**Spinal vs General Anesthesia for Laparoscopic Cholecystectomy**

*Interim Analysis of a Controlled Randomized Trial*

George Tzovaras, MD; Frank Fafoulakis, MD; Kostantinos Pratsas, MD; Stavroula Georgopoulou, MD; Georgia Stamatiou, MD; Constantine Hatzitheofilou, MD

**Objective:** To compare spinal anesthesia with the gold standard general anesthesia for elective laparoscopic cholecystectomy in healthy patients.

**Design:** Controlled randomized trial.

**Setting:** University hospital.

**Patients:** One hundred patients with symptomatic gallstone disease and American Society of Anesthesiologists status I or II were randomized to have laparoscopic cholecystectomy under spinal (n=50) or general (n=50) anesthesia.

**Methods:** Intraoperative parameters, postoperative pain, complications, recovery, and patient satisfaction at follow-up were compared between the 2 groups.

**Results:** All the procedures were completed by the allocated method of anesthesia, as there were no conversions from spinal to general anesthesia. Pain was significantly less at 4 hours (P<.001), 8 hours (P<.001), 12 hours (P<.001), and 24 hours (P=.02) after the procedure for the spinal anesthesia group compared with those who received general anesthesia. There was no difference between the 2 groups regarding complications, hospital stay, recovery, or degree of satisfaction at follow-up.

**Conclusions:** Spinal anesthesia is adequate and safe for laparoscopic cholecystectomy in otherwise healthy patients and offers better postoperative pain control than general anesthesia without limiting recovery.

**Trial Registration:** clinicaltrials.gov Identifier: NCT00492453


**LAPAROSCOPIC CHOLECYSTECTOMY under regional anesthesia alone has been reported only occasionally in the past; these reports included patients unfit to receive general anesthesia, mainly patients with severe chronic obstructive airway disease.**

Surprisingly, in the era of minimally invasive medicine, regional anesthesia has not gained popularity and has not been routinely used as a sole method of anesthesia in laparoscopic procedures. Johnson noted that “all laparoscopic procedures are merely a change in access and still require general anesthetic; hence the difference from conventional surgery is likely to be small.” This statement is predominantly based on the assumption that laparoscopy necessitates endotracheal intubation to prevent aspiration and respiratory embarrassment secondary to the induction of carbon dioxide pneumoperitoneum, which is not well tolerated in a patient who is awake during the procedure. However, it is surprising that regional anesthesia has been successfully used for laparoscopic cholecystectomy in patients unfit to have the procedure under general anesthesia.
but has not been tested in healthy patients in whom any
presumed risk would be theoretically much lower. Ha-
mad and Ibrahim El-Khatary7 used spinal anesthesia
for laparoscopic cholecystectomy for the first time in a
small series of healthy patients. In their study, however,
nitrous oxide pneumoperitoneum was applied instead
of the standard carbon dioxide.

We have recently shown the feasibility of successfully
and safely performing laparoscopic cholecystectomy with
low-pressure carbon dioxide pneumoperitoneum under
spinal anesthesia alone in healthy patients with sympto-
matic gallstone disease.8 We have also noticed that spinal
anesthesia results in exceptionally minimal postopera-
tive pain. After this pilot study, we designed a controlled
randomized trial to compare spinal anesthesia with the gold
standard general anesthesia for elective laparoscopic cho-
lecystectomy in healthy patients.

METHODS

From September 2004, all patients referred to our unit for elec-
tive laparoscopic cholecystectomy were considered eligible for
the trial, provided that they fulfilled the following inclusion cri-
teria: American Society of Anesthesiologists' status I or II, be-
tween 18 and 65 years of age, body mass index (calculated as
weight in kilograms divided by height in meters squared) of
30 or less, and normal coagulation profile. Exclusion criteria
were acute cholecystitis, pancreatitis or cholangitis, previous
open surgery in the upper abdomen, contraindication for pneu-
operitoneum, and contraindication for spinal anesthesia owing
to spinal deformity. Informed consent was obtained from
all patients and the trial protocol was approved by the institu-
tional ethics committee.

Patients were randomized to have a laparoscopic cholecs-
tectomy under either general or spinal anesthesia. Randomiza-
tion was created by a computer-generated list in blocks of 20
patients with sex stratification. Numbered and sealed enve-
lopes were placed in the operating room and only opened at
the patients' arrival there, so that both the patient and in-
volved physicians were unaware of the randomization arm
beforehand. The primary end point of the trial was any differ-
ce in postoperative pain between the 2 groups, and the
secondary end points were differences in complication rate, hos-
ter free flow of cerebrospinal fluid was obtained, 3 mL of hy-
drocortisone sodium and 0.5 mg of atropine sulfate were injected intrathecally.

The Trendelenburg position for 3 minutes. If the mean arterial
blood pressure decreased by more than 20% below the prean-
esthetic value, an intermittent intravenous infusion of phen-
ylephrine hydrochloride solution, 0.004%, was initiated and ti-
trated to effect.

In patients randomized to receive general anesthesia, anesthe-
thesia was induced with propofol (2-3 mg/kg), fentanyl citrate
(5 µg/kg), and atracurium besylate (0.5 mg/kg). Balanced an-
esthesia was continued with sevoflurane, 1% to 2%, and prop-
olol (2 mg/kg/h). After intubation of the trachea, the lungs
were ventilated with 50% oxygen in air using a semiclosed circle
system. Ventilation was controlled with a tidal volume of 8 to
10 mL/kg and the ventilatory rate was adjusted to maintain a
PaCO2 value of 35 to 40 mm Hg. Residual neuromuscular block
was antagonized with 25 µg of neostigmine methylsulfate and
1 mg of atropine sulfate at the end of surgery.

All patients were monitored continuously during the op-
eration. Both clinical observation and invasive hemodynamic
monitoring (electrocardiogram, heart rate, arterial blood pres-
sure, respiratory rate, pulse oximetry, arterial blood gas, and
acid-base balance) were recorded at 5-minute intervals, ex-
cept PaCO2 (15-minute intervals).

Laparoscopic cholecystectomy was performed by using the
same technical principles for both groups, with the standard
4-trocar technique as previously described.4 Pneumoperito-
neum was established by using the open (Hasson) technique
with carbon dioxide at a maximum intra-abdominal pressure
of 10 mm Hg, instead of the usual 14 mm Hg. Another modi-
fication of the technique was the minimal—if any—tilting of
the operating table, ie, head up and left tilt to minimize dia-
phragmatic irritation.

Operative time as well as any intraoperative events were
recorded. Specifically, for patients having spinal anesthesia,
and thus being alert during the procedure, we recorded any
symptoms related to either the anesthetic approach or the
pneumoperitoneum, such as shoulder pain, headache, nau-
sea, and discomfort. Drainage of the subhepatic space was not
used.

Postoperatively, all patients were given standard intrave-
nous fluids (1 L of Ringer solution and 1 L of dextrose, 5%, for
the next 24 hours) and intravenous analgesia (40 mg of pare-
coxib sodium every 12 hours, 500 mg of acetaminophen every
6 hours, and supplementary opioids on demand). Postopera-
tive pain was assessed at both relaxed and stressed (ie, after
coughing) conditions by using the visual analog scale at 4, 8,
12, and 24 hours after the completion of the procedure. Other
postoperative events related either to surgical or (especially)
anesthetic procedure, such as discomfort, nausea and vomit-
ing, shoulder pain, urinary retention, pruritus, headache, and
other neurologic sequelae, were also recorded. The patients
were fed orally the morning after the operation and dis-
charged 24 hours after the procedure, unless complications
had occurred.

All patients were followed up 10 to 15 days after the opera-
tion as outpatients by an independent physician who was not
involved in the procedure and was blinded to patients' type of
for methodological reasons) to decompress the stomach and
avoid vomiting and aspiration; this is especially useful for the
spinal group.8 After obtaining baseline vital signs, oxygen at
5 L/min was commenced through a face mask.

Patients randomized to spinal anesthesia were positioned
at the right lateral decubitus position and a 25-gauge pencil-
point spinal needle was introduced into the subarachnoid space
at the L2-L3 intervertebral space under aseptic conditions. Af-
ter free flow of cerebrospinal fluid was obtained, 3 mL of hy-
perbaric bupivacaine hydrochloride, 0.5%, 0.25 mg of mor-
phine, and 20 µg of fentanyl citrate were injected intrathecally.
Then, the patient was placed in the supine position, staying in
the Trendelenburg position for 3 minutes. If the mean arterial
blood pressure decreased by more than 20% below the prean-
esthetic value, an intermittent intravenous infusion of pheno-
ylephrine hydrochloride solution, 0.004%, was initiated and ti-
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anesthesia to assess their recovery and degree of satisfaction with the procedure by using a standardized questionnaire.\(^9\) This included a questionnaire, tailored to the relevant procedure, regarding quality of life assessment during the first 2 weeks after the operation. Questions targeted the severity of pain during patients’ recovery period; how this influenced their daily activities; the type, amount, and duration of analgesia required; the degree of satisfaction from the anesthetic procedure and the whole process; as well as their final impressions compared with their initial expectations. The answers were scored, with a total score ranging from 0 to 26. Another telephone contact was performed at 1 month postoperatively to detect late complications.

Statistical analysis was performed using the Arcus QuickStat Biomedical statistical package (Research Solutions, Cambridge, England). The Mann-Whitney U and Fisher exact tests were used as appropriate to detect differences between the 2 groups. Differences were considered significant at \(P < .05\) (2-tailed test).

**RESULTS**

Between September 2004 and September 2006, 100 patients entered our ongoing trial. They were randomized to have laparoscopic cholecystectomy under spinal (n=50) or general (n=50) anesthesia. One patient from the spinal anesthesia arm withdrew informed consent, and in 2 patients from the general anesthesia arm, the laparoscopic procedure was converted to an open approach. These 3 patients were therefore excluded from further analysis, leaving 49 patients in the spinal and 48 patients in the general anesthesia groups for analysis (Figure).

The 2 groups were similar regarding demographics (Table 1). All the procedures were completed by the allocated method of anesthesia, as there were no conversions from spinal anesthesia to general anesthesia. Intraoperatively, intravenous phenylephrine was administered in 29 (59%) patients from the spinal anesthesia group compared with 2 (4%) patients from the general anesthesia group owing to mean arterial blood pressure drops of more than 20% from the preanesthetic values. In all these cases, mean arterial blood pressure was then normalized and the procedure was completed uneventfully. Discomfort and/or right shoulder pain in some degree was present after the introduction of pneumoperitoneum in 21 patients (43%) who received spinal anesthesia. However, the pain was severe enough to require intravenous fentanyl administration in only 10 cases. The remaining patients did not require any additional medication or other intervention, and procedures were completed uneventfully in all cases.

Discharge from the hospital at 24 hours after surgery was possible for 48 (98%) patients from the spinal anesthesia group and 47 (98%) patients from the general anesthesia group. We had no mortality in either group and essentially no major morbidity. One patient from the regional anesthesia group who required catheterization for urinary retention developed a urinary tract infection and was treated with antibiotics, and 1 patient from the general anesthesia group was readmitted on day 10 with thoracic pain. This patient was found to have peripheral pulmonary embolism and was treated with anticoagulants. Workup for potential risk-factor detection revealed protein C deficiency.

Postoperative events related to surgical and/or anesthetic procedures, like nausea, vomiting, or urinary retention, are presented in Table 2. As presented in Table 3, pain assessed by the visual analog scale was significantly less for the spinal anesthesia group at 4, 8, 12, and 24 hours postoperatively, including both relaxed and stressed conditions. Supplementary postoperative opioid analgesia was administered in only 1 of the 49 (2%) patients who received spinal anesthesia compared with 12 of the 48 (25%) patients who received general anesthesia (\(P < .001\), Fisher exact test).

At 2 weeks’ follow-up, the quality of life and patient satisfaction scores were similar in the 2 groups: patients who received spinal anesthesia had a median score of 19

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### Table 1. Characteristics of Patients Who Underwent Laparoscopic Cholecystectomy

<table>
<thead>
<tr>
<th>Type of Anesthesia Used</th>
<th>Spinal (n=49)</th>
<th>General (n=48)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Characteristic</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sex, No.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>F</td>
<td>29</td>
<td>30</td>
</tr>
<tr>
<td>M</td>
<td>20</td>
<td>18</td>
</tr>
<tr>
<td>Age, median (range), y</td>
<td>44 (23-65)</td>
<td>46 (26-65)</td>
</tr>
<tr>
<td>Body mass index,a median (range)</td>
<td>25 (18-30)</td>
<td>26 (19-30)</td>
</tr>
<tr>
<td>ASA status, No.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>I</td>
<td>40</td>
<td>37</td>
</tr>
<tr>
<td>II</td>
<td>9</td>
<td>11</td>
</tr>
<tr>
<td>Preoperative ERCP, No.</td>
<td>4</td>
<td>3</td>
</tr>
<tr>
<td>Operative time, median (range), min</td>
<td>45 (20-90)</td>
<td>47 (20-110)</td>
</tr>
<tr>
<td>Total anesthesia duration,b median (range), min</td>
<td>61 (35-118)</td>
<td>62 (34-125)</td>
</tr>
<tr>
<td>Bile spillage, No.</td>
<td>14</td>
<td>12</td>
</tr>
<tr>
<td>Hospital stay, median (range), d</td>
<td>1 (1-4)</td>
<td>1 (1-2)</td>
</tr>
</tbody>
</table>

Abbreviations: ASA, American Society of Anesthesiologists; ERCP, endoscopic retrograde cholangiopancreatography.

\(^{a}\) Calculated as weight in kilograms divided by height in meters squared.

\(^{b}\) For the general anesthesia group, the time from induction to anesthesia to patient awareness; for the spinal anesthesia group, the time from induction to anesthesia to completion of the surgical procedure.
The interim analysis of our study not only confirmed the feasibility of safely performing laparoscopic cholecystectomy under spinal anesthesia as the sole anesthetic procedure but also showed the superiority of spinal anesthesia in postoperative pain control compared with the standard general anesthesia. Pain assessed at both relaxed and stressed conditions was significantly lower at any time during the postoperative hospital stay in patients having spinal anesthesia compared with those having general anesthesia. Furthermore, supplementary opioids were administered in significantly fewer patients having spinal anesthesia compared with those having general anesthesia. This difference could be attributed to a combination of several factors: the avoidance of endotracheal intubation–related discomfort; the presence of adequate levels of analgesia for the first few hours after the completion of the surgical procedure owing to the existing activity of the analgesia injected in the subarachnoid space; and the potentially minimal stress response associated with a minimal invasive anesthetic procedure, such as spinal anesthesia.\(^5\,^6\) Pain following laparoscopic cholecystectomy is not a major problem, but it has been a matter of interest in several studies during the last few years. Minimal invasive surgery has dominated because of the rapid and smooth recovery it offers, and postoperative pain control is probably the main factor that characterizes smooth recovery. Several researchers have tested intra-peritoneal instillation or aerolization of local anesthetic agents (eg, bupivacaine), use of the newer anti-inflammatory COX-2 inhibitors (ie, parecoxib, which was used in this study); addition of epidural analgesia, and oral or epidural administration of steroids, finding some effect on postoperative pain, which varies between studies.\(^3\,^{10}\,^{14}\) When we designed this trial comparing the 2 methods of anesthesia on several aspects of the intraoperative and postoperative course, we defined postoperative pain control as our primary end point based on the initial experience gained from our pilot study,\(^9\) in which the exceptionally good postoperative pain control became obvious very quickly. Our data presented herein confirm the superiority of spinal over general anesthesia in postoperative pain control.

Intraoperative events of note in the spinal anesthesia group included a decrease of the mean arterial blood pressure of more than 20% below the preanesthetic value as well as right shoulder pain. With regards to the former, this is a well known adverse effect of spinal anesthesia and is easily overcome after administration of phenylephrine, and therefore it does not essentially affect the planned procedure. Regarding the latter, 43% of the patients who received spinal anesthesia experienced some degree of shoulder pain or discomfort; however, less than half of those patients required treatment. Laparoscopy-related right shoulder pain has been reported in previous studies and attributed to diaphragmatic irritation from carbon dioxide pneumoperitoneum.\(^5\,^7\) At times, this symptom could be severe enough to result in conversion of the anesthetic approach.\(^3\) However, the pain was mild in most cases in our study and it did not result in conversion from spinal anesthesia in any of our patients. Even when present, shoulder pain was easily dealt with; reassurance and no medical treatment were used in most patients who experienced this symptom. This could be attributed to our lower cutoff pressure for pneumoperitoneum (10 mm Hg instead of the usual 14 mm Hg) combined with minimal tilting of the operating table; we have, thus, minimized the diaphragmatic irritation. A potentially useful maneuver to overcome this minor drawback in the future could be the intra-peritoneal aerosolization with local anesthetic agents like bupivacaine before the induction of pneumoperitoneum, which has been shown recently to significantly reduce postoperative shoulder tip pain.\(^11\)

As mentioned before, we have chosen a low-pressure pneumoperitoneum at a maximum of 10 mm Hg to

### Table 2. Postoperative Adverse Events in Patients Who Underwent Laparoscopic Cholecystectomy

<table>
<thead>
<tr>
<th>Postoperative Event</th>
<th>Received Spinal Anesthesia (n = 49)</th>
<th>Received General Anesthesia (n = 48)</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nausea/vomiting</td>
<td>7</td>
<td>8</td>
<td>.001</td>
</tr>
<tr>
<td>Dizziness</td>
<td>0</td>
<td>1</td>
<td>.001</td>
</tr>
<tr>
<td>Pruritus</td>
<td>1</td>
<td>0</td>
<td>.02</td>
</tr>
<tr>
<td>Urinary retention</td>
<td>3</td>
<td>0</td>
<td>.001</td>
</tr>
<tr>
<td>Sinus rhythm tachycardia</td>
<td>0</td>
<td>1</td>
<td>.001</td>
</tr>
</tbody>
</table>

Table 3. Pain Scores in Patients Who Underwent Laparoscopic Cholecystectomy

<table>
<thead>
<tr>
<th>Test Condition</th>
<th>Visual Analog Scale Score, Median (Range)</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Received Spinal Anesthesia (n = 49)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Received General Anesthesia (n = 48)</td>
<td></td>
</tr>
<tr>
<td>At 4 hours</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Resting</td>
<td>0 (0-4)</td>
<td>&lt; .001</td>
</tr>
<tr>
<td>Stress</td>
<td>2 (0-8)</td>
<td>&lt; .001</td>
</tr>
<tr>
<td>At 8 hours</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Resting</td>
<td>0 (0-6)</td>
<td>&lt; .001</td>
</tr>
<tr>
<td>Stress</td>
<td>2 (0-7)</td>
<td>&lt; .001</td>
</tr>
<tr>
<td>At 12 hours</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Resting</td>
<td>0 (0-2)</td>
<td>&lt; .001</td>
</tr>
<tr>
<td>Stress</td>
<td>1 (0-7)</td>
<td>&lt; .001</td>
</tr>
<tr>
<td>At 24 hours</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Resting</td>
<td>0 (0-4)</td>
<td>.02</td>
</tr>
<tr>
<td>Stress</td>
<td>1 (0-7)</td>
<td>&lt; .001</td>
</tr>
</tbody>
</table>

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minimize diaphragmatic irritation. The use of low-pressure pneumoperitoneum did not jeopardize the adequacy of our space—and subsequently the view—and virtually all the procedures were completed without any technical difficulty. This is especially true for the spinal anesthesia group, because this type of anesthesia offers sensory, motor, and sympathetic blockade at a high level and thus obviates the need for abdominal wall muscle relaxants, which sometimes are necessary when general anesthesia is used. To avoid technical problems with obese patients in whom a potentially higher intra-abdominal pressure is required, we designed the trial with a body mass index cutoff of 30. It is possible, however, that carefully selected patients with higher body mass indexes could have laparoscopic cholecystectomy under regional anesthesia, as our limited anecdotal experience with such obese patients outside the trial suggests.

With regards to the early (in-hospital) postoperative course, the only essential event detected in the spinal anesthesia group was urinary retention; again, this is known to be related to regional anesthesia with rates of up to 20% in some series. Postoperative urinary retention developed in 3 (6%) patients from the spinal anesthesia group (1 female and 2 male patients). Instant catheterization was the only treatment required in 2 patients and did not affect their recovery or time of discharge. However, the third patient developed a postcatheterization urinary tract infection requiring antibiotics and prolonged hospitalization. At 2 weeks’ follow-up, the vast majority of patients from both groups reported being satisfied with the anesthetic approach and experienced equally good recovery.

To our knowledge, this is the first controlled randomized trial that compares the application of spinal with general anesthesia in “the average” patient who undergoes elective laparoscopic cholecystectomy with carbon dioxide pneumoperitoneum. Our data so far have confirmed the preliminary results of our pilot study regarding the feasibility and safety of spinal anesthesia for this purpose. Moreover, it appears that spinal anesthesia is more effective than the standard general anesthesia on postoperative pain control during the patient’s hospital stay. On the other hand, postdischarge patients’ recovery after laparoscopic cholecystectomy under spinal anesthesia was reported to be equally good compared with the present standard method of anesthesia. From these preliminary data, it appears that spinal anesthesia is a promising method of anesthesia for laparoscopic procedures, and with proper refinements, it could potentially evolve as the new gold standard anesthetic approach for elective laparoscopic cholecystectomy in healthy patients.

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Author Contributions: Study concept and design: Tzovaras, Fafoulakis, and Hatzitheofilou. Acquisition of data: Tzovaras, Fafoulakis, Pratsas, and Georgopoulo. Analysis and interpretation of data: Tzovaras and Stamatiou. Drafting of the manuscript: Tzovaras, Fafoulakis, Pratsas, and Georgopoulo. Critical revision of the manuscript for important intellectual content: Stamatiou and Hatzitheofilou. Statistical analysis: Tzovaras and Stamatiou. Administrative, technical, and material support: Tzovaras, Fafoulakis, Pratsas, and Georgopoulo. Study supervision: Hatzitheofilou.

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