

A Study to Compare Local Complications in Use of Disposable versus Reusable Metallic Ports in Laparoscopic Surgeries - A Randomised Controlled Trial - General Surgery

Dr Tejbir Singh¹, Dr Manoj Kumar²

¹Resident, Department of Surgery AFMC, Pune 40, India

²Professor, Department of Surgery, AFMC, Pune 40, India

Abstract: *Introduction: Minimally invasive surgeries encompass surgical techniques that limit the size of incisions needed and so lessen wound healing time, associated pain, risk of infection and shorter hospital stay, quick recovery and a cosmetic scar. It has been enabled by advance of various medical technologies. Aim of study: To compare local complications in use of disposable versus metallic reusable ports in laparoscopic surgeries performed in a tertiary care teaching hospital. Material and methods: Total of 343 patients were included in the study. It was a randomized control trial and was carried for a duration of two years. All cases undergoing laparoscopic surgery at command hospital pune were included. Excluding immune compromised and those converted to open surgery. Results: There was a significant difference between the 3 groups in terms of Port Site Insertion Difficulty Score ($p = <0.001$), with the median Port Site Insertion Difficulty Score being highest in the overweight group. Post op pain, erythema and bleeding complication were significantly higher in overweight reusable ports compared to other BMI groups. Port site insertion difficulty was seen more in reusable group but with a non-significant difference. Conclusion: There was difference between the two groups (disposable and reusable groups) in terms of port site insertion difficulty, port site complications (erythema, bleeding and discharge), BMI, post-op pain but the difference was non-significant with regard to post-operative complications, port site pain port site insertion difficulty in either of the group. However, higher BMI associated with adverse perioperative outcomes irrespective of using either disposable or reusable instruments. To conclude, the study did not find any significant difference in using either reusable laparoscopic ports or the disposable ports.*

Keywords: Reusable and disposable ports, minimal invasive surgery, Port site complication, Port site insertion difficulty

1. Introduction

Minimally invasive surgeries encompass surgical techniques that limit the size of incisions needed and so lessen wound healing time, associated pain and risk of infection. It has been enabled by advance of various medical technologies.

There are various types of minimal invasive surgeries.

- Laparoscopic surgeries:** Laparoscope is used to look at abdominal organs and surgery is done under video camera guidance with abdomen insufflated using inert gas to help and insert instruments through cannulas and operate with ease and lesser incisions.
- Robotic surgeries:** Surgeon operates from a console equipped with two master controllers that maneuver four robotic arms. Computer software takes place of actual hand movements and can make movements very precise. It gives greater control and vision during surgery, allowing to perform safe, less invasive and precise surgical procedure.
- Endoscopic surgeries:** Endoscope is utilized to reach internal organs through small incision. A flexible tube with a video camera through small incision or natural orifice (mouth, nostril, anus). Tube has channel to insert and utilize tiny surgical instruments.
- Minimally invasive surgeries have various advantages which include smaller incision, lesser post-operative pain, lower risk of infection, shorter hospital stay, quick recovery and a cosmetic scar. complications associated with invasive surgeries could be physiological(DVT,

respiratory acidosis), access related(hematoma, hernia, bowel injury) or operative(bile leak, peritonitis).

2. Aims and Objective

Aim: To compare local complications in use of disposable versus metallic reusable ports in laparoscopic surgeries performed in a tertiary care teaching hospital.

Objective: To study safety and efficacy in use of disposable ports versus metallic reusable ports in laparoscopic surgeries, in terms of Port Site Infection, Post Op Pain, Port Site Insertion Difficulty

3. Material and methods

Total of 343 patients were included in the study. It was a randomized control trial (block randomization) and was carried for duration of two years. All cases undergoing laparoscopic surgery at command hospital Pune were included. Excluding immune compromised and those converted to open surgery.

Various scales used during study were: **1) Port Site Insertion Difficulty Score** – subjectively scored 1-10 by operating surgeon as mild (<3), moderate (<6), severe (>8). **2) Post op pain** scored from 1-10 on VAS and graded as mild (<3), moderate (<6) and severe (>7) by patient. **3) Port site infection** was graded by using Southampton scoring

Grade.4) Port site involved was divided as Umbilical port, Epigastric port, suprapubic port, Lateral ports

Data coded and recorded in MS excel spreadsheet program.

SPSS v23 was Used for data analysis. Group comparisons were made using independent sample t-test for continuously distributed data, and chi-squared test or categorical data. Pearson's correlation coefficient was calculated to explore the linear correlation between two continuous variables. Appropriate non-parametric tests (Wilcoxon test/Kruskal Wallis test/spearman correlation) were used when data were non-normally distributed. Level of significance was taken as p<0.005

4. Results

Table 1: Distribution of the Participants in Terms of Age (Years) (n = 342)

Age (Years)	
Mean (SD)	44.77 (15.01)
Median (IQR)	43 (24)
Range	16 - 88

The variable Age (Years) was not normally distributed (Shapiro-Wilk Test: p = <0.001).

The mean (SD) of Age (Years) was 44.77 (15.01). The median (IQR) of Age (Years) was 43.00 (24.00). The Age (Years) ranged from 16 - 88.

Table 2: Distribution of the Participants in Terms of Gender (n = 342)

Gender	Frequency	Percentage
Male	116	33.9%
Female	226	66.1%
Total	342	100.0%

33.9% of the participants had Gender: Male. 66.1% of the participants had Gender: Female.

Table 3: Distribution of the Participants in Terms of Port Type (n = 342)

Port Type	Frequency	Percentage
Reusable	186	54.4%
Disposable	156	45.6%
Total	342	100.0%

54.4% of the participants had Port Type: Reusable. 45.6% of the participants had PortType: Disposable.

Table 4: Distribution of the Participants in Terms of Port Site Insertion Difficulty (n = 342)

Port Site Insertion Difficulty	Port Type			Fisher's Exact Test	
	Reusable	Disposable	Total	X ²	P Value
Mild	176 (93.1%)	148 (96.7%)	324 (94.7%)	2.226	0.359
Moderate	10 (5.3%)	4 (2.6%)	14 (4.1%)		
Severe	3 (1.6%)	1 (0.7%)	4 (1.2%)		
Total	189 (100.0%)	153 (100.0%)	342 (100.0%)		

93.1% of the participants in the group Port Type: Reusable had Port Site Insertion Difficulty: Mild. 5.3% of the participants in the group Port Type: Reusable had Port Site

Insertion Difficulty: Moderate. 1.6% of the participants in the group Port Type: Reusable had Port Site Insertion Difficulty: Severe. 96.7% of the participants in the group Port Type: Disposable had Port Site Insertion Difficulty: Mild. 2.6% of the participants in the group Port Type: Disposable had Port Site Insertion Difficulty: Moderate. 0.7% of the participants in the group Port Type: Disposable had Port Site Insertion Difficulty: Severe.

There was no significant difference between the various groups in terms of distribution of Port Site Insertion Difficulty (X² = 2.226, p = 0.359).

Table 5: Distribution of the Participants in Terms of Post Site Complication: Erythema (n = 342)

Post Site Complication: Erythema	Port Type			Chi-Squared Test	
	Reusable	Disposable	Total	X ²	P Value
Yes	9 (4.8%)	3 (2.0%)	12 (3.5%)	1.960	0.162
No	180 (95.2%)	150 (98.0%)	330 (96.5%)		
Total	189 (100.0%)	153 (100.0%)	342 (100.0%)		

4.8% of the participants in the group Port Type: Reusable had Post Site Complication: Erythema: Yes. 95.2% of the participants in the group Port Type: Reusable had Post Site Complication: Erythema: No. 2.0% of the participants in the group Port Type: Disposable had Post Site Complication: Erythema: Yes. 98.0% of the participants in the group Port Type: Disposable had Post Site Complication: Erythema: No.

There was no significant difference between the various groups in terms of distribution of Post Site Complication: Erythema (X² = 1.960, p = 0.162).

Table 6: Distribution of the Participants in Terms of Post Site Complication: Discharge (n = 342)

Post Site Complication: Discharge	Frequency	Percentage
Yes	3	0.9%
No	339	99.1%
Total	342	100.0%

0.9% of the participants had Post Site Complication: Discharge: Yes. 99.1% of the participants had Post Site Complication: Discharge: No.

Table 7: Distribution of the Participants in Terms of Post Site Complication: Bleeding (n = 342)

Post Site Complication: Bleeding	Frequency	Percentage
Yes	4	1.2%
No	338	98.8%
Total	342	100.0%

1.2% of the participants had Post Site Complication: Bleeding: Yes. 98.8% of the participants had Post Site Complication: Bleeding: No.

Table 8: Distribution of the Participants in Terms of Post-Operative Pain (n = 342)

Post-Operative Pain	Port Type			Fisher's Exact Test	
	Reusable	Disposable	Total	X ²	P Value
None	174 (92.1%)	146 (95.4%)	320 (93.6%)	2.488	0.527
Mild	10 (5.3%)	6 (3.9%)	16 (4.7%)		
Moderate	4 (2.1%)	1 (0.7%)	5 (1.5%)		
Severe	1 (0.5%)	0 (0.0%)	1 (0.3%)		
Total	189 (100.0%)	153 (100.0%)	342 (100.0%)		

92.1% of the participants in the group Port Type: Reusable had Post-Operative Pain: None. 5.3% of the participants in the group Port Type: Reusable had Post-Operative Pain: Mild. 2.1% of the participants in the group Port Type: Reusable had Post-Operative Pain: Moderate. 0.5% of the participants in the group Port Type: Reusable had Post-Operative Pain: Severe. 95.4% of the participants in the group Port Type: Disposable had Post-Operative Pain: None. 3.9% of the participants in the group Port Type: Disposable had Post-Operative Pain: Mild. 0.7% of the participants in the group Port Type: Disposable had Post-Operative Pain: Moderate. 0.0% of the participants in the group Port Type: Disposable had Post-Operative Pain: Severe. There was no significant difference between the various groups in terms of distribution of Post-Operative Pain (X² = 2.488, p = 0.527).

Table 9: Distribution of the Participants in Terms of Port Affected: Epigastric (n = 342)

Port Affected: Epigastric	Frequency	Percentage
Yes	10	2.9%
No	332	97.1%
Total	342	100.0%

2.9% of the participants had Port Affected: Epigastric: Yes. 97.1% of the participants had Port Affected: Epigastric: No.

Table 10: Distribution of the Participants in Terms of Port Affected: Umbilical (n = 342)

Port Affected: Umbilical	Frequency	Percentage
Yes	4	1.2%
No	338	98.8%
Total	342	100.0%

1.2% of the participants had Port Affected: Umbilical: Yes. 98.8% of the participants had Port Affected: Umbilical: No.

Table 11: Distribution of the Participants in Terms of BMI (n = 342)

BMI	Frequency	Percentage
Underweight	2	0.6%
Normal	327	95.6%
Overweight	13	3.8%
Total	342	100.0%

0.6% of the participants had BMI: Underweight. 95.6% of the participants had BMI: Normal. 3.8% of the participants had BMI: Overweight.

5. Discussion

A total of 342 patients were evaluated who underwent laparoscopic surgery. Of these, standard metallic ports were

used totaling to 55.3% and in 44.7% patients' disposable ports were used. The mean Age (Years) in Reusable group was 43.32 years and in disposable group was 46.49 years. There was no significant difference between the groups in terms of Age (Years) (W = 12896.000, p = 0.077). The common laparoscopic procedures include laparoscopic cholecystectomy and laparoscopic appendectomy in our study. **Gender distribution:** 39.8% of the participants in Reusable group were Male and 60.2% of the participants were Females whereas in disposable group total males were 26.9% and females were 73.1%. **Port site insertion difficulty:** 93.1% of the participants Reusable port type had mild difficulty of port site insertion, 5.3% had moderate difficulty and 1.6% of the participants had severe difficulty. Whereas in disposable group, these numbers were 96.7% for mild, 2.6% for moderate and 0.7% for severe difficulty in port insertion with a non-significant difference between two groups. **Port site complications, erythema:** 4.8% of the participants in the group Port Type: Reusable had Post Site Complication: Erythema: Yes. 95.2% of the participants in the group Port Type: Reusable had Post Site Complication: Erythema: No. 2.0% of the participants in the group Port Type: Disposable had Post Site Complication: Erythema: Yes. 98.0% of the participants in the group Port Type: Disposable had Post Site Complication: Erythema: No. There was no significant difference between the various groups in terms of distribution of Post Site Complication: Erythema. **Port site discharge:** 1.1% of the participants in Reusable group had port site discharge whereas in disposable group port site discharge was seen in 0.6% participants with a non-significant difference between the two groups. **Port site bleeding:** 1.1% of the participants in Reusable group had port site complication of bleeding whereas in disposable group port site complication of bleeding was seen in 1.3% participants with a non-significant difference between the two groups. **Port site hernia:** None of the patients in either of the groups had port site hernia. **Post-op pain:** 92.1% of the participants in the group Port Type: Reusable had Post-Operative Pain: None. 5.3% of the participants in the group Port Type: Reusable had Post-Operative Pain: Mild. 2.1% of the participants in the group Port Type: Reusable had Post-Operative Pain: Moderate. 0.5% of the participants in the group Port Type: Reusable had Post-Operative Pain: Severe. 95.4% of the participants in the group Port Type: Disposable had Post-Operative Pain: None. 3.9% of the participants in the group Port Type: Disposable had Post-Operative Pain: Mild. 0.7% of the participants in the group Port Type: Disposable had Post-Operative Pain: Moderate. 0.0% of the participants in the group Port Type: Disposable had Post-Operative Pain: Severe. There was no significant difference. Patients were categorized based on BMI and 50% each of all the participants were distributed to disposable group and reusable group. Of the patients categorized in to normal BMI, 54.7% were in reusable group and 45.3% were in disposable group. Of all the patients in over weight category, 46.2% were in reusable group and rest 53.8% were in disposable group with a non-significant difference in the two groups. The mean of Port Site Insertion Difficulty Score in the BMI: Underweight group was 3.00, in normal group was 2.46 and overweight group was 5.62. There was a significant difference between the 3 groups in terms of Port Site Insertion Difficulty Score (p = <0.001), with the median

Port Site Insertion Difficulty Score being highest in the BMI: Overweight group. There was a significant difference between the various groups in terms of distribution of Post Site Complication: Erythema ($p = <0.001$) with the highest found in over weight patients. Participants who were Overweight had the largest proportion of Post Site Complication of Bleeding, higher number of all categories of severity of pain i.e. mild, moderate and severe compared to other groups. These were significantly higher compared to other BMI groups. Various studies have shown higher instance of infectious complications and poor wound healing in patients who have a higher BMI than normal. However, on contrary studies have shown a better clinical outcome of laparoscopic procedures in patients who have excessive BMI compared to those undergoing open procedures.

6. Conclusion

This study evaluated safety and efficacy of disposable and reusable laparoscopic ports. The study did not reveal any significant difference in difficulty of access either by disposable instruments or reusable instruments. There was difference between the two groups (disposable and reusable groups) in terms of port site insertion difficulty, port site complications (erythema, bleeding and discharge), BMI, post-op pain but the difference was non-significant with regard to post-operative complications, port site pain port site insertion difficulty in either of the group. However, higher BMI may be associated with adverse perioperative outcomes irrespective of using either disposable or reusable instruments. To conclude, the study did not find any significant difference in using either reusable laparoscopic ports or the disposable ports.

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