## EUROPEAN JOURNAL OF PHARMACEUTICAL AND MEDICAL RESEARCH

www.ejpmr.com

Research Article
ISSN 2394-3211
F.IPMR

# EVALUATION OF POST OPERATIVE PAIN AND COSMETIC OUTCOME BETWEEN SINGLE INCISION LAPAROSCOPIC APPENDECTOMY AND CONVENTIONAL THREE PORT LAPAROSCOPIC APPENDECTOMY: A RANDOMIZED CLINICAL TRIAL

### Dr. Rameshkumar Pandey<sup>1\*</sup>, Bhupendra Mehra<sup>2</sup> and Robert Keisham<sup>3</sup>

<sup>1</sup>Department of Surgery, Mahatma Gandhi Institute of Medical Sciences, Sevagram, Wardha, Maharashtra, India.

<sup>2</sup>Professor, Department of Surgery, Mahatma Gandhi Institute of Medical Sciences, Sevagram, Wardha, Maharashtra, India.

<sup>3</sup>Registrar, Department of Surgery, Mahatma Gandhi Institute of Medical Sciences, Sevagram, Wardha, Maharashtra, India.

\*Correspondence for Author: Dr. Rameshkumar Pandey

Department of Surgery, Mahatma Gandhi Institute of Medical Sciences, Sevagram, Wardha, Maharashtra, India.

Article Received on 29/01/2016

Article Revised on 22/02/2016

Article Accepted on 15/03/2016

#### **ABSTRACT**

BACKGROUND: Laparoscopic appendectomy is now considered the gold standard for appendicitis, even in complicated appendicitis. The recent trend of Trans-umbilical single incision laparoscopic appendectomy (SILA) is a further improvement of the conventional three port laparoscopic appendectomy (CLA). In this study we compared the postoperative outcomes of SILA with CLA in a tertiary care hospital located in central India. METHODS: In this randomized controlled trial, 60 patients of appendicitis were operated between Dec 2013 and Oct 2015. 30 patients underwent SILA and the remaining 30 underwent CLA. From the two groups, we compared the postoperative pain and the cosmetic outcomes between the two procedures. Post operative pain scores were recorded on the visual analogue scale (VAS) 24 hours and 7 days after surgery. Cosmetic outcome was evaluated using a body image questionnaire consisting of a body image score and a cosmetic score on the 7<sup>th</sup> and 30<sup>th</sup> postoperative days. RESULT: There were no significant difference in the post operative pain between SILA group and CLA group 24 hours after surgery (VAS 3.13± 0.34 v/s 3.10±0.30, p=0.69) and 7 days after surgery (VAS 2.03±0.12 v/s 2±0.00, p=0.321). However, the cosmetic outcome was in favor of the SILA group over the CLA group on both postoperative day 7 [(Body image score 5.13±0.43 v/s 5.93±0.58, p<0.01), (Cosmetic score 22.20±1.24 v/s 21±0.26, p<0.01)] and on follow up after 30 days [(Body image score 5.00±0.00 v/s 5.83±0.64, p<0.01), (Cosmetic score  $23.53\pm0.73$  v/s  $21.10\pm0.71$ , p<0.01)]. **CONCLUSION**: There is a distinct cosmetic advantage of SILA over CLA. There is no statistical difference in pain scores in immediate postoperative period or later.

**KEYWORDS**: Appendicitis, Laparoscopic appendicectomy, Single incision, SILS port, postoperative pain.

**ABBREVATIONS**: SILS- Single Incision Laparoscopic Surgery, CLA- Conventional three port Laparoscopic Appendicectomy, VAS- Visual analogue scale.

#### INTRODUCTION

Appendicectomy is one of the commonly performed procedures in general surgical practice. Laparoscopic appendicectomy has increasingly gained acceptance as a more advantageous approach over conventional appendicectomy. [1,2]

With the continuing advances in laparoscopic surgery one of the recent innovations is the "Single Incision Laparoscopic Surgery". The fundamental difference of single port laparoscopic appendicectomy to conventional multiport laparoscopic appendicectomy is to place all the ports through a single umbilical incision. Incision at the umbilicus which has natural skin folds, with virtually no

subcutaneous tissue and a natural depression is virtually scarless.

Although Single Incision Laparoscopic Appendicectomy (SILA) is being carried out in India, less number of studies are available regarding the technical difficulties, postoperative pain and acceptability of scar which would affect the feasibility of SILA.

The present study was undertaken to evaluate the postoperative outcomes of the SILA against the conventional three port laparoscopic Appendicectomy (CLA).

#### MATERIAL AND METHODS

The study was carried out in a rural medical college hospital located in central India during the period December 2013 to October 2015.

All patients aged 16 years or more presenting to surgery opd or emergency department with at least one complaint suggestive of appendicitis i.e. right iliac fossa pain, vomiting and fever were selected for the study. Selected patients were sent for ultrasound evaluation, and those who reported positive for appendicitis and who were fit for anesthesia were recruited in this study. A written informed consent was obtained.

#### Inclusion Criteria

- 1. Adult male and females more than 16 years of age
- 2. Symptomatic acute and chronic appendicitis, recurrent and catarrhal appendicitis
- 3. Ultrasound proven appendicitis
- 4. Elective appendicectomy (previous cases of appendicitis which were managed conservatively)

#### Exclusion criteria

- 1. Severe systemic illnesses
- Complicated appendicitis with perforation or periappendiceal abscess

- 3. Uncontrolled medical conditions compromising the fitness for surgery
- 4. Patients who have had previous open abdominal surgery through midline incision
- 5. Patients who have had previous umbilical hernia repair with mesh

They were assigned into two groups randomly i.e. Group A & Group B, using computer generated random number tables at the time of reporting. One intervention group (Group A) underwent Single Incision Laparoscopic Appendicectomy (SILA) while the other intervention group (Group B) underwent Conventional three port Laparoscopic Appendicectomy (CLA). Observations were made in tailor made master chart and result analyzed.

Visual analogue scale (VAS) is a 10 point scale that is used to measure pain with '0' point being "no pain" and 10 point being "worst possible pain".

The Body image questionnaire was used to assess the cosmetic outcome. It consists of two parts, the Body image scale and the Cosmetic scale. The body image scale measures patients' perception and satisfaction with their body after surgery. The cosmetic scale assesses satisfaction with surgical scars. Both are calculated by summing the response to specific set of questions and comparing the final score.

RESULTS

Table I: Compilation of Post Operative outcomes in SILA and CLA group.

Outcome	Group A	Group B
	SILA ( n=30)	CLA (n=30)
Visual analogue pain score on Day 1	3.13±0.34	3.10±0.30
Visual analogue pain score on Day 7	2.03±0.12	2.00±0.00
Body image score on POD 7	5.13±0.43	5.93±0.58
Cosmetic score on POD 7	22.20±1.24	21±0.26
Body image score on POD 30	5.00±0.00	5.83±0.64
Cosmetic score on POD 30	23.53±0.73	21.10±0.71

On comparing pain between the two interventional arms on first post operative day by visual analogue score, the difference was found to be statistically insignificant. Even on day 7 the pain was mild and did not require any pharmacological therapy in either group.

One week postoperative, the mean body image score for SILA was 5.13 with standard deviation of 0.43 and the mean score for CLA was 5.93 with standard deviation of 0.58. This difference was found to be statistically significant. The mean cosmetic score for SILA was 22.20 with standard deviation of 1.24 and the mean score for CLA was 21 with standard deviation of 0.26. This difference was found to be statistically significant.

Further comparison between SILA and CLA on day 30 was done. The mean body image score was 5.00 with standard deviation of 0.00, while the mean score for CLA was 5.83 with standard deviation of 0.64. This difference was found to be statistically significant. The

mean cosmetic Score for SILA was 23.53 with standard deviation of 0.73 and the mean cosmetic score for CLA was 21.10 with standard deviation of 0.71. This difference was also found to be statistically significant.

#### DISCUSSION

The randomized clinical trial was carried out in a medical college hospital located in central India during the period December 2013 to October 2015. During the present study the total sample size was 60 patients.

All of the patients were above 16 years of age. The youngest patient was 18 years old and the oldest being 66 years old with mean age 30.66 years. Appendicitis is commonest in the  $2^{\rm nd}$  and  $3^{\rm rd}$  decades of life. In infancy the lumen of the appendix is fairly large and in old age the appendix often undergoes involution. In the present study 51.67% patients were in  $2^{\rm nd}$  and  $3^{\rm rd}$  decades of life. This finding was in accordance to what is documented in the literature.

On first post-operative day we compared pain using the visual analogue scale (VAS). Though the VAS scores were less in SILA group than the CLA group, this difference was not found to be significant. Jungwoo Kang et al 2012<sup>[3]</sup> in their analysis of 217 patients (112 underwent SILS and 105 underwent conventional laparoscopic appendicectomy) observed that the number of injected painkillers was lower in the SILS group, but no statistical difference was found. Most of the reviewed literature reported that there was no statistically significant difference in post-operative pain scores. However, Hyung Ook Kim et al(2014)<sup>[4]</sup> and Seung Min Baik et al(2013)<sup>[7]</sup> reported statistically significant higher scores in SILA group than the Conventional laparoscopic appendicectomy group. Our hypothesis was that SILA would have lesser pain because of the reduced number of incisions and less tissue trauma than the conventional laparoscopic appendicectomy. The higher pain score reported in this study might be the length of the single fascial incision which tends to be longer as the number of ports are reduced to one. The pain related problem could be resolved by better instrumentation and additional experience.

The pain was reassessed on post-operative day 7 between SILA and conventional laparoscopic appendicectomy (CLA) group using the visual analogue pain score. We found that the mean visual analogue score for SILA group was 2.03±0.12 and for conventional laparoscopic appendicectomy it was 2.00± 0.00 (P =0.321, NS) which was not statistically significant. Ma Dolores Frutos et al (2013)<sup>[8]</sup> in their study of 184 patients showed a visual analog scale of 2.76  $\pm$  1.64 in SILA(n=91) and 3.78  $\pm$ 1.76 in CLA (n=93) group. Mr Irfan Ahmed, Dr Jennifer Burr et al. The SCARLESS Study Group (2015)<sup>[9]</sup> in their randomized controlled trial of 79 patients found SILS patients answered significantly more favorably in terms of pain scale both when resting [mean (SD) 19.4 (11.9) vs. 22.4 (10.8), p = 0.36)] and moving [23.5] (11.9) vs. 29.2 (12.2), p = 0.10]. We found higher pain scores in SILA group. However, the scores in both the group was statistically and clinically insignificant as the mean pain score on day 7 in Group A was 2.03 and in Group B was 2.0, which is suggestive of mild pain and did not require any pharmacological therapy.

In this study we compared the cosmetic outcome between the two study groups on 7<sup>th</sup> postoperative day. The mean Body Image Score in SILA group was found to be conventional 5.13±0.43 and in laparoscopic appendicectomy (CLA) group, it was 5.93±0.58. The Cosmetic Score in SILA group was 22.20±1.24 and in the CLA group it was 21±0.26. Thus cosmetic outcome of SILA group was significantly higher than conventional laparoscopic appendicectomy group. Parveen Bhatia et al (2011)<sup>[10]</sup> in their study of 17 cases of SILS appendicectomy using conventional laparoscopic instruments showed clear advantage of its cosmetic benefit. Similarly Ramon Vilallonga et al (2012)<sup>[5]</sup> also found the cosmetic result to be in favor of SILA over

CLA. Hyung Ook Kim et al (2012)<sup>[4]</sup> in their study to transumbilical compare single-port laparoscopic appendicectomy with conventional three-port laparoscopic appendicectomy showed better cometic results of SILA over CLA. Hung-Hua Liang et al (2014)<sup>[14]</sup> in their study of 688 consecutive patients, 618 of whom underwent CLA and 70 underwent SILA, showed that using a single incision provided several advantages over CLA, mainly better cosmetic effects. Most of the reviewed literature shows that cosmetic outcome is significantly better in SILA group compared to conventional laparoscopic appendicectomy group. Our findings are in agreement with the findings of other authors. The reason for better cosmetic outcomes could be because of the single scar which is well disguised in the umbilicus compared to multiple scars present in conventional laparoscopic appendicectomy.

The cosmetic outcome of the patients was followed up 4 weeks after surgery. The cosmetic outcome in SILA was significantly higher than that in conventional laparoscopic appendicectomy group. The umbilicus being a natural scar, with virtually no fat, healed with an inconspicuous scar. Similar finding was noted by Mr Irfan Ahmed, Dr Jennifer Burr et al, The SCARLESS Study Group (2015). [9] In their randomized controlled trial, 79 patients were randomized of which 39 patients underwent single port incision laparoscopic surgery (SILS) appendicectomy and 40 underwent Standard three-port laparoscopic appendicectomy. Of these 53 patients who completed the 6-week follow-up, SILS patients answered significantly more favorably to the items in the body image scale and the cosmetic scale. Hung-Hua Liang et al (2014)[14] in their study of 688 consecutive patients showed better cosmetic effects of SILA in the long run. The reviewed literature shows that cosmetic outcome is significantly better in SILA group compared to conventional laparoscopic appendicectomy group. The present study findings are in agreement to what is found in the literature.

#### CONCLUSION

From the findings of the present study it can be concluded that SILA is an equally good technique for laparoscopic appendectomies as compared to conventional method. There was a distinct advantage of the SILA over the conventional technique in terms of cosmesis. The operative time required for the SILA was more than the conventional method but can be overcome with experience and newer equipment's.

There was no statistically significant difference in the pain scores at day 1 after the surgery in both the groups. There was no significant difference in pain scores between the two groups on day 7 also. The cosmetic outcome was found to be significantly better in SILA group on day 7 and day 30 after the surgery.

#### ACKNOWLEDGEMENT

There is no conflict of interest. No finance has been taken from anyone.

#### REFERENCES

- 1. Masoomi H, Nguyen NT, Dolich MO, Wikholm L, Naderi N, Mills S, et al Comparison of laparoscopic versus open appendectomy for acute nonperforated and perforated appendicitis in the obese population. Am J Surg., 2011; 202: 733-8.
- Ceci F, Orsini S, Tudisco A, et al. Single-incision laparoscopic appendectomy is comparable to conventional laparoscopic and laparotomic appendectomy: our single center single surgeon experience. Il Giornale di Chirurgia., 2013; 34(7-8): 216-219.
- 3. Jungwoo Kang, Byung Noe Bae, Geumhee Gwak, Inseok Park, Hyunjin Cho, Keunho Yang, et al. Comparative study of a Single-Incision Laparosco\pic and a Conventional Laproscopic Appendectomy for the treatment of Acute Appendicitis. J Korean Soc Coloproctol., 2012; 28(6): 304-308.
- 4. Hyung Ook Kim, Chang Hak Yoo, Sung Ryol Lee, Byung Ho Son, Yong Lai Park, Jun Ho Shin, Hungdai Kim, Won Kon Han. Pain after laparoscopic appendectomy: a comparision of transumbilical single-port and conventional laparoscopic surgery. J Korean Surg Soc., 2012 Mar; 82(3): 172–178.
- Ramon Vilallonga, Umut Barbaros, Ahmed Nada, Aziz Sumer, Tugrul Demirel, Jose Manuel Fort, Oscar Gonzalez ans Manuel Armengol. Single-Port Transumbilical Laparoscopic Appendectomy: A Preliminary Multicentric Comparative Study in 87 Patients with Acute Appendicitis. Minimally Invasive Surgery Volume 2012, Article ID 492409,
- 6. Jun Suh Lee, Young II Choi, Song Ho Lim, Tae Ho Hong, Journal of the Korean Surgical Society Transumbilical single port laparoscopic appendectomy using basic equipment: a comparision with the three ports method, 2012; 83: 212-217.
- Seung Min Baik, Kyung Sook Hong and Yong Il Kim. A comparison of transumbilical single-port laparoscopic appendectomy and conventional threeport laparoscopic appendectomy: from the diagnosis to the hospital cost. J Korean Surg Soc., 2013 Aug; 85(2): 68–74.
- Ma Dolores Frutos, Jesus Abrisqueta, Juan Lujan, Israel Abellan, Pascual Parrilla. Randomized Prospective Study to Compare Laparoscopic Appendectomy Versus Umbilical Single-incision Appendectomy. Annals of Surgery., 2013; 257(3): 413-418.
- Mr Irfan Ahmed, Dr Jennifer Burr et al, The SCARLESS Study Group. Single port/incision laparoscopic surgery compared with standard threeport laparoscopic surgery for appendicectomy: a

- randomized controlled trial. Surg Endosc, 2015; 29: 77–85.
- Parveen Bhatia, Vinay Sabharwal, Sudhir Kalhan, Suviraj John, Jagpreet S. Deed and Mukund Khetan. Single-incision multi-port laparoscopic appendectomy: How I do it. J Minim Access Surg., 2011 Jan-Mar; 7(1): 28-32.
- Hua J, Gong J, Xu B, Yang T, Song Z. Single-Incision Versus Conventional Laparoscopic Appendectomy: A Meta-analysis of Randomized Controlled Trials. J Gastrointest Surg., 2013 Sept 4.
- 12. Buckley FP 3<sup>rd</sup>, Vassaur H, Monsivais S, Jupiter D, Watson R, Eckford J. Single incision laparoscopic appedectomy versus traditional three-port laparoscopic appendectomy: an analysis of outcomes at a single institution. Surg Endosc., 2013 Oct 4.
- 13. Tiwari MM, Reynoso JF, Tsang AW, Oleynikov D. Comparison of outcomes of laparoscopic and open appendectomy in management of uncomplicated and complicated appendicitis. Ann Surg., 2011; 254: 927–932.
- 14. Hung-Hua Liang, Chin-Sheng Hung, Weu Wang, Ka-Wai Tam, Chun-Chao Chang, Hui-Hsiung Liu, Ko-Li Yen and Po-Li Wei. Single-incision versus conventional laparoscopic appendectomy in 688 patients: a retrospective comparative analysis. Can J Surg., 2014 Jun; 57(3): E89–E97.
- 15. Lee JS, Choi YI, Lim SH, Hong TH. Transumbilical single port laparoscopic appendectomy using basic equipment: a comparison with the three ports method. Journal of the Korean Surgical Society., 2012; 83(4): 212-217. doi:10.4174/jkss.2012.83.4.212.
- Kim HO, Yoo CH, Lee SR, et al. Pain after laparoscopic appendectomy: a comparison of transumbilical single-port and conventional laparoscopic surgery. Journal of the Korean Surgical Society., 2012; 82(3): 172-178. doi:10.4174/jkss.2012.82.3.172.
- 17. Kang J, Bae BN, Gwak G, et al. Comparative Study of a Single-Incision Laparoscopic and a Conventional Laparoscopic Appendectomy for the Treatment of Acute Appendicitis. Journal of the Korean Society of Coloproctology., 2012; 28(6): 304-308. doi:10.3393/jksc.2012.28.6.304.

18.