yes, very different*
Is the color of the scar different?		o	o	o	o	o	o	o	o	o	o	
Is the scar more stiff?		o	o	o	o	o	o	o	o	o	o	
Is the thickness of the scar different?		o	o	o	o	o	o	o	o	o	o	
Is the scar irregular?		o	o	o	o	o	o	o	o	o	o	

Total score Patient Scar Scale :

Image 13: POSAS SCAR ASSESSMENT SCALE

- POSAS score calculated on pod 7,and 1 month postoperatively.
- All the patients in both groups were managed similarly.
- They were evaluated for signs of pain and abdominal discomfort from postoperative Day # 1 till date of discharge.
- Suture removal was done between post operative day between 7 to 10.
- Scars were assessed by patient and observer scar assessment scale POD 3 ,7 and after 1month on follow-up by a nonclinical personand the results were calculated as follows.

STATISTICAL ANALYSIS:

The data obtained was coded and entered in Microsoft Excel Spread sheet. The categorical data was expressed as rates, ratios and percentages and comparison was done using chi–square tests, Mann-Whitney U tests and Wilcoxon matched pairs test. Continuous data was expressed as mean ± standard deviation. A 'p' value of less than or equal to 0.05 was considered as statistically significant.

RESULTS

The data of 50 patients who underwent periumbilical incision and another 50 patients who underwent trans umbilical incision were analyzed. The results of the analysis are as follows.

Table: Comparison of group A and group B by age groups

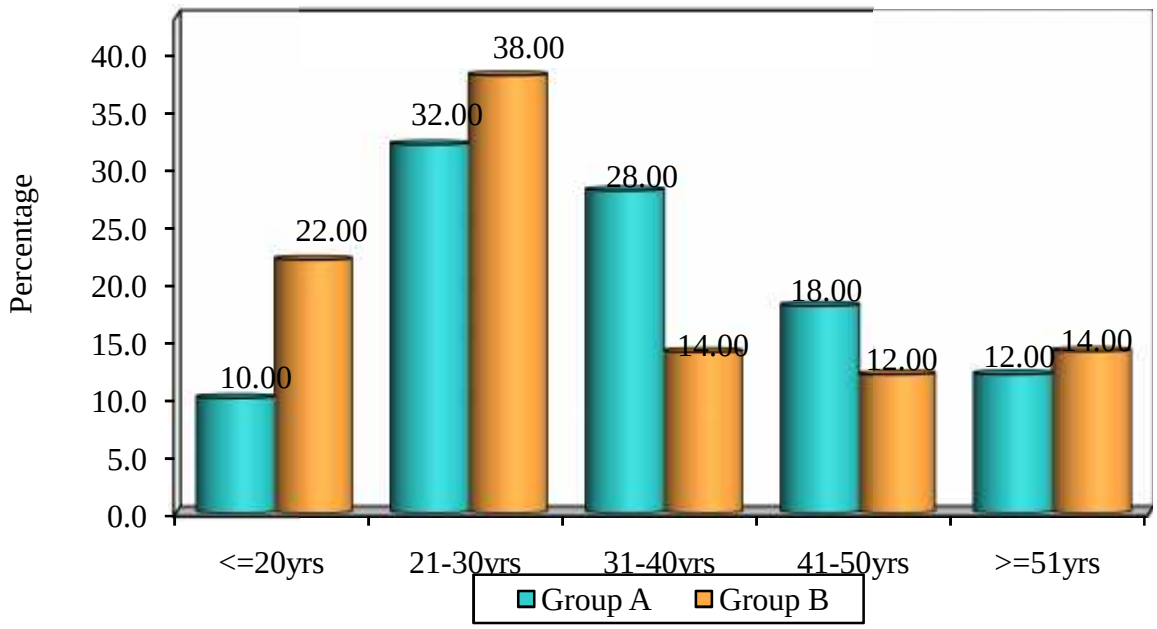
Group A: patients who undergone Periumbilical incision

Group B: patients who undergone Trans umbilical incision

Age groups	Group A	%	Group B	%	Total
<=20yrs	5	10.00	11	22.00	16
21-30yrs	16	32.00	19	38.00	35
31-40yrs	14	28.00	7	14.00	21
41-50yrs	9	18.00	6	12.00	15
>=51yrs	6	12.00	7	14.00	13
Chi-square=5.5173 P = 0.2385					
Total	50	100.00	50	100.00	100
Mean age	34.60		33.16		33.88
SD age	12.22		14.73		13.49

Table 1: Comparison of group A and group B by age groups

Figure1: Comparison of group A and group B by age groups



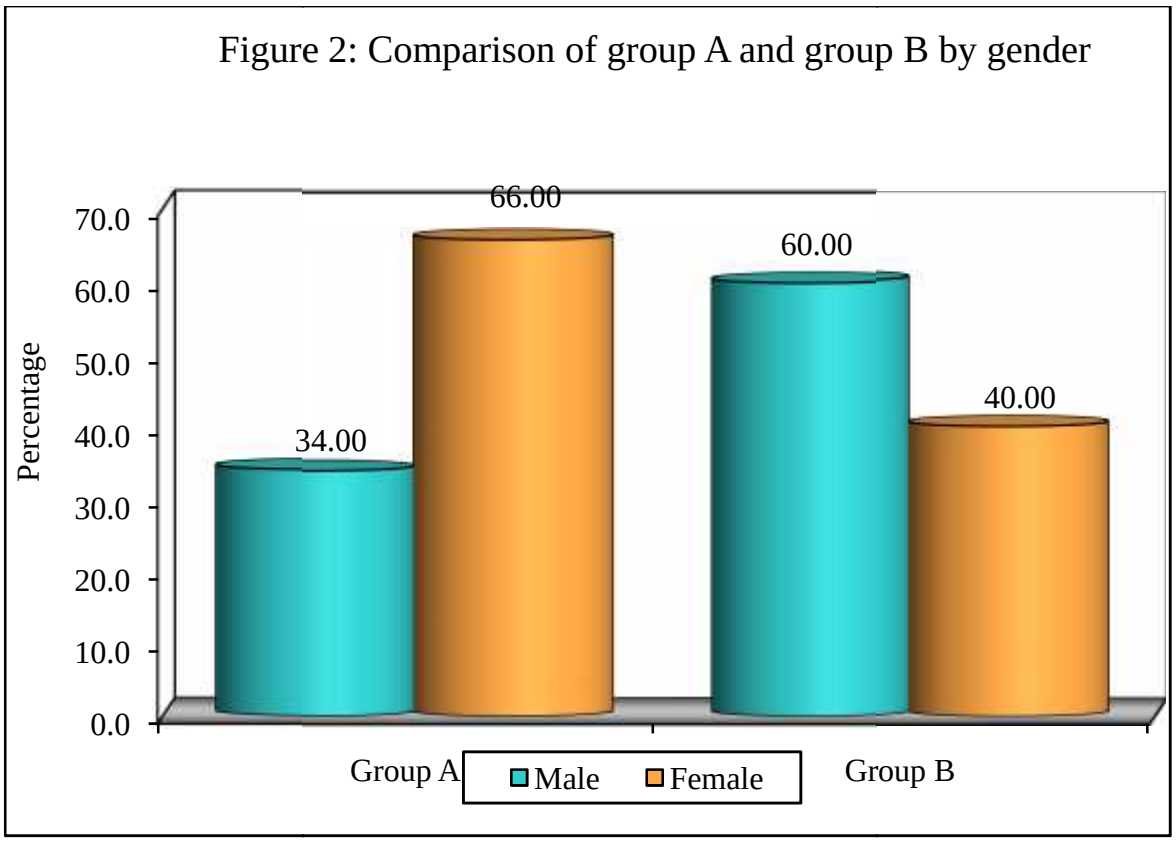
In the present study, distribution of age groups in group A (periumbilical) and group B(transumbilical) are 10% v/s 16% <20 yrs, 32% v/s 35% between 21-30 yrs,28% v/s 21% between 31-40 yrs, 18% v/s 15% between 41-50 yrs,12% v/s 13% between 50yrs and above are comparable.

In the present study, the mean age in group A is 34.60 ± 12.22 years compared to 33.16 ± 14.73 years in group B, the youngest patient being 18 yrs of age. However the difference was statistically not significant (p=0.2385)

Table 2: Comparison of group A and group B by gender

Gender	Group A	%	Group B	%	Total
Male	17	34.00	30	60.00	47
Female	33	66.00	20	40.00	53
Total	50	100.00	50	100.00	100
Chi-square=6.784 P = 0.0090*					

*p<0.05



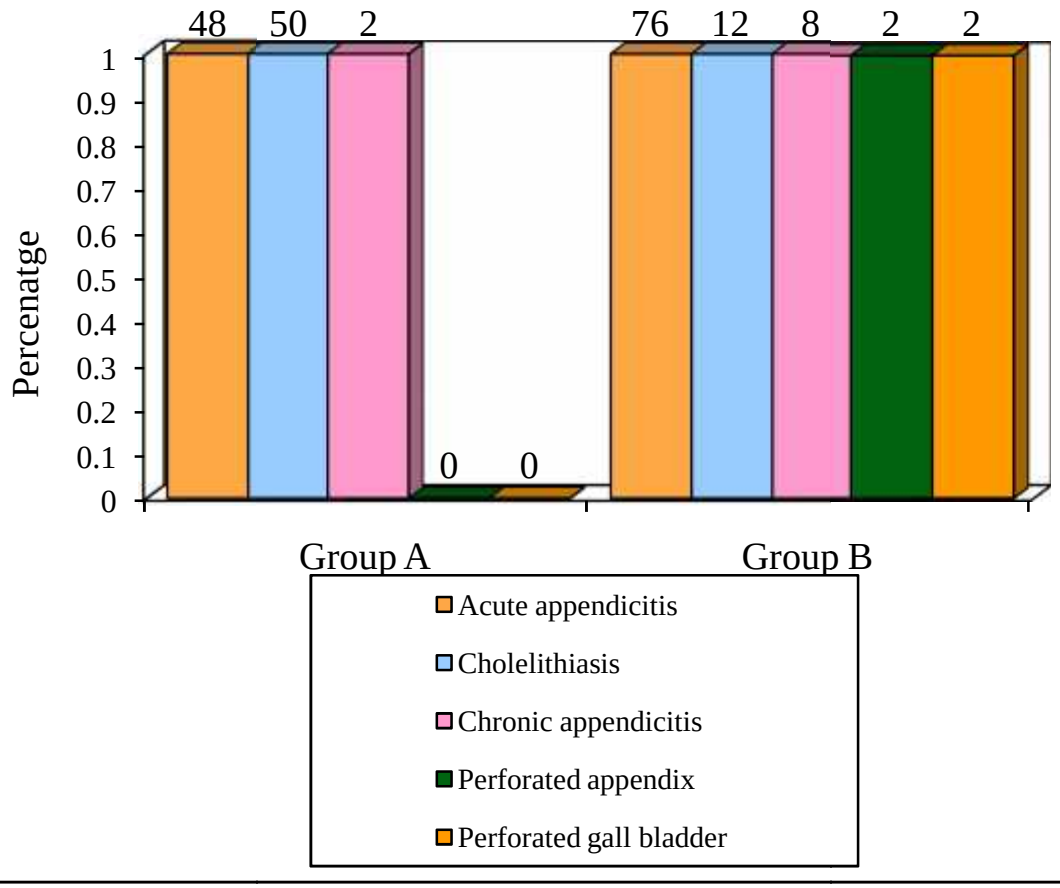
In the present study, 34% were males and 66% were females in group A and 47% were males and 53% were females.

Table 3: Comparison of group A and group B by diagnosis

Diagnosis	Group A	%	Group B	%	Total
Acute appendicitis	24	48.00	38	76.00	62
Calculous cholecystitis	25	50.00	0	12.00	31
Chronic appendicitis	1	2.00	4	8.00	5
Perforated appendix	0	0.00	1	2.00	1
Perforated gall bladder	0	0.00	1	2.00	1
Total	50	100.00	50	100.00	100
Chi-square=20.5902 P = 0.0001*					

*p<0.05

Figure 3: Comparison of group A and group B by diagnosis



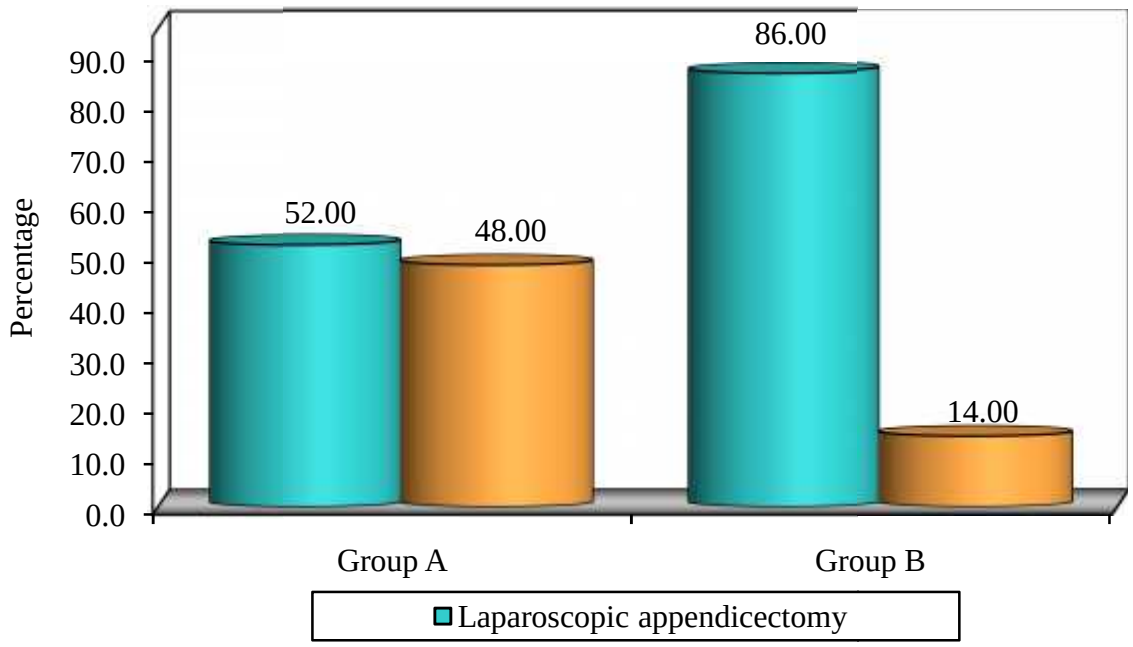
In the present study, based on diagnosis,48% were cases of acute appendicitis in group A and 76% in group B. 50 % were cases of calculus cholecystitis in group A and 12% in group B. 2% were cases of chronic appendicitis in group A and 8% in group B. in group B 2% cases are diagnosed with perforated appendix and another 2% cases are diagnosed with perforated gallbladder.

Table 4: Comparison of group A and group B by nature of operation

Nature of operation	Group A	%	Group B	%	Total
Laparoscopic appendicectomy	26	52.00	43	86.00	69
Laparoscopic cholecystectomy	24	48.00	7	14.00	31
Total	50	100.00	50	100.00	100
Chi-square=13.5111 P = 0.0001*					

*p<0.05

Figure 4: Comparison of group A and group B by nature of operation



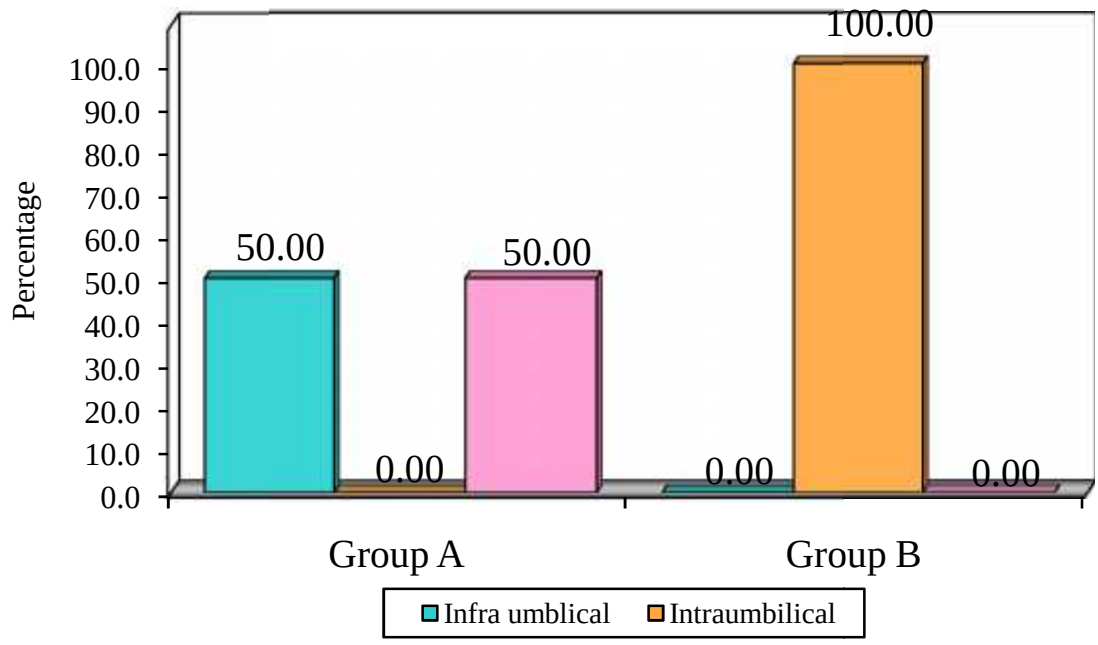
In the present study, in group A 52% cases underwent Laparoscopic appendectomy v/s 86 % cases in group B and 48% cases underwent Laparoscopic cholecystectomy v/s 14% in group B.

Table 5: Comparison of group A and group B by types of incision

Types of incision	Group A	%	Group B	%	Total
Infraumbilical	25	50.00	0	0.00	25
Intraumbilical	0	0.00	50	100.00	50
Supra umbilical	25	50.00	0	0.00	25
Total	50	100.00	50	100.00	100
Chi-square=100.0000, p=0.0001*					

* p< 0.05

Figure 5: Comparison of Group A and Group B by types of incision

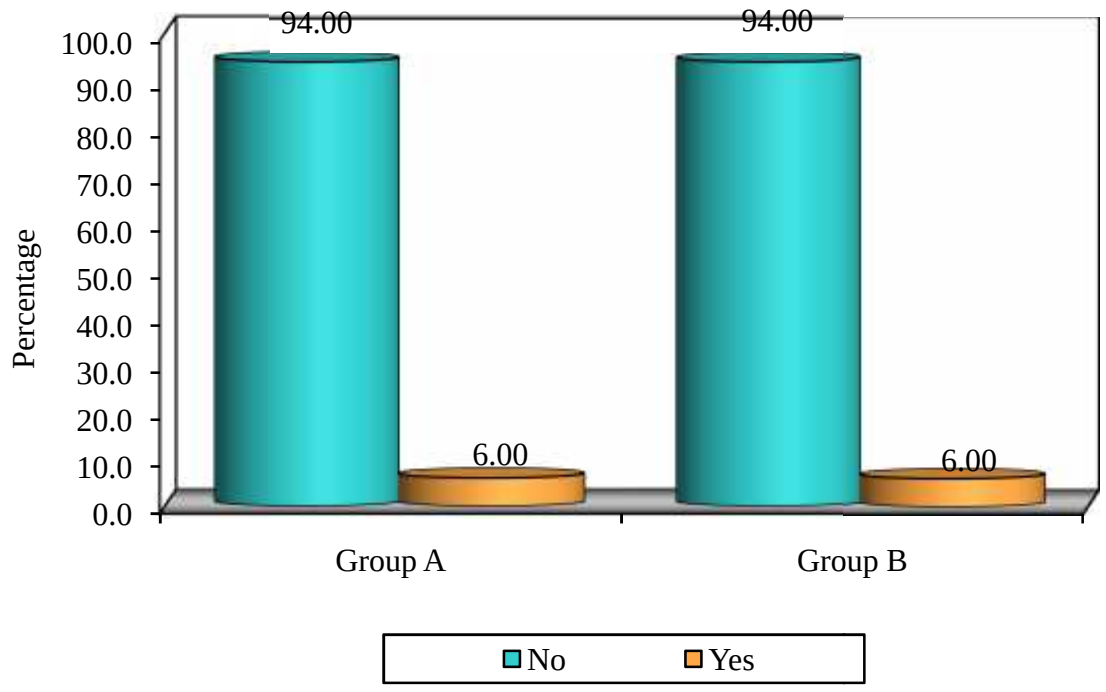


In the present study, 50% cases of Group A undergone supraumbilical incision and rest 50% have undergone infraumbilical incision, whereas 100% cases of group B undergone transumbilical incision.

Table 6: Comparison of group A and group B by SSI

SSI	Group A	%	Group B	%	Total
No	47	94.00	47	94.00	94
Yes	3	6.00	3	6.00	6
Total	50	100.00	50	100.00	100
Chi-square=0.0000, p=1.0000					

Figure 6: Comparison of group A and group B by SSI



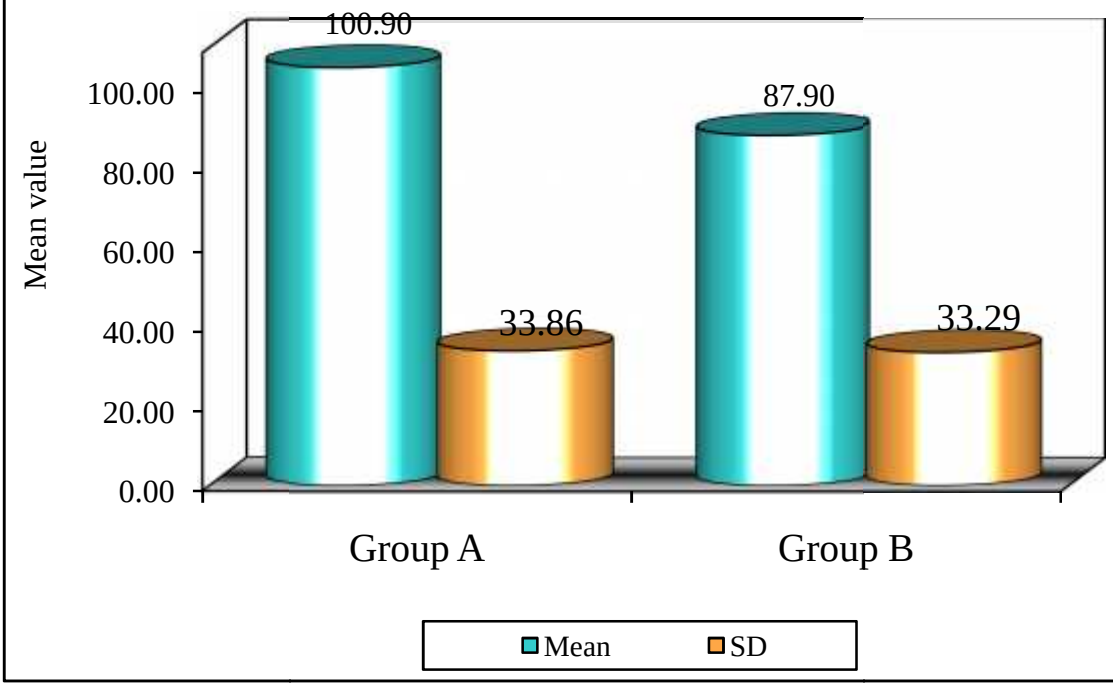
In the present study, the incidence of SSI is equal in both the groups i.e. 3%, which is considered statistically insignificant (p=1.0)

Table 7: Comparison of group A and group B with mean duration (in minutes) by t test

Groups	n	Mean	SD	SE	t-value	P-value
Group A	50	10.90	33.86	4.79		
Group B	50	7.90	33.29	4.71	2.5316	0.0129*

*p<0.05

Figure 7: Comparison of group A and group B with mean duration (in minutes)



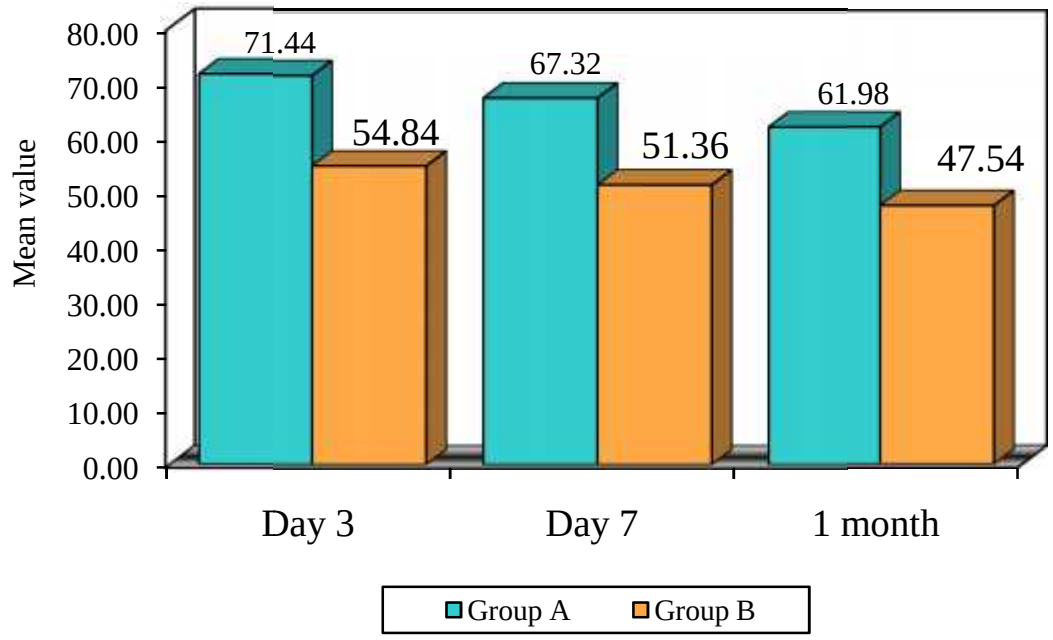
In the present study, the mean duration in minutes from time of incision to wound closure was compared, which shows it takes a mean time of 100.90 minutes in group A compared to 87.90 minutes in group B, which shows a 5% level of significance (p<0.05).

Table 8: Comparison of Group A and Group B with mean POSAS scores at different time points by t test

Time points	Group A		Group B		t-value	P-value
	Mean	Std.Dev.	Mean	Std.Dev.		
Day 3	71.44	7.51	54.84	12.81	7.9031	0.0001*
Day 7	67.32	8.11	51.36	13.01	7.3620	0.0001*
1 month	61.98	7.63	47.54	13.34	6.6456	0.0001*
Day 3 to Day 7	4.12	3.19	3.48	4.72	0.7950	0.4285
Day 3 to 1 month	9.46	5.21	7.30	6.14	1.8969	0.0608
Day 7 to 1 month	5.34	4.12	3.82	4.07	1.8564	0.0664

*p<0.05

Figure 8: Comparison of Group A and Group B with mean POSAS scores at different time points



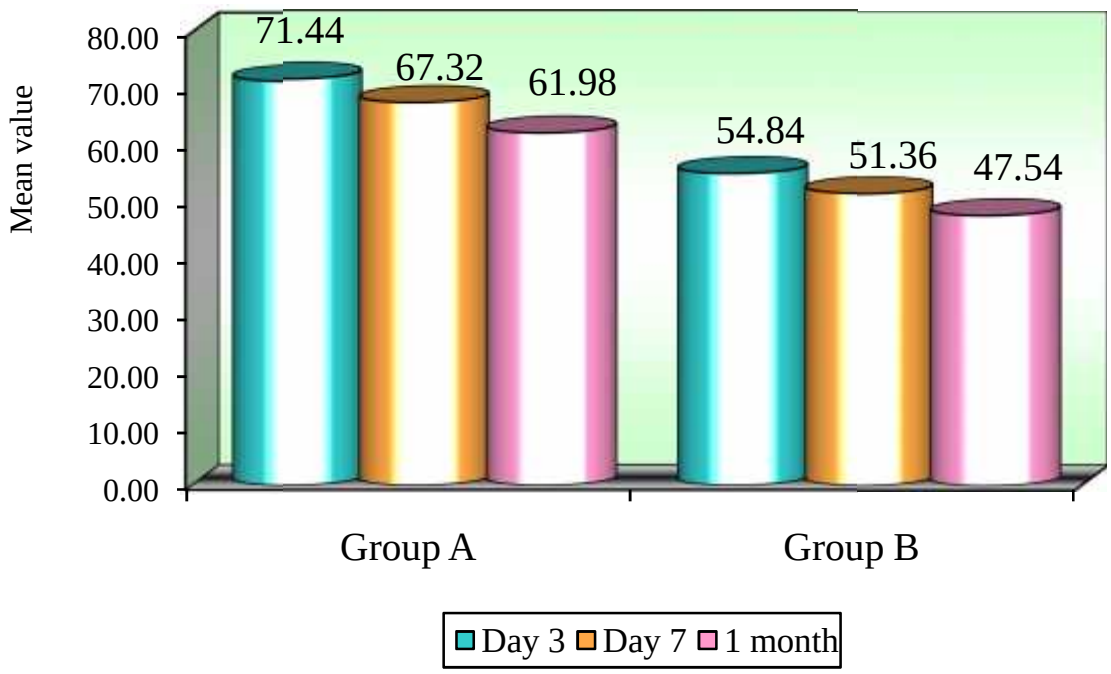
From the results from the above table, POSAS score obtained at different times, POD#3 mean is 71.44 ± 7.51 in group A v/s 54.84 ±12.81 in group B, whereas mean score on POD#7 is 67.32 ± 8.11 v/s 51.36 ± 13.01 between group A and group B and 61.98 ± 7.63 v/s 47.54± 13.34 on 1 month follow up between group A and group B. The results are statistically significant (P<0.05).

Table 9: Comparison of dya3, day 7 and 1 month time points with mean POSAS scores in group A and group B by Dependent t test

Groups	Time points	Mean	Std.Dv.	Mean Diff.	SD Diff.	% of change	t-value	p-value
Group A	Day 3	71.44	7.51					
	Day 7	67.32	8.11	4.12	3.19	5.77	9.1449	0.0001*
	Day 3	71.44	7.51					
	1month	61.98	7.63	9.46	5.21	13.24	12.8471	0.0001*
	Day 7	67.32	8.11					
	1 month	61.98	7.63	5.34	4.12	7.93	9.1678	0.0001*
Group B	Day 3	54.84	12.81					
	Day 7	51.36	13.01	3.48	4.72	6.35	5.2162	0.0001*
	Day 3	54.84	12.81					
	1 month	47.54	13.34	7.30	6.14	13.31	8.4042	0.0001*
	Day 7	51.36	13.01					
	1 month	47.54	13.34	3.82	4.07	7.44	6.6380	0.0001*

*$p<0.05$

Figure 9: Comparison of dya3, day 7 and 1 month time points with mean POSAS scores in group a and group B



The mean POSAS scores on day 3, day 7 and 1 month post operative (71.44± 7.51, 67.32± 8.11 and 61.98± 7.63) in Group A (periumbilical incision) was significantly higher than those seen on postoperative day 3, day 7 and 1 month (54.84± 12.81, 51.36± 13.01 and 47.54± 13.34 respectively) in Group B (transumbilical incision).The percentage of change in the POSAS score from day 3 to day 7 was slightly higher in Group B (6.35%) than Group A (5.77%). The percentage change from day 3 to 1 month postoperative was almost similar in both Group A and B (13.24% and 13.31%). However, patients in Group B with an intraumbilical incision started with a significantly lower POSAS score on day 3.

From the results from the above table, it is noted that at different points of time, the difference between POSAS score between the two incisions is statistically significant.

DISCUSSION

In day-to-day practice, laparoscopy surgeries are replacing the open surgeries, gaining of intraperitoneal access is the initial step for which various sites of entry such as umbilicus. Palmar's point, Lee–huang point, Jain point can be used. Umbilicus is the preferred site for first trocar entry. Generally two types of incisions are taken i.e. periumbilical and transumbilical incisions. Although several studies conducted earlier quote that transumbilical incision has better patient cosmetic satisfaction compared to periumbilical incision, most surgeons prefer periumbilical incision due to concerns regarding complications like wound infection or umbilical hernia. Studies conducted to compare the postoperative complications in transumbilical and periumbilical incisions have shown comparable results in both groups. However a cosmetic superiority is seen in often seen in patients undergoing a transumbilical incision. In our study, we aimed to compare the cosmetic appearance of the two incisions and incidence of several postoperative complications like pain, surgical site infection, and umbilical hernia.

The mean ages of group A and B were comparable 34.60±12.22 years and 33.16 ± 14.73 years respectively. This nullified the age factor bias that can occur in wound healing and thus form an important parameter in cosmesis of a wound.

A periumbilical incision was more commonly taken in females. Almost two thirds (66%) of Group A patients were females. Since umbilical hernia is more commonly seen in females, with a female to make ratio of 3:1, this could be an important cause for the surgeons' choice of a periumbilical incision (which is believed to cause lesser complications) in females.

A supraumbilical incision was preferred in surgeries involving the gallbladder. This was due to a lesser working distance attained with such an incision.

As seen in most other studies comparing periumbilical and intraumbilical incisions, in our study the surgical site infection rate was same. 3 (6%) patients developed a surgical site infection in both Group A and Group B. This finding counteracts the common notion amongst many surgeons with regards to higher risk of SSI in intraumbilical incisions.

The mean duration of surgery in patients undergoing a periumbilical incision (104.90 minutes) was seen to be significantly higher than those with a transumbilical incision (87.90 minutes). This could be an incidental finding in our study. Previous studies have shown a lesser working time in cases of intraumbilical incisions. However, in our case, surgeon's expertise can act as a confounding factor.

The POSAS (Patient and Observer Scar Assessment Scale) assessed the scar on day 3, day 7 and 1-month post surgery. The observer component included six parameters of scars: vascularity, pigmentation, thickness, relief, pliability and surface area. The patient component consisted to six parameters: scarrelated pain, itchiness, colour, stiffness, thickness and irregularity.

The mean POSAS scores on day 3, day 7 and 1 month post operative (71.44± 7.51, 67.32± 8.11 and 61.98± 7.63) in Group A (periumbilical incision) was significantly higher than those seen on postoperative day 3, day 7 and 1 month (54.84± 12.81, 51.36± 13.01 and 47.54± 13.34 respectively) in Group B (transumbilical incision). These findings were consistent with most studies trying to compare incision characteristics.

The percentage of change in the POSAS score from day 3 to day 7 was slightly higher in Group B (6.35%) than Group A (5.77%). The percentage change from day 3 to 1 month postoperative was almost similar in both Group A and B (13.24% and 13.31%). However, patients in Group B with an intraumbilical incision started with a significantly lower POSAS score on day 3. This signifies a similar healing rate in both the types of incisions and hence no one incision heals faster than the other when other parameters are normalised.

Audrey Bouffard- Cloutier, Alex Pare and Nathalie McFadden[14], Canada in their study "they have measured the patient cosmetic satisfaction score, incidence of surgical site infection and the operative time as primary outcomes and the value given by the patient to aesthetic appearance of umbilicus. CSS was evaluated using inverted 10 points facial grimace-type scale, obtained on 30days post-op and 180 days post-op and incidence of Surgical Site Infection was assessed by reviewing the 4-6 week postop attending surgeons evolution notes, operative time was extracted from patients electronic medical record. They included total of 63 patients, among which 56 patients produced analysable data and compared 27 in PUI group with 27 in TUI group. Results found in this study are comparable in both groups with regards to cosmetic satisfaction scores, incidence of surgical site infections and operative time. The 28% of patients who valued the appearance of their umbilicus prior to surgery has a significantly poor cosmetic satisfaction score (CSS) evolution. Preoperatively higher CSS was noticed to result in significant postoperative CSS decline." In the above study where they have used CSS, which is a subjective score, whereas in our study we have used POSAS scale which consists both objective and subjective evaluation that gives higher significant results.

Jun Suh Lee *et al*., [8], South Korea performed a retrospective study on 280 patients, among which 159 patients were treated with intraumbilical incision and 121 patients were treated with periumbilical incision were compared. Mainly, wound complication rates were compared along with operation time, postoperative hospital stay and cocluded that "There is no significant difference between postoperative complications between the two incisions." In our study also it is observed that pain scores as compared in POSAS scale were similar in both the groups and incidence of SSI is equal in both the groups.

The Canadian Task Force classification II-1[30] prospective study by Mehmet Baki Senturk et al. enrolled 105 patients undergoing laparoscopic surgery. They conducted the study to determine which of the umbilical entry routes for intraperitoneal access has a better cosmetic result. They have prospectively collected the data on demographics of patients, BMI, entry point of the trocars (infra-trans-supraumbilical), type of incision (vertical or transverse), duration of the operation, and scar properties at follow-ups and analysed. Scar assessment was performed at postoperative week 12 by another surgeon using Vancouver scar scale the healing of port entry site in the umbilical region, which includes assessment of vascularity, pigmentation, pliability, height, and cosmetic analysis was done. A total of 105 patients were included in the study with mean age of the patient 39.79 ± 11.99 yrs whereas in our study group with 100 patients with mean age is 34 ± 12.22. They observed that cosmetic results did not differ statistically between the patients with transumbilical, infraumbilical and supraumbilical incisions.

Nozaki et al.[43] showed that a U-shaped infraumbilical incision that is made traditionally along the umbilical ring and the standardized site for access to the

abdominal cavity for laparoscopy are well known; however, this type of incision leaves a more postoperative scar or umbilical deformity. Therefore, the umbilical depression had been everted, and the longitudinal skin incision of the umbilicus was made at the midline. The incision length was within the depression of the umbilicus. The scar receded into the umbilicus and was hardly visible. Our study also shows similar results with the above study; therefore considering transumbilical incison scar can be concealed within the umbilicus is preferred over periumbilical incision.

Kim et al.[42] preferred entry to the peritoneal cavity with supraumbilical incision, which they thought had better cosmetic results, based on the complaints of postoperative scars of female patients. The scar at the supraumbilical incision was found to be barely visible. Both patients and surgeons were satisfied with the cosmetic results of the supraumbilical entry, and the scar was integrated into the natural umbilical fold 3 months after surgery. In our study,periumbilical incision was taken in 60% of female patients, in terms with the above article, however the cosmetic score are higher in peiumbilical group compared to transumbilicus incision, may be due to fact that female patients give more importance to aesthetic appearance of umbilicus.

The position, shape, size, depth of umbilicus influence the overall aesthetics of the abdomen and the incisions around the umbilicus play a vital role in overall aesthetic outcome and patient satisfaction postop.Considering various shapes of the umbilicus, surgeon can decide which type of incision can be taken, which gives a better cosmetic scar postop and also based on the incidence of postop complications[45].Various post op complications such as surgical site infection, wound dehiscence, umbilical hernia may affect the overall cosmetic outcome.Early studies have proved that there is no significant difference between incidences of postop

complications in either group, therefore this study was aimed to compare better cosmetic outcome between the two groups.

It is also to be kept in mind that type of suture material, skin staples and type of sutures put like vertical mattress, inverted mattress, subcuticular, glue used in the approximation may affect the cosmetic outcome and proper wound healing. In our study it is mentioned that all cases skin approximation done using vertical mattress suture with 3-0 Ethilon.Earlier studies showed that no difference in cosmetic outcome with various suture materials used to the periumbilical incision.

Sinha used all three techniques and found that the transumbilical incision, rather than a supra or infraumbilical incision, has a better cosmetic scar and a nearly normal-looking umbilicus[46]. Transumbilical camera port insertion leaves no scar, but it has higher complication rates. Many pediatric surgeons use supraumbilical or infraumbilical port incision owing to complications following transumbilical insertion, such as wound site infection or trocar site hernia[47]. According to our study transumbilical incision has better cosmetic outcome compared to other techniques with postoperative complications.

Study conducted by Akhila Vasudeva, Vidyashree G Poojari, Shanthala Rudrappa, Jyothi Shetty[21] mentioned “even though hypothetically subcuticular suture has better wound healing, objectively when assessed the wound with variables like induration,erythema,discharge,incidence of surgical site infections, they were equally distributed among the two groups” In this study in order to avoid confounding factors like type of suture material, length of incision, surgeons expertise, type of skin sutures, all patients in group A are operated by a single surgeon and another surgeon

operated all group B patients. In all the cases same suture material is used i.e. 3-0 Ethilon and also in all cases intermittent mattress sutures were placed.

Considering several factors that affect the overall cosmetic outcome of the two incisions such as size of blade, length of the incision, type of suture material and type of sutures, all these factors are taken same for all the cases in both the groups. Earlier studies suggested that periumbilical incision results in poorer aesthetic outcome our study also correlates with the hypothesis but with similar outcomes.In our study it is shown that there is no significant difference with the incidence of post operative complications like surgical site infection, wound dehiscence, umbilical hernia, hypertrophic scar formation.

Therefore it can be concluded from our study that intraumbilical incision holds a cosmetic superiority over periumbilical incision. Since the complication rates and surgical site infection rates are similar in both the type a of incisions, intraumbilical should be preferred over periumbilical incision for enhanced patient satisfaction.

CONCLUSION

In conclusion, Transumbilical incision has better cosmetic satisfaction compared to Periumbilical incision. Although the majority of patients give little importance to the appearance of the umbilicus, the patients who gave importance to appearance of umbilicus preoperatively had poorer cosmetic satisfaction scores postoperatively.

Since the appearance of umbilicus is a major concern for a certain amount of patients undergoing laparoscopic surgery, surgeons should discuss with the patient prior to the surgery regarding the various types of incisions and its outcomes for better satisfaction.

SUMMARY

The present study aimed to compare better cosmetic outcome between trans umbilical and periumbilical laparoscopic primary port incision.

This one year cross-sectional study was done with the Department of Surgery,KLES Dr.Prabhakar Kore Hospital and Medical Research Centre, Belagavi from January 2019 to December 2019. A total of 100 patients posted for laparoscopic appendectomy and laparoscopic cholecystectomy were studied. POSAS score was analyzed to compare better cosmetic outcome between trans umbilical and periumbilical incision. Total of 100 patients with 50 patients in each group, were followed on POD# 3,7 and 1 month follow up POSAS Score were calculated. From POSAS score obtained at different times, POD#3 mean is 71.44 ± 7.51 in group A v/s 54.84 ±12.81 in group B, whereas mean score on POD#7 is 67.32 ± 8.11 v/s 51.36 ± 13.01 between group A and group B and 61.98 ± 7.63 v/s 47.54 ± 13.34 on 1 month follow up between group A and group B. The results are statistically significant ($P<0.05$). Between the two incisions during POD# 3 and 7 there is significant difference between variables such as induration, erythema, SSI. In our study 3 cases had SSI in both the groups.

In the present study, POSAS score was calculated from the data obtained during Post op day 3, 7, 1 month follow up. It was found that patients with transumbilical incision have better cosmetic score compared to periumbilical incision.

Therefore trans umbilical incision has better cosmetic outcome compared to periumbilical incision.

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ANNEXURE I. ETHICAL CLEARANCE

K.L.E. ACADEMY OF HIGHER EDUCATION AND RESEARCH
(Deemed – to- be- University)
Accredited 'A' Grade by NAAC (2nd Cycle) Placed in Category 'A' by MHRD (GoI)
JAWAHARLAL NEHRU MEDICAL COLLEGE,
NEHRU NAGAR, BELAGAVI-590010 (KARNATAKA-INDIA)
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Ref: MDC/DOME/81 **Date: 24/11/2018**

To.

REGNO. BH0118009
PG student in Surgery,
J.N.Medical College,
BELAGAVI.

Sub: Institutional Ethical Clearance for the study.

With reference to the above, we wish to inform you that your proposed research project titled **"A COMPARISON OF COSMETIC OUTCOME OF PERIUMBILICAL VERSUS INTRAUMBILICAL INCISION IN LAPAROSCOPIC APPENDECTOMY AND CHOLECYSTECTOMY – A ONE YEAR RANDOMISED CONTROLLED TRIAL"**, is ethical and justifiable. The proposed research project has been cleared by the JNMC Institutional Ethics Committee on Human Subjects Research.

(Dr. Arathi Darshan)
Member Secretary
JNMC Institutional Ethics Committee
on Human Subjects Research,
J.N.Medical College, Belagavi.

(Dr. Roopa M Bellad)
Chairman,
JNMC Institutional Ethics Committee
on Human Subjects Research,
J.N.Medical College, Belagavi.

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ANNEXURE -II

INFORMED CONSENT

CONSENT FOR PARTICIPATION IN RESEARCH STUDY

Mr/Mrs/Miss. _____ we are requesting you to enroll yourself in the study"A COMPARISON OF PERIUMBILICAL VERSUS INTRAUMBILICAL INCISION AND ITS COSMETIC EFFECT IN LAPAROSCOPIC APPENDECTOMY AND CHOLECYSTECTOMY: ONE YEAR RCT AT KAHER,BELAGAVI.'' conducted by **REGNO. BH0118009**Post Graduate in M.S. GENERAL SURGERY under the guidance of Dr., PROFESSOR, Department of GENERAL SURGERY, J.N. Medical College, Belagavi.

Respected Sir/Madam we request you to enroll yourself to participate in our study as you are eligible for participating in the study. During the study you will be asked some questions regarding your present complaint and you are supposed to answer to the best of your knowledge.Your participation in research is voluntary. Your decision to or not to participate in the study will not affect your relationship with J. N. Medical College. If you decide to participate you are free to withdraw at any time.

Procedure Involved: All patients received 1 dose of antibiotic intravenously at the time of induction of anesthesia. After surgery, patients were administered two or more further doses of antibiotics will be given.while giving intraumbilical incision, the umbilicus was cleaned thoroughly with cotton swabs, using alcohol. After routine manual evacuation of debris. After cleaning the umbilicus, skin preparation will be done in the usual manner using betadine.Base of the shape of the umbilicus whether it is vertical or horizontal the

incision was placed accordingly i.e.,vertical or horizontal.A single suture at the midpoint using absorbable suture material (Vicryl, Ethicon Inc., Somerville, NJ, USA) will be used for wound closure. This single suture allowed approximation of the layers, and essential closure of the skin. A piece of balled-up gauze was placed in the umbilicus, and an adhesive bandage was applied. In the periumbilical incision, a curved incision below or above the umbilicus is made.After opening of the fascia, either direct trocar insertion or insertion after insufflation with a Veress needle is done. After appendectomy, facial layers is closed and skin is closed. Voluntary participation / Withdrawal Taking part in the study is voluntary; you may choose not to enroll yourself in this study. Your decision will not change present or future health care services offered to you at Dr. PrabhakarKore Hospital. Alternatives Even if you decline the participation in the study, you will get the routine line of management.

Confidentiality

All information collected about you during the study will be kept confidential. The code numbers will identify you in this study records and the information from this study may be published but your identity will be confidential in any publication. The only people to know that you are a research subject are members of the research team. No information about you or information provided by you during the research will be disclosed to other without your written permission except:

- In emergency to protect your rights and welfare.
- If required by law.

Authorization to Publish Results: When the results of the research are published or discussed, in a conference, no information will be displayed that would disclose your identity. Any information that is obtained in connection with this study and that can be identified with you will remain confidential.

Financial Incentives for participation No financial incentives are being offered to enrolled patients. It is purely being done with the idea of research.

Compensation In the event of injury, related to the study, treatment will be made available at Dr. Prabhakar Kore Hospital and MRC, Belagavi. No reimbursement, compensation or free medical care will be given by law.

Queries/ Contact details

In case you have any questions related to the study, in future or in case of study related injury or illness, you can contact **REGNO. BH0118009**Post Graduate student, Department of GENERAL SURGERY, JNM College, KLES Hospital and MRC, or Dr._____,Professor, Dept. of General Surgery, JNM College, KLES Hospital and MRC.

If you have any queries about your right as a study subject, you may call Dr. Roopa Bellad, Professor of Paediatrics as Chairman of J. N. Medical College Institutional Ethics Committee on Human SubjectsResearch at J.N. Medical College, Belagavi

CONSENT FOR PARTICIPATION IN RESEARCH TRIAL

I, _____ voluntarily agree toparticipate as a subject for the study. By signing this consent form I am not giving up any of my legal rights, I may withdraw myself from the study anytime. I am signing the consent form after having read or been read form in my own vernacular language, including the risks and the benefits and having all my questions answered.

Subject Name: _____

Signature or the Left Thumb Print :_____

Date: _____

Witness Name : _____

Signature:_____ Date:

Investigators Name: _____

Signature:_____

Date:_____ Place:_____

PROFORMA

PROFORMA / QUESTIONNAIRE TO BE USED FOR DATA COLLECION

The proposed proforma / questionnaire to be used for data collection for the study titled "A COMPARISON OF PERIUMBILICAL VERSUS INTRAUMBILICAL INCISION AND ITS COSMETIC EFFECT IN LAPAROSCOPIC APPENDECTOMY AND CHOLECYSTECTOMY: ONE YEAR RCT AT KAHER,BELAGAVI." **is as:**

Group:

Name: IP no.:

Sex:Age:

Address: Religion:

Education: Date of admission:

Occupation: Date of discharge:

CHIEF COMPLAINTS:

HISTORY OF PRESENTING COMPLAINTS:

PAST HISTORY:

PERSONAL HISTORY:

FAMILY HISTORY:

GENERAL PHYSICAL EXAMINATION:

Built and Nourishment:

Weight:

Pallor / Icterus / Cyanosis / Clubbing / Edema / Lymphadenopathy

Vital Signs: PR: /min; BP: mmHg; RR: /min; Febrile/Afebrile

SYSTEMIC EXAMINATION:

Abdomen:

Inspection:

Palpation:

Percussion:

Auscultation:

Cardio Vascular System:

Respiratory System:

CLINICAL IMPRESSION:

INVESTIGATIONS:

Hb: Total Leucocyte Count: Platelet count:

Random blood sugar :

Blood Group:

Blood urea: Sr. Creatinine:

PT/INR:

Urine routine and microscopy:

HIV: HBsAg:

ECG:

Chest Xray:

USG-Abdomen and Pelvis:

OPERATION DETAILS:

Date of Surgery:

Anesthesia: General Anesthesia

Duration of Surgery:

Observer Scar Assessment Scale

	Normal skin	1	2	3	4	5	6	7	8	9	10	*Worst scar imaginable*
Vascularity		o	o	o	o	o	o	o	o	o	o	
Pigmentation		o	o	o	o	o	o	o	o	o	o	Hypo _ Mixed _ Hyper _
Thickness		o	o	o	o	o	o	o	o	o	o	
Relief		o	o	o	o	o	o	o	o	o	o	
Pliability		o	o	o	o	o	o	o	o	o	o	

Total score Observer Scar Scale :

Patient Scar Assessment Scale

	No, no complaints	1	2	3	4	5	6	7	8	9	10	*Yes, worst imaginable*
Is the scar painful?		o	o	o	o	o	o	o	o	o	o	
Is the scar itching?		o	o	o	o	o	o	o	o	o	o	
	No, as normal skin	1	2	3	4	5	6	7	8	9	10	*Yes, very different*
Is the color of the scar different?		o	o	o	o	o	o	o	o	o	o	
Is the scar more stiff?		o	o	o	o	o	o	o	o	o	o	
Is the thickness of the scar different?		o	o	o	o	o	o	o	o	o	o	
Is the scar irregular?		o	o	o	o	o	o	o	o	o	o	

Total score Patient Scar Scale :

POSAS SCAR ASSESSMEN SCALE

A, Appearance of wound on post op day 3 in group A

B, Appearance of wound on post op day 7 in group A

C,Appearance of wound on post op day 3 in group B

D,Appearance of wound on post op day 30 in group B

Appearance of wound on immediate postop of a patient who underwent transumbilical incision for laparoscopic appendectomy

A,B, Appearance of wound on post op day 3 in group A

S.NO	IP NO	AGE	SEX	DIAGNOSIS	GROUP	NATURE OF OPERATION	TYPE OF INCISION	DURATION OF SURGERY	POD 3	POD 7	1 MONTH	SSI
1	934764	18 Y	F	ACUTE APPENDICITIS	GROUP A	LAPAROSCOPIC APPENDICECTOMY	INFRA UMBLICAL	75 MIN	69	68	57	N
2	932414	34 Y	M	CHOLELITHIASIS	GROUP A	LAPAROSCOPIC CHOLECYSTECTOMY	SUPRA UMBILICAL	75 MIN	68	66	62	N
3	935066	40 Y	F	CHOLELITHIASIS	GROUP A	LAPAROSCOPIC CHOLECYSTECTOMY	SUPRA UMBILICAL	80 MIN	73	72	65	N
4	931635	34 Y	F	CHOLELITHIASIS	GROUP A	LAPAROSCOPIC CHOLECYSTECTOMY	SUPRA UMBILICAL	135 MIN	76	72	68	N
5	933694	22 Y	M	ACUTE APPENDICITIS	GROUP A	LAPAROSCOPIC APPENDICECTOMY	INFRA UMBLICAL	90 MIN	72	65	65	N
6	921917	23 Y	M	ACUTE APPENDICITIS	GROUP A	LAPAROSCOPIC APPENDICECTOMY	INFRA UMBLICAL	90 MIN	65	62	61	N
7	923529	42 Y	M	CHOLELITHIASIS	GROUP A	LAPAROSCOPIC CHOLECYSTECTOMY	SUPRA UMBILICAL	150 MIN	64	62	59	N
8	921728	30 Y	F	ACUTE APPENDICITIS	GROUP A	LAPAROSCOPIC APPENDICECTOMY	INFRA UMBLICAL	105 MIN	68	65	64	N
9	991978	34 Y	M	CHOLELITHIASIS	GROUP A	LAPAROSCOPIC CHOLECYSTECTOMY	SUPRA UMBILICAL	105 MIN	66	62	58	N
10	922338	32 Y	F	CHOLELITHIASIS	GROUP A	LAPAROSCOPIC CHOLECYSTECTOMY	SUPRA UMBILICAL	160 MIN	65	64	62	N
11	928279	43 Y	F	CHOLELITHIASIS	GROUP A	LAPAROSCOPIC CHOLECYSTECTOMY	SUPRA UMBILICAL	135 MIN	75	73	70	N
12	923722	45 Y	F	CHOLELITHIASIS	GROUP A	LAPAROSCOPIC CHOLECYSTECTOMY	SUPRA UMBILICAL	150 MIN	73	67	62	Y
13	931168	45 Y	F	CHOLELITHIASIS	GROUP A	LAPAROSCOPIC CHOLECYSTECTOMY	SUPRA UMBILICAL	90 MIN	72	74	73	N
14	987300	34 Y	F	CALCULOUS CHOLECYSTITIS	GROUP A	LAPAROSCOPIC CHOLECYSTECTOMY	SUPRA UMBILICAL	120 MIN	77	72	67	N
15	940660	61 Y	F	CHOLELITHIASIS	GROUP A	LAPAROSCOPIC CHOLECYSTECTOMY	SUPRA UMBILICAL	150 MIN	75	72	69	N

16	977581	26 Y	F	ACUTE APPENDICITIS	GROUP A	LAPAROSCOPIC APPENDICECTOMY	INFRA UMBLICAL	60 MIN	54	52	53	N
17	926337	24 Y	F	CHOLELITHIASIS	GROUP A	LAPAROSCOPIC CHOLECYSTECTOMY	SUPRA UMBILICAL	150 MIN	80	78	74	N
18	936443	45 Y	F	ACUTE APPENDICITIS	GROUP A	LAPAROSCOPIC APPENDICECTOMY	INFRA UMBLICAL	70 MIN	79	77	75	N
19	936791	28 Y	F	ACUTE APPENDICITIS	GROUP A	LAPAROSCOPIC APPENDICECTOMY	INFRA UMBLICAL	60 MIN	58	55	52	N
20	929245	45 Y	M	CHOLELITHIASIS	GROUP A	LAPAROSCOPIC CHOLECYSTECTOMY	SUPRA UMBILICAL	90 MIN	76	73	65	N
21	932953	22 Y	M	ACUTE APPENDICITIS	GROUP A	LAPAROSCOPIC APPENDICECTOMY	INFRA UMBLICAL	95 MIN	65	63	61	N
22	931073	33 Y	M	ACUTE APPENDICITIS	GROUP A	LAPAROSCOPIC APPENDICECTOMY	INFRA UMBLICAL	80 MIN	74	77	72	N
23	977227	21 Y	F	CHRONIC APPENDICITIS	GROUP A	LAPAROSCOPIC APPENDICECTOMY	INFRA UMBLICAL	60 MIN	65	56	53	N
24	933315	25 Y	F	ACUTE APPENDICITIS	GROUP A	LAPAROSCOPIC APPENDICECTOMY	INFRA UMBLICAL	75 MIN	78	69	62	N
25	924418	60 Y	F	CHOLELITHIASIS	GROUP A	LAPAROSCOPIC CHOLECYSTECTOMY	SUPRA UMBILICAL	160 MIN	82	78	77	N
26	923756	23 Y	F	ACUTE APPENDICITIS	GROUP A	LAPAROSCOPIC APPENDICECTOMY	INFRA UMBLICAL	75 MIN	85	82	62	N
27	940471	35 Y	M	ACUTE APPENDICITIS	GROUP A	LAPAROSCOPIC APPENDICECTOMY	INFRA UMBLICAL	75 MIN	65	63	64	N
28	976957	36 Y	F	CALCULOUS CHOLECYSTITIS	GROUP A	LAPAROSCOPIC CHOLECYSTECTOMY	SUPRA UMBILICAL	90 MIN	89	82	75	N
29	933510	19 Y	M	ACUTE APPENDICITIS	GROUP A	LAPAROSCOPIC APPENDICECTOMY	INFRA UMBLICAL	70 MIN	76	72	65	N
30	931063	52 Y	M	ACUTE APPENDICITIS	GROUP A	LAPAROSCOPIC APPENDICECTOMY	INFRA UMBLICAL	80 MIN	65	63	54	N
31	919966	27 Y	F	ACUTE APPENDICITIS	GROUP A	LAPAROSCOPIC APPENDICECTOMY	INFRA UMBLICAL	105 MIN	62	54	45	N

32	927318	18 Y	F	CALCULOUS CHOLECYSTITIS	GROUP A	LAPAROSCOPIC CHOLECYSTECTOMY	SUPRA UMBILICAL	160 MIN	66	56	53	N
33	980065	42 Y	F	ACUTE APPENDICITIS	GROUP A	LAPAROSCOPIC APPENDICECTOMY	INFRA UMBLICAL	70 MIN	65	63	56	N
34	981476	21 Y	F	ACUTE APPENDICITIS	GROUP A	LAPAROSCOPIC APPENDICECTOMY	INFRA UMBLICAL	70 MIN	73	69	53	N
35	933609	42 Y	F	ACUTE APPENDICITIS	GROUP A	LAPAROSCOPIC APPENDICECTOMY	INFRA UMBLICAL	90 MIN	63	61	54	N
36	923600	63 Y	M	CALCULOUS CHOLECYSTITIS	GROUP A	LAPAROSCOPIC CHOLECYSTECTOMY	SUPRA UMBILICAL	150 MIN	76	65	62	Y
37	932596	50 Y	F	ACUTE APPENDICITIS	GROUP A	LAPAROSCOPIC APPENDICECTOMY	INFRA UMBLICAL	180 MIN	82	75	64	N
38	938304	23 Y	F	CALCULOUS CHOLECYSTITIS	GROUP A	LAPAROSCOPIC CHOLECYSTECTOMY	SUPRA UMBILICAL	130MIN	67	59	57	N
39	983258	34 Y	M	ACUTE APPENDICITIS	GROUP A	LAPAROSCOPIC APPENDICECTOMY	INFRA UMBLICAL	70 MIN	89	85	75	N
40	936650	40 Y	F	ACUTE APPENDICITIS	GROUP A	LAPAROSCOPIC APPENDICECTOMY	INFRA UMBLICAL	120 MIN	76	74	65	N
41	922640	61 Y	M	CALCULOUS CHOLECYSTITIS	GROUP A	LAPAROSCOPIC CHOLECYSTECTOMY	SUPRA UMBILICAL	150 MIN	76	72	64	N
42	920335	29 Y	F	ACUTE APPENDICITIS	GROUP A	LAPAROSCOPIC APPENDICECTOMY	INFRA UMBLICAL	120 MIN	65	62	54	N
43	926402	36 Y	F	CHOLELITHIASIS	GROUP A	LAPAROSCOPIC CHOLECYSTECTOMY	SUPRA UMBILICAL	90 MIN	65	53	51	N
44	935754	51 Y	F	CALCULOUS CHOLECYSTITIS	GROUP A	LAPAROSCOPIC CHOLECYSTECTOMY	SUPRA UMBILICAL	100 MIN	68	65	62	N
45	919867	30 Y	M	CALCULOUS CHOLECYSTITIS	GROUP A	LAPAROSCOPIC APPENDICECTOMY	SUPRA UMBILICAL	150 MIN	78	74	65	Y
46	930932	18 Y	M	ACUTE APPENDICITIS	GROUP A	LAPAROSCOPIC APPENDICECTOMY	INFRA UMBLICAL	70 MIN	67	64	61	N
47	934390	32 Y	F	CHOLELITHIASIS	GROUP A	LAPAROSCOPIC CHOLECYSTECTOMY	SUPRA UMBILICAL	90 MIN	76	74	65	N

48	931333	27 Y	F	CALCULOUS CHOLECYSTITIS	GROUP A	LAPAROSCOPIC CHOLECYSTECTOMY	SUPRA UMBILICAL	90 MIN	77	72	68	N
49	929652	19 Y	F	ACUTE APPENDICITIS	GROUP A	LAPAROSCOPIC APPENDICECTOMY	INFRA UMBLICAL	90 MIN	65	56	47	N
50	920718	36 Y	M	CALCULOUS CHOLECYSTITIS	GROUP A	LAPAROSCOPIC CHOLECYSTECTOMY	SUPRA UMBILICAL	150 MIN	67	57	52	N