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ORIGINAL ARTICLE

Sleeve Gastrectomy for Morbid Obesity: Robotic *vs* Standard Laparoscopic Sleeve Gastrectomy Methods

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ABSTRACT

Aim: The aim of this study is to compare robotic laparoscopic sleeve gastrectomy with standard laparoscopic sleeve gastrectomy done for morbid obesity with regards to operative time and short-term patient outcome in a developing world.

Background: Excision of the fundus and greater curvature of the stomach in sleeve gastrectomy not only restrict intake but also reduces the level of ghrelin in the circulating blood. Obesity surgery has benefited from the advent of surgical robot with its celebrated advantages (enhanced dexterity, precision and control of endowrist instruments, with 7º of freedom, 90º of articulation, intuitive motion and finger-tip control, motion scaling and tremor reduction). How this new technology under development affect patient outcome has only been reported in a few centers especially in the developed world.

Materials and methods: Data for 21-month retrospective comparative study was collected from the records of 20 adult patients who had robotic sleeve gastrectomy (RSG) and 20 standard laparoscopic sleeve gastrectomy (SLSG) (obtained by randomized sampling of the total number of SLSG during the study period).

Results and discussion: Duration of surgery, cost of operation, duration of hospital stay, percentage excess weight loss (%EWL)/BMI, quality of life, comorbidity resolution and complications were the measures of outcome studied in comparing RSG to SLSG. The mean duration of surgery of 143.05 minutes for SLSG and 152.7 minutes RSG (ratio 1:1.07) were in agreement with previous studies in which the duration of RSG was longer than SLSG. The RSG mean docking time of 12.6 minutes in this study obviously contributed to increasing the total operative time.

The cost of surgery was found to be higher RSG 9000 USD compared to 7500 USD for SLSG (ratio1.2:1). This value is relatively higher than that documented in a study in which 400 euros was quoted. Understandably, this varied from center to center. Three patients (15%) were observed to have some significant complications among the SLSG group as against one patient (5%) in the RSG group.

Conclusion: Sleeve gastrectomy by robotic method in a developing country experience, has comparative advantage over standard laparoscopic methods in reducing complications, though the duration and cost of surgery were higher in the robotic methods. The choice of the method would therefore depend on availability, surgeon's skills, the patient's informed choice and ability to afford.

Keywords: Robotic/standard laparoscopic sleeve gastrectomy, Gastric/vertical sleeve gastrectomy, Robotic *vs* standard laparoscopic sleeve gastrectomy.

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INTRODUCTION

Central to the development and progression of obesity is ghrelin, a peptide hormone secreted by X/A-like cells of the oxyntic glands of the fundus[1] (18-20 times than any other site)[2] of the stomach, which is involve in both stimulation of hunger and growth hormone secretion. It has been found to be an endogenous ligand[3-5] for the growth hormone secretagogues receptor (a specific G protein-coupled receptor) in the pituitary gland and hypothalamus thus, making this stimulating effect more potent (about seven times over) than that of growth hormone releasing hormone. Also, the increase in mRNA expression of hypothalamic neuropeptide Y (a potent stimulator of food intake) after intracerebroventricular administration of ghrelin in rodents, appear to demonstrate the orexigenic effect of this peptide. Thus, excision of the fundus and greater curvature of the stomach in sleeve gastrectomy not only restrict intake but also reduces the level of ghrelin in the circulating blood.

Obesity surgery has benefited from the advent of surgical robot with its celebrated advantages.[6] How this new technology under development affect patient outcome has only been reported in a few centers, especially in the developed world.

TECHNIQUE AND OPERATIVE TIME

The technique of surgery is similar for both robotic[7] and standard laparoscopic[8] sleeve gastrectomy with the exception of docking and undocking of robotic arms for robotic sleeve surgery. This involves longitudinal resection of the greater curvature of the stomach from the antrum to the angle of His. After achieving pneumoperitoneum, inserting trocars/

cannulas under the guidance of the standard laparoscopic camera (and docking of robotic arms) and retracting the liver, the essential steps commences from the greater curvature with the division of the gastroepiploic and short gastric vessels at the gastrocolic and gastrosplenic omentum up to the left crus of the diaphragm, thus completely freeing the stomach. Gastrolysis is performed from 5 cm[9] (authors vary: 2 cm,[8] 4 cm,[10] 10 cm[11]) proximal to the pylorus up to the angle of His. Approximately, 100 to 150 ml (60-200 ml[12]) of sleeve is created over size 38 Fr[13] (size 32 F14-60 F) bougie using Echelon Flex linear stapler with 60 mm. Smaller size bougie and shorter distance from the pylorus are preferred, especially when sleeve gastrectomy is intended as a sole procedure for morbid obesity. The staple line is imbricated with PDS (polydioxanone) 2-0 continuous sutures[15] to reduce the risk of leakage and bleeding. Peroperative endoscopy is done to rule out intraluminal bleed/leak and Biovac drain is placed in perisleeve region.

A comparative measure of the speed of surgery for both procedures is the duration of surgery (operative time). From published data, the average operative time varies from 65[11] to 120 minutes[15] in the standard laparoscopic sleeve method. This wide gap could probably be accounted for by the method employed in re-enforcing the staple line (oversewing takes longer time than use of prosthetic material), experience and learning curve of the different surgeons. Reported operative time for robotic sleeve gastrectomy varies from 70.1[16] to 165 minutes[17] with overall average of 101.1 minutes. Similar factors also apply. If the docking time (and undocking time) of 16 ± 4.2 is subtracted, only then will robotic sleeve gastrectomy (RSG) be considered to be shorter.

MEASURES OF OUTCOME

There are few publications on the outcome of RSG for morbid obesity with highlight on percentage excess weight loss, duration of hospital stay (and cost of operation), quality of life (QOL) and complications encountered. The relatively new status of the procedure may have strongly contributed to this. Also, available studies are of short follow-up duration and hence could not draw reasonable conclusions on long-term outcome of this procedure.

The duration of hospital stay for RSG varied from 2.5 to 4 days, comparable to that of standard laparoscopic sleeve gastrectomy (SLSG) (4-4.4 days). However, Frezza EE[11] reported the shortest of 1 day in a review of 10 patients. Burgos AM, in a study describing gastric leak after laparoscopic sleeve gastrectomy[8], reported a mean hospital stay of 28.8 days among 214 patients. It appears reasonable to conclude therefore that occurrence of complications negatively impact on sleeve patients and prolong their hospital stay.

The prime target of sleeve surgery is to effectively reduce excess weight and therefore reduce the negative impact this has on the morbidity (obstructive sleep apnea, diabetes mellitus, hypertension, osteoarthritis, etc.) of the patients. Available data on robotic sleeve gastrectomy revealed percentage excess weight loss of 65.5 ± 25.6% at 1 year. This also is comparable to that of standard sleeve gastrectomy of about 33 to 90% in a review study of 940 patients,18 and 60.8 ± 4.3% in a study of 25 patients.[19] The mean preoperative body mass index (BMI) varied from 40 to 67.7 kg/m^2 for robotic sleeve surgery and 35 to 74 kg/m^2 for standard laparoscopic sleeve studies.

The follow-up duration of available studies varied from 3 to 12 months for robotic sleeve and 4 months to 5 years for SLSG with an average of 1 year. There appeared to be a fall (35%-71.6% at 6 months, 45-83% at 1 year, 47-83% at 2 years and 66% at 3 years) in the peak of percentage of excess weight loss achieved after a while as reported by Trelles N and Gagner M.[12]

The percentage of main complications was reported less in robotic sleeve than in SLSG. Miller N et al[20] in a study of 317 patients demonstrated this in a ratio of 5:12% in favor of RSG. The precision and high maneuverability of the robotic arms coupled with the comfort of the sitting surgeon at the console, would have significantly contributed to this more than double complication rate.

It is worth noting from available studies that the following issues still call for attention for possible consensus: its use as single-stage procedure; use of intragastric balloon in high-risk and super-obese patients; resection distance from the pylorus; the size of the gastric bougie used (hence size of remaining gastric pouch), variation of bougie size with degree of obesity; reinforcement of the staple line and type of material used.

The aim of this study, therefore, is to compare RSG with SLSG done for morbid obesity with regards to operative time and short-term patient outcome in a developing country.

MATERIALS AND METHODS

Retrospective comparative study was done in a minimal access bariatric surgery unit of a busy hospital over 21 months (data collection of surgeries from October 2011 to October 2012, and follow-up to June 2013). Data was collected for 20 RSG and 20 SLSG (obtained by systematic sampling of the total number of SLSG during the study period.

Inclusion Criteria

Patients with BMI³ 40 kg/m², patients aged between 30 and 60 years.

Exclusion Criteria

Patients with BMI ≥40 kg/m². Operative technique used was similar: gastrolysis is performed from 5 cm proximal to the pylorus up to the angle of His. Approximately, 100 to 150 ml of sleeve is created over size 38 Fr[21] bougie using Echelon Flex linear stapler with 60 mm. The staple line is imbricated with PDS (polydioxanone) 2-0 continuous sutures and peroperative endoscopy is done.

The measures of outcome studied were: duration of surgery, cost of operation, duration of hospital stay, percentage of excess weight loss (%EWL)/BMI, quality of life, comorbidity resolution and complications.

RESULTS

The duration of surgery for SLSG was found to vary from 121 to 150 minutes with a mean of 142.7 minutes, while the overall operative time for RSG was between 132 and 188 minutes with an average of 150.4 minutes (Table 1). The mean docking time was 17.9 minutes.

The cost of surgery for SLSG was found to be 7500 USD while that of RSG was 9000 USD (Table 1 and Graph 1). The duration of hospital stay for SLSG varied from 3 to 11 days with a mean value of 4.6 days, while for RSG it span from 3 to 6 days with a mean value of 3.9 days.

The mean percentage excess weight loss for SLSG at 1 year was 83.8 and 82.0% for RSG (Table 2). The mean preoperative BMI for SLSG and RSG were 53.1 and 51.0 respectively (Tables 2 and 3). In this series, the progression of mean percentage excess weight loss by month for SLSG was 23.4% → 45.1% → 58.9% → 83.9%, and 23.7% → 40.8% → 60.8% → 82.8% for RSG at 1, 3, 6 months and 1 year. In this study, the mean preoperative body weight reduced from 139.2 to 79.6 kg at 1 year for SLSG and from 141.4 to 85.8 kg for RSG patients. Likewise, the mean preoperative BMI reduced from 83.8 to 30.3 among SLSG patients and 51 to 30.5 at 1 year for RSG patients.

The mean quality of life for SLSG rose from a preoperative value of 2.3 to 8.3 after surgery, and from a value of 2.3 to a postoperative value of 8.45 for RSG.

In this series, 14 out of 20 SLSG patients (70%) and 11 out of 20 RSG (55%) patients had obstructive sleep apnea. The resolution of obstructive sleep apnea was dramatic with a value of 78.6% observed within the first 1 month and 100% in 3 months for patients operated by SLSG. 81.8% in 1 month 100% in 3 months were observed for RSG patients. Eleven out of the 20 (SLSG 55%) and seven out of 20 (RSG 35%) had diabetes mellitus. There was a noticeable improvement in diabetic status as seen in the reduction in the percentage of patients on insulin from 81.9% in the first month to 18.1% at 1 year for SLSG patients, i.e. 81.9% being off their insulin at 1 year. A similar drop was noticed for RSG patients from 71.4 to 28.6% respectively, with 71.4% of diabetics going off their insulin at 1 year.

Sixty percent (12 out of 20) of SLSG patients and 70% (14 out of 20) of patients operated by RSG were hypertensive. From this value, there was a reduction in the number of patient taking antihypertensive agents to control their blood pressure from 100% in the first month to 41.7% (58.3% being off their drugs) at 1 year for SLSG patients and from 100 to 35.7% (64.3% off drugs) respectively for RSG patients. Three patients (15%) were observed to have some significant complications among the SLSG group as against one patient (5%) in the RSG group.

DISCUSSION

Duration of surgery, cost of operation, duration of hospital stay, %EWL/BMI, QoL, comorbidity resolution and

Table 1: Summary of parameters for SLSG and RSG

Parameters	*SLSG*				*RSG*			
	Mean value	χ^2	*p-value*	*Conclusion*	*Mean value*	χ^2	*p-value*	*Conclusion*
Mean operative time	142.7	17.4	30.144	$p > \chi^2$	150.4	17.003	30.144	$p > \chi^2$
Mean hospital stay	4.6	14.81	30.144	$p > \chi^2$	3.9	3.59	30.144	$p > \chi^2$
Mean postop QOL	8.3	0.899	30.144	$p >> \chi^2$	8.45	0.576	30.144	$p >> \chi^2$
Mean %EWL at 1 year	83.8	45.11	30.144	$p < \chi^2$	82	82	30.144	$p < \chi^2$
Mean preop body weight	139.2	138.36	30.144	$p < \chi^2$	141.4	146.60	30.144	$p < \chi^2$
Mean percentage of change in BMI at 1 year	41.5	15.309	30.144	$p > \chi^2$	40.1	4.323	30.144	$p > \chi^2$
Resolution of hypertension at 1 year (%)			58.3				64.3	
Resolution of diabetes mellitus at 1 year (%)			81.9				71.4	
Percentage of complications			15				5	
Mean cost of surgery			$7500				$9000	
Resolution of obstructive sleep apnea at 1 year (%)			100				100	

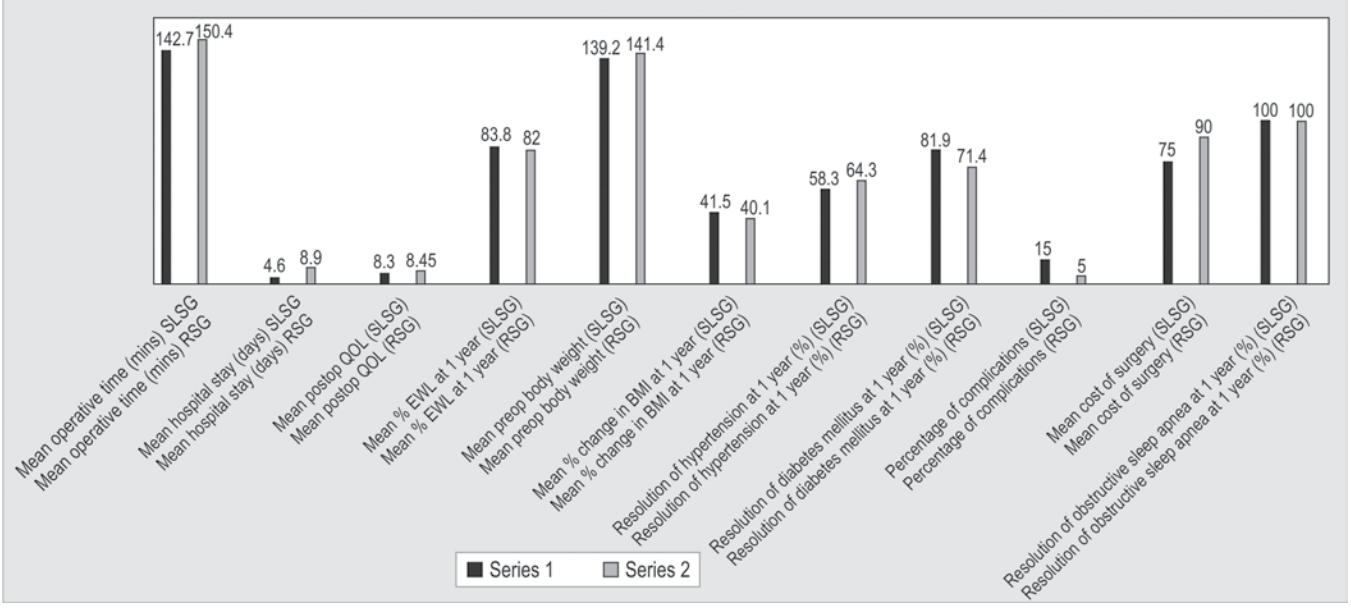
Note: Data is highly reproducible, if p-value >> χ^2; Data is reproducible, if p-value > χ^2; Data is nonreproducible, if p-value < χ^2

complications were the measures of outcome studied in comparing RSG to SLSG. The table below is a summarized highlight of the comparison between SLSG and RSG in terms of the measures of outcome.

The mean duration of surgery of 142.7 minutes for SLSG and 150.4 minutes RSG (ratio 1:1.05) were in agreement with previous studies[11,15-17] in which the duration of RSG was longer than SLSG. There was a wide variation in time from 121 to 150 minutes for SLSG and 132 to 188 minutes for RSG. The RSG mean docking time of 17.9 minutes in this study obviously contributed to increasing the total operative time and was comparable to a previous study by Diamantis T et al[19] in which 16 ± 4.2 was documented.

The cost of surgery was found to be higher RSG 9000 USD compared to 7500 USD for SLSG (ratio1.2:1). This value is relatively higher than that documented in a study[19] in which 400 euros was quoted. Understandably this varied from center/region to center/region as some online patient information manuals quoted 9500 to 22,000 USD with an average of 17,000 USD in the Indian subcontinent. The mean duration of hospital stay was 4.6 and 3.9 days (ratio 1.18:1) for SLSG and RSG respectively. The observation for SLSG was similar to the finding of Givon-Madhala O et al[15] in his study of 25 patients and Shi X et al in his study of 940 patients. Also, a value of 3.9 days observed for RSG is within the range of previous studies.[17,19,20] The study differs from Frezza EE et al report of duration of 1 day[11] and 28 days reported by Burgos AM et al[8] among 214 patients who had gastric leak. This observed difference was obviously due to absence of major complications in this study.

The mean percentage excess weight loss for SLSG at 1 year was 83.8 and 82.0% for RSG (ratio 1.02:1). This difference is less than significant. However, this value is similar to previous studies which reported 47 to 83%[12] and 33 to 90%[18] in 1 year, but differs from that of Damantis T et al[19] which recorded 60.8 ± 4.3. Varied patients adherence to postoperative exercise and dietary advice could probably have contributed to this observed difference. In this study, the mean preoperative body weight reduced from 139.2 to 79.6 kg at 1 year for SLSG and from 141.4 to 85.8 kg for RSG patients. Likewise, the mean preoperative BMI reduced from 83.8 to 30.3 among SLSG patients and 51 to 30.5 at 1 year for RSG patients. These values are also in agreement with a previous study.[21] However, the observed higher value of preoperative body weight/BMI for SLSG patients was contrary to findings in previous studies which advocated use of RSG method for patients with higher preoperative body weight/BMI. The explanation for this discrepancy could be that some patients with high body weight/BMI may not have been able to afford the high cost for robotic surgery in this developing or the initial learning curve of the surgeons in the team following acquisition of



Graph 1: Summarized chart—SLSG *vs* RSG

Table 2: SLSG *vs* RSG: mean percentage excess weight loss/BMI by months

	SLSG (mean BMI)	*RSG (mean BMI)*	*SLSG (mean %EWL)*	*RSG (mean %EWL)*
Preop BMI	53.1	51	—	—
1 month	46.5	44.9	23.4	23.7
3 months	40.8	40.8	45.1	40.8
6 months	36.7	38.3	58.9	60.0
1 year	30.3	30.5	83.8	82.0

Table 3: Mean percentage change in BMI at 1 year

Si/no.	*SLSG*			*RSG*		
	Preop BMI	*Postop BMI*	*Change in BMI (%)*	*Preop BMI*	*Postop BMI*	*Change in BMI (%)*
1	44.5	26.3	40.9	48.1	33.1	31.2
2	47.0	26.1	44.5	60.0	36.3	39.5
3	49.0	33.0	32.7	48.3	29.0	40.0
4	58.2	34.4	40.9	54.4	33.2	39.0
5	72.1	39.7	44.9	45.9	29.3	36.2
6	44.2	23.0	48.0	46.5	26.5	43.0
7	54.0	31.8	41.1	43.0	27.1	37.0
8	42.0	22.2	47.1	40.9	23.3	43.0
9	46.0	29.3	36.3	47.0	29.1	38.1
10	45.0	30.2	32.9	42.6	25.6	39.9
11	59.1	36.1	38.9	82.6	50.3	39.1
12	42.4	26.4	37.7	42.0	24.0	42.9
13	49.0	28.1	42.7	44.0	27.0	38.6
14	43.0	26.1	39.3	46.0	27.1	41.1
15	62.0	27.4	55.8	51.5	29.4	42.9
16	77.3	38.7	49.9	55.0	31.2	43.3
17	47.5	30.8	35.2	48.0	26.7	44.4
18	61.6	37.2	39.6	42.0	25.7	38.8
19	53.6	33.3	37.9	51.0	29.1	42.9
20	45.2	25.8	42.9	81.0	47.2	41.7
Mean	53.1	30.3	41.5	51.0	30.5	40.1

$p = 30.144$; $\chi^2 = 15.309$ (SLSG); $\chi^2 = 4.323$ (RSG); $p > \chi^2$; Data is reproducible; BMI: Body mass index

this new technology may have influenced their choice of patient selection.

The mean quality of life index for SLSG rose from a preoperative value of 2.3 to 8.3 after surgery, and from a value of 2.3 to a postoperative value of 8.45 for RSG. These values are in agreement with a previous study by Bindal V et al[21] which reported a rise in value from 2.7 to 8.2. This study was carried out in the same center and the surgeries were done by the same team of bariatric surgeons.

The resolution of obstructive sleep apnea was dramatic with a values of 81.8 and 78.6% (ratio 1.04:1) observed for RSG and SLSG patients respectively, within the first 1 month, and 100% for both in 3 months. Among diabetic patients, 81.9% in SLSG group and 71.4% of RSG patients (ratio 1.15:1) were off their insulin at 1 year. Fifty-eight (58.3%) of hypertensive patients were off their drugs at 1 year for SLSG patients and 64.3% (ratio 1:1.1) was the finding for RSG patients. Similar resolutions were observed by Bindal V[21] with values of 93% for OBSA; 78.94% for diabetes and 62% for hypertensive patients. It is also in agreement with the work of Noun R et al[22] with a value of 70.5% for comorbidities.

Three patients (15%) were observed to have some significant complications among the SLSG group as against one patient (5%) in the RSG group. These values corroborated the study conducted by Nathan Miller et al which reported a 12% for SLSG and 5% RSG as complication rates.

The findings above implied that the use of robotic Da Vinci in carrying out sleeve gastrectomy for morbid obesity had comparable outcome in terms of percentage excess weight loss, quality of life index, and duration of hospital stay. Though RSG attracted a higher operative cost and a longer duration of surgery, the complication rate was more than twice lower than SLSG. This is significant, as any major complication when it occurs could increase cost of care of such patient. Improved surgeon's comfort and uniqueness of the robot indirectly reduced complication rate.

That this study was done in a bariatric surgery center in which the same team of surgeons operated and followed up the patients and the findings came out to be in agreement with that of other researchers on this subject, is an area of strength. However, being a short-term retrospective study is a limitation. A prospective long-term study would have been preferred to enable one to draw conclusion on long-term benefit of the two methods.

CONCLUSION AND RECOMMENDATION

Sleeve gastrectomy by robotic method in a developing country experience, has comparative advantage over standard laparoscopic methods in reducing complications in the ratio of more than 2:1, as earlier reported in the developed world. The main advantage of the robotic method is to the surgeon, by improving comfort and reducing fatigue, and indirectly to

the patient reducing complications. The short-term outcome of percentage excess weight loss, quality of life index, duration of hospital stay and comorbidity resolution were similar to that of standard method, though the duration and cost of surgery were higher in the robotic methods. The choice of the method would therefore depend on availability, surgeon's skills, the patient's informed choice and ability to afford.

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ORIGINAL ARTICLE

Laparoscopic Vasectomy *vs* Laparoscopic Sterilization in Dogs: A Comparison of Two Techniques

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ABSTRACT

Twelve clinically healthy, adult male dogs randomly equally divided into two groups (I and II). Animals of both the groups received xylazine-ketamine anesthesia. Laparoscopic bilateral vasectomy was performed in group I, whereas in animals of group II in addition to vasectomy, spermatic artery-vein plexus were clipped with titanium clips at a distance of 1 to 2 cm. Insufflation of abdominal cavity was achieved by CO_2 (2 liter/minute) at 10 mm Hg pressure gradient. Clinical observations revealed no significant changes. Differential leukocyte count (DLC) revealed significant neutrophilia and comparative lymphopenia on 3rd postoperative in both groups. Significant increase ($p < 0.05$) in plasma alkaline and acid phosphatase level was observed on day 3 postoperatively. Indices of oxidative stress *viz* lipid peroxidation (LPO), catalase (CAT), superoxide dismutase (SOD), reduced glutathione activity and acute phase protein, ceruloplasmin level in plasma did not revealed any major significant changes but indicated that oxidative stress was more in group II animals. Plasma cortisol level increased significantly ($p < 0.01$) after operation and testosterone level showed gradual decrease ($p > 0.05$) up to 7th postoperative day in animals of group II. On the basis of the parameters studied, it can be concluded that capnoperitoneum at 10 mm Hg pressure gradient and CO_2 at the flow rate of 2 liter/minute provides optimum visualization of intra-abdominal organs and found suitable for laparoscopic sterilization in male dogs. The laparoscopic vasectomy alone in male dogs was found comparatively quick, less time consuming and can be successfully applied for mass sterilization program. Oxidative stress in laparoscopic vasectomy (group I) was less as compared to other group.

Keywords: Male dogs, Laparoscopic vasectomy, Sterilization, Oxidative stress, Lipid peroxidation, Catalase, Superoxide dismutase, Reduced glutathione, Acute phase proteins.

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INTRODUCTION

Laparoscopic surgery provides a wide field of its extensive application particularly in surgical sterilization of different animal species. Furthermore, high demographic urban and industrial area requires an effective animal birth control program, which can overcome the problem of hospitalization, postoperative complications and the overall cost reduction of operation.[1] Castration of male dogs by conventional open method have many disadvantages and postoperative complications, such as hemorrhage, wound dehiscence, infections, maggot infestations and scrotal swellings, etc. In a large scale animal birth control program, the conventional methods of sterilization requires a long period between capture of dogs and their release due to the time taken for the surgical wounds to heal. In this aspect, keyhole surgery or laparoscopic surgery can revolutionize the entire program, as it needs only very small surgical wound, which usually needs no postoperative care or regular dressings. The laparoscopic surgery has advantages, like minimal invasiveness with maximum visibility, shorter surgical time, decreased postoperative discomfort and pain, less incidences of infection, uncomplicated healing with minimal scarring and minimal surgical morbidity.[2] It also avoids postoperative complications, such as wound dehiscence, herniation, etc. and reduces the surgical stress to animal as well as recurring cost of each surgery. Therefore, the present study was undertaken to compare laparoscopic vasectomy and laparoscopic sterilization, i.e. vasectomy plus clipping of spermatic artery vein plexus, using clinical, hematobiochemical parameters and parameters related to stress.

MATERIALS AND METHODS

The study was conducted on 12 clinically healthy, adult male dogs having body weights of 13.0 to 18.5 kg (15.10 ± 0.68) and of age 20 to 28 months (24.57 ± 1.56). The

animals were randomly divided into two equal groups (I and II). In group I, laparoscopic vasectomy by cauterization and cutting of vas deferens was performed. In group II, along with laparoscopic vasectomy as done in group I, clipping of spermatic artery vein plexus was also performed. The animals were premedicated with atropine sulphate at the dose rate of 0.04 mg/kg body weight subcutaneously. Fifteen minutes later xylazine hydrochloride (at the dose rate of 1.0 mg/kg body weight) and ketamine hydrochloride (at the dose rate of 10.0 mg/kg body weight) were administered intramuscularly. Depth of analgesia was monitored during the entire period of surgery. Incremental doses of ketamine may be given if required. After administration of anesthesia the animals were placed in dorsal recumbency having a Trendelenburg position.

A small 0.5 cm skin incision was made at the level of umbilicus. By grasping the skin around the incision by one hand, simultaneous insertion of Veress needle was done by other hand. Intraperitoneal placement was confirmed by injecting 5 ml of saline through the needle. Insufflation of abdominal cavity was done by carbon dioxide gas at the rate of 2 l/min with pressure gradient of 10 mm Hg in both the groups. After attaining a sufficient pneumoperitoneum, Veres needle was removed and a 6 mm safety trocar and cannula unit was inserted into the abdominal cavity. A rigid type telescope (30º, 5 mm in diameter, Frontline Co, Germany) connected with light source (40 W, Halogen lamp) and digital camera was then introduced through cannula. Two ports of 6 mm size were created using 6 mm trocar-cannula unit under the guidance of telescope distal to the laparoscope insertion site and 4 to 6 cm bilaterally from the ventral midline. Through these ports, the operative instruments were inserted for surgical procedures. The intraperitoneal organs along with vas deferens were thoroughly visualized. The urinary bladder was visualized first by its characteristics tortuous structures of blood vessels. Then, the vas deferens and spermatic artery-vein plexus were visualized. The vas deferens was identified by its characteristic ivory-colored, cord-like structure (Fig. 1). Each vas deferens was observed at the site where both of them joined dorsal to the bladder, and they were easily traced to the point where they enter the abdominal cavity at the inguinal ring. The vas deferens was held by fenestered grasping forceps, inserted through the same side port (Fig. 2). The monopolar scissors was inserted through the opposite side port to cauterize the vas deferens and attached it with electrocautery unit. A 60 W monopolar current was used for cutting and cauterization. A piece of 2 to 3 cm of vas deferens was resected after coagulation and removed through the cannula (Fig. 3). The same procedure was repeated for the opposite vas deferens. In animals of group II, the procedure for vas deferens was repeated as mentioned in group I. After resection and removal of vas deferens, the spermatic artery-vein plexus were identified. Unlike in the scrotum, the vas deferens within the pelvic cavity was not associated with the spermatic artery-vein plexus that courses laterally along the dorsolateral portion of the abdominal wall. Clipping was done after holding these vessels by fenestered grasping forceps. The vessels were clipped by applying two titanium clips at a distance of 1 to 2 cm between them by using clip applicator (Fig. 4). The same procedure was repeated to the opposite one.

After completion of the procedure the carbon dioxide gas was removed and the port wounds were sutured with single interrupted mattress suture pattern using nylon. All the wounds were cleaned and dressed regularly at the portal and incisional site with povidone iodine and antiseptic cream. Dressing was done in the morning after recording the clinical parameters. Up to 7th postoperative day they were closely observed away from their sight, for any behavioral changes due to surgery.

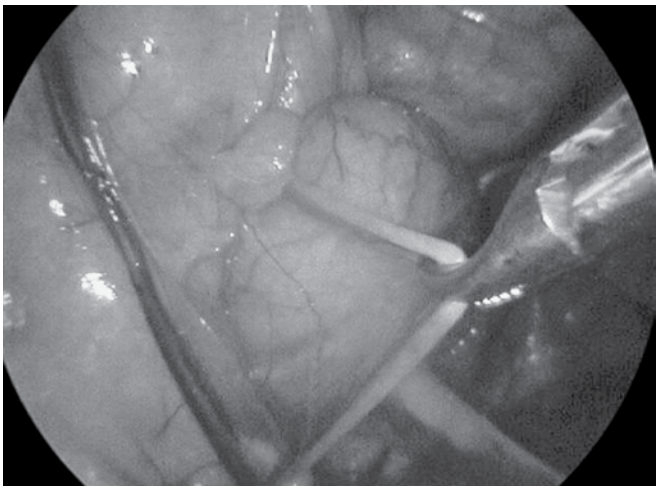

Fig. 1: Identification of the vas deferens by its characteristic ivory-colored, cord-like structure

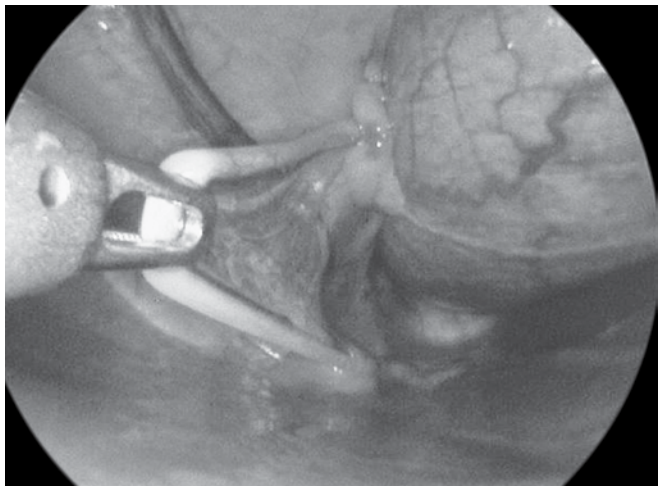

Fig. 2: Holding of the vas deferens by fenestrated grasping forceps in animals of group I

Fig. 3: A piece of 2 to 3 cm of vas deferens was resected after coagulation and removed through the cannula in group I

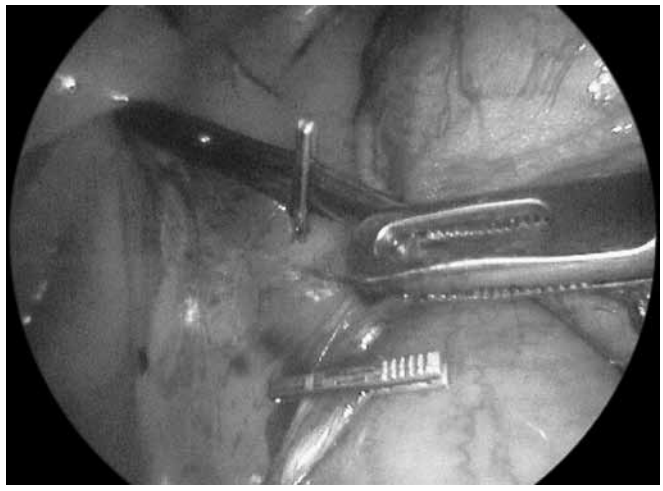

Fig. 4: After resection of vas deferens, the spermatic artery vein plexus was clipped by applying two titanium clips at a distance of 1 to 2 cm, using clip applicator in animals of group II

Intraoperative and Postoperative Observations

The two operative techniques were evaluated based on flow rate and total utilization of carbon dioxide for each operation, instrument required, organ manipulation and maneuverability, intraoperative complications and surgical time which was defined as from the beginning of first incision and up to the last skin suture. General behavior, including discomfort and uneasiness, feeding habits, defecation and urination, licking of the suture site, was observed up to 7th postoperative day. Each animal was carefully monitored for complications, like emphysema, port-site herniation, bacterial peritonitis, ascites and stitch abscess.

Clinical Observations

The respiratory rate (breaths/min), heart rate (beats/min) and rectal temperature (ºF) were recorded before start of operation, immediately after completion of operation and on days 1, 3, 5 and 7 after surgery.

Hematobiochemical Observations

Blood smears were made for differential leukocyte count (DLC) using standard procedure at before start of operation and immediately after completion of operation and on days 1, 3, 5 and 7 after surgery. Heparinized blood was collected at before start of and immediately after completion of operation and on day 1, 3, 5 and 7 after surgery. The plasma was separated for estimation of alkaline and acid phosphatase.[3]

Estimation of Oxidative Stress

The phosphate-buffered saline (PBS) suspended red blood cells (RBCs) were used to evaluate oxidative stress by estimating lipid peroxidation (LPO),[4] catalase (CAT),[5] superoxide dismutase (SOD)[6] and reduced glutathione.[7] The plasma samples were used to estimate the ceruloplasmin (acute phase proteins).[8]

Hormonal Estimation

The plasma samples were used to estimate the cortisol and testosterone hormone by radioimmunoassay (RIA) using RIA kit.[9]

The data were subjected to two-way analysis of variance (ANOVA) and the mean values of different time interval were compared with base level using paired 't' test.[10]

RESULTS

Intraoperative and Postoperative Observations

Surgical phase of anesthesia in all the animals were achieved by administering xylazine and ketamine combination. In both the groups no additional anesthesia was required in any animal during entire surgical procedure. The postsurgical recovery from anesthesia in both the groups was smooth and uneventful. Establishment of capnoperitoneum (CP) in each animal of both groups was found easy and safe. The CP was established at 10 mm Hg pressure gradient. This pressure was found adequate to perform laparoscopic surgery in the animals of both the groups. The CO_2 flow rate of 2 l/minute was also found sufficient to maintain intra-abdominal pressure during surgery. The total utilization of CO_2 gas for laparoscopic sterilization in group II (16.00 ± 0.78), which was significantly higher ($p < 0.01$) than animals of group I (8.04 ± 0.33).

For the laparoscopic sterilization, three ports were found sufficient to conduct the sterilization procedure but, the port size were different. In group I, three ports of 6 mm size were required whereas, in group II, one 6 mm size port for insertion of telescope (5 mm) and two 11 mm size ports for clip applicator (10 mm) were required. In group II, endoclips

were applied to the spermatic artery-vein plexus by using clip applicator. Two ports at paramedian site, either side of inguinal region, 4 to 6 cm lateral to mid-ventral line was found easy for laparoscopic sterilization. In all the animals of both groups monopolar coagulation current of 60 W was used and found effective for electrocautery as well as coagulation of the line of cutting of vas deferens. The visualization of vas deferens was better with trendelenburg position of the animals. All the animals were closely monitored for effective hemostasis before the final withdrawal of telescope.

Clinical Observations

All the animals were recovered smoothly from anesthesia. Return to normal appetite within 8 to 10 hours after recovery from anesthesia was observed in all animals. Urination and defecation were normal throughout the observation period. No significant change ($p > 0.05$) in respiration rate, heart rate and rectal temperature was observed. The values remained within the normal limits, without any significant change ($p > 0.05$) from base values at any postoperative time intervals (Table 1).

Hematobiochemical Observations

Differential leukocyte count of both the groups revealed a significant increase ($p < 0.05$) in neutrophils on 3rd postoperative day with comparative lymphopenia. No significant change ($p > 0.05$) was observed when comparisons were made between the groups at different time intervals. Significant increase ($p < 0.05$) in alkaline phosphatase (ALP) level was observed on 3rd postoperative day in animals of both the groups. Later on, it reduced and returned to base values on day 7 (Table 2). The acid phosphatase (ACP) level showed a significant increase ($p < 0.05$) on 1st and 3rd postoperative days (*see* Table 2).

Estimation of Oxidative Stress

The mean ± SE values of lipid peroxidation, catalase, superoxide dismutase reduced glutathione, ceruloplasmin are presented in Table 3. There was a mild, transient nonsignificant increase ($p > 0.05$) in LPO values after operation up to 3rd postoperative day in both the groups and it returned to base values on day 7. A significant increase ($p < 0.01$) in catalase was observed immediately after operation and on 1st and 3rd postoperative days in both the groups. Thereafter, the values of catalase enzymes decreased and returned to base line values on day 7 postoperatively. Values of SOD enzyme decreased nonsignificantly ($p > 0.05$) upto 3rd postoperative day in both the groups. The values increased on subsequent intervals and reached to base values on day 7 postoperatively in both the groups. A significant increase ($p < 0.05$) in reduced glutathione values upto day 1 was observed in both the groups. Later on, the values decreased and returned to base line values on day 7 postoperatively. No significant change ($p > 0.05$) was observed in ceruloplasmin level at any postoperative days. However, transient mild elevation ($p > 0.05$) of this protein was observed up to 7th postoperative day in both the groups.

Hormonal Estimation

The mean ± SE values of cortisol and testosterone are presented in Table 4. A nonsignificant increase ($p > 0.05$) in cortisol values was observed immediately after operation in group I. However, significant increase ($p < 0.01$) in cortisol level was observed immediately after operation in group II. On subsequent intervals, the cortisol level reduced and returned to base values on day 7 in both the groups. No significant change ($p > 0.05$) in testosterone was observed at different postoperative time intervals in group I. In group II, significant decrease ($p < 0.01$) in testosterone level was observed immediately after operation and there after the values showed gradual decrease ($p > 0.05$) up to 7th postoperative day.

DISCUSSION

The laparoscopic surgical techniques in both human and veterinary medicine have grown tremendously. Laparoscopy has been used to the routine diagnostic and therapeutic methods used especially in small animals. Therefore at present, laparoscopes provide a true panoramatic picture of the observed cavity. In addition to that, they can magnify to a certain degree, what makes visualization more precise and the picture brighter. For this reason, at using the laparoscopic techniques impairment of tissues hardly occurs. Since,

Table 1: Mean ± SE value of respiration rate, heart rate and rectal temperature recorded at different time intervals

Parameters	*Groups*	*Before operation*	*Immediately after operation*	*Day 1 PO*	*Day 3 PO*	*Day 5 PO*	*Day 7 PO*
Respiration rate (breaths/min)	I	24.20 ± 1.28	18.80 ± 0.58	25.40 ± 0.51	24.40 ± 0.75	24.40 ± 0.93	22.60 ± 0.81
	II	26.00 ± 0.89	20.60 ± 0.68	24.40 ± 0.93	24.80 ± 1.66	24.60 ± 1.57	22.60 ± 1.03
Heart rate (beats/min)	I	117.80 ± 5.00	110.60 ± 5.04	116.60 ± 3.23	116.60 ± 4.01	118.20 ± 4.08	115.20 ± 4.27
	II	115.40 ± 8.78	110.40 ± 7.39	108.40 ± 7.71	109.40 ± 6.37	112.00 ± 6.32	115.60 ± 5.78
Rectal temperature (ºF)	I	101.30 ± 0.25	101.10 ± 0.24	101.10 ± 0.40	101.10 ± 0.19	100.50 ± 0.16	100.60 ± 0.29
	II	101.30 ± 0.41	101.20 ± 0.25	101.50 ± 0.35	101.10 ± 0.29	100.90 ± 0.29	101.00 ± 0.16

an operator can see details of the organ surface (structures about 1.0 mm and less), he can avoid the blood sinus and so prevent the undesirable bleeding. The laparoscopy requires minor surgical intervention and it provides the only available practical means of making repeated direct observation of abdominal viscera.[11] Control of pain and stress being the beneficial aspects of minimally invasive surgery are important factors for treatment of veterinary surgical patients. Researchers are continually looking for more progressive and less stressful surgical way for sterilization in dogs. In the adult dog, intra-abdominal bilateral occlusion of ductus deferens using laparoscopy and electrocoagulation resulted in the immediate absence of motile spermatozoa from the ejaculate in long-term without increasing the occurrence of variant postsurgical effects.[12]

In the present study, the laparoscopic procedure was conducted under xylazine and ketamine general anesthesia. Both, induction as well as recovery from general anesthesia was smooth and uneventful in all the animals. Wildt et al[11] used this combination of anesthesia for direct observation of internal organs of dogs using laparoscopy. They found that induction was more rapid (5 minutes or less) in the dog. Drug tolerance was good with this combination even following frequent administrations requiring serial laparoscopy. Wildt et al[12] successfully used this combination of anesthesia for the sterilization of male dog by laparoscopic occlusion of the ductus deferens.

Intraoperative and Postoperative Observations

During laparoscopic sterilization in animals of groups I and II, CO_2 pneumoperitoneum or capnoperitoneum was established at 10 mm Hg pressure gradients intra-abdominally. The pressure gradient of 10 mm Hg and higher is required to conduct a laparoscopic surgery and has been reported by other workers in recent literatures.[13-15] The initial flow rate of carbon dioxide at 2 l/minute was found sufficient to achieve capnoperitoneum. Subsequently, after trocarization, the capnoperitoneum maintained by inflation of CO_2 at a flow rate of 2 l/minute. This pressure and flow rate provided adequate inflation and excellent working space. Maintenance of flow of CO_2 compensated the loss of CO_2 through the various ports during surgery. The findings

Table 2: Mean ± SE values of alkaline phosphatase (U/L) and acid phosphatase (U/L) recorded at different time intervals

Parameters	*Groups*	*Before operation*	*Immediately after operation*	*Day 1 PO*	*Day 3 PO*	*Day 5 PO*	*Day 7 PO*
Alkaline phosphatase (U/L)	I	11.37 ± 2.33	11.93 ± 1.68	10.89 ± 1.38	32.87 ± 3.97**	15.35 ± 4.76	9.77 ± 0.50
	II	9.71 ± 0.73	10.61 ± 0.58	9.87 ± 0.18	30.15 ± 2.37**	11.62 ± 0.50	10.66 ± 0.54
Acid phosphatase (U/L)	I	1.65 ± 0.03	1.69 ± 0.03	1.83 ± 0.02*	1.73 ± 0.03	1.72 ± 0.02	1.66 ± 0.03
	II	1.78 ± 0.04	1.80 ± 0.04	1.83 ± 0.04*	1.82 ± 0.03	1.67 ± 0.06	1.70 ± 0.03

*Differ significantly ($p < 0.05$) from base values (before operation); **Differ significantly ($p < 0.01$) from base values (before operation)

Table 3: Mean ± SE values of lipid peroxidation, catalase, superoxide dismutase, reduced glutathione and ceruloplasmin recorded at different time intervals

Parameters	*Groups*	*Before operation*	*Immediately after operation*	*Day 1 PO*	*Day 3 PO*	*Day 5 PO*	*Day 7 PO*
Lipid peroxidation (nM/ml packed RBCs)	I	4.92 ± 0.37	6.10 ± 0.67	6.77 ± 1.33	5.74 ± 0.97	5.23 ± 0.76	4.72 ± 0.83
	II	5.32 ± 0.22	5.74 ± 0.24	6.26 ± 0.17	6.00 ± 0.26	5.33 ± 0.30	4.87 ± 0.27
Catalase (nM H_2O_2 utilized/min/ml packed RBCs)	I	573.80 ± 164.2	1031.11 ± 137.2^{**a}	1555.88 ± 273.3^{**a}	960.01 ± 126.5*	573.80 ± 51.1	486.21 ± 30.2
	II	794.43d ± 164.2	1324.16 ± 137.2^{**b}	1246.91 ± 273.3^{**b}	1004.11 ± 126.5*	805.53 ± 51.1	617.94 ± 30.2
Superoxide dismutase (mg/ inhibition of 50% auto-oxidation of pyrogallol)	I	0.11 ± 0.01	0.07 ± 0.01	0.07 ± 0.02	0.10 ± 0.02	0.11 ± 0.01	0.13 ± 0.01
	II	0.08 ± 0.00	0.05 ± 0.02	0.07 ± 0.01	0.05 ± 0.01	0.06 ± 0.01	0.08 ± 0.01
Reduced glutathione (mM/ml packed RBCs)	I	0.26 ± 0.02	0.28 ± 0.02	0.34 ± 0.01*	0.30 ± 0.01	0.28 ± 0.01	0.27 ± 0.02
	II	0.20 ± 0.03	0.26 ± 0.03	0.29 ± 0.03	0.29 ± 0.02	0.25 ± 0.03	0.21 ± 0.03
Ceruloplasmin (gm/liter)	I	0.32 ± 0.02	0.36 ± 0.03	0.42 ± 0.07	0.33 ± 0.05	0.31 ± 0.04	0.30 ± 0.02
	II	0.30 ± 0.03	0.35 ± 0.03	0.37 ± 0.02	0.38 ± 0.03	0.34 ± 0.02	0.31 ± 0.03

Means with different superscripts (a, b) differ significantly ($p < 0.05$) within the group; *Differ significantly ($p < 0.05$) from base values (before operation); **Differ significantly ($p < 0.01$) from base values (before operation)

Table 4: Mean ± SE values of cortisol and testasterone recorded at different time intervals

Parameters	*Groups*	*Before operation*	*Immediately after operation*	*Day 1 PO*	*Day 3 PO*	*Day 5 PO*	*Day 7 PO*
Cortisol (nM/l)	I	25.59 ± 17.37	46.85 ± 16.39	31.99 ± 9.29	27.29 ± 16.48	27.88 ± 13.19	27.40 ± 8.45
	II	46.83 ± 4.99	129.08 ± 23.46**	59.41 ± 21.03	38.68b ± 12.78	23.55 ± 8.20	25.52 ± 5.36
Testosterone (ng/ml)	I	0.418 ± 0.05	0.321 ± 0.03	0.396 ± 0.08	0.438 ± 0.09	0.369 ± 0.03	0.372 ± 0.04
	II	0.437 ± 0.08	0.159 ± 0.03**	0.101 ± 0.02**	0.024 ± 0.00**	0.025 ± 0.01**	0.015 ± 0.01**

**Differ significantly ($p < 0.01$) from base values (before operation)

of the present study concurred with the observations of Dharmaceelan et al.[14] The total utilization of CO_2 during surgical procedures was recorded. Comparatively, less utilization of CO_2 was observed in group I because of less time taken to perform bilateral vasectomy. This method was comparatively simple, quick and easier than method of group II. In group II, utilization of CO_2 was significantly higher ($p < 0.01$) than that of group I, may be due to the longer operative time and may also be due to leakage of CO_2 during removal of resected tissue through 10 mm ports by 5 mm forceps.

The instruments used were differed in both groups. In group I, all the three ports were of 5 mm in size, two ports were created at left and right paramedian site distally to the telescope insertion site and 4 to 6 cm laterally at the inguinal regions and the rest one was at umblical site for insertion of telescope. In the group II, two ports were 10 mm in size and the rest one was 5 mm for telescopic insertion at the same sites as described in group I. These two 10 mm ports were needed mainly to insert the 10 mm clip applicator toward the contralateral spermatic artery-vein plexus and were converted into 5 mm size by applying adaptor for inserting fenestered grasping forceps to manipulate the vas deferens and testicular vessels for vasectomy as well as for clip application respectively. However, regarding the number of trocars and their respective sites, the present study concurred with the findings of Wildt et al.[12] The urinary bladder was visualized first with the introduction of telescope into the abdominal cavity and it was identified by its characteristics tortuous structures of blood vessels on it.

The 30º forward oblique, 5 mm rigid telescope used in this study covered sufficiently big exposure operative area in a single view without any remarkable loss of resolution and visibility. Most of the clinicians have reported the use of 5 mm telescope during ovariohysterectomy in dogs.[11,14,15] Laparoscopic occlusion of ductus deferens in male dogs and cats[12] and laparoscopic vasectomy in male dogs.[16] The separation of intra-abdominal organs from the ventral as well as lateral abdominal walls were adequate at 10 mm Hg pressure gradient intraperitoneally. Also, proper fasting prior to surgery emptied colon and urinary bladder[13] and thereby facilitated proper visualization of the vas deferens and spermatic artery-vein plexus.

The electrocautery with 60 W monopolar current revealed a good hemostatic measure in both groups. Rodgerson et al[17] found that application of coagulation current from monoplar electrocautery alone was sufficient for effective hemostasis for equine mesoovarium. However, before final withdrawal of telescope in all the animals of laparoscopy groups the resected sites were closely observed. The mean surgical operating time was significantly lower ($p < 0.05$) in group I as compared to group II. The decreased surgical operating time in group I was due to the reason that this technique was simple, quick and easier than other two groups. Wildt et al[12] reported the lower operative time required for bilateral vasectomy in dog. Increased surgical operative time in laparoscopic bilateral vasectomy with occlusion spermatic artery-vein plexus (group II) was due to additional time required for application of endoclips. All the animals were returned to their normal feeding habits within 8 to 10 hours after surgery. Urination and defecation were normal upto 7th postoperative day. The animals appeared quite alert and responsive. There was no postoperative infection, emphysema, port-site herniation as well as wound dehiscence in any animal.

Clinical Observations

No significant difference in physiological parameters, such as heart rate, respiration rate and rectal temperature, was observed at different time intervals. Heart rate, respiration rate and rectal temperature did not change significantly after surgery, so these variables could not be considered useful in the recognition of postoperative pain.[18] In both the groups, there was a decrease in respiration as well as in heart rate immediately after operation might be attributed to post-anesthetic effect of xylazine, also reported by Ilback and Stalhandske[19] in dogs. Luna et al[20] also reported xylazine and ketamine combination causes reduction in heart rate and respiration rate in dogs.

Hematobiochemical Observations

A significant increase ($p < 0.05$) in neutrophils and comparative lymphopenia was observed on 3rd postoperative day may be the result of release of endogenous glucocorticoids

in response to tissue trauma and inflammation.[21] However, on the contrary, Earley and Crowe[22] reported that surgical castration did not affect any of the hematological parameters from day 0 to 3 after surgery and indicate that the health of the animals was not compromised.

Alkaline phosphatase is a zinc metalloenzymes present in most of the tissues and having very high sensitivity in the dog in comparison to the cat.[23] In the present study, plasma ALP level in animals of both the groups were within the normal limit. But, significant increase ($p < 0.05$) in this enzyme was observed on 3rd postoperative day in both the groups. Increase may be attributed to tissue injury as a result of ischemia reperfusion induced oxidative stress in liver and kidney following capnoperitoneum.[24] It returned to the base level values on 7th day of operation. Acid phosphatase activity derived from lysosomal compartment of cells, predominantly in bone and some extent in other cells, like platelets, erythrocyte and spleen.[25] A significant increase of plasma ACP was observed on 1st and 3rd postoperative day. As there was no significant change between the groups, so the changes in serum ACP levels could not be correlated with the type of tissue injury occurred in both the groups because it is a weak marker of soft tissue injury.

Estimation of Oxidative Stress

A mild, transient increase in LPO was observed in both groups after operation up to 3rd postoperative days. The values returned to base level on 7th postoperative day in all the groups. Bisla et al[26] also reported significant increase in lipid peroxidation values after herniorrhaphy in buffaloes. In both the groups, the catalase activity significantly increased on 1st and 3rd postoperative day. This showed that the production of catalase as an antioxidant enzyme against reactive oxygen species (ROS) enhanced by increased lipid peroxidation. Comparatively, the catalase activity was significantly higher in group II on 1st day postoperatively. Whereas in group I, significant increase was observed immediately after operation. The result of the present study was supported with findings of Kumaraguruparan et al.[27] The increase in lipid peroxidation was accompanied by an enhanced antioxidant status, and also the SOD and CAT provide the first line of defence against ROS-induced damage. The increase in catalase level indicates that these enzymes were not utilized against H_2O_2 because the production of these radical from superoxide radical lowered due to decreased activity of SOD. However, the catalase level was significantly higher in group II indicating more oxidative stress. The increased activity of SOD dismutases the super oxides produced and results in the generation of H_2O_2, which is decomposed by CAT into H_2O and O_2.[28]

Superoxide Dismutase

In the present study, SOD activity was significantly lower in group II upto 3rd postoperative day, but it reached to base values on 5th postoperative day. The SOD, an antioxidant enzyme it catalyzes the conversion of superoxide anion radicals into hydrogen preroxide and oxygen molecule. The decreased SOD after operation attributed to decreased LPO in this group. Fridovich[28] reported that the increased activity of SOD dismutases the superoxides and results in the generation of H_2O_2, which is decomposed by CAT into H_2O and O_2.

Reduced Glutathione

In both the groups a significant increase in the reduced glutathione was observed immediately after operation and on 1st postoperative day. Bisla et al[26] also reported a significant increase in malondialdehyde (MDA), a main indicator of lipid peroxidation, GSH and oxidative stress factor (OSF) occurred after herniorrhaphy in buffaloes. Enhanced expression of GSH-dependent enzyme GPx has been documented to inhibit ROS-induced apoptosis in human breast cancer cell lines Gouaze et al[29]. Reduced glutathione was required for the disposal of H_2O_2 from erythrocytes by a reaction catalyzed by GPx. This reaction was important because accumulation of H_2O_2 might decrease the lifespan of erythrocytes by increasing the rate of oxidation of hemoglobin to methemoglobin. The present study showed that enhanced production of reduced glutathione occurred in both the groups in order to prevent oxidative stress due to different surgical procedures made on these animals.

Ceruloplasmin

The ceruloplasmin level in plasma remained elevated nonsignificantly up to 7th postoperative day in all the groups. Conner et al[30] also reported increase ceruloplasmin level in plasma after surgical trauma due to acute phase inflammatory process in the dog. Solter et al[31] reported that haptoglobin and ceruloplasmin have greater sensitivity as determinants of inflammation in dogs. Acute phase proteins (APPs) level increases in the circulation after surgery and its associated tissue damage[32,33] and are particularly associated with inflammation.[34]

Hormonal Estimation

Surgically induced stress responses are evoked by nociceptive afferent activity induced by tissue damage and manipulation, even in patients that are receiving adequate general anesthesia.[35] A significant increase ($p < 0.05$) in plasma cortisol was observed immediately after operation in both the groups. It might be attributed to the effect of

capnoperitoneum. Marcovich et al[36] reported the higher cortisol level at 4 hours interval, whereas the peak cortisol level at 2 hours after laparoscopy in dog has been observed by Hancock et al.[37] Testosterone is a male reproductive hormone often used to evaluate the reproductive status of the animal. Due to the source specificity, testosterone estimation has been indicated to assess the effects of two laparoscopic techniques in the present study. In group I, no significant change ($p > 0.05$) in testosterone was observed at different postoperative time intervals. It might be attributed to bilateral vasectomy which do not exert remarkable effect on steroidogenic functionality of the testicle as also reported by Batista et al.[38] Whereas, in group II, a significant decrease ($p < 0.01$) in plasma testosterone was observed immediately after operation up to 7th postoperative day. It might be due to the reduction of testicular blood flow and loss of testicular interstitial tissue. Pepe et al[39] reported laparoscopic sterilization using on endoscopic stapler application on spermatic cord showed decerase in serum testosterone concentration when postoperative stimulation with hCG in donkeys at 3, 6 and 12 months after surgery. Niu et al[40] reported that following castration, the serum concentration of testosterone decreased rapidly in 2 days. Ortega-Pacheco et al[41] also reported significant decrease ($p < 0.001$) in serum testosterone after surgical castration in dogs.

CONCLUSION

On the basis of the parameters studied, it can be concluded that capnoperitoneum at 10 mm Hg pressure gradient and CO_2 at the flow rate of 2 litre/minute provides optimum visualization of intra-abdominal organs and found suitable for laparoscopic sterilization in male dogs. The laparoscopic vasectomy alone in male dogs was found comparatively quick, less time consuming and can be sucessfully applied for mass sterilization program. Oxidative stress in laparoscopic vasectomy (group I) was less as compared to other group.

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ORIGINAL ARTICLE

A Comparative Randomized Parallel Group Study between the Classical TAPP Repair and Modified TAPP Surgical Method for Inguinal Hernia Repair

Sumanta Kumar Ghosh

ABSTRACT

Objective: To compare equality of clinical outcome of simultaneous bilateral transabdominal preperitoneal (TAPP) repair of inguinal hernia by classical TAPP, with meticulous closure of peritoneal flap and modified TAPP, with peritoneal nonclosure and controlled release of pneumoperitoneum. Study to answer the research question—'is meticulous closure of peritoneal flap, the only way to provide adequate cover for the mesh in TAPP repair?'

Summary and background data: The objective of meticulous closure of peritoneum is to prevent internal herniation while covering the mesh adequately to avoid contact between mesh and abdominal viscera. The study proposes same objective can also be achieved with nonclosure of peritoneum.

Patients and methods: Between August 2011 and July 2012, 130 inguinal hernias of 65 patients who underwent TAPP repair were randomized in two groups. One group (n = 65) of hernias received classical repair with peritoneal closure (control), while the other (n = 65) without closure (study). The primary end points were bowel related complications and recurrence.

Results: The two groups were comparable in age and types of hernia. Transabdominal preperitoneal was successfully done in all cases. No bowel-related complication and recurrence occurred in either group. Mean operating time was significantly less with modified TAPP (65 mins *vs* 76 mins, $p < 0.05$). Lower incidence of chronic pain (3 *vs* 13.84%, $p = 0.007$) and seroma (7.69 *vs* 15.38%) was achieved during mean follow-up of 628 days.

Conclusion: The randomized prospective parallel group study demonstrated equality in clinical outcome on both primary end points by providing equivalent peritoneal cover for the mesh as meticulous peritoneal closure does in classical TAPP.

Keywords: Laparoscopic repair, Inguinal hernia, Preperitoneal, Transperitoneal, Complication, Intestinal.

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INTRODUCTION

Gall stone disease and inguinal hernia are two most common surgical problems amenable to laparoscopic surgery but the acceptance and spread of laparoscopic inguinal hernia repair (LIHR) is significantly less than laparoscopic cholecystectomy (LC). Even today, only 15 to 20% of hernia repairs are done laparoscopically in America. Two factors limiting its acceptability among patients and surgeons are: stiffer learning curve for surgeons and cost associated with LIHR.[1] Without aversion for use of modern technology, efforts to simplify the technique should be made by sparing the use of costly disposable equipment, when possible, without compromising safety and efficacy of the procedure. This should make it cost effective and acceptable. Increased cost in LIHR is due to use of disposable equipment like hernia staple or tack and longer operating time. Honing little extra skill and avoiding unnecessary use of gadgets make the procedure shorter and cost effective. It is the cost and technology dependence that has overshadowed the obvious benefits of LIHR, like shorter convalescence, equivalent efficacy, and early return to work.[1-4] This trial is intended to answer the research question: 'is meticulous closure of peritoneal flap, the only way to provide adequate cover for the mesh in TAPP repair?' The study focuses on an alternate concept of functional closure of peritoneum, required to cover the prosthesis to avoid adhesion and internal herniation,[5-7] adhesion being the precursor of unacceptable postoperative complications like intestinal obstruction and fistulisation. It scientifically compares the clinical outcome of the modified technique of absolute nonclosure of peritoneal flap, which is only made larger and simply relaid in position with controlled DE insufflations abdominal viscera gliding along posterior wall presses the flap sequentially from below upward against the anterior abdominal wall where the repair is done and flap was initially harvested from, effectively covering the prosthesis and does exactly what meticulous closure do in

classical transabdominal preperitoneal (TAPP) repair. This saves cost and operating time while achieving comparable clinical outcome regarding bowel related complications and hernia recurrences as shown in follow-up.

With low recurrence and complication rate achieved with LIHR, emphasis is now on finer issues, like operating time, incidence of seroma and chronic pain. The study also compares the techniques in a randomized prospective fashion to see whether any difference of statistical significance exists on those parameters.

Overall, it wants to test the validity of null hypothesis regarding clinical outcome between modified TAPP (non-closure of peritoneum) and classical TAPP (meticulous closure of peritoneum).

PATIENTS AND METHODS

Between August 2011 and July 2012, all patients with bilateral inguinal hernia presented to us were assessed for eligibility in the proposed study. Inclusion criteria were male patients with bilateral hernia and suited for TAPP repair, aged more than 18 years and fit to undergo general anesthesia. Patients with recurrent hernia or with indication for concomitant surgery for other pathology or with past lower abdominal surgery were excluded. The research protocol was approved by the Institutional Ethics Committee of ESIC Medical College and Postgraduate Institute of Medical Research, Joka, Kolkata (where the trial was conducted), before the commencement of the trial. Informed consent was obtained before patients were included in the trial. One hundred and thirty hernias in 65 patients were randomized using digit 1 and 2 with the option of repetitions to create a random sequence of 130 digits. Two consecutive digits formed a double digit randomization code which is allotted to one patient. Digit 1 stood for classical repair and digit 2 for modified TAPP. First digit of the code dictates treatment option for right side while the second for the left. Randomization codes for patients were kept in sealed envelopes in the custody of theater nurse. Prospective data entry sheets were used for collection of data.

Modification of Technique with Rationale

The basic principle of TAPP repair with wide dissection of preperitoneal space and securely anchoring a large (15 cm × 10 cm) prolene mesh to cover all myopectineal orifices in the region remains same. However in order to harvest a larger peritoneal flap, initial peritoneal incision is made 2 cm higher than normal. Good parietalization of the cord keeps the lower margin of the mesh firmly wedged. Only two-point fixation of the mesh to Cooper's ligament is done with 2-0 prolene suture. The peritoneal flap is relaid back in position with controlled de insufflations of pneumoperitoneum. No attempt is made on peritoneal closure.

The repair and placement of mesh done in TAPP repair is on anterior abdominal wall, from where the peritoneal flap is harvested with its base at the line of reflection of peritoneum from posterior to anterior abdominal wall. On controlled release of insufflations and loss of Trendelenburg position viscera glides along posterior wall and puts sequential pressure on the flap from below and presses it back in position against the anterior wall. Weight of the viscera keeps it securely placed while rapid mesothelial healing takes place leaving no opportunity of direct contact between mesh and bowel.

Surgical Technique

Patients were operated under general anesthesia in supine and 10 to 15° Trendelenburg position with operating side tilted up and prophylactic antibiotic given on induction. Pneumoperitoneum was induced by supraumbilical Veress needle insertion. One 10 mm port for optics was introduced here and two 5 mm ports introduced at mid clavicular line at the level and on either side of umbilicus to accommodate operating instruments. In modified TAPP, initial curvilinear peritoneal incision starting at the level of anterior superior iliac spine laterally, is made 2 cm higher than in classical TAPP to make the flap larger. Dissection of preperitoneal space was carried out in similar fashion with parietalization of cord structure done adequately, the landmark for adequacy is to dissect up to the point where vas deferens crosses medial umbilical ligament. A 10 × 15 cm prolene mesh trimmed laterally to comfortably sit in the space of Retzius and Bogros, covering the myopectineal orifices is anchored to Cooper's ligament at two points by prolene sutures. Only in 27 cases when we used tack to close the peritoneum, this two-point fixation of mesh was done by tack. When in place, the lower margin of the mesh wedges at the line of dissected peritoneal reflection inferiorly, while its superior margin stays below the initial peritoneal incision. The peritoneal flap was held up by instrument while pneumoperitoneum is deflated in a controlled fashion, till it is relaid back in position on anterior abdominal wall.

Outcome Assessment

Primary end points were recurrence of hernia and any bowel related complications like intestinal obstruction and fistula. Presence or absence of recurrence was determined by clinical examination in follow-up, aided by radiological investigations like CT and US in selected cases. As regard to the gastrointestinal complications, combination of clinical history and examination backed up by radiology was used.

Three secondary parameters were compared and analyzed for any difference of statistical significance. Operating time,

incidences of seroma and chronic pain were compared between the groups. Seroma was defined as clinical presence of palpable fluid collection over the groin in the absence of bruising. Operating time was defined as the time taken from the skin incision to the last skin suture. Entry and closure time together were separately measured in each case and this common duration were added to either side repair time for equitable comparison. All time measurements were approximated to the nearest integer of 5. Total number of nights spent in the hospital after operation was defined as hospital stay.

Chronic pain was defined as discomfort /pain in the groin area at least 3 months after surgery and debilitating enough to interfere with daily activity requiring medical attention, in the absence of recurrence of hernia on the side of pain.

Postoperatively all patients received one 100 mg sustained released diclofenac tablet each day for 2 days, supplemented by 1 gm of oral paracetamol tablet (spaced 6 hourly) on demand basis. Paracetamol tablet was the prescribed analgesic for a maximum of 7 days on discharge. Analgesic requirement was calculated from the total amount of paracetamol consumed postoperatively, expressed in gram.

A sample size analysis was performed using a two-tailed t-test with a probability of type I error (alpha) of 0.05 and type II error (beta) of 0.2 (power 80%), and assuming a standard deviation of 10% (expected variance of 0.01) the required minimum sample size to prove equality of mean for the groups is calculated to be 63 in each group. In our study, both the groups (group 1 receiving classical TAPP repair and group 2 receiving modified TAPP repair) had a sample size of 65 each.

Statistical analysis was performed using computer software (MedCalC), and outcome measures were expressed with 95% confidence interval, p-value calculated from two-tailed t-test or chi-squared as appropriate.

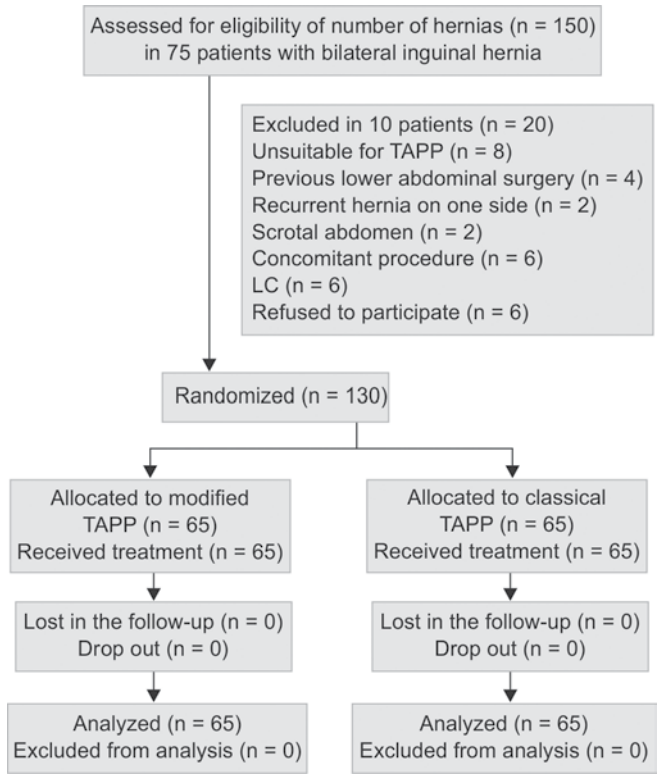

Fig. 1: Trial profile

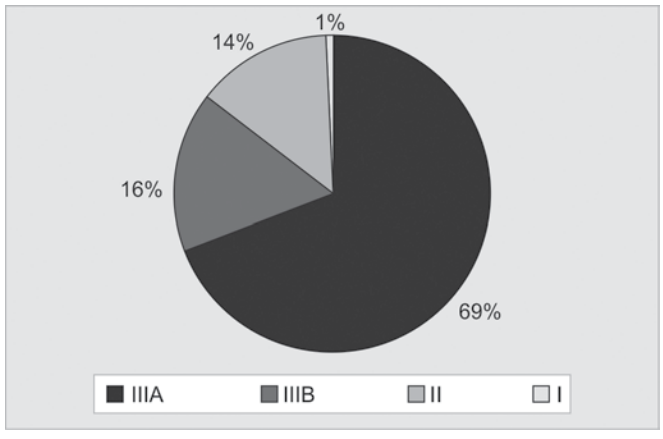

Fig. 2: Incidence of hernia type in bilateral setting as found in this clinical trial

RESULTS

Between August 2011 and July 2012, 75 patients presented with bilateral inguinal hernia were assessed for study eligibility. Figure 1 shows the profile of the trial according to the CONSORT statement. A total of 130 inguinal hernias with bilateral occurrence in 65 patients were randomized into study group (n = 65; Rx-modified TAPP) and control group (n = 65; Rx-classical TAPP). Out of 65 in the control group peritoneal closure was done with tack in 27 patients (n = 27) and by suturing in 38 patients (n = 38). The groups were comparable in age and Nyhus type of hernia as determined during surgery (Table 1). Figure 2 shows incidences of type of hernia in bilateral setting as found in this study.

Table 1: Patient's characteristics

Characteristics	*Modified TAPP (n = 65)*	*Classical TAPP (n = 65)*	*p-value*
Age in years [mean (range)]	50.93 (30-78)	47.66 (28-74)	0.116* —
Types of hernia [number (%)]			
I	0 (0)	1 (0.76)	—
II	8 (6.15)	10 (7.69)	0.422**
IIIA	46 (35.38)	44 (33.84)	0.945**
IIIB	11 (8.46)	10 (7.69)	0.461**

Nyhus classification; *t-test statistics; **Chi-square test

All the TAPP repairs were successfully performed and there were no conversion to open surgery. No gastrointestinal complication and hernia recurrence happened in study (x = 0) and control (x = 0) group during follow-up, which is self-explanatory regarding equality of clinical outcome

in view of statistically calculated minimum sample size chosen at the beginning. Mean follow-up was 628 days with range between 435 and 797 days. Operating time and corresponding standard deviation of different techniques are shown in Figure 3. The mean operating time in the study and control groups were 65.15 (50-90 mins) and 76.64 minutes (55-95 mins) respectively. p-value of < 0.0001 calculated from t-score of 7.294. There were no intraoperative complication, need for readmission or re-exploration and hospital mortality in either group. Table 2 summarizes the postoperative complications, while Table 3 illustrates comparison of techniques on analgesic requirement, hospital stay and time for return to work. Table 4 demonstrates cost effectiveness of the modified technique comparing against major variants that determine effective cost of a procedure. No wound or mesh infection was reported in any patient. The study group had significantly lower incidence of seroma. Overall incidence of seroma was 11.53% (95% CI; 6-17%). In study group, the incidence was 7.69% (95% CI; 1-14%), whereas, in the control group, the incidence was 15.38% (95% CI; 7-24%). However, with a p-value of 0.164, this observed difference lost statistical significance. Majority of seromas developed within couple of weeks and detected in follow-up visit 1 month after surgery and resolved spontaneously by 3rd month. Fourteen out of total 15 incidences of postoperative seroma, developed following repair of direct hernia (IIIA) treated by either method.

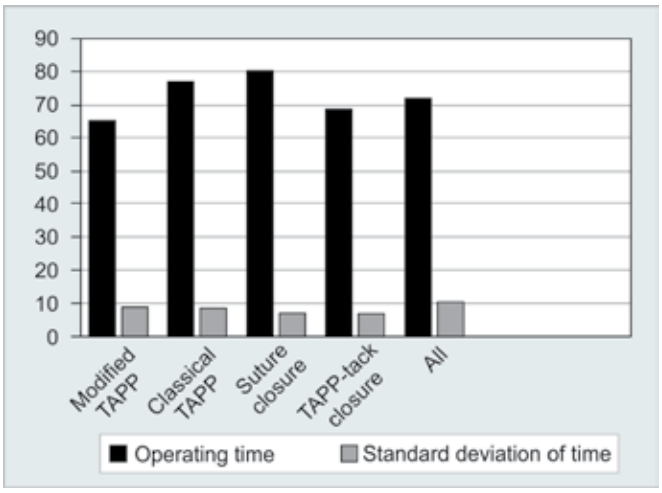

Fig. 3: Operating time with standard deviation in minutes with different techniques of TAPP repair

Table 2: Postoperative complications

Complication	*Modified TAPP (n = 65)*	*Classical TAPP (n = 65)*	*p-value*
	No. (%)	*No. (%)*	
Seroma	5 (7.69)	10 (15.38)	0.168*
Chronic pain	2 (3.07)	9 (13.84)	0.007*
Vaginal hydrocele	2 (3.07)	3 (4.61)	1**

*p-value from Z score; **Fisher's exact test

Regarding postoperative chronic pain, the overall incidence was 8.46% (95% CI; 3-13%) (n = 11). In the study group, it was 3% (95% CI; 0-7%) (n = 2) in contrast to higher incidence in the control group of 13.84% (95% CI; 5-22%) (n = 9). p-value of 0.0071 denotes significance of difference. One interesting finding was very high incidence of chronic pain when hernia tacker was used to fix the mesh with Cooper's ligament and for closure of peritoneum. Incidence was 29% (95% CI; 12-47%) (n = 8). Majority of chronic pain presented at 6 months follow-up visit (10/11), and had a slightly protracted course and resolved in all but two patients by 1 year follow-up. Two patients continued to have pain ever after a year, despite analgesics and neuromodulating medications and at present being cared for by pain clinic specialists. Chronic pain bore no relation with initial analgesic requirement at home after discharge.

Five patients developed vaginal hydrocele, all detected at 3 months follow-up visit and progressed to increased size and discomfort over time and had to be treated by surgery subsequently. On all occasions, TAPP was done for indirect hernia with high ligation of sac.

Ultrasound (US) was done on 40 separate instances in 34 patients in the follow-up period for investigation of postoperative seroma, chronic pain, vaginal hydrocele, abdominal pain and identifying recurrence of hernia. On two occasions when US could not conclusively eliminate recurrence in patients with chronic pain, computed tomography (CT) of involved groins was performed which successfully excluded recurrence on both occasion.

Average time taken for peritoneal closure by suturing was 12 minutes. Mean duration of follow-up has been 628 days.

Table 3: Comparison of techniques on analgesic requirement, hospital stay and time for return to work

Group	*Patient and technique*	*Analgesic requirement (gm) Mean (range)*		*Hospital stay in days Mean (range)*		*Return to normal work (days) Mean (range)*	
A	All TAPP repair (n = 65)	21.86 (12-28)		2.10 (1-3)		17.87 (11-30)	
B	Both sides by classical TAPP (n = 18)	20.16 (12-28)		2 (1-3)		17.875 (14-30)	
C	At least one side by modified TAPP (n = 47)	22.59 (12-28)		2.14 (1-3)		17.78 (11-26)	
				p-value when compared to			
		A	B	A	B	A	B
		0.468	0.096	0.597	0.181	0.896	0.934

Table 4: Comparison of cost effectiveness on variable determinants of cost

Variable determinants of cost	*TAPP with tack*	*TAPP with suture*	*Modified TAPP*
Type of anesthesia and related consumables	✓	✓	✓
Perioperative medications	✓	✓	✓
Hospital stay	✓	✓	✓
Readmission	Nil	Nil	Nil
Re-exploration	Nil	Nil	Nil
Loss of work day	±17 days	±17 days	±17 days
Cost of investigation in follow-up	✓	✓	✓
Cost of disposable surgical equipment	✓	–	–
Operating time	✓	✓✓	✓
Cost for treatment of complication	✓	–	–
1. Seroma	✓	✓	✓
2. Chronic pain	✓✓	✓	✓
3. Vaginal hydrocele	✓	✓	✓
4. Recurrence of hernia	✓	✓	✓
5. Bowel-related complication	✓	✓	✓

DISCUSSION

Laparoscopic inguinal hernia repair has evolved over the years as an alternative to the best method of open repair. However, it is still not the gold standard. Stiff learning curve and increased cost being the major constrains. Average extra cost LIHR incurs over open repair has roughly been estimated to be 300 to 350 UK pounds. Disposable equipment and longer operating time is the key cost driver.[8] Efforts to curtail cost without compromising safety and efficacy have led to many modifications of TAPP procedure. To be considered, a viable alternative to most successful method of conventional surgery the recurrence rate should be <2%.[9]

Central to successful TAPP repair is the need for wide dissection of preperitoneal space and placement of a large and anchored mesh to adequately cover all the myopectineal orifices.[9-11] Case reports and animal trials[12-14] have suggested increased visceral adhesion to exposed prolene mesh in intraperitoneal on lay placement, which forms the basis of preperitoneal or extraperitoneal placement of prolene mesh in TAAP and TEP respectively. However, there are reports of animal study that suggests—prolene mesh placed preperitoneally by intraperitoneal route, the adhesion increases on suture closure of peritoneal incision in comparison to leaving it open.[15] Apart from preventing internal herniation through imperfect closure of peritoneal incision, it also provides a reassuring peritoneal cover for the mesh when the peritoneal incision is meticulously closed in classical TAPP repair. Apprehension has been raised[14] and incidences cited[16] about bowel complications occurring postoperatively if strict adherence to the practice of peritoneal closure is breached. To minimize prosthesis induced intraperitoneal adhesions relatively nonreactive PTFE mesh has been introduced[17] which come with a price tag sufficient to compromise cost effectiveness further.

The study hypothesis proposed an alternative way of peritoneal reapproximation utilising the intra-abdominal biomechanics relevant to the area of repair that uses the pressure exerted on the flap by the viscera to keep it securely opposed to the anterior abdominal wall while healing takes place and thus provides equivalent peritoneal cover for the mesh. Absence of any adhesion with excellent peritoneal cover achieved (when modified TAPP was done earlier), as seen on two relook opportunities obtained during subsequent LC may not be entirely representative, but the finding strengthens the principle of hypothesis proposed. In order to satisfy the criteria set, one has to dissect the preperitoneal space widely with adequate parietalization, to the point of crossing of vas over medial umbilical ligament. Essentially it provides adequate space to accommodate a larger mesh comfortably with its inferior margin wedged firmly at peritoneal reflection without any tendency to be pushed up by the peritoneum during release of pneumoperitoneum, eliminating an important cause of immediate recurrence. This supplements medial anchorage to prosthesis provided by two-point fixation to Cooper's ligament, lateral anchorage being provided by the weight of viscera without any need for mechanical means.

Evolution of TAPP repair has been striking from late nineties to present day. Early reports show significant perioperative events, higher recurrences and longer operating time. Improved parameters in recent trials confirm the safety and efficacy of TAPP repair has improved with collective and individual experience over time.[11,18,19] Several trials have identified the factors that lead to recurrence following TAPP-like surgeon's inexperience, inadequate dissection, and insufficient size of prosthesis, improper fixation, twisting or folding of mesh and lifting of mesh by hematoma. Contrasting views exist regarding anchorage of the mesh,

while most advocates anchoring the mesh to prevent migration, many others suggest it unnecessary;[20,21] moreover, injudicious application of tack or staple below iliopubic tract carries an inherent risk of nerve damage.[22] Very high proportional incidence of chronic pain in patients on whom helical tack was used for mesh fixation and peritoneal closure in this study needs due attention as a potential cause of such pain of somatic and neural origin. Intraoperative complications though rare, are serious in nature, mostly in the form of visceral injury.[18,23,24] Trials have shown reduction of complications and operating time with increased experience. Postoperative gastrointestinal complications are port-site hernia, internal herniation from improper peritoneal closure and adhesion leading to intestinal obstruction and occasional fistulisation when bowel is involved.[4, 25-27] Bowel obstruction by herniation through trocar site or imperfect closure of peritoneum[3] occur earlier (8 days) than obstruction from adhesion which commonly happens after a month (mean onset 25 days),[2] just as majority of hernia recurrences following LIHR develops within a year.[6] Both these statistics fall within purview of follow-up done in this study.

With preoperative and major postoperative complication like recurrence brought down to acceptable level in LIHR, the focus now have shifted to other parameters like chronic pain, analgesic requirement, return to work and most importantly the cost of surgery which is so important that advantages of LIHR with shorter convalescence and early return to work when weighed against cost, it leaves only bilateral and recurrent hernias following anterior approach the undisputed indications of LIHR.[28]

Seroma developed early (within 1 month) though spontaneously resolved relatively quickly and occurred almost exclusively following repair of direct hernia in this study. This fact highlights the importance of inversion of fascia transversalis either by fixing it to pubic bone or by application of endoloop at the base of inverted fascia and amputating the redundant portion,[29,30] neither of which was performed in this study. Chronic pain developed late (by 6 months) and carried a rather protracted course, but resolved with counseling, analgesics and neuromodulating drugs like amitriptyline in vast majority of cases. As reported in an earlier study[18], postoperative hydrocele developed late, progressed with time and required surgery as they did not resolve spontaneously. They developed in larger indirect hernias where complete dissection of sac was not possible.

Regarding cost advantage, each procedure of modified TAP saved $ 130 by avoiding use of hernia tack,[20] over and above the savings from shorter operating time.

The study concludes that, while offering equality of clinical outcome regarding gastrointestinal complications and hernia recurrence, when compared with standard technique, it gave superior result regarding operating time and incidences of chronic pain. Cost of surgery was significantly less while giving compatible result regarding analgesic requirement, time for return to work and hospital stay. For ethical reason, direct evidence of effectiveness of this technique in providing peritoneal cover for the prosthesis was not collected during the trial, it provided enough indirect and limited direct evidence in support of the alternate hypothesis of peritoneal cover, as proposed in the study which did not assess and compared intra-abdominal adhesions in real time but it closely monitored the expected clinically significant effects of adhesion and found the end result extremely satisfactory and answered the research question comprehensively by providing a more physiological alternative way of proving a peritoneal cover for prosthesis and provokes the need for further studies to see if the study outcome can be reproduced.

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REVIEW ARTICLE

Polycystic Ovarian Syndrome: Pathophysiology and Infertility

Bassim Alsadi

ABSTRACT

Polycystic ovarian syndrome (PCOS) is recognized as the commonest endocrinopathy of women in the reproductive age. The definition, heterogeneity of clinical presentation, variability of symptoms in different age groups, overlapping instrumental and laboratory diagnostic criteria with physiological situations and the etiological hypotheses of PCOS are continuously evolving to accommodate expanding knowledge on the syndrome, which is now known to be more complex than purely a reproductive disorder. This article reviews the pathophysiology aspects known to underlie the ovarian and metabolic abnormalities characterizing PCOS. The interdependence between reproductive and metabolic aspects of PCOS and therapeutic implications for the management of PCOS are also discussed.

Materials and methods: Extensive review of literature of articles published in English language was conducted using the following engines: Google, Yahoo, Medline, PubMed and Medscape.

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INTRODUCTION

The polycystic ovary syndrome (PCOS) is the most frequent pathology among women of reproductive age. It was described for the first time by Stein and Leventhal in 1935.[1] There is still no international consensus on its definition.

The difficulties in finding an agreement on the criteria for establishing the diagnosis of PCOS are related to the intrinsic characteristics of the syndrome: heterogeneity of clinical presentation, variability of symptoms in different age groups, overlapping instrumental and laboratory diagnostic criteria with physiological situations and therefore lack cut-off shared and useful in clinical practice.

The definition of PCOS remains dynamic and controversial subject of debate for many scientific forums. In the publication of Stein and Leventhal in 1935, it was described for the first time the phenotype of seven cases of PCOS in women with oligo/amenorrhea, hirsutism, obesity and polycystic ovaries bilaterally.[1]

In 2003 in Rotterdam ESHRE (European Society of Human Reproduction and Embryology)/ASRM (American Society of Reproductive Medicine). The PCOS consensus workshop group has proposed a revision of the diagnostic criteria, defining PCOS as the presence of at least two of the following criteria together with the exclusion of other etiologies (congenital adrenal hyperplasia, hyperprolactinemia, thyroid dysfunction, androgen-secreting tumors and Cushing syndrome):[2]

- Oligoanovulation
- Hyperandrogenism (clinical or biochemical)
- Polycystic ovary (morphological sign found at the ultrasound examination)

The sonographic appearance of the ovaries is as defined prevalent in Europe at present, an essential criterion. However, there is still no agreement in the definition ultrasound of polycystic ovaries (PCO) (Fig. 1).

The classic sonographic criteria of Adams include the presence of at least 10 follicles with a diameter of 2 to 10 mm around a hyperechogenic stroma.[4,5]

Transvaginal ultrasound is the most widely used technique for the ultrasound assessment of PCO. The sonographic criteria have been subsequently modified and, therefore, the increase in ovarian volume (>10 cm^3) and the presence of >12 follicles with a diameter of 2 to 9 mm at least in one ovary.[6] Must be excluded from this rule women who use oral contraceptive as it transforms the ovarian morphology in healthy women and probably also in women with PCO.[2]

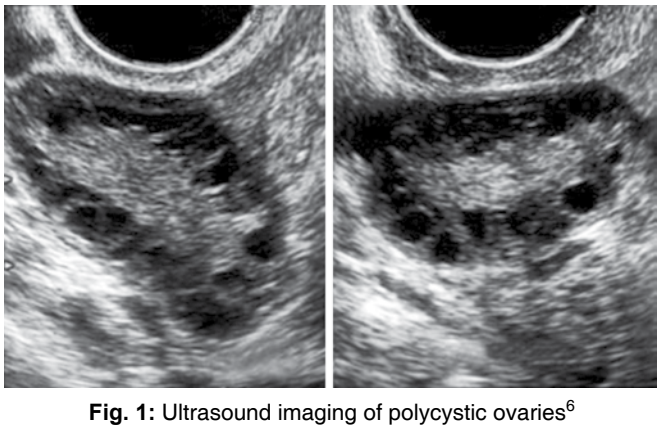

Fig. 1: Ultrasound imaging of polycystic ovaries[6]

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The prevalence of PCO is dependent on the age of the women, 21.6% in women < 35 years of age and in women > 35 years is 7.9%.[7]

The presence of PCO on ultrasound may be an isolated finding in asymptomatic patients, as well as patients with the typical clinical and biochemical manifestations of PCOS who have morphologically normal ovaries. Currently there is little data in the literature regarding ultrasound (US) parameters in women with PCO and PCOS. This is the subject of scientific debate for the interpretation of the pathophysiology of PCOS which is the base for future investigation and research.

The variability of the description of the ultrasound ovarian morphology (number and location of follicles, hyperechoic stroma) is a fact although recent studies regarding the increase of the volume ovarian (>10 cm^3) as the most reliable of ultrasound evaluation of PCOS.[8]

Other authors emphasize the rising importance of ovarian stroma or the relationship between ovarian stroma/total area.[9] Characteristic the increase in vascularity of the ovarian stroma using the echo-Doppler[11,12] which in turn can be related to changes in ovarian steroidogenesis in women with PCOS. It is believed that the vascular endothelial growth factor (VEGF) plays an important role associated with an increased stromal flow in patients with PCOS.[13]

CLINICAL PRESENTATION

Menstrual Irregularities

In most cases, menstrual irregularities in women with PCOS begin at menarche and consist of oligomenorrhea or amenorrhea less frequently. In the fourth decade of life more than 70% of women with PCOS spontaneously reaches the menstrual regularity.[34] The amenorrhea and oligomenorrhea are consequence of the chronic state of anovulation present in these patients. The anovulation in women with PCOS is related to the coexistence of endocrine and paracrine alterations. It has been documented an increased pulse frequency for the luteinizing hormone (LH).[35] The increased pulse frequency of the hypothalamic GnRH promotes the transcription of the beta subunit of LH compared to the beta subunit of follicle-stimulating hormone (FSH).[36] It is not clear whether this increased pulse frequency is due to an abnormality of the intrinsic GnRH pulse generator or caused by low levels of progesterone due to the chronic state of anovulation as the progesterone slows the GnRH pulse generator.[37] Increased concentration of intrafollicular androgens act in a paracrine manner.

The majority of women with this syndrome have oligomenorrhea interspaced with episodes of irregular vaginal bleeding. The cause of such menstrual like bleeding is not always report an occurrence of ovulation but can be caused by a sharp fall in plasma levels of estrogen.

Obesity

It is present in 30 to 60% of PCOS patients with body mass index (BMI) greater than 30. However, even in this case the choice of the cut-off can be discussed and amended on the basis of geographical and socioeconomic considerations. The visceral obesity with the increase in the WHR (waist-hip ratio) corresponding to the waist-hip ratio (normal range, 0.82-0.85) is frequent in obese women with PCOS.[22]

The presence of obesity in women with PCOS determines a deterioration in the clinical picture from both metabolic and reproductive points of view.[23]

Obese women with PCOS compared to normal weight women with PCOS have increased prevalence of glucose intolerance and diabetes mellitus type II,[24] higher prevalence of hirsutism,[25] increased risk of metabolic syndrome and risk of cardiovascular disease[26] as high level of PAI-1 (plasminogen activator inhibitor-1) found in PCOS patients may contribute to increased cardiovascular risk.[27] Obesity increases the prevalence of obstructive sleep apnea in patients with PCOS.[28]

In a recent study, it has been identified a dysregulation of lipolysis in PCOS patients,[29] because an increased lipolysis of visceral fat with a consequent increase of free fatty acids released directly into the portal circulation. The levels of free fatty acids in portal circulation are the major modulators of hepatic gluconeogenesis.[30] This increased lipolysis at the level of visceral fat may be one of the mechanisms for the increased risk of glucose intolerance.[31]

In obese women with PCOS, exercise, a low-calorie diet and the reduction of body fat lead to an improvement of ovarian function with possible restoration of spontaneous ovulation and reduced risk of type 2 diabetes mellitus.[32] Exercise and weight control are certainly to be recommended in view of their strong impact not only on metabolic panel, but also on ovarian function and fertility restoration.[33] If lifestyle measures are unsuccessful, then consider referral to a fertility specialist. Referral should be initiated early for women aged more than 35 years and in couples with additional factors contributing to infertility.

The success for the treatment of obesity requires a multidisciplinary approach involving the dietitian, psychological support and a gynecologist.

Growing evidence that PCOS is a disorder characterized by insulin resistance and hyperinsulinemia.

Insulin resistance is a condition in which a normal concentration of insulin produces attenuated biological effects in cases where the pancreatic function is intact, this involves a compensatory hyperinsulinemia. The presence of insulin

resistance does not imply a systematic glucose intolerance and blood glucose can be normal.

Prospective and retrospective observational studies show that at least 40% of women with PCOS has a glucose intolerance and that in 10 to 20% will develop in middle age (55-65 years) diabetes mellitus type II.[14,15]

Before the development of frank glucose intolerance, the defect in insulin action can remain latent and only in circumstances which increase insulin resistance may arise, for example, the occurrence of gestational diabetes or glucose intolerance in the case of treatment with corticosteroids.

The molecular mechanism responsible for insulin resistance in PCOS appears to be unique and specific to this syndrome and other than that present in obesity. The most likely mechanism would be an altered phosphorylation of the insulin receptor, resulting in a defect in signal transduction.[16]

In women with PCOS ovarian tissue remains sensitive to insulin, although there is a systemic resistance to the action of insulin hormone. Ovarian stimulation seems to involve a system of signal transduction different from that for the transport of glucose, in particular, a different second messenger, probably inositol phosphoglycan.[17,18]

Insulin and IGF-1 (insulin growth factor-1) are important regulators of ovarian function and influence directly and indirectly ovarian steroidogenesis and androgenic status. Insulin acts directly on theca cells by activating the cytochrome P450c17 with activity 17-alpha-hydroxylase and 17,20-lyase (key enzyme in androgen synthesis) and also enhances the synthesis of androgen synergistically induced by the hormone LH.

Insulin also acts indirectly by suppressing the circulating levels of sex hormone binding globulin (SHBG), resulting in increased free testosterone, the bioavailable fraction of the hormone to the tissues.[20]

Finally, insulin can suppress the hepatic synthesis of IGF-binding protein-1 (IGFBP-1), thus increasing the bioavailability of IGF-1, an important regulator of the synthesis of ovarian androgens. It also seems possible that the insulin may act at the level of the hypothalamus by modifying the pulsatile secretion of LH, influencing in this way also ovarian steroidogenesis.[19,20]

Currently, there is no screening test for insulin resistance, while it has been established a criterion for the definition of the metabolic syndrome associated with the syndrome of insulin resistance that includes the visceral obesity, hypertension, fasting hyperglycemia and dyslipidemia (Fig. 2).[21]

Hirsutism

It is a clinical sign of hyperandrogenism. The perception of the presence of hirsutism as a problem depends on cultural and ethnic factors. Commonly used the score Ferriman-Gallwey for clinical assessment and a score greater than 8 is considered diagnostic.[38] The fact remains that an assessment is extremely subjective.

The incidence of hirsutism in Caucasian women is 60 to 70%, while in Japanese women is 30%.[39]

In PCOS patients, moreover, hyperinsulinism contributes to an increase in the secretion of adrenal androgens in part by increasing the sensitivity to the hormone ACTH.[40]

Acne

A sustained polymorphic dermatosis by a chronic inflammation of the hair follicle. The clinical presentation of the acne includes four pathological events: hyperkeratosis of the follicular canal, the sebaceous hypersecretion, bacterial proliferation and inflammation.

Chronic hyperandrogenism causes an increase in sebum secretion thus forming a collection of fat resulting in overlapping bacterial infection.

It is estimated that roughly one-third of PCOS patients have acne,[41] while the majority of women with severe acne have PCOS.[42]

Acanthosis Nigricans

It is a mucocutaneous lesion with areas of hyperpigmentation and dark brown color with skin thickening. It is a cutaneous marker of a heightened insulin-resistance and can be present in up to 5% in women with PCOS.[41]

Infertility

The main cause of infertility in women with PCOS is due to chronic anovulation. However, it was reported a higher

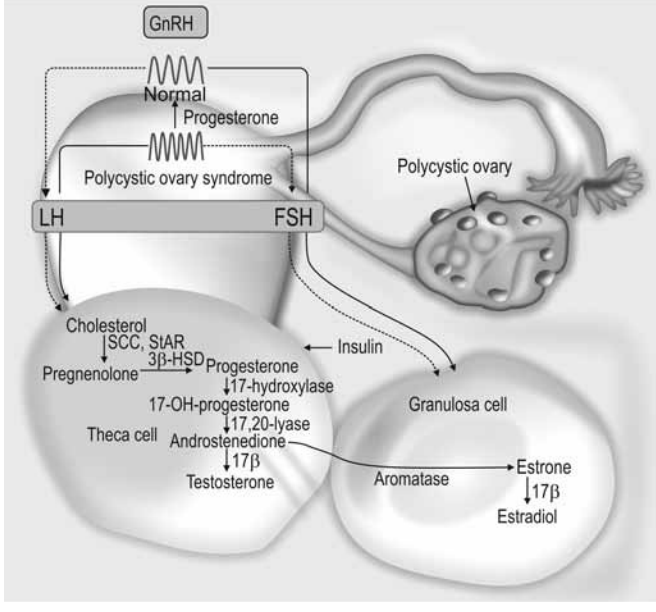

Fig. 2: The hypothalamic-pituitary-ovarian axis and the role of insulin (*Courtesy:* Ehrmann DA. Polycystic ovary syndrome. N Engl J Med 2005;352:1223-1236)

incidence of polycystic appearance of the ovary (PCO) on US in patients with normo-ovulatory but subfertile[43] and repeated pregnancy loss.[44]

The subfertility may be related to the increase in plasma levels of the LH in the follicular phase of the cycle that causes a resumption of the second meiotic division of the oocyte and the premature release of the oocyte.[45]

The mechanism linking PCOS and miscarriage is not yet well known; however, various factors involved in the process of steroidogenesis, folliculogenesis, oocyte maturation and reduced endometrial receptivity contribute to this vicious cycle between PCOS and miscarriage.[46]

The presence of chronic anovulation and high levels of estrogen that persists over the years may lead to an increased risk of endometrial hyperplasia and endometrial cancer.

It is highlighted an increased incidence of endometrial hyperplasia and endometrial cancer in women with PCOS.

In women with PCOS may be present obesity and diabetes mellitus type II, two conditions also associated with increased risk of endometrial cancer.

Therapeutic Implications and Management of Infertility

If pharmacological treatment is required, the best first line treatment is clomiphene citrate, which has a pregnancy rate of 30 to 50% after six ovulatory cycles, although in women with a BMI <30 to 32 kg/m^2, metformin may have a similar efficacy to clomiphene citrate.[3,10]

If clomiphene citrate, metformin or a combination of the two is unsuccessful in achieving pregnancy then gonadotropins are the next pharmacological options.[3]

Laparoscopy with ovarian drilling (LOS) is a suitable second line treatment, if clomiphene citrate with metformin has failed. The pregnancy rate with LOS is as effective as three to six cycles of gonadotropin ovulation induction.[3] If all of the above are unsuccessful or if there are other factors contributing to infertility, such as endometriosis or male factors, *in vitro* fertilization (IVF) or intracytoplasmic sperm injection is recommended.

CONCLUSION

The natural history of polycystic ovary and the role of extraovarian factors, such as obesity, insulin resistance and environmental factors in the phenotypic manifestations of PCOS are the subject of scientific debate.

The sonographic appearance of PCO even if found in isolation requires greater attention in its clinical evaluation.

The evolution of polycystic ovaries toward a phenotype of PCOS is still not well coded. The pathogenesis of PCOS and its natural history are the determining factors for a real assessment of the incidence in patients referred to the infertility clinic.

However, longitudinal studies are needed to clarify the pathophysiology of PCOS and its impact on reproductive health.

The metabolic alterations present in women with PCOS, therefore, require a change in the clinical approach to this syndrome, recognizing that this condition is chronic and with possible long-term consequences.

There are still controversies about the advisability of screening to identify a possible impaired glucose tolerance and insulin resistance in all women with PCOS.

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REVIEW ARTICLE

Comparing Extracorporeal Knots in Laparoscopy using Knot and Loop Securities

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ABSTRACT

Background: Laparoscopic knot tying is a basic surgical skill that has been practiced for centuries having their roots in fishing and sailing.[1-4] The advent of endoscopic surgery placed more challenges on the surgeons and this ever growing skills need to be acquired. Since endoscopic and arthroscopic knots must be delivered over a distance to a tissue with minimal access maintaining tension is more important than the knot configuration chosen.[5,6] The aim of this article review is to determine which hand tied knot configuration and possibly, suture size, and suture type that would be safe in laparoscopic surgery.

Materials and methods: A literature review was performed using PubMed, Springerlink, Highwire press and search engines, like Google and Yahoo. The following search terms were used: extracorporeal knot, arthroscopic knots, Roeder's knot, Meltzer's knot, Mishra's knot, Duncan knot, Nicky's knot, SMC knot, Weston knot and Tennessee extracorporeal knot. A total of 48,100 citations were found. Selected papers were screened for further references. Publications that featured illustrations of sliding knots with statistical methods of analysis were selected. More than 20 different sliding knots were used for this review.

Result: Eighty-one articles were reviewed. Most studies have evaluated knot security only and few studies have evaluated simultaneous both loop and knot security and also only a few compared knot and loop securities to the type of suture materials and their sizes. The addition of three RHAPs improves knot security of all sliding knots tested and improves the loop security of most of the sliding knots tested.

Conclusion: The safety of extracorporeal knot depends on knot configuration, especially when further RHAPs are included.

Keywords: Extracorporeal knot, Tissue approximation, Laparoscopic suturing.

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INTRODUCTION

Since 1978 when endoscopic suturing was first used for hemostasis by Semm in his pelviscopic surgery a lot of interest has been stimulated in endoscopic knotting and suturing.[1] Gastrointestinal intraluminal suturing was not considered a viable technique until 1984, when Buess reported his transanal endoscopic operative procedure for rectal polyps.[2] At the end of the last century, Roeder described a ligating technique that used a catgut ligature loop with a slipknot for tonsillectomies in children. This technique was modified with a pushrod-application system by Semm and used in pelviscopic surgery. It is now commercially available as the 'Endoloop'. Modification of Roeder's knot, to make it more secure are Meltzer's and Mishra's knot.[7] Over the years, there has been the development of several extracorporeal knots. A knot should secure tissue approximation, simple, easy, quick and reliable. Any good knot must fulfil two basic qualities: (1) the knot must be properly formed so the suture does not slip or cut into itself, and (2) it must be easily tightened to ensure maximum strength. For a knot to be effective, it must possess the attributes of both knot security and loop security.[8,9] Knot security is defined as the effectiveness of the knot at resisting slippage when load is applied and depends on three factors: friction, internal interference, and slack between throws. Loop security is the ability to maintain a tight suture loop as a knot is tied.[8-11] Thus, any tied knot can have good knot security but poor loop security (a loose suture loop), and therefore be ineffective in approximating the tissue edges to be repaired.

MATERIALS AND METHODS

A literature review was performed using PubMed, Springerlink, Highwire press, and search engines, like Google and Yahoo. The following search terms were used: extracorporeal knot, arthroscopic knots, Roeder's knot, Meltzer's knot, Mishra's knot, Duncan knot, Nicky's knot, SMC knot, Weston knot and Tennessee extracorporeal knot. A total of 48,100 citations were found. Selected papers were screened for further references. Publications that featured illustrations of sliding knots with statistical methods of analysis were selected. More than 20 different sliding knots were used for this review (Table 1).

Table 1: Different sliding knots in this review

Two half-hitches[7,8]
Reversed half-hitches[7,8,12]
Practical knot (simple version)[11-13]
Practical knot (advanced version)[11-13]
Nicky's knot or taut-line hitch[7-14]
Giant knot[15]
Modified taut-line hitch[15,16]
Tennessee slider[13]
Clinch knot[14]
Roeder's knot[7,16-18]
Secure knot[17]
Meltzer's knot[7,8,15,16]
Mishra's knot[7,8,16]
Duncan loop, blood slipknot, Hangman's knot, easy loop[17,18]
Weston knot[18,19]
SMC knot[15]
Tayside knot[19]
Hangman's knot[18,20-22]
Hangman's tie[20-22]

DEFINITIONS

Post limb: The straight portion of the suture limb purely defined as the suture limb under the most tension.

Wrapping limb: The free portion of the suture limb that wraps around the post limb.

Effective knot: Possesses the attributes of both knot security and loop security.

Knot security: The effectiveness of a knot to resist slippage when load is applied.

Loop security: The ability of a knot to maintain a tight suture loop as a knot is tied.[7,17,22]

COMMONLY USED COMPOUND SLIDING KNOTS

Compound sliding knots have more than one turn of the wrapping limb around the post (i.e. any sliding knot other than a half hitch). They can be used in situations where the suture slides smoothly and freely through the tissue and anchoring device. They are advantageous since compound sliding knots can be made to slide down the post limb without unraveling or jamming prematurely. Theoretical disadvantages include abrasion of suture against the anchor eyelet, suture cutting through tissue as it slides.[3,5,11,13] Mishra's knot is one important extracorporeal knot that combines the loop and knot securities of many other extracorporeal knot that is fast gaining wide acceptance by many laparoscopic surgeons. The steps in tying Mishra's knot is highlighted in Figures 1A to I.

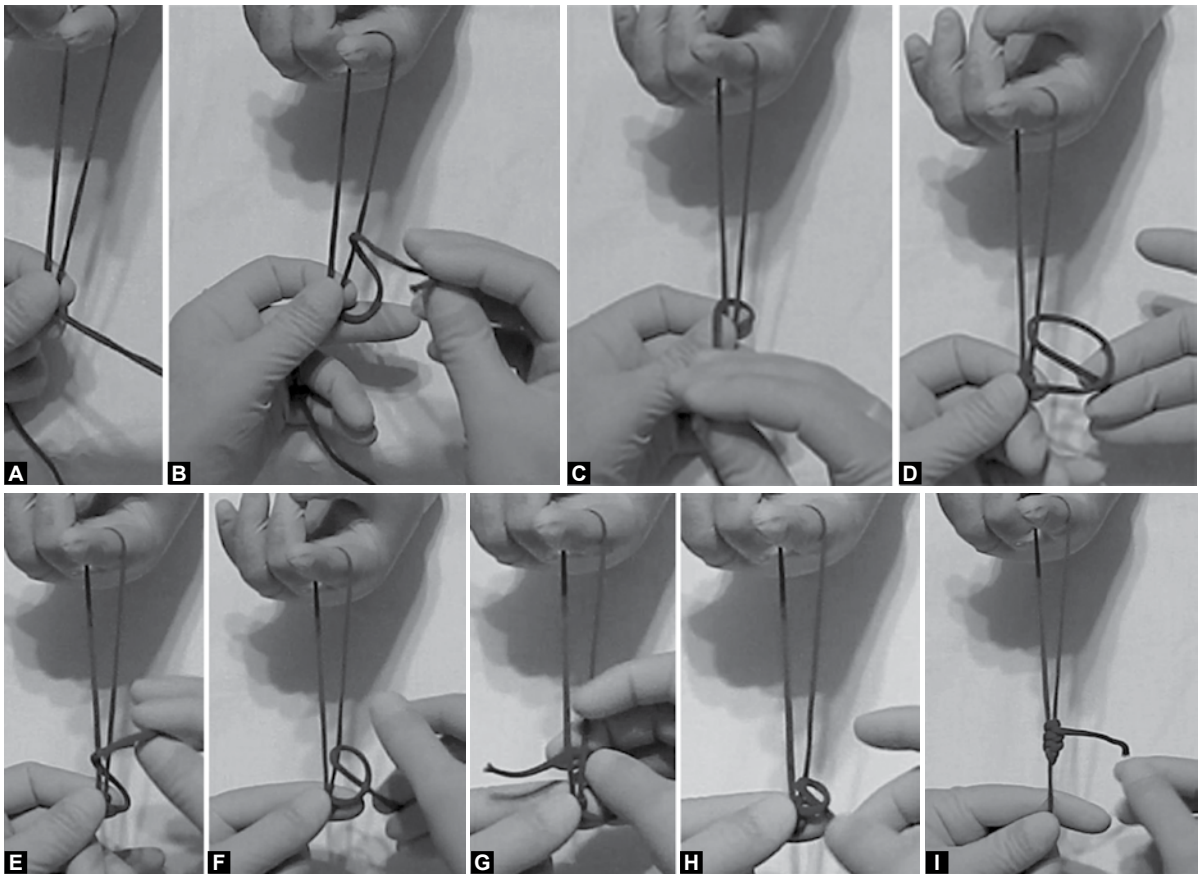
RESULTS

Using a servohydraulic materials testing system (MTS model 858, Bionix, Eden Prairie, MN) to test the knot and loop security of each combination of the knots and suture types (ethibond and fiberwire) and using 5N preload and critical loop circumference of 30 mm, it was found that in all cases, no knots failed by suture breakage, suggesting that all knots failed by a combination of knot slippage and suture elongation. When tied with no. 2 ethibond suture or no. 2 fiberwire suture, the Weston knot provided the highest load to failure when compared with the other sliding knots. However, the maximum force of the surgeon's knot was significantly higher than the Weston knot when tied with either ethibond or fiberwire suture.

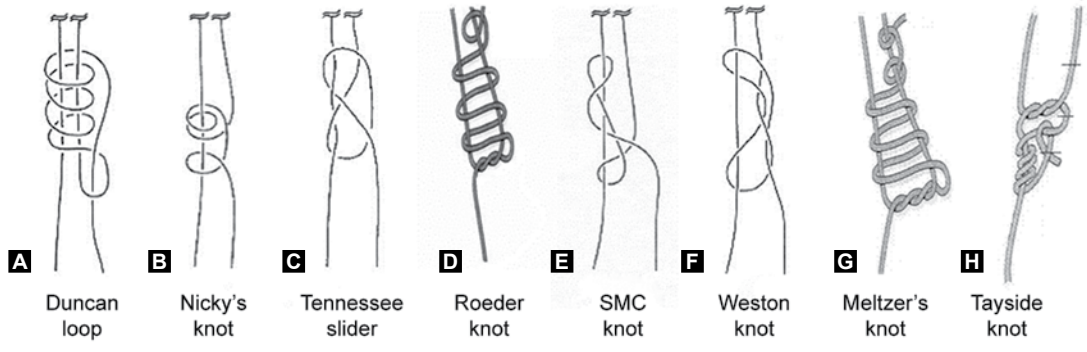
When the sliding knots were tied with three reversing half-hitches on alternating posts (RHAPs) using no. 2 ethibond suture, the Weston RHAP, Roeder RHAP, Mishra RHAP, and SMC RHAP provided the highest force to failure. These forces were not significantly different from the force to failure of the surgeon's knot tied with no. 2 ethibond suture.

When the sliding knots were tied with three RHAPs using no. 2 fiberwire suture, the Weston RHAP provided the highest force to failure. This force was not significantly different from the force to failure of the surgeon's knot. In all cases, tying with either no. 2 ethibond or no. 2 fiberwire suture, the addition of 3 RHAPs after a base sliding knot significantly improved the force to failure. Of the sliding knots tied with no. 2 ethibond suture, the Duncan loop, Roeder knot, Weston knot, Mishra knot and Tennessee slider all provided similar loop circumferences at 5N of preload, although the loop circumferences associated with these knots were significantly larger than the loop circumference of the surgeon's knot. When tied with no. 2 ethibond suture, the Roeder RHAP, Mishra RHAP, Duncan RHAP and Nicky's RHAP provided the smallest loop circumferences and were not significantly different from the surgeon's knot. Similarly, when tied with no. 2 fiberwire, the Roeder RHAP, Mishra RHAP, Duncan RHAP and Nicky's RHAP provided the smallest loop circumferences and were not significantly different from the surgeon's knot.

Does securing a sliding knot with three RHAPs decrease the loop circumference (improve loop security)? With knots tied with no. 2 ethibond suture, the addition of three RHAPs decreased the loop circumference of the Nicky's knot, Mishra knot, Roeder knot, the SMC knot and the Tennessee slider. No significant difference was found in the Duncan loop or the Weston knot when tied with or without three RHAPs. When tying knots with no. 2 fiberwire, the addition of three RHAPs decreased the loop circumference of the Nicky's knot, the Mishra knot and the Roeder knot. No significant



Figs 1A to I: Steps in tying Mishra's knot: (A) Place the short limb of the suture over the long limb, (B) take the first hinge, (C) take a wind, (D) make a half knot, (E) make the 2nd wind, (F) again make the 2nd half knot, (G) then make 3rd wind, (H) and make the 3rd and final half knot and (I) the final configuration of Mishra's knot



Figs 2A to H: Other common extracorporeal knots

difference was found in the other knot configurations when tied with no. 2 fiberwire.

Which knots provide the best balance of knot security and loop security? When evaluating all the knots, the knot that provided the best knot security and loop security in all cases, whether tying with no. 2 ethibond or no. 2 fiberwire, was the surgeon's knot. However, if one wishes to tie a sliding rather than a static knot, then the other knots must be considered (Table 2). When evaluating the sliding knots (Figs 2A to H) without RHAPs tied with no. 2 ethibond, the Weston knot provided the best knot security, and the Duncan loop, Roeder knot, and Weston knot provided comparable loop security. However, despite being the four best knots of the group, the Duncan loop, Mishra knot, Roeder knot, and Weston knot, had such poor loop security (all loop circumferences 32.5 mm), that none of these knots are recommended to be tied without RHAPs. With either no. 2 fiberwire or no. 2 ethibond, the Roeder knot and Mishra knot tied with three RHAPs provide the best balance of loop and knot security of all the sliding knots tested.

DISCUSSION

Despite the great usefulness of laparoscopy for the treatment of surgical and gynecological diseases suture tying in the

Table 2: Knot configurations providing optimal knot security and loop security in sliding knots tied with and without reversing half-hitches on alternating posts (RHAPs) using no. 2 ethibond or no. 2 fiberwire

Knot type	*Suture type*	*Best loop security*	*Best knot security*	*Recommendation*
Sliding knot (WR)	Ethibond	Duncan, Mishra, Roeder, Weston	Weston	None
Sliding knot (WR)	Fiberwire	Duncan	Weston	None
Sliding knot (R)	Ethibond	Roeder (R), Duncan (R), Nicky (R)	Weston (R), Roeder (R), SMC (R), Mishra (R)	Roeder (R), Mishra (R)
Sliding knot (R)	Fiberwire	Roeder (R), Duncan (R), Nicky (R), Mishra (R)	Weston (R), Mishra (R) Roeder (R)	Mishra (R), Roeder (R)

R: RHAPs; WR: Without RHAPs

cavity remains a great challenge. A knot to secure tissue approximation, which would be hand-made, secure, simple, easy, quick, reliable and extracorporeal without extra mechanical devices constitute the essence of surgical practice because an unreliable suture knot can spoil the outcomes of an otherwise beautifully performed surgical procedure.[17] Optimization of both knot security and loop security[3,11,22,23] for any given knot is critical, and recommendations regarding a specific knot should not be made without taking both characteristics under consideration.

Most of the studies showed that the loop security of almost all sliding knots tied without RHAPs was poor, hence RHAPs improve both the knot and loop securities.[11] It is believed that this increased knot security occurs because the wrapping limbs tighten (removal of slack) around the post until the internal interference and friction are high enough to resist the applied load.[20-22] Also, locking the knot by tensioning the wrapping limb and 'flipping' the knot also provided another potential mechanism of enlargement of the suture loop.[12] Although this locking mechanism is particularly useful in preventing the knot from sliding back, locking the knot also causes expansion of the suture loop.[7] This effect was seen in almost every knot that required a flipping maneuver to be locked. There has been previous classification of sliding knots as either lockable or nonlockable, with lockable knots further divided into proximal locking and distal-locking knot.[5,13,16] In lockable sliding knots, tensioning the wrapping limb distorts the post limb, resulting in a kink in the post, thereby increasing the internal interference that increases the resistance of the knot from backing off. Clinically, after properly seating the knot at the repair site, the wrapping limb is tensioned, flipping the knot and preventing the knot from backing off. This locking effect is also known as the 'one-way ratchet effect' or the 'self-locking effect'[16]

Locking knots have previously been divided into proximal-locking and distal-locking knots (as referenced relative to the surgeon) according to where the wrapping limb deforms the post limb when it is tensioned.[15,16] That is, a proximal-locking knot deforms in the portion of the knot that is closest to the surgeon, whereas a distal-locking knot deforms in the part of the knot that is furthest away from the surgeon. Proximal-locking knots include the Nicky's knot, and distal-locking knots include the Weston knot and Roeder knot. With the development of other knot configurations (the SMC knot), we propose that a third group be added, the middle-locking knot. In these knots, the wrapping limb emerges from the central part of the knot and include the SMC knot and the Tennessee slider. Mishra's knot appears to combines the characteristics of the three categories.[7]

CONCLUSION

A static surgeon's knot provides the best balance of loop security and knot security within the knot configurations tested. A sliding knot without RHAPs has both poor loop security and knot security and should not be tied. The addition of three RHAPs improves knot security of all sliding knots tested and improves loop security of most of the sliding knots tested. The addition of three RHAPs improved the knot security of all sliding knots to adequately resist predicted *in vivo* loads.

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REVIEW ARTICLE

CO_2-Pneumoperitoneum in Laparoscopic Surgery: Pathophysiologic Effects and Clinical Significance

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ABSTRACT

Background: Knowledge of the pathophysiological basis of laparoscopic procedures, in particular the impact of CO_2-pneumoperitoneum (PNP) on the body, can prevent onset of complications during laparoscopy.

Design and Methods: Standard intra-abdominal pressure (IAP), which is used during laparoscopic surgery, is 12 to 15 mm Hg. The direct effect of CO_2-pneumoperitoneum is a consequence of the mechanical action of the gas, and increased intra-abdominal pressure. The indirect effect of CO_2-pneumoperitoneum caused by the absorption of gas from the abdomen. Analysis of articles that evaluated the effects of CO_2-pneumoperitoneum on the body and intra-abdominal organs contributes to an even better use of the laparoscopic method.

Results: The results of numerous experimental and clinical studies have confirmed that increased IAP and CO_2-pneumoperitoneum intraoperatively causing reduction the portal venous blood flow, increasing venous stasis, reduced glomerular filtration, reduced Tiffeneau-index and pulmonary compliance what it can lead to hemodynamic and cardiac disorders. Consecutive intraoperative acidosis and hipercarbia impact the function of intra-abdominal organs and heart.

Conclusion: To avoid the side effects of CO_2-pneumoperitoneum, which is important in patients with ASA II and more often as necessary to be operate with low pressure (IAP: 6-8 mm Hg) or use gasless laparoscopy.

Keywords: Laparoscopic surgery, CO_2-pneumoperitoneum, Hepatic, Renal, Pulmonary and cardial changes, Venous stasis.

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INTRODUCTION

The pneumoperitoneum (PNP) is the crucial element in laparoscopic surgery. The surgeons performing laparoscopy should understand the basic physiologic changes occurring during PNP, recognize the clinical changes and make appropriate intraoperative adjustments to minimize the adverse changes.

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Controlled intra-abdominal pressure (IAP) within the abdominal cavity is tasked to facilitate smooth operation of the surgeon, raising the anterior abdominal wall up and suppressing the other abdominal organs and soft tissues of the back. Georg Kelling's first 1901th described technique of establishing PNP and first did a review of the method of the abdomen, which was then named after him celioscopy, now known as laparoskopy.[1,2] It is believed that Zollikofer, in 1924, first described the use of CO_2 for establishing PNP. Pneumoperitoneum with CO_2 has been used in clinical practice, since the introduction of laparoscopic cholecystectomy in the late 1980s.

Carbon dioxide is the most suitable gas for insufflation into the abdominal cavity, because it meets several important criteria: not flammable and it is possible to use electrocoagulation, very soluble in blood and tissues, it is easily eliminated through the lungs, is nontoxic and it is inexpensive.[3,4]

PHYSIOLOGIC EFFECTS OF CO_2-PNEUMOPERITONEUM

Physiological changes that occur in the body during laparoscopy are the result of different influences. First of all, present the effects of increased IAP on the body, the effects of the gas absorption, and should not be neglected surgical trauma caused by the surgery itself.[3,4] To a certain gas was used to establish PNP in laparoscopy must have certain qualities and meet certain criteria (Table 1).

CO_2 as an inert gas, which is found in the body and is very cheap, most are in use and more convenient than nitrous oxide.[5,6] Diffusion and decomposition of gas through the organism does not pose a risk to the patient or risk of embolism, since that its elimination from the body via the

Table 1: Features of ideal gas for insufflation in laparoscopy

- Antiknock
- Fireproof
- Limited ability resorption
- Limited physiological effects on the body after absorption
- Rapid excretion from the body after absorption
- Does not support the occurrence of burns
- Limited physiological effects in the case of intravascular embolization
- Very soluble in blood
- Colorless

Table 2: Comparison of gases used for PNP during laparoscopy

Gas	*Solubility/diffusion*	*Risk*		*Biological effects*
		Burns	*Gas embolism*	
CO_2	+ + +	Yes	Very low	Many
He	– – –	No	Very low	Inert
N_2O	+ +	Yes	Low	Anesthesia
Air	O_2: –	Yes	High	Oxidation
	N_2: +	No	High	Inert

lungs physiological. Using electrocoagulation is allowed since CO_2 is nonflammable. Sometimes, at longer laparoscopic procedures, carbon dioxide may lead to peritoneal irritation and postoperative pain. After being absorbed from the stomach sometimes leads to laparoscopic acidosis with the possibility of cardiac arrhythmias.[3-5]

Some surgeons for short laparoscopic procedures using nitrous oxide (N_2O), which does not lead to peritoneal irritation with resorption and does not lead to acidosis. It should be noted that more nitrous oxide is not soluble in the blood and, in theory, it is very risky in terms of the possibility of gas embolism. The use of electrocautery during N_2O-pneumoperitoneum is associated with the possibility of occurrence of burns because the gas is flammable.[6] The use of other gases, such as helium, argon, xenon and krypton was not entered into routine use in laparoscopy, because they are very expensive, although they are suitable for insufflation because of its properties.[7-9] Comparison of gases used for PNP during laparoscopy are shown in Table 2.

Physiological changes that occur in the body during laparoscopy are the result of different influences. Transient physiologic abnormalities in the body that may result in CO_2-pneumoperitoneum during laparoscopic procedures are shown in Table 3.

Intraoperative Acid-base Balance Changes

Carbon dioxide is currently the most commonly used gas for creating PNP. Significant elevation in serum levels of CO_2 (pCO_2) or end tidal CO_2 levels along with a concomitant fall in serum pH levels, have been observed during CO_2-pneumoperitoneum.[3,4,10] The effects of CO_2-pneumoperitoneum on acid-base balance are shown in Table 4.

Pneumoperitoneum can result in systemic absorption of CO_2 and alteration of acid-base balance. Hypercarbia is primarily due to transperitoneal absorption of intraperitoneal CO_2. In patients with severe cardiac or pulmonary disease has been associated with the development of more profound hypercarbia and acidemia during carboperitoneum that would be otherwise be seen in patients with normal cardiopulmonary function.[10] With respect of changes in oxygenation, the effect of PNP appears to be small and clinically unimportant. Hasukić et al[11] found no significant difference between the two group patients laparoscopic cholecystectomy *vs* open cholecystectomy (LC *vs* OC) in $PaCO_2$ and pH undergoing LC and OC 24 hours after operation (Table 5).

Pulmonary Changes

Physiologically, when the act breaths due to increased IAP, there is shifting abdominal wall forward. The muscles involved in this process are primarily the diaphragm, intercostal muscles and sternocostal, assisted and pectoral muscles. Expiratory flow is a passive process, with the exception of lung obstruction, when in the process include the expiratory abdominal muscles, and when this process becomes active.[12] Pains in the laparotomy wound and prevent these excursions too passive expiration converted to active process.[11-13] Changes in lung function during laparoscopy caused by PNP are shown in Table 6.

The underlying cause of respiratory function changes in the lung is able to reduce respiratory movements of the diaphragm resulting in decreased respiratory lung expansion. Reduce lung compliance caused a reduction in total lung capacity, functional residual capacity and residual volume[11,13-15] reduced vital capacity (VC), functional residual capacity (FRC) and forced expiratory volume in the first second (FEV1) are well documented.[10,13,15,16]

Intra-abdominal pressure value of 15 mm Hg reduces respiratory compliance by 50%.[16] Absorption of CO_2 leads

Table 3: Physiologic effects of PNP during laparoscopy

- Intraoperative acid-base balance changes
- Pulmonary changes
- Cardiovascular and hemodynamic changes
- Hepatic function changes in intraoperative portal venous flow
- Venous stasis
- Changes in intracranial pressure

Table 4: The effects of CO_2-pneumoperitoneum on acid-base balance

Function	*Status*
Arterial blood gas	
$PaCO_2$	↑
PaO_2	Unchanged
Bicarbonate	↓
Base excess	↓
pH	Unchanged/↓

Table 5: Mean (SD) values for blood gas measurements and pH preoperatively and 24 hours after laparoscopic and open cholecystectomy[11] (LC and OC)

	Preoperative		*24 hours after operation*	
	Laparoscopic (N = 30)	*Open (N = 28)*	*Laparoscopic (N = 30)*	*Open (N = 28)*
$PaCO_2$ (kPa)	4.3 (0.8)[a]	5.0 (0.5)	4.6 (1.1)[b]	5.4 (0.6)[b]
PaO_2 (kPa)	13.1 (4.5)	11.1 (0.8)	11.9 (3.5)[b]	10.4 (0.9)[b]
pH	7.4 (0.05)	7.4 (0.03)	7.4 (0.03)[b]	7.4 (0.02)[b]

[a]Values are mean (SD); [b]Not significant

Table 6: Pulmonary changes during laparoscopy

Function	*Status*
Respiratory mechanics	
Peak inspiratory pressure (PIP)	↑
Respiratory compliance	↓
Ventilatory changes	
Respiratory rate	↑
Tidal volume	↓
Minute ventilation (MV)	↑
Tiffeneau-index	↓

to hypercapnia, which along with hypoxemia may lead to transient acidose.[15-17] Position the patient on the operating table can also affect the respiratory disturbances during laparoscopy.[16,17] These changes were more pronounced in patients with cardiac and pulmonary diseases.

Diaphragm contractility reduce hypoxemia, acidosis, neuromuscular disease, malnutrition or surgery in the upper abdomen. Disturbances that have arisen directly affect the exchange of gases and which is becoming limited as it manifests itself through various ventilatory disorders.[11,12,17] In laparoscopic procedures, the intensity changes of respiratory function is less, recovery and normalization of spirometry significantly faster. Problems that might occur due to PNP, CO_2 absorption, and the occurrence of intraoperative hypercapnia and acidosis, quickly solve the need for cessation of gas.

Postoperative pulmonary ventilation disorders have a restrictive character.[11,14-17] The Tiffeneau index, the ratio between forced expiratory volume in 1 second (FEV1) and forced vital capacity (FVC) help to differentiate airflow limitations from restrictive abnormalities.[11,14-16] A meta-analysis of the literature was carried out, concerning the postoperative pulmonary function in both surgical techniques, focused on the Tiffeneau index. Hasukić et al[11] found a significant decrease in FEV1 and FVC on postoperative day 1 in both the LC and OC groups, but the decline was more important in the former group. In the current study, a significant decrease (15.5%) in $FEF_{25-75\%}$, as compared with preoperative values, was observed only on postoperative day 2 in the patients who underwent open surgery (Table 7).

Crema et al[18] found that esophagogastric surgery causes a transitory decrease in pulmonary function, and that this reduction is less pronounced in laparoscopic surgery than in open surgery. Damiani et al[19] in their meta-analysis of the Tiffeneau index in patients undergoing laparoscopic and open cholecystectomy suggests that the laparoscopic compared with the laparotomic technique can reduce airflow limitations and avoid postoperative pulmonary restriction. Laparoscopic cholecystectomy is associated with a significantly shorter hospital stay and a quicker convalescence compared with the classical OC.[20]

Cardiovascular and Hemodynamic Changes

Effects of increased IAP on the heart and major blood vessels, and hemodynamic disturbances which may occur, are generally well-tested. Patients during laparoscopy occur following physiological changes: decreased venous flow to the heart, increase in systemic vascular resistance is and increase in intrathoracic pressure.[3,4,12,16,20] Cardiovascular and hemodynamic changes caused by PNP are shown in Table 8.

Intra-abdominal pressure support splanchnic vasoconstriction and reduction in blood flow through the inferior cava vein, renal and portal vein, and all results in decreased venous flow to the heart.[3,4,10,16,26,27] An increase in systemic vascular resistance (SVR) is a consequence of activation neurohumoral vasoactive systems, which include: sympathetic activity, secretion of antidiuretic hormone (ADH) and the renin-angiotensin-aldosterone system (RAAS).[21-23] With increasing IAP, an increase of central venous pressure (CVP). PNP with moderately elevated IAP causes an increase in intrathoracic pressure, thus increasing the

Table 7: Mean (SD) values for pulmonary function tests preoperatively and 24 hours after laparoscopic and open cholecystectomy[11]

	Preoperative		*24 hours after operation*	
	Laparoscopic (N = 30)	*Open (N = 28)*	*Laparoscopic (N = 30)*	*Open (N = 28)*
FVC	3.5 (0.9)[a]	3.6 (0.8)	2.9 (1.0)[1]	2.4 (0.6)[2]
FEV_1	3.1 (0.7)	2.9 (0.6)	2.3 (0.8)[3]	1.4 (0.7)[4]
$FEF_{25-75\%}$	1.9 (0.9)	1.8 (0.4)	1.6 (0.7)[b]	1.4 (0.5)

FVC: Forced vital capacity; FEV1: Forced expiratory volume in 1 second; $FEF_{25-75\%}$: Aid expiratory phase of forced expiratory flow; [a]Values are mean (SD); [b]Not significant; 1 *vs* 2, $p < 0.01$; 3 *vs* 4, $p < 0.0001$

CVP.[24,25] Significantly greater increase in IAP squeeze blood from intra-abdominal organs in the venous reservoir. In these situations, an increase CVP does not reflect the real situation of effective blood volume.[21] Increased IAP leads to an increase in pulmonary vascular resistance to 65% of its normal value.[4,10,21]

The organism can occur and significant hemodynamic changes: increase heart rate, increase blood pressure and systemic vascular resistance[4,12] with increasing IAP, an increase in mean arterial pressure. Increase in systemic arterial pressure leads to an increase in intracranial pressure.

Hemodynamic stress response to the CO_2-pneumoperitoneum leads to increased O_2 consumption at the level of the heart muscle, which is very harmful for patients with heart disease. Effect of CO_2-pneumoperitoneum on cardiac output is reflected in the increase of the same or unchanged. In patients with hypovolemia venous flow to the heart is even smaller. Sufficient crystalloid volume replacement may improve venous flow to the heart and reduce the hemodynamic changes.[4,10,21] The insufflation of gas into the peritoneal cavity can provoke arrhythmias. Their incidence is as high as 14 to 27% of laparoscopies which is higher than in 'open' surgery.[28]

The increase in plasma renin activator in the blood plays an important role in the regulation of blood flow in the body during laparoscopy. Antidiuretic hormone (ADH) controls blood pressure through the receptors in the wall of blood vessels and plays a key role in the regulation of blood flow in the body during laparoscopy.[4,16,21,28]

Hepatic Function and Changes in Intraoperative Portal Venous Flow

An IAP of 15 mm Hg used in laparoscopic surgery is higher than the normal portal blood pressure (7-10 mm Hg). This PNP could therefore reduce portal flow and cause alteration in liver function. In healthy patients, increased IAP of 10 mm Hg at l5 mm Hg leads to a significant reduction in blood flow through various abdominal organs: the stomach by 54%, jejunum by 32%, in the colon for 4%, in the liver by 39%, peritoneum by 60 and 11% for duodenum. Splanchnic ischemia time was identical duration increased IAP.[27,29] The reduction of blood flow in the mesenteric blood vessels can occasionally lead to mesenteric ischemia.[27]

During the PNP of 12 mm Hg in dogs demonstrated a lower blood flow through the liver, the superior mesenteric artery and portal vein, 24% of preoperative values.[27] Reduction of intra-abdominal organ perfusion can be viewed as transitory effects of increased pre sure in the abdomen, which operates in three places: the liver and portal vein, splanchnic region and kidneys (Table 9).

Hepatic perfusion is characterized by a unique autoregulatory mechanism known as the 'hepatic arterial buffer response' (HABR), which indicates the relationship between the flow through the portal vein and hepatic artery. Reduced flow through the portal vein leading to reduced flow resistance through the hepatic artery, which thereby increases the allocation of liver blood and *vice versa*. It is proved that this mechanism automatically regulates blood flow through the liver is sufficient for normal IAP.[30]

In animal and human studies, the increased IAP at 15 mm Hg has been shown to reduce portal venous flow.[31] In an experimental study with rats, Richter et al[32] documented that during an IAP of 12 to 15 mm Hg, the rats experienced a loss of physiologic hepatic blood flow control (HABR). High-pressure PNP and its consequent intra-abdominal hypertension-induced hepatic ischemia appear to be the cause. These changes are clinically silent in patients with normal liver function. However, in patients with pre-existing liver dysfunction, these changes may be associated with a significant clinical course.[33-35]

In a clinical study of LC, Jakimowicz et al[36] reported a 53% reduction in portal blood flow with abdominal insufflation to 14 mm Hg. A reduction in portal venous blood flow during PNP may lead to hepatic hypoperfusion and acute hepatocyte injury. Hepatic hypoperfusion can lead to transient elevation of liver enzymes. Hasukic et al[35] reported transient increases in the level of hepatic transaminases

Table 8: Effects of PNP on cardiovascular and hemodynamic changes

Function	*Status*
Hemodynamics	
Heart rate	↑
Mean arterial pressure	↑
Cardiac function	
Cardiac output	Unchanged/↓
Stroke volume	↓
Systemic vascular resistance	↑
Filling pressures	
Mean pulmonary artery pressure	↑
Pulmonary artery wedge pressure	Unchanged
Central venous pressure	↑

Table 9: Hepatoportal and splanchnic changes during laparoscopic surgery

Function	*Status*
Intraoperative changes	
Portal venous flow	↓
Splanchnic flow	↓
Postoperative liver enzymes	
Aspartate aminotransferase (ASAT)	↑
Alanine aminotransferase (ALAT)	↑
Alkaline phosphatase (ALP)	Unchanged
Gamma-glutamyl transpeptidase (GGT)	Unchanged

(ALAT and ASAT) after LC, which returned to baseline by 48 hours postoperatively after comparison of postoperative hepatic function between LC and OC. Hasukić showed a worsening of the postoperative liver function tests (LFTs) when they compared high- and low-pressure PNP (14 *vs* 7 mm Hg) (Table 10).[37]

Many other studies have also confirmed the transient disturbances in liver enzymes after LC. Elevation of hepatic transaminases (ALAT and ASAT) occurred after LC but were transient and clinically silent in patients with normal liver function.[38-40] Laparoscopic cholecystectomy performed under a low pressure PNP or gasless LC using abdominal wall retractors might be feasible in patients with hepatic disfunction or cirrhosis.[41-43]

Application of laparoscopic procedures in the lower abdomen, such as laparoscopic colon resection does not lead to an increase in aminotransferase. This suggests that increased IAP due to a PNP, although important, is not the only cause of reduced blood flow through the liver during laparoscopic procedures. Location, type and extent of surgical organ manipulation represent an additional factor that locally in the tissues lead to certain disorders.[33] In their study, Ahmad[43] suggests that mild-to-moderate elevation in preoperative LFTs may not be associated with any deleterious effect, and, in the absence of clinical indications, routine preoperative or postoperative liver function testing is unnecessary.

Changes in Renal Function

Renal function during laparoscopy characterized by increased vascular resistance, with a secreted vasopressin and reduced 'cardiac output', leading to a reduction in renal blood flow and reduced glomerular filtration. The increase in plasma renin activator in the blood plays an important role in the regulation of blood flow in the body during laparoscopic surgery.[44] The increased IAP during laparoscopy has been shown to alter renal function (Table 11).

A reduction in intraoperative urine output has been well documented during laparoscopic operations.[44-46] The mechanism for oliguria is related to the acute increased IAP.[23] In contrast to these studies, Micali et al[46] compared 31 patients who underwent laparoscopic procedures with 28 similar patients treated by the open method. They found no difference in urinary N-acetyl-beta-(D)glucosaminidase levels in the urine and concluded that no significant renal tubular injury occurs during PNP.

Although this decrease in renal blood flow is well documented, it is unclear whether this is of any clinical significance. It is likely that these changes in renal blood flow are not significant in healthy patients under most normal conditions, but may be important in cases wherein renal blood flow is already compromised. Although the data demonstrate that renal function is decreased during PNP, the clinical significance of this phenomenon is not certain because it appears that renal function returns to normal after PNP is released.[34,45,46]

Venous Stasis during Laparoscopic Surgery

The true incidence of deep venous thrombosis after laparoscopic compared with open operation is unknown; however, some of the factors relating to Virchow's triad (endothelial injury, hypercoagulability and venous stasis) are altered during laparoscopy. The main factor that is adversely affected during laparoscopy is venous stasis. The increased IAP and reverse Trendelenburg position during laparoscopy have been shown to reduce femoral venous flow.[47,48] Nguyen et al[49] reported that increased IAP and reverse Trendelenburg positioning are independent factors that resulted in decreased femoral peak systolic velocity.

Many studies evaluating D-dimer during PNP and postoperative. D-dimer values were significantly higher in the examinees who underwent LC than in those operated by the classical method. In every subsequent measurement those values increased, particularly seen in the laparoscopic group of patients in the measurements taken after the 5th day postsurgery. The increase in D-dimer values in the LCH patients was far more expressed after the operation in the period after

Table 10: Doubling of alanine aminotransferase (ALAT) and aspartate aminotransferase (ASAT) from preoperative values 48 hours after operation in low- and high-pressure laparoscopic cholecystectomy (LC)[35,37]

Liver function tests		*Doubling values 48 hours after surgery*		*p-value**
		Patients	*%*	
ALAT				
	SPLC (N = 25)	11	44	0.0029[a]
	LPLC (N = 25)	2	4	0.0001[b]
	OC (N = 50)	5	10	0.0069[a]
ASAT				
	SPLC (N = 25)	8	32	0.0069[a]
	LPLC (N = 25)	0	0	
	OC (N = 50)	6	12	0.0004[b]

*Chi-square test; LPLC: Low-pressure laparoscopic cholecystectomy; SPLC: Standard-pressure laparoscopic cholecystectomy; OC: Open cholecystectomy; [a]SPLC *vs* LPLC; [b]LC *vs* OC

the 5th day, when there was no prophylaxis, while in the course of and 24 hours after the operation, during the period of active prevention, this increase was insignificant.[50,51]

Increased IAP, and with the presence of reverse Trendelenburg's position (head up) patient who is present in the majority of laparoscopic procedures increases venous stasis in the lower extremities and reduces the return of blood from the lower extremities for more than 40%. Potential risk of deep vein thrombosis is present in these patients.[47]

The negative effects of venous stasis in the lower extremities during laparoscopic procedures are given suppress the use of lower limb compression elastic bandages and giving prophylactic low-molecular heparin.[51] Millard et al[52] and Schwenk et al[53] reported that the use of sequential compre-ssion devices (SCD) during LC was effective in reversing the reduced femoral systolic velocity to baseline values. Effects of low-pressure or gasless laparoscopy on thromboembolic complications during laparoscopy are not well tested but expect the positive effects of these methods for the prevention of thromboembolism during laparoscopy.

Intracranial Pressure during PNP

During laparoscopic procedures, increased IAP leads to increased intracranial pressure (ICP), disrupts the flow of blood through the intracranial blood vessels and leads to abnormal resorption of cerebrospinal fluid. Increased ICP is quickly returning to normal after a gas leak from the abdomen. It was not proven that there are specific clinical consequences of increased ICP during laparoscopy.[54] Pathophysiological studies suggest that the increase in IAP leads to abnormal venous drainage of the lumbar venous plexus, which has a direct impact on reducing the absorption of cerebrospinal fluid during insufflation gas into the abdomen. Consequently, hypothetically possible that increased IAP directly leads to an increase in ICP which results in systemic pressure increase caused by the action of CNS. However, the exact pathophysiology of increased ICP during PNP remains unknown so far.[55] Experimental and clinical studies have established that the hemodynamic changes in the body during the PNP's followed directly by increasing ICP. Consequently, patients with intracranial injury or increased ICP due to other reasons, are not suitable for intra-abdominal laparoscopic procedures.[56] If needed laparoscopic treatment for these patients is a necessary quality monitoring, with the ability to use gasless laparoscopy, an operation with low pressure (6-8 mm Hg).[57] Using CO_2-pneumoperitoneum during laparoscopy may lead to hipercarbia and acidosis, with an impact on cerebral circulation.[54-56] Hypoventilation and hipercarbia lead to increased ICP compared with hyperventilation and hipocarbia. In acute increase in ICP, hyperventilation can not so effectively reduce ICP.[56] Intermittent pneumatic compression of the lower extremities increases cerebral oxygenation during laparoscopic surgery.[58]

Table 11: Effects of pneumoperitoneum on renal function and intraoperative urine output

Function	*Status*
Intraoperative urine output	↓
Intraoperative hormonal changes/renal function	
Antidiuretic hormone	↑
Aldosterone	↑
Plasma renin activity	↑
Glomerular filtration	↓
Postoperative renal function	
Blood urea nitrogen	↓
Creatinine	↓
Creatinine clearance	Unchanged

CONCLUSION

Increased IAP during laparoscopy has different effects on different abdominal organs acting through two mechanisms: directly and indirectly. The direct effect of PNP is a consequence of the mechanical action of the gas, and increased IAP. The indirect effect of PNP is caused by absorption of CO_2. Increased IAP mechanical effect on all intra-abdominal organs and tissues, bringing different pathophysiological responses, which were mostly transient. Increased IAP supports splanchnic vasoconstriction and reduction of flow through the inferior cava vein, renal vein and portal vein, all resulting in decreased venous flow to the heart. During laparoscopic procedures, increased IAP leads to increased ICP, disrupts the flow of blood through the intracranial blood vessels and leads to abnormal resorption of cerebrospinal fluid. Working with low pressure or gassless laparoscopy proline can drastically reduce the negative effects of increased IAP during laparoscopy.

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REVIEW ARTICLE

Differences between Thunderbeat, LigaSure and Harmonic Scalpel Energy System in Minimally Invasive Surgery

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ABSTRACT

Background: An essential part of surgery is dissection and securing hemostasis. This is easily done by the use of energy. Thunderbeat energy source has superseded the LigaSure and harmonic energy sources in this respect.

Aim: To review literature on the differences between thunderbeat, LigaSure and harmonic energy systems.

Materials and methods: These were drawn from previous research materials online in PubMed, Researchgate, Wikipedia and YouTube.

Conclusion: Thunderbeat has a higher versatility than other instruments. This new energy device is an appealing, safe alternative for cutting, coagulation, and tissue dissection during surgery and decreases time and increases versatility during surgical procedures.

Keywords: Thunderbeat, LigaSure, Harmonic, Energy systems, Versatility.

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INTRODUCTION

Minimally invasive surgery would require an energy source to dissect body tissues and at the same time achieve hemostasis.[1]

Over time, there are remarkable improvements in energy sources to increase the speed of surgery while reducing the side effects of energy on surrounding tissues due to lateral thermal spread.[2]

Lateral thermal spread of energy results in damage to tissues near the target site. Currently, thunderbeat has superseded the two most used energy sources *viz* LigaSure vessel sealing system (LVSS) and the harmonic scalpel (HS).

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Thunderbeat (TB) is the World's only integrated form of surgical energy from a single instrument. In January 21, 2013, a published work showed that endoalpha can fully control and directly interface with the revolutionary thunderbeat platform from Olympus (Japan). It simultaneously delivers ultrasonically generated frictional heat energy and electrically generated bipolar energy. Thunderbeat has higher bursting pressure and highly reduced thermal speed than LVSS and HS. It can achieve 7 mm vessel sealing.

The versatility of thunderbeat was based on the following five variables: hemostasis, histologic sealing, cutting, dissection and tissue manipulation. The versatile score is higher than LVSS and HS, and the dissection time with thunderbeat is shorter ensuring a faster surgery.

LigaSure vessel sealing system manufactured by Covidien under the brand name Valleylab is a bipolar apparatus for sealing vascular tissue. It seals tissue by administration of high current and low voltage that of 180 V as compared to conventional electrosurgery. Its unique combination of pressure energy causes fusion of vessels. In short LVSS applies a high coaptive pressure during the generation of tissue temperature under 1000°C, hydrogen cross-links are first ruptured and then renatured, resulting in a vascular seal that has high tensile strength. Melted collagen and elastin in the vessels forms a permanent plastic like seal. It provides secure seal of blood vessels measured up to 7 mm diameter.

Harmonic scalpel is manufactures and marketed by Ethicon. The HS is a high power system which works at a frequency of 55.5 KHz or 55,500 vibrations/sec.

Dissection by ultrasonic is called ultracision. The ultrasound (US) transducer located in the handpiece is composed of piezoelectric crystal sandwiched under pressure among metal cylinders. The US generator converts ultrasonic energy into mechanical energy. The sealing of the vessels is achieved due to denatured protein coagulum which occurs due to tamponade and coaptation.

It has three compatible probes that are the shear, blade and a hook. The shear has opposite silicon padding which the blade and hook lacks. The shear can coagulate vessels up to 5 mm, whereas the hook and blade only 2 mm in diameter. The HS probes reach the temperature of 8°C and even on prolonged use stays below 250°C which is far less than other electrosurgical sources resulting in reduced lateral thermal spread and charring. Vibration of the active probe prevents

sticking of coagulated tissues over it however mist production could minimally affect visibility.

AIMS AND OBJECTIVES

This study is designed to highlight differences between thunderbeat and the two other energy sources: LigaSure and harmonic.

MATERIALS AND METHODS

An extensive literature search online was done through PubMed, Wikipedia, Researchgate and videos via YouTube and video conferencing. References was made to available research and conference materials located at the World Laparoscopy Hospital, Gurgaon, Haryana, India.

RESULTS

The Figures 1 to 3 dipict the jaws of LigaSure, thunderbeat and harmonic probe respectively. Table 1 shows the differences in visibility, operation time, burst pressure and thermal spread among the three energy sources. Graph 1 shows the differences in bursting pressure between thunderbeat and LigaSure as demonstrated with a 7 mm blood vessel. Harmonic was not depicted in this figure because it cannot secure sealing of a 7 mm blood vessel. Graph 2 shows the differences in the duration of surgery performed with the three different energy sources.

DISCUSSION

The question arises what actually are the properties of an ideal energy system? An ideal energy system is one that offers precise and rapid dissection of tissues without compromising hemostasis and visibility. It is not clear whether the current energy systems are ideal. The LigaSure and harmonic predicate systems have been in use, but the revolutionary thunderbeat supersedes them as its qualities approaches an ideal energy system.

Thunderbeat provides fast dissection, fast cutting and immediate sealing of blood vessels. It is an integration of advanced bipolar energy and harmonic energy delivered through a single multifunctional instruments allowing a surgeon to simultaneously seal and cut vessels up to and including 7 mm in size with minimal thermal spread.[3,4]

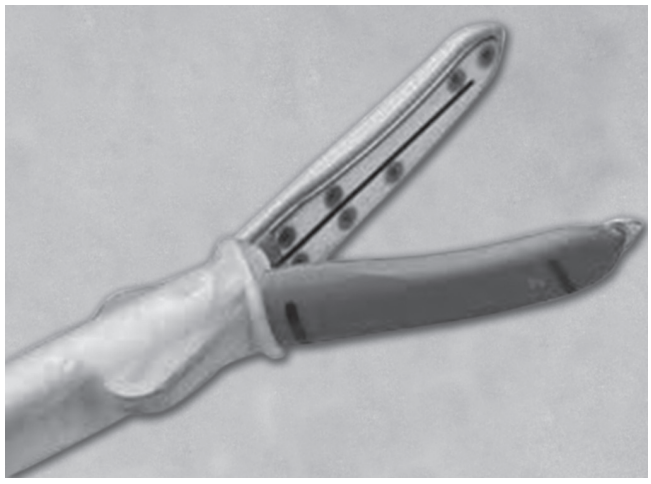


Fig. 1: View of LigaSure jaw

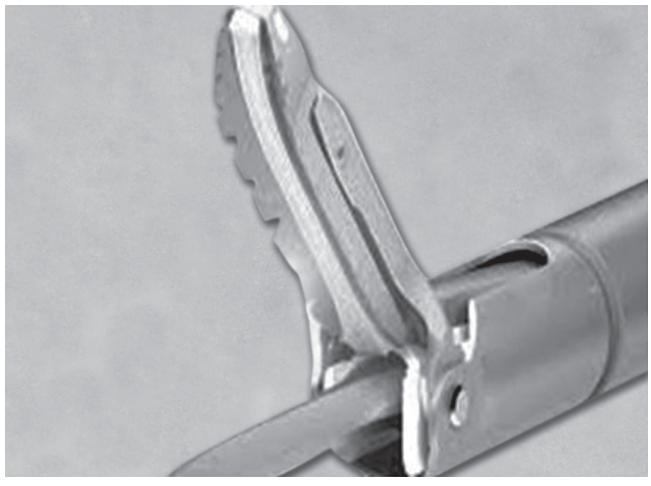
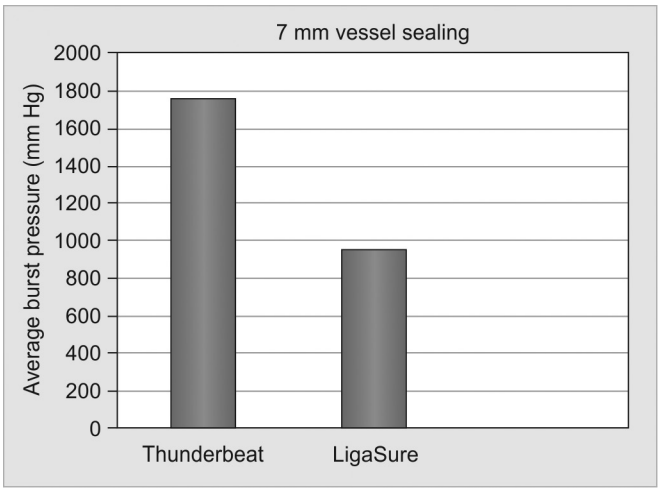


Fig. 2: View of thunderbeat jaw

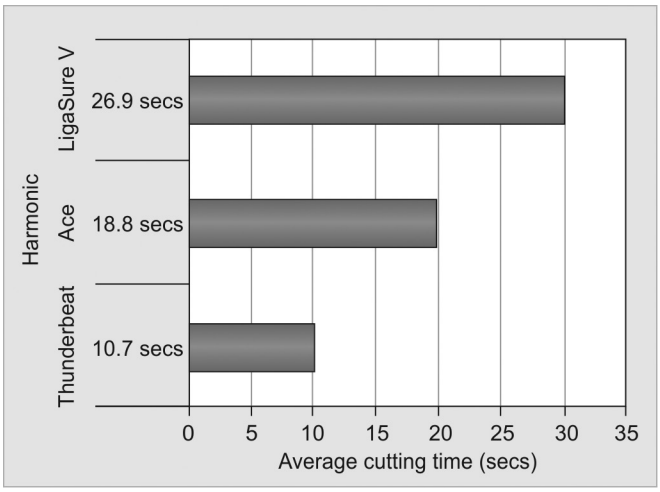
Fig. 3: View of harmonic jaw

Table 1: Differences in visibility, operation time burst pressure and thermal spread

Energy system	*Visibility*	*Operation time*	*Burst pressure*	*Thermal spread*
Thunderbeat	Unimpaired visibility	Fastest in class cutting	Highest mean burst pressure	Least lateral thermal spread
LVSS	Smoke production affecting visibility	Slow surgery	Moderate mean burst pressure	2 mm lateral thermal spread
HS	Mist production affecting visibility	Slower surgery	Lowest mean burst pressure	Less than 1 mm thermal spread



Graph 1: Differences in bursting pressure



Graph 2: Differences in duration of surgery

The patented Jaw design provides precise, controlled dissection and always bipolar coagulation without sacrificing grasping ability.

Surgeons no longer need to choose between rapid dissection and reliable hemostasis when selecting an advanced energy device.

Benefits of the unprecedented versatility thunderbeat provide the following:

1. Fastest in class cutting speed thereby reducing operation time.
2. Reliable 7 mm vessel sealing.
3. Precise dissection with fine Jaw design.
4. Always available bipolar energy for hemostasis without cutting.
5. Minimal thermal spread.
6. Fewer instrument exchanges.
7. Reduced mist generation helps to maintain visibility.

The surgical tissue management system subject device which thunderbeat represents is a modification to an ultrasonic generator to allow for independent or synchronistic use with previously cleared electrosurgical unit.

The predicate devices use either high frequency bipolar or ultrasonic energy to seal and/or cut vessels. When compared to the predicate electrical surgical instruments, the subject device thunderbeat instruments have similar technological features, such as the shaft length, shaft rotation and shaft diameter. The main difference is that the subject device thunderbeat does not require a mechanical blade for cutting and had a higher versatile score than the present US and LigaSure energy systems.

Generator: When compared to the ultrasonic energy, the thunderbeat has similar technological features, such as the number of instrument sockets, footswitch options, output levels and waveforms. There are subtle differences in the input current PF bipolar frequency, RF bipolar constant voltage and maximum wattage.

Combining and activating the ultrasonic output and the HF bipolar output simultaneously enable to seal and cut vessels and to cut and coagulate soft tissue. Activating the HF bipolar output enables vessels sealing and hemostasis. Activating the ultrasonic output enables to seal and cut vessels and to cut and coagulate soft tissues.

To use the thunderbeat, the handpiece plug of the thunderbeat transducer which converts drive current into ultrasonic output is connected to the thunderbeat socket of the USG-400. The HF bipolar current and drive current are supplied to the transducer via a cable eliminating the need to connect a cord of the ESG-400.

LVSS has a unique property of active tissue response which is a feedback from the tissue that controls the energy delivery and automatically discontinues it, when the seal cycle completes. This may eliminate the guesswork of operating surgeon; however, there is a minimal lateral thermal damage of approximately 2 mm. There is no sticking of the instruments on tissues with least charring of the tissues. The seal withstands thrice of normal systolic blood pressure. The LVSS generator detects the characteristics of the tissue in the Jaws of the instruments and delivers energy accordingly to provide a permanent seal.[5,6]

However, the LVSS produces smoke which may affect visibility, unlike the thunderbeat with its highly versatile characteristics.

An inference can also be made from a video available online on the site, www.youtube.com, which is a documentary highlighting the obvious differences in bursting pressure and operation time between the thunderbeat and the predicate devices.

The operation time of LigaSure electrosurgical bipolar sealing system is less than that of the ultrasonic device.[7-10] The operation time of the thunderbeat is less than that of LigaSure and harmonic devices.

CONCLUSION

After a literature search, we found that TB is different in many ways to LVSS and HS. Thunderbeat is more versatile than LVSS and HS as evidenced in its fastest in class cutting speed thereby reducing the operation time, reliable 7 mm vessel sealing, precise dissection with fine jaw design, insignificant thermal spread and best visibility at time of surgery. The safety efficacy and versatility of TB is very useful in other to achieve perfection in modern day surgery.

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CASE REPORT

The First Laparoscopic Vesicovaginal Fistula Repair in Iran

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ABSTRACT

Background: Vesicovaginal fistula (VVF) is the most common acquired fistula of the urinary system. Different surgical techniques exist, but having several advantages make laparoscopy as a favorable method. According to the recent data, we have performed the first laparoscopic repair of VVF in Iran.

Case report: A 19-year-old (G1P1) woman, referred to our center, complaining from continuous urinary incontinence from 7 months ago. She developed continuous wetting after her first cesarean section, performed 7 months ago. Methylene blue dye test, was positive for VVF and voiding cystourethrogram (VCUG) confirmed the diagnosis. Cystoscopy revealed the exact location of fistula in the bladder wall. Patient underwent laparoscopic VVF repair using transperitoneal transvesical approach in the supine position. Patient did not have any urinary leakage during hospitalization and discharged with urethral indwelling catheter at fourth day after the operation. Voiding cystourethrogram was done after 2 weeks, and it was normal without any extravasations.

Discussion: Dense pelvic adhesions and/or inflammation from prior abdominal surgery can make this approach less desirable in some patients. Furthermore, intracorporeal laparoscopic suturing requirement for VVF repair is an advanced skill many surgeons lack. We used transabdominally transvesical laparoscopic method and, according to the literature review, this is the first case of VVF laparoscopic surgery performed in Iran.

Keywords: Laparoscopy, Vesicovaginal, Fistula.

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INTRODUCTION

Vesicovaginal fistula (VVF) is the most common acquired fistula of the urinary system.[6] Since 1663, when Hendrik Von Roonhuyse described the first VVF surgery,[1] several surgical techniques have been developed, such as transabdominal approaches, which have their own advantages and disadvantages. Laparoscopic repair of VVF is an alternative way for traditional open surgery, and has short convalescence period and less morbidity.[2-5] According to the recent data, we have done the first laparoscopic repair of VVF in Iran.

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CASE REPORT

A 19-year-old (G1P1) woman was referred to our department with continuous urinary incontinence from 7 months ago. She had history of an elective cesarean section (CS) 7 months ago, and she had been developed continuous wetting postsurgically.

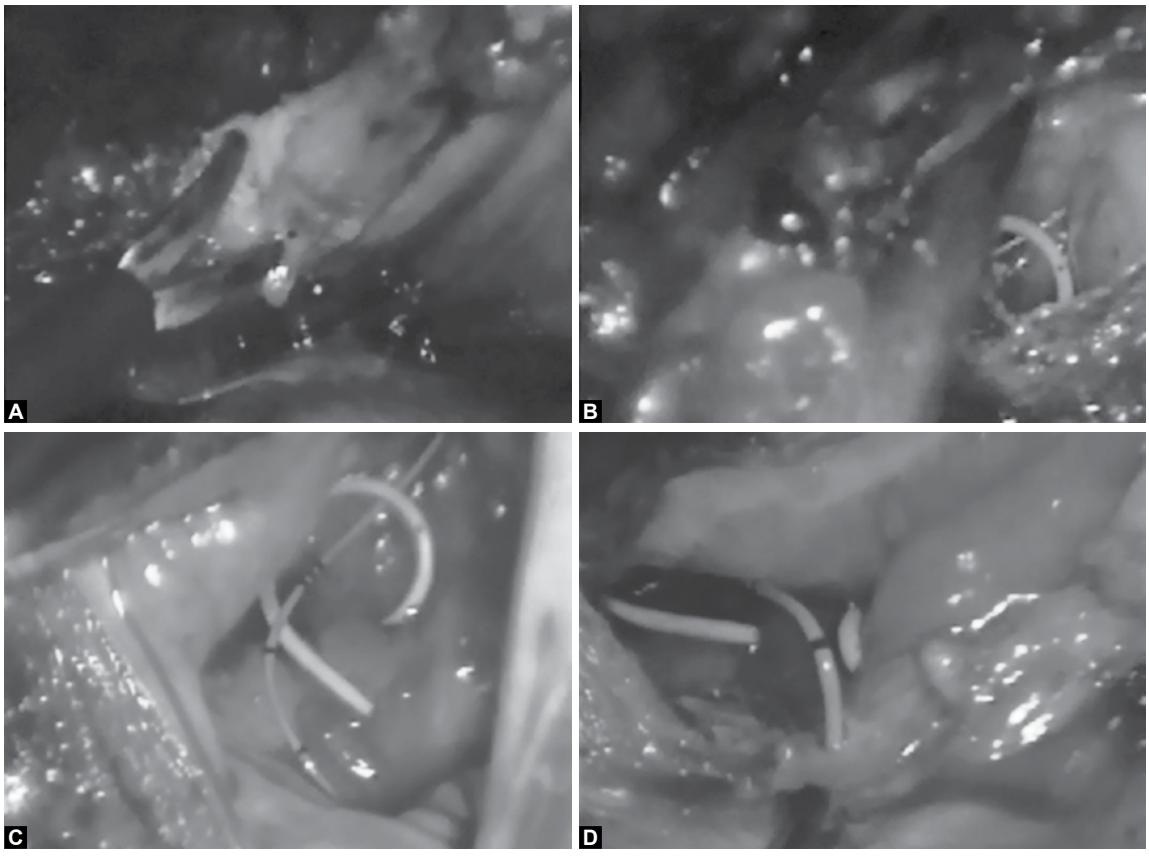
She did not have any history of another operation or urologic disease. The physical examination was normal with the, exception of vaginal watery discharge. Methylene blue dye test was positive of VVF. Afterward voiding cystourethrogram (VCUG) confirmed the diagnosis. The patient underwent cystoscopy and IVP. Cystoscopy revealed the intravesical location of fistula, with the hiatus at the posterolateral wall. Upper urinary tract was normal in IVP and it did not reveal coincidental ureterovaginal fistula.

Patient was considered for laparoscopic VVF repair. Bilateral ureteral DJ stents were placed by cystoscopy and an additional ureteral catheter was passed through the fistula into the vaginal portion for identification of the fistulous tract. Then, in supine position, three trocars (two 10 and one 5 mm) inserted into the abdomen. First trocar was placed under direct vision in the periumbilical area. And, the two trocars—10 and 5 mm were placed at the midclavicular line into the outer border of rectus muscle. A clamped Foley catheter with an inflated balloon and moist sponge was placed in the bladder and vagina. After releasing adhesion bands, result of previously CS surgery, a vertical incision was made from the dome of bladder toward the fistulous tract (Figs 1A to D). After entering to the posterior edge of fistula, the bladder was completely dissected from the vagina. The vagina was repaired using 3/0 vicryl sutures (Figs 2A to C) and a large omental flap was interposed between the vaginal sutures and bladder. Bladder wall was closed using 2/0 vicryl in one layer (Figs 3A and B).

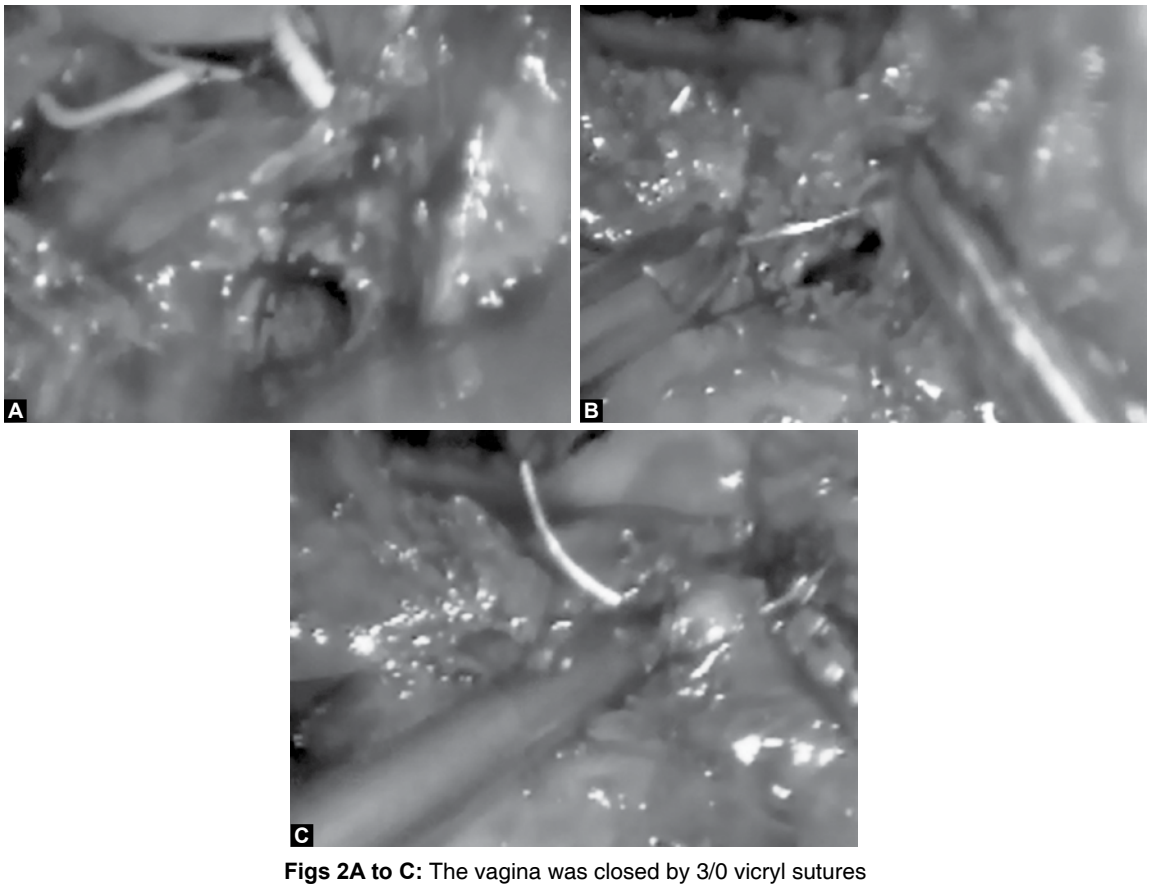
Patient did not have any urinary leakage during hospitalization and discharged with urethral indwelling catheter after 4 days. Voiding cystourethrogram was done at 2 weeks later and it was normal without any extravasations. The urinary catheter was removed at the same time. After 3 months, the patient did not have any urinary leakage.

DISCUSSION

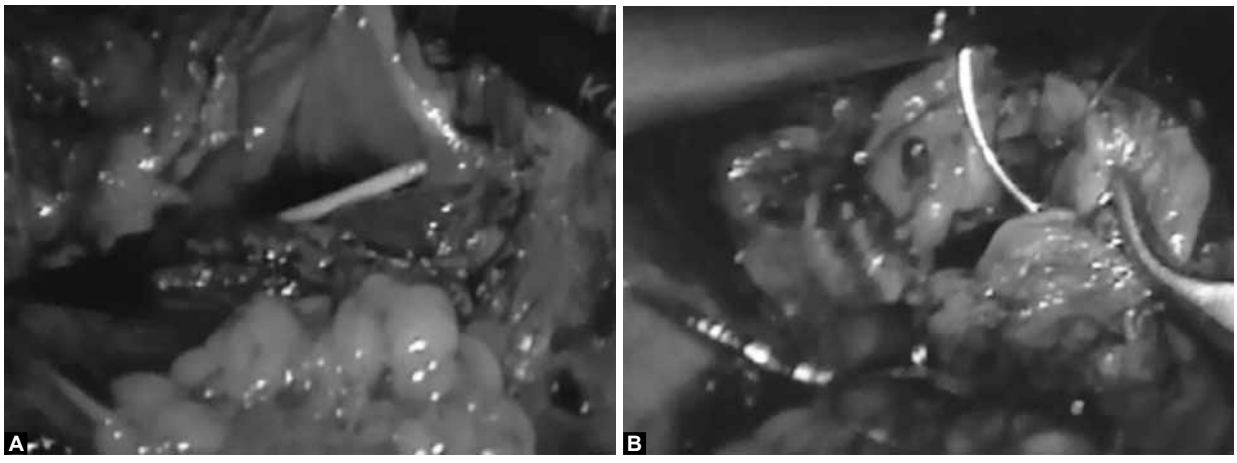
Dense pelvic adhesions and inflammation from prior abdominal surgery can make this approach less desirable in some patients.[1] Furthermore, intracorporeal laparoscopic



Figs 1A to D: A vertical incision was made from the dome of the bladder toward the fistula tract. The DJ stent in ureters, and gray stent in fistula hiatus



Figs 2A to C: The vagina was closed by 3/0 vicryl sutures



Figs 3A and B: A large omental flap was interposed between the vaginal sutures and bladder then bladder was closed by 2/0 vicryl in one layer

suturing requirement for VVF repair is an advanced skill many surgeons may lack. Regarding these limitations, the laparoscopic VVF repair has not been widely adopted.

We used transabdominal-transvesical laparoscopic method and, according to the literature review, this is the first case of VVF that has been repaired by laparoscopic technique in Iran. Although this method is difficult in VVF cases, but has long-time efficacy compared with the open transabdominal-transvesical approaches.[7]

Laparoscopy has been increasingly popular in reconstructive urology surgeries.[8] Considering the capabilities of Iranian surgeons in this field, laparoscopic surgery can be applied effectively in the management of VVFs. The approach is safe and provides all advantages of minimally invasive surgery. Shorter hospital stay and shorter recovery time have a positive effect on the patients' well being.[7,8] More recent methods have been described, such as laparoendoscopic single-site surgery (LESS), using the triport and skipping the bladder intact.[9] More prospective studies are needed to fine out its differences with traditional method in outcome and morbidity-mortalities. This method has been used in cases with recurrent VVF too, and studies have shown acceptable results.[10]

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