ประสิทธิผลของเครื่องมือ จุฬา เร็กตัสชี้ท ลิฟติ้ง (จุฬาลิฟท์) ในการตรวจพยาธิสภาพของอวัยวะในอุ้งเชิงกรานหญิงด้วยกล้องส่องภายใน (ประเมินผลการใช้เครื่องยกผนังหน้าท้องแบบเกี่ยวยกจากชั้นพังผืด)

นาย ธันวา ตันสถิตย์

วิทยานิพนธ์นี้เป็นส่วนหนึ่งของของการศึกษาตามหลักสูตรปริญญาวิทยาศาสตรมหาบัณฑิต
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EFFICACY OF THE CHULA RECTUS SHEATH LIFTING DEVICE (CHULALIFT) FOR DIAGNOSTIC LAPAROSCOPIC GYNECOLOGIC PROCEDURE

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รูปแบบการวิจัย : การศึกษาแบบทดลอง โดยการแบ่งกลุ่มตัวอย่างโดยวิธีสุ่ม

สถานที่ : การศึกษาในโรงพยาบาลมหาวิทยาลัย

การทดลอง : ผู้ป่วยหญิงที่เข้ารับการการตรวจพยาธิสภาพของอวัยวะในอุ้งเชิงกรานด้วยกล้องส่องภายใน ในภาควิชาสูติศาสตร์นรีเวชวิทยา ช่วงระหว่างเดือน ตุลาคม 2543 ถึง เดือน กุมภาพันธ์ 2544 รวม 40 คน แบ่งออกเป็น 2 กลุ่ม เท่า ๆ กัน โดยการสุ่ม กลุ่มเปรียบเทียบ ได้รับการตรวจพยาธิสภาพของอวัยวะในอุ้งเชิงกรานด้วยกล้องส่องภายในโดยใส่ก๊าซคาร์บอนไดออกไซด์เข้าสู่ช่องท้อง กลุ่มทดลองได้รับการตรวจพยาธิสภาพของอวัยวะในอุ้งเชิงกรานด้วยกล้องส่องภายในโดยใช้เครื่องมือยกผนังหน้าท้อง จุฬา เร็กตัสชี้ท ลิฟติ้ง (จุฬาลิฟท์) ทั้งสองกลุ่มได้รับการตรวจพยาธิสภาพของอวัยวะในอุ้งเชิงกรานโดยแพทย์กลุ่มเดียวกัน

ลักษณะพื้นฐานของผู้ป่วย : ทั้งกลุ่มควบคุมและกลุ่มทดลองไม่ต่างกันทั้ง อายุ ขนาดของร่างกาย กลุ่มโรคที่เป็น ประวัติการตั้งครรภ์ และอาการที่นำผู้ป่วยมารับการตรวจวินิจฉัย

ผลการทดลอง :

อัตราความสำเร็จของการตรวจพยาธิสภาพของอวัยวะในอุ้งเชิงกรานในกลุ่มทดลองได้ผลเท่ากับกลุ่มควบคุมคือประสพความสำเร็จ 100%

ไม่พบอัตราการเกิดปัญหาแทรกซ้อนของการใช้เครื่องมือ

ผลของเครื่องมือที่มีต่อการเปลี่ยนแปลงทางสรีระของผู้ป่วยในขณะที่รับการตรวจพยาธิสภาพของอวัยวะในอุ้งเชิงกรานมีน้อยมาก โดยการใส่ลมในท้องมีผลต่อการเปลี่ยนแปลงทางสรีระของผู้ป่วยมากกว่าการเกี่ยวยกผนังหน้าท้อง

การสร้างช่องว่างเพื่อการตรวจพยาธิสภาพของอวัยวะในอุ้งเชิงกรานของเครื่องมือใหม่ทำได้น้อยกว่ากลุ่มควบคุม

สรุป : ขั้นต้นของการทดสอบเครื่องมือจุฬาลิฟท์ในคน พบว่าการสร้างช่องว่างภายในท้องด้วยเครื่องมือ จุฬา เร็กตัสชี้ท ลิฟติ้ง (จุฬาลิฟท์) เพื่อการตรวจพยาธิสภาพของอวัยวะในอุ้งเชิงกรานหญิงด้วยกล้องเป็นอีกทางเลือกหนึ่งที่อาจกระทำได้อย่างปลอดภัยในคนไข้กลุ่มที่มีขนาดร่างกายปกติ

ภาควิชา คณะแพทยศาสตร์ ลายมือชื่อนิสิต.....

สาขาวิชา การพัฒนาสุขภาพ ลายมือชื่ออาจารย์ที่ปรึกษา.....

ปีการศึกษา 2544

437 54236 30 : MAJOR HEALTH DEVELOPMENT PROGRAMME
KEY WORD : GASLESS LAPAROSCOPIC / CHULALIFT / CHULA RECTUS SHEATH / ABDOMINAL WALL LIFTING
TANVAA TANSATIT : EFFICACY OF THE CHULA RECTUS SHEATH LIFTING DEVICE (CHULALIFT) FOR DIAGNOSTIC LAPAROSCOPIC GYNECOLOGIC PROCEDURE. THESIS ADVISOR: ASSOCIATE PROFESSOR KIANGSAK PRASOPSANTI, M.D. 87 pp. ISBN 974-03-0689-6

Objective : To explore the efficacy of the Chula Rectus Sheath Lifting Device(ChulaLift) for diagnostic laparoscopic gynecologic procedure considering in : success rate, complication rate, and effect of Chula Rectus Sheath Lifting Device(ChulaLift) on the patients

Research design : A randomized controlled allocation, single blinded, phase II of the clinical trial.

Setting : University hospital.

Study population : Forty adult female patients that were subjected to be operated for diagnostic laparoscopic gynecologic procedure in the department of obstetrics and gynecology during October 2000 to February 2001. Twenty patients were allocated into the control group to be operated using carbon dioxide insufflation method, and the other twenty patients were allocated into the Chula Rectus Sheath Lifting Device group. All operations were performed by the same experienced laparoscopic surgical team, and general anesthesia of all the patients were done by the same anesthesiologist.

Both control and experimental groups were not different in the baseline data: ages, body sizes, diseases, underlying diseases, gravida, previous surgeries, and main symptoms.

Results : The success rate for diagnostic laparoscopic gynecologic procedure of the ChulaLift Device group was equal to the control insufflator group. They were 100% success, no failure rate in both groups.

No complications related to the ChulaLift Device occurred in this study : no intestinal perforation, no abdominal wall hematoma, no infection of the hooking sites.

Physiologic changes of the patients during the diagnostic procedure were minimized. The insufflator effectd the patients more than the ChulaLift Device

The insufflator provided exposure greater than the ChulaLift Device measured by the difficulty of the procedure and the operative time.

Conclusion: Result of the initial clinical phase of the ChulaLift was: exposure provided by the Chula Rectus Sheath Lifting Device (ChulaLift) for diagnostic laparoscopic gynecologic procedure might be created safely in normal-weight patients.

Department Faculty of Medicine Student's signature .....
Field of study Health Development Advisor's signature .....
Academic year 2001

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CHAPTER 1

BACKGROUND AND RATIONALE

Carbon dioxide pneumoperitoneum is the conventional technique of tissue exposure in minimal-access surgery. However, laboratory and clinical studies have shown that positive-pressure pneumoperitoneum, 12 mm Hg, is associated with complications and adverse physiologic effects (Table 1.1). Ever since the introduction of CO_2 as insufflating gas for surgical exposure during laparoscopic surgery, attempts have been made to find alternative techniques (1). These include the uses of CO2 at lower pressure, insufflation with inert gas, eg, helium, and abdominal wall lift (AWL).

In the AWL technique, the abdominal wall is lift up with the use of a mechanical lifting device attached to or inserted through the anterior abdominal wall. The lift of the anterior abdominal wall creates adequate space for the introduction of instruments and the performance of the surgical task. The technique potentially eliminates the need for gas insufflation, hence avoid some of the adverse effects of conventional pneumoperitomeum. It has been

suggested that AWL could be beneficial for high-risk patients. The technique was first described by Gazayerli (2) and many different systems have been developed and used in a variety of clinical settings since then.

Table 1.1. Problems with carbon dioxide pneumoperitoneum

Cardiorespiratory
Cardiac output decreases
Cardiac arrhythmia
Mean arterial pressure increases
Pulmonary compliance decreases
Airway pressure increases
Acidosis
Pneumothorax
Visceral ischemia
Surgical emphysema
Gas embolism
Others
Intracranial pressure increases
Hypothermia
Local dissemination of malignancy
Organ injury (Veress needle)
Prolonged postoperative mental recovery
Postoperative pain

AWL systems

In its simplest form, the AWL is achieved by conventional hand-held retractors inserted through a small abdominal incision, with the laparoscope introduced through the same or a separate opening (3,4). This set up is limited in scope and, for the conduct of most operations, specific AWL are needed. Most AWL systems consist of 2 distinguishable components: one for anchorage and the other for traction. The anchoring devices come in a variety of shapes, and are

inserted either in the subcutaneous layer of the anterior abdominal wall or into the peritoneal cavity (Table 1.2). The subcutaneous devices examplified by the Laparo Tenser (Lucini, Milan, Italy) have the theoretical advantage of avoiding damage to the intraabdominal organs during the insertion. Moreover, they avoid pressure trauma to the parietal peritoneum that results from prolonged lift with intraabdominal systems. The area of ischemic peritoneum at the point of lift may cause intraperitoneal adhesion. In most system the anchoring device is attached either to a supporting frame via a chine or a wire, or to a mechanical lifting arm. In others, the anchoring device is an integral part of the traction component (22,23).

Depending on which AWL system is used, the result is one of point, linear, curvilinear, or planar lifting (Fig 1.1). All give a smaller intraabdominal workspace and poorer exposure than that provided by conventional positive-pressure pneumoperitoneum, which lifts and stretches the peritoneal cavity. There are 3 main reasons for the smaller workspace obtained by the AWL technique. First, the exposure in AWL is restricted to 1 area of abdomen only. This limitation has been addressed in some AWL systems by the use of 2 or more curvilinear anchoring devices that simulate the dome-shape exposure of pneumoperitoneum (22,23).

Table 1.2. Abdominal Wall Lift Systems

System	Description of Anchoring Device	Subcutaneous/ Peritoneal	Gas/Gasless/ Low pressure	Method of Lift
Gazayerli[2]	T-shaped	PT	LP	P
Semm[5]	T-shaped	PT	GL	P
Geister[6]	T-shaped	PT	GL (IG)	P
Dragojevic[7]	T-shaped	PT	GL (IG)	P
Cuschieri[8]	Sling	PT	LP	P
Kitano[9]	U-shaped	PT	GL (IG)	L
Araki[10]	K-wire	PT	GL (IG)	L
Nagai[11]	K-wire	S/C	GL (IG)	L
Hashimoto[12]	K-wire	S/C	GL	PL
Akimura[13]	K-wire	S/C	GL	L
Maher[6]	Coat hanger	PT	GL, LP (IG)	L
Voltz[5]	Steel spring	PT	GL (IG)	PL
Suzuki[14]	Modified retractors	PT	GL	PL
Nishii[15]	I- and T-type lifting bars	PT	GL	L, PL
Schaller[16]	2 sleeves & organ retractor	PT	LP (IG)	L
Gutt[17]	Lifting fork & organ retractor	PT	GL	PL
Chin[18]	Fan-shaped	PT	GL	PL
Lucini[19]	2 semicircular needles	S/C	GL, LP	PL
Chang[20]	Airlift balloon retractor	PT	GL	PL
Tintara[21]	Fan-shaped	PT	GL	PL
Nakamura[22]	Fishing-rod-type	S/C	GL, LP	CL
Frank[23]	Superelastic rods	S/C	GL, LP	CL

Abbreviation: S/C,Subcutaneous; PT,Peritoneal; G,Gas; GL,Gasless; LP,Low-pressure; IG,Initial gas needed; P,Point lifting; L,Linear lifting; PL,Planar lifting; CL,Curvilinear lifting.

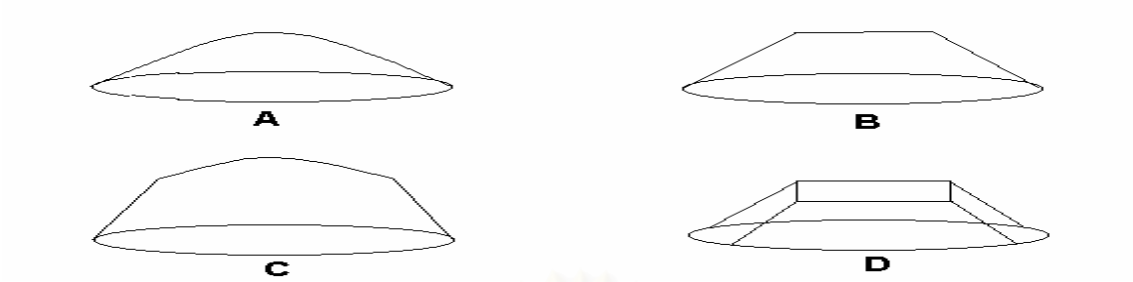


Figure 1.1. Four methods of lifting: (A) Point; (B) Linear; (C) Curvilinear; (D) Planar

Second, and perhaps more importantly, unlike the conventional pneumoperitoneum, most gasless AWL systems do not have the added advantage of pushing the abdominal contents downwards. This limitation can be overcome by the use of either a posterior organs retractor system (16,17) or low pressure CO_2 pneumoperitopneum (8) in addition to the AWL. The third reason accounting for suboptimal workspace results from the tenting effect that tends to flatten the parieties towards the point of lift.

The researcher designed new system of abdominal wall lifting device. This technique has the advantage of avoiding damage to the intraabdominal organs during the insertion. Moreover, they avoid pressure trauma to the parietal peritoneum that results from prolonged lift with intraabdominal systems. The method is logical. Direct lifting at the strong fascial layer of the abdominal wall

should be effective more than indirect lifting at the loose subcutaneous tissue. In order to introduce this system to the surgical and gynecologic communities, the efficacy and safety of the device should be tested scientifically.

CHAPTER 2

REVIRWS OF THE RELATED LITERATURES

2.1 Results of randomized controlled clinical trials on the relative merits of gas versus gasless laparoscopy

A MEDLINE search was carried out, up to an including January 2000. All articles with gasless, abdominal lift, isopneumic, or apneumic in the title or abstract were identified. The relevant articles were retrieved and a hand search of their references was carried out. Inclusion criterior were [1] randomized controlled trials of AWL versus pneumoperitomeum, [2] English language, and [3] human subjects.

Each article was assessed using Evans' qualitative scoring system, (24) (Table 2.1) which scores on design and conduct of the trial (maximum score of 50), the analysis (maximum score of 30), and presentation (maximum score of 20). A total of 213 relevant articles were identified, 19 of which met the inclusion criterior (25-43) (Table 2.2).

Table 2.1. Evans' qualitative scoring system

Design and conduct :50	Presentation :20
Is the sample defined? 2	Is the title accurate? 2
Are exclusions specified? 2	Is the abstract accurate and helpful? 3
Are known risk factors recorded? 3	Are the methods reproducible? 3
Are therapeutic regimens recorded? 5	Are the sections clear-cut? 2
Is the experimental regimen appropriate? 5	Can the raw data be discerned? 2
Is the control regimen appropriate? 5	Are the results credible? 3
Were appropriate investigations carried out? 2	Do the results justify the conclusions?3
Are end points defined? 5	Are the references correct? 2
Are end points appropriate? 5	
Have numbers required been calculated? 2	
Was patient consent sought? 1	
Was the randomization blind? 3	
Was the assessment blind? 4	
Were additional treatments recorded? 4	
Were side effects recorded? 2	
Analysis :30	
Withdrawals: are they listed? 3	
Is their fate recorded? 4	
Are there fewer than 10%? 4	
Is there a comparability table? 3	
Are risk factors stratified? 3	
Is the statistical analysis of proportions correct? 3	
Are confidence interval reported? 2	
Are values of both test statistic and probability given? 1	
In negative trials is the type II error considered? 4	

There consisted of 11 randomized clinical trials (RCTs) laparoscopic gynecologic operations. The quality, using Evans'criterior, of the 19 RCTs was

variable, with a median score of 56 out of a maximum score of 100, and a range of 28 to 71. The greatest defects were in data analysis, with 16 reports scoring less than 12 of 30 on this parameter. This variability in quality is important in assessing the overall picture.

2.2 Cardiovascular and respiratory changes

There is no clear verdict on the relative changes in the cardiac output between the 2 arms in the RCTs that addressed the cardiovascular changes. The conflicting data are almost certainly the result of poor design and methodological defects of the studies. In the first instance, none of the trials calculated the power of the study and the cohort size needed to detecting significant differences in cardiac output between the 2 arms. Second, several methods of differing validity were used to measure the cardiac output of patients entered into the 2 arms, e.g., thoracic impedance, radial pulse pressure-derived technique, transesophageal echocardiography, and esophageal Droppler studies. The thoracic impedance and radial pulse pressure techniques, although noninvasive, are of doubtful validity, (44) and conclusions based on these methods are suspect.

Table 2.2. Randomized Controlled trial of AWL Versus Conventional Pneumoperitoneum

Author(year)	Country	Type of Surgery	Areas of Assessment	No. of Patients
Kitano[27]1993	Japan	LC	Technical,	82
Lindgren[28]1995	Finland	LC	Technical, haemodynamics, respiratory function, postoperative drowsiness, pain, nausea and vomiting	25
Koivusalo[29]1996	Finland	LC	Stress response, renal function	24
Koivusalo[30]1996	Finland	LC	Postoperative recovery, Respiratory function, pain, nausea and vomiting	26
Meijer[31]1997	Holland	LC	Technical, haemodynamics, respiratory function, gas exchange	20
Casati[32]1997	Italy	Ovarian Surg.	Haemodynamics, respiratory function, pain	20
Koivusalo[33]1997	Finland	LC	Technical, renal function, splanchnic perfusion, haemodynamics, gas exchange, pain	30
Yoshida[34]1997	Japan	LC	Technical, stress response	17
Goldberg[35]1997	USA	Gyne surg.	Technical, haemodynamics, respiratory function, pain, nausea and vomiting	57
Koivusalo[36]1997	Finland	LC	Postoperative recovery, nausea and vomiting	25
Johnson[37]1997	USA	Tubal ligation	Technical, haemodynamics, respiratory function, pain, nausea and vomiting	18

Table 2.2. Randomized Controlled trial of AWL Versus Conventional Pneumoperitoneum (continue)

Author(year)	Country	Type of Surgery	Areas of Assessment	No. of Patients
Guido[38]1998	USA	Tubal ligation	Technical, pain	54
Ninomiya[39]1998	Japan	LC	Haemodynamics, gas exchange, renal function, stress response	20
Koivusalo[40]1998	Finland	LC	Technical, haemodynamics, respiratory function, renal function, body temperature, surgical stress response	26
Perner[41]1999	Denmark	Colectomy	Biochemical changes, renal function, gas exchange, haemodynamics	17
Cravello[42]1999	France	Gyne surg.	Technical, pain	103
Schulze[25]1999	Denmark	Coletomy	Technical, haemodynamics, respiratory function, gas exchange, pain, surgical stress response, convalescence	22
Ogihara[26]1999	Japan	Ovarian surg.	Technical, haemodynamics, respiratory function, gas exchange, surgical stress response, renal function	12
Vezakis[43]1999	UK	LC	Technical, pain	36

Abbreviations: GL, Gasless; PP,Pneumoperitoneum; LC,Laparoscopic cholecystectomy

Transesophageal echocardiography is both valid and accurate, (45) but it is technical demanding, making continuous monitoring of intraoperative cardiac

output difficult. However, esophageal Droppler ultrasound probes are simple, noninvasive, and valid, making them ideal for continuous monitoring of trends in cardiac output (46) during surgery. Significantly lower cardiac output was observed in the pneumoperitoneum group with this technique. (25) By contrast, no significant differences in cardiac output between the 2 arms were observed by other measurement techniques, e.g., radial pulse pressure, (31) thoracic impedance, (25) and transesophageal echocardiography. (39) The low cardiac output in the pneumoperitoneum group was not associated with any significant increase in the incidence of myocardial ischemia compared to the AWL group. (25) The mean arterial, central venous, and femoral venous pressures were consistently reported to be higher in the pneumoperitoneum arms. (28,33,40)

Constant minute ventilation produced a larger drop in the pH in-patients allocated to the pneumoperitoneum arms. (26,35) However, there were no differences in pH between the 2 groups in those studies where minute ventilation was varied to keep end-tidal CO2 constant during the operation. (25,31,41) The majority of studies showed that lung compliance was higher (26,28,32,40) and peak airway pressure was lower (26,35,37) during surgery in the AWL group.

One RCT evaluated the postoperative lung function and found no difference between the 2 arms. (25)

2.3 Organ perfusion and stress response

The AWL technique better preserves the intraoperative urinary output, (26,29,33,40) renal plasma flow, (39) glomerular filtration rate, (39) and renal medullary oxygenation. (40) It also causes less renal tubular damage (33) when compared with the pneumoperitoneum technique. However, none of these changes lasted for a long time after surgery. Although stress hormone (adrenaline, noradrenaline, antidiuretic hormone, and plasma rennin activity responses (29,40) appeared to be more pronounced in the pneumoperitoneal group, 1 study showed higher levels of inflammatory marker (interleukin-6, interleukin-10, CPR and circulating lymphocyte) in the AWL group (34).

2.4 Postoperative course

Table 2.3 shows the protocol for postoperative pain assessment and management. Three RCTs calculate the power of study and used single-blind technique. (35,38,43) However only 1 trial (43) evaluate postoperative pain in the

2 arms using a standardized analgesic protocol after the same operation (laparoscopic cholecystectomy). This trial reported no difference in postoperative abdominal pain between the 2 arms, but surprisingly more postoperative shoulder pain in the AWL group. (43)

The incidence of nausea and vomiting was assessed in various ways; by the number of patients needing antiemetics, (28,35) number of patients vomiting, (30,36) or by visual analogue scale. (37) Three studies (35,37,43) showed no significant difference in postoperative nausea and vomiting between the two arms, whereas 3 others (28,30,36) reported increased postoperative vomiting rates in the pneumoperitoneum groups. The only RCT using a standardized antiemetic protocol and visual analogue scale found no difference in postoperative nausea between the 2 arms. (37) There was enough information in 13 reports to calculate the mean body mass index (BMI) of the AWL group (Table 2.4). The range of BMI in the AWL patients recruited to these studies was 20.4 to 27.0. The patients undergoing laparoscopic gynecological procedures had a lower average BMI (22.4) compared those having laparoscopic cholecystectomy (25.6). A sizeable cohort varying from 16%to 40% of gasless gynecological procedures were converted to low-pressure AWL for better exposure. (35,37,42)

Table 2.3. Postoperative Pain in Randomized Trials of AWL Versus Conventional Pneumoperitoneum

Author	Measurement Tool	Protocol	Subjects Blind?	Finding
Lindgren[28]	10 cm VAS and analgesic consumption	Oxycodone in recovery and 24 hrs, Ketorolac for 24 hrs	_	More shoulder pain in PP, same analgesic consumption
Casati[32]	10 cm VAS	_	_	1 hr postoperative, more pain in AWL; 6 hrs, no difference
Koivusalo[33]	Verbal rating (0-3), and analgesic consumption	Oxycodone in recovery and 24 hrs, Ketorolac for 24 hrs	_	More shoulder pain in PP, same analgesic consumption
Goldberg[35]	10 cm VAS and analgesic consumption	Oral Ketorolac and fentanyl in recovery	Yes	No difference in pain and analgesic consumption
Johnson[37]	10 cm VAS and analgesic consumption	Standard dose of morphine and NSAID	Yes	No difference in pain and analgesic consumption
Guido[38]	30 cm VAS	Combination of analgesic used	Yes	No difference in shoulder, periumbilical or lower abdominal pain
Cravello[42]	Analgesic consumption	_	_	No difference in analgesics consumption
Schulze[25]	VAS	Intra- and postoperative Epidural for 48 hrs and additional 5-10 mg	_	More pain in AWL group. No difference in analgesic consumption

Table 2.3. Postoperative Pain in Randomized Trials of AWL Versus Conventional Pneumoperitoneum (continue)

Author	Measurement Tool	Protocol	Subjects Blind?	Finding
Vezakis[43]	10 cm VAS and analgesic consumption	Same dose paracetamol and codeine for all	Yes	No difference in abdominal pain, more shoulder pain in AWL group. No difference in analgesics consumption

Abbreviation: VAS,Visual analogue scale; PP,Pneumoperitoneum; NSAID, Nonsteriodal anti-inflammatory drug.

Patients requiring low-pressure pneumoperitoneum in addition to the AWL had a higher average BMI than those who underwent a totally gasless technique. (42) In one RCT, the participating surgeons found completely gasless laparoscopic cholecystectomy impossible to perform. They completed the trial with low-pressure AWL. (31) Two additional RCTs, performed by using a subjective scoring system, reported better exposure of pelvic organs and easier execution of the procedure in the pneumoperitoneum compared with AWL arm. (35,37) Intraoperative cholangiography is generally regarded as the most technically demanding step of laparoscopic cholecystectomy, requiring good surgical exposure. Only 3 studies (28,34,43) reported on routine use of

Table 2.4. Technical Aspects in Randomized Trials of AWL Versus Conventional Pneumoperitoneum

Author	Type of Surgery	Type of Lift	IAP in PP group (mmHg)	AWL/PP Operation Time (min)	BMI in AWL (Kg/m^2)	Conversions
Kitano[27]	LC$	U-shaped retractor	_	53/62	_	1 AWL and 5 PP
Lindgren[28]	LC#	Hoffman' trocar	11	103/86	26.7	_
Koivusalo[29]	LC#	Hoffman' trocar	11	86/107	26.6	_
Koivusalo[30]	LC$	Laparolift	12-15	108/85*	25.1	_
Meijer[31]	LC#	Laparolift	15	72/50*	25.6	1 AWL and 1 PP
Casati[32]	Ovarian surgery$	Inflatable ring-shaped retractor	12	_	22.2	_
Koivusal[33]	LC$	Laparolift	12-13	76/86	25.3	_
Yoshida[34]	LC#	K-wires	8	121/114	25.8	_
Goldburg[35]	Gynecological operation$	Laparolift	15	80/56*	_	6/28 AWL to PP
Koivusalo[36]	LC#	Hoffman' trocar	12-15	_	_	_
Johnson[37]	Tubal ligation$	Fan-shaped electric lifting device	_	56/28*	_	4/10 AWL to PP

Table 2.4. Technical Aspects in Randomized Trials of AWL Versus Conventional Pneumoperitoneum (continue)

Author	Type of Surgery	Type of Lift	IAP in PP group (mmHg)	AWL/PP Operation Time (min)	BMI in AWL (Kg/m^2)	Conversions
Guido[38]	Tubal ligation$	Laparolift	15	44/31*	24.6	1 AWL and 1 PP
Ninomiya[39]	LC$	U-shaped retractor	10	85/94	22.6	_
Koivusalo[40]	LC$	Laparolift	12-13	108/85	25.7	_
Perner[41]	Colectomy $	Laparolift	<1.83 kPa	120/180	_	_
Cravello[426]	Gynecological operation$	Laparolift	_	62/51	22.2 (25.9 in converted group)	1 AWL and 1 PP, 8/51 AWL to PP
Schulze[25]	Colectomy $	Laparolift	_	145/150	_	AWL and 3 PP
Ogihara[26]	Overian carcinoma resection$	K-wires	12-13	153/153	20.4	_
Vezakis[43]	LC$	Laparotenser	8	95/73*	27	2 AWL to PP

$Represents gasless abdominal wall lift versus pneumoperitoneum.

#Represents low-pressure AWL versus pneumoperitoneum.

*Represents statistically significant difference.

Abbreviations: LC,Laparoscopic cholecystectomy; PP,Pneumoperitoneum; BMI,Boby mass index; LAP,Intraabdominal pressure.

intraoperative cholangiogram for laparoscopic cholecystectomy. Two of these studies (28,43) reported fewer failed attempts at cholangiograms in the pneumoperitoneal group compared with the AWL group, but in another study, (34) the surgeons successfully carried out cholangiograms on all the AWL cases. These were no intraoperative complications in either arm in 7 RCTs. (25,28-32,40,43) One study reported an instance of intraoperative bleeding in each group, both of which required laparotomy, (38) and another documented a bladder injury in the pneumoperitoneum arm. (35) These were no major postoperative complications reported in any of these RCTs.

2.5 Introduction of the ChulaLift Device

Comparing all these kinds of gasless method, the method that does not insert instrument into abdominal cavity will not apply direct traction force to the peritoneum which are skin hook lifting and subcutaneous wiring technique. The subcutaneous wiring lifting will provide surgical space and exposure superior to the skin hook lifting. But both skin hook lifting and subcutaneous wiring lifting method require more surgical wound comparing to the Intra-abdominal instruments lifting and the Intra-abdominal ring balloon lifting. These later

methods required no more wound because the instrument used in these methods were inserted directly through the same surgical wound as the laparoscope and camera. But the wound usually is extended out 10-20 millimeters more.

This new invented device is **the Chula Rectus Sheath Lifting Device (ChulaLift).** The theory of the device is: the surgical field could be created sufficiently in gasless technique if the lifting force is applied directly at the framework of the abdominal wall, the musculoaponeurotic layer, the rectus abdominis muscle and sheaths. In this device, the anterior rectus sheath is hooked by the instrument. The lifting force distributes through the musculoaponeurotic layer creating a dome-like configuration of the lifting site providing a sufficient cavity for surgical field and for mobilization of the intestines. This new equipment does not produce peritoneal irritation, so shoulder pain is not induced. No long tract of subcutaneous wires are left and no additional port sites is required. The traction force will be applied at the strongest layer of the abdominal wall, the anterior rectus sheath of which the rectus muscles protects the underlying epigastric vessels and peritoneum. Data from the pilot study, this new instrument is practical and safe to install, less tissue trauma and irritation, less expensive, flexible to be used for each

operation, harmony with other operative instruments, and it does not obstruct the surgical motion.

This surgical lifting device includes a gripping portion for hooking the anterior rectus sheath, placed between the umbilical port and the suprapubic region. This installation is done by direct puncture of the hook of the gripping portion manually through the skin and redirection of the tip of the hook placing between the anterior rectus sheath and the rectus abdominis muscle. The alternative method is installation by insertion through the surgical puncture wound of the surgical blade. The site of installation by direct puncture is paramedian at the proximal one-third of the distance between the umbilicus and the pubic symphysis. The device further includes a lifting portion that extends outwardly from the gripping portions. This lifting portion is a rigid double curves frame attached to the siderail of the operative table to the left of the assistant and opposite the surgeon. The first curve of the lifting portion is for the patient's abdomen and the second curve is for the edge of the operative table. The lifting portion can be adjusted the height and can be moved along the siderail of the operative table.

CHAPTER 3

RESEARCH METHODOLOGY

3.1 Research Questions and Objectives

3.1.1 Research Question

Primary research question

What is the efficacy of the Chula Rectus Sheath Lifting Device for diagnostic laparoscopic gynecologic procedure.

Secondary research questions

1.Are there any complications related to the Chula Rectus Sheath Lifting Device in diagnostic laparoscopic gynecologic procedure?

2.How the Chula Rectus Sheath Lifting Device affects the patients during diagnostic laparoscopic gynecologic procedure?

3.How the Chula Rectus Sheath Lifting Device creates exposure during diagnostic laparoscopic gynecologic procedure?

3.1.2 Research Objectives

General objective

1.To explore the efficacy and complications of the Chula Rectus Sheath Lifting Device in diagnostic laparoscopic gynecologic procedure.

2.To form interdepartmental research team including anatomist, gynecologist and anesthesiologist.

Specific objective

1.To determine the success rate, and complications of the Chula Rectus Sheath Lifting Device in diagnostic laparoscopic gynecologic procedure.

2.To measure the effect of the Chula Rectus Sheath Lifting Device on the patients during the operation.

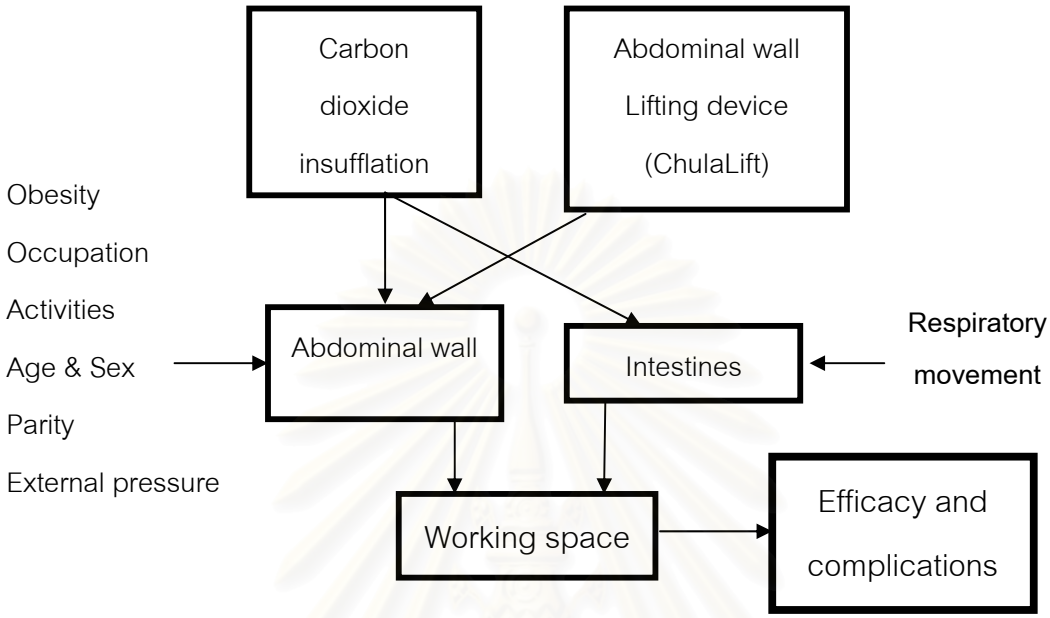
3.To examine the exposure created by the Chula Rectus Sheath Lifting Device

3.1.3 Hypothesis

This is the phase II of the clinical trial. The efficacy and the complications of the device will be explored, no hypothesis is tested.

Assumption There is no assumption.

3.2 Conceptual Framework



3.3 Key Words

- gasless laparoscopic
- ChulaLift device
- pneumoperitoneum
- insufflation
- exposure
- working space
- Chula Rectus Sheath Lifting Device
- efficacy
- abdominal wall lifting

3.4 Operational Definitions

Success : Surgeon can evaluate extent of pathology, all pelvic structures can be inspected carefully.

Failure : The equipment does not create space. The surgeon can not do any diagnostic laparoscopic procedure, all the pelvic structures can not be seen. The surgeon converts the operation to other equipment or conventional open laparotomy.

Complication : Infection, Hematoma, Intestinal perforation.

Operative time : First cut to last stitch.

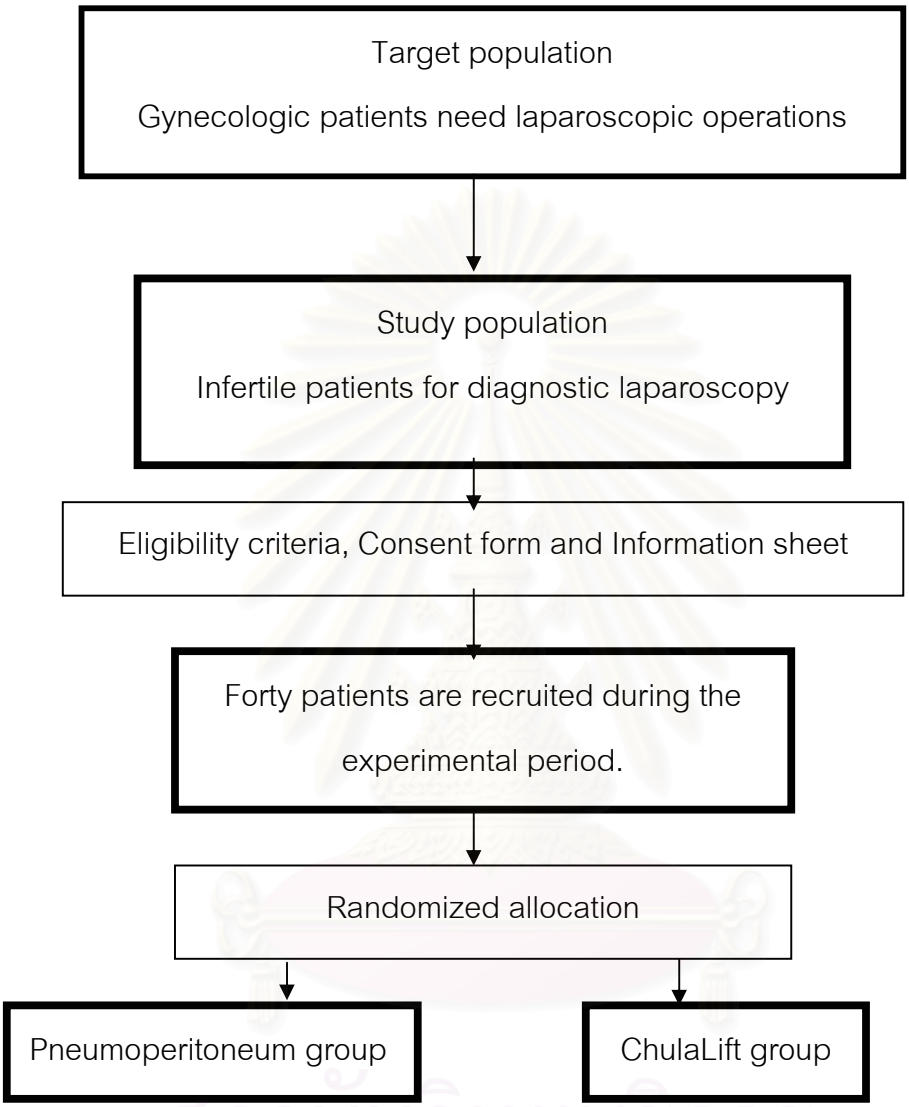
DLGP : Procedure in evaluation of pathology in pelvic cavity.

ChulaLift: Instrument for abdominal wall lifting in gasless laparoscopic surgery.

3.5 Research Design

Randomized controlled allocation, single blinded, phase II of the clinical trial.

3.5.1 Research Design model



3.6 Population

3.6.1 Target population

Female adult patients aged more than 15 years which are subjected to be operated for diagnostic laparoscopic procedure.

3.6.2 Study population

Female adult patients aged more than 15 years which are subjected to be operated for diagnostic laparoscopic procedure in the department of obstetrics and gynecology, King Chulalongkorn Memorial Hospital.

3.6.3 The eligible criteria are

Inclusion criteria

1.Do not have any contraindication for diagnostic laparoscopic procedure.

2.Female patients aged between 15 and 45 years who sign informed consent.

Exclusion criteria

1.Patients who have serious chronic disease or ASA grade III, IV, V and E.

2.Patients who refuse to participate in this trial.

3.Body weight exceeds 100 kilograms.

3.6.4 Sampling Techniques

No sampling technique, 40 female patients which were subjected to be operated for diagnostic laparoscopic procedure by the surgeon of the investigating team were recruited during the experimental period.

3.6.5 Sample Size Determination and Randomized Allocation

The phase II of the clinical trial related to the novel intervention requires 20-30 cases for the intervention group.(47) The efficacy and complications of the new surgical device should not be studied in a large group of subjects because of the ethical issue. The further large-scale clinical trials should be conducted, only if this phase demonstrated excellent results. Forty cases of the patients were randomly allocated into two groups by two sets of random permutations of 20 numbers combined in a sequence of sealed envelopes. Twenty patients were allocated to the control group to be operated using carbon dioxide insufflation and the other group of 20 cases was the group to be operated with the Chula Rectus Sheath Lifting Device in diagnostic laparoscopic gynecologic procedure. A reason of studying both experimental and positive controlled groups in this study was to demonstrate the understandable magnitude of efficacy compared to the conventional method. After informed consents were obtained, The randomized process was done by opening the allocation envelopes when the patient was in the operating room.

3.7 Observation and Measurement

3.7.1 Outcome variables

Primary outcome

1) The success rate : Surgeon can evaluate extent of pathology, all pelvic structures can be inspected carefully. The diagnosis and treatment planning are established.

Secondary outcome

1) The operative times of the two groups. Start from the first cut to the last stitch.
2) The intraoperative and the postoperative complications such as bleeding ,local wound infection, systemic infection, intestinal perforation.
3) The scores representing the difficulty of the operation rating by the surgeon who do the procedure and a blinded surgeon after watching the video tape of the operation. The difficulty of the operation is measured by categorizing the degree of difficulty in 5 levels(1-5).
4) The post operative pain evaluated by the visual analogue pain rating scale evaluated at 1 hour post operative period.

5) Blood pressure, heart rate, end-tidal CO_2 concentration (capnogram), peripheral arterial oxygen saturation (pulse oxymetry), and expired minute volume of ventilation were recorded every 5 minutes during the operation.

3.7.2 Independent variables

The insufflator and the new device will separate the patients into two groups, The first control group is the conventional insufflation group and the second group is the new device group.

3.7.3 Confounding factors

The body size of the patient.

The extension of the diseases.

3.7.4 Reliability and validity test

The inter-rater reliability of the surgeon and the blinded surgeon who was the assessor was tested. All the equipment used in this study was calibrated weekly during the study.

3.7.5 Measure Instruments

Table 3.1 Measure Instruments

Outcome variables	Measure Instruments
Operative times, success rate, complications	Operative records
Difficulty of the operation	Degree of difficulty, video tapes of the operation
Post operative pain	Visual analogue scale
Blood pressure, heart rate, end-tidal CO_2 concentration, peripheral arterial oxygen saturation, and expired minute volume of ventilation	Noninvasive blood pressure, Anesthetic machine

3.8 Intervention

3.8.1 Diagnostic laparoscopic procedure

The study protocol was approved by the ethics committee of the faculty of medicine, Chulalongkorn University. The written informed consents were obtained from all the patients. Forty patients undergoing diagnostic laparoscopic procedure were randomly allocated into two groups. In one group, the operation was performed using insufflation. The intra-abdominal pressure was 30 mmHg. In the other group, a mechanical retractor, the Chula Rectus Sheath Lifting Device was used to elevate the anterior part of the abdominal wall upward. No carbon dioxide was used in this group. All operations were performed by the same experienced laparoscopic surgical team, and general anesthesia of all the patients were done by the same anesthesiologist. The laparoscope was inserted

into the abdominal cavity for evaluation of the visualization obtained by the two methods and equipment. The patients were allowed to go home in the evening of the operative day. After discharge from the hospital, the patients were asked to come back to have an examinations at the fourth day postoperative period for detection of the complications.

3.8.2 Prevention of biases

As many clinical experimental studies, there were many steps which biases might occur. This study was designed to aviod biases in many steps and described below.

1. Selection bias. Using two sets of random permutations of 20 numbers combined in a sequence of sealed envelopes could prevent selection bias and a research anesthsiologist determined type of the device for the patients when the patients entered the operative room. The surgeon team could not determine the type of the device by themselves.
2. Measurement bias. Measurement bias was prevented by blinding the evaluator about the type of the device by asking him the difficulty of the procedure after watching the video recorded from the laparoscopic

camera. The patients were educated about the visual analog pain scale in the recovery room. The anesthesiologist nurse who did not know the type of device marked the scale where the patient pointed.

3.8.3 Criteria for conversion

The surgeons made their best effort to finish the assigned operation. In case that it might be harmful to the patients, they convert to the other equipment. In this situation, they have a chance to convert from ChulaLift device to insufflator.

The criteria for conversion were

1.The device does not create sufficient surgical space. In this situation, conversion to insufflator is required. It could be (1) no space created by the new device or (2) the ChulaLift device does not create enough space for diagnostic laparoscopy. This situation may be from (1) the new device itself, it can not function properly or from (2) the patient factor. If the preperitoneal fat is thick and bulgy and the omental fat is very thick or the pathology ;ovarian cysts, myoma uteri, adenomyosis, are very large.

2.Complications occur such as active bleeding or intestinal perforation, which can not be controlled or corrected by laparoscopic means. In this situation, open laparotomy is required.

3.9 Data management

3.9.1 Observation and Measurements.

The clinical outcomes were observed, measured and recorded in details

1.Success rate and failure rate of the procedure

The surgeon and his assistant recorded the result of the procedure both in the conventional hospital operative records and in the case record forms. The surgeon drew a picture of the operative field and illustrated every details of the pathology of the patients. All of these details included diagnosis of the disease, extent of the pathology, deformities of the organs, patency of the uterine tubes, severity of the disease, adhesion of the organs and estimate size of the ovarian cyst or myoma.

2.Complication rate of the ChulaLift device

The griping portion of the ChulaLift device was a hook. This hook was 4 millimeters in diameter and 3 centimeters in transverse plane. Length of the hook

is 4.5 centimeters. The hook seemed to be hazard to the abdominal wall. The possibility of the complication could be bleeding, infection, and intestinal perforation.

When the hook was applied to the abdominal wall, the subcutaneous vessels could be accidentally penetrated by the hook. The hook could damage the anterior abdominal muscle, the rectus abdominis. The inferior epigastric vessel could be pierced if the hook was inserted too deep into this layer. This event could cause ecchymoses or hematoma of the abdominal wall both in the subcutaneous layer and in the rectus abdominis muscle.

Intestinal perforation could occur if the hook penetrates into the abdominal cavity and the intestines were fixed to the anterior abdominal wall from the adhesion process. Unaware of this complication might lead to serious and fatal infection in the abdominal cavity, the bacterial peritonitis. To cope with this complication, the abdominal cavity should be washed vigorously by suction and irrigation with normal saline or ringer lactate solution. If the opening was large enough for the intestinal contents, the hole should be sutured and tied.

The infection could be occurred in the abdominal wound of the hook site. This situation was not serious. Oral antibiotics or local wound care should be enough. However this event should be recorded and reported

3.Operative time of the procedure

The anesthesiologist and the assistant of the surgeon recorded the time independently, began from the start of the general anesthesia, continued through all the process; the abdominal entry procedure, the installation of the device, and the diagnostic procedure, finished after the last stitch of the suture placement. After each procedure of each patient, the anesthesiologist examined the accuracy of the recorded time with the operative record of the surgeon recorded by the assistant of the surgeon.

4.Difficulty of the procedure

The surgeon evaluated this aspect by himself and recorded in the case report form after each procedure. And then, after they finish all the procedure of that day, the blinded assessor was asked to judge the difficulty of the procedure by watching the videotape recorded from the laparoscopic camera.

The sequence of the tape was rearranged before the blinded assessor watched them. The blinded assessor was not informed the name of the patient,

the diagnosis, and the device used in that patient. The blinded assessor was asked that he could tell, for sure, what was the device used in that patient.

Criteria for evaluation of the difficulty of the operation

Level 1.The surgeon can evaluate extent of pathology, all the pelvic structures can be inspected carefully, cauterization and biopsy can be done if required.

Level 2.All the pelvic structures can be examined. Instrument is often used to mobilize the intestines , cauterization and biopsy can be done if required.

Level 3.The surgeon completes diagnostic procedure with difficulty. By carefully mobilizing the intestines, all pelvic structures can be inspected. Cauterization and biopsy can be done.

Level 4.The surgeon can do diagnostic procedure with very difficulty, some of the pelvic organs can be inspected , cauterization and biopsy can not be safely done.

Level 5.The equipment does not create space. The surgeon can not do any diagnostic procedure, all the pelvic structures can not be seen.

5.Physiologic change of the patient during the procedure affected by the instruments

The anesthesiologist and the anesthesiologist nurse recorded the physiologic changes of the patient during the procedure, began from the start of the general anesthesia, continued through all the process; the abdominal entry procedure, the installation of the device, and the diagnostic procedure, finished after the endotrachial tube withdrawal. All the physiologic change included; heart rate, blood pressure, electrocardiogram, end –tidal CO2, pulse oxymetry, airway pressure, and blood gas in some cases. The anesthesiologist used the same non-invasive blood pressure monitor to observe these changes.

6. Postoperative pain at one hour

The patients and the anesthesiologist nurse who took care of the patients after the operation were blinded. The results of the pain of the insufflator and the ChulaLift device were evaluated by the visual analog pain scale separately into; abdominal wound sharp pain, dull aching shoulder pain, and discomfort of the pelvic pain. The anesthesiologist nurse marked on the line of the visual analog pain scale at the point the patient intended to express her magnitude of pain. All the pain were asked with non-leading question.

The visual analogue pain scale is:

How much is your pain now?

Dull pain at the shoulders

No pain ☐ Can not tolerate

Sharp pain at the surgical wounds

No pain ☐ Can not tolerate

Dull pain at the pelvis

No pain ☐ Can not tolerate

All clinical outcomes were recorded in a case report form of the surgeon, the operative record, and/or the anesthesiologist record form.

3.9.2 The baseline variables

The baseline variables; age, weight, body mass index, past history and associated disease, were recorded and evaluated to show the distribution between the two group.

3.9.3 Data Collection

The operative procedures were recorded in video tape by the nurse. All the operative findings, the procedures, the difficulty of the operation were recorded by the operating surgeon. Blood pressure, heart rate, end-tidal CO_2

concentration, peripheral arterial oxygen saturation, and expired minute volume of ventilation were recorded by anasthesiologist. After the operation the blinded surgeons made a judgement on the video tapes for the difficulty of the operation. The pain scores of the patients were evaluated by the anesthesiologist at 1 hours postoperatively. The demographic data of the patients including body mass index were kept separately as a reference by the investigator.

3.10 Data Analysis

3.10.1 Analysis of zero state variables : These variables were reported in mean, range, S.D., percentage

3.10.2 Analysis of outcome variable : Because the main objective of this study was to explore the efficacy of the new device, **Difference of the outcomes between the conventional insufflation group and the new device group was trend not conclusion.** Differences between continuous variables were evaluated with the unpaired student's t test for variables that were normally distributed and the Mann-Whitney U test for variables that were not normally distributed. All tests were two–sided. The differences were considered significant only if $p < 0.05$. Differences between categorical variables were evaluated with Chi-squared test or Fisher's

exact test. Repeated measures such as vital signs, end-tidal CO_2 concentration were presented by graphics plotting curves joining the means of every time points from each group. Analysis of repeated measures were interpreted by comparing the change at 0, 5, 10, 15 minutes time points.

1.Descriptive statistics of the data set.

Variables	Type of variables	Statistics
Demographic data and baseline variables		
Age (years), Weight (kg.), Height (cm.)	Continuous data	Mean, range, S.D.
Parity	Discrete data	Mean, range, S.D.
Diagnosis/pathology	Nominal data	Percentage
Primary outcome variable		
Success rate	Nominal data	Percentage
Secondary outcome variables		
Operative times	Continuous data	Mean, range, S.D.
Complication rate	Nominal data	Percentage
Difficulty of the operation	Ordinal data	Percentage
Post operative pain	Continuous data	Mean or median, range, S.D.
Blood pressure	Continuous data	Mean, S.D.
Heart rate	Discrete data	Mean, S.D.
End-tidal CO_2 concentration	Continuous data	Mean, S.D.

2.Statistical test

Variables	Statistical test
Primary outcome variable	
Success rate	Chi-squared test or Fisher's exact test
Secondary outcome variables	
Operative times	unpaired student's t test or Mann-Whitney U test
Complication rate	Chi-squared test or Fisher's exact test
Difficulty of the operation	Mann-Whitney U test
Post operative pain	Mann-Whitney U test

3.11 Ethical Consideration

The study protocol was approved by the ethics committee of the faculty of medicine, Chulalongkorn University. The details of the study protocol were explained to the subjects and written informed consent were obtained in all cases before enrolling in the study. The informed consent document contained a statement that the consent was freely given, the patient was aware of the risks and benefits of entering the study, and the patients were free to withdraw from the study at any time whenever they want, without interference with regular care. The investigating team consisted of surgeons, anasthesiologist, nurses who were competent in this field. Any complications related to the new instrument were aware and the patients were treated with full responsibility by the investigating team.

3.12 Limitation

The clinical trial required large amount of budget and cooperation of the related personals. The investigator monitored all the steps of the trial closely to be certain the trial was conducted correctly.

3.13 Expected Benefits and Application

If this new instrument can provide enough surgical area and better exposure, the surgeon will be satisfied to use it. This instrument will be available in any hospital due to the inexpensive price. The new instrument will expand the opportunities to conduct many clinical trials in different kinds of operations such as in other gynecological procedure and general surgery operation. Gasless technique provides opportunity to develop complicated surgical procedure such as reconstruction surgery that insufflation does not allowed due to limitation of the close system.

3.14 Obstacles and strategies to solve the problems

The study of efficacy of the new surgical device should be conducted carefully. If there is an evidence that the instrument will harm the patients, the study should be terminated completely. The patients should be closely monitored for any complication related to the new device.

3.15 Administration and Time Schedule

Administration and Time Schedule	1	2	3	4	5	6	7	8	9	10
Instrument invention	→									
Adjustment		→								
Planning			→							
Apply for funding				→	→					
Interventions						→	→	→		
Data collection						→	→	→		
Data analysis									→	
Report the results										→

3.16 Budget

The total cost is 136,000 baths.

Cost of general anesthesia	3,000*40=120,000
Cost of blood gas examination	300*40= 12,000
Cost of video tapes	100*40= 4,000

CHAPTER 4

RESULTS

Results: The following result was based on analysis of 40 diagnostic laparoscopic gynecologic procedure. Each group contained 20 patients. The analysis was based on intention to treat basis.

4.1 Baseline data

Table 4.1. Baseline data

	ChulaLift group (n=20)	Insufflator group (n=20)
Age (year) (mean±SD)	33.9±4.3	34.0±6.5
Weight (Kg.) (mean±SD)	50.8±6.1	51.5±8.1
Height (cm.) (mean±SD)	156.1±6.1	158.8±7.3
Body mass index(mean±SD)	20.8±2.0	20.7±3.1
parity	0 (infertile)	0 (infertile)

Table 4.2. Pathology or Disease [Number , Percent (%)]

	ChulaLift group (n=20)	Insufflator group (n=20)
Endometriosis	11 (55%)	13 (65%)
Ovarian cyst	4 (20%)	8 (40%)
Myoma or Adenomyosis	6 (30%)	5 (25%)
Pelvic adhesion	5 (25%)	4 (20%)
Severe pelvic disease	4 (20%)	6 (30%)

The baseline characteristics of the two groups were comparable. Mean body mass index which was the most importance confounding factor were 20.8 kg/m^2 in the ChulaLift group and 20.7 kg/m^2 in the insufflator group respectively. The pathology in the pelvis was similar. Most of the patients of

this trial came from the infertile clinic of the King Chulalongkorn Memorial Hospital.

4.2 Success rate and failure rate of the procedure

Table 4.3. Two by two table of Success rate of the procedure [Number , Percent (%)]

	ChulaLift group (n=20)	Insufflator group (n=20)
Success rate (n)	100%(20)	100%(20)
Failure rate (n)	0%(0)	0%(0)
total	100%	100%

Success rate: The rate of the procedures that the surgeon could evaluate extent of pathology, all pelvic structures could be inspected carefully. Failure rate: The rate of the procedures that the equipment,ChulaLift device or insufflator, did not create sufficient space. In this situation, the surgeon could not complete the diagnostic laparoscopic procedure because some important structures such as fimbriae of the uterine tubes, ovaries, and cul-de-sac or all of the pelvic structures could not be seen. So, the surgeon converted the operation to other equipment or conventional open laparotomy in order to continue and complete the diagnostic laparoscopy. In this study, no conversion to other arm occurred. The success rates of the two groups were 100%. The statistical test was not required in this result.

4.3 Complication related to the Chulalift device.

There was no complication that related to the procedure. Physical examination on the fourth day after the diagnostic procedure revered that no hematoma or ecchymosis above the site of the hook application. The wound was sealed by blood clot, no sign of local wound infection. No sign of intestinal perforation was detected during the diagnostic procedure, The hook was not penetrated the peritoneum into the abdominal cavity. All of the patients did not complain any symptom of severe abdominal pain or persisting high-grade fever suggesting peritonitis in the follow-up day.

There was one complication related to the procedure, not related to the ChulaLift device. During the mobilization of the uterine tube by using the Veress needle to expose the fimbriae in one patient, the surgeon accidentally ruptured the serous ovarian cyst. This event was not serious. The surgeon aspirated the content of that ovarian cyst and sent for cytological examination. Then he continued the diagnostic procedure, injected the blue dye through out the uterine cavity and the uterine tubes to confirm patency of the uterine tube.

4.4 Operative time

Table 4.4. Operative time of the diagnostic laparoscopy

	ChulaLift group (n=20)	Insufflator group (n=20)
mean±SD (min)	21.5±9.9	15.9±5.6
median interquatile range (min)	18.0 10.5	15.0 8.8

Table 4.5. Test Statistics of Operative time

Mann-Whitney U	132.500
Asymp. Sig. (2-tailed)	.067

Mann-Whitney U test for the difference between the ChulaLift and insufflator group was not statistic significance, p value = 0.067. Because this study did not aim at the difference of the two group, the sample size was not calculated. Although this result obviously showed that the operative time in the ChulaLift group was longer than the insufflator group. The surgeon spent more times during open technique of abdominal entry procedure in the ChulaLift group compared to the standard abdominal entry technique using Veress needle and specific port and trocar in the insufflator group. However, the open technique did not required specific laparoscopic instrument, from economic point of view, this procedure was applicable to our country. Because of the simple and very plain steps of installation of the ChulaLift device and the well-trained surgeon, the installation time of the ChulaLift device was less than 5 nimutes in all cases.

4.5 Difficult of the procedure

Table 4.6. Difficulty of the procedure of the diagnostic laparoscopy scored by the surgeon

	ChulaLift group (n=20)	Insufflator group (n=20)
mean±SD (min)	1.70±0.73	1.30±0.55
median interquatile range (min)	2.00 1.00	1.00 0.75

Table 4.7. Difficulty of the procedure of the diagnostic laparoscopy scored by the blinded assessor

	ChulaLift group (n=20)	Insufflator group (n=20)
mean±SD (min)	1.85±0.75	1.20±0.41
median interquatile range (min)	2.00 1.00	1.00 0.00

Table 4.8. Test Statistics of **Difficult of the procedure of the diagnostic laparoscopy**

	Surgeon	Assessor
Mann-Whitney U	138.000	102.000
Asymp. Sig. (2-tailed)	.054	.003

Table 4.9. Crosstabulation of Surgeon and Blinded assessor

Count	Surgeon				Total
Blinded assesor		1.00	2.00	3.00	
	1.00	21	2	0	23
	2.00	3	8	2	13
	3.00	0	2	2	4
Total		24	12	4	40

Table 4.10. Agreement between Surgeon and Blinded assessor

Probability of observe value	0.8875
Probability of expected value	0.6675
Kappa	0.66

Mann-Whitney U test for the Difficult of the procedure of the diagnostic laparoscopy scored by the surgeon was not statistical significance, p value = 0.054. But. Mann-Whitney U test for the Difficult of the procedure of the

diagnostic laparoscopy scored by the blinded assessor was statistic significance, p value = 0.003. This result scored by the blinded assessor obviously showed that the exposure in the ChulaLift group was inferior to the insufflator group. The surgeon spent more effort during the procedure in the ChulaLift group compared to the insufflator group. Weighted Kappa statistic testing agreement between the surgeon and the blinded assessor was 0.66, This meant that the agreement between the blinded and open assessor was good, which was acceptable.

4.6 Postoperative pain

Table 4.11. Wound pain of the diagnostic laparoscopy

	ChulaLift group (n=20)	Insufflator group (n=20)
mean±SD (min) range	2.8±3.1 0.0-10.0	1.9±2.9 0.0-10.0
median interquatile range (min)	1.5 5.0	0.0 4.8

Table 4.12. Shoulder pain of the diagnostic laparoscopy

	ChulaLift group (n=20)	Insufflator group (n=20)
mean±SD (min) range	0.2±0.9 0.0-4.0	0.0±0.0 0.0-0.0
median interquatile range (min)	0.0 0.0	0.0 0.0

Table 4.13. Pelvic pain of the diagnostic laparoscopy

	ChulaLift group (n=20)	Insufflator group (n=20)
mean±SD (min) range	0.05±.22 0.0-1.0	0.5±2.2 0.0-10.0
median interquatile range (min)	0.0 0.0	0.0 0.0

Table 4.14. Test Statistics: **Wound pain, Shoulder pain, and Pelvic pain of the diagnostic laparoscopy**

Pain	Wound	Shoulder	Pelvic
Mann-Whitney U	163.000	190.000	199.500
Asymp. Sig. (2-tailed)	.283	.317	.971

Table 4.15. Crosstab **of Wound pain of the diagnostic laparoscopy**

Count		Wound pain		Total
		No	Yes	
Group	Insufflator	12(60%)	8(40%)	20
	ChulaLift	8(40%)	12(60%)	20
Total		20	20	40

Table 4.16. Chi-Square Tests **of Wound pain of the diagnostic laparoscopy**

	Value	df	Asymp. Sig. (2-sided)	Exact Sig. (2-sided)
Continuity Correction[a]	.900	1	.343	
Fisher's Exact Test				.343
N of Valid Cases	40			

Table 4.17. Crosstab of **Shoulder pain of the diagnostic laparoscopy**

Count		Shoulder pain		Total
		No	Yes	
Group	Insufflator	20(100%)	0(0%)	20
	ChulaLift	19(95%)	1(5%)	20
Total		39	1	40

Table 4.18. Chi-Square Tests **of Shoulder pain of the diagnostic laparoscopy**

	Value	df	Asymp. Sig. (2-sided)	Exact Sig. (2-sided)
Continuity Correction	.000	1	1.000	
Fisher's Exact Test				1.000
N of Valid Cases	40			

Table 4.19. Crosstab **of Pelvic pain of the diagnostic laparoscopy**

Count		Pelvic pain		Total
		No	Yes	
Group	Insufflator	19(95%)	1(5%)	20
	ChulaLift	19(95%)	1(5%)	20
Total		38	2	40

Table 4.20. Chi-Square Tests **of Pelvic pain of the diagnostic laparoscopy**

	Value	df	Asymp. Sig. (2-sided)	Exact Sig. (2-sided)
Continuity Correction	.000	1	1.000	
Fisher's Exact Test				1.000
N of Valid Cases	40			

The patients and the anesthesiologist nurse who took care the patients after the operation were blinded. The result of the pain comparing between the insufflator and ChulaLift device was not statistically significant in all statistical tests. Mann-Whitney U test for the postoperative pain of the procedure of the diagnostic laparoscopy scored by the blinded patients was not statistic significance, p value of the wound pain=0.283, p value of the shoulder pain=0.317, p value of the pelvic pain=0.971. After collapsed the score to categorical data; pain or no pain, The Fisher's Exact Test for the postoperative pain of the procedure of the diagnostic laparoscopy scored by the blinded patients still was not statistically significat, p value of the wound pain=0.343, p value of the shoulder pain=1.000, p value of the pelvic pain=1.000. This implied that postoperative pain at one hour of the two groups, were the same. The Chulalift device did not harm more than the insufflator in the patients' aspect.

4.7 Physiologic Changes of the Patient during Operation

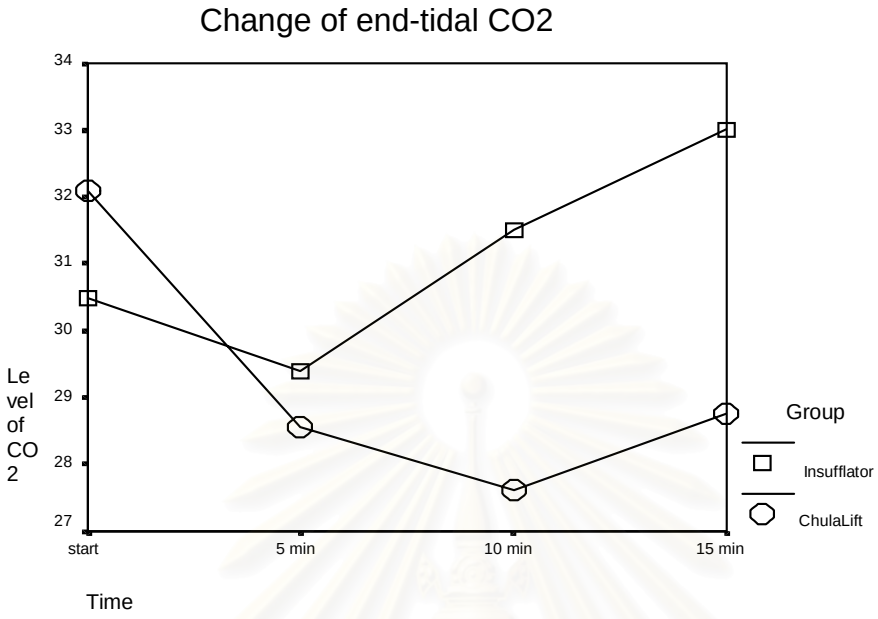


Figure 4.1. Change of the End-tidal CO_2

Table 4.21. End-tidal CO_2 of ChulaLift group (n=20)

time	Mean	Std. Deviation	Std. Error
start	32.100	5.2002	1.163
5 min	28.550	3.6631	.819
10 min	27.600	4.1977	.939
15 min	28.750	4.6439	1.038

Table 4.22. End-tidal CO_2 of Insufflator group (n=20)

time	Mean	Std. Deviation	Std. Error
start	30.500	4.3347	.969
5 min	29.400	4.1977	.939
10 min	31.500	4.5364	1.014
15 min	33.000	5.9736	1.336

The mean End-tidal CO_2 of Chulalift group was higher than of the insufflator group at the beginning of the procedure (32.1 mm Hg in ChulaLift versus 30.5 mm Hg in insufflator). At five minute, both groups declined, but the

insufflator group declined a little bit less than the ChulaLift group. Then at 10 minute, the insufflator group began to rise up more than the starting point and sustained above that level (33 mm Hg). On contrary, the ChulaLift group continued at the level that they declined and maintained at that level (27.6-28.8 mm Hg).

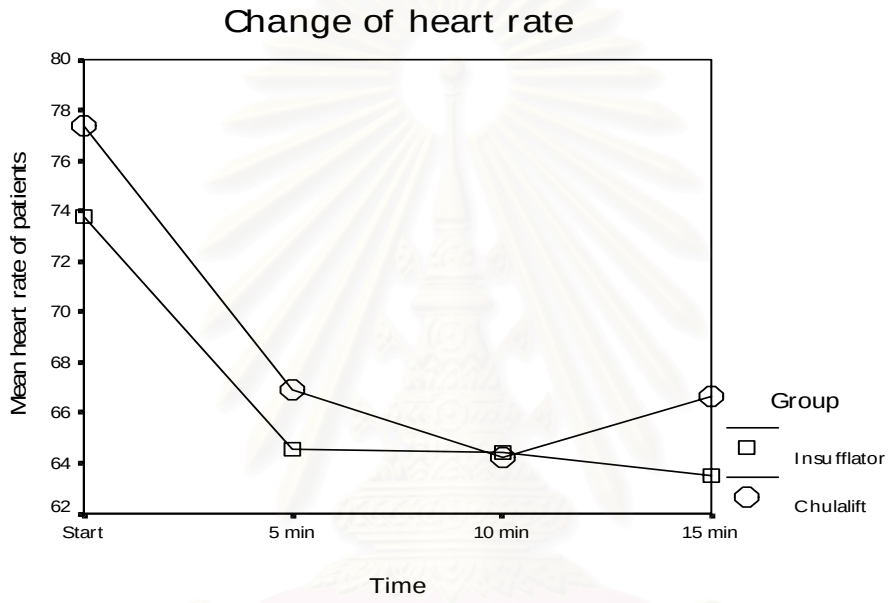


Figure 4.2. Change of the Mean heart rate

Table 4.23. Heart rate of the Insufflator group (n=20)

time	Mean	Std. Deviation	Std. Error
start	73.750	13.3017	2.974
5 min	64.550	12.9715	2.901
10 min	64.400	9.3887	2.099
15 min	63.500	11.2414	2.514

Table 4.24. Heart rate of the ChulaLift group (n=20)

time	Mean	Std. Deviation	Std. Error
start	77.400	10.8647	2.429
5 min	66.900	7.2250	1.616
10 min	64.200	8.3199	1.860
15 min	66.650	10.8301	2.422

Mean heart rate of both groups changed over time at the same pattern. They started at almost the same point (77 beat/min in insufflator and 74 beat/min in ChulaLift) and suddenly declined and maintained their values at around the certain level (64-67 beat/min).

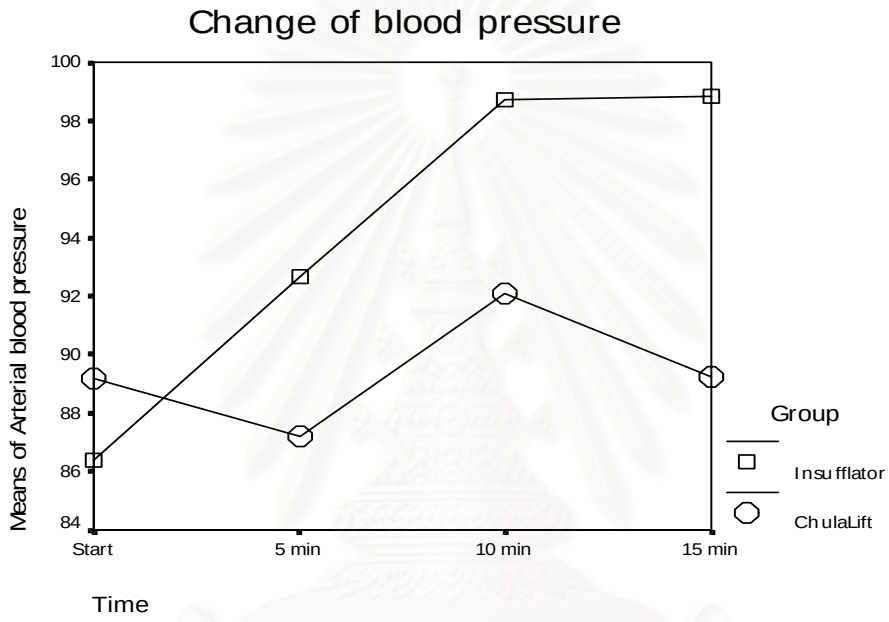


Figure 4.3. Change of the Mean blood pressure

Table 4.25. Mean arterial blood pressure of the ChulaLift group

time	Mean	Std. Deviation	Std. Error
start	89.175	15.9310	3.562
5 min	87.175	15.7482	3.521
10 min	92.100	14.2216	3.180
15 min	89.225	11.6996	2.616

Table 4.26. Mean arterial blood pressure of the Insufflator group

time	Mean	Std. Deviation	Std. Error
start	86.400	12.7832	2.858
5 min	92.650	13.4840	3.015
10 min	98.700	15.9550	3.568
15 min	98.850	13.9841	3.127

Mean blood pressure of the ChulaLift group was higher than insufflator group at the starting point (89 mm Hg in ChulaLift versus 86 mm Hg in insufflator). Blood pressure of the ChulaLift group dropped at five minute might be due to the Trendelenburg position of the patient, after that it might be from compensation of the circulatory function, the blood pressure increased and came back to the level at the starting time (89 mm Hg). On the other group, blood pressure of the insufflator group continued to increase in ten-minute interval and tend to sustain at the higher level than the start point (98.8 mm Hg). This pattern might be due to the high-pressure compression effect of the pneumoperitoneum on the abdominal surface of the diaphragm and the inferior vena cava.

4.8 Summary of the Results

Table 4.27. Summary of the Results

Outcome	Result
Primary outcome variable	
Success rate	100% both
Secondary outcome variables	
Operative times (mean)	ChulaLift/Insufflator 21.5/15.9min
Complication rate	none
Difficulty of the operation (surgeon)	ChulaLift/Insufflator 1.7/1.3
Difficulty of the operation (assessor)*	ChulaLift/Insufflator 1.9/1.2
Post operative pain (wound)	ChulaLift/Insufflator 2.8/1.9
Blood pressure	ChulaLift : sustain /Insufflator: increase
Heart rate	ChulaLift: decrease /Insufflator: decrease
End-tidal CO_2 concentration	ChulaLift: decrease /Insufflator: increase

*Statistical significant (nonparametric test)

CHAPTRE 5

DISCUSION, CONCLUSION AND RECOMMENDATION

5.1 Discussion

The Chula Rectus Sheath Lifting Device (ChulaLift device) is a newly invented abdominal wall retractor for gasless laparoscopic procedure. This device is based on the new concept of the rectus sheath hooking method. The researcher is patenting the ChulaLift device in the name of Chulalongkorn University by the Chulalongkorn Intellectual Property Institute. Now this device and related instruments is supported for further developments by the National Metal and Materials Technology center. This initial clinical study was supported by the Ratchadapiseksompotch Fund, Faculty of Medicine, Chulalongkorn University.

Because of the introducing a new concept including techniques and devices and the ethical issue, this early clinical research is aim primarily at the efficacy and safety of the Chula Rectus Sheath Lifting Device in the specific short and simple procedure, the diagnostic laparoscopic gynecologic procedure. The main purpose of the study is to determine the efficacy of

providing sufficient exposure for laparoscopy of the device by comparing with the standard conventional equipment, the insufflator. This phase of the clinical study is confined only in the small groups of normal weight and fairly healthy patients. For this reason, the result of the study is only providing the clue or trends not the definite conclusion. The power of the statistical test used in this study is certainly low from the result of the small sample size.

1. Success and failure rates

The success rates of the two groups were 100%. The statistical test was not required in this result. The surgeon can evaluate extent of pathology with minimal difficulty; all pelvic structures can be inspected carefully. All-important structures to be inspected in this diagnostic procedure such as fimbriae of the uterine tubes, ovaries, and cul-de-sac have been seen. No need for the surgeon to convert the operation to other equipment or convert to conventional open laparotomy in order to continue and complete the diagnostic laparoscopy. This is the result of small sample size and specific group of patients. The patients allocated to both arms in this study are slim. This study can not imply the efficacy of the ChulaLift device in obese patients. For overweight patients and/or having severe disease such as: large ovarian cyst,

large myoma, or severe adhesion in the pelvic cavity, failure rate of the procedure may be happen due to inability to create sufficient space for evaluate extent of pathology. How much BMI of the patients does the device still work well is not known. And what kinds of patients are that the device fails to be used. These questions are waiting to determine in the next trial.

2. Operative times

The operative time of the ChulaLift group was almost one-third times longer than the insufflator group (21.5 versus 15.9 min.). That prolongation is resulted from to the abdominal entry procedure of the open technique. This open technique, the surgeon dissected the abdominal wall by conventional instruments, scissors and forceps and enter the abdominal cavity by direct naked eyes vision. After cutting the peritoneum with a pair of scissors, a cut-end syringe was inserted into the abdominal cavity for laparoscopic scope placement. This technique required more time and special attention. Contrarily, the procedure in the insufflator group was simpler but required delicate instrument and equipment, the Veress needle, specific laparoscopic trocar, and the expensive insufflator. The surgeon puncture the abdominal cavity by the Veress needle after stabbing the abdominal wall with a surgical

blade, then inflate the abdominal cavity with carbon dioxide using insufflator before inserting the sophisticated trocar with sleeve.

Another reasons for the operative time of the ChulaLift group that prolongs is the result of relatively small operative field. Some patients, the thick abdominal wall of the fatty abdomen tended to project into the abdominal cavity and the intestine was distended and gradually migrated up in the operative field during the procedure. Migration of the intestines was the effect of the respiratory movement of the diaphragm that was not freezing by the pneumoperitoneum. This circumstance has not been report before. Some time the surgeon need to mobilize the intestine down out of the pelvic cavity by the tip of the scope or gasper.

3. Complication rate

This is the other main issue of the study. Every new device based on a new concept that has never been used before, and no one is familiar with its use, should be tested with meticulous and cautious research team. Every procedure should be performed under fully equipment and monitoring. The patients' safety comes first. If some situation tends to be uncontrolled or it seems to be hazard to the patient, the procedure should be

terminated. If any complications occur, the specialist should be consulted immediately. Fortunately, this trial was free of complication, maybe, due to the short and simple procedure. The patients in the period of reproductive age with strong abdominal wall, complication could rarely occur. Loose preperitoneal tissue makes abdominal perforation of the hook impossible. In cadaveric phase of the study, Inspection of the site of the hook installation by the scope revealed that every time the hook was place blindly, the hook was not perforated through the rectus sheath into the preperitoneal tissue. The longitudinal installation of the hook can avoid perforation of the abdominal wall vessels. The abdominal wall vascular injury leading to hematoma formation was nearly impossible. The sharpness of the tip of the hook can prevent excessive trauma to the rectus abdominis muscle in case of paramedian installation of the hook. For multiparous patients with lax and weak abdominal wall, perforation of the anterior abdominal wall to the peritoneal cavity of the hook could occur and careful placement of the hook is required. To test how weak and lax of the abdominal wall is, the surgeon lightly press his hand on the patient abdomen. If the abdominal pulse from the great vessel are easily felt by palpation, the wall is thin and lax. In this case, stretching the abdominal

wall by the assistant's hand or manually lifting the wall up from the great vessel and gradually placing the hook is wise.

4. Postoperative pain

Post-operative pain varies from individual more than different of the groups. Patients express wound and shoulder pain more in the ChulaLift group but this is not statistical different. Wound pain in the new device group may caused by dissection of the open technique, more traumatic procedure was done in this group. Shoulder pain may be due to the patient compliance. Because in the new device group, normal atmospheric air, entrapped in the peritoneal cavity, composed of nitrogen and oxygen, that absorb slower than carbon dioxide used in insufflator group may cause the patients discomfort by irritating the diaphragmatic peritoneum in the postoperative period.

5. Difficulty of the operation

The blinded assessor rated the difficulty of the procedure in the ChulaLift group difference from the insufflator group, with statistical significance (1.85 versus 1.20). We can conclude that the assessor clearly seen the difference of the operative field from the monitor, especially in the

patient that thick fatty preperitoneal tissue. The blinded assessor can notify the different of the difficulty of the procedure because he can see the migration of the intestine rhythmically synchronizing with the respiration and the preperitoneal tissue bulging. But the surgeon who was not blinded concentrates only in the essential structures to be inspected so he is not irritating by the movement of the intestines.

In normal weight patients the different can not be notified when focus in the specific organ in the pelvic cavity. On the other hand, when the scope showed the total view of the pelvis, the narrow shape of the abdominal wall together with the respiratory movement of the intestines notified the rater the type of the device used. The poor exposure of the gasless method was reported previously by numerous investigators. (8,16,17,22,23,31,35,37)

6. Physiologic changes during operation

Minimal fluctuation of CO2 concentrations occur even in the high-pressure insufflator group. Because the patient can compensate by their well reserve healthy cardiopulmonary function. During uneventful carbon dioxide pneumoperitoneum, PaCO2 progressively increases to reach a plateau 15-30 minutes after the beginning of CO2 insufflation in patient under controlled

mechanical ventilation during gynecologic laparoscopy in the Trendelenburg position. The ChulaLift group, the effect of the device reduces the normal resistance of the abdominal content during respiration. This effect was seemed like the patients were hyperventilated. On contrarily, in the insufflator group, the diaphragm was stretch and compressed; the patients hardly moved the diaphragm during pneumoperitoneum condition. Rising of the blood carbon dioxide concentration in the pneumoperitoneum group was widely known. (25,26,31,35,41)

In addition to this, the inferior vena cava and the intestines were compressed by the intraperitoneal compressed carbon dioxide too, venous return is partial obstructed from returning to the heart. Blood pressure of the insufflator group were increase with times. (28,33,40) No definite reason for the heart rate that decrease in both group in this study. Theoretically, the pneumoperitoneum cause slightly rises of the heart rate. (25) These phenomena might be explained by different mechanisms of parasympathetic stimulation in each group. In the pneumoperitoneum group, stretching and distension of the parietal peritoneum might be the cause, but in the ChulaLift

group, the venous distension of the carotid sinus during deep Trendelenburg position of the patients stimulated the parasympathetic activity.

Peritoneal insufflation to intra-abdominal pressures higher than 10 mm Hg induces significant alterations of hemodynamics. Decreases of cardiac output, elevations of arterial pressure, and increases of systemic and pulmonary vascular resistance characterize these disturbances as could be demonstrated in this study. Increasing circulating volume before the pneumoperitoneum can attenuate the reduction in venous return and cardiac output. Increased filling pressures can be achieved by fluid loading. (25) In the ChulaLift group, the mean arterial blood pressure was not influenced. This advantage is suitable for the height- blood pressure patients and the patient having the increase intracranial or intraoccular problems.

5.2 Clinical applications

The physiological and technical advantages of AWL over the conventional positive-pressure gas insufflation technique need to be balanced the poorer surgical exposure the lift technique offers (Table 5.1). The surgical exposure is particularly poor in the present of (1) high intraperitoneal fat content; (2) gaseous distension of hollow viscera, e.g., stomach or colon; and

(3) low abdominal wall elasticity. It is not surprising that surgical endoscopic exposure by AWL is best achieved in thin, multiparous, elderly patients who have lax abdominal walls.

The combination of AWL with low-pressure pneumoperitoneum usually creates adequate exposure for the surgical task performance, even in obese

Table 5.1. Advantages and Disadvantages of AWL Over Conventional Pneumoperitoneum.

Advantages
Decrease in adverse physiological changes and complications.
Surgery under regional anesthesia possible[48,49]
Use of conventional instruments[50-52]
Use of high-flow suction-irrigation
Disadvantages
Poorer exposure
Tissue plane less clear
Complex assembly
Anchoring device obscuring radiographs
Lifting arm obscuring view of the monitors
Ports levering against anchoring device
Diathermy smoke

patients. The low-pressure AWL (4 mm Hg) is simple to apply, very effective in optimizing the surgical exposure, and does not cause any of the adverse physiologic changes that are attributed to the conventional pneumoperitoneum. Preoperative bowel preparation, light liquid diets the day

before surgery, and insertion of a nasogastric tube during surgery will minimize the gaseous distention of the gastrointestinal tract. The use of anesthesia with muscle relaxation ensures a compliant abdominal wall and at the same time reduces the ventilatory tidal volumes, hence the visceral movement associated with artificial ventilation.

Complications directly related to the use of anchoring devices are rare; they include abdominal wall hematoma, visceral damage including perforation, and trapped omentum. There are no established contraindications specific to the use of AWL system. Unlike AWL, conventional positive-pressure pneumoperitoneum (approximately 12 mm Hg) is associated with a drop in both cardiac output (25,53) and lung compliance, (25) and a rise in peak air way pressure (26). Hence, the use of AWL technique seems to be the sensible choice in patients with poor cardiorespiratory reserve, and there are some favorable reports on its use in the high-risk patients (54).

The risk of abdominal wall metastases (port-site deposits) after laparoscopic cancer surgery with positive-pressure pneumoperitoneum may be higher than would deposits after equivalent open surgery,(55) although more recent clinical data from large series indicate that the risk is much lower

than earlier estimates. Despite extensive animal research, the pathogenesis of port-site deposits is not completely understood. Several factors, mainly mechanical, biological and immunologic, are most likely involved.(56) There is good evidence from animal experiment to suggest that gasless AWL may reduce the risk of port-site and peritoneal metastasis following laparoscopic surgery for cancer.(57-59) However, this protective effect observed in animal tumor models needs to be confirmed by randomized clinical trials.

The gasless (isopneumic) laparoscopic approach has been advocated in the assessment and treatment of patients with abdominal trauma, in view of its advantages, e.g., use of conventional instruments, ease of high-volume suction-irrigation of the peritoneal cavity, (60) and avoidance of the risk of gas embolism. For patients with abdominal trauma associated with head injury, the only safe laparoscopic evaluation is with the AWL gasless technique because positive-pressure pneumoperitoneum increases the intracranial pressure (ICP) significantly above baseline, (61) whereas the gasless technique(62) does not. In these patients, even a small intracranial volume change can result in a dangerous rise in ICP.

The use of gasless AWL devices instead of the positive-pressure gas insufflation approach has also been advocated in pregnant women. (63-65) In this instance, AWL avoid hypercarbia and increased in intraamniotic pressure, both of which are potentially detrimental to health of the fetus. A wide variety of gastrointestinal, (25,66-70) hepatic, (71) vascular, (72) gynecologic, (73,74) urologic, (1,14,75,76) and pediatric (77,78) procedures have now been successfully carried out using the AWL technique. As expected, the most common operation performed using the AWL system has been laparoscopic cholecystectomy.

5.3 Conclusion

Result of the initial clinical phase of the ChulaLift was: exposure provided by the Chula Rectus Sheath Lifting Device (ChulaLift) for diagnostic laparoscopic gynecologic procedure might be created safely in normal-weight patients.

Gasless technique still has its value in specific patient and to do some complex procedure. Surgical maneuvers are made easier owing to the possibility of using traditional surgical instruments. Washing and continuous aspiration allow a good control of intraoperative hemostasis, and reduce the

phenomenon of lens misting without the risk of losing pneumoperitoneum. Less visibility of the surgical field was reported, particularly in obese patients, above all because of the reduced diaphragmatic distension and the lack of displacement of the intestinal loops. In the authors' opinion the gasless technique is suitable above all in patients affected by cardiopulmonary disorders in whom hypercapnia might represent a significant operating risk.

AWL is a save technique that causes significantly fewer adverse pathophysiologic effects during surgery than conventional positive-pressure pneumoperitoneum approach, and is the technique of choice for high-risk patients with compromised cardiorespiratrory function. With the ChulaLift device, AWL system provides less optimal exposure and incurs longer operating times than the positive-pressure pneumoperitoneum approach. The combination of mechanical lift with low-pressure pneumoperitoneum appears to overcome this problem and provides good surgical exposure without adverse physiologic effects. These benefits of AWL with low-pressure pneumoperitoneum (3-4 mm Hg) need to be further substantiated by randomized controlled clinical trials in high-risk patients.

5.4 Recommendation

Further studies should be conducted on:

1. Development of the appropriate techniques and devices for simple, rapid and safe abdominal entry in gasless method to shorten the operative times and decrease the risks of the patients. These are included : new trocar-canula systems, trocarless canula for abdominal access, hooks or vacuum devices for abdominal wall fixation and peritoneal elevation during the trocar insertion, or optical trocar for insertion under direct vision.
2. Modifying the effective abdominal wall retractor is necessary to effectively create sufficient space in most patients and to reduce conversions. This consists of : the system for lifting and the system for fastening and expanding the abdominal wall.
3. Convenient power sources for the abdominal wall retractor such as : ceiling electric line, high-current batteries, remote induction coils, small systems of pneumatic or hydraulic tools and various types of mechanical elvators.

4. Knowledge of the various effective methods to create optimal working space in abdominal lifting technique, e.g., numbers of lifting-points, dimensions and shape of anchoring system for intra-peritoneal insertion.
5. Comparison of working space and exposure provided between all the commercial-available abdominal wall retractors in various groups of patients.
6. Gasless accessory instruments for providing enough surgical space and sufficient exposure such as intra-abdominal bowel retractors, intra-abdominal net accompanied with an effective abdominal wall retractor to overcome the stiff and rigid abdominal wall, narrow abdominal cavity and obesity patients.
7. Other gas used, e.g., nitrogen, nitrous oxide, helium or argon; combined gas used, e.g., oxygen and cerbon dioxide, room air, deoxygenated room air, nitrous oxide and carbon dioxide, nitrous oxide and oxygen; or combine used of retractor and low-pressure pneumoperitoneum at 4-8 mmHg.
8. Other expanding media for the laparoscopy such as normal saline and crystal-clear fluid.

9. Research in specific groups of patients, e.g., pregnant women, pediatrics, geriatrics, or specific diseases, e.g., cirrhosis, chronic renal disease and cardiopulmonary compromised patients or research in specific operative procedures using gasless technique, e.g., tubal ligation and laparoscopic assisted vaginal hysterectomy.

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APPENDICES

ข้อมูลสำหรับผู้ป่วย

การศึกษาทางคลินิก: ประเมินผลการใช้เครื่องยกผนังหน้าท้องแบบเกี่ยวยกจากชั้นพังผืด

เรียน ผู้ป่วยทุกท่าน

ท่านได้รับเชิญจากแพทย์ให้เข้าร่วมการศึกษาทางคลินิกเพื่อประเมินผลการใช้เครื่องยกผนังหน้าท้อง แบบเกี่ยวยกจากชั้นพังผืด ก่อนที่ท่านจะตกลงเข้าร่วมการศึกษาดังกล่าว ขอเรียนให้ท่านทราบถึงเหตุผลและรายละเอียดของการศึกษาวิจัยในครั้งนี้

โดยปกติการส่องกล้องเพื่อตรวจหรือทำผ่าตัดในช่องเชิงกราน จะใช้การใส่ก๊าซคาร์บอนไดออกไซด์เข้าในช่องท้องประมาณ 2-4 ลิตรให้มีช่องว่างพอในการตรวจดูอวัยวะหรือทำผ่าตัดในช่องเชิงกรานได้สะดวก โดยไม่มีอวัยวะภายใน เช่น ขดของลำไส้มาบัง อย่างไรก็ตาม การใส่ก๊าซคาร์บอนไดออกไซด์ในช่องท้องที่เป็นวิธีที่ยอมรับและนิยมใช้ทั่วโลกในปัจจุบันนี้ มีผลกระทบต่อระบบไหลเวียนโลหิตและระบบการหายใจ โดยเฉพาะในผู้ป่วยที่มีโรคปอดหรือโรคหัวใจอยู่ก่อนแล้ว อาจทำให้เกิดภาวะการหายใจล้มเหลว หรือ ภาวะหัวใจเต้นผิดปกติที่เป็นอันตรายได้

ทางเลือกใหม่ที่ไม่มีผลเสียต่อระบบการไหลเวียนและระบบการหายใจ คือ การยกผนังหน้าท้องขึ้นโดยวิธีต่างๆ ปัจจุบันการยกผนังหน้าท้องแทนการใส่ก๊าซคาร์บอนไดออกไซด์ในช่องท้องมีการปฏิบัติอยู่ในสถาบันที่มีชื่อเสียงทั้งในอเมริกาและญี่ปุ่น ทีมผู้วิจัยเล็งเห็นข้อดีของวิธีการยกผนังหน้าท้องนี้และได้วิจัยพบอีกว่าการยกผนังหน้าท้องจากการเกี่ยวยกชั้นพังผืดของหน้าท้อง สามารถก่อให้เกิดช่องในการทำผ่าตัดได้มากที่สุดกว่าวิธีอื่นที่เคยมีในการยกผนังหน้าท้องขึ้น

ในแง่ของอันตรายที่อาจเกิดขึ้นก็มีน้อยมาก เพราะการเกี่ยวยกไม่ได้เข้าไปในช่องท้อง ชั้นทีรับแรงดึงเป็นชั้นพังผืดของหน้าท้องที่เป็นชั้นที่แข็งแรงที่สุด ผลของการเกี่ยวยกอาจเปรียบได้เท่ากับถูกตะปูตำเท่านั้น จะมีแผลกลมเล็กขนาด 3 มม. ที่บริเวณที่เกี่ยวยกซึ่งจะหายได้เร็วกว่าแผลผ่าตัดอื่นโดยไม่ต้องเย็บเลย การเกี่ยวยกนี้จะไม่ส่งผลใดต่อการตรวจรักษา การผ่าตัด หรือโรคที่ท่านกำลังเป็นอยู่ วัสดุที่ใช้เกี่ยวยกเป็นสเตนเลสชนิดที่ใช้ในทางการแพทย์ ซึ่งจะไม่มีการดูดซึมพิษใดสู่ร่างกายของท่าน

อาจมีโอกาสน้อยมากที่การเกี่ยวยกอาจพลาดเข้าสู่ช่องท้องและทะลุเข้าสู่ลำไส้ ซึ่งผลของเหตุการณ์นี้สามารถแก้ไขได้ทันทีโดยการล้างบริเวณนั้นให้สะอาดและให้ยาปฏิชีวนะแบบฉีดและรับประทาน โดยไม่ต้องเย็บซ่อมใดๆ ทั้งสิ้น

ทีมผู้วิจัยได้วางแผนเพื่อการป้องกันและเตรียมพร้อมสำหรับการแก้ไข หากเกิดภาวะแทรกซ้อนดังกล่าว กรณีที่มีภาวะแทรกซ้อนที่เกี่ยวเนื่องกับเครื่องมือยกผนังหน้าท้องทีมผู้วิจัยจะให้การรักษาอย่างเต็มที่โดยท่านไม่ต้องเสียค่าใช้จ่ายใดๆ เพิ่มในส่วนนี้

หากท่านตกลงที่จะเข้าร่วมการศึกษาวิจัยนี้ จะมีข้อปฏิบัติร่วมดังต่อไปนี้

1. ท่านไม่ต้องเสียค่าใช้จ่ายใดๆ เพิ่มจากวิธีการใหม่นี้ นอกจากค่ารักษาพยาบาลตามปกติ

2. ก่อนเริ่มต้นการผ่าตัดและการพบแพทย์แต่ละครั้ง แพทย์จะตรวจร่างกายทั่วไป ตรวจภายในและ
3. มะเร็งปากมดลูก รวมทั้งตรวจดูแผลผ่าตัดหลังจากที่รับการผ่าตัดแล้ว

4. การเข้าร่วมการศึกษาครั้งนี้เป็นไปโดยสมัครใจ ท่านอาจปฏิเสธที่จะเข้าร่วมได้โดยไม่มีผลกระทบต่อการ ดูแลรักษาที่ท่านจะได้รับจากแพทย์

<u>ประการสำคัญที่ท่านควรทราบ</u> คือ ผลของการศึกษานี้จะใช้สำหรับวัตถุประสงค์ทางวิชาการเท่านั้น โดยข้อมูลต่างๆ จะถูกเก็บไว้ในคอมพิวเตอร์และไม่มีการแพร่งพรายสู่สาธารณชน ขอรับรองว่า จะไม่มีการเปิดเผยชื่อของท่านตามกฎหมายหากท่านมีปัญหาหรือข้อสงสัยประการใดกรุณาติดต่อ

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ซึ่งยินดีให้คำตอบแก่ทุกท่านขอขอบคุณในความร่วมมือของท่าน มา ณ ทีนี้คณะแพทย์ผู้ประเมินผลการใช้เครื่องยกผนังหน้าท้อง แบบเกี่ยวยกจากชั้นพังผืด

ใบยินยอมของผู้ร่วมการศึกษา

เลขที่คนไข้.....**ชื่อ**.....**นามสกุล**.....

ข้าพเจ้าได้รับทราบจากแพทย์ผู้รักษา ซึ่งได้ลงนามด้านท้ายของหนังสือนี้ถึงวัตถุประสงค์ ลักษณะและแนวทางการศึกษา เครื่องยกผนังหน้าท้องแบบเกี่ยวยกจากชั้นพังผืด รวมทั้งทราบถึงผลดี ผลข้างเคียง และความเสี่ยงที่อาจเกิดขึ้น ข้าพเจ้าได้ติดตามทำความเข้าใจเกี่ยวกับการศึกษาดังกล่าวนี้เป็นที่เรียบร้อยแล้ว

ข้าพเจ้ายินดีเข้าร่วมการศึกษาวิจัยครั้งนี้โดยสมัครใจ และยอมรับสิ่งไม่พึงประสงค์ที่อาจเกิดขึ้นและจะปฏิบัติตัวตามคำแนะนำของแพทย์ทุกประการ

ข้าพเจ้ายินดีให้ข้อมูลของข้าพเจ้าแก่คณะแพทย์ผู้รักษา เพื่อเป็นประโยชน์ในการศึกษาวิจัยครั้งนี้ โดยผู้วิจัยรับรองจะเก็บข้อมูลเฉพาะเกี่ยวกับตัวข้าพเจ้าเป็นความลับและจะเปิดเผยได้เฉพาะในรูปที่เป็นสรุปผลการวิจัย การเปิดเผยข้อมูลเกี่ยวกับตัวข้าพเจ้าต่อหน่วยงานต่างๆ ที่เกี่ยวข้อง กระทำได้เฉพาะกรณีจำเป็นด้วยเหตุผลทางวิชาการเท่านั้น

สุดท้ายนี้ข้าพเจ้าได้อ่านข้อความข้างต้นแล้วและมีความเข้าใจดีทุกประการ และได้ลงนามในใบยินยอมนี้

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(ลงนาม)_____ **ผู้ป่วย**

(...../...../.....)

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(ลงนาม)_____ **แพทย์ผู้ให้การรักษา**

(...../...../.....)

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(ลงนาม)_____ **พยาน**

(...../...../.....)

VITAE

Dr. Tanvaa Tansatit was born on December 29, 1961 in Bangkok, Thailand. He graduated from Chulalongkorn University in 1986 after accomplishment of a six-year course and earned the Doctor of Medicine. After graduation, he worked in the Department of Anatomy, Faculty of Medicine, Chulalongkorn University as an instructor.

During that time, he founded the Anatomical Museum, Donator-registration database and the Surgical training Center. His work included demonstration specimens, medical models, learning packages, anatomical atlas and texts.

Since June 2000, he has been admitted in the Master Degree Program of Health Development in Faculty of Medicine of Chulalongkorn University. His principal research interest has been the development of the surgical instrument since then. During this course, he has conducted a clinical trial to test the efficacy and safety of the ChulaLift device, a gasless abdominal wall retractor he invented.