GENERAL GYNECOLOGY

A randomized trial of day-case vs inpatient laparoscopic supracervical hysterectomy

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OBJECTIVE: To determine whether women having day-case laparoscopic supracervical hysterectomy are more or less satisfied with the length of hospital stay compared with women who stayed overnight after the procedure.

STUDY DESIGN: An randomized control trial of 49 women randomized to day-case or overnight hospital stay after laparoscopic supracervical hysterectomy. Satisfaction with length of hospitalization and quality of life were compared using the Mann-Whitney U test.

RESULTS: No group differences were found in satisfaction with length of hospital stay (P = .13). There was a nonsignificant trend toward greater anxiety in the day-case group (P = .06 on day 1 postoperative). Quality of life was lower in the day-case group on days 2 (P = .02) and 4 (P = .03), postoperatively.

CONCLUSION: Women having a day-case hysterectomy were discharged after median of 5 hours postoperative and were similarly satisfied as women hospitalized overnight. Quality of life, however, does appear to be compromised by day-case surgery.

Key words: ambulatory surgical procedures, day-case surgery, hysterectomy, laparoscopy, quality of life

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Improvements in surgical technology, analgesia, and anesthetics, along with an increasing pressure on hospital resources, have led to a decline in the length of time that patients stay in hospital. Indeed, the UK government target is to increase the day-case elective surgery rate within the National Health Service to 75% by 2010, having been found to be 68% in 2001.1 Outpatient hysterectomy, whether as vaginal hysterectomy, laparoscopic-assisted vaginal hysterectomy, or total laparoscopic hysterectomy and laparoscopic supracervical hysterectomy (LSH), have been a focus of interest of gynecologists for more than 2 decades2-8 and the feasibility and safety of LSH as a day-case procedure has been demonstrated.4-7,9-12 There are relatively few studies, however, that have considered women’s experiences of day-case hysterectomy. For example, Theli and Gamelin,9 in their small retrospective study of data obtained from patient notes, reported that the majority of women (95%) were satisfied with their day-case total laparoscopic hysterectomy and would recommend the procedure to others. Similarly, Lieng et al,7 in their prospective study of day-case supracervical hysterectomy found that almost all (95%) women were satisfied with the procedure and would recommend it to a friend. Whereas these studies do suggest that the women selected to day-case surgery were happy having a day-case hysterectomy, they do not examine whether this can apply to nonselected patient populations needing hysterectomy. None of these studies examines whether the experiences of women having their procedure done as a day-case procedure are different from those having it done as an inpatient.

In the Oslo University Hospital Ullevål, day-case LSH has been performed, in selected cases, since 2003. A prospective case study in 2005 demonstrated safety and high patient satisfaction with this approach.7 Since that time, the day-case facilities have gradually been expanded, and today approximately equal numbers of LSH procedures are performed in inpatient and in day-case settings. What remains unknown, however, is whether women having a day-case LSH are less satisfied with the shorter length of stay in hospital after their operation. We report on the findings of a randomized controlled trial that set out to answer this question.

MATERIALS AND METHODS

Our hypothesis was that women who had a day-case LSH would be less satisfied with the length of hospital stay when compared with women who had an overnight stay after a LSH. The null hypothesis was that there was no difference in satisfaction with length of hospital stay.

The study was performed at the Department of Gynaecology, Oslo University Hospital Ullevål, in Oslo, Norway, and was approved by the Regional Committee for Medical and Health Research Ethics South-East Region, Norway. The population from which we recruited our sample were women listed to have a hysterectomy between November 2008 and
May 2009. Women were excluded if they had a previous history of cervical dysplasia, an abnormal smear test within the last 2-3 years, abnormal histology or cytology at endometrial sampling, a history of endometriosis, advanced endometriosis diagnosed intraoperatively, previous major abdominal or pelvic surgery (patients with previous cesarean section were considered as eligible), a mental disorder or somatic disease that would interfere with a normal recovery pattern such as substance dependence disorder, psychosis, or American Society of Anesthesiologists score 3 and 4 patients, and inability to understand and execute oral and written Norwegian language. Women were also excluded from the study if they did not have an adult carer (a relative or a friend) staying with them during the first night after discharge, or they were living or staying at a hotel more than an hour’s drive from the hospital, and if they did not have access to a telephone.

All eligible women were invited to participate in the study once a decision to have a hysterectomy was made at the outpatient clinic. They were provided with information about the study and were then contacted 1-2 weeks later to ascertain whether they were happy to take part in the study. Having agreed to participate in the study, women were randomized to either have a day-case or inpatient care.

The randomization process was carried out using a Web-based randomization number generator (www.randomisation.com) and was undertaken by an external center for clinical research at the Norwegian Radium Hospital. Once women agreed to participate in the study, the clinician obtaining consent telephoned the external center to ascertain the group allocation. Women were then informed about what group they were in so that they could plan for their surgery. It was not possible to blind either the participants or the medical and nursing staff caring for the women.

Sample size
The sample size calculation was based on the primary outcome measure, satisfaction with length of hospital stay. It was measured on a 100-point visual analogue scale, a score of 100 indicating that women were completely satisfied. Although there are published data on general satisfaction with outpatient LSH, there do not appear to be any data on satisfaction with length of stay in hospital. We therefore conducted a pilot study to allow us to make a sample size calculation. In this pilot study, 11 consecutive women who had an inpatient LSH were surveyed by telephone. All women had their procedures performed during February or March 2008, approximately 1 month before they were surveyed. They were asked to imagine a scale ranging from 0-100, where 0 meant not at all satisfied and 100 meant completely satisfied with the length of time they spent in hospital after their surgery, and then asked to say where on the scale they would rate their satisfaction. The mean satisfaction score was 93.22 (SD, 11.11). Because general satisfaction after LSH is high, with the majority of women reporting total satisfaction,
There was a 64% response rate when recruiting women for the study; 49 of the total of 77 women scheduled for a LSH.

LSH, laparoscopic supracervical hysterectomy.

ference in the treatment received by the 2 groups was the length of hospitalization after the surgery, the primary outcome of the study is defined as patients’ satisfaction with the length of hospitalization after the surgery. This was measured on a visual analogue scale from 0-100, with 0 representing not at all satisfied and 100 representing complete satisfaction.

Health-related Quality of Life (HrQoL) was measured using a generic measure, the self-completed EQ-5D (EuroQol Group, Rotterdam, The Netherlands) descriptive scale. The EQ-5D has 5 domains: mobility, self-care, usual activities, pain/discomfort, and anxiety/depression, each of which is generate a score from 0-2. A final score, EQ-5D index, ranging from −0.59 to 1 is then calculated: 1 representing the best possible health. The instrument has been shown to be valid and reliable for use in a wide range of health conditions and can be administered daily. The EQ-5D is also simple and quick to complete.

Anxiety was measured using the State-Trait Anxiety Inventory for Adults (STAI). In addition to the measures previously described, we also asked women some questions about their overall experiences of having the surgery.

To follow the progress of recovery during the first week after the operation, the EQ-5D was administered on days 0, 1, 2, 4, and 7; the STAI was administered on days 0, 1, 2, and 7 postoperatively and the satisfaction with length of hospital stay was measured on day 7 postoperatively.
Data analysis
The data were analyzed according to an intention-to-treat analysis. Group differences were investigated in the following ways: Nonparametric data (satisfaction with length of hospital stay, EQ-5D, STAI) were analyzed using the Mann-Whitney U test. Similarly, potential differences in nonparametric baseline measures (ie, age, size of uterus body mass index [BMI], previous surgery, education level) were analyzed using the Mann-Whitney U tests and χ² tests. P values of less than .05 were regarded as significant.

RESULTS
Recruitment
A total of 77 women were considered to be potentially eligible for the study, but 28 of these women were not recruited (11 did not meet the inclusion criteria, 6 did not have the language skills to participate, and 5 had multiple morbidities). Of the remaining 17 nonincluded women, 6 were informed in advance by the referring gynecologist that their LSH would be performed as day-surgery and they did not want to be randomly assigned. 5 women insisted on an overnight stay for various reasons, 4 women in the absence of the study coordinator were seen by other consultants in the department who failed to invite the patients to take part in the study and finally 2 women did not want to participate in research studies in general.

Twenty-five women were recruited to the day-case group and 24 to the inpatient group. Two women in the day-case group were lost to follow-up, as was 1 woman in the inpatient group. An additional woman in the inpatient group dropped out of the study when she cancelled her operation (Figure 1). This left a total of 23 women in the outpatient group and 22 in the inpatient group.

Six women in the inpatient group did not complete their treatment according to the group allocation as they requested to be discharged home on the day of their operation. In addition, 2 women in the inpatient group had prolonged hospitalization because of complications (1 required surgical repair of a bladder perforation, which was detected on the first postoperative day, and the other had a hypertensive crisis on the first postoperative day). All women in the day-case group completed the treatment according to the allocation, although 1 woman was readmitted to the hospital approximately 6 hours after she was discharged because she felt dizzy.

Baseline measures
Analysis of the baseline measures for women in both groups revealed that the groups were similar (Table 1), apart from BMI, with women in the day-case group being larger (median BMI 26) than women in the inpatient group (median BMI 22) (P = .03). Although statistically significantly different, this finding was not considered to be clinically significant.

Women in the day-case group had their operation at an earlier time of the day (median of 09.55 AM) than women in the inpatient group (median of 11.17 AM) (P = .003). This was because some of the operations in the inpatient group started later than planned because of emergency cases.

Satisfaction with length of stay in hospital
As displayed in Table 2, women having an inpatient hysterectomy appeared to be more satisfied (median score, 100; range 40–100) than those having a day-case procedure (median score 90; range 0–100), although these differences did not reach statistical significance (P = .13).

Quality of life and anxiety
Thepossible EQ-5D index values range from 1.00 to −0.59 to where 1.0 = perfect health and −0.59 is worst imaginable health state. As displayed in Figure 2 and Table 3, based on the measures taken over the first postoperative week, women having a day-case hysterectomy reported a lower quality of life after surgery than those in the inpatient group (P = .03). Looking at the quality of life measures on individual days, we found significant differences in quality of life occurring on day 2 and day 4, postoperatively (Table 3).

Within group analysis of the quality of life measures revealed that each of the groups had a lower quality of life on the day of the operation (measures taken median 9 hours postoperatively) when compared with the preoperative values (P < .01). The quality of life measures did not improve in either group from day 0 to day 1 but by day 2, the inpatient group started to report an improved quality of life when compared with day 1 (P < .01). Both groups reported a statistically significant improvement in quality of life between days 2 to 4 and days 4 to 7 after the operation. By day 7, the quality of life scores reported by the inpatient group were not statistically significantly different from the preoperative values, but the day-case group would have been lower due to the nature of the day-case procedure.

TABLE 2
Satisfaction with length of stay in hospital

<table>
<thead>
<tr>
<th>Satisfaction with length of hospital stay</th>
<th>Inpatient n = 22</th>
<th>Day-case n = 23</th>
<th>Mann-Whitney U (P value)</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>0</td>
<td>4</td>
<td></td>
</tr>
<tr>
<td>40</td>
<td>1</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>60</td>
<td>1</td>
<td>2</td>
<td></td>
</tr>
<tr>
<td>70</td>
<td>0</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>80</td>
<td>4</td>
<td>2</td>
<td></td>
</tr>
<tr>
<td>90</td>
<td>2</td>
<td>2</td>
<td></td>
</tr>
<tr>
<td>100</td>
<td>14</td>
<td>11</td>
<td></td>
</tr>
<tr>
<td>Median (range)</td>
<td>100 (40–100)</td>
<td>90 (0–100)</td>
<td>.13</td>
</tr>
</tbody>
</table>

0 = totally unsatisfied, 100 = totally satisfied.

continued to report a lower quality of life compared with preoperatively ($P = .02$).

There was a trend toward women having a day-case hysterectomy reporting greater anxiety than those in the inpatient group on days 0, 1, and 2, postoperatively, although these differences did not reach statistical significance (Table 4).

**Pain and nausea**

Women having a day-case hysterectomy did not report any higher levels of pain or nausea on the first postoperative day than those women in the inpatient group ($P = .44; P = .89$).

**COMMENT**

This study shows that women having a day-case LSH and those having an inpatient procedure were equally satisfied with the length of stay they had in hospital. However, although the groups were equal in their satisfaction, the women having a day-case hysterectomy reported a poorer health-related quality of life on days 2 and 4 postoperatively compared with women having an inpatient procedure. Similarly, although not statistically significant, there was a trend toward greater anxiety after surgery among women having a day-case hysterectomy, compared with women having an inpatient procedure.

It is important to recognize that, although we did not find an overall group difference in the satisfaction with length of hospital stay, 4 women (17%) in the day-case group reported being extremely dissatisfied with the length of time they spent in hospital, rating this as 0 on a 0-100 point scale. Furthermore, 6 women (27%) allocated to the inpatient group, spontaneously discharged themselves on the day of their operation. Being part of the trial highlighted women to the fact that it was possible to go home on the day of surgery, despite their being allocated to the inpatient group. As described in the Materials and Methods section, however, the data were analyzed on an intention-to-treat basis. The fact that almost a quarter of women in both of the groups appeared to be unhappy with their length of stay in hospital (illustrated by self-discharge or by rating their satisfaction with length of stay as poor) suggests that there is a need for individual choice over whether to have a day-case or inpatient procedure. This confirms the findings by Dobbs et al, where 31% of women having either a diagnostic laparoscopy or a laparoscopic sterilisation stated that they would have preferred to have had an overnight stay in hospital.

Although we found an overall poorer quality of life and a daily trend toward poorer quality of life reported by women having a day-case hysterectomy when compared with those having an inpatient procedure, the specific days when we observed significant differences were on days 2 and 4, postoperatively. One possible explanation for these significant differences on days 2 and 4, postoperatively, may relate to women’s expectations of how they should feel by the second and fourth postoperative day. For example, it is possible that when you have a day-case procedure, your percep-
tion of the severity of the operation may mean that you expect to be mobile and pain-free more quickly than if you have an inpatient procedure. This would fit with other research that has demonstrated that anxiety and pain levels are particularly problematic on the fourth postoperative day after abdominal surgery \(^1\) and that following day-case laparoscopic surgery, women continue to have pain and fatigue up to 4 days postoperatively.\(^1\)

A further explanation might be that women who have stayed in hospital overnight have had the opportunity to recover more fully from their operation and are more rested when they go home, whereas women having a day-case procedure may struggle to cope on the first postoperative day and become more uncomfortable by the second and fourth postoperative day. Indeed, in a follow-up study of women having either a day-case diagnostic laparoscopy or laparoscopic sterilization, 11 (8\%) of women called out their family doctor within 24 hours of being discharged from hospital.\(^1\) Because we found a nonsignificant trend toward women having a day-case hysterectomy being more anxious after surgery than women having an inpatient procedure, it would seem that for some women, the ability to cope after discharge on the day of surgery may influence reported quality of life.

Although we were looking specifically for group differences, it is worth noting that the daily measures of HrQoL improved after the initial postoperative drop on the day of surgery. Indeed, by day 7, both groups of women had almost reached their preoperative quality of life level, suggesting that recovery from LSH is speedy.

One of the strengths of this study is that it is a randomized controlled trial and therefore potential biases have been minimized. Although we experienced some difficulties maintaining group allocation, our use of an intention-to-treat analysis means that we have presented the data that would reflect the “real world” situation. Moreover, we had a good response rate when recruiting women for the study; 49 of the total of 77 women scheduled for a LSH (64\%), which means that we can be confident of the generalizability of our results.

One possible limitation to the study is that despite our intention to measure purely the patients’ satisfaction with the length of stay in the hospital— we made it clear in the recruitment material as well as in the follow-up questionnaire that we wanted them to rate their satisfaction in length of hospital stay—women’s responses may partially reflect their overall satisfaction with the whole hospital experience.

A further concern is that although our study was designed to detect changes in satisfaction with length of hospital stay (to detect a 10 point difference on a 0-100 scale), the sample size may not have been adequate to detect fairly small, but clinically relevant differences in anxiety. Further research in this area should focus on investigating whether there are clinically important differences in anxiety and quality of life between women having day-case procedures and those having an inpatient procedure.

In conclusion, women having a LSH generally report being satisfied with the hospital length of stay and having the procedure performed as a day-case or an inpatient does not appear to influence this satisfaction. Nevertheless, a small minority of women having both a day-case and an inpatient procedure, appear to be very dissatisfied with the length of hospital stay, suggesting that individual choices over hospital stay should be offered.

Women having a day-case procedure appear to report a poorer HrQoL during the postoperative period, which may be

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**TABLE 3**

**Quality of life**

<table>
<thead>
<tr>
<th>Measurement day</th>
<th>Inpatient 21 (^a)</th>
<th>Outpatient 23</th>
<th>Mann-Whitney U (P value)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Day 0</td>
<td>0.56 (0.26-0.65)</td>
<td>0.26 (0.22-0.58)</td>
<td>.22</td>
</tr>
<tr>
<td>Day 1</td>
<td>0.59 (0.36-0.69)</td>
<td>0.43 (0.26-0.58)</td>
<td>.24</td>
</tr>
<tr>
<td>Day 2</td>
<td>0.69 (0.58-0.76)</td>
<td>0.59 (0.26-0.69)</td>
<td>.02</td>
</tr>
<tr>
<td>Day 4</td>
<td>0.76 (0.68-0.88)</td>
<td>0.69 (0.26-0.76)</td>
<td>.03</td>
</tr>
<tr>
<td>Day 7</td>
<td>0.79 (0.69-0.91)</td>
<td>0.76 (0.69-0.88)</td>
<td>.47</td>
</tr>
<tr>
<td><strong>AUC EQ-5D index</strong></td>
<td>4.7 (2.6-6.2)</td>
<td>4.1 (1.0-5.8)</td>
<td>.03</td>
</tr>
</tbody>
</table>

Quality of life measured by EQ-5D (EuroQol Group, Rotterdam, The Netherlands) administered on days 0, 1, 2, 4, and 7. AUC, area under the curve.

\(^a\) One woman did not complete the quality of life measures.

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**TABLE 4**

**Anxiety scores**

<table>
<thead>
<tr>
<th>STAI-state score (^a)</th>
<th>Inpatient median (range)</th>
<th>Day-case median (range)</th>
<th>Mann-Whitney U (P value)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Day 0</td>
<td>30 (20-44)</td>
<td>35 (21-48)</td>
<td>.11</td>
</tr>
<tr>
<td>Day 1</td>
<td>30 (20-44)</td>
<td>35 (21-63)</td>
<td>.09</td>
</tr>
<tr>
<td>Day 2</td>
<td>30 (20-50)</td>
<td>33 (23-59)</td>
<td>.12</td>
</tr>
<tr>
<td>Day 7</td>
<td>28 (20-51)</td>
<td>27 (20-50)</td>
<td>.60</td>
</tr>
</tbody>
</table>

STAI, State-Trait Anxiety Inventory for Adults.

\(^a\) The range of STAI scores is 20-80, the higher the score indicates greater anxiety.

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related to greater levels of anxiety. It is possible that provision of a telephone support line may provide women with easy access to a health care professional, who can help with any postoperative concerns. Further research, should investigate the possible reasons for a poorer reported quality of life during the postoperative period and whether a phone-in support line is of value.

ACKNOWLEDGEMENTS
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REFERENCES