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RESEARCH ARTICLE

LOW PRESSURE PNEUMOPERITONEUM VERSUS STANDARD PRESSURE PNEUMOPERITONEUM IN LAPAROSCOPIC CHOLECYSTECTOMY-AN EXPERIENCE.

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Key words:-
Pneumoperitoneum, pressure, laparoscopic cholecystectomy.

Abstract

Aims and objectives: The aim of the study was to evaluate safety and complication rate differences, surgery time differences and need to convert to open cholecystectomies differences between the two groups.
Materials and methods; A prospective randomized study was carried out on 80 patients. The patients were randomly allocated and divided into two groups A and B. Group A was standard pressure pneumoperitoneum group and group B was low pressure pneumoperitoneum group. All patients were subjected to necessary baseline investigations, informed consent was taken and institutional ethical clearance was also sought.
Results: There were significant differences between the two groups. Group B i.e low pressure pneumoperitoneum group showed less number of all the known complications, less operating time taken, less hemodynamic and arterial blood gas changes and less incidence of need to convert to open cholecystectomies.
Conclusion: Low pressure pneumoperitoneum laparoscopic cholecystectomy is safe in experienced hands.

Introduction:-

Biliary diseases known since ages constitute a major portion of digestive tract disorders world over. Among these cholelithiasis being the fore runner,causing general ill health, thereby requiring surgical intervention for total cure[1]. The gall stone disease is as old as 2000BC as seen in archaeological remains of young Egyptian women[2]. Alchemist used to treat disease with magnesium sulphate rich water as treatment. John Bobbs, an Indianan surgeon attempted to perform cholecystolithotomy in 1867, with the removal of gallstones but leaving the organ in situ[3]**.** This procedure when adopted by others was associated with high incidence of recurrence andwas considered by most as an incomplete treatment. The first cholecystectomy was performed on July 15, 1882 by Karl Langenbuch in Berlin[4] and with him immortalized the quotation, “The gall bladder should be removed not because it contains stones, but because it forms them.”

The first endoscopic examinations of peritoneal cavity were accomplished early in 20th century. In 1901, George Kelling, a German Surgeon, used a cystoscope to examine the intra- abdominal viscera of a dog after insufflating the peritoneal cavity with air, and coined the term celioscopy. Jacobeus performed the first human celioscopy in Sweden in 1910[5]. For the last hundred years open cholecystectomy has enjoyed unchallenged supremacy as the treatment of choice for symptomatic gall stones. However introduction of laparoscopic techniques to perform cholecystectomy has revolutionized this procedure.

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Liver biopsies were the first laparoscopic procedures attempted by general surgeons in 1982[6]. The advent of laparoscopic cholecystectomy was the catalyst that aroused the interest of general surgeons worldwide in laparoscopy[7].

The first laparoscopiccholecystectomy was performed by Muhe, a German surgeon in 1985. However the first laparoscopic cholecystectomy recorded in Medical literature was performed by Philip Mouret in 1987 in Paris, France[8]. Reddick &Oslen devised the currently used method for laparoscopic cholecystectomy performing their first case in Sept. 1988.Overnight, the technique was accepted and rapidly developed into a procedure thatis now the standard for management of calculus disease of the biliary system[9].

Laparoscopic surgery was performed for the first time in India by T.E. Udwadia in April, 1990 in Bombay[10].

Laparoscopic cholecystectomy has replaced conventional cholecystectomy as there are limited surgical incisions, decreased post-operative stay, less post-operative pain and decreased need for post-operative analgesia[11,12,13].

Traditionally, one of the first steps in laparoscopic cholecystectomy is the creation of pneumoperitoneum[14] using carbon dioxide (CO_2) through Veress needle[15] or through a port (hole) in the abdominal wall. Traditionally, the pressure used is around 15mmHg[16].

The commonly seen complications due to pneumoperitoneum are shoulder tip pain and cardiopulmonary changes[17]. These changes seen are directly due to pressure effects on peritoneum and diaphragm and indirectly due to absorbed carbon dioxide and hypercarbia, leading to decreased cardiac output.[18] these complications may be well tolerated by healthy and young individuals but lead to significant complications in old and those who have underlying cardiopulmonary diseases[19].Seeing all these complications it lead researchers to think in terms of low pressure pneumoperitoneum cholecystectomies.

The main criticism of low pressure pneumoperitoneum is its inability to provide adequate surgical exposure and hence its safety.[20]

Materials and methods:-

A prospective randomized study was carried out on 80 patients. The patients were randomly allocated and divided into two groups A and B. Group A was standard pressure laproscopic cholecystectomy(SPLC) group and group B was low pressure laproscopic cholecystectomy(LPLC) group. All patients were subjected to necessary baseline investigations, informed consent was taken and institutional ethical clearance was also sought.

Patients in Group A were subjected to standard pressure pneumoperitoneum of 15mmHg and in Group B were subjected to a low pressure pneumoperitoneum of 9 mm Hg. Pre-poeratively patient were taught about visual analogue pain score (VAS) from 0-10. Patients also received tetanus toxoid and antibiotic prophylaxis. Immediately after induction an arterial line was established, NG tube was placed in and arterial blood gas analysis was done and recorded. ABG monitoring were done before insufflation, after insufflation and after deflation.In addition hemodynamic monitoring was also doneand recorded Pain score, analgesic requirements and hospital stay of all the patients were recorded.

The operating surgeons had experience of more than one hundred laparoscopic cholecystectomies to their credit. All the patients received 75mg of diclofenac before extubation and subsequent analgesic were given on demand. After the study, all the data was tabulated and subjected to standard statistical analysis. The data was described as mean+_ S.D and percentage. The intergroup variance of metric variables was measured by students t-test at 95% confidence interval whereas proportional difference within non metric variables was measured by Man-Whitney U test and chi-square analysis. M.S Excel, SPSS statistical program(17.0 version), Minitab and Javastatsoftwares were used for data analysis.

Criteria For Inclusion:-

1. Uncomplicated symptomatic cholelithiasis.
2. Normal common bile duct (on pre-operative ultrasound)

Criteria For Exclusion:-
1. Gall Bladder malignancy.
2. Acute inflammation or any other complication of gall stone disease.
3. Choledocholithiasis.
4. Patients with other preoperative causes of shoulder pain like bursitis, rheumatoid arthritis, tendinitis and other musculoskeletal conditions.
5. Coronary artery diseases, COPD, asthma.
6. Patients with significant portal hypertension, uncorrectable coagulopathies, cirrhosis and generalized peritonitis.
7. Previous upper abdominal surgery.

Results and conclusions:-

Table 1:-Age (yr) distribution of the Studied Subjects.

Age (yr)	SPLC		LPLC		p value
	n	%	n	%	
≤ 20	1	2.5	2	5.0	0.749 (NS)
21 to 30	2	5.0	3	7.5	
31 to 40	9	22.5	7	17.5	
41 to 50	19	47.5	18	45.0	
> 50	9	22.5	10	25.0	
mean ± SD	44.8 ± 9.7 (15, 60)		44.1 ± 11.1 (18, 61)		

The mean age of patients in the SPLC group was 44.8 ±9.7 years and that in LPLC group was 44.1±11.1 years. The difference was not statistically significant.

Table 2:-Gender distribution of the Studied Subjects

		SPLC		**LPLC**		**p value**
		N	**%**	**n**	**%**	
Gender	Male	13	32.5	14	35.0	0.814 (NS)
	Female	27	67.5	26	65.0	

Females formed 67.5% in SPLC group and 65% in LPLC group. The difference was not however statistically significant.

Table 3:-Anthropometric Characteristics of Studied Subjects

	SPP	**LPP**	**p value**
Weight(kg)	66.2 ± 9.0 (51, 90)	65.1 ± 7.4 (51, 81)	0.572 (NS)
Height (cm)	162.5 ± 7.2 (149, 179)	163.5 ± 9.0 (147, 182)	0.574 (NS)
Body Mass Index (BMI)	25.2 ± 4.2 (18.9, 37.0)	24.5 ± 3.4 (18.2, 31.5)	0.416 (NS)

The anthropometric characteristics were similar in both the groups.The difference in height and weight of patients in both the groups is statistically insignificant.

Table 4:-Intraoperative Findings

		SPLC		**LPLC**		
		n	**%**	**n**	**%**	
Gall Bladder	Normal	20	50.0	22	55.0	0.656 (NS)
	Distended	12	30.0	11	27.5	
	Contracted	8	20.0	7	17.5	
Adhesions of GB	Yes	12	30.0	9	22.5	0.449 (NS)
	No	28	70.0	31	77.5	
No. of gall stones	Single	9	22.5	11	27.5	0.608 (NS)
	Multiple	31	77.5	29	72.5	
Cholesterosis	Yes	3	7.5	5	12.5	0.459 (NS)
	No	37	92.5	35	87.5	

The intraoperative findings were similar in both the groups with statistically insignificant differences noted in adhesion formation, gall bladder morphology and cholesterosis.

Table– 5:- Operative time in the Studied Subjects

Group	mean ± SD	p value
SPLC	40.0 ± 5.7 (33, 52)	0.056 (NS)
LPLC	42.4 ± 5.6 (33, 55)	

The mean operative time in the LPLC group was more(42.4±5.7 min) as compared to SPLC group(40.0 ± 5.7) but the difference between the mean operative times of the two groups was statistically insignificant(p<0.05).

Table– 6:-Total No. of patients having Shoulder Tip Pain in two groups.

Group	n	%	p value
SPLC (n=40)	15	37.5	***0.010 (Sig)***
LPLC (n=40)	5	12.5	

Shoulder tip pain was noted in 15 (37.5%) of patients in SPLC group whereas only 5 (12.5%) patients complained of shoulder tip pain in the LPLC group. This difference was statistically significant ***(P < 0.05).***

Table– 7:-Number of patients having Shoulder Tip Pain at different time intervals.

Time after Surgery	**SPP**		**LPP**		**p value**
	N	**%**	**n**	**%**	
4hr	1	2.5	0	0.0	0.317 (NS)
8hr	11	27.5	5	12.5	0.095 (NS)
12hr	13	32.5	2	5.0	***0.002 (Sig)***
24hr	4	10.0	0	0.0	***0.041 (Sig)***
Overall	15	37.5	5	12.5	***0.010 (Sig)***

Over the first 8 hours after surgery the number of patients complaining of shoulder tip pain in both the groups were not statistically significant although**.**

Table – 8:-Comparison of Intensity of Shoulder Tip Pain (VAS) between two groups.

Time after Surgery	SPLC	LPLC	p value
4hr	4.0 ± 1.2 (2, 8)	2.4 ± 0.8 (1, 4)	***<0.001 (Sig)***
8hr	4.8 ± 1.7 (2, 8)	3.7 ± 1.7 (2, 6)	***0.003 (Sig)***
12hr	5.7 ± 1.4 (4, 9)	3.8 ± 1.1 (3, 6)	***<0.001 (Sig)***
24hr	3.6 ± 1.2 (2, 6)	1.2 ± 0.9 (0, 3)	***<0.001 (Sig)***

At any time during the first 24 hrs the mean pain scores were higher in the SPLC group as compared to the LPLC group. The differences observed at 4 hour, 8 hour, 12 hour and 24 hour postoperatively were all statistically significant.

Table – 9:-Total number of Analgesic doses required during at different time intervals.

Timing	SPLC		LPLC		p value
	N	**%**	**n**	**%**	
0 - 4 hr	3	7.5	0	0.0	0.079 (NS)
4 - 8 hr	15	37.5	11	27.5	0.343 (NS)
8 - 12 hr	15	37.5	4	10.0	***0.010 (Sig)***
12 - 24 hr	4	10.0	0	0.0	***0.041 (Sig)***
Total analgesics required	***37***		***15***		

The total number of analgesic doses(number of diclofenac 75 mg ampoules in our study) consumed in the SPLC group was 37 and that in LPLC group was 15. This was statistically significant.

Table – 10:-Total number of patients requiring analgesics.

		SPLC		LPLC		
		n	%	n	%	
Patients requiring Analgesics		23	57.5	13	32.5	***0.011 (Sig)***

Twenty three patients in the SPLC group required analgesics whereas only 13 patients in the LPLC group required analgesics. A maximum of 3 doses of analgesics by any patient were required in the SPLC group whereas a maximum of two doses by any patient were required in the LPLC group. The difference was statistically significant.

Table 11:-Frequency of Analgesics Given.

		SPLC		LPLC		p value
		n	**%**	**N**	**%**	
Number of Administered Doses	Single dose	11	27.5	12	22.5	***0.012 (Sig)***
	Two doses **Table**	10	25.0	1	7.5	
	Three doses	2	5.0	0	0.0	
	mean ± SD	1.6 ± 0.7 (1, 3)		1.4 ± 0.6 (1, 2)		

Table – 12:-Comparison of mean duration of hospital stay.

Hospital Stay (days)		
Group	**mean ± SD**	**p value**
SPLC	1.7 ± 0.6 (1, 3)	***0.002 (Sig)***
LPLC	1.4 ± 0.5 (1, 2)	

The mean duration of hospital stay was 1.7±0.6 days in SPLC group and the mean duration of hospital stay was 1.4±0.5 days in LPLC group. This was statistically significant.

Table – 13a:-Compariso of Variation in mean Pulse between two groups during surgery.

		SPLC	LPLC	p value
Pulse (beats/min)	5 min Before Insufflation	75.2 ± 4.6 (68, 82)	76.2 ± 4.1 (69, 83)	0.329 (NS)
	30 min after creation of pneumoperitoneum	79.9 ± 4.6 (72, 89)	78.9 ± 4.2 (71, 86)	0.279 (NS)
	After deflation	77.7 ± 4.6 (70, 87)	77.0 ± 4.3 (68, 84)	0.455 (NS)

There was no statistically significant difference observed in the mean pulse rates before insufflation, 30 minutes into pneumoperitoneum or after deflation in the two groups although pulse rate increased after creation of pneumoperitoneum and it was more in SPLC group.

Table – 13b:-Comparison of Variation in mean systolic blood pressure between two groups during surgery.

		SPP	LPP	p value
Systolic Blood Pressure	5 min Before Insufflation	123.5 ± 8.3 (110, 136)	121.3 ± 7.4 (110, 136)	0.230 (NS)
	30 min after creation of pneumoperitoneum	135.0 ± 9.0 (118, 154)	132.0 ± 7.7 (118, 152)	0.113 (NS)
	After deflation	129.0 ± 8.9 (114, 148)	126.4 ± 7.5 (111, 144)	0.175 (NS)

There was no statistically significant difference observed in the mean systolic blood pressures before insufflation, 30 minutes into pneumoperitoneum or after deflation in the two groups although it was seen to be more increased in the SPLC group.

Table – 13c:-Comparison of Variation in mean Diastolic Blood Pressure between two groups during surgery.

		SPP	LPP	p value
Diastolic Blood Pressure	5 min Before Insufflation	80.2 ± 4.7 (70, 88)	79.5 ± 4.8 (68, 89)	0.495 (NS)
	30 min after creation of pneumoperitoneum	85.3 ± 3.6 (77, 92)	84.6 ± 5.6 (72, 94)	0.507 (NS)
	After deflation	81.9 ± 3.1 (75, 87)	80.4 ± 5.6 (70, 92)	0.126 (NS)

There was no statistically significant difference observed in the mean diastolic blood pressures before insufflation, 30 minutes into pneumoperitoneum or after deflation in the two groups.

Comparison of Arterial Blood Gas Analysis (14a – 14d):-

Table – 14a:-Comparison of mean pH.

		SPLC	LPLC	p value
pH	5 min Before Insufflation	7.40 ± 0.05 (7.33, 7.48)	7.40 ± 0.04 (7.33, 7.49)	0.619 (NS)
	30 min after creation of pneumoperitoneum	7.37 ± 0.05 (7.28, 7.46)	7.38 ± 0.04 (7.31, 7.47)	0.489 (NS)
	After deflation	7.35 ± 0.06 (7.25, 7.46)	7.37 ±0.04(7.27,7.45)	0.652 (NS)

Although there was a trend towards aciodosis in both the groups as time passed by in the surgery it was more seen in SPLC. We concluded in our study that there was no statistically significant difference observed in the mean pH scores before insufflation, 30 minutes into pneumoperitoneum or after deflation in the two groups

Table – 14b:-Comparison of PO_2 between two groups.

		SPLC	LPLC	p value
Po_2	5 min Before Insufflation	219.2 ± 5.3 (212, 230)	221.1 ± 5.7 (212, 230)	0.129 (NS)
	30 min after creation of pneumoperitoneum	209.4 ± 5.5 (199, 223)	207.5 ± 7.8 (188, 221)	0.224 (NS)
	After deflation	204.4 ± 6.2 (191, 220)	229.8 ± 7.9 (211, 243)	***<0.001 (Sig)***

A statistically significant difference was noted in the partial pressure of oxygen after deflation in the two groups with LPLC group showing a higher mean PO_2 after deflation

Table – 14c:-Comparison PCO_2 between two groups.

		SPLC]	LPLC	p value
PCO_2	5 min Before Insufflation	33.9 ± 0.4 (33.1, 34.8)	34.0 ± 0.5 (33.2, 34.9)	0.387 (NS)
	30 min after creation of pneumoperitoneum	37.1 ± 1.1 (35.2, 38.8)	36.7 ± 1.1 (34.8, 38.8)	0.069 (NS)
	After deflation	39.6 ± 1.5 (37.0, 42.4)	39.1 ± 1.3 (36.7, 41.3)	0.099 (NS)

There was no statistically significant difference observed in the mean partial pressures of CO_2 before insufflation, 30 minutes into pneumoperitoneum or after deflation in the two groups although it was more in the SPLC group after creation of pneumoperitoneum and at deflation.

Table – 14d:-Comparison of HCO_3^- levels between two groups.

		SPLC	LPLC	p value
HCO_3^-	5 min Before Insufflation	22.5 ± 0.5 (21.0, 23.2)	22.6 ± 0.6 (21.0, 23.3)	0.460 (NS)
	30 min after creation of pneumoperitoneum	20.8 ± 0.9 (18.9, 22.2)	24.0 ± 1.1 (22.1, 25.7)	***<0.001 (Sig)***
	After deflation	21.7 ± 1.0 (20.1, 23.4)	22.9 ± 1.1 (21.5, 25.1)	***<0.001 (Sig)***

A statistically significant difference was noted in the mean HCO_3^-levels 30 minutes after creation of pneumoperitoneum and after deflation in the two groups with LPLC group showing a higher mean HCO_3^-

Table – 15:-Complications and intraoperative manipulations required.

		SPP		**LPP**		
		n	**%**	**n**	**%**	
Bile Duct Injury		0	0.0	0	0.0	1.000 (NS)
Injury to adjacent viscera		0	0.0	0	0.0	1.000 (NS)
Need for increased pressure		0	0.0	0	0.0	1.000 (NS)
Need for conversion to open		0	0.0	0	0.0	1.000 (NS)
Need for additional ports		0	0.0	0	0.0	1.000 (NS)

No complications were noted in either of the groups. There was no need for increased pressure in the LPP group. No conversions were reported .There was no need for additional ports in either of the groups.

Discussion:-

Table 1,2,3 and 4 show tabulated patient demographic characteristics and body mass index(BMI) without any statistical significant information.

The mean operative time in the LPLC group was more(42.4±5.7 min) as compared to SPLC group(40.0 ± 5.7) but the difference between the mean operative times of the two groups was statistically insignificant ($p<0.05$). Thus no extra time taken in LPLC group as contrary to expectation due to limited visual field but compensated in hands of experienced surgeons. Similar results seen in other studies as well.

Shoulder tip pain was noted in 15 (37.5%) of patients in SPLC group whereas only 5 (12.5%) patients complained of shoulder tip pain in the LPLC group. This difference was statistically significant ***(P < 0.05).*** Over the first 8 hours after surgery the number of patients complaining of shoulder tip pain in both the groups were not statistically significant although. At any time during the first 24 hrs the mean pain scores were higher in the SPLC group as compared to the LPLC group. The differences observed at 4 hour, 8 hour, 12 hour and 24 hour postoperatively were all statistically significant. The total number of analgesic doses(number of diclofenac 75 mg ampoules in our study) consumed in the SPLC group was 37 and that in LPLC group was 15. This was statistically significant.Twenty three patients in the SPLC group required analgesics whereas only 13 patients in the LPLC group required analgesics. A maximum of 3 doses of analgesics by any patient were required in the SPLC group whereas a maximum of two doses by any patient were required in the LPLC group. The difference was statistically significant.

Similar results were also seen by Srli et al [21.]Barczynski in his study showed 2.1 times low incidence of pain in LPLC group[22.] In another study by Faisal et al[23] also demonstrated similar results.

There was no statistically significant difference observed in the mean pulse rates before insufflation, 30 minutes into pneumoperitoneum or after deflation in the two groups although pulse rate increased after creation of pneumoperitoneum and it was more in SPLC group.

There was no statistically significant difference observed in the mean systolic blood pressures before insufflation, 30 minutes into pneumoperitoneum or after deflation in the two groups although it was seen to be more increased in the SPLC group.

There was no statistically significant difference observed in the mean diastolic blood pressures before insufflation, 30 minutes into pneumoperitoneum or after deflation in the two groups. Similar results were observed by Smith et al[24] and Deepaesh[25] et al in their respective studies.

Although there was a trend towards acidosis in both the groups as time passed by in the surgery it was more seen in SPLC. We concluded in our study that there was no statistically significant difference observed in the mean pH scores before insufflation, 30 minutes into pneumoperitoneum or after deflation in the two groups.
A statistically significant difference was noted in the partial pressure of oxygen after deflation in the two groups with LPLC group showing a higher mean PO_2 after deflation.

There was no statistically significant difference observed in the mean partial pressures of CO_2 before insufflation, 30 minutes into pneumoperitoneum or after deflation in the two groups although it was more in the SPLC group after creation of pneumoperitoneum and at deflation.

A statistically significant difference was noted in the mean HCO_3^-levels 30 minutes after creation of pneumoperitoneum and after deflation in the two groups with LPLC group showing a higher mean HCO_3^-. The results in our study were coparable to those seen by Mc Dermott et al[26] and Volz et al[27].

No complications were noted in either of the groups. There was no need for increased pressure in the LPP group. No conversions were reported .There was no need for additional ports in either of the groups.

Conclusion:-

Laparoscopic cholecystectomy is feasible and safe at 9mm Hg intra-abdominal pressure in uncomplicated symptomatic gall stone disease group of patients and in the hands of experienced surgeons and can be used routinely. It is significantly advantageous in terms of reduction of postoperative shoulder tip pain, use of analgesics, preservation of pulmonary function, andhospital stay. On the basis of the results of our study routine use of low pressure pneumoperitoneum should be adopted in laparoscopic cholecystectomy although further safety needs to be established. By this simple expedient of reducing the pressure of pneumoperitoneum from 15mmHg to 9mmHg the benefits of laparoscopic cholecystectomy can be extended to high risk patients who otherwise have contraindications for undergoing laparoscopic cholecystectomy due to compromised cardiorespiratory status.

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