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24-Hour Discharge Post Laparoscopic Ovarian Cystectomy: A Feasibility Study

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ABSTRACT

Minimally invasive surgery results in faster recovery. The objective of this study is to identify criteria for the feasibility of 24-hour discharge post laparoscopic ovarian cystectomy. This is a prospective cross-sectional study that was carried out at the Obstetrics and Gynaecology Department in Putrajaya Hospital between 1 January and 31 December, 2016. The inclusion criteria were: age between 15 and 45, no comorbidities, no family history of malignancy, BMI of less than 30, mass size less than 18 weeks, single uninoculated simple cyst and no ascites. The exclusion criteria were post-menopause women, known medical illness, family history of malignancy, mass size more than 18 weeks, multiloculated or bilateral ovarian cyst, presence of solid area within the cyst and ascites. The sample size was calculated to be 14. A total of 16 participants were identified. Results showed that using the Visual Analogue Score (VAS), the mean pain score post operatively in the first six hours, 24 hours, 48 hours, two weeks and three months were 3.67, 2.57, 0.5, 0 and 0, respectively. Two of the subjects experienced post-operative nausea and vomiting, one had urinary tract infection and one had minor bleeding from the surgical site. All the participants were discharged within 24 hours post-operatively. There was no readmission. In conclusion, 24-hour discharge post laparoscopic cystectomy is safe and feasible. Factors determining the success must be adhered to closely to ensure a good and satisfactory outcome. This research did not receive any specific grant from funding agencies in the public, commercial or not-for-profit sectors.

Keywords: Laparoscopic cystectomy, 24-hour discharge

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INTRODUCTION

Ovarian cyst is common among the reproductive age group of women. It may be both symptomatic or asymptomatic (National Institue of Health Census Development Conference Statment, 1994). Six percent of

5000 healthy women in a study reported by Campbell et al. (1989) had detectable adnexal masses on transabdominal ultrasound. Of these, 90% were cystic in nature, with most cases diagnosed as benign cysts (Royal College of Obstetricians & Gynaecologist and British Society for Gynaecologic Endoscopy, 2011). Ovarian cysts were the fourth most common gynecologic cause of hospital admission according to a late 1980s study by Grimes and Hughes (Grimes & Hughes, 1989). Most cysts spontaneously resolve, while some will persist. The persistent ovarian cysts are most likely to be surgically managed. It has always been the standard practice to do an ovarian cystectomy. Previously, this was done via laparotomy. Being a major surgical procedure, the patient usually stays for at least two or more days prior to discharge. Recovery usually takes about four to six weeks.

With the advancement of minimally invasive surgery, surgery can be done in comparable time to conventional laparotomy. The advantages are enormous, as access is minimal and there is less pain, minimal blood loss, less risk of post-operative adhesion formation, shorter hospitalisation, fast recovery and earlier return to normal activity. Within two weeks, the patient can return to work. Hence, the laparoscopic approach has been regarded as the gold standard approach in managing women with ovarian cysts (Royal College of Obstetricians & Gynaecologist and British Society for Gynaecologic Endoscopy, 2011). Putrajaya Hospital has been practising laparoscopic surgery since 2000 even though this technique was established in the early1990s. Since then the laparoscopic approach has been the preferred approach in more than 90% of cases dealing with benign ovarian cysts.

The objective of this paper was to look into the criteria and feasibility of 24-hour discharge post laparoscopic ovarian cystectomy. It is a pilot study as there is no reference to 24-hour discharge post laparoscopic ovarian cystectomy in the literature. Therefore, cross reference to daycare laparoscopic cholecystectomy was done.

METHOD

This was a prospective cross-sectional study that was carried out in the Obstetrics and Gynaecology Department in Putrajaya Hospital. Based on the inclusion and exclusion criteria, women who were referred to the Obstetrics and Gynaecology Department at Putrajaya Hospital from 1 January till 31 December, 2016 for further management of ovarian cysts were recruited as part of this cross-sectional study. The following were the inclusion and exclusion criteria:

1. Inclusion criteria
    a. All patients with confirmed diagnosis of ovarian cyst
    b. Pre-menopausal patient (age 15 to 45)
    c. No known medical illness
    d. No family history of malignancy
    e. Body Mass Index (BMI) of less than 30
    f. Mass size less than 18 weeks
    g. Single uniloculated simple cyst
    h. Has no ascites

2. Exclusion criteria
   a. Presence of solid area within the cyst
   b. Women who did not consent to take part in this study
   c. Operation lasted more than two hours
   d. Intra-operative findings of severe adhesions
   e. Other clinical or intra-operative features suspicious of malignancy (such as papillary projections and increased vascularity on imaging, solid area found intra-operatively)

Tumour markers, including Ca 125, were not requested. Patients selected were pre-menopause with ultrasound features that only included patients with uniloculated cyst with no solid areas or ascites. Taking tumour markers would also have had significant cost implication in conducting the study. In view of this, risk for malignancy index was not calculated.

Sample size was determined by using the following formulae (Daniel, 1999):

$$N = (Z^*\sigma/\Delta)^2 = (1.96^*1.9/1)^2 = (3.724)^2 = 13.86$$

where, N = number of sample size; Z = statistic for a level of confidence (1.96); σ = standard deviation [4]; Δ = precision (1)

The sample size was 14 patients in order to estimate the mean with a precision of 1 unit. We decided to take 16 patients with an additional 20% for anticipated non- response cases.

Procedure

All patients who reported to the Obstetrics and Gynaecology Department at Putrajaya Hospital for ovarian cysts who fulfilled the inclusion and exclusion criteria were enrolled into the study. There was no comparison group in this study. The duration of subject participation was 12 months.

Those who agree to participate in the study were required to sign the consent form provided during consultation at the outpatient clinic. Patients who were under the age of 18 years old were required to have their parents or guardians give written consent for the surgery on their behalf. This was in accordance to the requirements of the Malaysian Medical Council Guideline when obtaining consent from minors (Malaysian Medical Council, 2016). The patients were counselled thoroughly. Participation in this study was based on voluntary basis. Patients were free not to participate or to withdraw from the study at any point of time without jeopardising the care given. If they had doubts or questions or needed more time to think about the surgery, a second appointment was arranged accordingly.

An anaesthetist reviewed all the patients within the four weeks before surgery and assigned the ASA physical status score grade. Patients were given an information booklet outlining the procedure, potential problems and details of perioperative care.

The procedure was performed in the morning by a well-trained surgeon with an assistant. Patients were admitted to the ward one day before the surgery. Surgery was done as per routine.

Post operatively, patients were shifted to the post-operative recovery room and maintained on intravenous fluids for four hours post-surgery. The patients were assessed at regular intervals by a member of the surgical team and attending nurse for post-operative complaints and vital signs. Analgesic and antiemetic were given for pain and nausea or vomiting as required.

After four hours, the operating surgeon along with the anaesthesiologist evaluated each patient for consciousness level, vital signs, pain, nausea and vomiting. They were encouraged to sit up, drink and go to the toilet under supervision. Pain was assessed on the 0-10 Visual Analogue Scale (VAS): 0-4 (mild pain), 5-7 (moderate) and 8-10 (severe pain) (Vaughan, Gurusamy, & Davidson, 2013). Patients who fulfilled all the following criteria were discharged within 24 hours:

1. The surgeon did not anticipate that there would be any problems stemming from the operation.
2. Intra-operative blood loss was less than 500cc
3. Duration of surgery less than two hours
4. No intra-operative visceral injuries
5. Stable vital signs
6. Patient able to understand instructions and can ambulate
7. Patient relieved of nausea, vomiting and pain
8. Able to tolerate liquids and void urine
9. No bleeding from surgical sites
10. Patient feels comfortable and is ready to go home willingly

It was decided that patients would not be discharged within 24 hours if:

1. There were conversion to open cystectomy
2. Discharge criteria were not met
3. Unexpected medical problems or complications attributed to the surgery arose

The patients were given tablet Celecoxib acid 200 mg orally two times daily. They were provided with the hospital phone number and advised to contact the hospital if required or to report to the 24-hour emergency department if necessary. They were contacted the next morning at 48 hours to assess their general well-being, pain, discomfort, nausea, vomiting or any other side effects attributable to the anaesthesia or surgery. Patients with a pain score of more than 5 over 10 during follow-up were asked to return to the hospital immediately for further assessment of any complications. All the patients were given another appointment to visit the gynecology outpatient clinic after two weeks and three months to assess any early and late complications. Early complications are defined as any complication that arises within two weeks and late complications, within three months of surgery.

The patients' details were made known only to the primary investigator. All the results were confidential and all data extracted from this research for use in reports did not, under any circumstances, contain names or identifying characteristics. The duration and means of storage and archival of medical records and study data was per standard regulation i.e. a period of seven years. The study data will be destroyed after the period. No payment was made for taking part and patient did not have to pay for the study treatment and procedures.

The data obtained was entered into the Statistical Package for the Social Sciences (SPSS) version 15 for Windows. The data was analysed descriptively.

The ethical issue in this study was that the subjects were discharged earlier than the routine practice. As such, they were at risk of experiencing early complications at home that would go unnoticed but which would have routinely been recognised had they still been warded. This risk was managed by terminating any study subject who developed complications intra-operatively or who had to return to hospital for complications within 48 hours. This study was approved by the Medical Research and Ethics Committee of Malaysia (NMRR-14-1129-21265).

RESULTS

A total of 16 patients with ovarian cyst were recruited for this study. The age range was from 25 to 38 years old, with the mean age of 32. Nine were referred from health clinics and seven were referred by private general practitioners. All of the recruited patients had mass size per abdomen of less than 18 weeks. Eight cases were done by consultants and the rest were done by specialists. The mean operation time by consultants and specialists were 86.7 and 75.11 minutes, respectively. Seven cases had mild to moderate adhesions intra-operatively. Adhesionolysis was done successfully with no complications. A total of 15 (93.7%) patients had blood loss of less than 100 ml and one patient had blood loss of 400 ml. Table 1 summarises these findings. During the post-operative assessment, all the patients were orientated to time, place and person, ability to ambulate and ability to tolerate orally and none developed shoulder tip pain. We evaluated the post-operative pain score using the Visual Analogue Score (VAS) at the first six hours, 24 hours, 48 hours, two weeks and three months post-operatively. The results are shown in Table 2.

Table 1
Summary of research outcome

Criteria	Mean (SD)	N (%)
Age	31.6 (3.58)	
Operative time (minutes)		
Overall	80 (28.9)	
Consultant	86.7 (28.6)	
Specialist	75.11 (29.7)	
Surgeon		
Consultant		7 (43.8)
Specialist		9 (56.3)
Adhesion		11 (68.8)
Spillage		10 (62.5)
Estimated blood loss		
<100ml		15 (93.75)
>100ml		1 (6.25)

Table 2
Pain-score chart using the visual analogue score (vas) against time

Duration Post-Operation	Mean Pain Score (Visual Analogue Score)
Immediate	1.5
1 hour	1.8
2 hours	2.3
3 hours	2.58
4 hours	3.33
5 hours	3.58
6 hours	3.67
24 hours	2.57
48 hours	0.5
2 weeks	0
3 months	0

None of the patients developed early post-operative complications such as emphysema and late post-operative complications such as incisional hernia or wound infection. However, one patient had urinary tract infection, two experienced nausea and vomiting and one had minimal surgical site bleeding that was stopped by direct compression. Mean systole, diastole blood pressure and pulse rate at the time of arrival at ward from the operation theatre, 0 h, 1 h, 2 h, 3 h, 4 h, 5 h and 6 h were normal throughout, as shown in Figures 1 and 2.

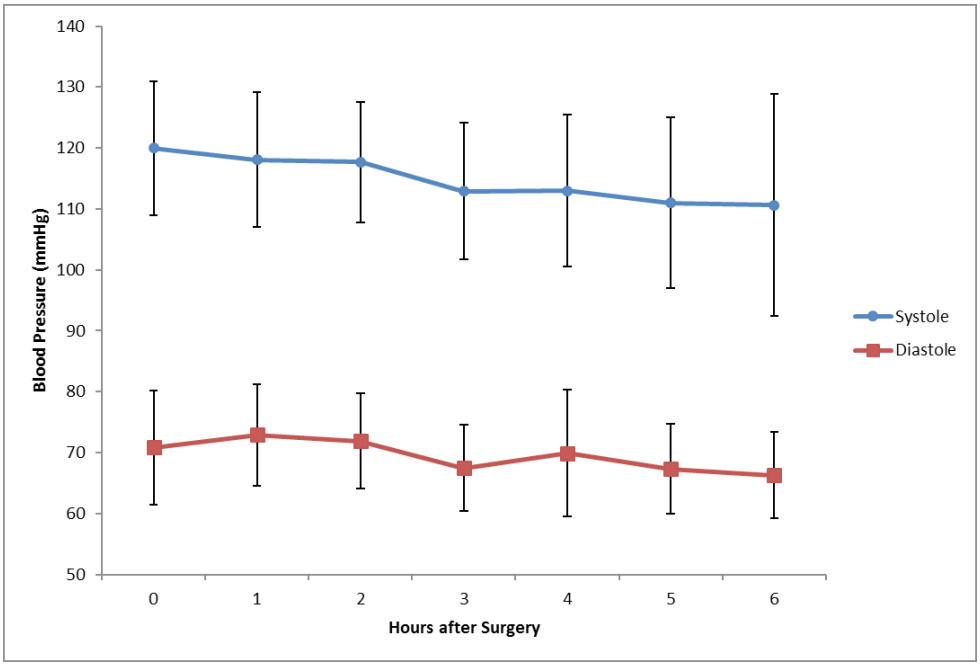


Figure 1. Post-operative (first 6 hours) mean systole and diastole blood pressure (mmHg)

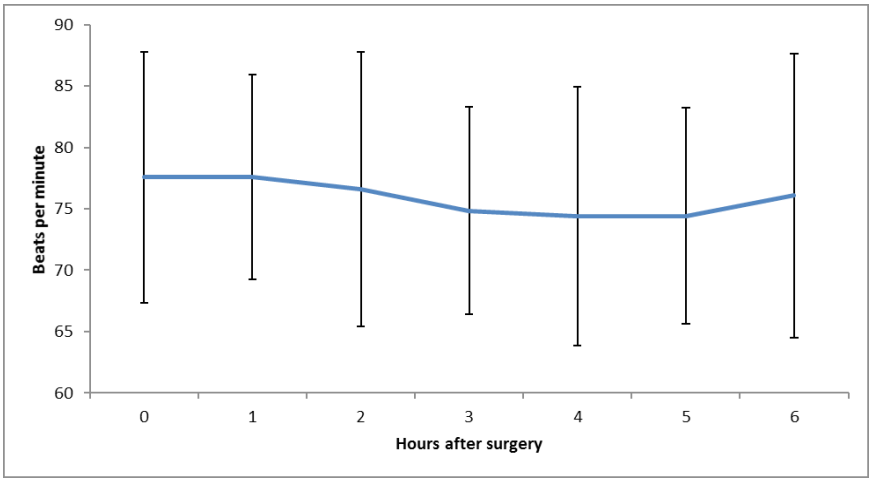


Figure 2. Post-operative (first 6 hours) mean pulse rate (bpm)

DISCUSSION

The feasibility of 24-hour discharge post laparoscopic cholecystectomy was demonstrated in this study to be safe (Kaman, Iqbal, Bukhal, Dahiya, & Singh, 2011). However, to the best of the authors' knowledge no similar data were available on 24-hour discharge laparoscopic cystectomy. In this study, 24-hour discharge was demonstrated to be safe, feasible and cost effective when applied carefully to patients who fulfilled a set of criteria (Kaman et al., 2011). In our series of laparoscopic cystectomy, we used the standard three or four-port technique using 5-mm instrument ports for dissection as well as for the camera. The main finding demonstrates that no critical complications occurred throughout the period of this study. We recorded the pain score at within six hours after surgery and discharge was proceeded with once the criteria were fulfilled. There was an initial increasing trend in pain score during the first 6 h due to the weaning effect of the general anaesthesia. This improved subsequently as the patients took an oral analgesic, with a mean pain score of less than 4 at 24 h. This shows that laparoscopy itself is associated with better pain control and early recovery. Initial follow-up was via telephone interview within 48 hours, then two weeks and finally three months (outpatient review) post-operatively. None of the patients had prolonged pain episodes after 48 hours post-operative in this series. The absence of readmission in this study indicated the safety and feasibility of 24-hour discharge post laparoscopic cystectomy.

Among other outcomes were post-operative nausea and vomiting. Post-operative nausea and vomiting (PONV) is unpleasant and exhausting for patients. It prolongs recovery time and delays patients' discharge, leading to increased hospital cost. The aetiology of PONV after laparoscopic cystectomy is not entirely clear. The intra-operative use of isoflurane and fentanyl, nitrous oxide, carbon dioxide insufflations, stretching of the peritoneum and increased blood pressure in the peritoneal cavity and post-operative administration of opioids was thought to contribute to PONV (Gan et al., 2003). Two patients developed PONV. Nevertheless, PONV was managed well and it did not delay the timing of discharge. The longer operative time taken

by the consultants was the result of more difficult surgery being needed. There was, however, no significant difference in the operative time between consultants and specialists (p=0.408). Four specialists were involved in this study. The experience range was from a minimum of two to eight years' experience in laparoscopy. The three consultants had more than 10 years' experience in laparoscopic surgery.

Psychologically, earlier discharge saw the advantage of better pain control, perception of quick recovery and self-confidence. This series exhibited that discharge within 24 hours of laparoscopic cystectomy was safe. It can be performed safely in any hospital equipped with trained supporting staff and surgeons. Careful selection of patients and good team work with the anaesthetist during induction and post-operative recovery enhance the good outcome. A strict criterion for discharge is an important requirement for ensuring that the safety of the patient will not be compromised. For a patient to be discharged the next day after the operation, certain patient selection criteria must be met, such as premorbid well patients with no medical illness, no family history of malignancy, normal body mass index, mass size less than 18 weeks- no intra-operative complications, not requiring post-operative blood transfusion, surgery duration of less than two hours, stable post-operative vital signs and pain score less than 4 using VAS.

Discharge with 24 hours post laparoscopic cystectomy is feasible, as reduced post-operative pain reduces requirement of an analgesic, has a better cosmetic effect in the long term and reduces the risk of post-operative infection compared to in the case of a laparotomy. The length of hospital stay required is significantly shorter with laparoscopic surgery. Most patients can return to their everyday lives much sooner than after open surgery.

The strength of this study was that it was a prospective study. Patient selection was strictly adhered to, resulting in a comparable group of patients. The limitation of this study includes the small sampling size and the fact that it was done in one laparoscopic centre rather than in several. Discharge within 24 hours in the case of simple laparoscopic cystectomy may not be applicable in other centres that may have a different operating procedure and a different set of patients and expertise.

CONCLUSION

Discharge within 24 hours of laparoscopic cystectomy is safe and feasible in carefully selected patients with no intra-operative complications and a post-operative VAS less than 4. Factors determining success must be adhered to closely to ensure a good and satisfactory outcome.

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