

International Journal covering Surgery, Anaesthesiology, Nursing and Management Issues in Day Surgery



IAAS operations and the activities that arise from the IAAS 2013 WORK PLAN EASTERN EUROPEAN YEAR, have received funding, in the form of an operating grant, from the European Union, in the framework of the Health Programme.

The content of the journal represents the views of the authors and it is their sole responsibility; it can in no way be taken to reflect the views of the European Commission and/or Executive Agency for Health and Consumers or any other body of the European Union. The European Commission and/or the Executive Agency do(es) not accept responsibility for any use that may be made of the information contained in the journal.



Co-funded by the Health Programme of the European Union





Editorial	115
Survey on incidence of surgical procedures and percentage of ambulatory surgery in 6 European countries JD Brökelmann & C. Toftgaard	116
Day surgery laparoscopic cholecystectomy: comparative analysis in two consecutive periods in a cohort of 1132 patients F. Docobo Durántez, M. Arance García, A. Navas Cuéllar, J. Mena Robles, J.M. Suárez Grau, F.J. Padillo Ruiz	121
Patient Perspectives of Noise During Minimal Sedation Procedures K. Sanniec & M. Gellis	127
Anterior-Apical Mesh Repair System in an ambulatory setting D.Sinhal, J.Iyer, M.Mous, R.Muller, A.Rane	130

Editorial

Doug McWhinnie

In this edition of the journal, we have an eclectic collection of articles, both in terms of content and in origin. From Townsville, Australia we have a descriptive, prospective series of 111 women treated for vaginal prolapse by mesh repair on an ambulatory basis. Traditional repair carries a failure rate of somewhere between 40-60% but in this study, subjective success rate using mesh was almost 90%, albeit with only a 24 month follow-up. However, the authors report a commendable 93.4% day case rate.

From Arizona, we have an interesting survey on patients' perception of noise in the operating room during surgical procedures performed under sedation. It is well recognised that music in the OR can help patients relax and may even improve the surgeons' performance, but interestingly, not the anaesthetists'! This study of 120 patients addresses the issue of surgeon/patient conversations during the surgical procedure and the patients' views on 'idle chatter' on the OR. This survey demonstrated that 77.5% of respondents actually enjoyed talking with the staff during the procedure with 75.5% stating that it helped them relax. Of note is the fact that 85% of patients felt that 'idle chatter' in no way interfered with proper care

Laparoscopic cholecystectomy performed on a day case basis has been with us for more than 20 years. From Seville, Spain we have a paper comparing and contrasting their early and later results of 1132 patients over a 13 year period. Not surprisingly. day case rates have significantly increased but most importantly, so has patient satisfaction. Sometimes it is worthwhile having a reality check to confirm how much progress has been made in ambulatory surgery over the past few years!

Finally from Germany and Denmark we have our IAAS biennial report on ambulatory statistics from a number of countries using the new Organisation for Economic Co-operation and Development (OECD)definitions for ambulatory surgery. This classification offers three ambulatory outcomes: 'in-patient', 'day case ' and 'outpatient'. The more organisations and countries that adopt a standard classification, the more valuable and influential IAAS reviews will be in the future. Accurate benchmarking allows valid and indisputable statements to be made regarding progress in ambulatory surgery, on both a national and international basis and restricts the effects of lame excuses for lack of progress in day surgery.

Doug McWhinnie

Editor

Survey on incidence of surgical procedures and percentage of ambulatory surgery in 6 European countries

J.D. Brökelmann^a, C.Toftgaard^b

Abstract

- Aim: To continue the biennial survey of surgical statistics in member countries of the International Association for Ambulatory Surgery (IAAS).
- **Methods:** All member countries of IAAS were asked to submit national statistics on the state of ambulatory surgery in their country in 2011 with respect to a basket of 37 procedures (the IAAS basket). The new definitions of the Organisation for Economic Co-operation and Development OECD were applied ie: assignment to "inpatient", "daycase" and "outpatient".
- **Results:** Only 6 countries (Denmark, England, Finland, Germany, Scotland and Sweden) met the criteria of the new OECD definitions for their statistics in 2011. The most interesting results were seen

when comparing the indicator procedures with a) the incidence of operations/procedures as frequency ratio per 100.000 of population and b) the percentage of ambulatory surgery. The frequency ratio was higher in Germany than in the other countries examined and the percentage of ambulatory surgery lower.

Conclusion: The new definitions and rules of OECD allow a comparison of surgical activities between countries. The most valuable indices in demonstating differences in health management appeared to be the parameters "frequency ratio" and "percentage of ambulatory surgery". It is recommended that case-based statistics using OECD definitions should become the international norm.

Keywords: surgical statistics, case-based statistics, frequency ratio, percentage of ambulatory surgery.

Authors' addresses: ^a Bundesverband für Ambulantes Operieren BAO, 53111 Bonn, Sterntorbrücke I, Germany

^b CTKonsult on behalf of Danish Regions, Denmark.

Corresponding author: J. D. Brökelmann, c/o BAO Geschäftsstelle, BAO-Geschäftsstelle *Tel*: +49228-692423 *E-mail*: baobonn@t-online.de

Introduction

The IAAS has collected data on the progress of ambulatory surgery since 1998 [1]. The primary reason for this action was to monitor progress in ambulatory surgery as percentage of overall surgical procedures in different countries for 20–37 index procedures.

Over the last few years, several questions regarding these data have emerged:

- Is the national data complete and who collects the figures?
- Does the data cover 100 % of the population and what proportion of the population has private insurance or is not insured at all?
- Are data available for privately insured patients, for cosmetic surgery, and for worker's accident insurance as it exists in Germany?
- Are statistics based upon procedures or patients?
- Are both public and private clinics included?

Recently the OECD switched to data based only upon patients discharged from hospitals with respect to the incidence of a procedure per 100.000 population, i.e. the frequency ratio (OECD. StatExtracts [2], in press). In addition new definitions concerning the unit where surgery is performed were used. These new rules and definitions were employed in a report of OECD to the German Government (2013) [3].

Methods

The IAAS survey 2011 was conducted in the same manner as before [1], collecting data for 37 procedures, the so-called basket of ambulatory procedures.

In addition the representatives of 18 member countries were asked to judge completeness of data, internet address of statistical source, whether statistics are covering privately insured people, cosmetic surgery and procedures in relation to industrial accidents.

The terms ambulatory and inpatient surgery were used according to the new definitions of OECD as "inpatient", "day-surgery" (hospital admitted) and "outpatient" (for other ambulatory surgery) (Fig. 1).

Results

Out of 18 member countries 10 responded and 6 countries could provide statistical data of 2011 based upon cases (Table 1). These were Denmark, England, Finland, Germany, Scotland and Sweden.

All available data on 37 procedures were collected in a "long list" (Table 2). These data showed the following peculiarities:

- 1. England shows a subcategory called "emergency" which has to be added to the inpatient numbers.
- 2. Germany could provide data from 2 different insurance systems:
 - a) DRG statistic from hospital inpatient treatment, with hourly cases listed as day cases
 - b) EBM statistics from the Association of Statutory Health Insurance (SHI) Physicians (Kassenärztliche

Fig. 1: OECD Definitions 2012. Questionnaire for surgical statistics.

Surgical procedures (shortlist)

Surgical procedures are medical interventions involving an incision with instruments usually performed in an operating theatre and normally involving anaesthesia and/or respiratory assistance. Surgical procedures can be performed either as inpatient cases, day cases or, in certain instances, as outpatient cases. Procedures performed on an inpatient case and day case should be reported for all the procedures on the shortlist. For two procedures, the number of outpatient cases in hospitals and outside hospitals should also be reported where possible.

Notes:

- The method to count procedures should be based on a count of the number of patients who have received a given procedure or on a count of only one code per procedure category for each patient, in order to avoid double-counting procedures for which more than one code may be used in certain national classification systems. (For example, if a percutaneous coronary intervention with a coronary stenting is recorded as two separate codes, it should be reported as only one patient/procedure. Another example: if a cataract surgery is performed on the two eyes, only one patient/procedure should be counted.)

- The mapping with ICD-9-CM codes is available for information at the following link: http://stats.oecd.org/HEALTH_QUESTIONNAIRE/Surgical procedures/JQNMHC_MAPPING ICD-9-CM.pdf

a) Inpatient cases: See definition of inpatient cases.

b) Day cases: See definition of day cases.

c) Outpatient cases (collected only for cataract surgery and tonsillectomy):

Procedures on patients who are not formally admitted in hospital or in any other health care facility. Included are procedures performed in outpatient departments in hospitals or in emergency departments and procedures performed outside hospitals (ambulatory sector). Excluded are inpatient cases and day cases.

Inpatient cases

An **inpatient discharge** is the release of a patient who was formally admitted into a hospital for treatment and/or care and who stayed for a minimum of one night.

Inclusion

- Emergency cases and urgent admissions when they resulted in an overnight stay and formal admission
- Patients admitted as day-care patients but who have been retained overnight due to complication
- Exclusion
- Day cases
- Outpatient cases (including emergency department visits)"

Day cases

A day-care discharge is the release of a patient who was formally admitted in a hospital for receiving planned medical and paramedical services, and who was discharged on the same day.

Inclusion

- Non-admitted patients who were subsequently admitted for day-care

Exclusion

- Inpatient cases
- Outpatient cases (including emergency department visits)
- Patients admitted as day-care patients but who have been retained overnight due to complication

Bundesvereinigung) responsible for the ambulatory health sector.

c) For Germany no data was available for: privately insured outpatient cases (about 10 % of the population), for patients treated in hospitals for ambulatory procedures according to § 115 b SGBV (KG 2 statistics), for cosmetic surgery and for patients treated in specialized hospitals for work accidents which are insured in the Statutory Accident Insurance (see Country Report Germany 2013 [4]). To simplify the survey this "long list" was shortened. Only the most frequent procedures were collected; these were 16 procedures with a frequency of more than 97.000 procedures per year in one country (Germany). In addition the percentage of ambulatory surgery (% AS) and the incidence (frequency ratio) were extracted, and the lowest rate of ambulatory surgery and the highest incidence per 100.000 population were marked yellow and red (Table 3).

The results show, that with the exception of one procedure (Dupuytren's contracture) Germany always has the lowest rates of ambulatory surgery within these 6 countries. With few exceptions

Hospital Hospital day Outpatient Statistics -Statistics inpatient cases cases cases procedurecase-based based England $^{+}$ ++ _ _ Finland + + + _ Germany + + + + _ Scotland + + _ _ + Sweden +? $^{+}$ +_ + + Denmark + + + Belgium (year 2012) +? +? no numbers no numbers Spain + $^+$ + _ ? ? Australia + no numbers + India no numbers no numbers

Table I Statistics available from six European countries.
 All representatives of 18 members countries were asked to participate.

Table 2 Comparison of selected surgical procedures based upon cases according to OECD rules.¹

	England	Finland	Germany	Scotland	Sweden	Denmark
Population in million (m)	53.01	5.43	82.03	5.25	9.51	5.60
Cataract						
Inpatient	5.494	365	² 131.255	1.396	1.587	471
special inpatient	³ 668		424.010			
Total inpatient	6162	365	155.265	1.396	1.587	471
Day cases	330.873	42.492	⁵ 5.797	33.308	76.750	44.284
Outpatient			601.912			
Total AS ⁶	330.873	42.492	607.709	33.308	76.750	44284
Total	337.035	42.857	762.974	34.704	78.337	44.755
% AS ⁷	98 %	99 %	80 %	96 %	98 %	99 %
Incidence FR ⁸	636	789	930	661	824	813
Squint						
Inpatient	627	91	4.765	49	181	248
Special inpatient	11		140			
Total inpatient	638	91	4.905	49	181	248
Day cases	10.471	768	45	359	1.850	1.704
Outpatient			288			
Total AS	10.471	768	333	359	1.850	1.704
Total	11.109	859	5.238	408	2.031	1.952
% AS	94 %	89 %	6 %	88 %	91 %	87 %
Incidence FR	21	16	6	8	21	3

Thanks to Statistisches Bundesamt/Federal Statistical Office, Germany, for providing OECD rules 2

DRG statistics of hospitals (Germany)

3 emergencies (England)

 EBM statistics for "Belegkrankenhäuser" (Germany)

5 hourly cases of DRG statistics of hospitals. Day cases of KG 2 statistics (§ 115b SGB V) not available

6 AS = ambulatory surgery: day cases + outpatient cases (specialized doctor's offices, Day Surgery Centers)

7 Percentage of ambulatory surgery (AS) to total cases

Incidence = frequency ratio (FR): cases per 100.000 population

Table 3 Comparison of selected surgical procedures based upon cases according to OECD rules.¹

Most frequent procedures (>97.000 cases per year) Marked yellow: lowest rate of ambulatory surgery (AS) Marked red: Highest incidence per 100.000 population

	England	Finland	Germany	Scotland	Sweden	Denmark
Population in million (m)	53.01	5.43	82.03	5.25	9.51	5.57
Cataract: % AS ²	98 %	99 %	<mark>80 %</mark>	96 %	98 %	99 %
Incidence FR ³	636	789	930	661	824	813
Tonsillectomy: % AS	38 %	70 %	<mark>4 %</mark>	29 %	41 %	37 %
Incidence FR	86	168	201	32	81	88
Rhinoplasty: % AS	31 %	65 %	<mark>25 %</mark>	32 %	62 %	68%
Incidence FR	3	42	312	2	40	46
Surgical removal tooth% AS						95%
	95 %	90 %	<mark>65 %</mark>	97 %	95 %	
Incidence FR	207	39	137	95	58	43
Dilatation + curettage of						95%
uterus: % AS	88 %	69 %	<mark>53 %</mark>	91 %	75 %	
Incidence FR	100	45	148	115	190	161
Knee arthroscopy:						95 %
% AS	83 %	83 %	<mark>24 %</mark>		86 %	
Incidence FR	18	42	476		62	41
Arthroscopic meniscus						97%
% AS	84 %	94 %	<mark>51 %</mark>		96 %	
Incidence FR	196	223	364		140	173
Removal bone implants						90 %
% AS	64 %	74 %	<mark>34 %</mark>	74 %	75 %	
Incidence FR	65	90	270	54	206	259
Carpal tunnel release						95%

¹ Thanks to Statistisches Bundesamt destatis for providing OECD rules

² Percentage of ambulatory surgery AS to total cases

³ Incidence = frequency ratio FR: cases per 100.000 population

Germany also has the highest frequency ratio of procedures.

Discussion

Between 2005 and 2013 Germany had no data for outpatient procedures because of a change of the accounting settlement system (EBM) in 2004. As an example cataract operations in 2010 were listed 153.832 in OECD statistics [2]. One year later in 2011 (the present study) there are 155.265 cataract procedures as inpatient procedures plus 607.912 as day cases and outpatient cases. This demonstrates that until 2010 statistics were distorted because the whole ambulatory sector ("outpatient") of more than 600.000 cataract procedures was neglected.

Ambulatory surgeons in Germany have tried again and again to influence the National Association of SHI-Accredited Physicians (KBV) to provide data on operations and procedures, without success. It was only after the IAAS officially asked the German Health Ministry to provide information that the data was received regarding the 37 basket operations. these data, IAAS received data on 37 procedures.

This study shows that two parameters seem to be invaluable in comparing health care systems:

- 1. Incidence of operations/procedures as frequency ratio per 100.000 of population and
- 2. percentage of ambulatory surgery (% AS) of indicator procedures.

It could be shown that in Germany most procedures are performed more often per 100.000 population than in the 5 countries compared. This coincides with the recent report of OECD on hospital management in Germany (OECD [3]). The reason for this has to be examined by national experts; the German Minister of Health Bahr has already initiated correspondent inquiries.

Secondly, the comparatively low rate of ambulatory surgery in Germany is the result of economics: In Germany for the same procedure the fee in the ambulatory sector paid for by the EBM insurance system is only 25 % of what is paid for in the inpatient DRG system (Vescia 2008 [5], Lemos 2012 [6]). For hospitals this means that the hospital administration gets four times as much if the patient offers some medical reason to be operated as inpatient and thus releases a full DRG.

The strict division of the ambulatory and inpatient sector in Germany is a peculiarity of the system which nowadays lacks justification.

In contrast to the situation in Germany the countries of England,

Finland, Scotland, Sweden and Denmark seem to be rather uniform in the rate of ambulatory surgery and in the incidence per 100.000 population. The few anomalies require investigation and explanation by national experts. They may bepartly explicable by improper coding and may not represent a systemic difference. With increased use of the new OECD rules, fewer anomalies should occur.

It should be the task of national governments to collect statistical data from the various health care organisations independently of insurance status and location of surgical treatment.

- I Toftgaard, Claus. Day Surgery Activities 2009. International Survey on Ambulatory Surgery conducted 2011. *Ambulatory Surgery* 17.3, January 2012.
- 2 OECD Health Data 2012. Definitions, Sources and Methods. Surgical procedures by ICD-9-CM. See OECD Homepage: Link http://stats. oecd.org → Health → Health Care Utilisation → Surgical procedures → show information → Definitions, Sources and Methods→ Surgical procedures by ICD-9-CM
- 3 http://www.managing-hospital-volumes.de
- 4 Brökelmann J. Country Report Germany. Ambulatory Surgery, in press 2013.
- 5 Vesica F. Vergütung ambulant und stationär durchgeführter vi Operationen in Bayern. Angleichung an die Fallpauschalen der DRG erstrebenswert. Ambulant Operieren 4/2008, 184–186.
- 6 Lemos P. Financing Day Surgery An International Perspective. *Ambulatory Surgery* 18.2, October 2012.

Day surgery laparoscopic cholecystectomy: comparative analysis in two consecutive periods in a cohort of 1132 patients

F. Docobo Durántez^a, M. Arance García^b, A. Navas Cuéllar^a, J. Mena Robles^a, J.M. Suárez Grau^a, F. J. Padillo Ruiz^a

Abstract

Aim: To evaluate factors preventing discharge in patients scheduled for laparoscopic cholecystectomy (LC) in a day Surgery Unit in a University Regional Hospital.

Methods: Selection criteria: Adult patients, American Society of Anesthesiology (ASA) physical status classification class I-II or III compensated, and BMI < 35, uncomplicated acute cholecystitis. Between 1997 and 2002 (Group A) and between 2003 and 2010 (Group B) a total of 1132 patients underwent LC. Clinical characteristics, Substitution Day Surgery Index, causes for inpatient, postoperative complications, pathological studies, patient satisfaction index and 3 months clinical results were compared. **Results:** 306 patients in the group A and 826 in group B were selected for day-case laparoscopic cholecystectomy. In group A only 1.31% were day cases and in group B 82.5% were day cases. Symptoms such as abdominal pain or nausea and/or vomiting were less frequent in group B.The incidence of complications was low and similar in both groups of patients. There were no differences in the presence of events in the three months following surgery. Satisfaction rates were high in both groups but higher in the group B.

Conclusions: Outpatient laparoscopic cholecystectomy is a safe and reliable procedure with a high level of patient acceptance.

Keywords: Laparoscopic cholecystectomy, Day Surgery, Inpatient, Substitution Day Surgery Index.

Authors' addresses: ^aGeneral and Digestive Surgery Department. ^bAnesthesiology Department. University HospitalVirgen del Rocío. Sevilla. Spain.

Corresponding author: F. Docobo Durántez. Tel: +34 629548336 E-mail: fdocobod@yahoo.es

Introduction

Laparoscopic cholecystectomy (LC) is now the treatment of choice for non-complicated cholelithiasis, especially on a short stay or day case basis [1.2].

Despite this, several questions remain unsolved. Is LC safe as an ambulatory procedure? Is it a cost-effective procedure? Are both surgical and anaesthetic teams involved in this ambulatory procedure? What are the views of patients and relatives regarding LC as a day surgery procedure? What is the implication to hospital administrators?

If this surgical activity is going to be carried out in Sort Stay Surgical Units (SSSU) as well in Day surgery Units (DSU), safety and efficacy of the procedure are necessary. Therefore, any LC ambulatory programme requires appropriate patient selection according to clinical, biochemical, ultrasonography and social criteria, with the establishment of protocols for each phase of the patient pathway, and formal evaluation of the service. If appropriate pathways are present in both (short stay surgical units) SSSU's and (day surgery units) DSU's, which factors determine hospital stay and contribute to the observed differences between the programmes?

The aim of this study is to evaluate the incorporation of LC in an ambulatory surgery unit and to identify clinical and surgical factors which could be determinants in the decision to discharge patients on same day or after an overnight stay.

Methods

Patients. A prospective study of patients undergoing LC for chronic cholecystitis from 1997 to 2010 was conducted.

The study groups were composed of patients followed-up for 3 months postoperatively. Patients were selected according to the following criteria: patient adherance to the ambulatory programme after previous personal interview, signed consent information, own phone, support of a responsible adult, and a home distance less than 1 hour from the hospital. Patients were classified following the American Society of Anesthesiology (ASA) physical status classification class I-II or III compensated, and BMI < 35. Patients with cholestasis, choledocholithiasis, acute cholecystitis, treated or drained by percutaneous approach, or recent acute pancreatitis, were not included.

Two consecutive groups were compared. Group A patients received their operation between 1997 and 2002, and group B between 2003 and 2010, and time to discharge noted (same day or overnight stay). The following clinical characteristics were recorded in both groups: Substitution Day Surgery Index (SSDI), reason for inpatient stay, postoperative complications, histopathology, patient satisfaction index, and 3 months post-operative clinical results.

Anaesthetic and surgical technique. Patients were admitted in the morning of the day of surgery. The procedures were performed before 12 noon to allow a postoperative recovery period of about 8 hours.

The anaesthetic procedure was as follows: premedication with oral midazolam (0.1 mg/kg) in the 30 min before surgery. Induction was performed with propofol (3–5 mg/kg) and muscular relaxation with a non depolarizing muscle relaxant (cisatracurium 0.3-0.5 mg/kg). Anaesthesia was maintained with a continuous infusion of propofol, 2–4 µg/mlTarget Controlled Infusion (TCI) and remifentanyl (0.3 µg/kg/min) or fentanyl (3 µg/kg) as an ultra short-acting analgesic drug. Intravenous ketorolac (60 mg) was injected at the end of the procedure. Nausea and vomiting, and thromboembolism prophylaxis

were given when risk factors were present. No routine antibiotic prophylaxis was done.

Surgical procedures were performed by 2 trained-surgeons assisted by surgical residents in a teaching-programme. Surgical technique involved the creation of a pneumoperitoneum (10 mm Hg) using a Verress needle inserted into the left hypochondrium with 3 or 4 ports as necessary. No routine drains were inserted.

Postoperative analgesia consisted of: ketorolac 60 mg/8 h, and paracetamol 1g, if necessary and omeprazole 20 mg/12 h. If pain persisted, tramadol (50–100 mg, i.v.) was used as analgesic rescue.

Oral liquids were normally taken 2 h after the procedure. Postanaesthetic Discharge Scoring System (PADSS) [3] (Appendix 1) was selected for discharge criteria. The surgeon discharged the patients and managed their expectations in the post-operative period. In particular they were informed about possible warning signs of complications (several abdominal pain, abdominal distension, nausea and/or vomiting, fever, etc.). All patients were contacted by phone 24 after surgery and interviewed using a standardized questionnaire. Patients were clinically evaluated one and three months after discharge.

Statistical analysis. Statistical comparative analyses were performed using Chi-Square and Student t- tests. A p value < 0.05 was considered significant.

Results

The study group consisted of a total of 1132 patients undergoing LC for chronic gallstone cholecystitis, and followed-up for 3 months postoperatively between 1997 and 2010.

Between 1997 and 2002 (group A) 306 patients (27.04%) were included and between 1998 and 2010 (Group B) 826 (72.96%) were selected for LC in a DSU.

The characteristics of the patients are shown in Table 1. Mean BMI was 29 ± 1.47 kg/m² in group A and 28 ± 0.82 kg/m² in group B (p<0.001). Mean total bilirrubin was 0.69 ± 0.03 mg/dl in group A and 0.57 ± 0.03 mg/dl in group B (p<0.001).

Average surgical time was 39 ± 10 minutes in group A and 28 ± 7 minutes en group B (p<0.001).

Number of ports, 3 in 35/306 (11.4%) group A and 825/826 (99.88%) group B (p<0.01).

The length of hospital stay of each patient, as well as the rate of substitution for both study groups is shown in Table 2. The percentage of patients who were discharged the same day of surgery was higher in the group B compare to the group A (82.5% vs 4%) substitution index of both groups (p < 0.01).

All patients selected for surgery were scheduled to be discharged home on the same day of surgery. The reasons for hospital stay in both groups are shown in Table 3. In Group A, only 4 of 306 patients (1.31%) were discharged on the day of surgery. The reasons for failed discharge in the other 302 patients were as follows: abdominal pain 84 patients (27.4%), nausea and/or vomiting 69 patients (22.5%), general discomfort 68 patients (22.2%), social criteria and/or patient preference 48 patients (15.6%) and a further 33 patients failed to go home due to conversion to the open procedure. (10.7%). In group B, 144 (17.43%) patients were admitted due to: abdominal pain 30 (3.63%), nausea and/or vomiting 25 (3.02%), general discomfort 38 patients (4.6%), social criteria 40 (4.8%) and 11 open conversions (1.33%).

The readmission rate was 2/306 (0.6%) in group A and 3/826 (0.36%) in group B (p= ns). Symptoms after 3 months was also uncommon in both groups with 291/306 (95.09%) asymptomatic in group A and 809/826 (97.94%) asymptomatic in group B. Occasional abdominal pain was present in 7/306 (2.28%) in group A and 9/826 (1.08%) (p= ns). Histopathology findings were similar in both study groups with chronic cholecystitis present in 244/306 (79.7%) of

Table I Characteristics of the patients distribution in relation both groups.

	Group A (997–2002)	Group B (2	2003–2010)	
	n = 306	(27.04%)	n = 826	(72.96%)	
Gender (p< 0.05)					
Female : Male	247:59	80.71:19.28	663 : 163	80.26 : 19.73	
Age (p < 0.05)					
20 – 39	49	16.01	193	23.36	
40 –59	128	41.83	323	39.10	
60 – 79	129	42.15	310	37.53	
ASA (p < 0.05)					
l	51	16.66	184	22.27	
II	206	67.33	543	65.73	
III	49	16.01	99	11.98	
Mean BMI (Kg/m²) (p<0.001)	29±	1.47	28±	0.82	
Mean total bilirubin (mg/dl) (p<0.001)	0.69:	±0.03	0.57	7±0.03	
Average surgical time (min) (p<0.001)) 39±10 28:		±7		
Number of ports (p< 0.01)					
3	35	11.4	825	99.88	
4	271	88.6	I	0.12	

Table 2	Discharge	time and	substitution	index	distribution	in	both	group	os.
								0	

	Group A (1997–2002)	Group B (2	2003–2010)
	n = 306	(27.04%)	n = 826	(72.96%)
Discharge time (hours) (p< 0.001)				
No overnight	4	1.31	682	82.5
< 24	186	60.78	129	15.6
24 – 28	106	34.64	7	0.84
≥ 48	10	3.26	8	0.96
Sustitution DS index	4 : 306	1.30	686 : 826	83.05

Table 3	Reasons for failed discharge discharge. Major complications. Histopathological studi	ies. Clinical and quality 3 months
distributic	n in both groups.	

	Gro	oup A	Gro	oup B
Causes of no DS discharge (p<0.05)	n	%	n	%
Abdominal pain	84	27.4	30	3.63
Nausea and/or vomiting	69	22.5	25	3.02
Discomfort	68	22.2	38	4.6
Social criteria	48	15.6	40	4.8
Open conversion	33	10,7	11	1.33
Total	302/306	98,69	144/826	17.43
Mayor complications (p ns)		1	1	1
Biliary leakage	2/306	0.6	3/826	0.36
Hemoperitoneum			1/826	0.1
Readmission rate	2/306	0.6	3/826	0.36
After 3 months (p ns)			L	
Asymptomatic	291/306	95.09	809/826	97.94
Sporadic abdominal pain	7/306	2.28	9/826	1.08
Diarrhea	2/306	0.65	2/826	0.24
Subhepatic collection	3/306	0.98	5/826	0.6
Umbilical hernia	1/306	0.32	-	-
Infection surgical wound	1/306	0.32	1/826	0.12
Retained stone	1/306	0.32	-	-
Histopathological study (20 days) (p ns)				
Unspecific chronic cholecystitis	244/306	79.7	633/826	76.63
Cholesterolosis	44/306	14.4	140/826	16.94
Adenomiomatosis	18/306	5.9	53/826	6.41
Satisfaction Index (p < 0.001)				
High	178/306	58.16	569/826	68.88
Moderate	117/306	38.23	245/826	29.66

group A patients and 633/826 (76.63%) of patients in group B (p=ns). Patient satisfaction was high in 178/306 (58.16%) in group A and 569/826 (68.88%) in group B. (Table 3)

Discussion

Day Surgery is a predefined pathway requiring shorter and less intensive postoperative care. Therefore patients do not need to remain in the hospital and can be discharged a few hours after surgery [4].Laparoscopic cholecystectomy has, over time, become readily achievable through SSSU's and DSU's for the treatment of noncomplicated cholelithiasis [1,4].

In Spain, most of the LCs are performed as part of an inpatient SSS programme. The experience in day surgery laparoscopic cholecystectomy (DSLC) is very limited even today. Perhaps there are several outstanding questions which must be addressed in this country before widespread adoption can occur:

Is LC safe as an ambulatory procedure? To be included in a DSU programme, LC must be both safe and effective. Therefore patient comorbidity needs to be controlled with patients selected according to clinical, biochemical, ultrasonography and social criteria. Reddick and Olsen published in 1990 the first LC outpatient series [5]. Thereafter, several other series confirmed that LC is a safe and effective procedure in DSU with a substitution index between 80% and 92.7%. Nowadays, laparoscopic cholecystectomy (and indeed laparoscopic groin hernia repair) is a well-recognised and safe day case procedure [6,7].

Clinical pathways must be defined from both the surgical and anaesthetic points of view with appropriate postoperative evaluation, including an assessment of quality [8,9]. Several series have demonstrated the safety and efficacy of outpatient LC in selected patients [10–13]. However, comparative studies are infrequent. In this present study, 1132 patients were included for day case LC between 1997 and 2010. Anaesthetic and surgical procedures were standardised to obtain a short hospital stay with the same level of safety and quality as those patients who did not receive DS.

The study showed that the need for hospitalization decreased in Group B compared to Group A (82.5% vs 4% : p< 0.01). This difference could be explained by the development of a learning curve for surgeons and anaesthetists resulting in fewer complications and/or side-effects. Other authors show that these early postsurgical events are factors that most commonly determine the need of admission [14-18]. However the incidence of major complications after LC in large series are between 1-5% [17], with most (bile leakage or intestinal perforations) diagnosed 24-36 hours after surgery, when the patients are already home, even in an inpatient programme [17-19]. In our series, major complications were infrequent in both groups. Biliary leakage for bile duct damage was detected in only 0.6% of cases in Group A and 0.3% in Group B. These results are similar to previous series, where bile duct lesions were recorded in 0.3-0.5% of cases. The recognised incidence of bleeding in the immediate post-operative period is between 0.05-0.1% [17,18]. In our series, one patient in Group B suffered this complication with no long term effects.

Is LC a cost-effective procedure? A DSU permits an increase in surgical activity which is not limited by bed numbers, while reducing the costs through shorter length of stay [20].but maintaining safety. 25-30%(6,10,14,15).

A further question relates to clinical willingness, by both surgeon and anaesthetist, to undertake day case LC. The reasons for this are complex and sometimes obscure. Nevertheless, there are those who do not wish to undertake the perceived greater workload of day surgery or perhaps loss of surgical esteem or administrative power by operating on less invasive cases.

To minimize the unplanned overnight admission rate, potential complications must be avoided. In our study, the inclusion of multimodal model of analgesia and prophylaxis for nausea and vomiting in Group B patients resulted in a significant reduction in postoperative complication rate from 27.4% to 3.63% and abdominal pain, from 22.5 % to 3.02% for postoperative nausea and vomiting, which is similar to results in other series. [1,6,8,16].

Are patients and relatives prepared for day surgery? Some authors suggest that over 70% of cholecystectomies can be performed as day cases [14,21,22]. Even so, many patients choose an inpatient stay for no apparent reason. Could it be that they are reassured by the presence of health care professionals overnight? Since they prefer the direct observation and care of professionals. This "social" reason for staying in hospital is a factor that significantly increases unplanned admissions in a DSU and may account for 18-30% of unexpected stays [23-26]. In our study 15.6% in Group A and 4.8% in Group B overnight admissions occurred for this reason. In our study, 83.05% of the patients in Group B were same-day discharges, a level similar to that reported in other series [27-29]. However, this figure may be biased as patients with acute cholecystitis and recent acute pancreatitis were excluded. Relaxation of our criteria to include ASA grade III compensated patients, was not associated with any increase in the incidence of postoperative complications and others have shown that exclusion criteria such as age >65 years or BMI >30 or 35 kg/m², have shown no relationship to the incidence of major complications after LC [26, 30-34].

An operating time >60 minutes correlates with day case failure [4,7,16]. In our study, the average operating time was 39 ± 10 minutes in the A Group and 28 ± 7 minutes in Group B (p<0.001). Open conversion where Calot's Triangle could not be readily identified was only 1.33% in Group B versus 10.7% in Group A, and was similar to that of other studies [9,10,20].

Safe discharge requires clear patient instructions for their return home with appropriate follow-up if required [35] and low rates of readmission. In our study, the readmission rate was low in both study periods, 0.6% in first 4 years and 0.36% in the last period. This rate was lower than that reported by others [7,20,36]. The low incidence of adverse postoperative events in the short and medium term did not allow statistically significant conclusions.

Conclusions

Outpatient laparoscopic cholecystectomy is a safe and reliable procedure with a high level of acceptance. In general, events emerging in the early postoperative period can be considered similar to inpatients. Variables such as the doubt or insecurity of patients at discharge can be important factors when it comes to deciding on unplanned admission. Comprehensive patient may reduce admissions for 'social' reasons. We believe that same-day discharge is the treatment of choice for uncomplicated LC.

- Martínez A. Docobo F. Mena J. et al. Colecistectomía laparoscópica en el tratamiento de la litiasis biliar: ¿cirugía mayor ambulatoria o corta estancia? Rev Esp Enferm Dig 2004; 96: 452–9.
- Bermúdez I. López S. Sanmillán A. et al. Colecistectomía laparoscópica en régimen ambulatorio. *Cir Esp* 2004; 76: 159–63.
- Frances Chung, Vincent W.S. Chan, Dennis Ong. A Post-Anesthetic Discharge Scoring System for home readiness after ambulatory surgery. *J Clin Anesth* 1995; 7(6): 500-6.
- Bueno Lledó J. Planells Roig M. Arnau Bertomeu C. et al. Colecistectomía laparoscópica ambulatoria. ¿El nuevo "gold standard" de la colecistectomía?. Rev Esp Enferm Dig 2006; 98: 14–24.
- Reddick EJ. Olsen DO: Outpatient laparoscopic laser cholecystectomy. *Am J Surg* 1990; 160: 485–7.
- Fatas JA. Blanco FJ. Ara JR. Dobon MA. Criterios para la realización de colecistectomía laparoscópica dentro de un programa de Cirugía Mayor Ambulatoria. *Cir May Amb* 2000; 5: 25–8.
- Gurusamy K. Junnarkar S. Farouk M. Davidson BR. Meta-analysis of randomized controlled trials on the safety and effectiveness of day-case laparoscopic cholecystectomy. *Br J Surg* 2008; 95: 161–8.
- Victorzon M. Tolonen.P. Vuorialho.T. Day-case laparoscopic cholecystectomy: treatment of choice for selected patients? Surg Endosc 2007, 21: 70–3.
- Psaila J. Agrawal S. Fountain U. Whitfield T. Murgatroyd B.Dunsire M.F. Gonzalez. J.G. Patel A.G. Day-Surgery Laparoscopic Cholecystectomy: Factors Influencing Same-Day Discharge. World J Surg 2008, 32: 76–81.
- Gurusamy KS. Junnarkar S. Farouk M. Davidson BR: Day-case versus overnight stay for laparoscopic cholecystectomy. *Cochrane Database Syst Rev* 2008. 16: CD006798.
- 11. Sharma A. Hayden JD. Reese RA. Sedman PC. Royston CMS. O'Boyle CJ: Prospective comparison of ambulatory with inpatient laparoscopic cholecystectomy: outcome. patient preference and satisfaction. *Ambul Surg* 2004, 11: 23–6.
- Paquette IM. Smink D. Finlayson SR: Outpatient cholecystectomy at hospitals versus freestanding ambulatory surgical centers. J Am Coll Surg 2008; 206: 301–5.
- Ahmad NZ. Byrnes G. Naqvi SA: A meta-analysis of ambulatory versus inpatient laparoscopic cholecystectomy. *Surg Endosc* 2008: 22; 1928–34.
- Keuleman Y. Eshuis J. de Haes H. de Wit LT.Gouma D. Laparoscopic cholecystectomy: day-care versus clinical observation. *Ann Surg* 1998; 228(6): 734–40.
- Johansson M. Thune A. Nelvin L. Lundell L. Randomized clinical trial of day-care versus overight-stay laparoscopic cholecystectomy. *Br J Surg* 2006; 93(1): 40–5.
- Serralta S. Bueno L. Sanhauja S y col. Evolución del dolor postoperatorio en la colecistectomía bajo anestesia-analgesia multimodal en régimen ambulatorio. *Rev Esp Anestesiol Reanim* 2002; 49: 461–7.
- Soper NJ. Dunnegan DL: Laparoscopic cholecystectomy:experience of a single surgeon. World J Surg 1993; 17: 16–20.
- Sarotto L. Ferraro A. Suárez F. Franzosi R. Carlucci D. Ferraina P. Colecistectomía laparoscópica ambulatoria. Experiencia sobre mil casos. *Rev. Argent. Cirug* 2006; **90 (3–4)**: 85–92.
- Morales García D. Martín Öviedo J. García Somacarrera E. Cagigas de la Piedra MA. Naranjo Gómez A. Introducción de la colecistectomía laparoscópica en un programa de cirugía mayor ambulatoria. *Cir May Amb* 2002; **7**: 173–6.
- Serralta A. García Espinosa R. Martínez Casañ P. Hoyas L. Planells M. Cuatro años de experiencia en colecistectomía laparoscópica ambulatoria. *Rev Esp Enferm Dig* 2001; **93**: 207–10.
- Ferraina P: Cirugía ambulatoria. Relato Oficial. LXII. Congreso Argentino de Cirugía 1991. Rev Argent Cirug N° Extraordinario. p 2.
- Robinson BL. Donohue JH. Gunes S. et al. Selective operative cholangiography: appropriate management for laparoscopic cholecystectomy. *Arch Surg* 1995; 130: 625–31.
- T.W. Ógg, M. Hitchcock, S. Penn. Day surgery admissions and complications. *Ambul Surg* 1998; 6: 101–6.
- 24. Ji W, Ding K, Li LT, Wang D, li N, Li JS. Outpatient versus inpatient laparoscopic cholecystectomy: a single center clinical analysis. *Hepatobiliary Pancreat Dis Int* 2010; 9(1): 60–4.
- Shirakami G, Teratani Y, Namba T, Hirakata H, Tazuque-Nishimura M, Fukuda K. Delayed discharge and acceptability of ambulatory surgery in adult outpatients receiving general anesthesia. *J Anesth* 2005; 19(2): 93–101.

- Marinis A. Stamatakis E. Tsaroucha A. Dafnios N. Anastasopoulos G. Polymeneas g. Theodosopoulos T. "Safety and effectiveness of outpatient laparoscopic cholecystectomy in a teaching hospital: a prospective study of 110 consecutive patients. BMC research Notes 2010; 3: 207–11.
- Pardo J. Ramia R. Martín JM. López A. Padilla D. Cubo T. et al. Colecistectomía laparoscópica ambulatoria. *Cir Esp* 1998; 64: 37–9.
- Narain PK. DeMaria EJ. Initial results of a prospective trial of outpatient laparoscópica cholecystectomy. Surg Endosc 1997; 11: 1091–4.
- MjAland O. Raeder J. Aasboe V. Trondsen E. Buanes T. Outpatient laparoscopic cholecstectomy. Br J Surg 1997; 84: 958–61.
- 30. Briggs CD. Irving GB. Mann CD et al. "Introduction of a day-case laparoscopic cholecystectomy service in the UK: a critical analysis of factors influencing same-day discharge and contact with primary care providers". Ann R Coll Surg Engl 2009; 91(7): 583–90.
- Bona S. Monzani R. Fumagalli Romario U. Zago M. Mariani D. Rosati R. Outpatient laparoscopic cholecystectomy: a propective study of 250 patients *Gastroenterol Clin Biol* 2007; 31: 1010–5.
- 32. Briggs CD. irving GB. Mann CD. cresswell A. Englert L. Peterson M. Cameron IC. Introduction of a day -case laparoscopic cholecystectomy service in the UK: a critical analysis of factors influencing same-day discharge and contact with primary care providers. *Ann R Coll Surg Engl* 2009; **91**: 583–90.
- Hollington P. Toogood G.J. Padbury T.A. "A propective randomized trial of day-stay only versus overnight-stay laparoscopic cholecystectomy". *Aust N Z J Surg* 1999; 69: 841–3.
- Clarke MG. Wheatley T. Hill M. Werrett G. Sanders G. An effective approach to improving day-case rates following laparoscopic cholecystectomy. *Minim Invasive Surgery* 2011:564–587.
- 35. Dirksen CD. Schmitz RF. Hans KM. Nieman FH.Hoogenboom LJ. Go PM. Ambulatory laparoscopic cholecystectomy is as effective as hospitalization and from a social perspective less expensive : a randomized study. Ned Tijdschr Geneeskd 2001; 145: 2434–9.
- Lau H. Brooks DC. Contemporary outcomes of ambulatory laparoscopic cholecystectomy in a major teaching hospital. World J Surg 2002; 26,fd,(9): 1117–21.

Vital signs	
2	Whitin 20% of preoperative value
1	20%-40% of preoperative value
0	40% of preoperative value
Activity, mental status	
2	Oriented and steady gait
1	Oriented or steady gait
0	Neither
Pain, nausea, vomiting	
2	Minimal
1	Moderate
0	Severe
Surgical bleeding	
2	Minimal
1	Moderate
0	Severe
Intake and output	
2	Per os fluids and voided
1	Per os fluids or voided
0	Neither

Appendix I	Postanesthetic Discharge Scoring System	(PADSS).
		(

Patient Perspectives of Noise During Minimal Sedation Procedures

K. Sanniec^a, M. Gellis^b

Abstract

Aim: To evaluate patient perspectives on the amount of noise, idle chatter, and staff communication during minimal sedation procedures.
 Methods: A ten-question survey was given to 120 consecutive patients to evaluate perceptions about the amount of noise, idle chatter, and communication during the procedure.

- **Results:** Survey results demonstrated 77.5% of respondents enjoyed talking with the staff during the procedure with 75.5% stated it helped them relax, and 85% of patients felt the side conversations did not prevent them from receiving proper care.
- **Conclusion:** Communication between patient and surgeon or patient and nurse can decrease anxiety and can optimize the patient's experience during the procedure.

Keywords: surgery communication, operating room noise, patient surgeon communication, "awake" procedures, minimal sedation procedures.

Authors' addresses: ^aUniversity of Arizona College of Medicine Phoenix, 550 EVan Buren St, Phoenix, AZ, USA ^b Sono Bello – Aesthetic Physicians, PC, 8900 E. Pinnacle Peak Rd., Suite E200 Scottsdale, AZ, USA. Corresponding author: M Gellis *Tel*: 623-738-3613 *Fax*: 480-212-4958 *Email*: mgellis@sonobello.com

Introduction

In recent years, there has been a trend to utilize less sedating anesthetic. The adverse effects of general anesthesia have been well documented and additional adverse effects are still being investigated [1–4]. This has led many physicians to utilize regional and local anesthetics for many procedures [5–7] that previously had required general anesthesia. Additionally, new evidence is being presented that shows decreases in cost, post-anesthetic morbidity, and length of hospital stay [6] in patients who receive locoregional anesthesia compared with general anesthesia [5].

As surgeons alter their anesthetic approach, they must become more conscious of their operative environment. The use of background music in the operating room has been around for decades. It has been used to create a more soothing environment for the operating room staff [8], to help quell patient anxiety [9], or to provide a diversion from the ambient background noise [10]. Most operating room staff enjoys music being played during the operative case [11].

The conversation during surgery, while common to members of the operating room team, is foreign to most patients. In fact, the banter that occurs between the surgeon and other members of the operating room team, may lead some patients to question the surgeons focus. A recent article in the Winnipeg Free Press [12], referenced this very phenomenon of "idle chatter". The surgeon and scrub tech were discussing a recent sporting event, while the patient was under local anesthetic. This led the patient to question the surgeon's concentration and made the patient feel very uncomfortable. The patient subsequently filed a complaint about this surgeon with the College of Physicians and Surgeons of British Columbia, even though the surgery was successful and mistake free.

As healthcare continues to evolve into a more patient-centered experience, surgeons must evaluate the amount of idle chatter in the OR. This study evaluates the patient's perspective on the amount of noise, idle chatter, and staff communication during an awake procedure. It is the hope of this study to assist the operating room staff in maximizing the patient experience in order to provide optimal patient-centered care.

Methods

A ten-question survey was given to 10 consecutive patients at 12 surgery centers. The questionnaire consisted of questions relating to appropriateness of conversation, use of music, patient preferences on conversation or music played, as well as patients' beliefs on the amount of noise in the operating room. Additionally, patients were given space to write in any other comments.

The patients were given an addressed and stamped envelope to return their survey results, with the direction to return the survey within 24 hours. The patients were explicitly told their surgeons and clinics would be blinded of their responses, as the questionnaire was sent to a central location, independent of the clinic. The survey was numbered for tracking purposes, but the reviewers were blinded to the patient's identity. The returned surveys were input into an Excel spreadsheet, and kept in a central location.

Results

Of the 120 surveys that were given to the patients, 48 were returned for a response rate of 40%. None of the patients felt that the operating room staff side conversations prevented them from caring for the patient. A large majority of the patients (93.8%) thought that the conversation between the operating room staff was appropriate. Additionally, only 4.08% thought a silent operating room would have been better, with more than three quarters of patients stating their intraoperative conversation with the surgeon helped them relax and a similar number or patients (77.55%) stating they enjoyed their conversation. Table 1 shows the individual responses to the survey.

Discussion

The above results show that patients are generally understanding of the utilization of music in the operating theatre. Previous studies have documented the benefits of music in limiting patient anxiety during the procedure and even decreasing the amount of local Table I Survey questions and Results in percentages.

Question	Yes	No	Don't Remember	Not Applicable
Did you enjoy conversing with your surgeon/nurse during your surgery?	77.55	2.04	16.33	4.08
Was music or radio being played during your surgery?	69.39	2.04	28.57	0
Did anyone ask if you wanted music or radio played or what type of music				
you would like played	53.06	28.57	18.37	0
Was the music of radio helpful to relax during your surgery?	65.31	4.08	20.41	10.2
Was the surgeon/nurse attentive to your needs during surgery?	93.99	2.04	4.08	0
Would silence be better in the operating room?	4.08	81.63	6.12	8.16
Did the surgeon talk to you during the surgery?	81.63	2.04	16.33	0
Did the conversation help to relax you?	75.51	4.08	8.16	12.24
Before or after the operation, was the conversation between staff				
members (nurse to nurse, doctor to nurse) appropriate	93.88	2.04	4.08	0
Did you feel that their side conversations prevented them from caring for				
you?	0	85.71	8.16	6.12

anesthetic required [13]. Music has also been shown to improve surgeon performance and increase the speed and accuracy of specific tasks [14].

While the above data show the importance of music to the operating surgeon, the other members of the surgical team (anesthesia, nursing staff) may not be so appreciative of the music. Many anesthesiologists believe that music in the OR interferes with their effectiveness. In a study by Hawksworth et al [15], looking at anesthesiologists' perception of music in the OR, 26% felt the music reduced their vigilance and impaired their communication, while 11.5% felt music distracted them from their alarms. Even more interesting was a majority of anesthesiologist surveyed, 51%, stated music was distracting when complications occurred during anesthesia.

In this study, the patients were awake and the procedure was done under local anesthesia. This allowed surgeon-patient communication during the procedure. Our results show that three-quarters of all study participants thought that communication with their surgeon helped alleviate their anxiety. This shows the important role the surgeon plays in the patients emotional response to surgery. Donchin and Katz [16] analyzed the psychological effects of wakefulness during a surgical operation. They measured the patient's anxiety and found that the most anxiety producing events occurred when the operating room staff was talking about the patient.

The previous study [16] demonstrates the great importance surgeonpatient communication has on overall patient psychological response. It is our belief that encouraging statements during the operation ("things are going great", "we are progressing nicely") can greatly enhance the patient's overall operative experience. Much is made in today's medical school curriculum about physicians having good "bedside manner". It is our strong opinion that a good bedside manner should not cease at the operating room doors. This is even more important during an awake surgical procedure, as the patient is already under a great deal of anxiety from the procedure itself.

One of the most important things that our study exposed is the recall ability of our patients. In fact, 81% of patients remembered the surgeon talking with them during their procedure and over 75% of patients felt the conversation helped them relax during the procedure. This shows the importance of communicating calming words during the procedure to the patient, even when we may believe them to be falling on deaf ears. The reality is our patients hear them and remember them.

The patient is the center of everything we do as physicians, and the patient should carry that feeling during the entire operating process. Idle chatter can be very disruptive and may be harmful to the patient in the long run. Most patients have heightened perceptions during the surgical experience, and a bad memory of an event could be the catalyst to an actual complaint in the future. Whereas a good experience may quell future bumps in the road.

Conclusion

The above study shows that most patients understand and even appreciate background music in the operating room theatre. There is nothing wrong with silence in the operating room, and as surgeons, it is paramount that our patient's care is the center of all we do. Music in the OR during an awake procedure has its place, but only at the patient's request, and the music should be tailored toward that patients preferences. Lastly, patients benefit greatly from calming words during the surgery, and this can help alleviate some of their anxiety during the procedure. All surgeons performing awake procedures should utilize the same "bedside manner" during the procedure as they would during a clinic visit.

- Vlisides P, Xie Z. Neurotoxicity of general anesthetics: an update. *Curr Pharm Des.* 2012: [Epub ahead of print].
- Mendels EJ, Brunings JW, Hamaekers AE, Stokroos RJ, Kremer B, Baijens LW. Adverse laryngeal effects following short-term general anesthesia: a systematic review. Arch Otolaryngol Head Neck Surg. 2012;138(3):257–264.
- Hudsons AE, Hemmings HC Jr. Are anesthetics toxic to the brain? Br J Anaesth. 2011; 107(1):30-37.
- Perouansky M. Liasons dangereuses? General anaesthetics and longterm toxicity in the CNS. *Eur J Anaesthesiol*. 2006;24(2):107–115.
- Bhattacharva SD, Vaslef SN, Pappas TN, Scarborough JE. Locoregional versus general anesthesia for open inguinal herniorrhaphy: a National Surgical Quality Improvement Program analysis. *Amb Surg.* 2012;**78(7)**:798–802.
- Schechter MA, Shortell CK, Scarborough JE. Regional versus general anesthesia for carotid endarterectomy: the American College of Surgeons National Surgical Quality Improvement Program perspective. Surgery. 2012;152(3):309–314.
- Colque A, Eisemann ML. Breast augmentation and augmentationmastopexy with local anesthesia and intravenous sedation. *Aesthet Surg J.* 2012;32(3):303–307.
- Siu K, Suh IH, Mukherjee M, Oleynikov D, Stergiou N. The effect of music on robot-assisted laparoscopic surgical performance. *Surg Innov.* 2010;17(4):306–311.
- Byers JS, Smyth KA. Effect of a music intervention on noise annoyance, heart rate, and blood pressure in cardiac surgery patients. *Am J Crit Care.* 1997;6:183–191.
- Lepage C, Drolet P, Girard M, Grenier Y, DeGagne R. Music decreases sedative requirements during spinal anesthesia. *Anesth Analg.* 2001;93:912–916.
- 11. Makam JG, Ameh EA, Eguma SA. Music in the operating theatre: opinions of staff and patients of a Nigerian teaching hospital. *African Health Sciences* 2010;10(4):386–389.
- Oetter H. Idle chatter in the OR during surgery. Vancouver Sun, Front Page, April 8, 2011.
- Matsota P, Christodoulopoulou T, Smyrnioti ME, Pandazi A, Kanellopoulos I, Koursoumi E, Karamanis P, Kostopanagiotou G. Music's use for anesthesia and analgesia. J Altern Complement Med. 2012; [Epub ahead of print]:1-10.
- 14. Moris DN, Linos D. Music meets surgery: two sides to the art of "healing". Surg Endosc. 2012;[Epub ahead of print].
- Hawksworth C, Asbury AJ, Millar K. Music in theatre: not so harmonious: a survey of attitudes to music played in the operating theatre. *Anaesthesia* 1997;52(1):79–83
- Donchin Y, Katz A. Emotional reactions during lumbar extradural anaesthesia. *Anaesthesia* 1980;35:822824.

Anterior-Apical Mesh Repair System in an ambulatory setting

D. Sinhal^a, J. Iyer ^{*a,b,c*}, M. Mous^{*b*}, R. Muller^{*c*}, A. Rane^{*a,b,c*}

Abstract

Aim: To examine use of Anterior –Apical mesh repair system for anterior prolapse ≥stage3 in an ambulatory setting .

Methods: This is a prospective case series of 111 women at our centre, who underwent an anterior and apical repair with mesh (graft augmented repair) over a consecutive 24 month period.

Results: We found a high objective (68.5%) and subjective (87.6%) success rate, with a mesh extrusion rate of only 3.8%. Most cases could be done in a day surgery setting (93.4%).

Conclusion: Anterior-Apical mesh repair system has the potential to be used in an ambulatory day surgery setting as demonstrated in our study.

Keywords: Cystocele, apical suspension, graft augmented repair.

Authors' addresses: ^a Department of Obstetrics and Gynaecology, The Townsville Hospital, 100 Angus Smith Drive, Douglas, 4814 (Australia). ^b Mater private Hospital, 21-27 Fulham Road, Pimilico, 4812, (Australia). ^c James Cook University, I James Cook Drive, Douglas, 4811, (Australia)..

Corresponding author: D.Sinhal Tel: +61-430242182 E-mail: drdeepasinhal@gmail.com

Introduction

Traditional anterior fascial repair of cystocele has reported failure rates in the range of 40–60% possibly owing to the fact these utilise previously weakened tissues [1]. Furthermore these repairs only result in the plication of tissues in the midline and do not sufficiently address lateral defects at the arcus tendineus fascia pelvis or apical level 1 support [1, 2].

A recent Cochrane review has shown that mesh use in the anterior compartment has a lower failure rate versus traditional repair [3,4]. First generation mesh kits like Perigee and Anterior Prolift resulted in robust support of the bladder, and initial studies have shown cure rates in the range of 87–96% [5–7]. These kits however, lacked proper level 1 support, which may have contributed to it apical failures. Furthermore, these operations necessitated groin incisions and 'blind' needle passes through the obturator foramina which served as conduits for the mesh arms, and presented a significant risk of vascular and visceral damage mainly in the hands of inexperienced surgeons [8, 9]. Other disadvantages were vaginal or pelvic pain from the mesh arms being pulled too tight, as well as high mesh extrusion rates up to 15% [10–12].

Abdominal sacralcolpopexy has long been described in contemporary literature to have the highest cure rates for vault prolapse and achieves good level 1 support. It is only recently though that so called "second generation" vaginal mesh augmentation procedures have also been utilised to achieve this type of support. Both procedures result in relatively tension free repairs, restore the anatomy and do not rely on the patients' stretched and weakened tissue to provide support.

The Anterior Elevate (TM) Device is a "second generation" mesh that has integrated apical (level 1) support in addition to providing level 2 support via a four point attachment through anchors in the obturator internus muscles and sacrospinous ligaments respectively. This is achieved through a single vaginal incision and does not require blind passes through the obturator foramen like its precursor PerigeeTM. We believe that the single incision access also reduces postoperative pain and has increased the feasibility of performing this procedure in a day surgery setting.

Material and methods

This study is a descriptive prospective case series of 111 women that underwent anterior repair with mesh (graft augmented repair) and vaginal apical suspension using the Anterior Elevate System by AMS (American Medical Systems, Minnetonka, MN, USA) over a consecutive 24 month period at our center. Comprehensive preoperative urogynecologic exams were completed including prolapse quantification utilizing the International Continence Society Pelvic Organ Prolapse Quantification (POPQ) staging system. Additional procedures performed pre-operatively included, urodynamics to rule out the presence of overt or occult stress urinary incontinence (SUI) and /or detrusor instability. Statistical analysis was done using the 'paired t' tests and the Mc Nemar test.

Inclusion criteria were patients with symptomatic anterior, primary or recurrent, prolapse \geq stage 3. In our practice, we avoid the use of the device in immuno-compromised patients and those with previous pelvic radiation. If patients had urodynamically proven SUI, they were also scheduled for a mid-urethral sling, but we did not perform any prophylactic slings.

Surgical technique:

A solution of local anaesthetic and adrenaline, approximately 30 ml, is injected into the anterior vaginal wall to facilitate hydrodissection. The bladder neck is then identified and an incision commenced below it. Full thickness vaginal wall dissection carries the dissection to the bladder serosal lining, laterally to the sacrospinous ligaments and the obturator internus muscles. The lateral tunnels to the sacrospinous ligament are created using gentle blunt dissection, keeping the pressure of the dissecting finger away from the bladder. The ischial spines are identified and the tissue overlying the ligament, 2 cm medial to the spine, is swept off. The tunnels to the obturator internus muscles are developed using sharp dissection taking care not to button-hole the vaginal fornices. The sacrospinous anchors are then inserted about a finger's breadth medial to the ischial spines. 2/0 PDS sutures are taken below the bladder neck in the midline and to the vaginal vault or through the pericervical ring to attach the mesh to these structures. The mesh is then fed through the PDS suture

below the bladder neck and the obturator internus anchors gently inserted under the ischiopubic ramus into the muscle. The tail of the mesh is trimmed to the required dimensions and the sacrospinous anchors fed through the eyelets and eased in to place using the spatula provided. An intra-operative cystoscopy is performed to rule out bladder or urethral trauma. The mesh is locked into place with locking eyelets and a 2 layered closure done using 2/0Vicryl. It is important to exercise great care to ensure that the mesh is not placed under tension. We avoid excising any vaginal skin and reserve vaginal trimming for only those cases where the skin overhangs the introitus after the prolapse is repositioned. If an incontinence or other prolapse procedure is deemed necessary these are achieved through separate colpotomy incisions.

A vaginal pack is placed for 1–2 hours and after removing this, patients will start with trial of void (TOV). Within the TOV, patients are allowed only 300 ml in the first 2 post-operative hours after which they are asked to void. If a patients voids 400 ml or more and the residual urine measures less than 100 ml, patients are deemed to have successfully passed the trial of void. If a patient doesn't pass the trial of void, another trial of void is attempted after 1–2 hours.

The patient is discharged the same day after a successful trial of void with antibiotics and analgesics. If more than 2 TOV's are unsuccessful, an indwelling catheter is placed overnight, the patient is discharged and reassessed the next day for a TOV. After discharge patients have direct access to an emergency number if they experience any problems. A designated nurse contacts all patients telephonically the next day to enquire about any ongoing problems and assess their post-op status utilising a visual analogue score for pain, bleeding and voiding.

Follow-up

Patients were evaluated in the office at 12 weeks, 6 months and 2 years. Prior to each appointment, standardized and validated Quality of life questionnaires like Incontinence Impact Questionnaire-Short form (IIQ-7) and the Urogenital Distress Inventory-Short form (UDI-6) were sent to each patient. At the appointment, ICS POP-Q staging was completed and patients were asked about "feeling or seeing a bulge", as a subjective assessment of prolapse. Furthermore subjective success rate was evaluated by satisfaction scores.

All patients were asked about complaints of urinary incontinence, urgency and frequency symptoms. Objective cure was defined as the midline anterior vaginal wall (points Aa and Ba) <1.0 cm inside the hymenal ring and the vaginal vault (apex) less than or equal to stage I.

Results

Between November 2009 and October 2011, 111 patients were eligible for an Anterior Elevate Procedure. Sixty-six (59,5%) had a stage 3 anterior wall prolapse, the remaining 45 (40.5%) had a stage 4 prolapse. Seventeen patients had a previous anterior vaginal wall repair of which three had a Perigee.

Table 1 shows the general characteristics of these 111 patients. No concomitant hysterectomies were performed (61 patients had uterus in situ at the time of anterior elevate). No patient had any other vault support besides the anterior elevate system.

Intra-operatively only one complication was defined. This was a bladder injury that was repaired at the same time and the mesh placed thereafter. Postoperatively 99 patients did not need a catheter (89.2%), 8 patients needed one for one day (7.2%) and only 4 patients (3.8%) had an indwelling catheter for more than a day with one patient needing it for a total of 8 days. Of all 111 patients, 94 (93.4%) could be treated in day surgery. The remainder needed

Table I General characteristics.

Age (years +/- SD)	62,8 +/- 9.2 (range 35-85)
Parity	2,9 +/- 1.2 (range 1-8)
Postmenopausal	N=108 (97.3%)
Previous hysterectomy	N=50 (45%)
Previous incontinence surgery	N=17 (15,3%)
Chron resp pathology	N= 27 (24.3%)
Smoking	N=11 (9.9%)
Prolapse stage 3	N= 66 (59.5%)
Prolapse stage 4	N= 45 (40.5%)

overnight admission mainly for administrative reasons (long distance to travel, lack of local accommodation etc).

Patients were followed up postoperatively at 12 weeks ,six months and two years. Out of 111 patients, six (5.4%) were lost to follow up. In the 105 patients eligible for follow-up, few complications were noted in the postoperative period. Mesh exposure was found in 4 cases (3.8%), new onset symptoms urgency frequency in 3 cases (2.9%), new onset stress urinary incontinence in 2 cases (1.9%) and dyspareunia in 1 case (1.0%). Only one patient presented 6 months after surgery with pain in the left lateral vaginal fornix and was found to have a tight band in the track corresponding to the obturator internus anchor; this was divided and the patient had an uneventful recovery.

The anatomical pre-operative and postoperative results at the 6 month visit are shown in Table 2. The objective success rate, defined as Ba < -1, was 68.5% (P<0.001 Mc Nemar test). Postoperatively mean Ba value was -1.9 +/- 0.8, mean C -6.6 +/- 3.4, mean total vaginal length (TVL) was 8.3 +/- 3.5.

Table 2	Complications.
---------	----------------

	Frequency	Percentage(n=105)
No complication	86	81.9
Dyspareunia	I	I
Mesh erosion	4	3.8
Prolapsed	I	I
SUI	I	I
Urge incontinence	I	I
Bowel dysfunction	2	1.9
Groin pain	I	I
lleus	I	I
Suprapubic pain	3	2.9
UTI	4	3.8

Subjective success was defined as "absence of a lump sensation". "No lump sensation at all" was stated by 92 (87.6%) patients, 17 (16.2%) noticed some improvement and only 2 patients (1.9%) had more symptoms than before surgery. Furthermore subjective success rate was evaluated by satisfaction scores as shown in Table 3. The highest satisfaction score of 9–10 was achieved by 77 (73.3%) patients

	Pre-operative	Post-operative	P Value (t-test)
Aa (+/-SD)	0.5 +/- 1.3	-2.0 +/- 0.8	<0.001
Ba (+/-SD)	1.2 +/- 1.4	-1.9 +/- 0.8	<0.001
C (+/-SD)	-4.1 +/- 3.4	-6.6 +/- 3.4	0.010
Ap (+/-SD)	-1.8 +/- 1.4	-2.6 +/- 0.9	0.008
Bp (+/-SD)	-1.6 +/- 1.5	-2.4 +/- 1.2	0.010
TVL (+/-SD)	8.1 +/- 2.0	8.3 +/- 3.5	0.683

 Table 3
 Pre-operative versus post-operative POP Q classification.

Table 4 Postoperative satisfaction scores.

Very satisfied (9-10)	77 (73.3%)	
Satisfied (6-8)	30 (28.6%)	
Partially satisfied (3-5)	2 (1.9%)	
Not satisfied (0-2)	2 (1.9%)	

Discussion

In this study of the Anterior Elevate device in an ambulatory setting, we found a high rate of objective (68.5%) and subjective (87.6%) success, with a mesh extrusion rate of only 3.8%. Most cases could be done in a day surgery setting (93.4%) without the need of a catheter and a pack.

The Anterior Elevate was developed as an improvement over the existing first generation devices. The Mesh Delivery System allows for access via a single vaginal incision, avoids blind passes through the obturator foramen and provides good apical (level 1) in addition to level 2 support. Additionally the monofilament polypropylene mesh ,called 'Interprolite', is purportedly lighter.

Two earlier studies, by Moore et al [13] and Lukban et al [14], have shown high objective and subjective success rates of Anterior Elevate of up to 90%. In our study the objective success rate was slightly lower but this may well be caused by the difference in inclusion criteria. As earlier described, in our study only patients with a stage 3 or stage 4 prolapse were eligible for Anterior Elevate whilst in the two earlier published studies patients with a stage 2 prolapse were also included. As objective success is defined as Ba<-1, it is reasonable to assume that this condition is easier achieved if the pre-operative size of the prolapse is smaller. We think it is important though to set strict criteria for the use of mesh and only use it in cases with symptomatic large or recurrent prolapse.

In the earlier two published studies mesh extrusion rates varied between 0–6.5%. In this study, we used a deeper dissection plane together with a two layer closure technique, to minimize the chance of mesh extrusion. The combination of these may have lead to an extrusion rate as low as 3.8% in our study. With extrusion being one of the main complications of mesh repairs, it is very important that every possible effort be made to minimize the development of this condition.

One of the highlights of this study that distinguishes it from earlier studies is all procedures were done in a day surgery facility and most 93.4% were discharged the same day. Interestingly no patient had an indwelling catheter placed postoperatively and vaginal packing stayed in place for one to two hours only and was removed prior to TOV. In earlier published studies all patients received a catheter and vaginal pack for 24 hours. Most of our patients (82.9%) were able to void

within a few hours and could leave the hospital the same day without a catheter. Performing this procedure in day surgery without using a bladder catheter or prolonged vaginal packing, reduces chance of developing infection, postoperative pain and discomfort.

The Anterior single incision mesh delivery system was developed in the aftermath of the USFDA notification in 2008 (16) in an attempt to reduce operative complications involving pelvic viscera and blood vessels. The most recent USFDA update has again drawn the mesh debate into the limelight (17). For that reason all our patients are given an information leaflet that discusses surgical and nonsurgical options for prolapse and a list of questions that patients are encouraged to ask us before choosing mesh as a surgical option. Furthermore by employing strict selection criteria, good preoperative counseling, a 24 hour phone number and standardized postoperative care, we ensured ambulatory day surgery for the vast majority of our patients. Finally we continually audit our practice both in-house and invite external reviewers from time to time.

We believe the Anterior Elevate device to be a viable alternative to native tissue repair for large and recurrent cystocele, with or without concurrent apical prolapse, and that it has the potential to be used in an ambulatory day surgery setting as demonstrated in our study.

- Maher C, Baessler K.Surgical management of anterior vaginal wall prolapse: an evidence based literature review. *Int Urogynecol J Pelvic Floor Dysfunct* 2006; 17:195–201.
- Moore RD, Miklos JR. Vaginal mesh kits for pelvic organ prolapse, friend or foe: a comprehensive review. Scientific World Journal 2009;9:163–189.
- Maher C, Baessler K, Glazener CM et al. Surgical management of pelvic organ prolapse:a short version *Cochrane review. Neurourol Urodyn* 2008;27(1):3–12.
- Maher C, Feiner B, Baessler K, Glazener CMA. Surgical management of pelvic organ prolapse in women. *Cochrane Database of Systematic Reviews* 2010;Issue 4. Art. No.:CD004014. doi:10.1002/14651858. CD004014.pub4
- Rane A, Kannan K, Barry C, Balakrishnan S, Lim Y, Corstiaans A. Prospective study of the Perigee system for the management of cystocoeles--medium-term follow up. Aust N Z J Obstet Gynaecol;48(4):427-32. http://www.ncbi.nlm.nih.gov/ pubmed/18837851?log\$=activity - #
- Rane A, Iyer J, Kannan K, Corstiaans A. Prospective study of the Perigee[™] system for treatment of cystocele - our five-year experience. Aust N Z J Obstet Gynaecol 2012 Feb;52(1):28–33.
- Withagen MI, Milani AL, den Boon J, Vervest MD, Vierhout ME. Trocarguided mesh compared with conventional vaginal repair in recurrent prolapse:a randomized trial. **Obstet Gynecol** 2011; **117(2)**:242–250.
- Moore RD, Beyer RD, Jacoby K, Freedman SJ, McCammon KA, Gambla MT. Prospective multicenter trial assessing type I, polypropylene mesh placed via transobturator route for the treatment of anterior vaginal prolapse with 2-year follow-up. *Int Urogynecol J Pelvic Floor Dysfunct* 2010; 21(5):545–552.
- Altman D, Falconer C. Perioperative morbidity using transvaginal mesh in pelvic organ prolapse repair. *Obstet Gynecol* 2007; 109(2 Pt 1):303–308.

- Margulies RU, Lewicky-Gaupp C, Fenner DE, McGuire EJ, Delancy JO.Complications requiring reoperation following vaginal mesh kit procedures for prolapse. *Am J Obstet Gynecol* 2008;199:678. e1–678.e4
- Moore RD, Mikos JR. Vaginal repair of cystocele with anterior wall mesh via transobturator route: efficacy and complications with up to 3-year follow-up. Adv Urol 2009;743831. (in press).
- Ridgeway B, Walters MD, Paraiso MF, Barber MD, McAchran SE, Goldman HB, Jelovsek. Early experience with mesh excision for adverse outcomes after transvaginal mesh placement using prolapse kits. Am J Obstet Gynecol 2008; 199:703.e1–703.e7.
- Iglesia CB, Sokol AL, Sokol ER, Kudish BI, Gutman RE, Peterson JL, Shott S. Vaginal mesh for prolapse: a randomized controlled trial.
 Obstet Gynecol 2010; I 16(2 Pt 1):293–303.
- Moore RD, Mitchell GK, Miklos JR. Single-incision vaginal approach to treat cystocele and vault prolapse with an anterior wall mesh anchored apically to the sacrospinous ligaments. *Int Urogynecol J.* 2012 Jan;23(1):85-91. Epub 2011 Aug 25.
- Lukban JC, Roovers JP, Vandrie DM, Erickson T, Zylstra S, Patel MP, Moore RD. Single-incision apical and posterior mesh repair: I-year prospective outcomes. *Int Urogynecol J.* 2012; Mar 15. [Epub ahead of print]
- 16. FDA Public Health Notification: Serious Complications Associated with Transvaginal Placement of Surgical Mesh in Repair of Pelvic Organ Prolapse and Stress Urinary Incontinence. Date Issued :October 20, 2008.
- 17. FDA Safety Communication: UPDATE on Serious Complications Associated with Transvaginal Placement of Surgical Mesh for Pelvic Organ Prolapse. Date Issued: July 13, 2011.

Ambulatory Surgery is the official clinical journal for the International Association for Ambulatory Surgery.

Ambulatory Surgery provides a multidisciplinary international forum for all health care professionals involved in day care surgery. The editors welcome reviews, original articles, case reports, short communications and letters relating to the practice and management of ambulatory surgery. Topics covered include basic and clinical research, surgery, anaesthesia, nursing; administrative issues, facility development, management, policy issues, reimbursement; perioperative care, patient and procedure selection, discharge criteria, home care. The journal also publishes book reviews and a calendar of forthcoming events.

Submission of Articles

All papers should be submitted by e-mail as a Word document to one of the Editors-in-Chief. Anaesthetic papers should be sent to **Beverly K. Philip** and surgical papers to **Doug McWhinnie**. Nursing, management and general papers may be sent to either Editor.

Electronic submissions should be accompanied, on a separate page, by a declaration naming the paper and its authors, that the paper has not been published or submitted for consideration for publication elsewhere. The same declaration signed by all the authors must also be posted to the appropriate Editor-in-Chief.

Doug McWhinnie Division of Surgery, Milton Keynes Hospital, Standing Way, Milton Keynes, Buckinghamshire MK6 5LD, UK Email: dougmcwhinnie@uk2.net

Beverly K. Philip Day Surgery Unit, Brigham and Women's Hospital, 75 Francis Street, Boston, MA 02115, USA. Email: hphilip@zeus.hwh.harvard.edu

Email: bphilip@zeus.bwh.harvard.edu