Original Research Article

TRANSCUTANEOUS NYLON SUTURE VERSUS TRANSCUTANEOUS SKIN STAPLING FOR CLOSURE OF MIDLINE INCISION IN ELECTIVE ABDOMINAL SURGERY: ASSESSMENT OF SURGICAL SITE INFECTION AND COSMESIS IN A NIGRIAN TERTIARY HEALTH FACILITY.

ABSTRACT

Background: Wound closure is as important as any other procedure done by the surgeon. Skin staples are an alternate method to regular sutures in offering an aesthetically acceptable scar in abdominal surgeries.

Objectives: To compare the clinical outcome of staples versus nylon in skin closure of elective midline incision in laparotomy patients in terms of superficial surgical site infection and scar cosmesis.

Materials and method:This was a prospective comparative hospital-based study.Sixty - six patients who met the criteria were randomized into two equal groups.Group A had their incision closed with skin staples while Group B had their incision closed with nylon suture.The post operative outcomes of the wounds were documented.

Data collection and analysis:A proforma prepared for the purpose of this study was used to collect data. Data analysis was done using the SPSS 22 for windows SPSS Inc. Chicago Illinois.Calculations of mean and standard deviation were done.Associations

between variables were tested for statistical significance.For all statistical test $p<0.05$ was significant. Results were displayed using tables.

Results: There was no superficial surgical site infection in both groups, however scar cosmesis was better in the group Awith low mean POSAS total score than group B.

Conclusion: Scar cosmesis was close to normal in group A, with no superficial surgical site infection in elective midline laparotomy incision closure in both groups.

Key words: laparotomy, midline incision, nylon suture, skin stapler,

INTRODUCTION

Surgical site infection(SSI) is defined as infection occurring within 30 days of surgical procedure and involving the operative area.Where an implant has been used, the time period is extended to one year if the infection appears to be related to the procedure.[1]Surgical site infections are caused by microbial contamination of the surgical wound with dirty surgical wounds associated with a high rate of wound infection.[2]Post operative wound infections have a significant impact on health resources. The cost and sequelae of wound infections can result in significant long-term problems.[3]

SSIoccurs in up to 40% of surgical procedure requiring further surgical procedure.[4] It has an overall incidence of 2.5-20%.[1,4] The SSI annual incidence in America is 2-5% despite the improvement in surgical technique, advances in infection control practices, and a near universal practice of peri-operative antibiotic prophylaxis[5].According to WHO, the risk of SSI in developing countries is higher than in equivalent surgical procedures carried out in high-income countries.[6] This is especially so in sub-Saharan Africa. The cumulative SSI rate in Nigeria is 14.5%[7] and ranges from11-23.6% in the various parts of Nigeria.[7,8,9,10]

A system of classification for operative wounds based on the degree of microbial contamination was developed by the US National Research Council group in 1964.[11] Four wound classes with an increasing risk of surgical site infection were described. Class I (clean wound)is elective, non - traumatic cases, no acute inflammation, no break in aseptic technique, respiratory, gastrointestinal, biliary and genitourinary tracts not entered.Class II (Clean-Contaminated) wounds are emergency cases, that is otherwise clean, elective opening of respiratory gastrointestinal, biliary or genitourinary tract with minimal spillage.Class III (contaminated) wounds are non-purulent inflammation, gross spillage from gastrointestinal tract, entry into biliary or genitourinary tract in the presence of infected bile, major break in aseptic technique, penetrating trauma less than 4 hours old.Class IV (dirty infected) wounds are purulent inflammation (e.g. abscess), pre-operative perforation of respiratory, gastrointestinal, biliary or genitourinary tract, penetrating trauma of more than four hours old.[12]Infection rates in the four surgical classifications have been previously reported to range between 1-2% for clean wounds, 6-9% for clean-contaminated wounds, 13-20% for contaminated wounds and about 40% for dirty wounds.[13]

Laparotomy incisions can be classified as midline, transverse, oblique or paramedian incision.[14] Midline incision is a common access into the abdominal cavity, reasons being that it can be made rapidly and it causes minimal damage to muscle, nerves and blood supply of the abdominal wall. [14]

The method of skin closure has been implicated as an important risk factor for surgical site infection.[15]Historically, there were few surgical options for wound closure: catgut, silk,and cotton.There is now an ever-increasing array of wound closure devices. An example is the skin stapler. Stapling devices have been used for years in closure of

surgical incisions and have proven an efficient alternative to suture even for traumatic wounds.[16,17]

The advantages of stapler include rapid speed of closure, a decreased risk of infection as there is less chance of bacteria migration into the wound and also, the capillaries in the sub-cuticular layers are not damaged during placement of the staples[18,] improved wound edge eversion without strangulation of tissue and results in minimal cross hatch scarring,[19] and less foreign body reaction[14]. Staple closure also eliminates the risk that a health care provider will experience a needle prick injury which is particularly important in caring for patients with unknown medical histories. Several studies in favour of sutures have shown that they are used to obtain a meticulous wound closure with greatest tensile strength and lowest likelihood of dehiscence[20]. Wound closure by sutures have been shown to be better than staples in the context of being less painful[17], yielding a much-improved cosmetic result, being significantly cheaper[21], having lower rates of superficial wound complication[12], and not requiring a special device for its removal as one is required for staple removal. The work by Meiring and colleagues showed superiority in cosmetic outcome in favour of stapler over suture.[13] Skin staplers have recently become common place in the closure of surgical incisions.,[14,16,22]

The surgical scar as seen by human eyes remains the only evidence of the surgeon's skill and not infrequently, all of his efforts are judged on its final appearance.One of the lasting reminders of any abdominal surgery and most noticeable to the patient is the scar made by the incision.Various scar assessment scales are available.Some reviews showed that along with the Vancouver Scar Scale (VSS), which is deemed to be broadly used, the Patient and Observer Scar Assessment Scale (POSAS) has been used with the highest frequency, it was used in more than 70% of scar studies. Additionally in 2012, Nicholas

et al[23]noted that the POSAS was more suitable for scar assessment. ThePOSAS assesses vascularity, pigmentation, thickness, relief, pliability, and surface area, and it incorporates patient assessments of pain, itching, colour, stiffness, thickness, and relief.[24] The total score for each scale ranges from 6 (best that is similar to normal skin) to 60 (worse a scar very different from normal skin).

This study aimed to assess surgicalsite infection and cosmetic outcome in transcutaneous nylon suture versus transcutaneous skin stapling for closure of midline skin incision in elective abdominal surgery.

MATERIALS AND METHODS

This is a prospective study carried out on sixty-six patients,18 years and above who had elective laparotomy procedure in our tertiary health facility. All patients who consented to the study within the duration of the study with abdominal pathologies requiring elective exploratory laparotomy were recruited for this study. Patients who had traumatic abdominal wounds, incisions which require to be closed under tension, patients with uncontrolled co-morbidities, patients with previous laparotomies, patients with metastatic malignancy, patients that have a known predilection for keloids or hypertrophic scars, and patients with cognitive impairsment were excluded from the study.

Diagnosis was made clinically after detailed history taking, physical examination, and augmentation with abdominal ultrasound scan, plain abdominal x-rays while, electrolytes, and full blood count were done as indicated.

Ethical clearance approval was obtained from the hospital's ethical and research committee and a written informed consent was obtained from each of the patients

recruited into the study. Patients were given the free will to withdraw from the study at any time they decide to without any consequences.

The formula for calculating the minimum sample size for comparison groups when one wishes to test differences regarding a population between two populations or group (in this case comparing closure of abdominal incision using skin stapler and nylon suture) was used in determination of the sample size per study group.

The formula for calculating the minimum size for a comparative study was employed as shown below.

$n= 2Z^2 pq/d^2$ [90]

where n=number per group, Z=Standard normal deviate corresponding to level of significant at a confidence level of 95%, p= proportion of exploratory laparotomy out of all surgical cases presenting in our hospital in the preceding year =4.1%

q= Proportion or prevalence of non-surgical cases= 1-p,

d= desired level of precision which is 0.05.

An additional 10% was added to account for possible attrition

This was the minimum sample size per group A (transcutaneous skin stapler closure) and B (transcutaneous nylon closure) was 33.

A simple random sampling method was used to assign the participants to group A (transcutaneous skin stapler closure) and group B (transcutaneous nylon closure).

The patients were placed on the operating table, general anaesthesia with endotracheal intubation and muscle relaxants were administered.They were positioned supine on the operating table,administered intravenous ceftriaxone 1g at induction of anaesthesia.Skin

preparation was done using 5% povidone iodine painting from the nipple line to the mid-thigh. Sterile drapes were applied to cover the patient exposing the midline. The patients had either an upper or lowermidline incision depending on the pre-operativewas deepened with a monopolar diathermy through the subcutaneous tissue to expose the linea alba. The two edges were picked with Kockers forceps and incised using a monopolar diathermy to expose the peritoneum which was picked with two artery forceps and incised with a monopolar diathermy to expose the peritoneal cavity. The pre operative diagnosis was confirmed and the appropriate procedure carried out. The peritoneum was closed with vicryl 2-0 continuous suturing, the linea alba was closed using nylon 1 continuous suturing, and the subcutaneous tissue closed using interrupted vicryl2-0 suturing. The skin was closed based on the randomization using nylon 2/0 or B/BRAUN Manipler 35 W skin stapler.

Post-operative pentazocine was administered intravenously at 1 mg/kg 6 hourly over 48 hours. Wound dressing was changed at post operative day 3 looking out for signs of wound infection. Thosein group B had their skin closed using nylon 2/0.

The nylon 2/0 suture and skin staples were removed aseptically on post-operative day 10 by a surgical ward nurse.Scar assessment was done atpost-operative day10 and90.

The primary outcome measure was scar cosmesis at post-operative day10 and90using the patient and observer scar assessment scale. This validated scar assessment tool was used to evaluate each patient's scar. Patients evaluated their scars using the patient scar assessment scale.The second outcome measure was assessment of wound infection within thepost-operative30 days period.

Statistical data was summarized using the statistical Package for Social Sciences (SPSS for Windows Version 22). Continuous data wereanalysed using two-sided student t-test and categorical data evaluated by means of Chi squared test.

RESULTS

A total of sixty-six patients who met the inclusion criteria were standardized into the groups (A and B). Group A had their wound closed with skin stapler while Group B had their wound closed with nylon suture. The age range of participants was 18-69 years with a mean age of 44.3 year. The sex and age distributions of the study participants is as shown in figure 1 and table 1 respectively.

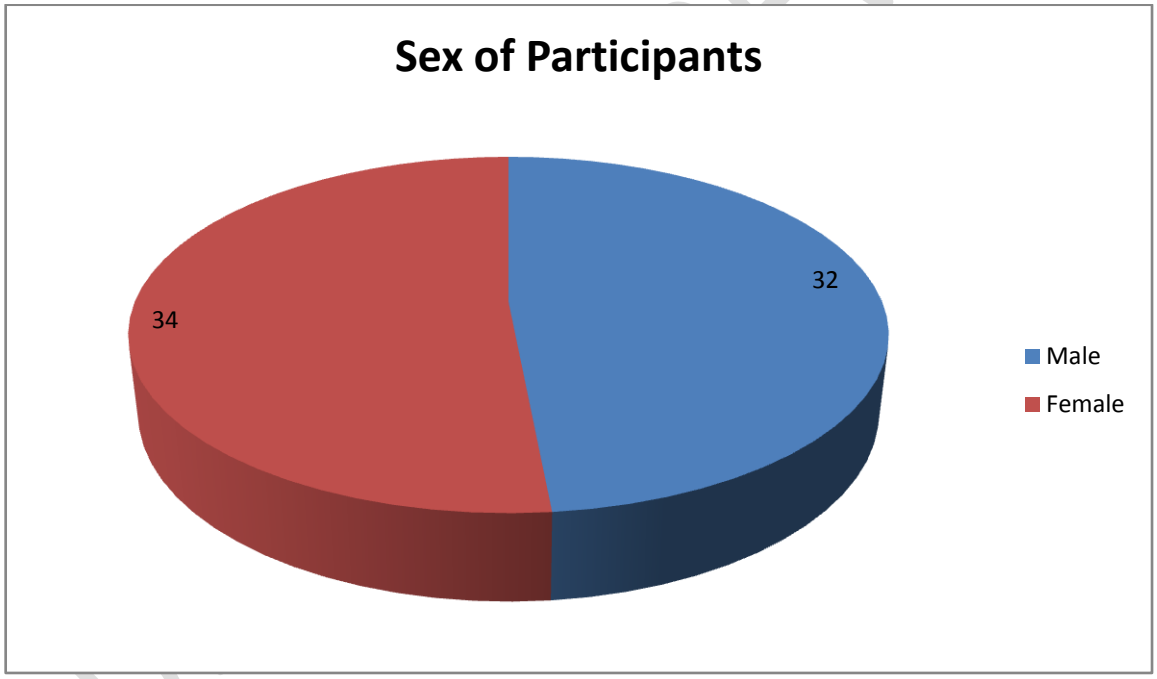

Figure 1: Sex of Participants

TABLE 1: Age Group of study participants.

Variables	**Stapler Group A N=33(%)**	**Nylon Group B N=33 (%)**	**Test Statistical Chi Square test (X^2)**	**p-value**
Age Group	Staple group	Nylon group	X^2test statistics	p-value
10-19	1 (30%)	0 (0.0%)		
20-29	7 (21.2%)	3 (9.1%)		
30-39	6 (18.2%)	8 (24.2%)	4.352	0.500
40-49	6 (18.2%)	10 (30.3%)		
50-59	7 (21.2%)	8 (24.2%)		
60-69	6 (18.2%)	4 (12.1%)		

There was no statistically significant difference in the wound parameters of the study participants in groups A and B (table 2).

TABLE 2: WOUND PARAMETERS ACROSS STUDY GROUPS

Variables	**Stapler Group A N=33(%)**	**Nylon Group B N=33 (%)**	**Test Statistical Chi Square test (X^2)**	**P-value**
Class of Wound				
Class 1	10 (30.3%)	15 (45.5%)	1.61	0.20

Class 2	23 (69.7%)	18 (54.5%)		
Type of incision				
Upper Midline	23 (69.7%)	23 (69.7)	0.0001	1.000
Lower Midline	10 (30.3%)	10 (69.7%)		

The duration of skin closure for the class of wound and type of abdominal incision for both groups are shown in table 3. There was a longer duration of skin closure with mean time of 8.33 ± 3.03 minutes for the group B when compared to the group A with 2.50 ± 0.53 minutes in class 1 wounds.In the class II wounds, duration of skin closure was also longer in group B with 12.00 ± 3.00 minutes compared to the group A with 4.34 ± 0.83 minutes.Those who had upper midline incision and had their wound closed with nylon had a mean time of 10.56 ± 3.65 minutes compared to the stapler group with a mean closure time of 4.08 ± 1.08 minutes.In the lower midline incision group, the duration of wound closure was longer for the nylon group/group B with mean closure time of 9.50 ± 3.31minutes when compared to stapler group/group A with a mean time of skin closure of 3.10 ± 0.99 minutes.

TABLE 3: Duration Of Skin Closure

Variables	**Stapler Group A (mean ±sd)**	**Nylon Group B (mean ±sd)**	**T-Test**	**p-Value**
Class 1	2.50 ± 0.53	8.33 ±3.03	35.60	< 0.0001*

Class 2	4.34 ± 0.83	12.00 ±3.06	131.60	< 0.0001*
Upper Midline incision	4.08 ±1.08	10.56 ±3.65	66.47	< 0.0001*
Lower Midline Incision	3.10 ±0.99	9.50 ±3.36	36.50	< 0.0001*
Total	3.79 ±1.14	10.33 ±3.53	102.60	< 0.0001*

Participants had a longer mean hospital stay for the group A compared to the group B in both classes of wound and type of abdominal wall incisions (table 4).

TABLE 4: Length of Hospital Stay (In days)

Variables	**Stapler GroupA (mean ±sd)**	**Nylon Group B (mean± sd**	**T-Test**	**P value**
Class 1	3.90 ± 0.99	4.53 ± 2.09	0.784	0.385
Class 2	9.43 ± 4.12	8.83 ± 1.75	0.334	0.556
Upper Midline incision	7.56 ± 4.09	7.13 ± 2.94	0.171	0.681
Lower Midline incision	8.20 ± 4.98	6.39 ± 2.79	1.106	0.307
Total	7.75 ± 4.31	6.87±2.88	0.947	0.334

Furthermore, as shown in table 5, the 10th day POSAS observer score was higher in the group B with 9.5 ± 2.33 in the class 1 wound when compared with the group A with POSAS observer scoreof 8.6 ± 1.96 in the same wound class.In the class 2 wound, the score was higher in the group B with 9.61 ± 2.11 as compared to the group A with score of 8.00 ± 1.31.

Participants who had upper midline incision had a mean POSAS observer score of 9.61 ± 2.43 in the nylon group/group B and the stapler group had a score of 8.17 ± 1.50.For those who had lower midline incision, the mean POSAS observer score in the nylon group was 9.50 ± 1.58 compared to the stapler group with a score of 8.20 ± 1.69.

TABLE 5: 10TH DAY POSAS/OBSERVER SCORE

Variables	**Stapler Group A (mean ±sd)**	**Nylon Group B (mean± sd**	**T-Test**	**P value**
Class 1	86 ± 1.96	9.5 ± 2.33	1.09	0.307
Class 2	8.00± 1.31	9.61 ±2.11	8.95	0.005 *
Upper Midline incision	8.17±1.50	9.61±2.43	5.83	0.020*
Lower Midline incision	8.20±1.69	9.50±1.58	3.16	0.092
Total	8.18±1.53	9.58±2.18	9.04	0.004*

10TH DAY POSAS PATIENT SCORE

The 10th day POSAS Patient score was higher in the group B with 14.20 ± 2.40 in the class 1 wound when compared with the group A 8.30 ± 1.83 in the same wound class.

In the class 2 wound the score was higher in the group B with 15.33 ± 2.57 as compared to the group A with score of 9.22 ± 2.11.

Participants who had upper midline incision had a mean POSAS Patient score in the nylon group of 14.48 ± 2.15 and the stapler group had a score of 8.30 ± 1.83.

For those who had lower midline incision, the mean POSAS Patient score in the nylon group was 15.60 ± 3.20 as compared to the stapler group with score of 8.60 ± 3.65.

TABLE 6: 10TH DAY POSAS/PATIENT SCORE

Variables	**Stapler Group A (mean ±sd)**	**Nylon Group B (mean± sd**	**T-Test**	**P value**
Class 1	8.30 ± 1.83	14.20 ± 2.40	43.47	0.0001
Class 2	9.22± 2.11	15.33±2.57	70.17	0.0001
Upper Midline incision	9.09±2.21	14.48±2.15	70.18	0.0001
Lower Midline incision	8.60±1.65	15.60±3.20	37.76	0.0001
Total	8.94±2.05	14.82±2.52	108.36	0.0001

The 10th day POSAS Total score was higher in the group B with 23.73 ± 4.27 in the class 1 wound when compared with the group A 16.90 ± 3.64 in the same wound class.

In the class 2 wound the score was higher in the group B with 24.94 ± 2.71 as compared to the group A with score of 17.61 ± 3.12.

Participants who had upper midline incision had a mean POSAS Total score in the nylon group of 24.09 ± 3.62 and the stapler group had a score of 17.26 ± 2.41.

For those who had lower midline incision, the mean POSAS Total score in the nylon group was 25.10 ± 3.28 as compared to the stapler group with score of 16.80 ± 2.90.

TABLE 7: 10TH DAY POSAS TOTAL SCORE

Variables	**Stapler Group A (mean ±sd)**	**Nylon Group B (mean± sd**	**T-Test**	**p-value**
Class 1	16.90± 3.64	23.73 ± 4.27	17.24	< 0.0001*
Class 2	17.22±3.12	24.94±2.71	69.39	< 0.0001*
Upper Midline incision	17.26±2.41	24.09±3.62	43.32	< 0.0001*
Lower Midline incision	16.80±2.90	25.10±3.28	35.94	< 0.0001*
Total	17.12±3.23	24.39±3.50	77.00	< 0.0001*

The 90-day POSAS score for group B and group A was 5.00 ± 0.0 for the POSAS observer score and 6.00 ± 0.0 for both in the POSAS patient score with a score of 11.00 ± 0.0 for both in the POSAS total score.

TABLE 8: 90TH DAY POSAS SCORE

Variables	Stapler Group A (mean ±sd)	Nylon Group B (mean± sd	T-Test	P value
Observer Score	5.00± 0.0	5.00± 0.0	0.0	0.0
Patient Score	6.00±0.0	6.00±0.0	0.0	0.0
Total Score	11.00±0.0	11.00±0.0	0.0	0.0

DISCUSSION

A total of sixty -six patients who had elective laparotomy were seen during the study period. Access in surgery is a major factor in laparotomy and the outcome of skin closure is vital to the patient. Stapling devices have been used for decades in wound closure of surgical incisions and have proven an efficient alternative to suture.[6]The advantages of skin stapler include rapid speed of closure, decreased risk of infection and improved cosmesis.

The mean closure time in this study was 4.3 minutes and 12 minutes for groupA and group B respectively. This was also seen in the work done byCochetti and colleagues.[25]Medina et al found in their work the mean skin closure time with stapler to be 5 minutes and 25 minutes with nylon suture.[26]

The time saving benefit of stapler might have a psychological effect on surgeons and theatre staff particularly after a long operation.This also limits the rate of cancellation of elective cases as the turn over time is shorter with stapler than nylon.

Wound cosmesis wasstatically significant for stapler group with lower mean POSAS total score compared to the nylon group.

This was also seen in the work by Meiring and colleague who showed superiority in cosmetic outcome in favour of stapler group.[13]A work done in USA by Kanagaye showed better cosmetic outcome with stapler.[27]Lavazzo et al however showed comparable outcome in both methods.[28]

Ronaboldo and Rowe-Jones[20]compared the results of staples with subcuticular absorbable suture for laparotomy wounds and divided them into lower and upper abdominal regions no mention was made by them regarding the appearance of the scar at various site. There was no significant benefit of staples over subcuticular sutures in their study.Dos Santos and colleagues[29] compared the cosmetic results of staples with nylon suture. They observed that the wounds closed with staples were cosmetically superior in 80% of cases. Therewere no studies available in the literature comparing the results of application of staples to various anatomic sites[26]

In the 90-day scar cosmesis assessment there was no statistical difference in both groups hence the cosmesis outcome was better in the early assessment of the wound. Cosmetically skin staples produce good wound eversion and have a minimal cross-hatch scar. Skin staples are relatively inert and can be left in situ for a longer period of time without any complication and in addition patients can take a bath in the early post operative period.

There were certain studies that out favoured staples in view of higher incidence of inflammation and spreading of the healing scar.[6,9,13,18]Furthermore, many studies favoured the use of staples for better cosmetic result. [13,20,25]

A meta-analysis comparing the use of staples versus suture for surgical procedures supported staples theoretically as it reduces the operative time, and reduction in the operative time has the potentials to reduce tissue handling and associated tissue injury.[18]

There was no infection rate in thisstudy aswas also noted in the work by Kanagaye et al, who studied forty –five paediatric cases and observed no complications in the staple group.[27] In the work done by Pickford[30] the infection rate was significantly lower in the stapler group than nylon 6.3% to 17%. There were higher rates of SSI in many parts of Nigeria and Africa.[7,8,9,10]The reason for nosuperficialSSI rate in this study may be connected with good patient selection and aseptic techniques.The number of people in the operating room during surgery affects the infection rate.This increase with increase in number of people.There is less chance of bacteria migration into the wound and also the capillaries in the sub-cuticular layers are not damaged during placement of the staples.[29]Periodic surveillance of bacteria and antibiotic susceptibility coupled with the implementation of strict protocol for antibiotic administration and operative room regulations are important to minimize the burden of surgical site infection with resistant bacteria pathogens.[31]

CONCLUSION

Several options are available to close laparotomy skin incision. A cosmetic scar gives satisfaction to the patient and surgeon alike. Preventing wound infection is as important as it can lead to ugly scar. From this study, skin staples significantly shortened the operative time, withno incidence of post operative wound infection, and provided better cosmesis. Skin staples should be used for elective and clean procedures.

Ethical approval

This study was approved by the Ethics and Research Committee of Irrua Specialist Teaching Hospital, Irrua, Edo State, Nigeria (ethical approval number: ISTH/HREC/20170926/24).

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