

# Safety and efficacy of laparoscopic cholecystectomy during pregnancy: A comparative study between low-pressure and gasless laparoscopy

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## **Abstract**

*Pregnancy and high parity increase the risk of cholelithiasis and its complications during pregnancy. Laparoscopic cholecystectomy for failed conservative treatment of symptomatic cases during pregnancy is no longer been a contraindication. The potential risk of pneumoperitoneal pressure and CO<sub>2</sub> insufflation triggered the use of modified techniques as gasless and low pressure cholecystectomy for materno-fetal safety.*

*Patients and methods: Thirteen pregnant patients with indicated cholecystectomy were randomly assigned for either low-pressure laparoscopy (LPL) (6 patients) or gasless laparoscopy (GL) (7 patients). Patients were compared for respiratory and blood gases changes, hemodynamic changes, anesthetic requirements, surgical and early postoperative outcomes and materno-fetal well-being during hospitalization and they were followed up till delivery.*

*Results: After CO<sub>2</sub> insufflation there were significant differences between the 2 groups with increase in the cardiopulmonary parameters namely; PaCO<sub>2</sub>, PetCO<sub>2</sub>, peak airway pressure, heart rate and the mean arterial blood pressure and a decrease in pH in the LPL group. The operating time and anesthetic drugs used were significantly more for the GL group. No recorded differences in the postoperative abdominal pain, postoperative nausea and vomiting (PONV) and fetal heart rate changes.*

*Conclusion: Both low pressure and gasless laparoscopy provide a safe technique for laparoscopic cholecystectomy during pregnancy. However, gasless technique is associated with lower cardiopulmonary effects, despite its longer operating time. In patients with compromised cardiopulmonary function during pregnancy, the gasless technique provides a safer method to avoid the potential adverse effects of pneumoperitoneal pressure and CO<sub>2</sub> insufflation.*

*Key words: Pregnancy - Laparoscopic cholecystectomy - Gasless - Abdominal wall lift - Low-pressure cholecystectomy.*

## **Introduction:**

The incidence and prevalence of cholelithiasis together with its complications are high in Saudi Arabia.<sup>1,2</sup> The principle factors are contributed to overweight, early age of menarche, early marriage and high parity.<sup>3</sup> Repeated pregnancies and multiparity are accepted as risk factors for cholelithiasis.<sup>4,5</sup> Acute cholecystitis is the second most common non-obstetric emergency during pregnancy, after acute appendicitis.<sup>6,7</sup>

Surgical intervention should be delayed until after delivery, unless conservative treatment fails with persistence of symptoms or symptoms recur.<sup>8,9</sup> Although pregnancy was once considered an absolute contraindication to the performance of laparoscopic procedures, the laparoscopic management of symptomatic cholelithiasis in pregnancy showed better outcomes than open cholecystectomy, with decreased risk of spontaneous abortion and preterm labor.<sup>6,10</sup>

The potential risks on the mother and fetus caused by pneumoperitoneum and insufflation of carbon dioxide during conventional laparoscopy,<sup>11,12</sup> have stimulated the development of alternative approaches to perform laparoscopic cholecystectomy in pregnancy; such as the low-pressure pneumoperitoneal insufflation,<sup>13</sup> abdominal wall lift with low-pressure pneumoperitoneum<sup>14</sup> and the use of gasless laparoscopy.<sup>15,16</sup>

Comparative studies between these methods in terms of safety and efficacy during pregnancy have not been published yet.

### **Aim of the study:**

Is to compare the safety and efficacy of low-pressure versus gasless laparoscopic cholecystectomy for symptomatic cholelithiasis during pregnancy.

### **Patients and methods:**

This study was carried out at Prince Abd El-Aziz Bin Mosaed hospital, MOH (Saudi Arabia), in the period from December 2006 to February 2009. The study included thirteen patients with symptomatic cholelithiasis during pregnancy who failed conservative management and cholecystectomy was indicated during pregnancy. Exclusion criteria involved those patients with ASA score of III or more, previous upper abdominal operations, choledocholithiasis and obesity (BMI>30Kg/m<sup>2</sup>). All patients were assessed by an obstetrician during hospitalization and cardiotocogram (CTG) was done preoperatively and repeated 1, 6 and 12h postoperatively. A written informed consent was obtained from each patient included the potential risk of abortion/preterm labor and fetal morbidity/mortality.

General anesthesia was induced with fentanyl 2ug/kg and sodium thiopental 3-5mg/kg and was maintained using isoflurane 0.6%. Supplemental boluses of fentanyl and atracurium were given as needed. Nitrous oxide was not used. The ventilation settings were 10breath/min, the inspiratory to expiratory ratio was 1:2 and tidal volume (VT) was 8mL/kg. No end-expiratory positive pressure was used. The minute ventilation was increased

by changing the respiratory rate to keep end-tidal CO<sub>2</sub> (PetCO<sub>2</sub>) of 32-36 mmHg and PaCO<sub>2</sub> of 40- 45 mmHg.

After the induction of general anaesthesia, patients were randomly allocated to either low-pressure laparoscopy (LPL) group or gasless laparoscopy (GL) group using closed envelopes. For both groups, a bladder catheter and a nasogastric tube were in place during the operation, and were removed at the end of the operation. Monitoring of all patients involved the recording of pulse oximetry (SaO<sub>2</sub>), heart rate, noninvasive blood pressure measurement, PetCO<sub>2</sub> and peak airway pressure. A radial arterial line was fixed for blood gases and acid-base analysis. Samples were withdrawn before induction of anesthesia and then every 15min intraoperatively with another sample at 3 and 12h postoperatively. In order to include complete data for all patients intraoperatively, only the first 45 min were recorded, starting from the insufflation of CO<sub>2</sub> in LPL group or lifting the abdominal wall in GL group.

Laparoscopic cholecystectomy was performed using the standard 4-trocar technique. The first umbilical trocar was inserted using the open technique (Hasson method) and then patients were placed in a 30° reverse Trendelenburg position and a 10° left lateral tilt, to displace the gravid uterus from inferior vena cava thereby maintaining venous return. Ephedrine 10mg was given if the systolic blood pressure decreased by more than 20% of the baseline.

In LPL group, pneumoperitoneal insufflation was kept at 10 mmHg with the insertion of the rest of trocars under vision. In GL group, 2 large towel-clip forceps were fixed to the abdominal wall, one in the midline and the other one at the right hypochondrial area close to the insertion of upper abdominal trocars, which were placed under vision after traction. Traction over these two forceps was achieved by the means of cords hanged over a side bar fixed on each side of the operating table **Figure(1)**. Orthopaedic traction weights were used to achieve the required working space **Figure(2)**. A third towel-clip forceps was applied just above the umbilical port site, upward traction on such forceps is needed only

at the introduction of the camera, without the need to be fixed to a cord.

Laparoscopic cholecystectomy proceeded in the same manner for both groups. Intraoperative cholangiogram was not done. Suction tube drain was placed at the gallbladder bed for all patients and removed after 24hs. The operation time was calculated from the first skin incision till the last stitch.

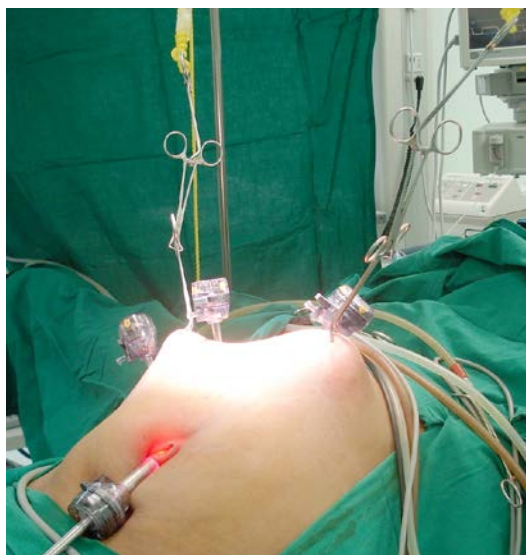
Postoperative recordings were performed by a trained nurse, unaware of the method used during operation. The patients were monitored postoperatively for: The occurrence of postoperative nausea and vomiting (PONV), right shoulder pain, intensity of pain (measured by the visual analogue scale (VAS 0-10)) at 2, 6, 12, 18 and 24h postoperative, the analgesic requirements (Paracetamol 1gm i.v for VAS above 5) and paralytic ileus time (calculated in hours from the end of the procedure to the

ability to pass stool or gas). Patients were re-assessed by the obstetrician for materno-fetal well-being and followed-up till delivery.

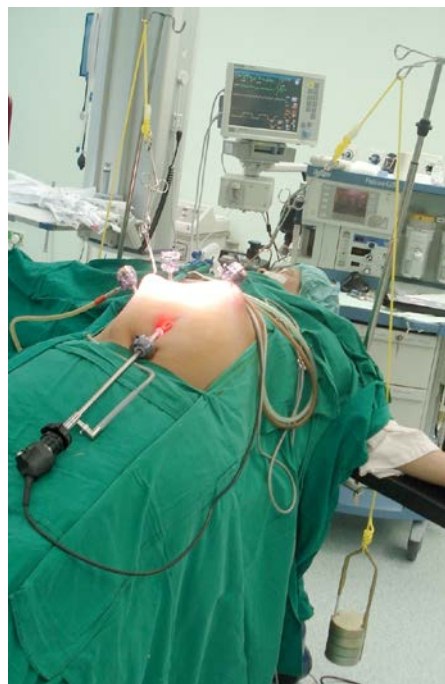
Respiratory function test performed 24h prior to surgery and repeated 48h postoperatively including: Forced vital capacity (FVC), forced expiratory volume in 1 second (FEV1) and peak expiratory flow rate.

#### **Statistical analysis:**

The differences of means between the groups were analyzed using *t*-test. The chi-square test, Fisher's exact test and Mann-Whitney *U*-test were used where appropriate. Data were analyzed using SPSS version 8.0.0. A *p* value of less than 0.05 was considered to represent statistically significant difference between tested groups. Data are expressed as mean  $\pm$ SD, number (%) or median (range).



*Figure (1): Abdominal wall lifting.*



*Figure (2): Traction with orthopedic weights.*

## Results:

### Demographic data:

A total of 13 patients were included in the study. Low pressure laparoscopy (LPL) group included 6 patients and gasless laparoscopy (GL) group included 7 patients. Patient characteristics are summarized in **Table(1)**. There appeared to be no significant difference in patient characteristics between the 2 study groups preoperatively.

### Respiratory and blood-gas parameters:

The mean values of PaCO<sub>2</sub>, PetCO<sub>2</sub> and peak airway pressure were significantly higher in the LPL group starting from the 15min after insufflation or abdominal wall lifting and continued throughout the intervention till desufflation. In the LPL group, a decrease in pH (p<0.001) was noted following CO<sub>2</sub> insufflation, which continued till desufflation of gas was completed with significant differences at 30 and 45min **Table(2)**. At 3 and 12h postoperatively, pH and PaCO<sub>2</sub> showed no significant difference between the groups. At 3h postoperatively, PaCO<sub>2</sub> values remained above the basal readings and pH lower than the basal readings in the LPL group and both returned to normal at the 12h recording. Respiratory function tests were comparable in the pre- and postoperative period in both groups **Table(3)**.

### Hemodynamic parameters:

The heart rate and mean arterial blood pressure were significantly raised in the LPL group (p<0.001) after 15min from abdominal insufflation and remained elevated till complete desufflation of gas **Figure(1,2)**.

### Anesthetic parameters:

Patients in the GL group consumed more fentanyl and atracurium **Table(4)**. The minute volume of ventilation needed to be increased during the first 15 min of insufflation in the LPL group (p<0.001) to achieve normoventilation and no changes were required in the GL group **Table(5)**.

### Surgical and early postoperative data:

No statistical difference noticed in comparing the pain using VAS and analgesic requirements at all times (p>0.05). **Table(6)** shows the rest of parameters.

### Obstetric data:

Monitoring of fetal heart rate (CTG) did not show significant difference in comparison between the groups pre- and postoperatively (p=0.68, 0.07, 0.16, 0.17). Tocolytic agents were not needed in the study. No preterm labour or abortions were recorded.

*Table (1): Patients characteristics.*

	LPL group (n=6)	GL group (n=7)	p value
Age (y)	27 ±4.9	26.6 ±4.5	0.87
BMI (Kg/m <sup>2</sup> )	28.7 ±1.21	28.3 ±1.11	0.57
Gravidity	4 (3-5)	3 (2-6)	0.38
Gestational age (wk)	19 ±2	17 ±4	0.25

Table (2): Respiratory and blood-gas parameters.

	LPL group (n=6)	GL group (n=7)	p value
<b>Arterial pH:</b>			
Before induction	7.43 ±0.03	7.43 ±0.05	1.00
At 15 min	7.42 ±0.04	7.41 ±0.06	0.74
At 30 min	7.35 ±0.06	7.42 ±0.03	0.02*
At 45 min	7.35 ±0.04	7.41 ±0.05	0.04*
3h postop.	7.40 ±0.03	7.41 ±0.04	0.63
12h postop.	7.42 ±0.03	7.41 ±0.07	0.75
<b>PaCO<sub>2</sub> (mmHg):</b>			
Before induction	33 ±3	34 ±2	0.50
At 15 min	42 ±4	36 ±3	0.01*
At 30 min	43 ±1	36 ±1	<0.001**
At 45 min	42 ±2	36 ±2	<0.001**
3h postop.	37 ±2	33 ±7	0.21
12h postop.	34 ±3	33 ±1	0.42
<b>PetCO<sub>2</sub> (mmHg):</b>			
Before surgery	30 ±2	30 ±3	1.00
At 15 min	35 ±3	30 ±1	0.002*
At 30 min	36 ±2	31 ±2	<0.001**
At 45 min	36 ±3	31 ±1	<0.001**
<b>Peak airway pressure (cmH<sub>2</sub>O):</b>			
Before surgery	19.5 ±3	18.5 ±4	0.63
At 15 min	25.3 ±2	19.6 ±3	0.002*
At 30 min	28.2 ±1	22.1 ±4	0.004*
At 45 min	27.7 ±4	21.5 ±2	0.004*

\*Statistically significant difference.

\*\*Highly significant difference.

Table (3): Respiratory function test.

	LPL group (n=6)	GL group (n=7)	p value
<b>Preoperative:</b>			
Forced vital capacity (L)	2.53 ±0.81	2.48 ±0.87	0.92
Forced expiratory volume in 1 sec (L)	2.66 ±0.89	2.82 ±1.31	0.81
Peak expiratory flow rate (mL/sec)	6.72 ±1.22	6.34 ±1.63	0.65
<b>Postoperative:</b>			
Forced vital capacity (L)	2.47 ±1.10	2.37 ±0.97	0.86
Forced expiratory volume in 1 sec (L)	2.45 ±0.76	2.60 ±0.86	0.75
Peak expiratory flow rate (mL/sec)	6.28 ±2.14	6.11 ±1.75	0.88

Table (4): Anesthetic requirements.

	LPL group (n=6)	GL group (n=7)	p value
Isoflurane concentration (%)	1.3 ±0.1	1.2 ±0.2	0.29
Fentanyl (ug)	125 ±15	155 ±18	0.01*
Atracurium (mg)	50 ±4	60 ±3	<0.001**

\*Statistically significant difference. \*\*Highly significant difference.

Table (5): Ventilatory parameters.

	LPL group (n=6)	GL group (n=7)	p value
Minute ventilation (L/min)	8 ±2	5 ±1	0.005*
Peak inspiratory pressure (cmH2O)	28 ±3	21 ±2	<0.001**

\*Statistically significant difference. \*\*Highly significant difference.

Table (6): Surgical & postoperative data.

	LPL group (n=6)	GL group (n=7)	p value
Operative time (min)	62.2 ±8.49	72.3 ±6.95	0.04*
Conversion to open	0	0	0
Postop. Ileus (h)	15 ±3.5	16 ±2.6	0.57
PONV	2 (33)	1 (14)	1.00
Right shoulder pain	4 (67)	2 (29)	0.29

\*Statistically significant difference.

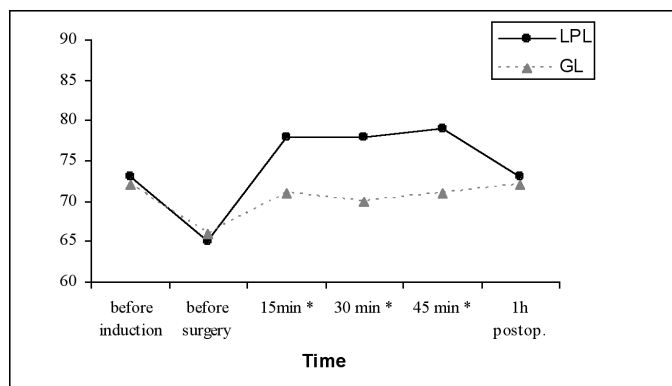


Figure (1): Mean values of heart rate  
\*Highly significant differences

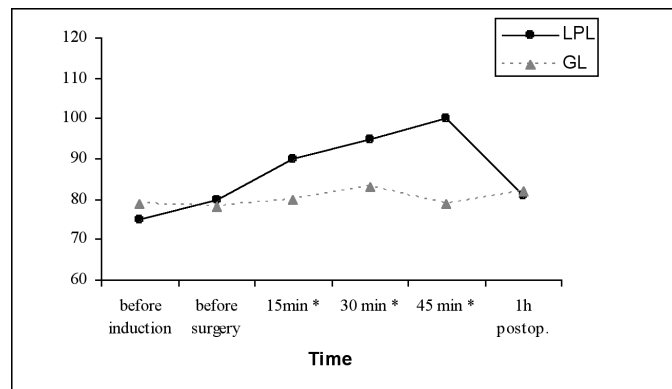


Figure (2): Mean values of the mean arterial blood pressure.  
\*Highly significant differences.

### Discussion:

Being a referral hospital for the northern area of Saudi Arabia, where complications of cholelithiasis during pregnancy are frequently met, gave us the chance to conduct this prospective study on such population group, comparing the outcomes between two reported methods for laparoscopic cholecystectomy during pregnancy.

Pregnant women develop a restrictive pulmonary physiology owing to an enlarged uterus. They are more prone to develop hypoxemia and hypocapnia secondary to an increase in minute ventilation and  $O_2$  consumption, increase in peak airway pressure and decreased thoracic cavity compliance.<sup>17</sup> In accordance with other investigators,<sup>18,19</sup> we found a significant differences in  $P_{et}CO_2$ ,  $P_{a}CO_2$ , peak airway pressure and pH values between abdominal wall lift group and pneumoperitoneal group despite the adjustment of minute ventilation volume. The use of  $CO_2$  pneumoperitoneum, even with a very low pressure of 5mmHg,<sup>19,20</sup> is also associated with a significant difference in  $PCO_2$  and pH from the base line values. This is in agreement with others too,<sup>21</sup> who showed that, the increase of  $PCO_2$  is not linearly related to the intra-abdominal pressure of  $CO_2$  pneumoperitoneum. It is suggested that, peritoneal absorption area is an important factor to determine the rate of  $CO_2$  absorption from the peritoneal cavity<sup>21,22</sup> and hence its consequences. Putting in mind that the fetus is more acidemic than the mother<sup>11,12</sup> and to ward-off these consequences, one should seek a completely gasless technique rather than the use of abdominal wall lift plus low-pressure  $CO_2$  pneumoperitoneum.

We have found a significant increase in heart rate and mean arterial blood pressure values after insufflation and remained high throughout the procedure till desufflation. Similar results were reported by Lindgren et al.<sup>23</sup> and by de Waal et al.<sup>20</sup> with even lower pressures (2.7 and 5mmHg respectively). The later suggested that catecholamine release is the cause of such differences. Elevated catecholamine levels have been seen as a response to  $CO_2$  pneumoperitoneum as reported by Joris and Lamy.<sup>24</sup> Similarly, Adresson et al.<sup>25</sup> concluded that abdominal wall lift increased cardiac index while pneumoperitoneum did not. And, cardiac filling pressures and systemic vascular resistance were increased by pneumoperitoneum but unaffected by abdominal wall lift. Furthermore, Cunningham et al.<sup>26</sup> found that  $CO_2$  insufflation increased left ventricular end-systolic wall stress. These effects may be deleterious in patients with compromised cardiac function or having pre-eclampsia.

Different instruments and techniques have been used in order to accomplish the gasless space away from the potential side effects of pneumoperitoneum and the insufflation of  $CO_2$  such as: Laparolift™ and laparofan,<sup>27</sup> Laparotenser® device,<sup>28,29</sup> traction on straight metal rods,<sup>30</sup> traction on Foley's catheter,<sup>31</sup> the use of a semi-loop-shaped abdominal retractor<sup>32</sup> and the use of towel clips with a ceiling-mounted laplift.<sup>33</sup> Some of these instruments are complex, expensive and are not available in all hospitals; others are tedious to mount and assemble with loss of extra time or need extra stab wounds. We have used a simple abdominal wall traction technique to achieve

gasless, isobaric laparoscopy by the means of two cords attached to large towel-clip forceps, hanged over a side bar on each side of the operating table **Figure(2)**, where orthopedic weights, readily available in ordinary operating rooms, are applied to achieve the required intra-abdominal working space. Creation of a sufficient space in the abdomen, despite the presence of gravid uterus, was not difficult because the population study were females with most of them of high parity with a soft abdominal wall musculature.

The operating time was longer in GL group ( $p=0.038$ ), and this is in accordance with other investigators<sup>18,34</sup> in non-pregnant patients. On the other hand, non-significant difference in the operating time in comparing pneumoperitoneal group to abdominal wall lift group was noticed by Alijani et al.,<sup>35</sup> Galizia et al.<sup>36</sup> and Ortiz-Oshhiro et al.<sup>37</sup> The later in his comparison, divided the operating time into phase 1, which is the time employed to create the surgical field and phase 2, which is the actual operating time. This difference between studies may be explained by the use of different methods to create gasless space from one side and on the other side due to the difference in defining the "start-end" points for time calculation.

In accordance with other investigators<sup>18,27,34</sup> on non-pregnant patients, we didn't find a significant difference in comparing our 2 groups for the postoperative abdominal pain. Although the occurrence of right shoulder pain was more frequent in LPL group, it doesn't attain statistical significance ( $p=0.29$ ). However, the reported results of the same investigators regarding shoulder pain are contradictory; while Koivusalo et al.<sup>27</sup> reported that shoulder pain is more with the pneumoperitoneal group, Vezakis<sup>34</sup> and Uen et al.<sup>18</sup> reported the reverse; as the pain was more with traction group. This contradiction may be related to the different degrees of diaphragmatic stretching resulted from excessive upward traction of the abdominal wall according to the instruments used and the technique applied to perform gasless space. Uen et al.<sup>18</sup> for example, has used 2 curved subcutaneously inserted for traction.

## Conclusion:

Both low pressure and gasless laparoscopic cholecystectomy provide a safe technique in pregnancy for symptomatic cholelithiasis. However, gasless laparoscopy is associated with lower cardiopulmonary effects, despite its longer operating time. In patients with compromised cardiopulmonary function during pregnancy, where cholecystectomy is indicated, the gasless technique provides a safer method to avoid the potential adverse effects of pneumoperitoneal pressure and CO<sub>2</sub> insufflation. A larger series is recommended.

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