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Paediatric ENT day surgery
Is it safe practice?

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Abstract

Day-case surgery is convenient and safe allowing patients to have the appropriate medical service without long waits. The issue of safety has been extensively studied and presented in the literature. In this paper, the Security Forces Hospital experience with otolaryngology day-surgery cases is presented.

Objective: To evaluate the rate of complications and their timing and to assess the safety of day-surgery procedures.

Methods: A total of 300 children undergoing tonsillectomy, adenotonsillectomy, adenoidectomy, myringotomy, and other minor surgeries (e.g. reduction of fracture nasal bone, foreign body removal, etc.) were observed. Post-operatively after recovery from anaesthesia, a number of parameters were recorded at intervals of 15 min for the first 4 h, 30 min for the following 3 h, and hourly until discharge. Bleeding was considered to have occurred only if medical attention was required.

Results: In the evaluation of *haemorrhage* as an important complication, nine cases (3%) bled in the first 6 h (six following adenoidectomy and three following tonsillectomies) after day-surgery procedures, while six cases bled after 3 days (2%). Results were compared with post-operative haemorrhage after operations done in the main OR and there it was reported in 11 out of 101 cases in whom adenotonsillectomy was performed: only one patient (1%) needed control in the OR.

Conclusion: Post-operative complications after day-surgery procedures are comparable to that after main OR procedures. The common paediatric ENT procedures, e.g. adenoidectomy, tonsillectomy, adenotonsillectomy, and myringotomy, can be done safely as day-case procedures in a busy hospital.

Keywords: Adenoidectomy; Bleeding; Day surgery; ENT procedures; Safety; Tonsillectomy

1. Introduction

Elective day surgery has become an integral part of otolaryngology practice because it is less disruptive to the life of the patient and requires less psychological preparation which is particularly important for the paediatric population. The paediatric ENT procedures, i.e. adenotonsillectomies, are becoming the commonest procedure performed either as an in-patient or as a day case. Studies have shown that after the first 6–8 h, morbidity is very low allowing the patient to be discharged home [1–3].

In fact, there is a trend to discharge patients even sooner than 6 h [4,5].

Most of these studies are North American and mainly focus on the risk of reactionary haemorrhage.

As the vast majority of complications occurred in the first few hours after operation, the potential for undertaking day-case adenotonsillectomy is therefore clear.

2. The aims of this study

To evaluate the rate of complications and their timing and to assess the safety of day-surgery procedures in relation to

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Table 1
Age and number of children entered into the study

Age	Number (%)
<12 months	8 (2.6%)
12–24 months	22 (7.4%)
2–6 years	180 (61%)
6–13 years	90 (30%)
Total	300 (100%)

the occurrence of haemorrhage, fever, and emesis in the early post-operative period.

3. Materials and methods

This is a prospective study carried out for 8 months from April to October 2001.

A total of 300 children undergoing tonsillectomy, adenotonsillectomy, adenoidectomy, myringotomy, and other minor surgeries (e.g. reduction of fracture nasal bone, foreign body removal, etc.) were observed.

All operations were performed under general anaesthesia. The duration of operation ranged from 15 to 75 min. Post-operatively after recovery from anaesthesia, a number of parameters were recorded. These included pulse rate, vomiting, temperature, analgesia given, and signs of bleeding (i.e. increased pulse and hypotension). Observations were undertaken at intervals of 15 min for the first 4 h, 30 min for the following 3 h, and hourly until discharge. Bleeding was considered to have occurred only if medical attention was required and was classified as minor "no surgical action taken", or severe "patient returned to the operating room". All patients were discharged home 3–6 h post-operatively except tonsillectomy patients who were kept in the hospital overnight and discharged home the following morning.

4. Results

The number of children operated on was 300 [122 boys (40.7%) and 178 girls (59.3%)]. Their ages ranged from 11 months to 13 years (Table 1). The most common paediatric ENT procedures encountered are shown in Table 2.

Twenty-eight children with medically controlled diseases, e.g. asthma (16), sickle cell trait (11), and coagulopathies (1), were included.

5. Post-operative complications

Table 3 demonstrates the overall complications which included haemorrhage, fever, vomiting, and the period of observation.

In the evaluation of *haemorrhage* as an important complication, nine cases (3%) bled in the first 6 h (six following adenoidectomy and three following tonsillectomies). The bleeding was minor in all cases except for one tonsillectomy that needed re-admission from the recovery room and haemostasis performed under general anaesthetic. In addition to the above, six cases bled after 3 days (2%) but the bleeding was minimal and a conservative approach (bed rest, analgesics, antibiotics, and fluids) was enough to manage them (Table 4).

Fever was recorded in 46 children (15.3%), and in most of these cases, it subsided within 24 h. Fever was generally low grade. Only in 2.8% of the adenotonsillectomy group and in 1.3% of the adenoidectomy group the temperature was around 38 °C. All children were afebrile on discharge. *Vomiting* was observed in 103 children (34.3%) (Table 3).

Results were compared with post-operative haemorrhage following 141 of the same procedures done in the main OR during the same period. The reason for operating in the main OR was general medical problems (e.g. asthma, cardiac, etc). Operation types are shown in Table 2. Eighteen cases underwent adenoidectomy, 15 adenoidectomy and ventilation tubes, 20 cases adenotonsillectomy, 14 cases adenotonsillectomy with ventilation tube insertion, 6 cases microlaryngoscopy, 2 cases limited septoplasty, and 3 cases foreign body removal. Forty-eight cases had bronchial asthma, 6 had epilepsy, and 24 cases had other/unknown medical problems. Haemorrhage was reported in 11 cases. In four cases (3.96%), bleeding occurred within 6 h. One out of 101 cases (1%)

Table 2
ENT procedures in day surgery and main OR, numbers, and percentages

Type of operation	Day surgery	%	Main OR	%
Adenoidectomy	52	18	33	23.40
Tonsillectomy	70	23	34	24.11
Adenotonsillectomy	106	35	34	24.11
Myringotomy + tubes	45	15	29	20.57
Minor surgery (e.g. foreign body removal, microlaryngoscopy, reduction of fracture nasal bone, limited septoplasty, etc.)	27	9	11	7.80
Total	300	100	141	100

Table 3
Complications in day-surgery cases and time observed with number and percentage

Complications	6 h	12 h	24 h	3 days	>3 days	Number (%)
Haemorrhage	9	0	0	0	6	15 (5%)
Fever	32	14	0	0	0	46(15.33%)
Vomiting	87	14	2	0	0	103(34.33%)

Table 4
Comparison between cases of haemorrhage in main OR and day surgery

Complications	Day-surgery unit	Main OR
Haemorrhage		
Early	9 (3%)[a]	4 (3.960%)[a]
Late	6 (2%)	7 (6.930%)

[a] One case only taken to OR for control of bleeding.

in which adenotonsillectomy was performed needed to be returned to the OR to stop the bleeding. This was a $3\frac{1}{2}$-year-old child 1 h post-tonsillectomy. The other three cases were managed conservatively. Bleeding occurred in seven cases (6.930%) beyond 3 days and was also managed conservatively.

6. Discussion

Day surgery for common paediatric ENT procedures is increasingly being practiced in light of the low complication rate in the published literature. We recorded nine cases (3%) of post-operative bleeding that was considered reactionary haemorrhage occurring during the first 6 h. The management was conservative in all but one case which needed active interference. This compares with an early post-operative bleeding rate in procedures done in the main OR, of 3.96% (four cases). Out of these four cases, only one patient (1%) was taken back to the OR for haemostasis. This is comparable to the post-operative bleeding rate after day-case operations. Panarese et al. [9] studied 392 cases, found six cases (1.53%) developed bleeding a few hours post-operatively, of which only two cases needed active management. It should be emphasized that bleeding can occur after discharge from the hospital whether these cases are undertaken as day cases of in patients. In our study, six cases (2%) developed secondary haemorrhage after the third day post-operatively.

Tewary and Curry [6] in a retrospective study of day-case tonsillectomy in children, reported that 4 out of 363 children had to be re-admitted in the first 24 h and 2 (1%) were returned to the operating theatre for hemostasis. Kendrick and Gibbin [7], in a retrospective study of 413 patients, reported that post-operative haemorrhage occurred in 16 cases (3.9%). Three children with severe bleeding (0.7%) required a return to theatre.

Fraser and Johstone [8] stated that early pyrexia after any surgical procedure is common in most cases. It is of low grade and does not indicate or predict the presence of an infection. In our study 46 cases (15.3%) developed low grade fever less than 38 C within the first 24 h. They were afebrile on discharge.

Panarese et al. [9] reported the incidence of fever in 43% depending on the type of surgery and the duration of anaesthesia.

The incidence of vomiting in the post-operative period in our study was 34.3% (103 cases). Litman et al. [10] reported the highest incidence in their review (73%) while Panarese et al. [9] observed vomiting in 41% of their cases. Vomiting is one of the most common reasons for unscheduled re-admission in day-case centres [11]. The aetiology appears to be multifactorial (swallowed blood, pain, opiate, and/or direct oropharyngeal irritation). All these factors seem to contribute to post-operative nausea and vomiting. The use of propofol as the anaesthetic agent [12] and the prophylactic administration of metoclopramide have been reported to reduce the incidence of post-operative nausea and vomiting [13].

7. Conclusion

In view of the low incidence of post-operative complications, the common paediatric ENT procedures, e.g. adenoidectomy, tonsillectomy, adenotonsillectomy, and myringotomy, can be done safely as day case provided certain conditions are considered, i.e. proper patient selection, patient education pre-operatively and post-operatively, and the assurance of early access to hospital when any complications emerge.

A suitable day-case anaesthesia protocol including the routine use of an anti-emetic is likely to reduce the incidence of post-operative nausea and vomiting and make day-case ENT procedures more acceptable to patients and parents alike.

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Day surgery for gynaecological laparoscopy: Clinical results from an RCT

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Abstract

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

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

1. Introduction

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

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

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

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2. Methods

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

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

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

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

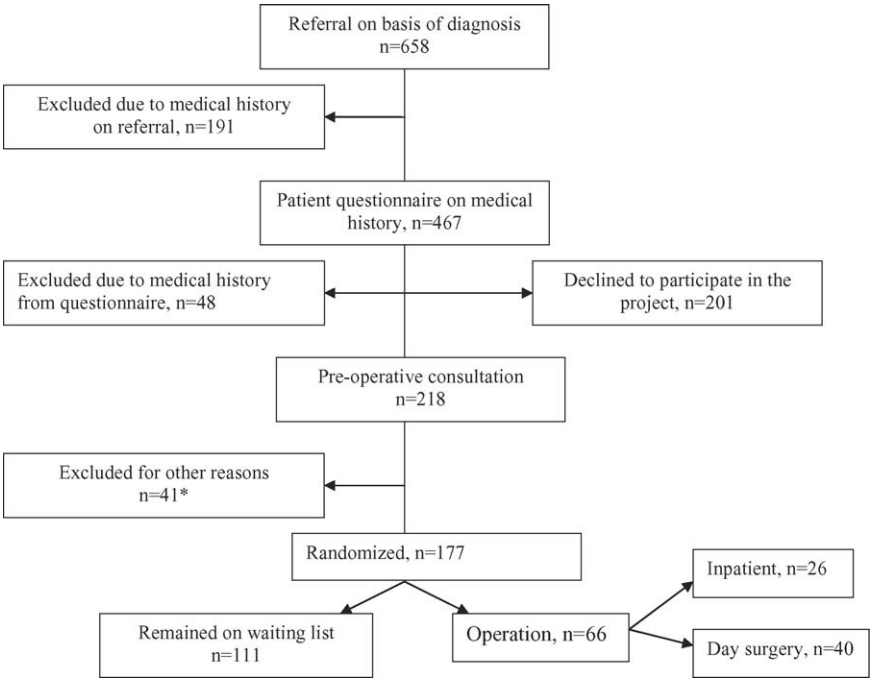

Fig. 1. Patient participation in randomized controlled trial of gynaecological laparoscopic surgery. (*) Includes 22 patients excluded on basis of clinical history obtained at the pre-operative consultation, 9 patients with acute admission before randomization, 4 patients who requested treatment at other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

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

2.1. Statistics

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

3. Results

3.1. Representativeness of patient sample

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

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

3.2. Sociodemographic variables and medical history

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

3.3. Operation characteristics

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

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

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

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

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

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

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

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

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

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

Table 3
Operation data for inpatient surgery and day surgery groups

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

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

3.4. Immediate recovery period

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

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

Table 4
Recovery data for inpatient surgery and day surgery groups

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

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

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

3.5. Later recovery period

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

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

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

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

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

4. Discussion

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

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

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

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

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

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

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

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

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

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Use of the substitution index to identify improvement opportunities in major ambulatory surgery☆

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Abstract

Major ambulatory surgery (MAS) is an alternative to traditional hospitalization. Its goals are to reduce cost while increasing patient safety and satisfaction. The substitution index of MAS has been used to identify those surgical procedures, which present the largest impact in avoidable stays. There is a wide margin for improvement in relation to the performance of MAS. Five DRG's account for more than 50% of the avoidable stays. To promote MAS, it would be necessary to introduce changes in financing and incentive policies, include new procedures, review clinical guidelines and establish benchmarking strategies.

Keywords: Major ambulatory surgery; Substitution index; Benchmarking

1. Introduction

The term major ambulatory surgery (MAS) is used to refer to surgical cases performed under general, regional or local anaesthesia or sedation that require low intensity short term post-operative care and allow the patient to return home a few hours after surgery with no need for hospitalization. As an alternative to the traditional approach, it can be used to reduce both costs and waiting lists and increase the efficiency and quality of patient care in order to achieve a high level of patient satisfaction and safety. MAS has become a paradigm for the changes taking place in the healthcare system as a whole [1].

The substitution index (SI) is a very important indicator for monitoring the quality of surgical activity at the hospital level, because it is not possible to use the usual clinical indicators (average pre- and post-operative stays, hospital infections, surgical mortality, etc.) when discussing MAS.

For several years, public hospitals in the Region of Murcia have kept records of specialized ambulatory care cases in order to determine how many MAS interventions were performed in each of them. Other regions in Spain use the same approach and can provide data on this type of care.

For these reasons we decided to undertake the task of calculating the SI for each hospital and for each diagnosis related group (DRG), determining the number of potentially avoidable admissions and stays, and identifying the DRG's which offer the best opportunities for improvement.

2. Methods and materials

We analyzed MBDS databases of specialized ambulatory care and hospitalization for the years 2002 and 2003 in six of the nine public hospitals in the Region of Murcia. As regards the remaining three hospitals, two of them kept no record of this type of care and the other one had not yet instituted out-

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Table 1
Percentage of cases excluded by DRG

DRG	Emergency admissions	Length of stay > 14 days	Mental deficiency, psychiatric diseases or drug-addictions	Total excluded[a]	Excluded/ total[b] (%)
6. Carpal tunnel release	22	–	–	22	29.73
36. Retinal procedures	74	8	–	76	26.67
38. Primary iris procedures	3	–	–	3	–
39. Lens procedures with or without vitrectomy	71	–	3	74	24.67
40. Extraocular procedures except orbit, age >17 years	40	2	1	40	41.67
41. Extraocular procedures except orbit, age <18 years	22	–	–	22	–
42. Intraocular procedures except retina, iris and lens	80	19	1	85	31.14
55. Miscellaneous ear, nose, mouth and throat procedures	52	1	13	66	8.20
59. Tonsillectomy and/or adenoidectomy only, age >17 years	4	–	1	5	8.62
60. Tonsillectomy and/or adenoidectomy only, age <18 years	17	1	–	17	6.80
119. Vein ligation and stripping	16	–	–	16	5.52
158. Anal and stomal procedures without CC	516	15	4	526	61.38
160. Hernia procedures except inguinal and femoral, age >17 without CC	164	11	4	170	26.28
162. Inguinal and femoral hernia procedures, age >17 years without CC	292	9	12	304	26.07
163. Hernia procedures, age <18 years	44	–	1	45	31.03
225. Foot procedures	102	11	4	104	25.81
227. Soft tissue procedures without CC	109	5	2	110	39.57
229. Hand or wrist procedures, except major joint procedure, without CC	219	2	1	219	65.96
231. Local excision and removal of internal fix devices except hip and femur	100	39	8	116	26.91
232. Arthroscopy	13	4	–	14	18.42
262. Breast biopsy and local excision for non-malignancy	30	1	1	32	31.68
267. Perianal and pilonidal procedures	81	1	3	84	28.47
339. Testes procedures, non-malignancy age >17 years	19	3	2	20	9.17
340. Testes procedures, non-malignancy age <18 years	23	–	–	23	12.85
342. Circumcision, age >17 years	9	–	–	9	–
343. Circumcision, age <18 years	9	–	–	9	22.50
351. Sterilization, male	2	–	–	2	–
361. Laparoscopy and incisional tubal interruption	26	–	1	27	34.18
362. Endoscopic tubal interruption	6	–	1	6	–
364. Dilation and curettage, conization except for malignancy	621	2	2	621	87.71
494. Laparoscopic cholecystectomy without CC	288	38	10	296	27.26
Total	3074	172	75	3163	33.12

Region of Murcia 2002–2003. DRG: diagnosis related group; CC: complication-comorbidity.

[a] The total could be higher than the sum of parts given that some episodes can have more than one exclusion criteria simultaneously.

[b] The percentage has been calculated, only for those DRG's with more than 30 cases in the hospitalization minimum basic data set.

Table 2
Number of procedures performed and SI by DRG

DRG	MAS	In-patient	Total	SI
6. Carpal tunnel release	854	52	906	94.26
36. Retinal procedures	137	209	346	39.60
38. Primary iris procedures	30	3	33	90.91
39. Lens procedures with or without vitrectomy	8565	226	8791	97.43
40. Extraocular procedures except orbit, age >17 years	1107	56	1163	95.18
41. Extraocular procedures except orbit, age <18 years	275	21	296	92.91
42. Intraocular procedures except retina, iris and lens	424	188	612	69.28
55. Miscellaneous ear, nose, mouth and throat procedures	677	739	1416	47.81
59. Tonsillectomy and/or adenoidectomy only, age >17 years	50	53	103	48.54
60. Tonsillectomy and/or adenoidectomy only, age <18 years	778	233	1011	76.95
119. Vein ligation and stripping	238	274	512	46.48
158. Anal and stomal procedures without CC	465	331	796	58.42
160. Hernia procedures except inguinal and femoral, age >17 years without CC	335	477	812	41.26
162. Inguinal and femoral hernia procedures, age >17 years without CC	743	862	1605	46.29
163. Hernia procedures, age <18 years	121	100	221	54.75
225. Foot procedures	562	299	861	65.27
227. Soft tissue procedures without CC	216	168	384	56.25
229. Hand or wrist procedures, except major joint procedure, without CC	503	113	616	81.66
231. Local excision and removal of internal fix devices except hip and femur	341	315	656	51.98
232. Arthroscopy	327	62	389	84.06
262. Breast biopsy and local excision for non-malignancy	564	69	633	89.10
267. Perianal and pilonidal procedures	398	211	609	65.35
339. Testes procedures, non-malignancy age >17 years	98	198	296	33.11
340. Testes procedures, non-malignancy age <18 years	41	156	197	20.81
342. Circumcision, age >17 years	746	3	749	99.60
343. Circumcision, age <18 years	266	31	297	89.56
351. Sterilization, male	537	0	537	100
361. Laparoscopy and incisional tubal interruption	58	52	110	52.73
362. Endoscopic tubal interruption	1	9	10	10
364. Dilation and curettage, conization except for malignancy	167	87	254	65.75
494. Laparoscopic cholecystectomy without CC	16	790	806	1.99
Total	19640	6387	26027	75.46

Region of Murcia 2002–2003. DRG: diagnosis related group; CC: complication-comorbidity; MAS: major ambulatory surgery; SI: substitution index.

patient surgery services. The number of beds in the hospitals in the study ranged from 78 to 944.

We considered as MAS cases all scheduled interventions which required 0 days of hospitalization and were included in 1 of the 31 DRG's that had been previously selected to be part of this study.

In preparing our list, we took into account the DRG's on the MAS list used by INSALUD[1] and the reality of the region as regards the use of these procedures in the hospitals included in the study. To do so, we did an initial search of the databases to identify cases of specialized ambulatory care for the years 2002 and 2003. We generally excluded medical DRG's, except category 351 (male sterilization). We also excluded those which had a high probability of producing confusion given the different type of procedures included under some headings (for example: "other surgical procedures"). Finally, we also excluded all DRG's with complications-comorbidity (CC).

The SI was calculated as the percentage of ambulatory care interventions (0 hospital days) in relation to the total number of scheduled interventions for the selected DRG's.

The number of potentially avoidable admissions and stays was obtained using the total number of cases that required hospitalization, with the exception of emergency admissions and cases that involved complications, psychiatric pathology, drug addiction, mentally handicapped persons and/or stays of more than 14 days [2].

DRG's with the best prospects for improvement were those in which the percentage of potentially avoidable stays was the highest.

In order to ensure the reliability of the indicators that were studied and to avoid random variability, all results were calculated as the average for the 2 years included in the study.

3. Results

Table 1 shows the cases which were rejected as potentially ambulatory after applying the exclusion criteria which were used for each one of the 31 selected DRG's. The cases

[1] The Federal Institute that managed the health care system in the Autonomous Region of Murcia until 2002.

with complication-comorbidity are not included because the DRG's that included an annotation of this type were excluded from the study.

The table shows that the application of the exclusion criteria eliminated 33.12% of all potential ambulatory cases. Of all of the factors that were studied, the one with the greatest impact was whether the admission was emergency or scheduled. This factor was found in 97.19% of the excluded cases.

Table 2 shows the number of interventions performed in the region for each DRG and its SI. The average overall SI for both years was 75.46%. The highest SI (100%) was for DRG 351 (male sterilization) and the lowest was for DRG 494 (1.99%) (laparoscopic cholecystectomy without CC). Apart from male sterilization, we find a SI of 90% or higher for adult circumcision, carpal tunnel procedures and some ophthalmologic procedures. Laparoscopic cholecystectomy and endoscopic tubal interruption had a SI of 10% or lower.

Table 3 shows the SI for each DRG in each hospital as well as the total for the region and the rates ratios. In this case DRG's have been organized from the highest to the lowest SI for the whole region. The SI for the hospitals in the study ranged from 82.75% for H1 to 61.85% for H2 (rates ratio of 1.34).

Table 4 shows the DRG's listed from highest to lowest impact on avoidable stays. The average annual admissions

Table 3
Substitution index by hospital and rates ratios

DRG	Total region	H1	H2	H3	H4	H5	H6	RATESRATIO
351. Sterilization, male	100	–	–	100	100	100	100	1
342. Circumcision, age >17 years	99.60	100	–	99.63	100	97.83	99.65	1.02
39. Lens procedures with or without vitrectomy	97.43	99.78	99.64	99.28	88.91	87.91	97.27	1.13
40. Extraocular procedures except orbit, age >17 years	95.18	87.63	98.32	99.58	90.48	95.76	95.65	1.14
6. Carpal tunnel release	94.26	95.32	98.44	10	95.43	93.65	99.66	9.97
41. Extraocular procedures except orbit, age <18 years	92.91	95.83	100	72.22	94.74	100	57.14	1.75
38. Primary iris procedures	90.91	100	100	100	–	100	86.96	1.15
343. Circumcision, age <18 years	89.56	89.87	–	77.17	93.55	100	100	1.30
262. Breast biopsy and local excision for non-malignancy	89.10	86.57	51.52	93.40	60.87	97.30	96.69	1.89
232. Arthroscopy	84.06	92.96	87.5	0	0	0	91.37	Cases with zero
229. Hand or wrist procedures, except major joint procedure, without CC	81.66	87.22	82.47	11.54	86.42	70.59	86.70	7.56
60. Tonsillectomy and/or adenoidectomy only, age <18 years	76.95	82.69	–	0	23.81	8.82	87.77	Cases with zero
42. Intraocular procedures except retina, iris and lens	69.28	88.89	72.5	98.25	68.18	37.50	37.50	2.62
364. Dilation and curettage, conization except for malignancy	65.75	92.59	66.67	61.90	43.86	66.15	–	2.11
267. Perianal and pilonidal procedures	65.35	37.14	2.35	40	88.89	97.10	95.88	41.27
225. Foot procedures	65.27	70.97	98.14	0	32.26	12	63.64	Cases with zero
158. Anal and stomal procedures without CC	58.42	17.50	2.61	16.67	58.24	78.02	81.01	31.05
227. Soft tissue procedures without CC	56.25	27.08	76	39.13	60	20	72.57	3.80
163. Hernia procedures, age <18 years	54.75	54.30	0	0	77.78	100	81.82	Cases with zero
361. Laparoscopy and incisional tubal interruption	52.73	96.36	0	0	40	50	–	Cases with zero
231. Local excision and removal of internal fix devices except hip and femur	51.98	41.80	51	19.05	64.52	20	69.57	3.65
59. Tonsillectomy and/or adenoidectomy only, age >17 years	48.54	25	–	12	0	–	68.66	Cases with zero
55. Miscellaneous ear, nose, mouth and throat procedures	47.81	22.81	–	4.67	6.98	8.47	66.81	14.32
119. Vein ligation and stripping	46.48	6.90	1.03	10	38.89	17.02	76.98	74.67
162. Inguinal and femoral hernia procedures, age >17 years without CC	46.29	4.42	0.54	2.74	39.37	70.34	81.77	151.27
160. Hernia procedures except inguinal and femoral, age >17 years without CC	41.26	20.27	2.46	2.53	35.87	75.49	59.77	30.70
36. Retinal procedures	39.60	44.05	67.62	100	48.28	–	2.59	38.67
339. Testes procedures, non-malignancy age >17 years	33.11	0	100	3.49	19.44	0	56	Cases with zero
340. Testes procedures, non-malignancy age <18 years	20.81	18.06	–	0	33.33	0	60.87	Cases with zero
362. Endoscopic tubal interruption	10	0	–	–	0	50	–	Cases with zero
494. Laparoscopic cholecystectomy without CC	1.99	0	0	0	4.60	1.30	2.52	Cases with zero
Total	75.46	82.75	61.85	69.41	69.97	66.72	79.61	1.34

Region of Murcia 2002–2003. DRG: diagnosis related group; CC: complication-comorbidity.

Table 4
Number and percentage of avoidable stays

DRG	H1	H2	H3	H4	H5	H6	Total region	
	N	*N*	*N*	*N*	*N*	*N*	*N*	%
494. Laparoscopic cholecystectomy without CC	170	36	494	196	244	1063	2203	14.19
55. Miscellaneous ear, nose, mouth and throat procedures	591	0	284	81	114	866	1936	12.47
160. Hernia procedures except inguinal and femoral, age >17 years without CC	293	159	339	206	98	569	1664	10.72
162. Inguinal and femoral hernia procedures, age >17 without CC	280	469	196	279	203	232	1659	10.68
231. Local excision and removal of internal fix devices except hip and femur	307	137	196	60	70	197	967	6.23
158. Anal and stomal procedures without CC	278	140	48	81	44	332	923	5.94
36. Retinal procedures	193	60	0	28	0	419	700	4.51
225. Foot procedures	51	15	187	82	147	175	657	4.23
119. Vein ligation and stripping	55	145	41	77	106	129	553	3.56
339. Testes procedures, non-malignancy age >17 years	19	0	217	105	50	127	518	3.34
42. Intraocular procedures except retina, iris and lens	69	56	7	9	8	313	462	2.98
227. Soft tissue procedures without CC	200	36	52	21	34	103	446	2.87
60. Amigdalectomía y/o adenoidectomía solo, edad <18 years	83	0	91	58	41	141	414	2.67
39. Lens procedures with or without vitrectomy	24	4	19	117	64	132	360	2.32
267. Perianal and pilonidal procedures	56	206	4	13	5	23	307	1.98
340. Testes procedures, non-malignancy age <18 years	200	0	50	5	23	17	295	1.90
229. Hand or wrist procedures, except major joint procedure, without CC	30	75	78	24	18	40	265	1.71
262. Breast biopsy and local excision for non-malignancy	100	26	13	16	2	9	166	1.07
163. Hernia procedures, age <18 years	143	10	2	2	0	6	163	1.05
40. Extraocular procedures except orbit, age >17 years	95	2	2	6	8	35	148	0.95
361. Laparoscopy and incisional tubal interruption	5	112	15	11	1	0	144	0.93
364. Dilation and curettage, conization except for malignancy	8	11	34	65	24	0	142	0.91
59. Tonsillectomy and/or adenoidectomy only, age >17 years	11	0	50	14	0	51	126	0.81
232. Arthroscopy	10	1	14	15	36	36	112	0.72
6. Carpal tunnel release	13	3	43	16	6	1	82	0.53
343. Circumcision, age <18 years	17	0	38	3	0	0	58	0.37
41. Extraocular procedures except orbit, age <18 years	11	0	9	3	0	11	34	0.22
362. Endoscopic tubal interruption	2	0	0	10	1	0	13	0.08
38. Primary iris procedures	0	0	0	0	0	6	6	0.04
342. Circumcision, age >17 years	0	0	1	0	2	1	4	0.03
351. Sterilization, male	0	0	0	0	0	0	0	0
Total	3314	1703	2524	1603	1349	5034	15527	100

Region of Murcia 2002–2003. DRG: diagnosis related group; CC: complication-comorbidity.

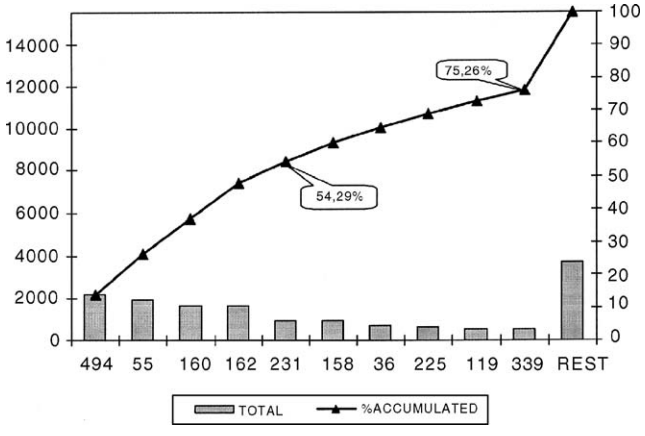

Fig. 1. Number and percentage of avoidable stays, 2002–2003.

and potentially avoidable hospital days was 3194 and 7764, respectively. 54.29% of the avoidable stays (Fig. 1) pertained to five DRG's (494, 55, 160, 162 and 231).

4. Discussion

The study of the SI of MAS requires previous decision making related to the classification system that should be used to study this kind of surgery, the number and the type of procedures to include and the exclusion criteria to be used.

As regards the first point, most of the comparative studies done internationally use one of the following classification systems: the ICD-9-MC, the DRG or systems developed by the researchers themselves [3]. Although the most frequently used system is the ICD-9-MC, we chose to use the DRG system because it has become one of the most commonly used by clinicians and management alike [4].

One of the problems with using DRG's is that they are comprised of more or less homogeneous groupings of patients with similar resources consumption. This creates a risk that a procedure that is not on the list might be included in the study. We have tried to solve this problem by selecting a limited number of DRG's that appear in most of the lists used by the health authorities in Spain and by the now defunct INSALUD, excluding besides all those that include "other surgical procedures" in their headings.

The alternative to this solution would have been to study these procedures using the corresponding code from the ICD-9-MC system under the heading of main surgical procedure according to the MBDS. It is important to point out that this field is not always the same in the MBDS's of all of the hospitals in the study (most of the times is the field T1 but other times is the C1 one) and that there exists a wide margin for improvement in the collection of this variable in their data sets [5]. This is due to the fact that the procedure indicated is not always the principal one related to the main diagnosis. We agree with other authors who feel that this factor could seriously affect the results [6].

As regards the exclusion criteria, we have used the surgical exclusion criteria for out-patients that have been adapted for use in the MBDS's which were agreed to in a Delphi study carried out in Valencia [2]. However, we must point out that no restrictive criteria related to age have been applied due to the large number of MAS interventions involving children under 15 years of age performed at the hospitals involved in the study and to the existence of studies that include paediatric cases [7].

In addition to this, it is important to understand that the use of clinical–administrative MBDS databases in this kind of study does not allow us to monitor other factors such as previous cases of complications due to anaesthesia, unaccompanied patients, the condition of the patient's home, or patient consent. This means that the study might include cases considered to be potentially ambulatory which were really not.

Table 1 shows the impact on inclusion in the study of cases of MAS according to the three exclusion criteria used. As mentioned earlier, the most important factor was whether the admission was scheduled or emergency. However, given that the criteria used to record this variable (type of admission) varies from hospital to hospital and that some studies do not exclude cases that were emergency admissions when calculating this indicator [8] (and since there are many cases, this affects in great measure the calculation of the SI), it would be wise to analyze the impact of this factor for each DRG by calculating two SI values, one for all of the cases and another one for scheduled procedures only.

The DRG's with the highest number of exclusions were 364 (dilation and curettage, conization except for cases of malignant neoplasia), 229 (hand or wrist procedures, except major joint procedures, without CC) and 158 (anal and stomal procedures without CC).

The SI's obtained in this study are shown in Tables 2 and 3. The global SI was 75.46%, similar to the average of 75% obtained in the Delphi study done in Catalonia in 1995 [9] and a bit higher than the 65% and 70% found in the United Kingdom and the United States in the 2-year period 1998–1999 [10], although we should consider the time that has passed in both cases and the differences in the procedures included and the exclusion criteria used.

Even though it was not possible to monitor all of the factors, could lead us to think that the SI might be even higher that the one we report, the use of a small list of DRGs, the problem with the type of admission variable and the fact that some hospitals might not offer this kind of surgery suggests that the SI is probably even lower than the one we obtained in this study. In other words, the margin for improvement is even greater.

As regards SI for DRG, it is useful to compare this study to another one carried out in Catalonia where this patient classification system was also used to analyze this type of care [11]. In this paper, the SI was also high for the public hospitals in cases of lens, hand or wrist surgery and for non-malignant dilation and cutterage, non-malignant breast tumours and adult circumcisions; and low in inguinal and femoral hernias in adults, paediatric hernias and laparoscopic tubal interruption. For this last type of surgery, the SI in Murcia was much higher than the one found in Catalonia, while just the opposite was true for endoscopic tubal interruption in which the SI was much lower in Murcia.

The results of this study are only applicable to those hospitals similar to the ones that have participated in the study and that use similar methods. In addition to this, we have to bear in mind in order to compare, that in some studies, cases that involve a hospital stay of more than 23 h post-operatively are being counted as MAS. These patients should be considered inpatients, because this sort of surgery is less cost-effective than MAS and the inclusion of these cases produces a distortion of the results [10].

There is a wide margin for improvement in relation to the performance of MAS procedures in the six hospitals that were included in this study in the Region of Murcia. In addition, we should also mention that there are two hospitals that provided no information about this type of surgery and another one where it has not been implemented yet.

Five DRG's (laparoscopic cholecystectomy, miscellaneous ear, nose, mouth and throat procedures, hernia procedures in adults and the removal of internal fixation devices except hip and femur) account for more than 50% of potentially avoidable days of stay. This is a relevant factor because these are procedures for which there are more efficient treatment alternatives and because the waiting lists for these procedures in the public health-care system are quite long [1]. According to the latest data published by the Spanish Ministry of Health, inguinal hernia procedures and cholecystectomies appear in second and sixth place, respectively, in the number of patients on waiting lists [12]. In addition, these are procedures for which the SI's for the different hospitals studied vary greatly and surpass, in all the cases, the average reached for all of the DRG's (Table 3). Due to this

variability, it is easy to identify the hospital with the highest incidence of this type of intervention for each specific procedure.

At a more specific level and with respect to laparoscopic cholecystectomies, the SI obtained in this work (1.99% average with a maximum of 4.60%) is much lower than the one reported in a national study (90%). This high SI was reached thanks to the use of preventative analgesics, non-opiate anaesthesia and intra-operative intraperitoneal anaesthetics during the procedure [13].

In order to promote this approach to surgery, changes in financing and incentive policies and new procedures should be introduced, protocols should be updated, and benchmarking strategies should be established.

Other studies that have been done show that financing is the most important factor in promoting this option [2,4,14–18]. In 1999, INSALUD changed the payment structure from one based on fixed payments to one based on payment per procedure using the DRG's. This meant that the hospital received the same funding when they used a MAS approach for interventions as they did when they used an inpatient approach. This was a significant change and increased the use of this kind of intervention as we can see monitoring the SI for each type of process. The future use of patient classification systems specifically designed for ambulatory care will bring about yet more changes in this regard.

One solution regarding incentive policies could be to change the present system for another one that better discriminates merit and achievement among professionals [18].

Over the last few years, the development of minimally invasive surgical techniques (arthroscopy, laparoscopic sterilization, therapeutic or surgical endoscopy, etc.) has increased the number of outpatient procedures [10,17]. While modifying the technological competence of the hospital is necessary in order to offer more ambulatory surgery, it is not the only change that needs to be made. In some cases, inpatient surgery is done when outpatient surgery would be just as good so that the hospital can comply with the goals set by the government as regards the reduction of hospital stays for inpatients.

The revision of current protocols should take into account the most recent advances in both anaesthesia, with the emergence of shorter action drugs that have fewer side effects [2,10,13,17,19], and in post-operative care techniques. The success of ambulatory surgery depends to a great extent on these factors which make it a much more attractive option for the patient. Patients will be able to count on the support of the healthcare staff who will make a follow-up call 24 h post-operatively and be available 24 h a day to answer any questions they might have [10,20].

The high variability that we see in the SI's of the DRG's with the highest number of avoidable stays, suggests that benchmarks should be established among the hospitals that show the highest SI's and those with lower values for a specific process.

There is no reason why this approach should not be implemented given that procedures performed in this way are more efficient and safer than those done using some of the traditional approaches and patient satisfaction is also higher. There is a wide margin for improvement and for the implementation of corrective measures.

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Evaluation of inguinal hernia in ambulatory surgery: A prospective monocentric study on 1009 inguinal hernia

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Abstract

Ambulatory surgery for inguinal hernia has not been really developed in our country.

Aim: We evaluated the feasibility of inguinal hernia surgery on ambulatory.

Patients and methods: From January 1995 to June 2004, we performed 1009 inguinal hernia. There were 934 men (92.8%) and 75 women (7.2%). Middle age was 58.36 years (range: 7–95 years). All the patients were examined by their primary doctor on the first and the third day and by the surgeon on the tenth day after discharge. Telephone follow-up on the patient's condition was performed by a registered nurse on postoperative days 1 and 3.

Results: Eight hundred and thirty three patients were operated on by ambulatory surgery (82.5%). Overall morbidity was 8.5% ($n=86$). Satisfaction index was excellent for 93.8% ($n=948$). Locoregional anesthesia alone or associated with general anesthesia was used for 900 patients (98.1%). Only 466 patients (46.2%) were painful, 258 (25.55%) had a discomfort, and 285 (28.24%) had no symptomatology.

Conclusion: Tension-free technique under locoregional anesthesia for inguinal hernia allows ambulatory surgery with a low rate of morbidity and high satisfaction index.

Keywords: Inguinal hernia; Ambulatory surgery; Locoregional anesthesia

Ambulatory surgery, or day surgery, is defined as the whole of the surgical acts carried out under technical conditions requiring imperatively the safety of an operating theatre suite under an anesthesia of variable modalities allowing, without raised risk, the exit of the patient the same day of its admission. In our country this surgery has not been really developed. In 1998, there were 130,000 operations for inguinal hernia. Only 6% were conducted in ambulatory (adults and children) and only 1.6% concerned adult surgery [1]. We put in place a structure which allowed us the practice of inguinal hernia repair in ambulatory surgery. Mortality and morbidity are not any more the only criteria to evaluate the feasibility of this kind of surgery. Quality of life and security seem to be important. In this study, we evaluated the feasibility in our institution of inguinal hernia surgery in ambulatory. In addition to the study of early morbidity, pain and index of satisfaction were analyzed. These criteria are necessary to evaluate a technique in ambulatory surgery.

1. Patients and methods

This is a monocentric prospective study conducted from January 1995 to June 2004. On this period, 1009 patients were operated for inguinal hernia. Ambulatory surgery was

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Table 1
Medicolegal criteria for ambulatory surgery

Psychological criteria	Medical criteria
Having a home	Age > 6 months
Having a phone number	ASA < grade 3
Not be alone at home	
No psychologic trouble	
Good understanding	

ASA: American Society of Anaesthesiology.

proposed for all the patients after exclusion of some not corresponding to the legal criteria of ambulatory (Table 1). Decision of ambulatory surgery was not influenced by the medical history, the age, or the body mass index. All the patients were visited by the surgeon and the anesthesiologist before their exit, by their doctor on days 1 and 3, and by the surgeon on day 10.

1.1. Population

There were 934 men (92.8%) and 75 women (7.2%). Middle age was 58.36 years (range: 7–95 years). Majority of patients were between 40 and 80 years of age. American Society of Anaesthesiology (ASA) grade I or II risk for general anesthetic was 43% ($n = 434$) and 42.8% ($n = 432$), respectively. 51.3% ($n = 509$) of the patients were retired at the time of surgery. Patients who were operated in ambulatory surgery corresponded to the legal criteria (Table 1).

1.2. Surgical procedure

Patients underwent open mesh hernioplasty (tension-free). None surgery was realised under laparoscopy. We used a polypropilen mesh MS 90 (12/65), 90 g/cm^2 from Textile Hi-Tec® for Swing-technologies®.

1.3. Postoperative management

After separate assessments by the operating surgeon and the anesthetist, patients were discharged on the same day with a letter for their doctor. All patients were prescribed an oral compound analgesic (paracetamol and codein), and a 24-h telephone hotline was available to patients in case of any problems or queries. All patients had follow-up at the tenth day after discharge. Telephone follow-up on the patient's condition was performed by a registered nurse on postoperative days 1 and 3.

1.4. Anesthetic technique

Ilio inguinal block and monitored anesthesia care was mostly used. This technique consisted in three punctures combined with an infiltration of surgical incision. The block was performed with short bevel needle (45°, 50 mm, 24 G) and 40 ml of local anesthetic was used (Ropivacaine 0.75 or Bupivacaine 0.50). A light sedation was given before punctures (Midazolam). In case of anesthesia was not sufficient Lidocaine 1% was given locally by the surgeon and/or intravenous sedation was given by the anesthetist.

2. Statistical analysis

Simple descriptive analysis was performed to describe the population. Statistical difference was determined by Chi-square test for qualitative variant. For the comparison between qualitative and quantitative variant, variance analysis or Kruskall test was performed where appropriated. A p-value of less than 0.05 was regarded as significant.

3. Results

3.1. Descriptive analysis

On 1009 patients, 82.5% ($n = 833$) were operated on ambulatory. Hernia was not complicated for the majority (97.1%; $n = 980$). Surgical procedure was principally an open mesh hernioplasty (tension-free technique): 84.9% ($n = 857$). 98.1% ($n = 900$) of them were operated with locoregional anesthesia alone or associated with general anesthesia (details of the population are given in Table 2). None of the patients presented a preoperative complication. Operative time was 31.6 min (10–135 min). Theatre suite duration was 64.6 min (40–435 min). The remaining patients were not operated in ambulatory surgery ($n = 176$; 17.5%). The principal cause was the respect of the medicolegal criteria of ambulatory surgery. Overall morbidity was 8.5% ($n = 86$): hematoma (3.2%), ecchymosis (5.3%), and urinary infection (0.1%). None mesh infection has been diagnosed. The postoperative pain evaluation was made according to the Analogic Visual Evaluation (EVA): 466 patients (46.2%) presented a real pain ($3 < \text{EVA} < 10$) and 374 (37.1%) had only a simple discomfort ($\text{EVA} < 3$). Majority of the patients walked the day of their surgery (94.8%; $n = 957$). Overall satisfaction was excellent for 93.8% of the patients ($n = 948$).

3.2. Risk factors for hospitalisation

Details of the results are summarized in Table 3. The preoperative symptomatology of the hernia was a determinant factor for an hospitalisation. Patients who presented

Table 2
Type of anesthesia used for the inguinal hernia repair

Type of anesthesia	Number of patients
Locoregional anesthesia alone	696 (69%)
Locoregional anesthesia + intravenous sedation	173 (17.1%)
Locoregional anesthesia + general anesthesia	121 (12%)
General anesthesia alone	19 (1.9%)

Table 3
Risk factors for hospitalisation versu ambulatory surgery for inguinal hernia

	Ambulatory	Hospitalisation	p
Age (years)	56.8	65.6	$<10^{-6}$
ASA	1.6	1.9	$<10^{-6}$
BMI	24.44	24.4	NS
Surgery duration (min)	30.9	35.15	0.001
Total duration (min)	63.61	69.8	NS
Preoperative pain	6%	13.6%	0.01
Bilateral hernia	4.9%	13.3%	0.0002
General and local anesthesia	12.3%	21.7%	0.01

ASA, American Society of Anaesthesiology grade; BMI, body mass index; NS, no statistical difference.

a pain before surgery was usually hospitalised conversely to the patients with no symptomatology: 13.6% versus 6%, respectively ($p = 0.01$). The presence of a bilateral hernia brought about a frequent hospitalisation: 13.3% versus 4.9% ($p = 0.00008$). In the same way, general associated with local anesthesia is a risk factor of hospitalisation: 21.7% versus 12.3% ($p = 0.01$).

3.3. Risk factors of postoperative morbidity

Overall morbidity (surgical and medical) represented 8.5% ($n = 86$). Age of the patients was a determinant factor. Older patients had more morbidity than younger: 63 years old versus 57.9 years old ($p = 0.005$). Patients who presented a dysury (11.8%) before surgery had more complications than the patients without dysury (6.8%) ($p = 0.007$). The symptomatology of the hernia (pain during a walk or a rest) was statistically significative for the morbidity in comparison with none symptomatology ($p = 0.0014$). In contrast, type of hernioplasty, anesthesy, ASA score were not find as risk factors.

Table 4
Risk factors of postoperative pain

Risk factors	Postoperative pain	p
Ambulatory/hospitalisation	46.7%/44%	NS
Age (years)	60.6/55.75	0.000001
Tabagism (Y/N)	43.9%/59.1%	0.004
Constipation (Y/N)	45.3%/61.8%	0.007
Pain during walking (Y/N)	43.8%/56.2%	0.0009
Pain during rest (Y/N)	41.9%/58.1%	0.0009
Surgical techniques (Shouldice/Lichtenstein)	66.7%/48.4%	0.005
Duration (surgery/anesthesia)	64%/68%	0.001

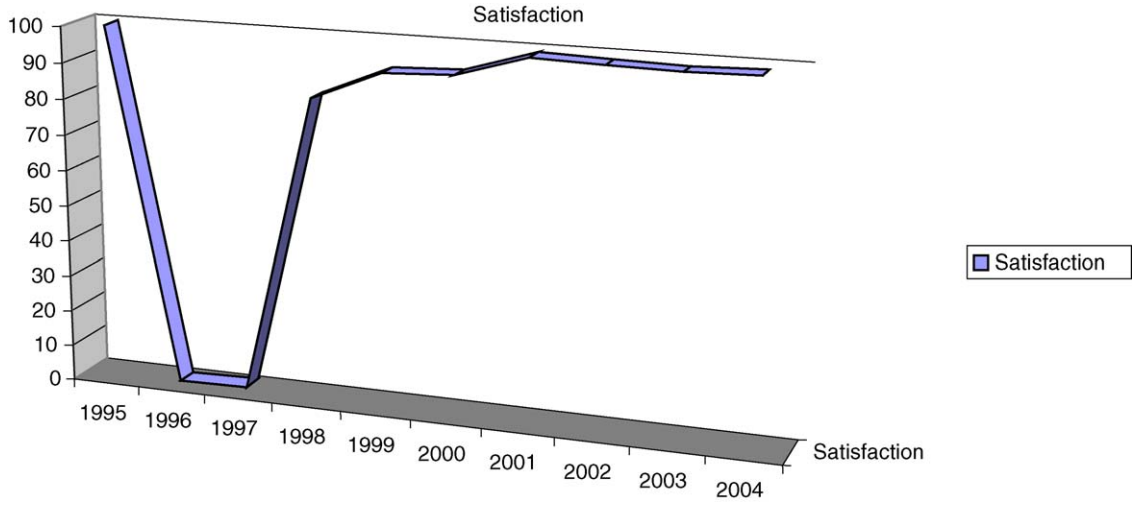
Results are expressed in percentage of patients presenting pain in each category. Y (yes), presence; N (no), absence.

3.4. Postoperative pain

Pain is a criteria difficult to evaluate. We determined two level of pain depending of the EVA. Four hundred and sixty six patients (46.2%) were painful ($3 < \text{EVA} < 10$), 258 (25.55%) had a discomfort, and 285 (28.24%) had no symptomatology. In the majority of cases, pain was soothed as 80% of all the patients signaled no symptomatology after oral analgesic. Results of the risk factors for postoperative pain are summarize in Table 4. Two characteristics statistically significative have been founded. This is the constipation and tabagism ($p = 0.0009$).

3.5. Satisfaction index

This is a patient's subjective evaluation of their taking charge during the hospitalisation in the ambulatory structure when they visit the surgeon on day 10. Since 1980, satisfaction index is around 80% and more than 98% from 2000 to 2004 (Graph 1). The most important parameter encountered for a non-satisfaction was the insecurity of the first night.



Graph 1. Satisfaction index evaluation during the years 1995–2004.

4. Discussion

Ambulatory surgery, or day surgery, permit to the patient to go home the same day of its surgery. It justifies a better quality of care for a lesser cost [2]. In this study we proved that the "tension-free" is a good technique for this surgery under local anesthesia. We present a study with 82.5% of the patients who are operated in ambulatory with a satisfaction index superior to 98% the last 4 years. In our country, ambulatory surgery for inguinal hernia is not still enough developed compare to European countries (6% versus 11%, respectively) [3]. In contrast, De Lathouwer et al. showed that the United State and the Canada practice usually this surgery (84% and 43%, respectively) [4]. Difficulties encounter were essentially the absence of discussion with the patient and the structure necessary to practice ambulatory surgery [5]. In France, on 130,000 inguinal hernia, only 1.6% are operated in ambulatory (except the children) [1]. In this study, we do not excluded patients. The difference in this study, compare to others, is the absence of selection of the patients even if it was a big hernia, a recurrence, a body mass index to high, or bilateral hernia [6–10]. We proposed ambulatory surgery depending of the medicolegal criteria describe by Hollender et al. [11]. The overall rate of satisfaction is 93.9% with more than 98% the last 4 years. It is no more the risk of pain which contribute to the absence of satisfaction but the apprehension about the first night outside the hospital [12]. We found in this study a parameter classically describe for hospitalisation such as bilateral hernia (13.5% versus 4.9%; $p = 0.0002$). In contrast, we do not found statistical difference for obesity which is a criteria commonly exclude of the studies [6,9]. Pain of the hernia before surgery seems to play an important role for the risk of hospitalisation. Indeed, 13.6% versus 6% of our patients who presented pain at rest and with walk were hospitalised more than 24 h ($p = 0.01$). The surgical procedure used in this study was mainly the "tension-free" technique (84.9%; $n = 857$ patients) as it was first described by Lichtenstein [13] and Shulman et al. [14]. It is a procedure reproducible, easy to learn, and realised under locoregional anesthesia [15]. This technique, described by Lichtenstein, must be the gold standard for inguinal hernia in ambulatory surgery [16]. The meta-analysis of the European Union Hernia Trialist Collaboration showed better results for the laparoscopic versus the open procedure (pain and return to work). However, this technique is longer, costly, general anesthesia is necessary, and the learning curve is longer and difficult [17].

Majority of our patients were operated under locoregional anesthesia (86.1%; $n = 869$). This procedure was used isolated (696 patients or 69%), or associated to a intravenous sedation (173 patients or 17.1%). The number of patients operated under this procedure shows that it is a good technic for ambulatory surgery. Indeed, it permits anesthesia but also extended reduction of postoperative pain [18,19]. Song et al. published a randomised study on the type of anesthesia for inguinal hernia [20]. They founded that locoregional anesthesia was better than general or peridural anesthesia for postoperative pain, return to work, and cost ($p < 0.05$). These results are similar to ours even if we did not compare the different type of anesthesia (satisfaction rate at 93.8% in our study). This procedure permits a real reduction of adverse effects of anesthesia such as vomiting, orthostatic hypotension, to meet the deadline of discharge [21–23]. The major side effect for locoregional anesthesia is the risk of crural paresis as we founded in this study. Thirteen patients presented this complication and seven could not be discharged the same day of the surgery. It represented 1.5% of the patients operated with locoregional anesthesia. It is a side effect well known by the injection of Ropivacaïne too deep in the muscle [24,25] for 20–30% of the patients [26]. When we studied the postoperative morbidity, we do not found urinary retention as it is described for inguinal hernia surgery under general anesthesia [27] or under laparoscopy [28]. Among the complications, we found two parameters which seem to occur in their apparition and they are not describe in the literature. This is the presence of dysury or not (16.8% versus 7.6%; $p = 0.0006$), and preoperative painful hernia or not (6.4% versus 16.4%; $p = 0.014$). The postoperative pain is a criteria difficult to estimate even if the patient visit his medical doctor on days 1 and 2 and the surgeon on day 10. The first symptomatology, when they return to their home, seems to be reduced the tenth day for the visit. In this study, 466 patients (46.2%) were painful ($3 < \text{EVA} < 10$), 258 (25.55%) had a discomfort, and 285 (28.24%) had no symptomatology. In the majority of cases, pain was soothed as 80% of all the patients signaled no symptomatology after oral analgesic. It looks like that locoregional anesthesia associated with the use of oral analgesic, before apparition of pain, permit a reduction of postoperative pain [29]. In the same way, for a better control of pain, it is necessary to identify patients with a chronic tabagism and constipation. We founded a higher risk of postoperative pain for such patients and it will be necessary to increase oral analgesic for them. The overall satisfaction was 93.8% with more than 98% for the last 4 years. It is reported that pain is the essential factor of non-satisfaction [30]. In this study, it seems that this parameter is not predominant. Insecurity during the first night was the first criteria. To avoid this feeling, we tried to move the hospital to the home of the patient. We give all the information necessary before surgery, and the patient make a visit of the ambulatory structure. He is seen by the surgeon and the anesthetist before his discharge with a letter, the report of surgery, a data record hospital-city, oral compound analgesic, and a 24-h telephone hotline is available to patients in case of any problems or queries. The application of a legal protocol for ambulatory surgery allowed us to develop this surgery. In 1995, 60% of the hospitalised patients were due to the surgeon or the patient himself and only 20% by the respect of the protocol. The latest years, 66.6–80% of the hospitalised patients were due to the application of the protocol. The remaining patient was hospitalised for disfunction (morbidity, administrative complications). Our attitude concerning ambulatory surgery

changed during the years to allowed us the practice of this kind of surgery in an adapted structure.

The tension-free technique for inguinal hernia in ambulatory surgery is workable (82.5% of our patients). Using a locoregional anesthesia for ambulatory seems to be better (98.1% of the patients) with a satisfaction rate of 93.8%. We need to take care about quality of life and security after ambulatory surgery. This study showed a high level of satisfaction with a low morbidity rate for inguinal hernia. This is the result of a good postoperative analgesia and the use of an adapted structure for ambulatory surgery.

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Review

Ambulatory surgery in Germany 2004 and historical aspects

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Abstract

Ambulatory surgery in Germany is mostly performed in private units like day clinics, specialized doctor's offices and ambulatory surgery centres. In contrast, hospitals prefer inpatient treatment. Their hierarchical system often inhibited introduction of new techniques like endo-microsurgery. Total costs of tracer procedures are half in private units as compared to hospitals, and this at the same quality level. This points to an inherent inefficiency of the hospital system for most procedures that can be handled on an ambulatory base.

Keywords: Hospital system; Staff organisation; Day clinics; Quality assessment system; Patient questionnaires; Total costs per case; Costs per operating hour; DRG-based fees

Contents

1. History of progress in surgical techniques

Surgery throughout the centuries mainly depended upon the progress in surgical techniques.

The beginning of advanced surgery may well be put to a date around 300 B.C. when vascular ligature was practiced in Alexandria. Throughout the Roman Empire and the Middle Ages there was little progress in surgical treatment. Paré (1510–1590), "Father of the French Surgery", and Vesalius (1514–1564) stand for the beginning of a new era in surgery and surgical anatomy. Between 1850 and 1900 great progress

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was made in the fields of hygiene, anaesthesia and hemostasis (electrocautery, suture material). After 1947 antibiotics (penicillium), microsurgery (using the microscope or magnifying glass) and endoscopy (laparoscopy) allowed advances in surgery so that after approximately 1992 major surgical procedures like hysterectomy, cholecystectomy and sigma resection could be performed by endo-microsurgery.

2. History of outpatient/ambulatory versus inpatient surgical treatment

Throughout the ages up to the middle of the 19th century surgery was mostly performed at home or on the battle field, that means in an ambulatory situation. However we know that the Romans already used some kind of hospital (valetudinarium) in their camps. It was only around 1800 under the influence of rationalism that hospitals for the sick changed into hospitals where diseases were treated. Around 1880—after progress in anaesthesia, hygiene and hemostasis—a wave of new hospital construction took place leading to a centralisation of surgery inside hospitals. Hospitals became larger and larger (Vienna "Allgemeines Krankenhaus", Klinikum Aachen) almost up to the end of the 20th century.

But in 1971 the first day surgery center was built in Phoenix, Arizona (USA). This was the start into a new era where surgery—mainly because of financial reasons—was performed more and more on an ambulatory basis. By around 1995 already 75% of all surgery in the United States took place as outpatient or ambulatory procedures! Other countries like Germany did not take part in this process because the German health care system is favouring inpatient treatment, which is remunerated 3–10 times better than ambulatory treatment. Thus looking at ambulatory surgery in Germany only 3% is performed in hospitals, 97% in freestanding units.

3. History of hospital staff organisation

In order to understand the "German way" in hospital organisation especially in surgery we should look at hospital staff organisation in Germany. Since the 18th century the Prussian Military Academy in Berlin steadily expanded. After the defeat of the Prussians by Napoleon in 1806 the Prussian king enlarged the Military Academy and founded several universities with surgery departments, e.g. the "Charité" in Berlin and the University in Bonn. In the 19th century the Prussian Military Academy was the best-known surgical department in Germany, its head surgeons were at the same time professors for surgery at the Charité. Thus the military staff organisation of the Prussian Academy with its hierarchy (Ober- und Unterarzt, superior and inferior physician) was taken over by the Charité-University and afterwards by the rest of the German universities.

At about 1850 the clinical professors in Bonn usually had one assistant only. They had to do clinical and research work mostly by their own. At about 1900 they had up to four assistants and one superior (head) assistant (Oberarzt). Thereafter the staff increased steadily. At about 1980 one "Chief" (head of the clinic = medical superintendent) in larger universities often directed 4–8 head assistants and 20–50 assistants. Thus the influence and the income of the head of such hierarchical structure—called "Chefarztsystem"—became great. This "Chefarztsystem" only flourished with hospitalized patients, not with outpatients. Therefore ambulatory surgery was not supported by the "Chiefs" although every university department had a policlinic and thus could have performed surgical procedures on an ambulatory base.

4. Hospital owners/hospital finance

About 80% of all German hospitals now are public or non-profit, only about 20% are private. There used to be less private hospitals.

In 2003 94% of the public hospitals run a deficit and had to be supported by public resources. On the other hand private hospitals mostly managed a profit.

5. Primary reason for ambulatory surgery

Originally the primary reason for performing surgery on an ambulatory base was an ethical one. For instance, children are known to recover faster in the arms of her mother at home than in a hospital. That was the reason why Nicoll [4] started ambulatory surgery in children and Bourmer [1] did alike in Germany.

In the last 30 years other reasons for ambulatory surgery appeared, namely financial reasons (USA) and in Germany freedom to conduct surgery in his own unit without the hierarchy of a German "Chefarztsystem". This could be achieved in Germany as a freelancer, either as surgeon with an adequate private clientele or as a panel doctor (a social health insurance [SHI] accredited doctor = Kassenarzt). The doctor's fees of the SHI are very low, so these ambulatory surgeons will run an occupational risk as price for their freedom of profession.

6. Ambulatory surgery

Ambulatory surgery in Germany can be performed as panel doctors of the SHI or as a freelancer treating private patients. Since 1993 all hospitals are opened to ambulatory surgery at the same fees as panel doctors get. Because of the low prices only 3% of all ambulatory surgery in Germany is being done in hospitals on an outpatient basis.

Since January 1, 2004, all sickness funds of the SHI are allowed to contract directly with panel doctors without interference of the National Association of SHI-Accredited Physicians (Kassenärztliche Vereinigung), which hitherto acted as

a monopoly. This new law opened part of the SHI to the free market. The first dozen contracts of this so-called "integrated service" were DRG-based payments at the height of 50–90% of the DRG for inpatient procedures.

This new free market for ambulatory procedures does mean for freelancers:

- competition amongst doctors in day clinics and hospitals;
- full occupational risk;
- the quality in day clinics should be better than in hospitals;
- there is a strong need for quality management with feedback by patients.

7. History of day clinics

Germany has a long tradition of day clinics. The legal insurance against working accidents (Berufsgenossenschaft BG) holds a nationwide net of surgical offices with operating room facilities for working accidents. These offices called "D-Arztpraxen" are run by specialised surgeons with specific operating room facilities.

In 2003 altogether 29,599 of the 124,203 panel doctors of the SHI, i.e. 24%, were holding the license to perform ambulatory surgery. This surgery takes place in doctor's offices (minor surgery), in day clinics and in the outpatient departments of hospitals.

Since 1993 all offices for ambulatory surgery (day clinics) have to be equipped in a similar way as for working accident surgery. Recently the requirements for day clinics increasingly are enforced. Therefore and because of deteriorating fees the number of panel doctors and also day clinics participating in ambulatory surgery is diminishing.

Today 1350 ambulatory surgeons—representing approximately as many offices or day clinics—are now members of the Federal Association for Ambulatory Surgery (BAO), which was founded in 1992. Most of these day clinics have small teams with one or two surgeons and 500–2000 surgical procedures per year.

The limit for the number of procedures per surgeon per year is much higher than in hospitals. In the field of gynecology it is approximately:

- 1400 procedures/a/surgeon if abortions are included;
- 1100 procedures/a/surgeon without abortions.

8. Size of day clinics

The largest day clinic is a gynecological day clinic in Hamburg where on the average 8500 procedures are performed per year in five operating rooms.

There is a large Eye Clinic in Bremen where even vitreoretinal eye surgery is done on an ambulatory basis. Other surgeons routinely perform cholecystectomies (Cologne) and advanced vascular surgery (Essen).

9. Major ambulatory procedures

Supracervical hysterectomy, breast cancer treatment, cholecystectomy, vascular shunts and vitreoretinal eye surgery, diskectomy and partial thyroidectomy are all procedures which many clinicians cannot think of as being done on an ambulatory basis. Yet they are established in German day clinics since years.

10. Quality management

Traditionally quality management is divided into three types: structural, procedural and outcome quality.

Structural quality is good to have but so far it has not been shown to have an influence on wound infection.

Procedural quality plays an important role in process management and therefore has mainly financial aspects.

Outcome quality is most important for patients. It is best measured by complication rates on the basis of patient questionnaires. This is now established in the quality assessment system AQS1, a nationwide private system using questionnaires for each – surgeon, anaesthetist and patient – and benchmarking for every procedure (http://www.medicaltex.de).

11. Complication rates (Bonn)

Since 1990 the gynecological day clinic Bonn routinely uses patient questionnaires. The complications rates and anonymous case reports are being published yearly and send to the referring doctors. The overall complication rate over the last 10 years including hospital referral was 0.7% and the wound infection rate was 0.1% [2].

Since 2002 the day clinic participates in the quality assessment system AQS1.

12. Total costs per case of tracer procedures

In 1999 a study was published under the auspices of the German Ministry of Education, Science, Research and Technology on the evaluation of endoscopic and open procedures in hospitals and day clinics. Data on total costs per case of specific procedures were gathered and calculated. This study was undertaken in 1994–1995 [3]. The total costs including direct and indirect costs (care at home, time off work) were investigated for the following procedures: cholecystectomy, appendectomy, exstirpation of adnexal masses, extrauterine pregnancy, tubal sterilisation, subacromial decompression and meniscectomy. Total costs were substantially less for laparoscopic procedures in comparison to open ones; endoscopic procedures in day clinics cost about half as much as inpatient treatment (Fig. 1).

	Hospital - endoscopic	Hospital - open (laparotomy)	Day clinic endoscopic
Cholecystectomy	3869,- €	5294,- €	1601,- €
Adnexal tumorectomy	2711,- €	4753,- €	1415,- €

Fig. 1. Total costs per case [3].

These figures never have been doubted, yet they were hidden from the public because they would implement a drastic reform of the Germany hospital system.

13. Actual costs in a day clinic (gynecology, Bonn)

Since 1990 all costs were related to one operating room hour (ORH) because during this ORH a fulltime ambulatory surgeon is earning most of his income. These costs include the profits for the surgeon, which corresponds to the salary of a head assistant in hospitals.

In 2004 the average costs per 1 ORH and 1 surgeon were 640 €/h or 10.67 €/min. With two surgeons costs were 769 €/h calculating 129 €/h as doctor's fee.

The price for individual procedures will have to be adjusted taking into account (1) the extent of technical equipment, (2). the surgeon's training and (3) the work stress using a relative value scale like RBRVS (USA) or tarmed (Switzerland).

14. DRG-based fees for ambulatory surgery

Since 1.1.2004 a new law allows so-called integrated health provision ("Integrierte Versorgung"). This means that the "wall" between hospitals and day clinics/doctor's offices shall be bridged by contracts which individual sickness funds can sign with panel doctors for single or multiple procedures. These contracts mainly are based upon the DRG system and amount to 50–90% of the DRG fees for inpatient treatment. All procedures are characterized by OPS-301 codes, which are correlated to DRGs.

15. Summary

Surgical progress and quality of work seem to be independent of the building (hospital, day clinic) where procedures are performed. They mainly are dependent upon the competence of the individual surgeon.

Pronounced progress in surgery recently came through endoscopic microsurgery as well as quality assessment by questionnaires of patients. Bench marking of tracer procedures will further increase outcome quality.

Economy plays a major role in medicine. In surgery a team around one operating room with one or two surgeons seems to be most efficient performing procedures up to 1 h operating time.

The total costs of surgical procedures are substantially less when surgery is performed on an ambulatory basis in freestanding units.

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True day surgery or 23-hour admission for unselected elective laparoscopic cholecystectomy?

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Abstract

Background: Day case laparoscopic cholecystectomy in the UK is reported in selected patient groups but its role in managing the majority of patients with symptomatic gallstones is unclear. We examined use of the ambulatory surgery unit (ASU) for unselected elective laparoscopic cholecystectomy.
Methods: Data were collected for 1 year. High-risk patients with known bile duct calculi, BMI > 40 and/or previous upper abdominal open surgery were excluded from ASU laparoscopic cholecystectomy. Standard surgical or anaesthetic protocols were used and standard criteria for discharge were employed.
Results: In 1 year, 258 of 275 patients (94%) admitted for elective laparoscopic cholecystectomy via the ASU were discharged within 23 h of admission including 62 patients (23%) discharged on the day of surgery. There were 16 (5%) conversions to open surgery and 10 (4%) unplanned readmissions to inpatient beds. Forty 'high-risk' patients underwent laparoscopic cholecystectomy from inpatient beds of which 29 (73%) were discharged within 23 h.
Conclusion: The ASU is the optimal location for elective laparoscopic cholecystectomy to maximize day case throughput and minimize impact on inpatient bed occupancy.

Keywords: Laparoscopic cholecystectomy; Day case; Ambulatory surgery

1. Introduction

True day case laparoscopic cholecystectomy (DCLC), defined as discharge on the day of surgery, is becoming established in the United Kingdom (UK) [1–3] and continental Europe [4,5] after a large number of studies, predominantly from North America, have established its safety, patient acceptance and cost-effectiveness [6–11]. However, most UK reports are based on carefully selected patient groups, leaving a large proportion of patients requiring elective laparoscopic cholecystectomy via the conventional inpatient route [1–3]. DCLC is included in the British Association of Day Surgery list of approved procedures and the UK Audit Commission "basket" of day surgery procedures but only 1% of laparoscopic cholecystectomies performed in the UK are true day cases [12,13]. Although DCLC is clearly feasible, its role in the overall management of the UK symptomatic gallstone population is not clearly defined.

In September 2002, surgical services in Edinburgh were consolidated in separate hospitals (oesophagogastric and hepatopancreaticobiliary surgery in the Royal Infirmary of Edinburgh (RIE) and colorectal surgery in the Western General Hospital). In addition, relocation of the RIE to a new building in April 2003 saw a reduction in inpatient bed numbers and the development of an expanded 5-day ambulatory surgery unit (ASU). These changes prompted development of a unit policy aiming to perform elective laparoscopic cholecystectomy within the ASU for as many patients as possible, with deliberate extension of normal day surgery selection criteria.

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All patients followed a clinical pathway, with inpatient care limited to patients with severe co-morbidity or high surgical risk.

The aim of this study was to assess the place of DCLC within our unit policy for elective management of gallstone disease in its first year by auditing duration of admission and reasons for delayed discharge.

2. Patients and methods

All elective laparoscopic cholecystectomy cases performed in the Royal Infirmary of Edinburgh between May 2003 and April 2004 were included. Patient details were retrieved from the Lothian Surgical Audit database and cross-checked with the record of admissions from the ASU and inpatient wards. Data on operative details and factors responsible for delayed discharge were obtained from the Lothian Surgical Audit database and/or from review of individual case records.

Surgical exclusion criteria for laparoscopic cholecystectomy in the ASU were patients with known common bile duct calculi or perceived high risk of conversion to open surgery (e.g. previous open upper abdominal surgery). Patients assessed preoperatively as having a high risk of bile duct calculi (biliary dilatation on ultrasound, a history of jaundice or markedly deranged liver function tests) underwent magnetic resonance cholangiography and/or endoscopic retrograde cholangiography to identify and where necessary remove ductal calculi; these patients were then considered suitable for treatment within the ASU.

All patients underwent nurse-led preoperative assessment according to unit protocol. Patients with myocardial infarction within 3 months of the proposed date of surgery or BMI > 40 were excluded from surgery in the ASU. All other co-morbid conditions were considered acceptable unless severely restricting daily activities. In borderline cases additional investigations (e.g. pulmonary function tests, echocardiography, etc.) were performed after discussion with anaesthetic or surgical staff.

Surgery was performed by, or by trainees under the supervision of, 14 consultant surgeons and 13 consultant anaesthetists. A standard four-port technique was employed with carbon dioxide pneumoperitoneum insufflated to 12 mmHg. Decisions regarding intraoperative cholangiography and placement of abdominal drains were left to the discretion of the operating surgeon. Bupivicaine 0.5% was infiltrated into skin wounds at the end of the procedure. Anaesthesia was performed according to individual anaesthetist preference and included routine nausea prophylaxis and multimodal per- and post-operative analgesia. The ASU was staffed 24 h per day on a 5-day basis. Standard criteria for discharge were employed. Nursing staff prospectively documented the reason(s) why patients could not be discharged on the day of surgery.

3. Results

A total of 315 patients were admitted electively for laparoscopic cholecystectomy at RIE from May 2003 to April 2004, 275 via the ASU and 40 via inpatient beds (Table 1). There was no significant difference between the groups by median age or male:female ratio. Of the ASU group, 62 patients (23%) underwent laparoscopic cholecystectomy as true day cases and 196 patients (71%) were discharged after a single overnight stay (23-h admission). Seventeen patients (6%) required admission beyond 24 h: 16 after conversion to open cholecystectomy and one patient who developed an early bile leak (treated by endoscopic retrograde cholangiography and insertion of a biliary stent). Ten patients (4%) required unplanned readmission to an inpatient bed within 30 days of surgery, of whom one required ultrasound-guided percutaneous drainage of a subhepatic fluid collection. In the remaining nine patients, tests to exclude significant post-operative complications or retained ductal calculi were normal and symptoms settled with simple analgesia. There were no other major post-operative complications in patients discharged within 24 h. There were no deaths.

Of the 40 patients admitted to inpatient beds, 12 had bile duct calculi, 11 had severe co-morbidity, 5 underwent a concurrent procedure and 3 had previous open upper abdominal surgery. Ten patients would have been suitable for surgery within the ASU. Of these, 7 were scheduled for Friday theatre lists and because the ASU is a 5-day unit were admitted directly to inpatient beds. In three patients, case-note review

Table 1
Comparison of patient demographics, duration of admission, conversion and readmission rates for elective laparoscopic cholecystectomy in ASU and inpatient units at Royal Infirmary of Edinburgh, May 2003–April 2004

	ASU ($n = 275$)	Inpatient ($n = 40$)	P
Age (median, range)	51 (16–84)	59 (16–81)	0.076
Male/female ratio	207/68	28/12	0.112
Duration of admission			
True day case	62 (23%)	–	
23-h admission	196 (71%)	29 (73%)	
>24 h	17 (6%)	11 (27%)	
Conversion to open surgery	16 (5%)	4 (10%)	
Unplanned readmission within 30 days	10 (4%)	3 (7%)	

Table 2
Reasons documented for overnight admission after ASU elective laparoscopic cholecystectomy

Anticipated overnight admission		Unanticipated overnight admission	
Afternoon theatre list	73	Surgical drain	21
High co-morbidity	23	Conversion to open surgery	16
Social support absent	22	Pain	16
		Nausea/vomiting	14
		Surgeon preference	10
		Drowsiness	6
		Urinary retention	4
		Other/not documented	8
Total	118		95

identified no clear reason for inpatient admission. Twenty-nine of the 40 inpatients (73%) were discharged within 23 h after a single overnight stay whilst the remainder required admission for a median of 2 days (range 2–11 days). The rate of conversion to open surgery was higher for inpatients than for ASU cases (10% versus 5%). Three patients (7%) required emergency readmission with post-operative abdominal pain and after investigation as above required only additional analgesia. There were no deaths or major complications in the inpatient group.

Reasons documented for inability to discharge patients from ASU on the day of surgery are shown in Table 2. Anticipated overnight admission was required for 73 patients undergoing surgery on afternoon theatre lists, high co-morbidity (23 patients) and social constraints (22 patients). The most frequent reasons for unanticipated overnight admission were presence of a surgical drain (21 patients), conversion to open surgery (16 patients), pain (16 patients) and nausea/vomiting (14 patients).

4. Discussion

The ideal day case operation is simple, short, uncomplicated and low-risk: laparoscopic cholecystectomy does not meet these requirements. Technical problems are not easily predicted and the operation may take in excess of the day surgery limit of 90 min with the additional possibility of conversion to open surgery. There is a significant incidence of early complications such as haemorrhage or bile leakage, which may require further surgical or endoscopic intervention. The first reports of day case laparoscopic cholecystectomy appeared soon after its introduction but surgical caution has delayed the widespread implementation of a routine day case policy for the procedure. However, surgeons have gained increasing experience with laparoscopic techniques which are now part of routine work. Complication rates are falling. Surgeons are better able to predict likely technical difficulty and to identify early post-operative problems. This increased comfort with laparoscopic cholecystectomy, coupled with reduced access to inpatient beds and financial imperatives have also played a role in driving a trend towards shorter hospital stays and wider consideration of day surgery. Whilst super-selection of patients for DCLC is possible with a high degree of success [1,2], it is difficult to assess from these reports how day surgery might fit into the overall pattern of gall stone management within the whole patient population.

In this study, we have audited our first year's experience of elective laparoscopic cholecystectomy experience in the relocated RIE. This is an expert centre where all surgeons perform a large number of varied laparoscopic cases and houses a regional hepatobiliary centre. A conscious and collective decision was made to divert as many laparoscopic cholecystectomy patients as possible to the ASU where the option of overnight stay existed, rather than aiming to select a group specifically for day case surgery. Eighty-seven percent of elective cases (275 of 315) were undertaken in the ASU setting and 20% (62 of 315) were performed as true day cases. The readmission rate for our ASU patients was 4% (comparable to that of recent reports from the UK [2] and North America [14]) and only one patient suffered a significant complication, suggesting our policy is safe. Despite minimal case selection, our rate of true DCLC is also comparable with recent UK studies of patients specifically selected for day case treatment: Leeder et al. [2] achieved day case laparoscopic cholecystectomy in 132 of a total of 357 (37%) cases in 2 years, whilst Ammori et al. [1] reported 117 of 744 (16%) over 6 years. Both of these studies employed stricter selection criteria than ours, for example excluding ASA III and IV patients.

In Table 2 we have listed reasons documented by nursing staff for failure to discharge patients on the day of surgery. It is immediately apparent that modest alterations might yield a major improvement in the rate of same day discharge. For example, patients undergoing surgery on afternoon lists might be moved to morning lists, or in a unit such as ours which is staffed 24 h per day, simply discharged later in the evening. The high number of surgical drains in this group was surprising; if required, these can be removed after a few hours observation and should not prevent same day discharge. Patient co-morbidity and social constraints may be valid reasons for overnight observation in some patients, but may also reflect reluctance of patients and staff to early discharge.

However, some reasons for delayed discharge are not predictable and may be more difficult to overcome. Armanath et al. reported a 29% admission rate in unselected patients admitted for DCLC whilst 20% of selected DCLC patients in a recent UK study required overnight admission [3,15]. Post-operative nausea, pain and drowsiness may be improved by tailored anaesthetic and analgesic protocols [16,17] but continue to be commonly cited reasons for unanticipated admission after day case laparoscopic cholecystectomy [18]. Our conversion rate of 5% of ASU cases is acceptable but higher than that quoted by other recent studies (2%, Leeder et al. [2]; 2%, Bal et al. [19]; 3%, Richardson et al. [20]). No individual amongst 14 surgeons in our group was more likely to convert to open surgery, but the higher conversion rate

suggests that the procedure should be limited to a core number of interested consultants; the average of approximately 20 laparoscopic cholecystectomies per consultant per year in this report is substantially less than annual numbers from other single-surgeon series [2,21].

In this series, 91% of 315 consecutive elective laparoscopic cholecystectomy cases were safely performed and discharged within 23 h of admission and 20% were discharged as true day cases. Managing these cases via the 5-day ASU has potential to maximize same day discharge but provides the option of an overnight stay if required whilst minimising inpatient bed occupancy. We feel that the ASU is the ideal environment for performing almost all elective laparoscopic cholecystectomies and only a few cases with high risk of conversion to open surgery or severe co-morbidity require elective admission to inpatient beds.

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Use of paracervical analgesia for outpatient hysteroscopic surgery: A randomized, double-blind, placebo-controlled study

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Abstract

Twenty-five women receiving sedation for outpatient hysteroscopic polypectomy were injected with 0.25% bupivacaine 10 mL (paracervical group) and another 25 received the same volume of saline (control group) at the cervical fornix. Both groups were given target-controlled propofol sedation during the procedure. More propofol (mg/min) was needed for adequate anesthesia in the control group compared to the paracervical group (6.5 versus 4.6). In addition, the postoperative pain scores were lower in the paracervical group than in the control group. Hemodynamic changes and postoperative side effects were similar in the two groups. This prospective, randomized, double-blind, placebo-controlled study confirmed the effective use of paracervical blocks. This approach has the effect of reducing the amount of intraoperative propofol and decreasing postoperative pain in outpatient hysteroscopic surgery.

Keywords: Outpatient hysteroscopy; Paracervical block; Postoperative pain; Propofol

1. Introduction

Outpatient hysteroscopy has replaced traditional dilatation and curettage under general anesthesia for diseases involving the uterine cavity. This effective alternative has been shown to have an improved sensitivity for diagnosis of 98% compared to 65% for dilatation and curettage [1,2]. This has the advantage of allowing direct visualization of the uterine cavity, thus more easily distinguishing between polyps and myomas, as well as allowing for the removal of small polyps hysteroscopically [3].

In a recent review of hysteroscopy, success rates are reported from 69 to 100% and acceptability rates, assessed by questionnaires, ranged from 83 to 99% [4]. The most common reason for failure is pain. When analgesia protocols are reviewed, no one is better than another for the control of pain. Paracervical anesthesia can reduce pain and vasovagal reactions at hysteroscopy [5]. However, recent reports have failed to find substantial or conclusive evidence for the use of the paracervical block as the sole anesthetic in outpatient hysteroscopy [6–10]. The technical approach including grasping the cervix with a tenaculum and injection of local anesthetics can be more painful than the hysteroscopy itself [11].

The purpose of this prospective, randomized, double-blind, placebo-controlled trial was to assess the postoperative analgesic efficacy of preoperative paracervical block using 0.25% bupivacaine for outpatient hysteroscoic polypectomy. We also evaluated the sparing effect of propofol after paracervical analgesia.

2. Materials and methods

This study was approved by the Hospital Ethics Committee for clinical research. Fifty women scheduled for

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outpatient hysteroscopic surgery, to remove small cervical polyps, were enrolled after written consent was obtained. Participants were randomized into two groups using a computer generated block number put inside a sealed envelope. The randomization and medication were prepared by a nurse who was not involved in the procedure. The surgeon, anesthesiologist and the patient were all blinded to the identity of the medication used. No premedication was given.

After baseline recording of electrocardiogram, heart rate, noninvasive blood pressure and peripheral oxygen saturation, a standardized sedation regimen was initiated in the lithotomy position. The target-controlled infusion (TCI) system runs on a microcomputer connected to an infusion pump (Becton-Dickinson infusion system, Le Grande Chemin, France). An infusion of propofol with a preset target concentration of 4.0 μg/mL was started until the patient had reached and maintained adequate sedation (sedation level 5 on a 1–5 sedation scale: eyes closed, not aroused on mild physical stimulation). A bivalve speculum was then inserted to expose the cervix under antiseptic conditions. The anterior lip of the cervix was grasped with a single-tooth tenaculum. A paracervical block was performed using a 25-gauge spinal needle. The paracervical group ($n = 25$) received 10 mL of 0.25% bupivacaine and the placebo group ($n = 25$) received the same volume of normal saline. After negative aspiration, a solution was injected at 4 and 8 o'clock around the cervical fornix. Hysteroscopy was started 5 min after the injection. No prior cervical dilatation was performed. A rigid 25.5 French hysteroscope with a 30° fore-oblique view (Hystero-Resectoscope, Richard Wolf GMBH, Knittlingen, Germany) was inserted into the uterine cavity under direct vision. Uterine distension was maintained by a steady stream of glycin solution (Urion, Choongwae Pharma Corp., Whasung, Korea) at 100 mmHg using a hystero-insufflator (2220 Hystero-Pump, Richard Wolf GMBH, Knittlingen, Germany).

Easy operability without patient's movement was the main end point of the sedation. This was defined as a deep sedation in which the patients achieved unconsciousness but kept purposeful responsiveness with intolerable pain. If this clinical end point was not reached with the target concentration of 4 μg/mL, the target concentration was increased in steps of 0.5 μg/mL until the procedure could be performed. Once sedation was properly maintained, the target concentration was decreased in steps of 0.1 μg/mL every 1 min. When an inadequate sedation sign was observed (making a grimace, movement or abrupt increase of heart rate) the target concentration was increased in the same way. During the entire procedure, 5 L/min of oxygen was administered via face mask. Positive pressure ventilation was available as required in the event of hypoxemia ($SpO_2 < 90\%$). No opioids were administered.

Blood pressure and heart rate were measured and recorded at 2 min intervals during the procedure. Total dose of propofol, target-concentration, calculated-concentration and effective site-concentration of propofol on the TCI system, were recorded at the end of surgery. Each woman was asked to report the pain experienced using the visual analogue pain score (VAS from 0 to 10) before the sedation, 1 h after the procedure, at discharge and 24 h after procedure by direct in person or telephone interview. For postoperative pain in the recovery room, 30 mg intramuscular ketorolac tromethamine was given if needed. All patients were instructed to take 400 mg of ibuprofen orally every 6 h for 24 h after discharge whether or not they were experiencing pain.

The patients were assessed regularly to establish their readiness for discharge with 15 min interval: stable vital signs, controllable pain, level of nausea, ability to walk without dizziness and ability to retain oral fluids. An independent observer, blinded to the study protocol, collected the data in the recovery room.

A power analysis was performed to determine the sufficient sample size required to establish a significant difference in the hemodynamic variables and in the postoperative pain scores. Data used was collected from a preliminary study, using an α-value of 0.05, and power of 0.9. All results are expressed as the mean ± S.D. or by percentage. Student t-test and Mann–Whitney U-test where appropriate were used for the study variables. Repeated measured ANOVA was performed to compare changes of intraoperative hemodynamics. Chi-square and Fisher's exact test were applied to the variables of postoperative assessments. A P-value < 0.05 was considered statistically significant. Statistical calculations were performed using SPSS 10.0.

3. Results

Both groups were similar in terms of age, weight, height and parity (Table 1). The mean duration of hysteroscopy was longer in the control group than in the paracervical group (Table 2). In addition, significantly more propofol was used for sedation in the control group compared to the paracervical group. During the procedure, total fluid administered

Table 1
Patient characteristics of the two groups

	Control group ($n = 25$)	Paracervical group ($n = 25$)
Age (years)	41.4 ± 9.3	39.5 ± 8.2
Weight (kg)	58.5 ± 7.1	55.7 ± 6.3
Height (cm)	161.3 ± 9.7	159.8 ± 8.8
Parity		
Nulliparous	2 (8)	3 (12)
Multiparous	23 (92)	22 (88)
Menopausal status		
Premenopausal	18 (72)	16 (64)
Postmenopausal	7 (28)	9 (36)

Values are given as mean ± S.D. or number of patients (proportion). There are no significant differences between the two groups.

Table 2
Intraoperative data and discharge time of the two groups

	Control group ($n=25$)	Paracervical group ($n=25$)
Duration of surgery (min)	22.1 ± 11.5	16.3 ± 8.6*
Dose of propofol (mg/min)	6.5 ± 1.0	4.6 ± 1.4*
Fluid administered (mL)	235.4 ± 66.7	242.1 ± 46.7
Urion used (mL)		
Input	3718 ± 2885	2184 ± 2299
Output	3206 ± 2505	2607 ± 1929
Discharge time (min)	104.8 ± 33.9	89.9 ± 38.9

Values are given as mean ± S.D.
* $P<0.05$ compared to the control group.

intravenously as well as total urion used were similar in the both groups. Discharge time from the end of procedure in the paracervical group was shorter when compared to the control group, but these differences were not statistically significant.

At the end of the procedure, the target concentration (target conc.), calculated concentration (calculated conc.) and effective site concentration (effective conc.) of propofol on the TCI system are presented in Table 3. The concentrations of propofol administered for the maintenance of sedation were significantly lower in the paracervical group when compared to the control group.

The blood pressure and heart rate measures during sedation and the procedure showed no significant differences between the two groups, although there was a trend to lower values when these parameters were compared to the baseline measures (Fig. 1).

The postoperative pain scores, at one hour after the procedure and at discharge were significantly lower in the paracervical group compared to the control group (Fig. 2). At discharge, pain scores in the paracervical group were almost zero these measures were significantly lower than in the control group. More patients received intramuscular ketorolac, as an analgesic rescue, for postoperative pain in the control group when compared to the treatment group.

There were no major complications and no patient required hospital admission after the hysteroscopy. There was no case of local anesthetic intravasation (persistent bradycardia and severe hypotension, tremor, convulsion, etc.) observed. The incidence of shoulder tip pain, nausea, dizziness and headache were similar in the both groups (Table 4).

Table 3
The concentrations of propofol on the TCI system for sedation at the end of hysteroscopy

	Control group ($n=25$)	Paracervical group ($n=25$)
Target conc. (μg/dL)	5.16 ± 1.4	3.36 ± 1.0*
Calculated conc. (μg/dL)	5.17 ± 1.4	3.39 ± 0.9*
Effective conc. (μg/dL)	5.04 ± 1.4	3.75 ± 1.1*

Values are given as mean ± S.D. Conc.: concentration.
* $P<0.05$ compared to the control group.

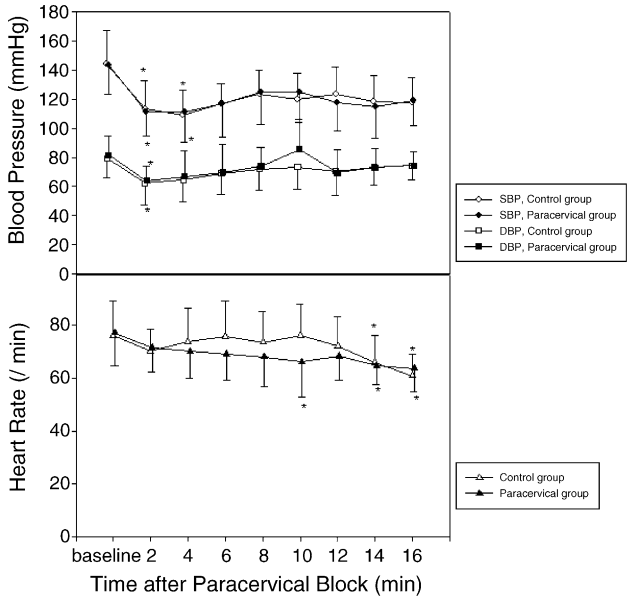

Fig. 1. Blood pressures and heart rates during the procedure. The changes of systolic and diastolic blood pressures were similar in the two groups. Heart rates of every epoch showed no significant differences between the groups. *$P<0.05$ compared to the baseline values.

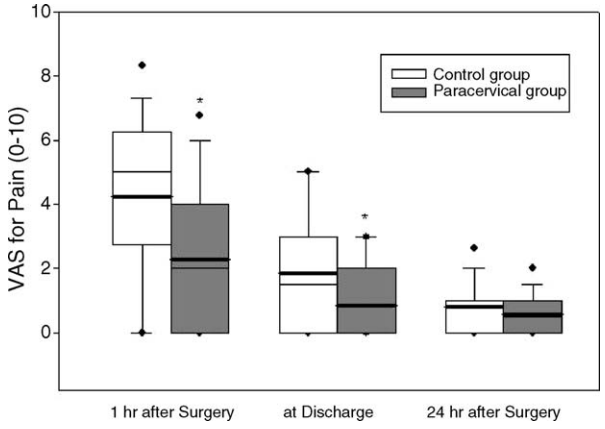

Fig. 2. Postoperative pain scores. VAS in 1 h after procedure and at discharge were significantly lower in the paracervical group than in the control group. However, VAS at 24 h after procedure was similar in the two groups. Box plots are showed 5th/95th percentile with entire ranges (dots), means (bold solid lines), and median (simple solid lines). *$P<0.05$ compared to the control group.

Table 4
Postoperative complications in the two groups

	Control group ($n=25$)	Paracervical group ($n=25$)
Ketorolac rescue	4 (16%)	0 (0%)*
Shoulder tip pain	2 (8%)	1 (4%)
Nausea	5 (20%)	6 (24%)
Dizziness	4 (16%)	3 (12%)
Headache	1 (4%)	1 (4%)
Urinary difficulty	0 (0%)	1 (4%)

Values are given as the number of patients (proportion).
* $P<0.05$ compared to the control group.

Intraoperative bradycardia and hypotension occurred more frequently in the paracervical group (2.8%) compared to the control group (0%), but these findings were not statistically significant. All of the participants recovered spontaneously after a few minutes. The number of patients needed a positive pressure ventilation for hypoxemia was 2 (8%) in the control group and 1 (4%) in the paracervical group ($P > 0.05$). In one patients of them reached 82% SpO_2 (lowest value), recovered immediately after positive ventilation with oxygen. One patient in the paracervical group complained of difficulty of urination after the procedure but recovered uneventfully after two and half hours.

4. Discussion

Peripheral nerve blocks can be used as part of a multimodal analgesic technique to provide safe intraoperative and effective postoperative pain management with minimal side effects. Many studies have shown that patients who receive peripheral nerve blocks experience reduced postoperative pain and analgesia requirements and report improved satisfaction with their pain management [12,13]. In the outpatient setting, peripheral nerve blocks have facilitated early ambulation and discharge by decreasing side effects of sedative drugs, such as drowsiness, nausea and vomiting [14,15]. However, the propofol concentrations reached in the control group are indicative of general anesthesia; if sedation is the goal, providing separate analgesia such as with paravervical blocks is critical.

The results of the present study suggests benefits from paracervical blocks using 0.25% bupivacaine combined with propofol sedation for patients at higher risk for experiencing pain, especially those with cervical stenosis, polyps or adhesions. In addition, patients with a high level of anxiety were considered at higher risk for pain. However, there are limitations. The use of peripheral nerve blocks requires skilled and knowledgeable clinicians. Clinicians with specific technical expertise are required for the administration of the nerve block and other, equally skilled clinicians are required to monitor patients intraoperatively and postoperatively. Furthermore, additional time is required for induction and onset of the effects of the block. This time requirement could be met easily by administering the block before surgery in a designated preoperative holding area where appropriate monitoring is available. However, the expected onset time of the paracervical block using lidocaine has been known less than 5 min [5,9,10], the impact of this onset period on the sedation may be minimal in the clinical use.

We responded to the patient's movement and heart rate changes by changing the target-concentration of propofol. In this study, we assessed adequacy of anesthesia by the absence of patient movement. In a report by Jacoby et al. [16] movement is reported to be a sensitive sign for assessing adequacy of anesthesia, since the EEG only monitors hypnosis. This assumes that adequate anesthesia involves both prevention of movement in response to a pain stimulus (analgesia) and hypnosis. The heart rate and electrocardiogram can be also used to monitor anesthetic adequacy. For example, an increase in the degree of respiratory sinus arrhythmia accompanies decreases in the depth of propofol anesthesia [17]. Although these signs are most extensively used to monitor anesthesia, they are modified by disease, drugs and surgical technique. In addition, the degree of interpatient variability is high. Furthermore, these clinical signs are not always helpful in detecting awareness under anesthesia. Measuring and monitoring of the depth of sedation using a processed-EEG technique such as bispectral analysis could have been helpful.

In conclusion, we confirmed that preoperative use of paracervical blocks with 0.25% bupivacaine has a propofol sparing effect during outpatient hyteroscopic surgery. This protocol has the benefit of improving postoperative pain management until the patient discharge.

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Blocks at the wrist using nerve stimulation for ambulatory hand surgery

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Abstract

One hundred and fifty-five patients were included in this prospective, open, multicenter study to examine the use of nerve stimulation to locate the median and ulnar nerves in ambulatory hand surgery. A sensory response was obtained in 65% of cases and a motor response in 65% with median nerve: the failure to elicit a motor response during median nerve stimulation was related to a higher failure rate of blocks ($P = 0.041$). A sensory response was reported in 63% and a motor response in 70% of the cases concerning the ulnar blocks: a sensory response was associated with greater success in the ulnar nerve ($P = 0.01$), while fourth and fifth fingers flexion increased the likelihood of failure ($P = 0.075$). This technique does not impair the organization of the surgical theatre (4 ± 3 min, mean $\pm$ S.D. block performance time) and 96% of patients were satisfied with the technique.

Keywords: Regional anesthesia; Wrist block; Median block; Ulnar block; Nerve stimulation; Surgery; Hand

1. Introduction

Ambulatory practice for hand surgery is wide used. Hand surgery with tourniquet under wrist blocks was first described in the early 1970s [1], but interest in this technique has recently increased. Wrist blocks appear to be effective, rapidly to perform and well tolerated by patients [2–4]. They are appropriate for short time procedures in ambulatory hand surgery including carpal tunnel release. They also reduce the time for discharge patients home [5] and may also offer cardiovascular stability when compared to general anesthesia [5]. Nerve trunks are usually identified by searching for paresthesia at this level but actively seeking paresthesia may increase the risk of postanesthetic neurological sequelae [6,7]. The use of a nerve stimulator is appealing in this setting. In wrist blocks for hand surgery, it has not been previously studied. Therefore, the current study have evaluated the easiness and acceptance, and tried to determine the most appropriate responses (either motor or sensory) of nerve stimulation at the wrist.

2. Methods

After Ethics Committee's approval and patient's written informed consent, 155 ASA I-III patients scheduled for carpal tunnel release were included in this prospective open, multicenter trial.

The local anesthetic was always plain 2% mepivacaine. Punctures sites were located 10 cm above the wrist crease. When surgery included the cutaneous distributions of radial and musculo-cutaneous nerves, both were blocked with a subcutaneous injection of 6 and 3 ml of solution, respectively. Nerve stimulation of the median and ulnar nerves used a nerve stimulator (HNS 111, B. Braun, Melsungen, Germany) with a 22 gauge, 30° bevel, 50 mm long insulated needles (Stimuplex, B Braun, Germany). The output of the nerve stimulator was initially set at an intensity of 1 mA (1 Hz) and then decreased as soon as any kind of response was observed until this one disappeared. The pulse duration was kept at the

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same setting for motor and sensitive responses. Then, 6 ml of 2% mepivacaine were injected on the site. No sedation was used during the performance of the block.

When stimulating the median nerve that is located between flexor carpis radialis and palmaris longus we looked for three kinds of responses: (1) fingers flexion, (2) thenar movements and (3) paresthesia in the fifth finger. The ulnar nerve (stimulated under flexor carpi ulnaris), was identified by four different responses: (1) fourth and fifth finger flexion, (2) thumb adduction, (3) hypothenar movements, (4) paresthesia in the fifth finger. After the block, patients were asked to grade discomfort during block performance on a graduated scale: 0 no pain, 1 medium pain, 2 severe pain.

The sensory block was assessed by a pin-prick using a 22 gauge needle, 15 min later. The ulnar distribution was tested at the medial aspect of the hand. The median nerve was evaluated at the palmar aspect of the hand at the level of the second finger and in the lateral part of the wrist was checked to test the cutaneous distribution of radial and musculocutaneous branches. If required, the anesthesiologist repeated the peripheral block by injecting, additional local anesthetic (3 ml per trunk) and reported any unblocked area (primary failure). When surgical incision was painful (secondary failure), physicians had the choice among, general anesthesia with 2–4% sevoflurane via a face mask, local infiltration by the attending surgeon (1–4 ml of 2% mepivacaine) and/or i.v. injection of alfentanil.

The values are expressed as mean ± S.D. The statistical analysis used Mann–Whitney test was used to compare quantitative values when a χ^2-test served for qualitative values.

3. Results

In 155 patients (50 ± 17 years old, male/females: 46%/54%), 143 median nerve blocks, 127 ulnar nerve blocks and 119 radial nerve and musculocutaneous nerve infiltrations were performed combined. No minor or severe complication related to the use of local anesthetics was reported. For median nerve blocks, paresthesia was elicited in 65% of the cases and a motor response was obtained in 65% of the cases. Fifty eight per cent of patients had thenar movements and 19% of them had fingers flexion. For ulnar nerve blocks, paresthesia was obtained in 63% and a motor response in 70% of the cases: 58% of fourth and fifth finger flexion, 26% of thumb adduction and 26% of carpe flexion.

Reinjections were performed in 14% of the cases: 4.6% for the median nerve, 8% for the ulnar nerve and 2% for the radial nerve. Secondary failure rate occurred in 15% of the cases: local infiltration was used to treat failure in 11.3% of the cases, i.v. alfentanil injections in 0.7% of the cases and general anesthesia in the remaining 3%. As soon as any kind of adjustment was needed, either pre or intra-operative, the block was considered as unsuccessful (global failure): the total failure rate was 25%. Age, sex, premedication (intravenous midazolam 0.5–1.5 mg accordingly to clinical judgment at arrival in the operating room), emergency surgery, difficult anatomical landmarks or time between blocks and surgery did not seem to have any impact on the rate of anesthesia failure or success.

In the median nerve territory, failed motor response was associated with significant 10% primary failure rate ($P = 0.041$). We identified a group of 25 people who received only single median nerve block. No failure was observed when a motor response was elicited while failure rate reached 40% when only paresthesia were elicited ($P = 0.0075$). Thenar or fingers movements had the same positive predictive value, i.e. success if a motor response was elicited. Primary and global failure rates were 2 and 14%, respectively, for finger movements, 0 and 16% for thenar movements and 7 and 13% when both of movements were found.

Obtaining paresthesia was statistically associated with a lower rate of primary failures in the ulnar nerve distribution ($P = 0.01$). In a group where motor responses were obtained (whether they were associated or not with sensory response), we noticed that fourth and fifth finger flexion was correlated with a higher rate of primary failure ($P = 0.014$).

No patient experienced severe pain during block performance, 30% of them described moderate pain and 70% described the technique as not painful. The average block performance lasted 4 ± 3 min.

4. Discussion

The use of nerve stimulation to block the median and ulnar nerve at the wrist is rapidly performed and well accepted by patients' in hand ambulatory surgery.

The only way to predict success may be to examine the quality of the responses. Examination of the types of motor sensory responses showed that median nerve motor responses and ulnar nerve sensory responses were associated with a higher rate of success. Some anatomical consideration may explain these findings. The median nerve is located between the flexor carpi radialis and the palmaris longus, just under a superficialis aponeurosis. Its motor fibers are mostly posterior and the sensitive fibers are more superficial [8,9]. Therefore, we consider that an only paresthesia could indicate a too shallow location of the tip of the needle. In this case, the local anesthetic may spread above the aponeurosis (Fig. 1). Furthermore, we know that the sensitive dorsal branch of the ulnar nerve arises at an average distance of 8.5 cm from the wrist crease and then passes dorsal to the flexor carpi ulnaris [10]. The path of the ulnar nerve suggests that the lack of a paresthesia could mean that this dorsal branch is not stimulated (because it may be already separated from the main branch). As a consequence, this dorsal branch may be excluded from local infiltration (Fig. 2). Fourth and fifth finger flexion is due to flexor digitorum profundus whose nerve emerges from the ulnar several centimeters above our puncture site (Fig. 3). Therefore, this response may be the

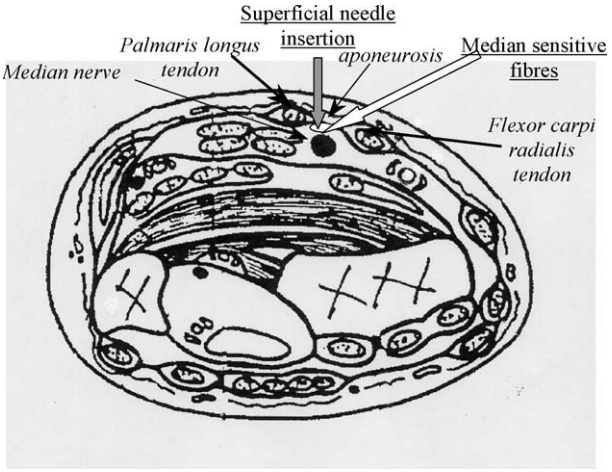

Fig. 1. Forearm section 10 cm above the wrist crease: median sensitive fibers are superficial. Just sensitive responses correspond to superficial needle localizations. Local anesthetic is injected partly above aponeurosis.

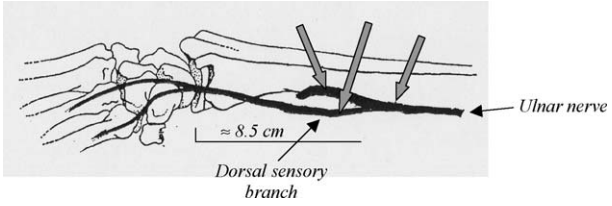

Fig. 2. Ulnar dorsal sensory branch: anatomy and different punctures sites.

result of a direct muscular stimulation leading to a useless, intramuscular injection (Fig. 4).

The main limit of our study is the inability to determine which nerve was insufficiently blocked during surgery (secondary failure). This constraint prevented us from finding any relation between nerve stimulation and global failure (that

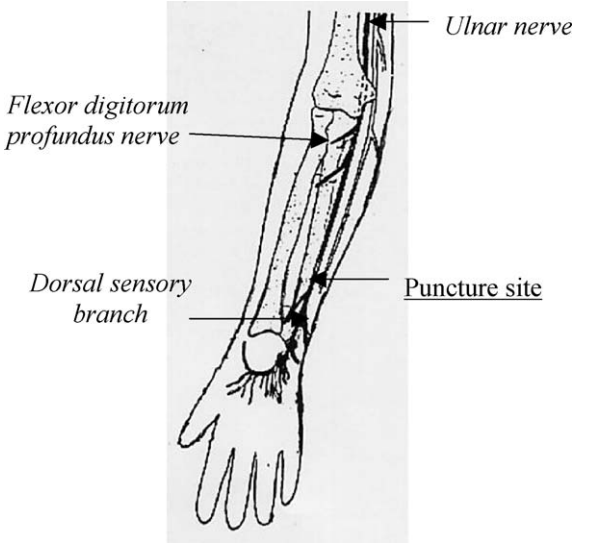

Fig. 3. Ulnar nerve anatomy. Flexor digitorum profundus nerve emerges several cm above our puncture site.

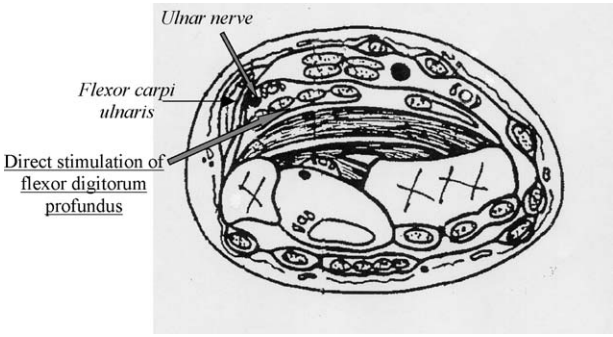

Fig. 4. Forearm section 10 cm above the wrist crease. A needle inserted in a posterior direction can stimulate directly flexor digitorum profundus.

totals pre and intra-operative adjustments and as a result is less specific than primary failure). On the other hand, per operative adjustments are undesirable events that should have been avoid by testing. We link this observation to our pinprick method which stimulates only A beta and A delta fibers when C fibers are not tested [11].

Despite these drawbacks, our results led us to believe that response analysis could help to determine needle position. If one stimulates the median nerve and obtains just a paresthesia and no motor responses, the needle is certainly placed on the surface of the nerve. When no sensitive response is found at ulnar stimulation, the needle may have been inserted after the emergence of the dorsal branch. As a fourth and fifth finger flexion is obtained, the needle is too posterior, in flexor digitorum profundus muscle. The rate of 25% of global failure may seem high. However, it is lower than those observed in previous studies that did not use neurostimulation [4]. Furthermore, we have shown that some stimulated responses may induce poor results. As a result, we think that it would be possible to improve the technique in the future by searching for the right response during neurostimulation.

In conclusion, nerve stimulation at distal forearm may be an alternative to other more extensive regional techniques [12]. Time to perform the block was short and discomfort produced by the technique was well tolerated. Elicitation of a motor response for median nerve and of a sensory response for ulnar nerve block may improve the results of this technique.

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The impact of pediatric obstructive sleep apnea on ambulatory surgery

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Abstract

The purpose of this paper is to review pediatric obstructive sleep apnea syndrome (OSAS) with an emphasis on ambulatory adenotonsillectomy. Difficulties in establishing a diagnosis by clinical criteria alone are discussed. Diagnostic tests to establish a diagnosis of OSAS are discussed. The child with severe obstructive sleep apnea is at increased risk for post-adenotonsillectomy respiratory morbidity. The perioperative management with a focus on the ambulatory candidate is discussed.

The child with OSAS presents a challenge to ambulatory surgery because of the high prevalence of OSAS, difficulty in establishing a diagnosis of OSAS and the increased risk of respiratory morbidity.

Keywords: Pediatric; Obstructive sleep apnea syndrome; Ambulatory adenotonsillectomy; Anesthesia

Obstructive sleep apnea syndrome (OSAS), affecting 1–3% of children, is characterised by sleep fragmentation and nocturnal episodic asphyxia [1]. The prevalence may be as high as 10–20% in children who habitually snore. The peak incidence of childhood OSAS occurs between 2 and 5 years coinciding with maximal adenotonsillar hypertrophy [2]. In children, as in adults, OSAS has a negative impact on quality of life, somatic growth, cardiovascular health, neurocognitive function and behaviour [3,4]. The impact of adult OSAS on the practice of anesthesia has recently been reviewed [5]. Whereas it is predicted that the next decade will see a 5- to 10-fold increase in adults with OSAS undergoing surgery [5], the last two decades have already seen a dramatic change in the indication for adenotonsillectomy from one of chronic tonsillitis to obstructive breathing. Today, 80% of children presenting for adenotonsillectomy have a history of sleep associated obstructive breathing [6,7]; an impressive statistic when one considers the annual caseload. This review discusses the impact of OSAS on the practice of pediatric anesthesia with an emphasis on the management of ambulatory adenotonsillectomy.

Although there is no centralized reporting mechanism to record mortality following adenotonsillectomy, mortality following adenotonsillectomy in children is estimated to be 1 per 16,000 or 0.6 per 10,000 [8]. Consensus opinion [1,9] suggests that a significant morbidity following adenotonsillectomy for OSAS exists. The risk of post-adenotonsillectomy respiratory morbidity in the unselected pediatric population is less than 1% [10–12]. A diagnosis of severe OSAS increases the risk of respiratory morbidity following adenotonsillectomy by a factor of at least 20 [13–19]. The potential risk in children with severe OSAS has provoked quite a lot of controversy. The root of this controversy lies in the difficulty in making a diagnosis of OSAS and establishing its severity and the cost implications to the health care providers of both preoperative screening and post-operative care, given the magnitude of the annual pediatric caseload for adenotonsillectomy. Recent editorials suggest that anesthesiologists should assume a leading role in resolving this controversy [20,21].

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1. Establishing a clinical diagnosis of OSAS

Most of the published literature has focused on identification of high-risk patients with OSAS, in order to exclude them from ambulatory programs. Many patient characteristics predispose the child to OSAS. African-Americans have a three-fold higher incidence of OSAS [22,23]. In addition during airway obstructive events, the African-American child desaturates more profoundly compared with Latino and Caucasian children with OSAS [24]. Unlike the adult presentation, there is no gender difference in the incidence of OSAS in children. Many coexisting medical conditions are associated with OSAS including Achondroplasia, Down syndrome and other craniofacial syndromes characterized by micrognathia or maxillary hypoplasia; chromosomal abnormalities; hypotonia and neuromuscular disorders; asthma; prematurity and obesity [1,25–30]. The Prader–Willi syndrome presents the dual problems of obesity and hypotonia [31].

The trilogy of sleep fragmentation, nocturnal intermittent hypoxia and episodic hypercapnea which is characteristic of OSAS affects multiple organ systems. Somatic growth is affected and either failure to thrive or obesity may be exist [30,32,33]. Neurocognitive dysfunction and a history of daytime sleepiness, behaviour problems and poor school performance support a diagnosis of OSAS [3,34,35]. Evidence for a link between learning and OSAS is found in the experimental rat model. Intermittent hypoxia is associated with long-term sequelae on the hippocampal functions of learning and memory. In addition, the arousal index has a significant influence on the prefrontal cortical functions influencing behaviour and attention [36,37].

It is well known that young age less than 3 years, is an independent risk factor for airway complications following adenotonsillectomy [38]. The combination of young age, an associated medical condition and OSAS results in a high risk of post-adenotonsillectomy respiratory morbidity [13,14,17,18].

Although a history of an associated medical condition, obesity, failure to thrive, behavioural problems, poor school performance and sleep disordered breathing suggest a diagnosis of OSAS, the fact remains that the majority of patients, including children, with OSAS are undiagnosed [2,5]. The OSA-18 clinical score is a questionnaire that could be administered in advance of the surgical date. Developed in 60 non-obese children, it presents a scoring system to diagnose OSAS by clinical criteria [4]. It assesses the frequency of symptoms known to be associated with OSAS including sleep disturbance, physical symptoms, emotional distress, daytime dysfunction and parental concern. When applied to a non-obese, pediatric population, there was a high correlation between the total score and the respiratory distress index, analogous to the apnea hypopnea index (AHI), and with the degree of adenotonsillar hypertrophy. The practice guidelines for perioperative management of patients with obstructive sleep apnea [9] propose a clinical scoring system based on physical characteristics, sleep disordered breathing and daytime somnolence. However, it is important to recognize that a diagnosis based on clinical scores alone will correlate poorly with findings on polysomnography [33,39–42]. Scoring systems based on clinical criteria will result in both false positive and negative diagnoses for OSAS.

Severe OSAS is associated with important cardiovascular pathophysiology including pulmonary and systemic hypertension, both right and left ventricular dysfunction [43,44], recurrent pulmonary aspiration [45] and abnormalities of ventilatory control [46] including an increased sensitivity to opioid respiratory depression [47]. These sequalae of OSAS are difficult to diagnose in the pre-operative examination. Conventional clinical assessment in a group of children with sleep disordered breathing and witnessed apnea did not suggest right ventricular dysfunction. However a reduced right ventricular ejection fraction was present in one-third of the children [44]. At present less than 10% of children are being tested for OSAS prior to adenotonsillectomy [7]. The challenge is to identify the otherwise well apparent-American Society of Anesthesiology (ASA) class 1 child with obstructed breathing during sleep who has severe OSAS.

2. Diagnostic testing for OSAS

2.1. Testing during sleep

The gold standard for diagnosis of OSAS is polysomnography involving the assessment of sleep and breathing from a computerized recording of electroencephalographic and cardiorespiratory signals with the simultaneous video recording in the sleep laboratory. The polysomnogram in OSAS shows episodic obstructive respiratory events which, in children, typically cluster during active, rapid eye movement (REM) sleep. Unlike adult OSAS, sleep architecture is preserved and REM content is normal [48,49]. Polysomnography is expensive, labour intensive and the waiting lists are prohibitive. Abbreviated cardiorespiratory recordings at home present a less costly option [50–52].

The diagnostic thresholds for OSAS by sleep laboratory criteria are based on statistical deviation from normative sleep parameters. Sleep data recorded in an asymptomatic, normative population of children indicates that an apnea index greater than 1 apnea per hour is abnormal [1,53], a threshold which is lower than the diagnostic threshold of 5–10 apneae per hour in adult sleep laboratories [53,54]. A nadir saturation, defined as the lowest saturation recorded during the night's sleep, which is below 92% is statistically abnormal in a normative, asymptomatic population of children. This value is similar to the diagnostic threshold of 90% in adult sleep laboratories [53]. The upper airway resistance syndrome (UARS) is associated with long periods of hypoventilation during sleep and is considered an OSAS equivalent in children [33,48]. An AHI in excess of 10 events per hour and

a nadir saturation less than 80% are the thresholds which are predictive of increased risk for post-operative respiratory morbidity [13,14,17–19,55]. These thresholds are consistent with a diagnosis of severe OSAS.

We [17,19,52,56] and others [55,57] have explored the diagnostic potential of oximetry because it is widely available and pre-operative desaturation during sleep correlates with the AHI. Nocturnal oximetry has a high specificity albeit imperfect sensitivity for a diagnosis of OSAS by polysomnographic criteria [57] and is also a good predictor of peri-operative risk [17,19]. The McGill oximetry score was developed to stratify OSAS severity (Fig. 1). A positive McGill oximetry score demonstrates at least three clusters of desaturation below 90% during sleep. This pattern in addition to the nadir saturation has a positive predictive value for a diagnosis of OSAS in otherwise healthy children. The McGill oximetry score is also predictive of post-operative risk. Oximetry reporting by trend analysis is easily learned [19]. Furthermore, trend reporting of computerized records is amenable to electronic reporting from telehealth systems.

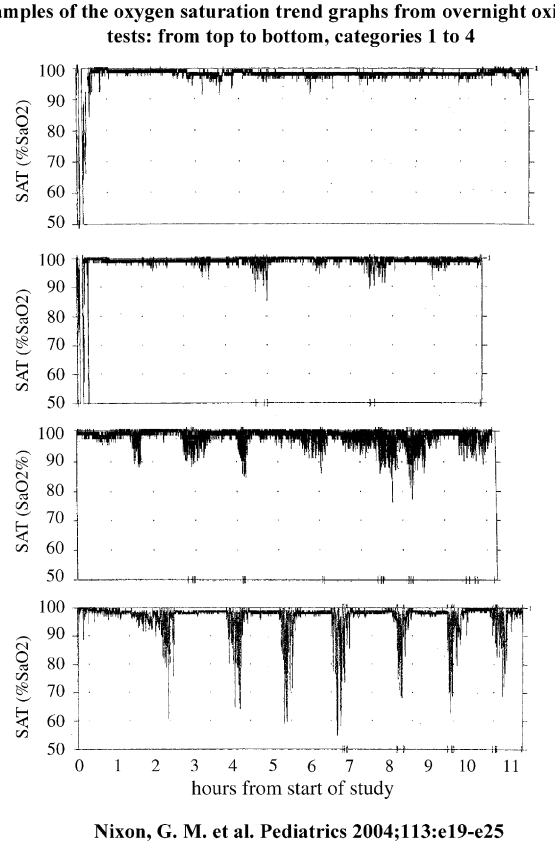

Fig. 1. Representative nocturnal oximetry trend traces for McGill oximetry scores 1–4 (top to bottom). McGill oximetry score of 1 is an inconclusive study. McGill oximetry scores 2, 3 and 4 are distinguished by the nadir desaturation which are 90%, 85% and 80%, respectively. Reproduced with permission from Pediatrics 113:19–25, Copyright 2004 by the American Academy of Pediatrics.

2.2. Testing during wakefulness

Two tests are available to diagnose OSAS in awake children. The presence of a compensatory metabolic alkalosis with or without hypercarbia on a capillary blood sample drawn during wakefulness is consistent with recurrent nocturnal hypercarbia and supports a diagnosis of severe OSAS [1,9].

Acoustic pharyngometry is a non-invasive test to measure the cross-sectional area of the pharynx in awake children. In addition, the collapsibility of the pharynx can be assessed by measuring the cross-sectional area before and after the application of topical anesthesia. Pharyngeal cross-sectional area is smaller in children with OSAS compared with controls [58,59]. Whereas pharyngeal cross-sectional area decreased 5% in a control population, in children with OSAS, it decreased 40%, supporting the notion of increased upper airway collapsibility, in OSAS [59–61].

3. Anesthetic management of children with OSAS

3.1. Pre-operative preparation

The single most important pre-operative preparation is to identify the child with severe OSAS, since this diagnosis will exclude the child from ambulatory programs. However the reality is that only a minority of children are tested for nocturnal desaturation prior to adenotonsillectomy [7]. Given the poor specificity for OSAS severity of the clinical scoring systems, and the endorsement, by the American Society of Anesthesiologists, of the clinical diagnostic criteria within the context of practice guidelines for OSAS [9], pre-operative testing for OSAS may in future prove cost effective.

Treatment of OSAS, is associated with an improvement in systemic hypertension, myocardial function, and normalization of carbon dioxide responsiveness [34,44,51,62–65]. However there is no review of the role of pre-operative optimization in children with OSAS. The child who has a worsening of obstructed breathing due to an upper airway infection presents a dilemma. These children may have life threatening airway obstruction with profound desaturation during sleep. To proceed with adenotonsillectomy increases the risk of serious respiratory morbidity [19]. An alternate option is to treat pre-operatively with antibiotics, steroids [66] and the insertion of nasal trumpets during sleep while hospitalized in an intensive care setting. Our experience with one child managed in this fashion reported an improvement in the airway obstruction, resolution of the respiratory acidosis and an uncomplicated adenotonsillectomy [17]. Some of these children may be candidates for delayed adenotonsillectomy following a course of antibiotics and steroids at home. However, our experience indicates that there may be a risk that some may be lost to follow-up until the next infectious process compromises respiration.

3.2. Conduct of anesthesia

The influence of anesthetic technique on reducing peri-operative respiratory morbidity post-adenotonsillectomy for OSAS is largely unreported. The risk of post-operative desaturation may decrease if surgery is performed in the morning [67]. Additionally administration of intra-operative atropine decreases the risk of post-adenotonsillectomy desaturation [18]. This decreased risk may involve cholinergic mechanisms which may play a role in both sleep regulation [68], sleep disordered breathing [69] and the function of the genioglossus musculature [70]. The recent trend away from the routine administration of atropine in pediatric anesthesia may need further thought in the management of children with severe OSAS.

First described in 1981, continuous positive airway pressure (CPAP) therapy during sleep normalizes sleep architecture and abolishes nocturnal asphyxia in OSAS [64]. CPAP therapy remains the mainstay of OSAS treatment in the adult population. The use of CPAP is also extremely useful to manage the airway in a child with OSAS during anesthesia [71], principally because it acts to increase the cross-sectional area of the pharynx [61,72]. Fig. 2 shows the relationship between airway pressure and the cross-sectional area of the pharynx. Fifty percent of the maximal pharyngeal area is achieved at 5 cm H_2O. The closing pressure at which the pharynx collapses correlates with the severity of OSAS [60,61] and the closing pressure during anesthesia may identify the patient with OSAS [73].

3.3. Analgesic management

Children with untreated OSAS demonstrate a blunted responsiveness to hypercarbia and greater respiratory depression with opioids [46,47]. Morphine consumption following adenotonsillectomy is decreased in children with OSAS who demonstrate recurrent episodic desaturation during sleep [74], and therefore the child with severe OSAS may require much less opioid for analgesia. An increased opioid sensitivity in children with severe OSAS is not a small issue for children who will be discharged home with opioids [20,75].

Morphine sparing adjuncts including dexamethasone [76] and acetaminophen [77] may be useful. The anti-inflammatory properties of dexamethasone may confer additional benefit since the nasal exudate in children with OSAS had a higher content of the inflammatory mediator leukotriene than children with chronic tonsillitis [78].

Sensory nerve blockade including glossopharyngeal nerve block should be used with caution in severe OSAS since topical anesthesia provokes an eight-fold greater decrease in pharyngeal cross-sectional area in the child with OSAS [59,79].

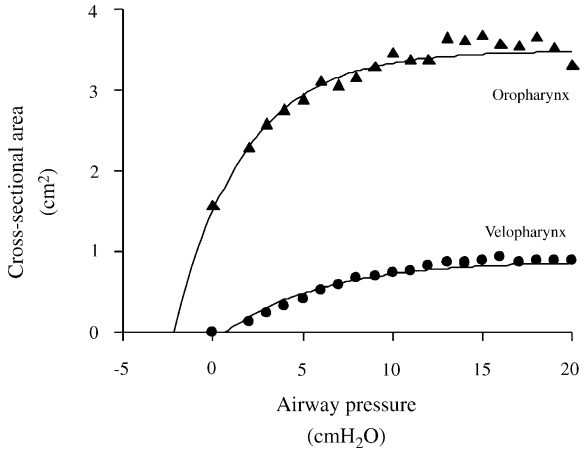

Fig. 2. The influence of positive pressure on the pharyngeal cross-sectional area for both the velo- and oro-pharynx. Reproduced with permission from J Appl Physiol 95:2257–64, Copyright 2003 by the American Physiology Society.

3.4. Discharge practice

Although adenotonsillectomy is curative in the majority of children with OSAS, the first post-operative night may be problematic [13,14,17,19,80]. Implicit in safety of ambulatory programs is the notion that a responsible, informed parent is a suitable caregiver at home, in the post-operative period. However the parent of a child with OSAS has feared for the child's sleep disordered breathing for months. For this parent, the baseline pattern of breathing is one which includes restless sleep, airway obstruction, apnea and desaturation during sleep and poor rousability [3,4,71,81]. This parent is ill-prepared to recognize a deterioration in respiratory status in the post-operative period.

The onset of respiratory distress may be delayed until a time remote from surgery. One-third of desaturation following adenotonsillectomy presented more than 8 h after surgery [17,67]. One-third of children who experienced major respiratory compromise presented 1–8 h after adenotonsillectomy [19]. Two prospective studies reported that the majority of desaturations following adenotonsillectomy on the first post-operative night, were associated with obstructive apneas [15,82]. Furthermore parameters of sleep disordered airway obstruction and desaturation worsen in the early morning hours [49]. A delayed onset of respiratory compromise is problematic for ambulatory programs and may require a prolonged period of observation and overnight monitoring during sleep in some children with OSAS. Supportive measures in the post-operative period may require the insertion of nasal airways, CPAP support, reintubation, ventilation and the administration of furosemide, salbutamol, racemic epinephrine, heliox and dexamethasone [13,14,17,18,83]. This level of pediatric respiratory support, in many hospitals, is only provided in an intensive care setting.

The implications of OSAS to ambulatory adenotonsillectomy programs is sobering, given the widespread prevalence of OSAS. A diagnosis of OSAS identifies a patient population at increased risk for peri-operative cardiorespiratory compli-

cations in a time when the majority of pediatric adenotonsillectomy in North America is performed through ambulatory programs [20] and the most common indication for adenotonsillectomy is obstructive breathing [7]. In a health care system designed to manage adenotonsillectomy through ambulatory programs, risk reduction strategies for OSAS will remain focused on case finding of high-risk children and exclusion of these children from ambulatory programs. It is the otherwise well apparent-ASA 1 child with undiagnosed severe OSAS who poses the greatest challenge to ambulatory programs. Establishing a diagnosis of OSAS has been hampered by the limited resource of sleep laboratories. Although the clinical scoring system to establish a diagnosis of OSAS recently published in the ASA's Practice Guidelines for the Perioperative Management of Patients with Obstructive Sleep Apnea has not been formally validated, the guidelines have empowered clinical criteria to both establish a diagnosis of OSAS and stratify its severity [9]. The clinical risk score combined with the surgical risk score yield an overall peri-operative OSAS risk score. A child with moderate to severe OSAS who requires adenotonsillectomy totals a risk score of 5–6 (maximum of 6). This risk score maybe sufficient to exclude the child from ambulatory programs. Prospective studies on cost effective risk reduction strategies following adenotonsillectomy for OSAS are urgently needed.

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Review

Informed consent for anesthesia in ambulatory surgery: A South African perspective

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Abstract

The nature and practice of anesthesiology problematises informed consent, particularly in the ambulatory setting. Timing and time-constraints counter an interactive free flow of information; access to understandable, contextual information forms the basis of free choice by empowering the patient to engage in an interactive conversation with the anesthesiologist, and broadens the base for further discussions and questions. Separate informed consent in anesthesiology is philosophically mandated by the requirement of rationality in choice and respect for personal autonomy, and legally to prevent litigation. The paradigmatic cascade model of consent entails determining competence, supplying information and promoting free choice. Particular measures to counteract the difficulties of anesthesiological informed consent in ambulatory surgery include measures to increase anesthesiologist–patient contact time, and wider use of pre-op clinics. Pre-printed forms are useful but do not replace an interview, tapered to the needs and requirements of the particular patient. Appropriate illustrative material and aids are advised.

Keywords: Informed consent; Ambulatory surgery; Anesthesiology

Contents

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"I wish my life and decisions to depend on myself, not on external forces of whatever kind. I wish to be the instrument of my own, not other men's act of will. I wish to be a subject, not an object; to be moved by reasons, by conscious purposes which are my own . . .." Berlin [1]

1. Introduction

The 1847 AMA *Code of Medical Ethics* reflects the paternalistic and asymmetrical "traditional" professional relation dating from Hippocratic times: knowledge-based authority trumped the ignorance of the patient, who was expected merely to *assent* to treatment—"The obedience of a patient to the prescriptions of his physician should be prompt and implicit. He should never permit his own crude opinions as to their fitness, to influence his attention to them." [2] Paternalism was overcome by the recognition of the moral significance of respect for personal autonomy [3]. Information empowers patients to make informed choices which promote autonomy by promoting the ability to decide for oneself, and oppose paternalism, thus justifying biomedical informed consent [4]. The skewed professional relation therefore becomes more symmetrical and contractual. Informed consent has become "the hallmark of our health care system" [5], but is problematic in anesthesiology, particularly ambulatory care.

Although the requirements for and practice of informed consent vary, certain basic principles are, or should be, universal. Section 2 consists of a short review of the requirements and difficulties of informed consent in anesthetic practice as a background to Section 3, a short discussion of particular difficulties vis-à-vis ambulatory care, and remedies.

2. Consent in anesthetic practice

Formal informed consent is a relatively recent development in anesthesiology, following the development of anesthesiology as a separate and independent specialty. The complexity of anesthesiology, and constant technological and pharmaceutical development, make the contextual understanding and consequent application of information in rational decision-making difficult, particularly in multi-cultured, multi-language developing countries. Furthermore, once an intervention requiring anesthesia is indicated, the need for some form of anesthesia is self-evident; therefore, some anesthesiologists argue that informed consent is either unrealistic or superfluous in anesthesiology. It is tempting to use these difficulties as excuses to limit the informed consent process and deny our patients their due. Nevertheless, informed consent is mandatory. Complex information should be simplified to promote its utilization in decision-making.

2.1. The prototype informed consent model

Legal, regulatory, philosophical and medical literature favours a five-point analysis of the components of informed consent: competence, disclosure, understanding, voluntariness and consent [3]. These can be arranged in a useful and practical simplified three-tiered cascade, each subsequent level presupposing the former (modified from Beauchamp and Childress [3], p. 145):

1. *Competence*: A competent patient should be able to grasp the essentials of proposed treatment, to think logically and to come to a reasoned decision. There is some disagreement whether this includes an equal understanding of risks and complications [5]. To promote informed choice and limit paternalism, the requirements for competence should not be unreasonably high. Persons of limited intelligence, and young children, are often competent in the context of the situation, and should be involved in the process. Competence is often assumed, but can be judged on the basis of five possible standards: evidence of choice, understanding of the reasonable outcome of choice, choice based on rational reasons, the ability to understand and actual understanding [5]. Competence may be limited by circumstances intrinsic to the patient (cognitive and mental limitations, although these patients may have sufficient insight to make reasonable choices), or extrinsic (imposed by law, relating to age, incarceration or institutionalisation).
2. *Disclosure*: Only informed, competent patients are able to make rational choices, i.e. utilize particular information in a process of logical reasoning. Rationality therefore presupposes the possession and understanding of sufficient information. Decisions based on the exchange of information constitute contractual arrangements. Contracts are invalid if significant information is withheld; therefore, a full explanation of techniques and outcome, morbidity, alternatives and their risks and complications, costs and the role of each team member is mandatory. Risks include those inherent to the procedure and disease, host risks relating to underlying disease and co-morbidity, and risks related, for example, to the hospital environment and experience of operators (so-called boundary risks) [6]. Interviews should take place at a cognitive level commensurate with that of the patient. Although patients do not necessarily utilize the supplied information in the decision-making process, they nevertheless benefit in other ways [3].
3. *Decision-making*: Based on the information supplied, and a recommendation by the anesthesiologist as to the most suitable treatment and/or technique, the patient can make a voluntary and uncoerced (i.e. not under the control of another person [3]) decision to undergo (*consent to*), or defer treatment, and, in as far as possible, regarding the nature of that treatment. He/she should be informed of the consequences of that decision, his/her right to withdraw consent at any stage and of the right to a second opinion.

The handling of decisions which appear to be irrational or inappropriate would depend on particular circumstances (see also Section 2.5).

2.2. Separate informed consent is mandatory

Anesthesiologists should obtain informed consent in a well-structured manner, and not rely on implied consent or consent obtained by the surgeon. Firstly, anesthesiology is an independent specialty, and anesthesiologists are finally accountable and responsible for their actions and omissions. It is invariable invasive, and has unique ends, risks and consequences, of which others have limited insight [7]. All forms of treatment – even touching a patient without consent – are unlawful without prior consent, and may constitute "the crime of battery and the tort of trespass to the person" [7]. Any doctor who provides treatment is responsible for obtaining informed consent. When this obligation is delegated to a competent person (another anesthesiologist or trainee), the person administering the anesthetic retains responsibility for the validity of consent [8].

Secondly, respecting the patient's autonomy implies treating her as a *subject* in the sense that Berlin uses the term in the introductory quotation: as a person with rights and interests [1]. We should not do things "to," but "at the request of" or at least "with" the co-operation of the patient. Ignoring informed consent is a return to the morally unacceptable "traditional" paternalism.

Thirdly, the contract between doctor and patient implies a responsibility to inform. Without adequate information this contract is void. Inadequate information is a common basis for court action, although less commonly against anesthesiologists.

2.3. Written consent and pre-printed consent forms

Since anesthesiology is invasive, complex and involves significant risks and side effects, some form of written consent is advisable, though not universally mandatory [7,8]. Written consent does not guarantee valid consent [7]. A signed consent form may supply evidence that consent was given, not that counselling was necessarily sufficient, appropriate and not negligent [9]. An allegation of improper conduct can be better *defended* with documented evidence of an *appropriate discussion*—particularly in actions brought years later [7]. Although some documentation is advised (in many countries *required*) in all forms of anesthesia, particular attention has been advised in obstetric regional anesthesia [10], presumably due to the high risk of litigation, or when the anesthesiologist is the primary treating physician. Documentation need not be detailed, but should at least include the nature and extent of the interview, particularly the discussion of risks and complications, since *contemporaneous* notes may be useful in later actions.

Reliance on pre-printed consent forms without a structured interview is inadequate; "clinicians can slip into the habit of asking patients to sign a piece of paper without any thought being given to either what is on the form or to its primary purpose." The nature and quality of the interaction between patient and clinician determines its ethical validity [4]. Pre-printed forms and information sheets may support the process, but cannot "replace individual counseling" [2]. Individual counselling is more effective in promoting the retention of specific risk information than a combination of counselling and printed forms [11].

2.4. Standards of disclosure

Paradigm civil cases determined the evolution of two competing norms of disclosure: the *professional practice* (*reasonable doctor*) and the *reasonable person* standards [3,12]. A third, the individualized "*subjective patient standard*," in which the requirements of the particular patient are taken as a guideline, is generally regarded as the preferable moral standard and best suited to contemporary practice and society [3,12]. Information should therefore be tapered to the requirements of the *particular* patient. These can only be determined during the interview. However, since inadequately informed patients cannot judge the adequacy of information supplied, exclusive reliance on this standard is neither legally nor morally acceptable, and there should be a reasonable connection between patient requirements and the professional standard [3,13]. Concerning the sort of information required by patients, 82–97% of respondents in a study by Farnill and Inglis responded that they would either would "like" to, or that they saw it as a "right" to be informed of the following categories of information (Table 1) [14].

Inadequately informed patients may be unable to enter into an interactive discussion, to ask follow-up questions and to comprehend the scope of information which is available to them, and to which they are entitled [15]. Limiting the anesthetic interview to asking "Do you have any questions or would you like me to discuss any aspect of the anesthetic?" when the patient knows very little is inappropriate. We have a moral responsibility to promote autonomous decision-making through pro- and interactive discussion [8].

It is possible to satisfy the needs of patients by understanding their requirements. El-Sayeh and Lavies required a study group of surgical patients to choose one of three levels of information: a full and detailed explanation, a simple description or as little as possible ("I expect that my best interests

Table 1
Information category

When allowed to eat and drink	When allowed to get up
Common complications	All complications
Details of pain/pain relief	How long you will be anesthetised
Where you will recover from anesthesia	Drip or bladder catheter on waking
Alternative methods of anesthesia	Details of premedicant drugs
Dangerous complications	Where you will be anesthetised
Details of needles/drips used	

will be followed"). At post-surgery re-interview, most subjects (83–94%) were satisfied with the level of information received, irrespective of the level requested [16].

The need and requirement to be informed is also evident in pediatric decision-making. Parents are the primary legal decision makers for their children, although most countries have legal procedures to override seriously inappropriate decisions. Litman et al. found that 74% of parents wanted to know all possible anesthetic risks, 24% only "likely" risks [17].

These data suggest that we can satisfy patients by understanding their needs. This is the route suggested by most authors [3,18].

2.5. Refusal to be informed—"waivers"

Since only informed individuals can make rational, autonomous decisions, patients have an *obligation* to accept appropriate information (at least a *duty* to know their fate) [19]. This is a reasonable demand since biomedical informed consent is mandatory to satisfy moral, legal and contractual demands. Although waiving the "right" to be informed may theoretically undermine personal autonomy, respect for personal autonomy may include respect for a wish *not* to be informed. Forcing information upon a patient might equate to psychological battery. Some studies indicate a majority of patients prefer to know very little about certain procedures and attendant risks, and only a small percentage may actually utilize information in decision-making [3]. There are primarily two ways of handling waivers: withhold the procedure until sufficient understanding is present, or accept that the waiver constitutes valid, if not informed, consent [3]. When, rarely, information is adamantly refused we should explain our obligations, and why information is crucial. If the competent patient remains inflexible, we should note the information withheld, and why. The concern that more information might increase stress or anxiety is unfounded (it only increases *knowledge* of anesthesia), and does not justify withholding information [20]. However, the way in which information is conveyed may influence the final results of treatment and even the healing process [21].

2.6. How much information should be supplied?

Any information that a patient might require, or reasonably use in order to make a decision, is appropriate. The level of information required may be much higher if the aim is legal defensiveness (justifying the "full disclosure model" in highly litigious societies). The more serious or likely a risk or complication, the greater is the requirement to inform since the likelihood of such knowledge influencing patient choice is increased [22].

Patients should be fully informed of the scope and extent of procedures (including lines, tubes and catheters). Significant sequelae ("potential but rare" consequences) should be discussed [23]. Courts may disagree with the professional or subjective standards of disclosure practiced, when in their opinion, particular risk information is "so obviously necessary that it would be negligent not to provide it" [24]. The legal, contractual and moral requirement to *adequately inform* with up-to-date information exists irrespective of whether the anesthesiologist considers the notion of informed consent inapplicable to anesthesia, and prefers to conceptualise of information and consent separately.

Table 2
Predicted incidence of anesthetic associated morbidity (from Jenkins and Barker [22], modified)

Event	Incidence
Peri-operative cardiac arrest	0.5–1:10000
Anaphylaxis	1:10000
Deafness, idiopathic	1:10000
Aspiration	1:3000
Awareness with pain	1:3000
Failure to intubate	1:500
Awareness without pain	1:300
Total dental damage	1:100
Headache	1:5
Sore throat, after LMA	1:5
PONV	1:4
Pain	1:3
Sore throat, after intubation	1:2

How much of the risk involved in a procedure should be divulged? Jenkins and Barker recently published a comprehensive review of the literature on anesthetic mortality and morbidity [22]. The expected incidence of anesthetic associated mortality is in the vicinity of 1:100,000 (in ASA1-11 patients; 1:50,000 overall). An illustrative list of anesthetic-associated morbidity is summarized in Table 2.

Our purpose – to convey a realistic sense of risk – is not served by reciting to out patients confusing statistical lists of alarming complications. Yet, it is impossible to conceptualise risks without some comprehensible reference to expected or probable incidences. We should have some basis to give a reasonably accurate assessment, such as personal or institutional complication figures, provided our database is adequate for statistical purposes.

As an alternative to statistical data that are difficult to conceptualise, Jenkins and Barker suggest the use of a scale that provides a practical sense of risk classification. Calman's verbal scale describes risk based on probability as *very high*, *high*, *moderate*, *very low*, *minimal* and *negligible*. These descriptives can be related to commonly encountered community groupings (Table 3), or similar comparisons relating to daily life, to provide alternative understandable measures of risk classification.

Where applicable the patient should be informed of clearly identifiable boundary risks (e.g. related to success and morbidity rates in particular institutions, and of particular operators), provided the intention is not to influence unduly (coerce or manipulate) but to inform. However, for self-evident reasons, this should be done with great circumspection.

Table 3
Alternative risk classification (data from Jenkins and Barker) [22]

Morbidity	Predicted incidence	Calman scale	Community grouping
PONV, sore throat	>1:10	Very high	Siblings
Death in emergency surgery	1:10–1:99	High	Street
Awareness without pain	1:100–1:9999	Moderate	School
Anaphylaxis	1:10000–1:99999	Very low	Small town
Post-epidural haematoma	1:100000–1:999999	Minimal	Town
Spontaneous epidural haematoma	<1:1000000	Negligible	City

2.7. The use of aids in informed consent

Written material, visual and other aids may be useful additional information, and in explaining complex issues [25–27]. It does not replace the informed consent interview, but broadens the basis for discussion. Another useful possibility is web-based information tools.

2.8. What is done in practice?

In a postal survey amongst tutors of the Royal College of Anaesthetists, only 4.5% of respondents used separate anesthetic consent forms; 72% thought them unnecessary. Oral consent is usually documented [28]. A particular concern is that the majority (70%) do not obtain consent to use patients in student training; 92% regard this superfluous.

3. Consent for anesthesia in ambulatory patients

The foregoing discussion applies equally to ambulatory practice. Two particular difficulties undermine proper informed consent: time and timing of consent.

1. *Timing*: It is suboptimal to have the first pre-anesthetic interview and a discussion of anesthetic morbidity immediately preceding a procedure. Appropriate informed consent is unlikely, and paternalism, coercion and inadequate information are potential risks. The informed consent interview should ideally take place a few days prior to surgery to facilitate a frank discussion, an unhurried, uncoerced decision, time to obtain more information if required, and to reflect on and review decisions taken. Although there may be less need for the latter than, for instance, in surgical informed consent, the need for an early interview was, for example, recognised and specifically legislated for anesthesiology (in all but emergencies) in France in 1994, with a predominantly positive result (and is practised in other countries in formal and less formal ways) [29]. The need for a clinical evaluation in good time to optimise host morbidity supports this practice.
2. *Time*: Managed care and time-management aim to limit doctor–patient contact to limit costs. Procedures are increasingly performed on ambulatory basis, and patients admitted even for major procedures, on the day of surgery [30]. A possible risk is that anesthesiologists may be pressured to expedite pre-op checks and tempted to downplay possible risks for the sake of expediency. With such constraints, "real" informed consent has been described as "difficult" in the NHS; "active, reciprocal and fluid discussion" is rarely possible; "it takes time to explain anaesthesia to patients, and time for them to reflect on this information and ask further questions" [7]. From a management perspective, increased doctor–patient exposure equates to increased workload or staff increases. Managers and funders do not always appreciate the importance and time-consuming nature of obtaining informed consent in anesthesia [7], which may tempt anesthesiologists to resign themselves to suboptimal practices perceived to be inevitable, instead of questioning their moral and legal soundness and justifiability. "Morality only really begins where one breaches customary behaviour, or works to change it" [31].

Other difficulties may include denying admission in favour of ambulatory procedures when the former is more appropriate, and limiting choice in anesthetic techniques and drugs. Most patients accept a limitation of free choice when joining a particular insurance or health care scheme, and similar limitations exist in the public sectors of almost all countries. No person is guaranteed access to the type and quantum of services that she might require, or want. However, as advocates of our patients, we should object when such limitations are to the detriment of patients. Our primary responsibility is to our patient, whose interests are our first concern.

Given these difficulties, we have three options:

1. *Regard these difficulties as insurmountable*: Informed consent for anesthesiology, particularly in ambulatory surgery, is bound to be insufficient and subservient to other needs and demands. This attitude is neither acceptable nor required. Firstly, informed consent is not an option but an imperative, and secondly, we have the power to alter the presently accepted paradigm. Furthermore, our unique knowledge and experience imply a *professional and moral duty* to correct this attitude where and when appropriate.
2. *Increase the amount of anesthesiologist–patient contact time*: For example, make funders and managers aware of the moral and legal requirements for informed choice in anesthesiology, including ambulatory surgery, which can only be satisfied by an increase in contact time. Additionally, this sound investment may provide worthwhile returns: improved patient-satisfaction [13,14,16,18] and consequently, less likelihood of litigation. We should explain that informed consent is only realistic if patients are empowered to make rational choices,

which presupposes adequately informed patients, and that informing patients is time consuming. Anesthesiology is unique; patients temporarily lose consciousness, increasing their vulnerability since they cannot fend for themselves; vulnerability defines a moral relation [32]. The moral response to vulnerability is *responsibility*. Explain that our responsibilities include empowering the patient with a full knowledge and understanding of treatment. We are guilty of misconduct if we neglect this, and have broken the implied tenets of our contract even without actual, direct acts of negligence.

3. *Improved time-management*: Promote aids like specific pre-printed information sheets in ambulatory surgery, and make these available as early as possible (e.g. as soon as an operation is scheduled), not to replace but enhance the pre-operative interview. Telephonic pre-admission interviews are useful, with the advantage that nursing staff can initially be employed, though the anesthesiologist remains finally responsible. Worthwhile, too, is the extension of pre-operative clinics to include ambulatory patients who are entitled to the same respect as complicated cases.

4. Take-home message

An ethically defensible and legally sound informed consent practice in anesthesiology should be based on the following principles: Separate anesthetic informed consent is mandatory. Although only some countries require written, patient co-signed consent, the process should nevertheless always be documented in some way or another. The crux of informed consent is the supply of information, and the dilemma is often how much; when in doubt, it is better to supply more, rather than less information, not to impress or dominate, but to inform. Use understandable and down-to-earth language, adjusted to the level of the patient, to discuss all invasive procedures and realistically expected extensions, all common and serious complications, and all options and alternatives.

Since both knowledge and the ability to reason are requirements, ill-informed patients cannot provide informed consent. Informed consent may be time consuming since more knowledge often leads to more questions and further discussion. Make a sincere attempt to come as close to the ideal given the limitations of time, language and cultural difficulties. Note that particular consent should be obtained when patients are to be used in teaching students, and that the requirements set out above are inadequate for informed consent in any form of research. Particular difficulties exist in ambulatory patients and those admitted on the day of surgery, since they, too, are entitled to proper informed consent.

Anesthesiology is a science, but its practice an art; obtaining adequate informed consent within the constraints of the ambulatory setting lies at the heart of this art.

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