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Day surgery for gynaecological laparoscopy: Clinical results from an RCT

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Abstract

This randomized controlled trial compared the clinical outcome from inpatient and ambulatory laparoscopy for benign gynaecological conditions. While 658 consecutive patients were considered for inclusion into the study, data from 26 inpatients and 40 ambulatory cases were analysed. Inpatient surgery was undertaken by more senior surgeons ($p < 0.001$), but complication rates were similar. For remedial surgery (but not diagnostic), ambulatory laparoscopy had shorter anaesthetic and operating times ($p < 0.05$) than inpatient surgery. Both inpatient and ambulatory patients reported significant improvements ($p < 0.01$) in immediate postoperative pain; similar proportions (64% and 74%, respectively) experienced postoperative nausea; 39% of inpatients and 58% of ambulatory patients reported problems after hospital discharge. Severity of pelvic pain was lower for both groups 1 month after operation in comparison to preoperative levels (inpatients: from 8.0 to 5.0, ambulatory: 6.0 to 3.0; on a 0–10 VAS). It was concluded that clinical and patient outcome was similar for the patients undergoing inpatient and ambulatory surgery for gynaecological laparoscopy.

Keywords: Day surgery; Gynaecological laparoscopy; Randomized controlled trial; Patient outcome

1. Introduction

Day surgery is used extensively for gynaecological procedures and especially for laparoscopy [1,2]. Chronic pelvic pain is the most frequent indication for laparoscopy, but it is also used to investigate and treat endometriosis and infertility and to perform sterilization [3,4]. In 1997, 36% of gynaecological operations in Denmark were conducted as day surgery and 79% of 31 gynaecological departments expected an expansion of their day surgical activity in the future [5]. At this time most day surgery occurred within surgical or outpatient departments and only 17% in a designated day surgery unit [5].

Despite the extensive use of ambulatory gynaecological laparoscopy, comparisons of clinical outcome between inpatient and ambulatory approaches appear limited to randomized controlled trials (RCTs) of day surgery for sterilization [6,7] and diagnostic microlaparoscopy [8]. RCTs have been undertaken, however, to investigate the relative benefits of various anti-emetic therapies and anaesthetic techniques during ambulatory gynaecological surgery [9–12]. The establishment of a dedicated gynaecological day surgery unit at Skejby Hospital offered the opportunity to conduct an RCT to determine whether there were differences in the clinical and economic consequences of ambulatory surgery compared to inpatient surgery for benign gynaecological conditions. This article reports the clinical results of the RCT.

The gynaecological day surgery unit was unfortunately closed at the end of 2002 as part of a cost-cutting exercise, after which all patients referred for gynaecological laparoscopy were again treated as inpatients. The RCT was thus stopped before all randomized patients had undergone operation, resulting in a smaller patient sample than expected. The study results were nevertheless considered important to report as they provide empirical data on the use of ambulatory surgery for gynaecological laparoscopy.

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2. Methods

All patients ($n = 658$) who were referred between 15 May 2001 and 2 December 2002 to the gynaecological unit at Skejby Hospital, Denmark, for laparoscopy to investigate benign gynaecological conditions were considered for inclusion in the study. Subsequent exclusion criteria were age <18 or >75 years; previous laparotomy (not including mini-laparotomy, Caesarean section, appendicectomy); recurrence of previous illness such as malignancy or infection; any acute illness within the previous 2 weeks; other medical illness; history of alcoholism, drug dependence or drug abuse; no relatives available to care for the patient after discharge from hospital (a requirement for day surgery). On the basis of the history given on referral, 191 patients were excluded (Fig. 1). The remaining 467 patients completed a questionnaire asking about previous illnesses and surgery, obstetric and gynaecological history, current symptoms and use of medicines. A further 48 patients were excluded on the basis of this information, while 201 patients declined to participate in the randomization study. Of the remaining 218 patients, a further 41 were excluded due to other events. A total of 177 patients were randomized to receive either inpatient surgery or day surgery, of whom 66 had surgery before the project was stopped.

The day surgery unit was established exclusively for gynaecological surgery and contained its own reception, operation and recovery areas as well as designated surgeons, anaesthetists and nursing staff. Patients attending for day surgery were admitted in the morning and discharged the same day after operation and thus had no overnight stay [13], while patients attending for inpatient surgery were admitted to the gynaecological ward the day before surgery and discharged the day after surgery. The anaesthetic and operative procedures for laparoscopy were the same for both groups of patients; most cases were performed under general anaesthesia using techniques suitable for day case surgery.

As most of the data required for the study was not routinely collected, considerable time was spent in devising and validating the questionnaires and collecting the necessary data. Operation data were obtained from the hospital administrative register supplemented by information provided by surgical and nursing staff. These data included referral date, diagnosis and source; date and outcome of the preoperative consultation; date and type of operation, number and seniority of surgical personnel, type of anaesthesia, instrument and drug use, complications and length of time under anaesthesia, operation and recovery; use of pain relief and anti-emetics in the recovery room.

Patients completed visual analogue scales (VAS) for pain at rest, pain on coughing and nausea on three occasions—immediately after waking from anaesthesia, 2 h later and 24 h after discharge. The VAS comprised 10 cm lines with endpoints of ‘No pain (nausea)’ and ‘Worst imaginable pain (nausea)’. Any vomiting while in recovery was also noted. One month after operation, patients completed a questionnaire asking about their pre- and postoperative

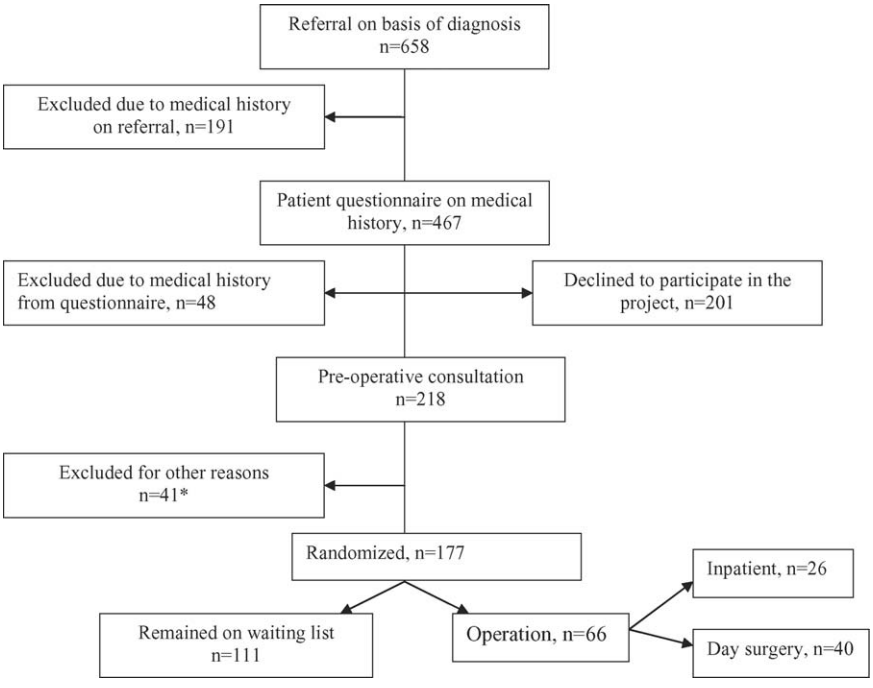

Fig. 1. Patient participation in randomized controlled trial of gynaecological laparoscopic surgery. (*) Includes 22 patients excluded on basis of clinical history obtained at the pre-operative consultation, 9 patients with acute admission before randomization, 4 patients who requested treatment at other hospitals, and 6 patients who later opted out of the project.

health state, including medications, sickness days, medical consultations, pain and effect of symptoms on everyday life.

2.1. Statistics

With few exceptions, the data were non-normally distributed (Kolmogorov–Smirnov test) and are therefore reported using the median and interquartile range (IQR) and analysed using non-parametric tests. Comparisons between inpatient and ambulatory groups were made using the Mann–Whitney *U* test or ANOVA for continuous variables and the Pearson chi square test for categorical variables. Change over time within each treatment mode was tested using the Wilcoxon test (continuous variables) and the McNemar test (categorical variables). The level of statistical significance was set at 0.05.

3. Results

3.1. Representativeness of patient sample

Of 658 patients referred for gynaecological laparoscopy, 280 (42.6%) were excluded before randomization on exclusion criteria or for other reasons such as acute hospital admission, pregnancy or referral to another hospital (Fig. 1). A further 201 patients (30.5%) declined to participate in the randomization study. A comparison between the 280 excluded patients and the 177 who were randomized indicated that excluded patients were significantly older and more likely to have a referral diagnosis of endometriosis (Table 1). There were no significant differences between the patients who declined ($n = 201$) and those who accepted to participate in randomization ($n = 177$). Among the randomized patients, the predominant referral diagnoses were endometriosis and chronic pelvic pain, and two thirds were referred by a general practitioner (Table 1).

Due to the study's untimely end, 111 patients were still on the waiting list when the study was stopped. The operated patients were significantly younger than those still on the waiting list; a greater proportion (20% cf. 2%) were referred for infertility and more were referred by a specialist (42% cf. 6%), see Tables 1 and 2.

3.2. Sociodemographic variables and medical history

After randomization, 26 inpatients and 40 ambulatory patients underwent surgery (Table 2). Operative and postoperative recovery data were virtually complete, while 73% (48/66) of operated patients completed questionnaires. The two groups were similar with respect to age, education, employment status (71% employed), referral source, body mass index (BMI) and number of medical consultations prior to surgery (Table 2). Most were referred for investigation of endometriosis or pelvic pain. In each group 75–80% of patients had experienced pelvic pain in the month prior to operation, with a lower median pain level among ambulatory patients. Overall, 68% of patients reported that their daily life was affected by gynaecological symptoms in the month before operation.

3.3. Operation characteristics

There were no statistically significant differences between the inpatient and ambulatory groups with respect to the aim of the operation, type of anaesthesia, use of intra-operative antibiotics and anti-emetics, presence of a supervisor during operation and number of complications (Table 3). Significant differences were found with respect to seniority of

Table 1
Characteristics of patients who were excluded from the study, patients who declined to participate and patients who were randomized

	Excluded from study ($n = 280$)	Declined to participate ($n = 201$)	Randomized ($n = 177$)	Randomized but still on waiting list ($n = 111$)
Median age (IQR)	41.3 years (18.0)[a]	35.4 years (15.0)	36.1 years (16.0)	41.7 (17)[b]
Min–max (years)	17–85	20–72	20–72	22–72
Referral diagnosis				
Endometriosis	53.9% ($n = 151$)[a]	48.3% ($n = 97$)	48.0% ($n = 85$)	48.6% (54)[c]
Infertility	2.5% ($n = 7$)	2.5% ($n = 5$)	8.5% ($n = 15$)	1.8% (2)
Ovarian cyst	2.1% ($n = 6$)	2.5% ($n = 5$)	2.8% ($n = 5$)	4.5% (5)
Pelvic pain	41.1% ($n = 115$)	45.8% ($n = 92$)	40.7% ($n = 72$)	45.0% (50)
Other	0.4% ($n = 1$)	1.0% ($n = 2$)	0	0
Referral source				
General practitioner	72.5% ($n = 203$)	78.1% ($n = 157$)	75.7% ($n = 134$)	87.4% (97)[b]
O&G specialist	18.9% ($n = 53$)	16.9% ($n = 34$)	19.8% ($n = 35$)	6.3% (7)
Other hospital dept	8.6% ($n = 24$)	5.0% ($n = 10$)	4.5% ($n = 8$)	6.3% (7)
Mean BMI (S.D.)	–	24.3 (4.0)	23.0 (3.0)	–

[a] Significant difference ($p < 0.05$) in comparison to patients who were randomized.
[b] Significant difference ($p < 0.001$) in comparison to patients who had laparoscopy after randomization.
[c] Significant difference ($p < 0.05$) for referral diagnosis in comparison to patients who had laparoscopy after randomization.

Table 2
Characteristics of patients who underwent surgery after randomization to either inpatient or day surgery

	Inpatient surgery ($n=26$)	Day surgery ($n=40$)
Mean age (S.D.)	35.0 years (9.9)	33.9 years (6.9)
Min–max (years)	20–60	21–51
Referral diagnosis		
Endometriosis	65.4% ($n=17$)	35.0% ($n=14$)[a]
Infertility	15.4% ($n=4$)	22.5% ($n=9$)
Ovarian cyst	0	0
Pelvic pain	19.2% ($n=5$)	42.5% ($n=17$)[b]
Referral source		
General practitioner	57.7% ($n=15$)	55.0% ($n=22$)
O&G specialist	42.3% ($n=11$)	42.5% ($n=17$)
Other hospital dept	0	2.5% ($n=1$)
Mean BMI (S.D.)	22.7 (2.5)	23.1 (3.3)
In month prior to operation		
Mean no. sick days (S.D.)	2.3 days (2.3)	1.3 days (2.7)
Consulted with doctor/hospital	87.5% (14/16)	78.1% (25/32)
Daily life affected by gynaecological symptoms	76.5% (13/17)	63.3% (19/30)
Pelvic pain		
Median (IQR; min–max)	8.0 (6.0; 0–10)	6.0 (7.0; 0–10)[a]
Number of patients with pain	14/17 (82.4%)	23/31 (74.2%)

[a] Significant difference between groups, $p<0.05$.
[b] $p=0.05$.

surgeon (fewer operations performed by senior surgeons in day surgery), instrument error (more common in day surgery), blood loss (greater with inpatient surgery) and use of some surgical instruments (greater use of a cauterizer and a Walchev manipulator with inpatient surgery). Day surgery patients had a significantly shorter time under anaesthesia but a longer time in recovery; inpatient surgery had a longer median operating time, but this difference was not statistically significant ($p=0.075$).

The observed differences in anaesthetic and operating times were further analysed to determine whether they were a function of the goal of the operation: while 53.8% of inpatient surgery aimed at treating the condition, 70% of the day surgery operation aimed at diagnosis or status assessment ($p=0.053$; Table 3). It was found that appraisal operations had significantly ($p=0.001$) shorter anaesthesia and operating times than remedial operations. For appraisal operations only, there were no significant time differences between inpatient and day surgery; for remedial operations only, inpatient surgery still showed a longer median anaesthetic and operating time in comparison to day surgery ($p=0.046$ and 0.02, respectively).

The surgeon's level of experience had no influence on anaesthetic or operating times, complication rates, blood loss or the number of patients reporting problems after discharge. Remedial surgery and greater use of a Walchev manipulator was associated with higher seniority of the surgeon, but these differences did not reach statistical significance.

Table 3
Operation data for inpatient surgery and day surgery groups

	Inpatient surgery ($n=26$)	Day surgery ($n=40$)
Surgeon		
Specialist/registrar	84.6% ($n=22$)	35.0% ($n=14$)[a]
Under training	15.4% ($n=4$)	65.0% ($n=26$)
Supervisor present	57.7% ($n=15$)	75.0% ($n=30$)
Aim of operation		
Diagnostic/status assessment	46.2% ($n=12$)	70.0% ($n=28$)
Diagnostic + end operation	53.8% ($n=14$)	30.0% ($n=12$)
Standard anaesthesia[b]	80.8% ($n=21$)	85.0% ($n=34$)
Intra-operative blood loss (ml)		
Median (min–max)	0.0 (0–200)	(0–30)[c]
Percent patients with no blood loss	53.8%	85.0%
Instrument error[d]	3.8% ($n=1$)	22.5 ($n=9$)[e]
Complications[f]	11.5% (3)	5.0% ($n=2$)
Median time in minutes (IQR)		
Anaesthesia	80.0 min (28.0)	62.5 min (29.2)[a]
Operation	42.5 min (34.0)	32.5 min (19.8)
Recovery	110.0 min (61.2)	250.0 min (70.0)[a]

[a] Significant difference between groups, $p<0.001$.
[b] Non-standard anaesthesia for inpatients comprised additional medication (two cases; ephedrine, atropine for bradycardia), avoidance of non-steriodal anti-inflammatory agents (NSAI; one case with gastric ulcer) and epidural approach (two cases). For ambulatory surgery this comprised additional medication (five cases) and avoidance of NSAI (one case).
[c] Significant difference between groups, $p<0.01$.
[d] Instrument error comprised defective light cable, scope or camera (five patients), defective cauterizer (one inpatient and 1 day surgery patient) or defective Verres cannula (two patients); unknown for one patient.
[e] Significant difference between groups, $p<0.05$.
[f] Operative complications for inpatient surgery comprised one patient with perforation of the uterus and two patients who had laparotomy due to a large ovarian cyst and a tumour. Among the day surgery cases, one patient was admitted overnight for observation of syncope and another stayed an extra 6 h for observation of bradycardia.

3.4. Immediate recovery period

Ambulatory patients had an average length of hospital stay of 2 days (Table 4). Three-quarters of the patients in both groups received pain relief while in the recovery room, and 10–20% received anti-emetics. There were no statistically significant differences between the inpatient and ambulatory groups with respect to pain within the first 24 h after surgery. For both groups, pain at rest was significantly less 2 h after waking from operation and either remained at this level or was lower the following day. Pain on coughing was also less than 2 h after waking from operation, but greater pain was reported the day after operation. The majority of patients in both groups (64% of inpatient and 74% of ambulatory) had nausea at some stage within the first 24 h, while three patients experienced vomiting.

At discharge, most patients felt confident to go home (Table 4), although many reported problems related to the operation. These included pain (26.1% of inpatients and 51.4% of ambulatory patients; $p<0.05$), nausea (17.4% and 10.8%, respectively) and bleeding from the wound (8.7%

Table 4
Recovery data for inpatient surgery and day surgery groups

	Inpatient surgery ($n=26$)	Day surgery ($n=40$)
Length of stay (S.D.)	2.3 days (1.0)	0.0 days (0.1)[a]
Medication while in recovery		
Pain killers	73.1% ($n=19$)	77.5% ($n=31$)
Anti-emetics	19.2% ($n=5$)	10.0% ($n=4$)
Pain at rest (median VAS score, IQR, min–max)		
On waking	35.0 (46) 0–83	22.5 (34) 0–81
2 h later	13.5 (19) 0–32[b]	13.0 (19) 0–67[c]
One day after operation	11.0 (22) 0–56[b]	13.0 (22) 0–83
Pain on coughing (median VAS score, IQR, min–max)		
On waking	52.5 (47) 0–98	23.0 (41) 2–97
2 h later	24.5 (42) 0–87[d]	16.0 (39) 0–91[c]
One day after operation	42.5 (55) 0–78	25.0 (38) 0–82[e]
Nausea (median VAS score, IQR, min–max)		
On waking	1.5 (7) 0–95	1.0 (5) 0–23
2 h later	0.0 (3) 0–34	0.5 (2) 0–39
One day after operation	0.0 (9) 0–34	0.0 (1) 0–40
Later complications	0	2.5% ($n=1$)
Felt confident to be discharged	100% (23/23)	89.5% (34/38)
Had problems after discharge	39.1% (9/23)	57.9% (22/38)

[a] Significant difference between inpatient and day surgery groups, $p<0.001$.
[b] Significant difference compared to pain on waking, $p<0.001$.
[c] Significant difference compared to pain on waking, $p<0.01$.
[d] Significant difference compared to pain on waking, $p<0.05$.
[e] Significant difference compared to pain at 2 h, $p<0.01$.

and 10.8%, respectively). Only one (ambulatory) patient felt a need to ask hospital staff for more information after discharge; only one (ambulatory) patient had a later complication, being admitted for one night after an episode of syncope.

3.5. Later recovery period

In the month after operation, both groups reported more days off work than before the operation and fewer visited their doctor (Table 5). Approximately the same number of patients as before operation had pelvic pain, but this was less severe than in the month prior to operation, and significantly so for ambulatory patients. Pain levels were significantly less

Table 5
Health in the month after operation, for inpatient surgery and day surgery groups

	Inpatient surgery ($n=17$)	Day surgery ($n=32$)
Mean no. sick days (S.D.)	8.4 days (8.0)[a]	5.7 days (5.2)[b]
Consulted with doctor/hospital	50.0% ($n=8$)	40.6% ($n=13$)[b]
Daily life affected by gynaecological symptoms	70.6% ($n=12$)	65.7% ($n=21$)
Pelvic pain		
Median (IQR; min–max)	5.0 (4.0; 0–10)	3.0 (4.0; 0–10)[c]
Number of patients with pain	15/17 (88.2%)	25/32 (78.1%)

[a] Significant difference in comparison to before operation, $p<0.05$.
[b] Significant difference in comparison to before operation, $p<0.001$.
[c] Significant difference in comparison to before operation, $p<0.01$.

1 month after operation for both appraisal ($p=0.028$) and remedial ($p=0.015$) operations. Three ambulatory and one inpatient reported a changed employment situation as a consequence of the operation, where all had reduced the number of hours worked per week. The only significant difference between the groups was that ambulatory patients reported significantly less severe pain after operation than inpatients ($p<0.05$), although similar proportions of patients had pain.

4. Discussion

This RCT of inpatient versus ambulatory surgery for gynaecological laparoscopy revealed no major differences in patient outcome between the two groups. There were no significant differences in the level of pain or nausea experienced within the first 24 h after surgery; both groups reported significantly lower levels of pain within the first 24 h after surgery, as well as 1 month after surgery. There were fewer in both groups who sought medical consultation after operation and a similar percentage of patients reported problems after discharge. There were no significant differences between the groups with respect to feeling confident to go home, desire for additional information or the proportion with daily activities affected by gynaecological symptoms within the month after operation.

There were statistically significant differences with respect to some operative variables, however. Ambulatory patients had shorter anaesthesia, longer time in recovery and shorter hospital stay; they were also operated on by less senior surgeons, with a higher rate of instrument error, but had lower blood loss. The differences in seniority of surgeon are a reflection of the local organizational setup, where ambulatory surgery was typically conducted by a junior doctor under supervision; the greater instrument error here was presumably coincidental. The shorter anaesthesia for ambulatory surgery was partly related to a higher proportion of appraisal rather than remedial operations; but within the group of remedial operations, ambulatory surgery was still shorter than inpatient surgery. The longer recovery time for ambulatory surgery could be interpreted as an artefact; these patients stayed in the recovery room until they were ready to go home, whereas inpatients were transferred to the gynaecological ward soon after waking from operation.

The randomization process appears to have been successful in that the inpatient and ambulatory groups had similar characteristics prior to operation. These groups were a highly selected patient sample, however, with respect to previous gynaecological investigations, comorbidity and the presence of relatives who could help them after discharge from hospital. From the initial sample of 658 patients who were referred with an appropriate diagnosis, 36.3% did not fulfil the inclusion criteria, while a further 30.5% declined to be randomized—presumably largely because they had strong preferences for either inpatient or day surgery. A further 6.2% of potential participants had to be excluded prior to

randomization, leaving only 26.9% ($n = 177$) of the original sample available for randomization. This is similar to a RCT that investigated outpatient versus ambulatory hysterectomy (for uterine bleeding), where only 22% (100/454) patients agreed to participate in randomization [14].

The relatively low participation rate of 27% for the study as a whole serves as a reminder of the difficulties in achieving sufficient patient samples. In view of the need to identify patients who are suitable for ambulatory surgery [13], the preferences of some women for either inpatient or day surgery, and the time that may be spent on a waiting list, careful attention needs to be paid to inclusion criteria and length of patient enrolment (1.5 years in the current study) to ensure a sufficiently large patient base for randomization. There was, however, a high response rate among the patients randomized and operated, with nearly 100% completion of operative data and 73% completion of patient questionnaires.

The immediate postoperative symptoms that were experienced by patients in this study appeared to be typical for patients undergoing gynaecological laparoscopy under general anaesthesia. During the 1980s, several studies reported high postoperative morbidity after gynaecological laparoscopy for diagnosis or sterilization [15], with high incidences of nausea, vomiting and pain. Overnight admission rates for postoperative recovery problems after day surgery were typically 10% and follow-up questionnaires reported that 30% of patients undergoing day surgery would have preferred an overnight stay in hospital [15]. Since then, changes in anaesthesia practice have led to improved antiemetic therapy and faster patient recovery. It would appear that anaesthesia practice varies widely [16], as does the incidence of postoperative pain, nausea and vomiting [15,17–19]. The rapid postoperative improvement of VAS pain scores in the current study (from a median of 25.0 immediately after operation to 13.0 1 day later, on a 0–100 scale) is similar to that reported elsewhere [15,20] and reflects improvements in surgical techniques, anaesthesia practice and pain relief. The low rate of postoperative complications in the current study is also similar to that reported in the literature [21].

The patients in this study reported high levels of morbidity before operation. Around two-thirds reported that their daily life was affected by their gynaecological symptoms and the average pain score was 7.0 (on a scale from 0 to 10), reflecting that 80% of them had been referred for either endometriosis or pelvic pain. Although there were still approximately two-thirds of women who reported pelvic pain within the month after operation, the level of pain experienced was significantly lower than prior to operation (median of 3.0 after operation). These findings reflect previous reports of the effectiveness of laparoscopy in treating endometriosis [22]. It was surprising that the percentage of women who reported that their daily life was affected by their symptoms was unchanged after operation. These results may reflect a prolonged recovery time after an operation requiring general anaesthesia. Marley and Swanson [19] noted the paucity of research on the period of recovery after discharge from the ambulatory facility and before resumption of normal activities (Phase III recovery period). Despite the low rate of immediate postoperative complications, the patient may still experience problems at least within the first month after surgery. Besides pain, nausea and vomiting, post-discharge complaints after day surgery commonly include insomnia, constipation, myalgia and headache [19].

To the authors' knowledge, this is the first RCT comparing inpatient and ambulatory surgery for benign gynaecological laparoscopy. Despite intensive efforts over a 1.5-year period, the study resulted in a relatively small and self-selected sample, in that many potential participants either did not fulfil the inclusion criteria or declined to participate in a randomization process. Data collection was also time-consuming as little of the required data was routinely collected. Despite these drawbacks the study provides valuable comparative empirical data on the use of inpatient and ambulatory surgery for gynaecological laparoscopy. The results suggest that, for the particular patient groups under study, there are no major differences in operative and clinical outcome between inpatient and ambulatory approaches. Both groups reported significantly less postoperative pelvic pain and similar proportions experienced postoperative nausea and problems following hospital discharge. The surgeon's level of experience may influence the operative process with respect to aim of operation (remedial or appraisal surgery) and instrument use, but these trends did not reach statistical significance.

Future studies need to carefully consider the issue of patient recruitment in an RCT design, and should also attempt to follow clinical progress over a longer postoperative period, as it would appear that many patients still have problems 1 month after surgery.

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