

A PROSPECTIVE RANDOMIZED TRIAL OF INTRAPERITONEAL SALINE WASH FOR REDUCTION OF SHOULDER TIP PAIN FOLLOWING LAPAROSCOPIC CHOLECYSTECTOMY

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ABSTRACT: Aims and Objectives: To find the effect of intraperitoneal saline wash for reduction of shoulder tip pain following laparoscopic cholecystectomy.

Introduction: Laparoscopic surgery is associated with lower morbidity. Recent reports have demonstrated that many patients experience considerable pain after laparoscopic cholecystectomy. Different modalities have been proposed to relieve post operative pain. The current study is to find a simple and effective manoeuvre as intraperitoneal saline wash to decrease postoperative pain.

Materials and Methods: The study was conducted on patients undergoing laparoscopic cholecystectomy .Patients were divided into Group A (study group) N = 50, intraperitoneal saline wash was done and in Group B (control group) N = 50, no saline wash was given. Post operative analysis was made by measuring Shoulder tip pain at 6 hours, 12 hours and 24 hours, pain abdomen and at other sites, Analgesic requirement postoperatively.

Results: ANOVA was used for analysis. Shoulder tip pain and abdominal pain were significantly reduced in Group A. Analgesic requirement was high in Group B. Conclusion: Instillation of normal saline at the end of laparoscopic cholecystectomy is effective approach in reducing shoulder tip pain and analgesic requirement.

1. INTRODUCTION

Laparoscopic procedures compared to open procedures are associated with lower morbidity, shorter hospitalization, smaller incisions, early return to normal activity and less post operative pain[1].But Many patients suffer pain after laparoscopy often referred to as the “post-laparoscopic pain syndrome”[2]. Pain arises from the trocar insertion sites, the intra-abdominal trauma and also from the rapid distension of the peritoneum with traumatic traction on blood vessels and nerves, irritation of the phrenic nerve and release of inflammatory mediators [3].

Post-laparoscopic pain is most frequently located in the upper abdomen, independent of the intra-abdominal localization of the operation site. The exact reasons for such pain are still unknown. Peritoneal biopsies taken after laparoscopy show peritoneal inflammation, capillary rupture and neuronal rupture[4]. Chemical irritation, intraperitoneal acidosis, mucosal ischemia and compression of the splanchnic nerve as a result of the pneumoperitoneum may also be contributory factors [4, 5, and 6]. Shoulder pain after laparoscopy is mainly attributed to stretching of subdiaphragmatic fibres of the phrenic nerve by the increased concavity of the diaphragm, which is induced by the pneumoperitoneum and the resulting loss of visceral surface tension [7]. Recent work has determined that the actual cause of nerve irritation is a result of cellular death caused by a combination of a temperature change from the gas at 21⁰C and the drying effect of the gas. Several other causes have also been suggested for shoulder tip pain like peritoneal stretching, diaphragmatic irritation, diaphragmatic injury and even shoulder abduction during surgery [8].

Surgeon is in a unique position to influence many of the causes by relative minor changes in techniques [2]. Carbon dioxide retention is a key factor in laparoscopy-induced upper abdominal pain, removing or washing out residual carbon dioxide might help reduce the occurrence or severity of this pain in both the shoulder and upper abdomen. Various methods are in use that helps us to take pre-emptive steps for pain following laparoscopic cholecystectomy especially unique shoulder tip pain. These include :Intra-peritoneal saline, Low pressure pneumoperitoneum ,Removal of insufflated gas or use of gas drains , Use of N₂O, helium or argon in place of CO₂ ,Bupivacaine infusion under right hemidiaphragm ,Gasless laparoscopy, Pulmonary recruitment manoeuvre[9-12].Currently no standard practice guidelines or recommendations exist regarding routine use of any method.

2. AIMS AND OBJECTIVES

To find the effect of intraperitoneal saline wash for reduction of shoulder tip pain following laparoscopic cholecystectomy.

3. MATERIALS AND METHODS

This randomized controlled trial was conducted in one hundred patients undergoing laparoscopic cholecystectomy for symptomatic cholelithiasis at Shri Guru Ramdass Institute of Medical Sciences and Research, Amritsar between October 2018 and September 2020 Patients were divided into 2 groups. In Group A (study group) N = 50, intraperitoneal saline wash was thoroughly done and in Group B (control group) N = 50, no saline wash was done.

3.1 Inclusion criteria for this study are

1. Signs and symptoms suggestive of symptomatic cholelithiasis
2. American Society of Anaesthesiologists (ASA) Grade 1 and 2
3. No clinical and USG findings of CBD stones

3.2 Exclusion criteria:

1. Multiple co-morbidities (severe hypertension, uncontrolled diabetes, tuberculosis and immunocompromised patients)
2. Presence of clinical and radiological finding of acute cholecystitis, biliary pancreatitis or empyema gall bladder at the time of admission
3. ASA Grades 3,4 and 5

After laparoscopic removal of gall bladder, in group A (study group), patients underwent liberal intraperitoneal saline irrigation of gall bladder bed. Normal saline 0.9% was used to

thoroughly irrigate and remove all debris; blood and possibly CO₂ gas out of abdominal cavity till clear fluid is seen in the peritoneal cavity. In group B (control group) no saline wash was used and in difficult cases only suction was done.

3.3 Post-operative analysis

Post operative analysis was made in terms of following parameters

1. Shoulder tip pain at 6 hours, 12 hours and 24 hours
2. Abdominal pain
3. Pain at other site
4. Analgesic requirement
5. Nausea and Vomiting

Intensity of pain was assessed on Visual Analog Scale (VAS) with evaluation at 6, 12 and 24 hours post operatively. Pre operatively at the time of enrolment of the patient to the study and taking informed consent for participation, patient was thoroughly explained the concept of Visual Analogue Scale in detail. VAS scores of 2 or more warrant administration of analgesic. Nausea and vomiting was assessed depending upon the number of episodes and need for anti-emetic medication. All patients were followed up in outpatient surgical department at one week after operation and evaluated for any other complication.

4. RESULTS

Patients included in this study were randomized into two groups - Group A (N = 50) patients in which intra peritoneal saline wash was done and Group B (N = 50) patients in which no saline wash was done. Presenting symptoms are varied in patients of cholecystitis as shown in the Table 1. Most common being pain right hypochondrium being present in all the patients, pain alone being present in 56% of patients. Pain associated with vomiting was present in 28% of patients, pain and dyspepsia was seen in 9% while pain, vomiting and dyspepsia were present in 7% of patients.

The mean VAS score for abdominal pain at 6 hours in Group A is 1.86 with a SD of 0.95 and that of Group B is 2.36 with a SD of 1.17 as shown in Table 2. When statistically analysed using ANOVA it was found to be statistically significant. There was significant reduction in abdominal pain occurred in Group A that is with intra peritoneal saline wash. Pain reduction at 12 and 24 hrs was statistically not significant. In the current study at 6 hours 12% of patients in Group A and 36% in Group B had right shoulder tip pain. At 12 hours 14% in Group A and 38% in Group B while at 24 hours 8% in Group A and 18% in Group B had shoulder tip pain. Shoulder tip pain incidence was significantly less at 6 and 12 hours in study Group A. This goes on to show that the incidence of shoulder tip pain after laparoscopic cholecystectomy was reduced by intraperitoneal saline wash.

According to the Table 3 and statistical analysis using ANOVA there was statistically significant reduction in right shoulder pain in Group A that is with intra peritoneal saline wash at 6, 12 and 24 hours when compared with Group B. The above observation is highly relevant to this study as it clearly shows that saline wash offered a simple method for reduction of shoulder tip pain both the incidence and severity.

In our study in first 6 hrs post op period 82% patients in Group A required only one injection of pain killer as compared to 44% in Group B. Only 18% patients in Group A required two injections as compared to 44% in Group B. None in Group A and 12% in Group B required three injections of pain killers in first six hours. 96% patients in Group A and 86%

in Group B required only NSAIDs. Both NSAIDs and opioids were needed in 4% in Group A and 14% in Group B. When Pearson chi test was applied to compare the no injections in two groups, it was found that a highly statistically significant reduction was made in the number of injections used in two groups. Opioid usage of Group A was also less than Group B at 6 hours.

Between 6 and 12 hours 74% patients in Group A and 54% in Group B required no analgesia between 6 and 12 hours. 24% patients in Group A required only one injection of pain killer as compared to 34% in Group B. Only 2% patients in Group A required two injections as compared to 12% in Group B. No patient was given opioid analgesia, only NSAIDs were used in 26% patients in Group A as compared to 46% in group B. When Pearson chi test was applied to compare the number of injections in two groups it was found that a statistically significant reduction was made. Analgesic requirement between 12 and 24 hours in both groups was not significant.

No statistical difference was found between the age groups of patients mean being 43.3 and 41.3 yrs in cases and controls respectively. Female patients were more in both groups due to the fact that gall stone disease is prevalent in females. Higher operative time was noted in Group A due to time taken to thoroughly wash the abdominal cavity but was not statistically significant.

Table 1: Clinical features distributed in both groups.

			Clinical Features				
			P	P,V	P,D	P,V,D	TOTAL
Group	Group A	Count	29	13	4	4	50
		% within Group	58%	26%	8%	8%	100.0%
	Group B	Count	27	15	5	3	50
		% within Group	54%	30%	10%	6%	100.0%
Total		Count	56	28	9	7	100
		% within Group	56%	28%	9%	7%	100.0%

P- Pain V- Vomiting D- Dyspepsia

Table 2: VAS score for abdominal pain at 6, 12 and 24 hours postoperatively

ABDOMINAL PAIN				
Group		VAS scores at 6 hours	VAS scores at 12 hours	VAS scores at 24 hours
A(N=50)	Mean	1.86	1.32	1.10
	SD	0.95	0.55	0.30
B(N=50)	Mean	2.36	1.48	1.16
	SD	1.17	0.71	0.37
	P value	0.021	0.210	0.377
	Significance	Significant	Not significant	Not significant

Table 3: VAS score for right shoulder pain at 6,12 and 24 hours post operatively

RIGHT SHOULDER PAIN				
Group		VAS scores at 6 hours	VAS scores at 12 hours	VAS scores at 24 hours
A(N=50)	Mean	1.20	1.18	1.04
	SD	0.54	0.44	0.20
B(N=50)	Mean	1.52	1.46	1.22
	SD	0.79	0.68	0.42
	P value	0.019	0.016	0.007
	Significance	Significant	Significant	Significant

5. DISCUSSION

Pneumoperitoneum is the basis of laparoscopic surgery as it provides the operating surgeon the space for clear visualisation of anatomical structures. The most frequently used gas for the creation of pneumoperitoneum is carbon dioxide and various studies have concluded that this gas is responsible for shoulder tip pain after laparoscopic cholecystectomy. The various theories cited are stretching of sub diaphragmatic fibres of the phrenic nerve by the increased concavity of the diaphragm induced by the pneumoperitoneum and the resulting loss of visceral surface tension, carbon dioxide retention within the abdomen, subsequently irritating the phrenic nerve and causing referred pain in the C4 dermatome[7]. The gas affects the physiology of the surrounding peritoneal tissue.

Several other causes have also been suggested for shoulder tip pain like peritoneal stretching, diaphragmatic irritation, diaphragmatic injury and even shoulder abduction during surgery [8]. It is also thought that abdominal and shoulder pain may be due to peritoneal irritation by carbonic acid and to the creation of space between liver and diaphragm. Other studies have suggested that abdominal and shoulder pain, as well as tachycardia, is due to hypothermia caused by CO₂, gas used for pneumoperitoneum. Thus, the heating of CO₂ gas to 37⁰C during laparoscopy significantly reduced intraoperative hypothermia, abdominal and shoulder pain, and tachycardia.

Low pressure pneumoperitoneum, removal of insufflated gas or use of gas drains, use of N₂O, helium or argon in place of CO₂, bupivacaine infusion under right hemidiaphragm, warm and humidified gas, gasless laparoscopy, pulmonary recruitment manoeuvre and intraperitoneal instillation of normal saline are some of the methods that have been studied for reduction of pain after laparoscopic cholecystectomy[13,14]. It may be seen that all the methods mentioned above are expensive, increase hospital stay, are dependent on some other drug or device and are difficult to follow in routine practice. Only two methods that is pulmonary recruitment manoeuvre and intraperitoneal instillation of normal saline are simple procedures found to be effective for reduction of shoulder tip pain after laparoscopic cholecystectomy.

The intraperitoneal infusion of normal saline at body temperature, until the liver is submerged, without fluid suction after deflation of the pneumoperitoneum, was first reported

by Perry and Trombello with encouraging results. These results were confirmed by Duchene, who reported no side effects. A comparative study by Tsimoyianniset al has also shown encouraging results for the use of intraperitoneal saline washing for reduction of abdominal pain [7]. Huang ML et al confirmed that intraperitoneal infusion of normal saline can reduce postoperative pain after laparoscopic cholecystectomy [13]. In their study, they infused a certain amount of saline fluid into the right hemidiaphragmatic area in order to reduce the remaining amount of CO₂ between the diaphragm and liver. They placed the patient in a 30⁰ Trendelenburg position, rather than a supine position. This position would allow them to infuse a minimum amount of saline fluid to eliminate the potential gas space between the liver and diaphragm. Postoperative pain scores were significantly reduced at 2 to 48 hours in the experimental group. The number of patients requiring additional analgesics was also reduced. They concluded that intraperitoneal infusion of normal saline can reduce postoperative pain after laparoscopic cholecystectomy. The present study confirms well this study demonstrating a definite role of saline wash for reduction of shoulder tip pain after laparoscopic cholecystectomy.

There are many studies as also mentioned in the review of literature that found that pulmonary recruitment manoeuvre effective in reduction of shoulder tip pain after laparoscopic cholecystectomy. Radke OCet al concluded that this simple clinical manoeuvre at the end of surgery appears to reduce shoulder pain as well as post operative nausea and vomiting after laparoscopic surgery by more than half[11]. A study titled “Manoeuvres to decrease upper and shoulder pain after Gynaecologic Laparoscopic Surgery” by Hsiao-Wen Tsai et al that directly compared these two procedures and concluded that both PRM and intra peritoneal normal saline infusion(INSI) could effectively reduce pain after laparoscopic surgery, but intra peritoneal normal saline infusion might be better for both upper abdominal and shoulder pain[14]. The postoperative shoulder pain scores were also significantly lower in the INSI group than in the control group at 12, 24 and 48 hours. They were significantly lower in the INSI group than in the PRM group at 48 hours. The infusion manoeuvre seemed to be much more effective at reducing laparoscopy-induced upper abdominal and shoulder pain than PRM, and the effect lasted longer.

The probable benefits of using a 0.9% normal saline solution for reduction of post operative shoulder tip pain is that it is a simple and non expensive method using a physiological solution, its effect is found to be more long lasting as compared to PRM and no additional drugs or devices are needed. In August 2013, a study “Techniques to reduce shoulder pain after laparoscopic surgery for benign gynaecological disease: a systematic review” by Buket Taş, Anders Meller Donatsky, Ismail Gögenur was published[15]. This review presents an overview of the currently evaluated techniques to reduce shoulder pain after laparoscopic surgery for benign gynaecological disease. It concluded that the pulmonary recruitment manoeuvre (PRM) and intraperitoneal drainage were found to reduce the incidence and severity of shoulder pain. Based on the current evidence, safety and possibility to implement the technique in daily practice, pulmonary recruitment manoeuvre can be recommended to reduce both the incidence and severity of shoulder pain. At the same time two of the above authors published a meta analysis titled “Intraperitoneal instillation of saline and local anaesthesia for prevention of shoulder pain after laparoscopic cholecystectomy: a systematic review” [16]. While the earlier paper focussed on

gynaecological surgeries, the latter was on laparoscopic cholecystectomy. Results regarding the effect intra peritoneal infusion of LA versus saline showed contradictory results in regards to both shoulder pain incidence and severity. They concluded that both intra peritoneal infusion of saline and LA can be used to reduce shoulder pain severity after laparoscopic cholecystectomy. Our study which is also a randomised controlled trial agrees with these results that shoulder tip pain induced by CO₂ pneumoperitoneum can be safely reduced with a simple procedure as thorough saline wash of the peritoneal cavity.

There are some limitations to our study. First shoulder pain has been reported to last up to 7 days or even 5 weeks in a small number of patients [17]. Because our follow-up period lasted 24 hours after discharge, we cannot draw conclusions about the lasting effects of the procedure we investigated. Secondly, the problem of shoulder pain has also frequently been reported in other types of laparoscopic surgery, e.g., gastric banding and gynaecologic surgeries[17,18]. However, based on the assumption that the underlying cause for shoulder pain is the residual CO₂, the procedure we investigated would be expected to be similarly effective in other clinical settings. Thirdly, no objective measure like an abdominal erect X ray was done to assess the reduction in the amount of gas after surgery.

The current study validates the above mentioned results. To put in simple words it may safe to assume that CO₂ is responsible for the shoulder tip pain experienced by a large number of patients that range from 30% to upto 80% in some studies. This pain may be responsible for late discharge from the hospital. Shoulder tip pain may be a contributory factor for failure of day care laparoscopic cholecystectomy in carefully selected patients due to its role in delaying discharge from the hospital. Our present study shows that a simple procedure of washing the peritoneal cavity with normal saline solution can prevent this pain. Normal saline solution works by dissolution of CO₂ gas from the abdominal cavity. As it removes the gas, blood, blood clots, debris and surgical smoke from the peritoneal cavity it leads to decrease in post operative pain including shoulder tip pain. The current study shows that the mean VAS scores for shoulder tip pain at 6 and 12 hours as well as the analgesic requirement at 6, 12 and 24 hours were significantly less in patients who underwent thorough saline wash of the peritoneal cavity after routine laparoscopic cholecystectomy.

6. CONCLUSION

The importance of the current study could not be over emphasised. Using an inexpensive low tech method i.e. instillation of saline at the end of Laparoscopic cholecystectomy reduces shoulder tip pain and analgesic requirement. A number of methods are available for the same but no current standard guidelines have been made. In the present study we intend to formulate a simple guideline to thoroughly wash the peritoneal cavity after removal of gall bladder in all patients so as to wash away CO₂ from the cavity thus reducing the shoulder tip pain.

7. REFERENCES

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