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Longterm functional recovery following day-case laparoscopic sterilisation: inhalational versus TIVA maintenance☆

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Abstract

In this study we have evaluated the influence of anaesthetic technique on functional recovery and symptom distress following gynaecological surgery. Previous studies in this area focus on in hospital recovery parameters and no anaesthetic technique comparison study has followed patients postoperatively, daily for a week. We studied 99 females undergoing laparoscopic sterilisation; they were randomly allocated to receive either total intravenous anaesthesia with propofol or isoflurane inhalational anaesthesia.

The results showed no significant differences between the two groups in respect to functional recovery, nausea, vomiting or pain over the 7 day study period.

In both groups, functional recovery was relatively slow; with some patients taking 7 days to achieve normal function and energy levels. We found that 90% of patients required help at home on Day 1.

Keywords: Propofol; Isoflurane; Recovery; Randomised controlled trial

1. Introduction

A number of previous studies have compared different induction and maintenance anaesthetic agents in the ambulatory setting; however, most studies have focused on the recovery parameters within the Day Surgery Unit [1–3] rather than functional recovery of the patients within their home. Studies comparing health economic comparisons [4–7] between intravenous and inhalational agents have primarily focused on cost to the Day Surgery Unit and not on basic functional recovery, requirement for home help, and days absent from work by either the patient or their partner. A few studies have followed patients for 24 h [8], 72 h [9,10] and intermittently up to 1 week after surgery [11] but there are no studies that have followed up patients daily for a week. We have measured a spectrum of parameters including recovery times, postoperative pain, nausea and vomiting (PONV) and progress through the day unit, as well as functional recovery and return to normal daily activities and work as well as patient reliance on medical or community help. We have tried to evaluate if any of these factors are influenced by the anaesthetic technique.

2. Methodology

Following Local Ethical Committee approval and informed consent we enrolled 99 female patients scheduled for day-case laparoscopic sterilisation into the study. Patients under 18 years of age and those with epilepsy, hiatus hernia or gastric reflux or who were otherwise unsuitable for day surgery were excluded. Preoperatively a research nurse conducted a structured interview with the patient to collect demographic data and known risk factors for PONV [12] including concurrent medication, date of the last menstrual period, history of migraine, motion sickness or previous PONV. Randomisation was by a computer generated

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random number scheme and sealed envelopes. We used a semi-open study design in which the attending anaesthetist was aware of the allocated treatment but the patient, the research nurse and recovery staff were not.

No premedication was given. Following the application of standard monitoring, venous access was obtained and a 1 l infusion of Hartmann's solution was started. All patients were pre-oxygenated, and they received intravenous glycopyrrolate 0.2 mg and fentanyl 1.5 μg · kg^{-1}. Anaesthesia was induced with propofol 0.5 mg · kg^{-1} followed by 10 mg every 10 s until loss of consciousness when a laryngeal mask airway was inserted.

Patients in the inhalational anaesthesia group (Group Iso) received nitrous oxide 66% in oxygen with isoflurane, initially 1% (inspired fraction) and subsequently 0.8% (end tidal concentration). Subsequent adjustments were made as clinically indicated with a minimum 0.6% end tidal concentration of isoflurane maintained until the end of surgery. Supplementary doses of fentanyl 25 μg were administered by the anaesthetist as was clinically indicated. Patients in the TIVA group (Group Ti) received an infusion of propofol 6–12 mg kg^{-1} h^{-1} and breathed an air/oxygen mixture. Supplementary doses of fentanyl 25 μg were administered as clinically indicated. In both groups, gentle manual ventilation was continued until there was adequate spontaneous ventilation returned. A fresh gas flow of 9 l min^{-1} was used in the anaesthetic room and 3 l min^{-1} in the operating room. At the completion of surgery, administration of anaesthetic agents was discontinued and all patients breathed 100% oxygen at 9 l min^{-1}.

Rectal diclofenac 100 mg was administered before commencement of surgery. Both fallopian tubes were occluded using Filshie clips and Bupivacaine 0.5% 10 ml was instilled onto the fallopian tubes at the end of the sterilisation and an additional 10 ml was infiltrated into the laparoscopy incisions by the surgeon.

No prophylactic anti-emetic was given, and when the patients were in the recovery area, they were questioned about nausea at 10 and 60 min after eye opening. Any patients experiencing nausea or vomiting were offered intravenous ondansetron 4 mg. If nausea or vomiting persisted for 30 min following administration of ondansetron then intramuscular prochlorperazine 12.5 mg was administered.

All personal recording data and following patients (research nurse and recovery staff) were blinded to treatment groups of patients. Pain scores were recorded in the recovery area at 10 and 60 min after the end of anaesthesia. If necessary, incremental doses of intravenous morphine 2 mg at 5 min intervals or two tablets of co-codamol 30/500 (codeine 30 mg and paracetamol 500 mg in each tablet) were given according to standard hospital protocols. At discharge, all patients were given a standard pack containing co-codamol 30/500 mg × 16 tablets and diclofenac 50 mg × 6 tablets and a written instruction sheet to take home.

Drugs recorded included total doses of anaesthetic agents (fentanyl, propofol), morphine and anti-emetic requirements in recovery. Pain during recovery from anaesthesia and surgery was scored by the patient using an 11 point scale from 0 (none) to 10 (worst imaginable) and the presence of nausea and vomiting was recorded. Times to various recovery parameters were documented including times spent in each part of the recovery area (Stage 1, high intensity nursing care; Stage 2, low intensity nursing care; Stage 3, self care pre-discharge waiting area).

Out of hospital, a research nurse followed up patients with daily telephone calls for 7 days. A structured questionnaire (Appendix A) was used which recorded pain, nausea and vomiting and included specific questions to elicit the patient's social function, mobility within the home, accidents, dependency on their partner, use of primary health care services and ability/inability to resume normal activities or employment (if applicable).

Statistical analysis was performed on Microsoft Excel 5.0 and SPSS 7.5 run on a personal computer. Tests used included student T-test, Mann–Whitney U-tests and Kaplan Meier analysis where appropriate. A P value $<$ 0.05 was taken as the point of statistical significance. If a 10% difference in longterm 100% recovery then 46 patients per group would have sufficient power (80%; 2 tailed; $P < 0.05$) to detect a significant difference [11].

3. Results

A total of 99 patients were enrolled into the trial, 50 randomised to Group Iso and 49 randomised to Group Ti. Groups were well matched for age, weight, and other epidemiological factors (Table 1). In particular the predicted risk of PONV [12,13] was similar in both groups.

Two patients were withdrawn from the study for protocol violations and no further data was collected from these patients. Five patients were admitted to hospital from the Day Surgery Unit. In the Iso group one patient was admitted for drowsiness/nausea and one for pain control. In the Ti group two patients were admitted for surgical observation and one patient was admitted for pain control. Of the five patients admitted to hospital, four patients (two in each group) required an overnight stay only and follow-up data was thereafter collected as normal. The fifth patient (Group Ti) required a stay of more than one night for surgical reasons and was therefore excluded from further follow-up.

Table 1
Demographic data

	Inhalational group (Group Iso) ($n = 50$)	Intravenous group (Group Ti) ($n = 49$)
Age (years)	34.7 (4.8)	35.0 (4.7)
Weight (kg)	64.9 (10.8)	64.0 (9.1)
Smokers	25	30
Menstrual cycle phase[a]	13/13/8/13/3	8/9/9/16/7
History of migraine	9	6
Previous PONV	7	5
History of motion sickness	9	14
Palazzo score	0.42 (0.015)	0.39 (0.003)
In paid employment	31	30
Resident partners	38	39

Data are mean (SD), or number as appropriate.
[a] 0–7/8–14/15–21/ > 21/unknown—days since start of last menstruation.

Whilst in the Day Surgery Unit there was no significant difference between the groups in the duration of anaesthesia or any of the recovery or discharge times (Table 2) or in the incidence of pain during their stay in the Day Surgery Unit (Table 3). There were no significant differences in the incidence of postoperative nausea between the two groups. However, more patients in the Iso group vomited (Table 3) but this was not statistically significant.

Median pain scores over the week at home were not significantly different between the two groups on any single day or overall (Fig. 1). The incidence of nausea at home was highest on the first 2 days after surgery (Fig. 1) but in some patients this lasted for up to 6 days. Vomiting on Day 1 was more frequent in the Iso group, but this was not statistically significant ($P = 0.07$).

Table 2
Anaesthetic details and early recovery

	Inhalational group (Group Iso) ($n = 49$)	Intravenous group (Group Ti) ($n = 48$)
Fentanyl ($\mu g \cdot kg^{-1}$)	2.8 (0.79)	3.1 (0.76)
Propofol ($mg \cdot kg^{-1}$)	2.89 (0.61)	5.91 (1.79)
Duration of anaesthesia (min)	18.4 (5.7)	20.2 (5.1)
Time in 1st stage recovery area (min)	16.5 (3.6)	18.0 (4.2)
Time in 2nd stage recovery area (min)[a]	160 (48.3)	143.8 (39.0)
Admitted overnight (n)	2	3

Data are means (SD), or number as appropriate and include all patients who received a per-protocol anaesthetic.
[a] This data does not include the five patients who were admitted to hospital.

Table 3
Pain, nausea and vomiting on day of operation

	Inhalational group (Group Iso) ($n = 49$)	Intravenous group (Group Ti) ($n = 48$)
Pain score at 10 min[a]	1.5 (0–8)	2 (0–9)
Pain score at 60 min[a]	4 (0–9)	4 (0–9)
Patients given morphine in recovery	9	4
Patients with nausea in recovery at 10 min[a]	1	0
Patients with nausea in recovery at 60 min[a]	5	4
Patients vomiting in recovery	11	6
Anti-emetic given in recovery	6	3
Journey time (min)[b]	27 (5–120)	21 (5–60)
Pain during journey home (median)[b]	3 (0–9)	3 (0–9)
Patients with nausea on journey home[b]	16	18
Patients vomiting on journey home[b]	6	4

Data are number of patients or median (range) as appropriate and include all patients who received a per-protocol anaesthetic.
[a] One patient in Group Iso was drowsy and could not co-operate with questioning at the 10 and 60 min time points.
[b] Excludes five patients (two Group Iso, three Group Ti) who were admitted to hospital.

There were no significant differences in the number of patients who sought advice, the nature of the advice sought or from whom the advice came. In the Iso group, 10 patients sought advice from their General Practitioner, 1 from the Day Surgery Unit, 1 from the Hospital and 3 from the Practice Nurse. The reasons for requesting advice included 7 patients with wound problems, 4 with pain and analgesia problems, 3 requiring medical certificates and 1 with an unrelated medical problem. In the Group Ti, 12 patients sought advice from their General Practitioner, and 1 from the Practice Nurse. Ten consultations were for wound related problems, 1 patient required a medical certificate, 1 was given an anti-emetic and 1 patient had an unrelated medical problem. No patients in this group sought advice regarding pain or analgesia.

There were no significant differences in the amount of help required at home by either group on any day or in total over the week (Fig. 2). One patient in the Iso group paid for additional help during the week, but no patients requested assistance from the Community Services.

The percentage of patients whose energy and activity levels (Fig. 2) had returned to normal over the 7 days was not significantly different between the two groups. There was a similar pattern in the time taken to return to walking normally (Fig. 2).

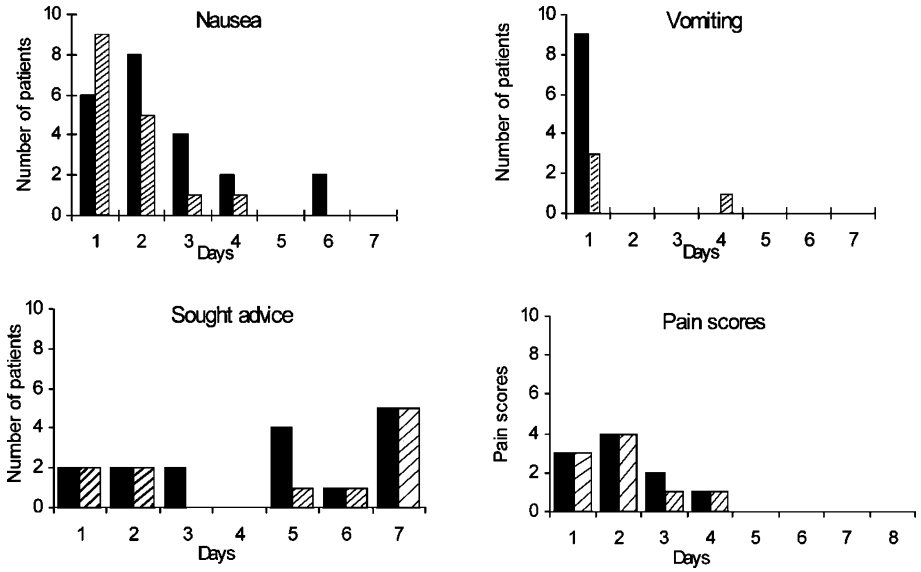

Fig. 1. Number of patients suffering nausea and vomiting, and those who sought advice in each group and median pain scores over the week post operatively. Solid columns represent the Group Iso and hatched columns represent the Group Ti.

Three patients in each group reported having accidents whilst at home. All the accidents were minor and involved spilling or dropping various domestic items. No patients received injuries from these accidents or required any treatment.

The total number of days taken off work by the patients who were in employment was statistically significantly different between the two treatment groups ($P = 0.04$). Of the employed patients, 89 of a possible 128 working days were taken off in the Iso group and 68 of a possible 119 days in the Ti group. There was no difference between the study groups in days taken off work by the partners.

4. Discussion

Few studies comparing intravenous and inhalational anaesthetic techniques in ambulatory surgery patients have extended their study period beyond discharge from hospital. Only one study by Swan et al. [11] followed patients for a week postoperatively, but unlike our daily questionnaire reporting occurred on Day 1, 4 and 7 and results were extrapolated. Our daily reporting provides a more detailed chronological account of functional recovery and symptom distress.

In this study we have tried to comprehensively evaluate the impact of the day-case laparoscopic ster-

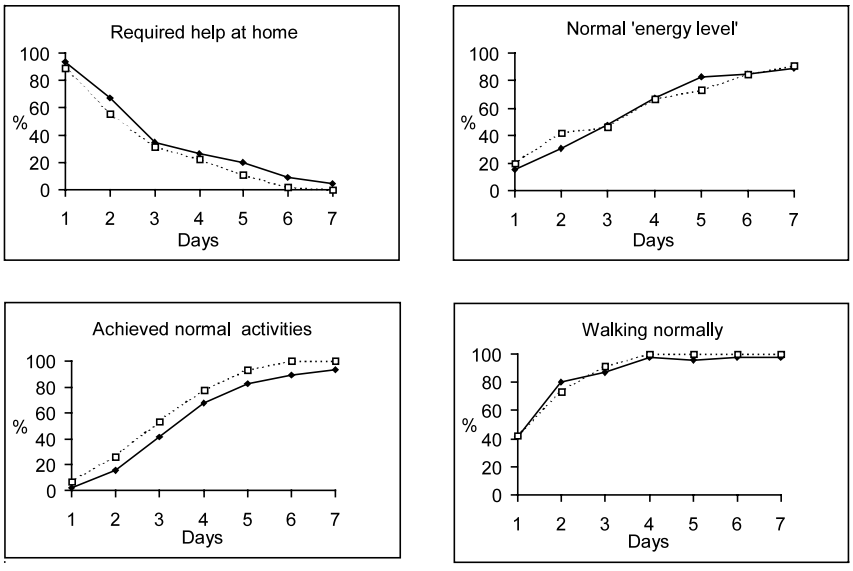

Fig. 2. Functional recovery of patients during the first 7 days. Graphs show percentages of patients reporting that they required help at home, had returned to their normal 'energy level', achieved their normal daily activities or were able to walk normally. (--□--) represent Group Ti, (—◆—) represent Group Iso.

ilisation on the patient and their carers in the community during the first postoperative week. In particular we focused on functional recovery and return to normal activities and the need for additional help at home. We selected this day case population as previous studies have suggested minimal pain and symptom distress in the postoperative period compared to other ambulatory surgery [14]. In our analysis, we chose to include those patients who were admitted to hospital and then discharged. This potentially contaminates the original experiment as the admitted group experienced different interventions during their overnight stay but adheres to the principle of an 'intention-to-treat' analysis.

Our 7 day structured telephone questionnaire was intended to explore functional recovery following minimally invasive ambulatory surgery and whether it was affected by the anaesthetic technique. We designed the study to evaluate the additional burden that postoperative dysfunction placed on their partners and the broader healthcare community. We were unable to demonstrate any differences in respect to functional recovery, return of 'energy level' and achievement of normal daily activities (Fig. 2) between the groups. We have clearly demonstrated a gradient of functional recovery and symptom distress following laparoscopic sterilisation (Figs. 1 and 2). The recovery patterns appear exponential, but patients on the whole, required the full 7 days to recover to baseline function. Our results differ from a previous study investigating the impact of balanced analgesia on laparoscopic sterilisation, which showed patients almost completely back to normal activities by Day 3–4 [15]. A questionnaire study by Philip [16] showed 38% of patients able to return to daily activities the day after surgery, the remainder required 3.2 ± 2 additional days. The difference may be due to system factors such as recommended recovery time as suggested by surgeons and the healthcare system. Pain management strategies and patient expectations will also influence recovery profiles.

Three patients in each group reported accidents whilst at home. All the accidents were minor and involved spilling or dropping various domestic items predominantly on the first postoperative day. These accidents may in part be due to residual cognitive impairment that has been shown to extend beyond 24 h post surgery [17].

Over 90% of patients required help on the first postoperative day, declining exponentially thereafter. There was no significant difference in the amount of help required at home by either group on any day or in total over the week (Fig. 2). One patient in the Iso group paid for additional help during the week, but no patients requested assistance from the Community Services. Partners, family and friends provided most of the help, which reduced the impact on healthcare and community facilities. Partners were the main providers and there was a correlation with days taken off work by the partners and help provided. Patients appeared to rely heavily on some form of help being available, however previous work has shown that nearly 30% of patients are alone at home following an operation in the ambulatory setting [18].

Measurement of time off work is fraught with difficulties. Firstly only 60% of our patients were employed and we have no data on the employed patients: whether self employed, expectations, nature of the job or if an anticipated period of leave was arranged. Many factors including age, education and income level, occupation, depression and patient's expectations have been shown to have a significant impact on the number of days taken off work [19]. In addition the timing of the operation in the week will affect time taken off work. We attempted to address these methodological problems by quantifying the number of days that could have been worked (i.e. days a patient would have worked if it was not for the surgery) and determining the proportion of these that were missed. Accepting the limitations of our analysis, the total number of days taken off work by the patients who were in employment was statistically significantly different between the two treatment groups ($P = 0.04$).

While not the primary objective of the study, we observed that the initial recovery and time spent in the day case unit were not significantly different. Similar periods were spent in the first stage recovery area and considering nurses were following standard discharge criteria, this suggests that the nursing staff blinded to the anaesthetic technique, did not perceive any differences in residual anaesthetic effects. The time spent in the 3rd stage of recovery was not included in the analysis as several patients spent no time waiting in the 3rd stage while others spent up to 2.5 h and we found that external factors including waiting for transport played a major role. The incidences of admission were also not significantly different between the two groups.

The incidence of PONV in this study was low and was similar between the two groups (Table 3). Both patient groups had similar predicted risks of PONV [12,13] (Table 1). These PONV findings should be taken with caution as the study is underpowered to detect potentially important differences with regard to nausea and vomiting and more patients in the Iso group received morphine rescue analgesia in recovery.

In summary, we have failed to show significant differences in functional recovery between propofol TIVA compared to propofol/isoflurane/nitrous oxide anaesthesia in day surgery gynaecological laparoscopic sterilisation. We have however observed that procedures described as '1-day' surgery are actually a '1-week' experience for the patient with slow functional recovery and resolution of symptom distress.

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Appendix A: Daily telephone questionnaire for patients

(1) How is your pain at the moment?

No pain *Worst pain I can imagine*
0 1 2 3 4 5 6 7 8 9 10

(2) How has your pain been in general since I last telephoned?

No pain *Worst pain I can imagine*
0 1 2 3 4 5 6 7 8 9 10

(3) Have you taken any painkillers? (*Yes*/*No*)

If yes, what have you taken? *Co-codamol 30/500 no. of tabs*
Diclofenac 50 no. of tabs
Others—specify

(4) Have you felt sick today? (*Yes*/*No*)
If yes, how bad has it been?

No nausea *Worst nausea I can imagine*
0 1 2 3 4 5 6 7 8 9 10

(5) Have you been sick today? (*Yes*/*No*)

If so, how many times were you sick? *Number of times*

(6) Have you needed to call your GP or anyone else for advice? (*Yes*/*No*)

If yes, who have you called? General Practitioner
Day Surgery Unit
Accident and Emergency Department
Other

Why did you seek advice? *Pain*
Sickness
Other—specify

(7) How much of what you *normally* do in and around the house have you managed? (e.g. cooking, cleaning, shopping, gardening, going out)

All or almost all/*Some*/*Little or nothing*

(8) Have you been walking about as normal today? (*Yes*/*No*)

(9) Compared with how you usually are, how much energy have you had today?

Much less	*0*
A little less	*1*
About normal	*2*
A little more than normal	*3*
Much more than normal	*4*

(10) Have you had any accidents today? (*Yes*/*No*)
(e.g. falling over, spilling something)
If yes, please specify what happened
Do you think that your recent DSU operation had any bearing on this accident? (*Yes*/*No*/*Don't know*)
If appropriate
Was today a working day for you? (*Yes*/*No*)
If yes, did you go to work? (*Yes*/*No*)
If appropriate
Was today a working day for your partner? (*Yes*/*No*)
If yes, did he/she take the day off because of your operation? (*Yes*/*No*)

(11) Is any one else helping you do the things you normally do? (*Yes*/*No*)
If yes, who is it? (*Partner*/*Other*)
Have you had to pay any money for extra help? (*Yes*/*No*)
(e.g. travel or childcare costs)

(12) Have you needed to get help from any Community Services that you would not normally use? (*Yes*/*No*)
If yes, please specify which ones. . .. .

(13) Have there been any other problems or things you would like to tell me? (*Yes*/*No*)
If yes, give details. . .. .

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