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**A research article entitled**

# **Cost-effectiveness of general anesthesia versus spinal anesthesia in fast track abdominal benign hysterectomy.**

by

<sup>1</sup>Ninnie BORENDAL WODLIN, MD, <sup>2</sup>Lena NILSSON, MD, PhD, <sup>3</sup>Per CARLSSON, PhD and <sup>1</sup>Preben KJØLHEDE, MD, PhD,

<sup>1</sup>Division of Obstetrics and Gynecology, Department of Clinical and Experimental Medicine, Faculty of Health Sciences, Linköping University. Department of Obstetrics and Gynecology, County Council of Östergötland, S - 581 85 Linköping, Sweden

<sup>2</sup>Division of Drug Research, Anesthesiology and Intensive Care, Department of Medical and Health Sciences, Linköping University. Department of Anesthesia and Intensive Care, County Council of Östergötland, S - 581 85 Linköping, Sweden

<sup>3</sup>Centre for Medical Technology Assessment, Department of Medical and Health Sciences, Linköping University, S - 581 85 Linköping, Sweden

Corresponding author:

Ninnie Borendal Wodlin, MD  
Department of Obstetrics and Gynecology  
University Hospital  
S-581 85 Linköping  
Sweden  
Phone +46 10 103 00 00  
Fax +46 13 14 81 56  
e-mail Ninnie.Borendal.Wodlin @lio.se

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## **Abstract**

*Objective:* The study objective was to compare total costs for hospital stay and postoperative recovery for two groups of women who underwent fast track abdominal benign hysterectomy, one group under general anesthesia, the other under spinal anesthesia. Costs were evaluated in relation to health related quality of life.

*Study Design:* Costs of treatment using data from a randomized multicenter study at five hospitals in Sweden were analyzed retrospectively. Of 180 women scheduled for benign abdominal hysterectomy; 162 were randomized for the study, 80 allocated to general anesthesia and 82 to spinal anesthesia.

*Results:* Total costs (hospital costs plus costs reduced productivity costs) were lower for the spinal anesthesia group. Women who had spinal anesthesia had a faster recovery measured by health related quality of life and QALYs gained in postoperative month one.

*Conclusion:* Use of spinal anesthesia for fast track benign abdominal hysterectomy was more cost-effective than general anesthesia.

*Name of the authors:*

Ninnie Borendal Wodlin; Lena Nilsson; Per Carlsson; Preben Kjølhede

*Keywords:*

Cost-effectiveness; Fast track hysterectomy; General anesthesia; Health economy; Spinal anesthesia

## **Introduction**

Hysterectomy is the most common major gynecological operation in Europe and the United States and is usually performed through laparotomy as an in-hospital procedure<sup>1</sup>. Various fast track strategies have been developed to enhance postoperative recovery and shorten hospital stay following general surgery<sup>2</sup>, but these strategies have hardly been studied at all for gynecological surgery<sup>3-5</sup>. Effective analgesia that allows early mobilization is essential for improved postoperative recovery<sup>6</sup>. Perioperative regional anesthesia is often used in fast track programs. Spinal anesthesia with intrathecally applied opioids may further optimize postoperative pain management after open hysterectomy<sup>7,8</sup>.

Economic evaluations are needed in addition to the evaluation of clinical effects in order to make rational decisions regarding the acceptance of new treatments and the resulting consumption of health resources<sup>9</sup>. Relating direct and indirect costs of different treatments to the perceived health related quality of life (HRQoL) of the patients enables comparison of cost-effectiveness. Such analysis is essential in order to determine the most cost-effective treatment and to strengthen the possibility of acceptance and implementation of a new health technology. Multimodal evidence-based care within fast track strategies in general surgery has been shown to enhance postoperative recovery but no economic analyses of these strategies have been presented<sup>6,10</sup>. Studies of fast track hysterectomy report encouraging improvements in clinical outcomes but these studies also lack health economic evaluations<sup>3-5</sup>.

We conducted the open randomized multicenter study comparing general anesthesia (GA) and spinal anesthesia with intrathecal morphine (SA) in fast track abdominal benign hysterectomy (the GASPI study). Results concerning clinical outcomes have been presented previously<sup>11-13</sup>. SA was found to have substantial advantages as concerned perceived postoperative symptoms during recovery, HRQoL and duration of sick leave.

One aim in the GASPI study was to investigate costs and HRQoL in relation to mode of anesthesia in order to evaluate the cost-effectiveness of SA compared with GA in fast track

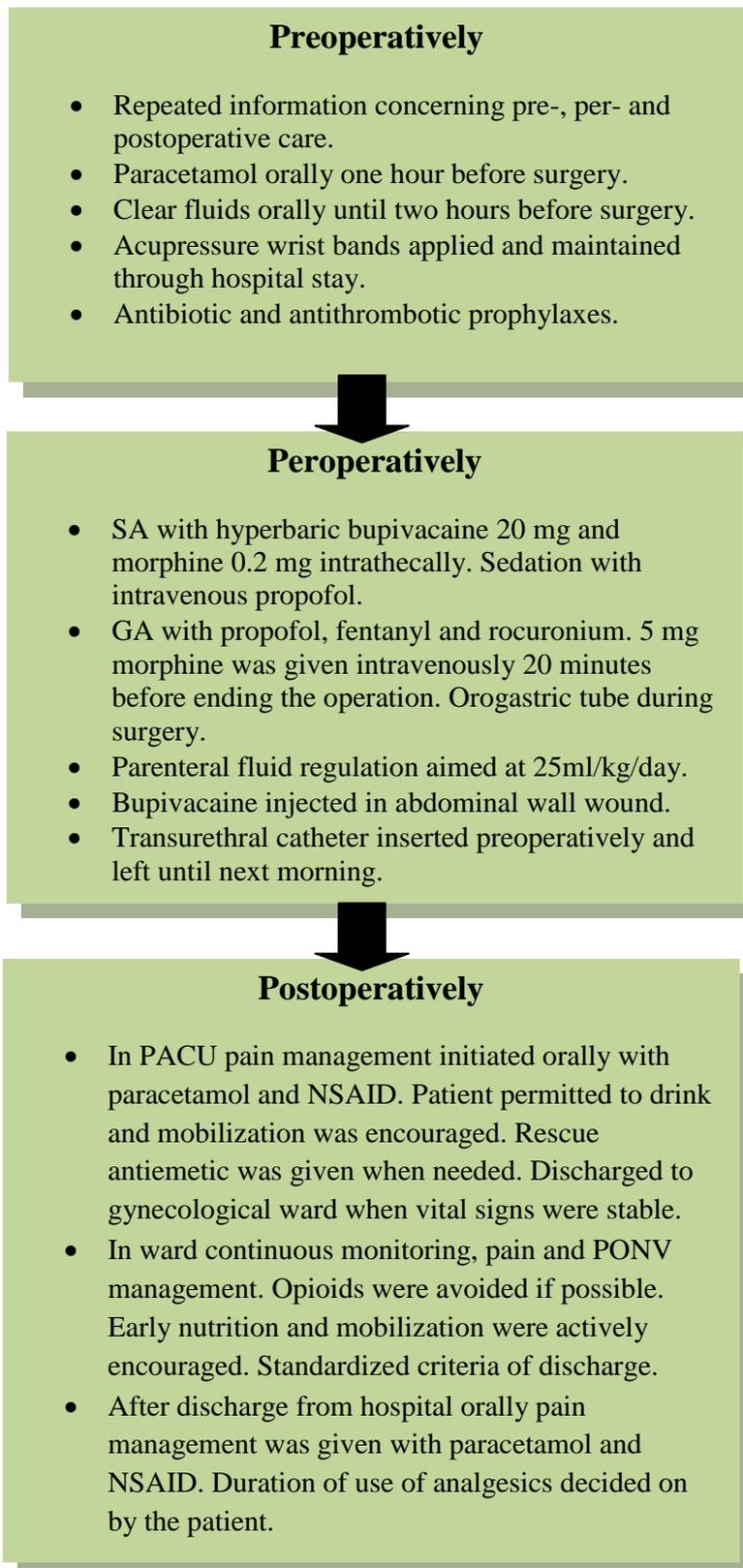
hysterectomy. The purpose of this health economic analysis was to evaluate whether costs from a societal perspective differed between women who underwent fast track abdominal benign hysterectomy in GA or in SA. The cost calculations were then evaluated in relation to effects on HRQoL.

## **Material and Methods**

The Departments of Obstetrics and Gynecology at five hospitals in the southeast health region of Sweden participated in the GASPI study. The study was approved by the Regional Ethical Review Board in Linköping (Dnr M159-06, approval date November 15, 2006) and registered in Protocol Registration System (NCT00527332; [www.ClinicalTrial.gov](http://www.ClinicalTrial.gov)) with initial release September 7; 2007. In the study, two different perioperative anesthetic techniques in a fast track program were compared.

The inclusion and exclusion criteria, randomization process, perioperative care, postoperative follow-up and study flow chart have been described previously<sup>11</sup> therefore only a brief summary is presented here. Women who were admitted to the hospitals for elective abdominal hysterectomy between March 2007 and June 2009 were asked to participate. After they had given verbal and written informed consent the enrolled women were randomized to receive either general anesthesia or spinal anesthesia including intrathecal morphine. Of the 180 women who were randomized, 162 completed the study. Both modes of anesthesia were standardized and given in conventional ways. Premedication, a summary of the modes of anesthesia and the content of the fast track program are presented in Figure 1.

In Sweden, the anesthetic service in the operation theatre is routinely provided by an anesthesiologist who is responsible for several concurrently ongoing operations. In addition, an anesthetic nurse is present in each single operation theatre and has responsibility for supervising the single operation in that theatre. The anesthesiologist, who participates in the induction of anesthesia and is present until the patient is stable, then supervises the anesthesia by making frequent visits to each patient. The anesthesiologist is continuously accountable and is available in each operating theatre on request of the anesthetic nurse. Spinal anesthesia is only performed by anesthesiologists. When the anesthetic level is found adequate and the patient is stable in vital signs, an anesthetic nurse is primarily responsible for the patient as in general anesthesia. The hysterectomy was performed as a standard extrafascial abdominal



GA=General anesthesia. NSAID=non-steroidal anti-inflammatory drugs. PACU=post anesthesia care unit. PONV=Postoperative nausea and vomiting. SA= Spinal anesthesia with intrathecal morphine.

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Figure 1. Fast track protocol with standardized regimes.

hysterectomy- total or subtotal with the surgeon's routine technique. All surgeons were accustomed to doing gynecological and obstetric surgery performed under spinal anesthesia, but abdominal hysterectomy is usually carried out under general anesthesia.

*Assessments of HRQoL*

The assessment of HRQoL was based on results from the EuroQol instrument EQ-5D. The woman completed the EQ-5D form preoperatively, then daily during the first week after surgery and then once weekly until the 5-week postoperative visit. The EQ-5D is a validated generic measure of health status comprising five dimensions of health (mobility, self care, ability to undertake usual activities, pain/discomfort and anxiety/depression). Each dimension comprises three levels ("no problems", "moderate problems" or "severe problems"). A unique EQ-5D health state is defined by combining one level from each of the five dimensions. This health state can be converted into utility using a weighted health state index by applying scores from EQ-5D value sets elicited from the general population samples to calculate HRQoL<sup>14</sup>. The index ranges from 0 to 1. Zero indicates the state of death and 1 full health.

In order to estimate the number of quality adjusted life-years (QALYs) we used the average differences in health state index scores between the SA group and the GA group. For the first week the differences in measured QoL (a weight 0-1) between the study groups were calculated for each day. For the second to the fourth week the average differences per week were calculated based on mean health state index scores on day 7, 14, 21 and 28, respectively. The day differences were summed together and divided by number of days with a gain in QoL ( $1.86/29=0,064$ ). We assume no effect after day 29. The gain in QoL during 29 days/365 days = 0.08 of a whole year is expressed in average gain representing Quality adjusted life year (QALY) per patient.

*Diary concerning informal care*

At discharge the woman was instructed to complete a diary once a day for 35 days postoperatively and to report in this diary the kind and extent of postoperative support with

informal care, if any, performed by a relative, friend, or neighbor. The time spent with informal care was reported by the patient in hours per week and subsequently added up for all weeks.

*Direct costs*

The most relevant direct costs related to hospital stay were calculated for the GA and SA group respectively using costs from year 2010. The costs were calculated in Swedish kronor (SEK) and converted into US Dollars (USD) by using the average exchange rate in 2010; 1 USD = 7.20 SEK.

A standard unit cost for time spent in the operating theatre was estimated based on cost accounting records from the University Hospital, Linköping, for the year 2010. The use of a standard unit cost was justified by the fact that there were no significant differences between the study groups concerning time of anesthesia, time of surgery and costs of devices and material. Furthermore, the duration of hospital stay prior to anesthesia was similar in the two groups. The cost included a fixed once-for-all cost and a variable cost depending on the duration of surgery. The costs for the anesthetic drugs and the time for the anesthesiologist to administer the anesthesia are presented separately.

The cost for the anesthesiologist was calculated as a mean of the yearly salary from all relevant categories of anesthesiologists in Sweden multiplied by 1.5 to include the social benefits regulated by law. A full-time anesthesiologist works approximately 200 days annually and the time spent in the operating theatre is approximately eight hours per day. With a mean annual cost of 128 600 USD this yields a cost per minute of 1.34 USD. The time for the anesthesiologist to administer the anesthesia was estimated to be 25 minutes for SA and 15 minutes for GA, respectively.

Time in the post-anesthesia care unit (PACU) was determined as time from arrival from operating theatre until discharge to the gynecological ward. A standard unit cost per minute was estimated from cost accounting records from the University Hospital, Linköping for the

year 2010. Duration of hospital stay in the gynecological ward was determined as time from start of anesthesia to discharge. Costs for hospital stay in the ward were derived from cost accounting records of the Department of Obstetrics and Gynecology, University Hospital, Linköping and included salaries for all types of personnel involved, analyses of blood samples and the use of pharmaceuticals. Costs for facilities, heating, cleaning and buildings were also included. Duration of hospital stay was calculated as time in hours from start of anesthesia until discharge from the gynecological ward.

Costs in USD for all items are shown in Table 1. There were no differences between study groups concerning rates of complications and outpatient visits, therefore no separate calculations of these costs were done.

#### *Indirect costs*

##### *Sick leave*

At discharge from the hospital the woman was granted sick leave for 14 days. On the basis of the woman's demand, the sick leave was prolonged by at most seven days at a time until the woman was able to return to work. The number of days of sick leave was registered, including adjustment for part time sick leave. Duration of the sick leave was defined as the time from the day of surgery to the day of return to work to the same extent as the woman had preoperatively. Women who were on sick leave for other reasons than the hysterectomy, were unemployed or who had a disability pension were excluded from the analysis of sick leave.

Costs for productivity loss due to sick leave were estimated by the human capital approach, based on the average annual income for women in Sweden 2008, aged 20-64 years, multiplied by 1.5 to include social benefits<sup>15</sup>. The annual income was divided by 365 to get the cost of productivity loss per day, weekends included (Table 1).

##### *Statistics*

All analyses were performed according to intention-to-treat principles. Data are expressed as mean and standard deviation or number and per cent. In case of missing data the number of

participants for the specific item is noted in the text or Table. Univariate analyses were performed with Student's t-test (two-sided) for continuous data and with Yates corrected  $\chi^2$  test or Fishers' exact test, as appropriate, for nominal data. Analyses of data measured repeatedly were done by means on repeated-measures analysis of variance. Level of significance was set at  $p < 0.05$ . The software Stat View for Windows, SAS Institute Inc. Copyright© 1992 - 1998, Version 5.0.1 was used for the statistical analyses.

## **Results**

The study flow chart is shown in Figure 2. Eighty women received GA and 82 SA. The SA did not provide sufficient analgesia for surgery to be carried out in eight women. These women therefore also received GA according to the study protocol. Two women in the GA group experienced severe pain in the immediate postoperative period in PACU despite having received accurately administered intravenous opioids. As a result they received a supplementary regional anesthesia for postoperative pain management consisting of a continuous epidural analgesia using ropivacaine in the one case and a single dose of intrathecal sufentanil in the other case.

Basic demographic and clinical data are presented in Table 2. Eleven women, seven in the GA group and four in the SA group, did not receive a sick leave. In the GA group five women had a disability pension and two women were on a sick leave preoperatively. In the SA group two women had a disability pension and two women had a present preoperative sick leave.

There was no significant difference between study groups concerning use of informal care. Total costs for SA and GA respectively, divided into direct and indirect costs, are shown in Table 3.

The health state index score at baseline did not differ significantly between the study groups. Health state index measured day-by-day the first week and then once weekly until day 28 postoperatively in the SA and GA group are shown in Figure 3. Estimation of gained QALYs was based on the summed average difference in health state index scores between the SA and the GA group for the first 29 postoperative days. Each woman in the SA group gained 0.0051 QALYs compared with those in the GA group during this time period.

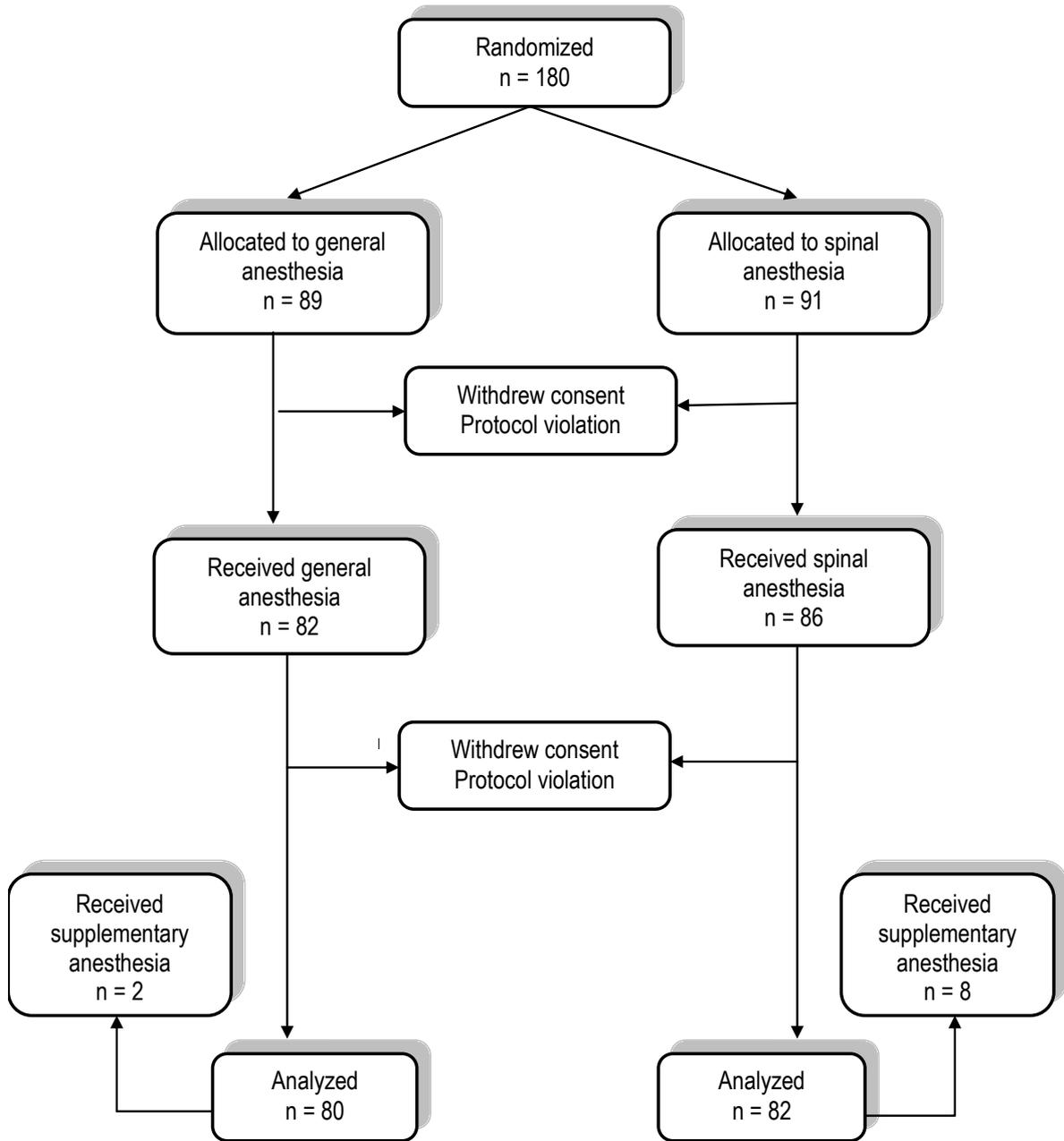
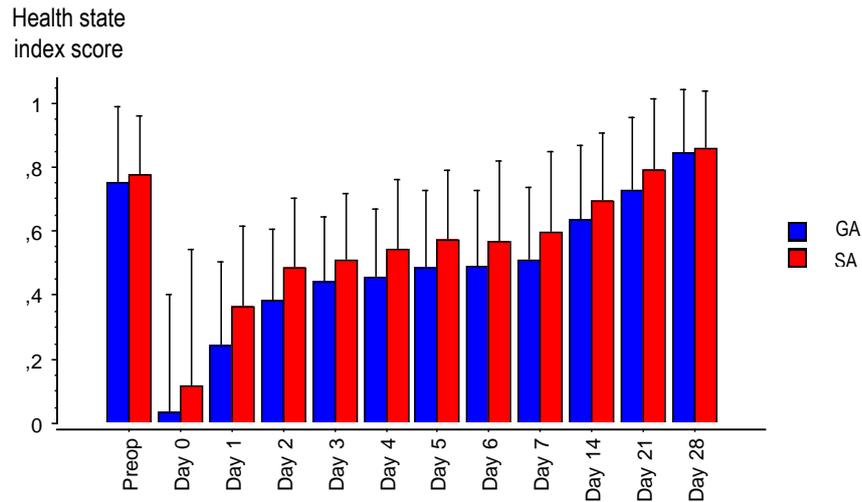


Figure 2. Flow chart of study participants.



Repeated measures analysis of variance  
(Day 0 – Day 28)

Main effect between mode of anesthesia	Main effect over time	Interaction effect
$F_{df=160} = 8.182$	$F_{df=10} = 204.914$	$F_{df=10} = 0.926$
$p = 0.0048$	$p < 0.0001$	$p = 0.5078$

Box plots represent means and bars indicate one standard deviation. GA = general anesthesia and SA = spinal anesthesia with intrathecal morphine.

Figure 3. EQ-5D health state index scores in relation to time of measurement.

## **Comment**

The main finding of this study was that spinal anesthesia with intrathecal morphine was more cost-effective than general anesthesia employed for benign hysterectomy in a fast track model. Spinal anesthesia contributed to lower costs, both direct and indirect, in comparison with general anesthesia. Women in the spinal anesthesia group had a faster recovery measured by HRQoL which consequently provided more QALYs gained for the initial 29 days postoperatively.

The primary endpoint of the GASPI study was duration of hospital stay but the health economic evaluation was included as a secondary endpoint in the study protocol. However, although data on clinical outcomes were collected prospectively the costs were estimated retrospectively using the de facto cost accounting records and hospital prices derived from the year 2010 and costs for productivity loss due to sick leave from annual income for women in Sweden 2008. This implies that the total costs are not exact, but the proportionality in the costs between the groups persists and thus makes comparison of costs between the two treatments valid.

The use of a standard unit cost in the operating theatre was justified by non significant differences in time of anesthesia and surgery and use of devices and material in association with the hysterectomy. Relevant costs that differed are presented separately including time for anesthesiologist to induce anesthesia and costs for anesthetic drugs.

Studies of fast track general surgery rarely include cost analyses<sup>2,16,17</sup>. Clinical outcomes speak in favor of cost-effectiveness even though no analyses have previously been presented. In previous studies concerning fast track hysterectomy no economic evaluations have been presented<sup>5,18</sup>. Studies of cost-effectiveness comparing hysterectomy performed via laparoscopy, vaginal or the abdominal route do not include fast track recovery programmes<sup>9,19,20</sup>. These studies were not able to identify the most cost-effective method for hysterectomy.

A few studies have presented results comparing SA with GA in abdominal hysterectomy<sup>5,21</sup>. In these studies SA provided substantial benefits regarding clinical outcomes as judged from the partial evaluations presented but HRQoL and cost-effectiveness were not covered. We have earlier presented outcomes concerning HRQoL in connection with fast track hysterectomy and demonstrated the advantages of SA regarding improvement in HRQoL and the rate of postoperative recovery including duration of sick leave<sup>13</sup>. In the present study we focused on costs and effectiveness. SA was a less costly procedure mainly dependent on the shorter duration of sick leave. We excluded an extreme outlier in the SA group in the analysis of sick leave. She had a prolonged sick leave of 258 days due to neuralgic pain in the right hip and thigh following several attempts to apply the anesthesia. This is a well-known but very rare complication to spinal anesthesia, otherwise providing several improvements for the patient. Neuropathy associated with spinal anesthesia occurs in less than 4 per 10 000<sup>22</sup>. In comparison, severe morbidity or mortality in association with general anesthesia has a similar prevalence<sup>23</sup>. The costs of a very rare complication that by chance may occur in a small sample have an inappropriate influence and will skew the health economic evaluation and thus not give a realistic comparison based on typical utilization and costs.

The women in the SA group had a significantly shorter sick leave possibly partly reflecting the faster recovery of HRQoL. In addition, sick leave in the SA group was apparently shorter than that usually reported after hysterectomy, which also could reflect the advantages of the enhanced postoperative recovery program<sup>13,24,25</sup>.

Informal care is a less visible part of total care in terms of costs and effects<sup>26</sup> and has so far never been presented in association with fast track surgery. Informal care was included in our study to visualize the total amount of provided hours of care by the caregivers. Informal care did not differ between study groups; hence no calculation of the value of care has been made. The trend in small numbers was in favor of GA but will not affect our conclusion. SA

provided faster improvement in HRQoL postoperatively. Therefore the SA group also gained more QALYs during the initial postoperative period. Within the first 29 days after hysterectomy the women in the SA group gained more QALYs than women in the GA group. The gain in QALYs was a small number for the individual woman but essential considering the total number of accomplished hysterectomies every year. SA dominated GA, i.e. higher effectiveness and lower costs; therefore we have not calculated cost per QALY gained. In the US, approximately 538,000 benign hysterectomies were performed in 2003<sup>27</sup> and the abdominal route was the most common one comprising 66.1% or 355,618. Thus performing the majority of abdominal hysterectomies by using SA could substantially benefit US women and the health care system with savings of more than 300 Million USD annually.

Health economic evaluations in health care are essential if we are to identify, quantify and evaluate concurrent costs and effects of alternative interventions<sup>28</sup>. We conclude that the previously reported encouraging improvements in clinical outcomes following fast track abdominal hysterectomy using SA are also accompanied by advantages in HRQoL and total costs. SA is considered cost-effective in comparison with GA.

## **Acknowledgements**

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TABLE 1

Mean cost per item and operation

	Cost (USD)
Fixed cost for the operation *	583.61
Variable cost for time of surgery (per minute) **	9.38
Anesthesiologist (per minute)	1.34
Anesthetic drugs (general anesthesia)	42.36
Anesthetic drugs (spinal anesthesia with morphine)	21.53
Time in PACU (per minute)	0.93
Hospital care in gynecological ward (per hour)	72.08
Sick leave (per day)	139.72

PACU = post anesthesia care unit

\* preparation and closing of theatre, sterilization, basal equipment, staff in theatre

\*\* staff in theatre during time of surgery

TABLE 2

Basic demographic and clinical data

Characteristics	General Anesthesia (GA) (n = 80)	Spinal-morphine anesthesia (SA) (n = 82)
Age (years)	45.5 (5.7)	46.0 (5.7)
Parity	2.0 (1.1)	1.9 (1.3)
Physical work load (no. of women)	n= 74	n= 78
Sedentary	19 (26%)	34 (44%)
Medium	25 (34%)	21 (27%)
Heavy	30 (40%)	23 (29%)
Indications of hysterectomy		
Bleeding disturbances	46 (58%)	46 (56%)
Mechanical symptoms	27 (34%)	29 (35%)
Cervical dysplasia/endometrial hyperplasia	4 (5%)	5 (6%)
Endometriosis/dysmenorrhea	3 (4%)	2 (2%)
Operating time (minutes)	83 (31)	77 (28)
Time of anesthesia (minutes)	127 (34)	120 (31)
Time in PACU (minutes)	282 (156)	234 (114) *
Blood transfusion (no. of women)	3 (4%)	0 (0%)
Duration of hospital stay (hours)	48.3 (16.6)	45.8 (20.4)
Sick leave (no. of women)	n=73	n=78
Sick leave (days) #	27.6 (12.1)	22.7 (11.4) *
Informal care (no. of women)	n = 77	n = 76
Informal care (hours)	22.4 (20.9)	24.1 (31.2)

Figures denote mean and standard deviation or number and per cent.

# one outlier in the SA group was excluded from the analysis due to an extremely prolonged sick leave (258 days). The range of sick leave was otherwise 2 – 81 days.

\*  $p < 0.05$

TABLE 3

Total mean costs per patient (in USD)

	General Anesthesia (GA)	Spinal-morphine anesthesia (SA)	Difference in costs (GA-SA)
<b>Direct costs</b>			
Time in operating theatre	1362	1305	57
Induction of anesthesia by anesthesiologist	20	33	-13
Anesthetic drugs	42	22	20
Time in PACU	263	218	45
Cost of supplementary anesthesia	1	6	-5
Hospital care in gynecological ward	3482	3301	181
Total hospital cost	5170	4885	285
<b>Indirect costs</b>			
Sick leave	3856	3172	684
Total cost (direct + indirect)	9026	8057	969

Round figures are used for the convenience of the reader.

PACU = post anesthesia care unit