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Exploring the world of ambulatory surgery☆

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Abstract

The 5th James H. Nicoll Memorial lecture was delivered at the 5th International Congress on Ambulatory Surgery, Boston, Massachusetts, 2003. A summary of historic events and modern concepts of care for the ambulatory surgical patient is summarized. Current guidelines of the American Society of Anesthesiologists were developed using an evidence-based model. Data, however, are lacking and conclusions based largely on consensus of experts. Morbidity and mortality are low frequency events. Large populations must be studied to identify and correct causative factors. Data from recent studies are noted and critiqued. Office-based surgery is a specific venue of concern.

Keywords: Nicoll Memorial Lecture, 2003; Ambulatory surgery; Evidence-based guidelines; Risk and location; Outcome research

I am honored to have been invited to deliver the 5th James H. Nicoll Memorial lecture. It is especially gratifying for me to be able to address the 5th International Congress on Ambulatory Surgery at which so many of my friends and professional associates are in attendance. In particular, I wish to especially express my admiration and appreciation to Dr. Bernard Wetchler who contributed greatly to my education on many historical events noted briefly at the beginning of this talk.

In 1999, when Professor Paul E.M. Jarrett authored a description of Dr. Nicoll's accomplishments [1], it marked the 100th anniversary of the year in which Dr. Nicoll initiated "modern" Day Surgery—the year, 1899.

Dr. Nicoll, a surgeon, published his landmark article on the surgery of infancy in 1909 [2]. In this he described a 10-year surgical experience at the outpatient clinic in the Glasgow Hospital for Sick Children in which 8988 patients were treated as outpatients after operation. Nearly one-half of the patients were children less than 3 years of age.

Dr. Nicoll performed 7392 of these operations himself. They included hare lips, cleft palates, hernias, and the like. Time precludes a more lengthy description of his amazing accomplishments and philosophy, especially his criticism of hospitalization and his insistence on getting the children back to their nursing mothers as soon as possible.

Again, due to time constraints, I will note briefly some of the other more recent milestones in the development of the field of ambulatory surgery.

In 1916, Ralph Waters opened The Down-Town Anesthesia Clinic in Sioux City, Iowa, a "free standing" center [3]. Later, among the recognized early hospital based ambulatory units were those developed in:

1959 - by Eric Webb and Horace B. Graves in Vancouver, BC [4];
1962 - by David Cohen and John Dillon, at The University of California, Los Angeles, California, USA [5];
1970 - by Marie Louise Levy and Charles S. Coakley, at The George Washington University Medical Center, Washington, DC, USA [6].

The first successful freestanding ambulatory facility was developed in:

☆ 2003 Nicoll Memorial Lecture.

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1970 - by John Ford and Wally Reed, in Phoenix, Arizona, USA [7].

In case you are wondering, my ticket was punched as a card carrying ambulatory anesthesiologist approximately 37 years ago, while working with Drs. Levy and Coakley.

What have we learned during and since that time? What are some of the issues, which have been resolved or are still outstanding? How valid are our supporting data? As seen through my eyes, a brief description and analysis follows. First, a look at what was and what is.

In 1966 with the opening of the outpatient surgical unit at George Washington, the goals and objectives were to:

- reduce the cost of medical care—commonly referred to as "COST CONTAINMENT",
- increase the availability of hospital beds for those who needed them, and
- offer the same quality of care as an inpatient without its inconveniences and the potential hazards of cross infection.

In 1966, acceptable patients were primarily those classified as ASA status 1 or 2, and procedures were short with no invasion of the body cavity. Currently ASA status 3 or 4 patients may be acceptable while procedures are often lengthy and frequently include those involving invasion of body cavities.

In the past, the primary anesthetic route was by inhalation while currently there is an emphasis on using the primarily intravenous or regional anesthesia techniques. Recovery required the use of rigid discharge criteria. These included a minimum stay and the requirement for ingestion of oral fluids and voiding (in adults) before discharge. Currently, there may be no requirement for a minimum stay. As a matter of fact, some facilities have established ground rules by which the "phase one" recovery unit may be bypassed entirely.

While inpatient surgery was the rule early on, outpatient surgery has now become the vogue. The current buzzwords continue to be cost containment. Additional concepts include patient satisfaction and patient safety. After 30 plus years we have a large database, which has been accumulated largely through observation and experience. What is left to study? How good are our reports? What is their design and biases? How valid are the conclusions?

This is the basis of my talk today. I have not made an active attempt to duplicate the presentations, which follow and will be presented in more detail later in the Congress. I will attempt to present on overview and perspective of where we are and where we should go from here. The data, which I shall present, are from the U.S. and Canada. I was unsuccessful in obtaining the results of recent studies from abroad.

1. Practice parameters of the American Society of Anesthesiologists

First, let us look at the American Society of Anesthesiologists (ASA) process for developing and defining these parameters. "Practice parameter" is the global term used by ASA and includes Standards, Guidelines and Advisories.

"Standards" are rules or minimum requirements. They include, for example, the Standard for Basic Anesthetic Monitoring. Standards were developed by consensus and before the current formal, evidence-based process was instituted.

Particularly relevant to outpatient surgery are several "Guidelines"—defined as recommendations or guides and one "Advisory" or report. All were subject to the application on an evidence-based model. They include:

- Practice Guidelines for Preoperative Fasting, published in 1999;
- Practice Advisory for Preanesthesia Evaluation, in 2002; and
- Practice Guidelines for Postanesthetic Care, in 2002.

Inherent in the development of these parameters is an extensive literature review in which the methodology, results, and validity of the data are quantified. In addition, the data are analyzed for the relationship between an intervention and an adverse outcome. For example, in the Practice Guidelines for Preoperative Fasting, there is a recommendation for withholding clear liquids for a minimum of 2 h prior to the administration of the anesthetic while a light meal should be withheld for at least 6 h [8]. Although these recommendations are based on gastric emptying times and seem prudent, published evidence in humans is silent on the relationship between fasting times, gastric volume, or gastric acidity and the risk of emesis/reflux or pulmonary aspiration, the adverse events.

The recommendations in the Practice Advisory for Preanesthesia Evaluation [9] are based on even softer data; hence the use of the term "advisory" as opposed to "guideline". In the past, most outpatients were required to make an additional visit to the facility prior to the day of surgery in order to obtain a detailed history, perform a physical examination, and obtain laboratory data. Currently, the Advisory recommends that the preoperative visit prior to the day of surgery be performed in patients with a high severity of disease and/or those undergoing procedures with high surgical invasiveness. Although this advice seems prudent and rational, it has never been field tested for validity and hard data to support the recommendation are lacking.

Likewise, the recent summary of recommendations for discharge in the Practice Guidelines for Postanesthetic Care [10] include:

- the requirement for urination prior to discharge is no longer a routine and is limited to selected patients,

- the ability to drink and retain clear liquids is no longer a requirement and is recommended only for selected patients, and
- a mandatory minimum stay should not be required.

The literature, however, is insufficient to evaluate the benefits of employing these new criteria. Although not the original intent, the recommendations are based mostly on the consensus of experts, as are all three ASA products noted above. This is not meant to be a criticism of the tireless, thorough, and expensive undertakings of the American Society of Anesthesiologists. The ASA has provided an authoritative set of recommendations, which have markedly improved patient satisfaction while presumably not increasing risk. Let us make it perfectly clear, however, that although outcome research is not supportive the benefits probably exceed the risks. In effect, then, the quality of care continues to be based primarily on:

- risk related to benefit,
- cost related to benefit,
- patient satisfaction, and
- physician comfort.

2. Outcome research

2.1. Association data

FASA: in 1984, nearly 20 years ago, Herb Natof participated in a study sponsored by the Federated Ambulatory Surgery Association (FASA) [11]. 87,492 outpatients were studied to determine the relationship between anesthetic technique and the incidence of complications. The highest incidence was found in patients whose surgery was performed using local and sedation. In 3000 of these patients, the sedation was administered by the surgeon. To this day, non-anesthesiologist administered sedation/analgesia remains a major source of morbidity and mortality. In addition, recent efforts by ASA have been directed at defining levels of sedation, the continuum, and the probability of adverse events as the depth is increased [12].

PIAA: The Physician Insurers Association of America (PIAA) represents 53 doctor owned insurance firms. It explores liability related to medical claims of their insured practitioners and some facilities. In the summer of 2002, their publication PIAA Research Notes was dedicated to the subject "Ambulatory Surgery Centers" [13]. Of note in the PIAA Data Sharing Project is that, since 1985, over all of their insured, there were 172,000 closed malpractice claims totaling $9.2 billion in indemnity.

One thousand eight hundred and eighteen claims, or 1%, involved Ambulatory Surgery Centers. In terms of money spent, $46 million was allocated for indemnity and $20 million for defense expenses. The claims for ambulatory surgery are increasing in frequency but at a rate slower than other medical malpractice claims.

Of particular note is the experience in the field of Anesthesiology. In 1985–2001, the average indemnity for anesthesiologists per claim was $167,180, the highest average indemnity of all physician specialties. Between 1997–2001, however, the average indemnity had decreased by two-thirds to $48,357. Much of the improvement in anesthesia care has been attributed to the development and implementation of the American Society of Anesthesiologists Standards for Basic Anesthetic Monitoring and the Practice Guidelines for the Management of the Difficult Airway. In the ASA's Closed Claims study, respiratory related claims have declined from 36% in the 1970s to 14% the 90s [14].

3. Outcome measures

Fried and Twersky have identified several measures for measuring outcomes for ambulatory surgery. These include: cancellations, admissions, morbidity and mortality, readmissions, resumption of activity and patient satisfaction [15]. Several of these parameters will be discussed.

3.1. Readmissions

In two studies of ambulatory surgery patients [16,17], the rate of return of the patient to the hospital, ambulatory surgery unit, or emergency room within 30 days ranged from 1.1 to 3.0%. Many readmissions were unrelated to complications of the surgical procedure or anesthetic care. In both studies, the primary predictor for readmission was genitourinary surgery. Once the patients had initially been discharged home after surgery, anesthesia-related symptoms did not cause readmission. As in much of the outcome studies on ambulatory patients, readmissions represent a low frequency event.

3.2. Admission and death in the elderly

As described in the previous section, readmissions were a low frequency event. In an effort to evaluate a large population, Fleisher et al. [18] focused their research interests on a Medicare administrative database. They studied admission and death within 7 days and 30 days after outpatient procedures in the elderly. Five percent of the claims for a 5-year period (1994–1999) were reviewed. Their review covered 564,267 procedures of which 360,780 had between performed in hospitals; 175,288 in ambulatory surgical centers; and 28,129 in an office setting.

The rate of the adverse events studied was lowest in the ambulatory surgical center and highest in the outpatient hospital units. The latter was expected; however, the fact that adverse events were more frequent in an office setting compared to

the ambulatory units was unanticipated. This subject will be discussed later.

The study of this large medicare administrative data set had its limitations. For example, during the 5 years studied, there were 156 deaths. Yet specific causes of neither mortality nor admission could be determined with certainty. They could have been influenced by anesthesia, surgery, patient disease or a combination as well as nonsurgical factors such as an automobile accident occurring post discharge. The authors concluded that the value of the study was to determine current practice patterns and to generate hypotheses for future studies.

3.3. *Office-based surgery*

The study of the medicare data base noted previously, is not the only one identifying the risk of procedures performed in an office setting. Vila et al. [19] compared surgical outcomes in offices and ambulatory surgery centers in the State of Florida. The data were obtained from the Florida Board of Medicine for Office Based Surgery and from the Florida Agency for Health Care Administration for Ambulatory Surgical Centers.

All adverse incident reports to the Florida Board of Medicine for procedures from April 1, 2000 to April 1, 2002 were reviewed. The number of office procedures performed during a 4-month period were used to estimate the total number of procedures; i.e. the denominator. Precise data were reviewed on procedures performed in the year 2000 in the ambulatory surgery centers since all were required to be reported.

Adverse events occurred at a rate of 66 and 5.3 per 100,000 procedures in offices and ambulatory surgery centers, respectively. The death rate per 100,000 procedures performed was 9.2 in offices and .78 in ambulatory surgery centers. There was an approximately 10-fold increased risk of adverse incidents and death in the office setting. These findings led to the establishment of many regulations to improve the safety of the patient in the office setting. They include a limitation in the duration of elective cosmetic and plastic surgeries as well stipulations when the presence of an anesthesiologist would be required. Experience in the State of Florida as well as other regions of the USA has led the American Medical Association and its partners to develop Office-based Surgery Core Principles for regulation of office-based surgery which can be adopted by States and other jurisdictions [20].

4. The future

By now, it should be obvious that we must require reporting of events from all centers performing ambulatory surgery. The precise identification of the risk of the patient's disease, anesthesia, and procedure can only be identified by prospectively collecting this information. Risk assessment is determined as follows:

$$\frac{\text{numerator}}{\text{denominator}} = \frac{\text{indicators or outcomes}}{\text{risk} - \text{adjustment}^*}$$

*age; American Society of Anesthesiologists physical status; surgical procedure; type of anesthetic administered, etc.

The goal is to identify "Benchmarking", or "Best practices", to ensure Quality Improvement, and to establish policies and procedures based on valid data. Conclusions based on information, which is incomplete, or limited to a local jurisdiction can be challenged. In addition, voluntary participation in the data collection process may fail to identify all adverse events. In other words, what is required is a national database with universal participation originated and directed by physicians or mandated and directed by government agencies, payers, and accreditation bodies.

The question is whether or not this is a pipe dream or is it being done at any level in the field of medicine. Believe it or not, a model was developed in 1994 by the largest single health care provider in the USA: The Veteran's Health Administration. Their system includes 123 VA medical centers, which perform major surgery.

They have implemented a National Surgical Quality Improvement Program known as NSQIP. It is the first nationally validated, outcome based, risk adjusted, and peer controlled program in major surgery. Preoperative and intraoperative data are collected prospectively. The data are used for benchmarking and quality improvement. In one of its more recent 30-day mortality study of 727,000 cases, mortality was reduced by 27% and mortality by 45% [21].

Why has this model not been duplicated by others? Why is it not in place in facilities in addition to the VA? It is costly and requires a tremendous effort to collect, input, and analyze the data. The U.S. Congress requires that outcomes in VA hospitals be reported and funds it accordingly. Currently, specialty organizations such as the American College of Surgeons have entered into a joint study with the VA to collect data from 14 non-VA hospitals. The study is funded by the U.S. Federal Agency for Health Care Research and Quality under a research grant.

Perhaps this could represent a method and model which the Society for Ambulatory Anesthesia and the Federated Ambulatory Surgery Association should pursue. One way or another we must collect large samples of meaningful data.

Thank you again for the opportunity to address the 5th International Congress on Ambulatory Surgery. It is has been a great privilege to attempt to follow in the footsteps of Dr. Nicoll.

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The role of the medical director

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Abstract

This article will provide information that can be used to create or enhance the position of a medical director in a surgical suite. Included are role descriptions and distinctions. Lists of tasks or responsibilities are also provided, along with a model that may be useful for medical director selection, development, and evaluation.

Keywords: Operating room management; Medical leadership; Medical director

The surgical suite can be compared to an airline or a restaurant, industries that also operate in an environment of efficient service. Call it "first empty room," "stand-by," or "please wait at the bar," customers must be accommodated whether they have reservations or not. This is just one of the responsibilities of the medical director, whose role can be thought of as integrating the administrative, medical, and financial tasks for the management of the surgical suite (Table 1). Although anesthesiology is the practice of medicine, the practice of anesthesia has become a business, and in the operating room, anesthesiologists have become prominent in the role of medical director [1].

As business professionals, doctors perform a range of tasks in common with other business managers [2–4], and the opportunities for the "physician executive" continue to evolve [5]. The two extremes of leadership or management style for a medical director can be thought of as authoritarian or advisory. The authoritarian style invests a significant amount of power in the medical director and may be most effective when this power is linked to time, money, or space. In the authoritarian style, the medical director retains both responsibility and authority. It is important to have clout where it counts [6].

The opposite management style is advisory, in which the medical director has little authority, but also little responsibility. The medical director's influence is not linked to money, space or time but stems from respect. With the advisory style, the director's position is delicate and difficult to maintain and it often carries the stigma of being a figurehead. Although most medical directors use a style somewhere between these two extremes, a position that offers responsibility without authority should be avoided [7].

The need for a medical director may be questioned and in one study, physician participation in hospital management did not improve hospital efficiency [8]. When other parameters (e.g., clinical and financial) were included in another study, physician-led organizations were conspicuous among the top hospitals [9]. Clearly, the position can have merit.

Perhaps one of the most difficult aspects of a medical director's job is protecting patients from another surgeon. To a surgeon, his are the only patients and deserve consideration before anybody else's patient. Although a surgical suite should always provide what surgeons need and always try to provide what surgeons want, a surgeon's *wants* should not be satisfied at the expense of the *needs* of another surgeon. Just as on the battlefield, triage is an important skill when unlimited health care resources are not available.

Even though the patient is a customer, the phrase "patient care" carries little incentive to modify the behavior of health care personnel. This term is most often uttered when a surgeon or an administrator is concerned about one particular patient. The medical director must recognize that he or she is

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Table 1
Medical director tasks (3)

Administrative
Employee evaluation, counseling and education
Responsibility for nursing and administrative staff
Personnel scheduling
Facility and equipment maintenance
Adherence to safety and legal requirements
Serves on or delegates representatives to hospital and medical staff committees
Maintains records
Projects unit needs and activities for future planning
Accreditation
Quality assurance/quality improvement programs
Medical
Scheduling of anesthesiologists and surgical procedures
Determining the appropriateness of patients and procedures for the facility
Liaison with the physicians who practice at the facility
Arbiter for the physicians
Maintenance of an efficiently managed unit
Keeper of the licenses (e.g., DEA, laboratory)
Accreditation
Quality assurance/quality improvement program
Financial
Budget preparation
Budget monitoring
Operation of the units within budgetary constraints
Budgeting for and purchasing capital equipment

responsible not just for one customer, this surgeon's particular patient, but also for all the other customers, including the surgeons and the nurses. The best way to provide good patient care is to take good care of all the health care providers; "nurse care" and "surgeon care" are just as important as "patient care".

The medical director sees to it that everybody plays nicely in the sandbox. To assure that no one plays favorites, policies and procedures should be adopted and periodically reviewed. Strict adherence to policy protects patients and facility staff. It is important that surgeons and facility staff participate in the formulation of these rules and regulations.

A problem with many current models of medical directorship may be the emphasis on management rather than on leadership. To have followers presupposes a leader, not a manager. Leadership [10], often a product of innate or intuitive factors, may be difficult to teach to others. Organizations may have to rely on models for management rather than leadership.

One such model was synthesized from a variety of existing models in the British National Health Service [2]. It was developed through iterations of a questionnaire in the pilot stages and in discussion with doctors and managers throughout the service. The task characteristics derived were divided into five broad clusters of capability (Table 2).

Table 2
Management model for doctors

Contextual awareness
Strategic thinking
Functional and operational skills and knowledge
Interpersonal and team skills
Self-management

The first cluster, contextual awareness, was defined as the understanding and ability to operate effectively at all levels in the context of organizational structures. It involves knowledge of central government health strategies, national funding, the roles of major constituents, the purchaser/provider concept, senior organizational roles, and the structure and process of local units.

The second cluster, strategic thinking, is based on understanding strategic processes and applying them. Strategic thinking includes the ability to generate a vision and long-term strategies, to contribute to the development of organizational goals, and to link daily activities to strategic plans.

Functional and operational skills and knowledge of a range of activities and methods are generally associated with the daily operation of units in health care organizations. Among these skills are recruitment and selection of non-medical staff, pursuit of equal opportunities policies, training non-clinical staff, appraising and implementing disciplinary procedures, negotiating contracts, monitoring business planning and performance, managing a budget, generating income, managing organizational crisis, handling official complaints, using information systems, and problem-solving and decision making. Quality issues such as implementing patient satisfaction and clinical audit are also included.

Interpersonal and team skills include communicating sensitive information; counseling and mentoring colleagues and subordinates; chairing and contributing to meetings; making presentations; dealing with the media; negotiating; conducting interviews for appraisal, selection, grievance and discipline; delegating work; resolving conflict; and goal setting for others.

Self-management skills used in the management of career and personal effectiveness at work include learning effectively from experience, managing a professional reputation, implementing difficult non-clinical decisions, acting independently with initiative, managing time, handling uncertainty, and demonstrating self-awareness and effective presentation.

While not exhaustive, the above lists can help to guide the development of the role of medical director and the assessment of performance. Formal courses have been created in response to the need for a medical perspective in this business endeavor. Courses are offered in many reputable business schools, and the American College of Physician Executives has been formed to develop educational programs for physician executives [11]. The American Association of Clinical Directors is also a valuable resource.

The role of the medical director is open to interpretation and application. Involvement and influence can be extensive or minimal. A medical director can be an all-powerful czar or nominally a consultant. Responsibilities vary greatly and depend upon the institution and the individual. The bottom line is that the medical director must find ways to do cases

and then maintain the processes for doing them. The main goal is to have a facility where surgeons want to bring their patients.

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Leadership in the ASC Opportunity and responsibility

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Abstract

Though many physicians do not think of themselves as leaders, anesthesiologists working in an ambulatory surgery center have a unique opportunity and indeed, a responsibility to exert leadership in a way that will positively impact the working environment. This article examines the pitfalls of different leadership styles frequently employed by physicians and the role of emotional intelligence in the ASC. The author offers practical advice on why and how to manage emotional outbursts in the operating room that can lead to stress, poor performance and may even threaten patient safety.

Keywords: Physician leadership; Emotional intelligence; Ambulatory anesthesia; Medical director; Ambulatory surgery center; Patient safety

1. Leadership defined

There are dozens if not hundreds of definitions of leadership, so when my partner, Dr. Manya Arond-Thomas and I founded our company to work with physician leaders, we determined that our first task was to create a definition of leadership that reflected our thoughts on the key elements. We developed the following definition of leadership.

Leadership is the act of exercising influence in the service of creating positive change

Our definition of leadership includes three key elements that we think are important:

1. *Exercising influence*: Leadership is rarely about coercion, rather effective leaders use influence to create the results they want or need and different situations call for different methods of exercising influence. Effective leaders move seamlessly between leadership styles that are appropriate to the situation.
2. *Creating change*: While management is about doing things right to optimize the status quo, leadership is about doing the right things to create change. If I do not see a need for change, I do not necessarily have to exercise leadership. In that case, leadership might be about being a good follower and acting as an integral part of a team.
3. *Positive*: We believe that leadership is about exercising influence with conscious intention to move self, team and/or organization in a positive direction.

2. Formal versus informal authority

Unfortunately, I think that few physicians think of themselves as leaders today. However, in most situations, and particularly in a healthcare delivery setting, people grant us "formal authority" by virtue of our degrees. As we build strong relationships in the workplace based on respect, integrity and commitment to excellence, others grant us "informal authority" as well because they like, respect and/or admire us. Either of these forms of authority provides a head start when it comes to leadership, but when the two are combined in one person there is tremendous potential for influencing others either positively or negatively. My hope is that more and more physicians will recognize this opportunity and begin to focus

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on becoming good leaders who influence others in a positive direction.

The position of anesthesiologist, especially in an ambulatory surgery center, is a key position from which to exercise leadership. As a physician, you already have *formal authority* and as someone who spends a lot of time in the facility, you have the opportunity to develop strong bonds with the nursing and business office staff as well as with the surgeons. The better you are at building relationships, the more *informal authority* you will be given by your co-workers. Like it or not, unless you do something to lose their respect, people will look to you for leadership so it is important to realize two things:

1. You have significant influence over the people you work with, both in the operating room and in the ASC as an organization.
2. Whether you use that influence positively or negatively is under your control. Using your influence to help create a positive working environment is a big responsibility that should go hand in hand with your position.

3. An "open-loop" system

We have known for quite some time that the seat of human emotion lies in the limbic system, the oldest part of the brain, and that the amygdala is the regulator of the system. Scientists who study human behavior now refer to human emotions as an "open-loop" system. This is because, unlike the closed-loop cardiovascular system which does not interact with the external environment, your emotions influence and can be influenced by the emotions of people around you. This is especially true of people who work closely together over a period of time like the staff in an ambulatory surgery center.

Most of the time, this system works well, for example, when a loving mother soothes her crying child or when friends succumb to a fit of "contagious laughter" and create a long-lasting memory of "that time we just could not stop laughing." Goleman et al. [1] (Primal Leadership, 2002) describe this phenomenon as *resonance*, which in musical terms means the intensification and enriching of a musical tone by supplementary vibration. Emotional resonance is very positive and has many benefits as will be discussed further.

But sometimes this open-loop system can backfire. Think of the last time you were in your facility and a surgeon came in ranting and raving about a schedule mix up or a piece of equipment that was missing. Even if it was not directed specifically at you, you probably felt that little knot of anxiety in the pit of your stomach. No matter how great you were feeling before, within minutes, you probably noticed that your mood began to sag. Goleman et al. refer to this as *emotional dissonance*. In musical terms, dissonance is a mingling of discordant sounds, *especially* a clashing or unresolved musical interval or chord. Emotional dissonance has negative effects on the individual as well as the team.

Each of these is an example of an "amygdala hijacking," when the emotions of one person hijack the emotions of another. An amygdala hijacking can be either resonant (positive) as in the example of contagious laughter or dissonant (negative) as in the case of the raging surgeon.

4. Emotions in the workplace

Many people think that emotions have no place in the business world and especially in a setting like the operating room. They believe that reason, logic and critical thinking are far more important. But we are learning that emotions and moods have a significant impact on performance in any human system. In fact, I think of emotions as the foundation that either supports or impairs human performance.

When people are feeling upbeat, they tend to think more clearly, use better judgement and create positive connections with other people. Leaders who use appropriate humor to lighten the situation in times of stress have been found to be far more effective than those who do not. Appropriate humor can be used quite effectively with nervous patients as well as to enhance the mood and, thus, performance in the operating room. Humor is one of the most effective tools for creating resonance.

Unfortunately, the flip side is also true. When people are feeling down they tend to focus on the negative, make mistakes and feel pessimistic about the future. In addition, the anxiety that goes along with intense negative emotions causes the body to secrete cortisol and other stress hormones that linger in the bloodstream for hours after the event has passed.

Low to moderate levels of anxiety actually enhance performance by sharpening the senses, for example, when the team is doing a quick room turnover to make up for lost time or when a well-oiled, high performance team is handling a trauma patient. But eventually, stress and anxiety reach a point of diminishing returns as high levels of anxiety impair the ability to think clearly and connect effectively with others. People begin to drop things, make mistakes, do things out of order and tempers flare more easily.

Absenteeism, low moral, employee turnover and poor performance are hallmarks of organizations where fear, anxiety and stress are the norm. And even more important, studies have clearly documented that chronically elevated levels of cortisol impair the immune system and significantly increase the risk of heart disease, diabetes and other serious health problems.

Long story short—the emotional health of your organization will impact your performance and your bottom line. How can you help to make sure emotions play a positive role in your workplace?

5. A leader's job

Daniel Goleman, author of several books on emotional intelligence and an authority on emotions in the workplace, says that the foremost job of leaders today is to drive the

collective emotions of their organizations in a positive direction and to clear the smog created by toxic emotions (Primal Leadership, p. 5). I think there is no better example of this than in the operating room.

As the leader of the team, your people, whether you like it or not, are exquisitely tuned into your emotional state. You set the emotional tone of your team and organization through your leadership style. Therefore, your first task as a leader is to learn how to recognize and manage your own emotions, to defend against being hijacked by others. Only then will you be in a position to drive the collective emotions of your organization in a positive direction.

6. Ineffective leadership styles

We learn our leadership styles haphazardly through life and unfortunately, the styles that many physicians learn are not only ineffective, but are also often down right counterproductive. In the book *Primal Leadership: Realizing the Power of Emotional Intelligence*, authors Goleman, Boyatzis and McKee describe six basic styles of leadership, two of which have a high likelihood of creating dissonance if used inappropriately. I believe that these are the styles that our medical education system and our industry reinforce and even reward. These predominantly dissonant styles are called *Pacesetting* and *Commanding*.

"Do what I do" is the mantra of a pacesetting leader. Pacesetters have exceptionally high standards for themselves and often work long hours. Because admission to medical schools requires hard work and academic excellence, it seems only natural that the system rewards pacesetters. This style creates resonance by meeting challenging and exciting goals and works well with high performing teams who are motivated to get results. Pacesetting can be effective in a well-oiled ASC, but because it is so often poorly executed, it most often creates dissonance. Some ineffective behaviors characteristic of pace-setting leaders include:

- *Hit and run management style*: Pacesetters often give commands, assign tasks or make requests but do not stick around long enough to make sure they are understood or that their expectations are clear. When the recipient of the command, task or request fails to meet expectations, the pacesetter often becomes critical and may just do it him/herself.
- *Impossible standards*: Pacesetters have high standards for themselves and are often perfectionistic and unreasonable in their expectations of others.
- *Lack of empathy*: Pacesetters often lack empathy because of their focus on perfectionism and the high standards they set for themselves. Pacesetters have difficulty putting themselves in the shoes of others.
- *Poor communication skills*: Pacesetters are usually so far out in front that they fail to develop the skills they need to work with others. They have little patience and may believe communication is a waste of time.
- *Lone ranger*: Pacesetters often prefer to work alone because they believe no one can keep up with them or meet their high standards. Their mantra is "if you want something done right, you have to do it yourself." Pacesetters often experience burnout.

"Do what I tell you" is the mantra of a command and control leader. Healthcare has long been a hierarchical industry where the doctor was considered God. Unfortunately, there are still many physicians who have failed to realize or refuse to admit that the ship of which they were "captain" has long been put into dry dock. While the commanding style works well in an emergency situation when people need clear immediate direction, it is very easily abused and creates extreme dissonance. Characteristics of commanding leaders include:

- *Failure to seek out and appreciate other perspectives*: Commanders are usually so certain of themselves that they are blinded to the value other perspectives might add to a situation. They often see differences of opinion as a threat to their ability to control the situation.
- *Micromanager*: Commanders want things done to exact specifications. They do not tolerate deviation and will often micromanage the situation to make sure they maintain control. This limits the opportunity for other members of the team to learn and grow and for the organization to develop capability that will allow it to weather and even thrive on the changes that characterize business today.
- *My way or the highway*: Commanders are rigid. They know what they want and do not hesitate to demand it. They often unconsciously sacrifice getting the results they really want in order to hold on to the position that they are RIGHT!
- *Lack of respect for others*: Commanders often consider others to be expendable. Organizations with a commander at the helm often experience constant employee turnover—a perpetually revolving door. The commanding leader usually holds the position that it's everyone else's fault.
- *Isolation*: Commanders do not like to hear dissenting opinions or negative feedback, so eventually they end up isolated and disconnected from their organizations. This is a dangerous position to be in. Since few people will talk to the commander, especially if talking involves delivering bad news, he or she never really knows what is going on and can be easily blindsided or will miss critical information. This can be deadly in a healthcare setting where failure to share information could mean life or death for a patient.

Effective leadership styles that create resonance like the coaching, visionary, affiliative and democratic styles described by Goleman et al., can be learned and involve developing emotional intelligence competencies. The first step is to develop self-awareness. Until you learn to recognize and manage your own emotions, you are in no position to recognize and manage the emotions of others. Working with a coach is an excellent way to develop these competencies.

7. Tips for "amygdala hijacking" prevention and management

In addition to your own awareness, it is helpful to increase awareness of your team about the phenomenon of amygdala hijacking and to develop strategies to deal with it effectively when it does occur. Here are some tips for hijack, prevention and management:

Before it happens:

- Raise your own awareness.
- Talk about this with your team before the fact.
- Create a plan for handling situations when emotions get out of control.
- Invest in conflict management training for all employees. This type of training will benefit the organization because everyone learns to deal more effectively with conflict before it escalates. This saves time, money and helps to foster a positive, resonant environment [2].
- Work with your Medical Staff Committee to develop a Code of Conduct that defines disruptive and unprofessional behavior, create a disciplinary plan, get buy-in from your Medical Staff and then enforce it for everyone on your Medical Staff.

In the moment:

- Do not take it personally—remember that it is very likely not about you.
- Stay calm, breathe deeply.
- Attempt to create emotional resonance. As the anesthesiologist, you have a much greater likelihood of success with this step if you have actively built good relationships with your surgeons, staff and other colleagues. Sometimes judicious use of humor can be quite effective in these situations, but know your audience because this can backfire!
- Tag team. If necessary and if possible, rotate people in and out of the situation to help keep nerves calm. This technique is helpful if emotions flare negatively during a long case that must be finished.
- Call in equal or higher authority if available. This is most likely you, especially if you are the Medical Director of your facility. If you are not comfortable in high conflict situations, I recommend working with a coach or getting some training in how to deal with conflict.

After the fact:

- Debrief with a support person or with the team. Talking it out can help to ease some of the lingering tension; however, gossip and focusing on the negative may tend to reinforce the detrimental effects of stress and may also increase the likelihood of future incidents with that individual. Use the debrief as an *after action review* to look for learning opportunities.
- Ask yourself and your team whether triggers could have been avoided. Look for the kernel of truth in any conflict situation. It is easy to write someone off as a jerk and miss an important issue that should be addressed such as an avoidable error with scheduling or a broken or missing piece of equipment.
- Meet with the perpetrator, especially if this is a common occurrence. Again, this will most likely fall into your lap, especially if you are the Medical Director. Do it immediately after or as soon as possible following the event. Come from a place of curiosity and make sure you are very calm yourself before you approach the person. Think through your intentions and make sure they are positive, clean and clear.
- If the problem continues, consider disciplinary action. If one individual continually loses emotional control, this is an issue that should be taken up with the governing body of your organization. Ideally, your organization has already developed standards for professional behavior and each member of the medical staff should be required to read and sign them as part of the credentialing process.

8. In summary

- As an anesthesiologist in an ASC, *you* are in a unique position to set the emotional tone of your organization.
- Your job is to drive emotions positively—to create emotional resonance—because a negative emotional environment can have a significantly negative impact on your team's performance as well as on the bottom line.
- As physicians, we may have learned counter productive leadership styles.
- The first step to creating a positive emotional environment in your workplace is to increase your awareness.
- You can prevent and manage emotional hijacking.
- You can develop new leadership styles and the payoff is high!

In closing, I leave you with this important question to ponder—"as a leader, which role do I play most often—driving positive emotions that enhance creativity, clear thinking and team effectiveness or am I the emotional hijacker from hell?"

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Pediatric patient selection and provider issues

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Abstract

In this article some factors that influence the safety of anesthesia care for infants and children are reviewed. In particular elements of training and ongoing experience necessary for the safe provision of pediatric anesthesia care are identified and also the necessary support needed in terms of personnel and facilities. Several guidelines relating to the provision of pediatric anesthesia care are reviewed. Finally, those infants and children who are at increased anesthetic risk are identified. It is essential that the needs of these at risk patients and the capabilities of the provider and facility are matched.

Keywords: Pediatric; Anesthesia; Training; risk; Competency

1. Introduction

The purpose of this article is to review some of the elements needed to undertake anesthesia care for infants and children most safely. For anesthesiologists whose practice is primarily ambulatory anesthesia care, pediatric patients may comprise a significant proportion of their practice. While some of the factors increasing pediatric anesthesia risk will not be relevant in ambulatory settings, such as surgeries requiring intensive care post-operatively, many other factors should be considered to minimize pediatric anesthetic risk. These include elements relating to the training or ongoing experience of the practitioners providing pediatric anesthesia care and also requirements for adequate facilities and support staff. Several studies have reported that perioperative morbidity and mortality from anesthesia is higher in infants and children than in adults [1–3]. Infants and children are anatomically and physiologically different from adults and this impacts their anesthetic risk. Several investigators have shown that centers doing higher volumes of complex cases (like cardiac procedures) have lower mortality than centers with limited case loads [4,5]. Despite the finding that larger centers have lower mortality rates than those who do a smaller number of cases, many hospitals continue to provide pediatric anesthesia for less than 100 cases per year. Of the hospitals in northern California doing a small number of pediatric cases, 75% are within 50 miles of a larger pediatric center [6].

In the past 15 years, several aspects of pediatric anesthesia have been evaluated, including clarification of competency levels in pediatric anesthesia, making more uniform the elements necessary for programs providing training to become pediatric anesthesiology sub-specialists, and developing guidelines for needed equipment, support and personnel for the anesthetic peri-operative environment for infants and children. We propose to review these developments, their current state, and then to list some of the pediatric subpopulations that deserve thoughtful consideration of the match between a facility's environment, provider expertise and the needs of such children and infants before undertaking their anesthetic care.

Infants undergoing anesthesia may have lower morbidity in the hands of trained pediatric anesthesiologists. Keenan et al. found that the incidence of bradycardia in a retrospective study looking at cases from 1983 to 1992 was 1.27% overall in infants undergoing anesthesia in the first year of life. Bradycardia was less than half as likely when a pediatric anesthesiologist was supervising the case [7]. A study from

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Switzerland was designed to examine risk factors for preoperative adverse respiratory events and found that children not anesthetized by a specialist pediatric anesthesiologist had a 1.7 times increased risk for an adverse respiratory event in the peri-operative period. ENT surgery was also found to be a risk factor [8]. However, a recent observational study from France showed that there is a relatively higher rate of adverse peri-operative events in infants as compared to older children, even in a pediatric teaching hospital with a high annual caseload [9].

2. History

In 1990, a panel discussion took place at the Society for Pediatric Anesthesia (SPA) meeting. Its topic was how to define a pediatric anesthesiologist. While eminent individual practitioners were easily identified (such as Bob Smith, Jack Downs, Al Conn, David Steward) there were diverse opinions as to what training was ideal. In this same time frame, the late 1980s and into the 1990s, the growth of managed health care plans and the change in financing of health care in the United States (US) resulted in pressure to accomplish as much care as possible for all patients within the "home" facility. Anecdotal evidence revealed instances where anesthesia staff felt pressure to undertake anesthesia care for patients (such as neonates or infants) outside of their comfort range.

3. Training

In 1991, as a follow-up to the SPA panel, a large ad-hoc group interested in pediatric anesthesia was formed. The Study Group on Pediatric Anesthesia included 60 members, with representatives from directors of the pediatric anesthesia components of the Accreditation Council for Graduate Medical Education (ACGME)-accredited anesthesiology residency programs, anesthesia chairs from pediatric hospitals, practitioners of pediatric anesthesia in non-pediatric hospitals, officers of the American Academy of Pediatrics (AAP) section on anesthesiology, SPA and the ASA Committee on Pediatric Anesthesia. They issued Clinical Competency Objectives for Training in Pediatric Anesthesiology in 1995 [10]. This statement divided the expectations for pediatric anesthesia practice for those finishing their core anesthesiology residency (CA-3) and those seeking sub-specialist training. Anesthesiologists finishing their core training were expected to be able to resuscitate neonates, infants and children and accomplish safe anesthesia and post-operative care for routine cases in healthy children and to recognize those infants and children whose clinical condition or planned procedure exceeded the capability of the facility (whether for staff, equipment or support reasons). Pediatric anesthesia sub-specialists should undertake a program of at least one additional year in duration to become proficient to administer anesthetic care to all neonates, infants and children, as well as accomplish their resuscitation, post-operative care and pain management.

The Association of Paediatric Anaesthetists of Great Britain and Ireland in their recommendations regarding training in pediatric anesthesia, published in 2004 [11] recognize three types of Consultant Anaesthetists (Attending Anesthesiologists). These guidelines refer not only to the initial training required for competency in pediatric anesthesia but also to the need for ongoing exposure to pediatric patients and involvement in continuing medical education.

A "Consultant Paediatric Anaesthetist" is involved with the pediatric patient for at least 50% of their work and devotes a substantial amount of their continuing medical education to pediatric anesthesia and related topics. He/she has received at least a year of training at a regional pediatric center in addition to the general pediatric training received as a normal part of residency (typically 3 months or more in total). This would be the equivalent of fellowship training in the US. A "Consultant Anaesthetist with a Special Interest in Paediatric Anaesthesia" will most likely be working in a District General Hospital. He/she will have at least one pediatric list per week (a half day). During training as a senior resident such a Consultant will have had at least 6 months of training at the regional pediatric center in addition to the more general training received earlier in residency. It is recommended that provision is made for such a Consultant to visit the regional or tertiary center for update and refresher experience. A "Consultant Anaesthetist in General Anaesthetic Practice" should be up to date with pediatric resuscitation and stabilization of the pediatric patient prior to transfer for children under the age of 5 years. These consultants should be able to anesthetize a child over the age of 5 years for common surgical procedures.

A survey conducted in the US by the Study Group on Pediatric Anesthesia and the SPA revealed that pediatric anesthesia fellowship programs were highly varied in case composition, number of trainees, duration of training and in the number and caliber of faculty. Uniformity of the elements needed to train good pediatric anesthesiologists was needed. Using the structure for specialty training available from the ACGME, the necessary components for pediatric anesthesia fellowship programs were developed. This process culminated in application to the ACGME for pediatric anesthesia program accreditation. Approved in 1997, it mandates an established curriculum, sufficient case volume and breadth and a faculty of pediatric anesthesiologists. Site reviews are part of the process, which is detailed and rigorous. Currently there are 43 accredited programs in the US. However there is not currently a process by which individual anesthesiologists can gain a subspecialty certification from the American Board of Anesthesiology in pediatric anesthesia, as there is for pain management and for critical care. Training programs are accredited, but individual practitioners are not certified in the subspecialty of pediatric anesthesia.

4. Environment

To address the concern that adverse events occurring during anesthesia for infants or children were attributed to the anesthesiologist but often had elements resulting from deficiencies in the patient care facility, the AAP section on anesthesiology drafted and published Guidelines for the Pediatric Anesthesia Perioperative Environment in 1999 [12] with input from the SPA and the ASA Committee on Pediatric Anesthesia. This document outlines the use of a written policy in each facility categorizing procedures and pediatric patient populations that may be safely anesthetized and it asks facilities, through their anesthesia department chief, to define a minimum number of cases necessary to maintain staff competency. Identification of infants or children at increased anesthetic risk should be used to assess facility capability and the need for anesthesiologists with special clinical privileges. The factors that increase pediatric anesthesia risk outlined included age (with neonates as the highest risk group), procedures requiring postoperative intensive care, and pediatric patients with coexisting medical conditions. Clinical privileges for anesthesiology staff would be divided. In order to have the special clinical privileges to care for pediatric patients, felt to be at increased anesthetic risk, an anesthesiologist needs to have documented, historic, continuous competence in care for such patients and/or to have graduated from an ACGME-accredited pediatric anesthesia fellowship.

The ASA Committee on Pediatric Anesthesia using a taskforce, also published a pamphlet, “Pediatric Anesthesia: Practice Recommendations” in 2002 [13]. Facilities need to have appropriate personnel, equipment, space allocation and a team of competent health care providers that includes an anesthesiologist with appropriate training and experience to provide safe anesthesia for infants and children. The minimum number of cases to maintain competency should be determined by the head of the department of anesthesiology, with medical staff approval. The elements outlined in this pamphlet overlap with the AAP Guidelines, showing agreement between these two specialty organizations.

“Guidelines for the provision of Anaesthetic Services” was published by the Royal College of Anaesthetists, UK in 1999 and is in the process of being updated in 2004. The guidelines are available on the Royal College of Anaesthetists website [14]. In the section “Guidance on Paediatric Anaesthetic Services”, recommendations are made concerning the provision for the needs of children and their families and the level of training recommended for the staff involved in their care. The guidelines state that provision must be made not only for anesthesia but also for intensive care services and/or the transfer of patients requiring more specialized intensive care. Acute pain relief and resuscitation services must also be provided. Throughout the document the comment is made that parents should be encouraged to be involved in the care of their children and the operating room environment should be suitable for the “emotional and physical needs of children”. This includes allowing for the presence of parents at induction and having separate or screened off areas for children in the recovery room. Pediatric anesthetic equipment should be available.

The British guidelines also specify that operating room nurses and other operating department practitioners should provide adequate assistance and have adequate training and skills, although the training for these personnel is not specified. Pediatric services should be led by a Consultant Anaesthetist (Attending) who anesthetizes children regularly, at least the equivalent of one operating list per week. All children under the age of 5 should be cared for by a Consultant or under the direct supervision of a Consultant. It is recommended that neonates are cared for in specialist centers and that children under the age of 5 are also transferred to specialist centers if there are no specialized local facilities.

Widely publicized cases of adverse outcomes in pediatric anesthesia in the US have accelerated the development of subgroups of pediatric anesthesiologists in many practices to provide access to pediatric anesthesia expertise at any time of the day or night. Some states, such as Florida and California, have developed guidelines to assist those dealing with this problem.

The California Society of Anesthesiologists has created a model policy, approved by their House of Delegates in June 2003 [15]. Elements modeled on the AAP and ASA documents include medical staff determining in writing which pediatric patients and procedures each facility can safely accomplish, determining criteria for pediatric anesthesia care with increased-risk patients requiring anesthesiologists with ACGME-accredited pediatric anesthesia fellowship graduation or continuous demonstrated competency of such care, and determination by the head of the department of anesthesiology of minimum case number for competency. Most recently, the SPA has published a policy statement on “Provision of Pediatric Anesthesia Care” on its website [16].

5. Risk population

We will finish this review with a list of some factors that define pediatric patients whose problems put them at increased anesthetic risk.

1. Age
   a. prematurely-born infants (up to 46–60 weeks post-conceptual age)
   b. neonates (0–1 month)
   c. infants (1–12months)
   d. children (e.g. in the UK any child less than 5 years is considered to be at increased risk for anesthesia and should have a provider with suitable experience)
2. Surgeries
   a. cardiac procedures
   b. thoracic surgery, including all open thoracotomies
   c. major abdominal procedures (e.g. Kasai, necrotizing enterocolitis exploration)

d. solid organ transplantation
e. neurosurgery, including craniotomies and meningomyelocele repairs
f. plastic reconstructive surgery, such as craniofacial reconstruction or giant nevus excisions.

Most of these surgeries are not pertinent to ambulatory centers.

3. Co-existing conditions
   a. residual lung disease from prematurity or diaphragmatic hernia
   b. palliated congenital heart disease
   c. neuromuscular disease, e.g. Duchenne's
   d. congenital syndromes, especially those which include airway anomalies such as:
      i. Goldenhar Syndrome
      ii. Treacher Collins
      iii. Pierre-Robin Anomalad
      iv. VATER Association
      v. Beckwith–Weideman
      vi. Epidermolysis bullosa

For those patients with identified syndromes, two good references are Baum and O'Flaherty's text [17] and Butler's article [18]. These are helpful in assessing if a child's needs fall within the capability of your facility.

6. Conclusion

Because anesthesiology has been so successful at decreasing overall morbidity and mortality during the last 20 years, many outside our field believe that there are virtually no risks associated with anesthesia care. This makes it even more critical for us as anesthesiologists to identify the fragile and assure that their needs and our capabilities are matched.

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Pediatric ambulatory surgery and wound infection: a review study of 812 operations in a Brazilian university hospital

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Abstract

Introduction: The pediatric ambulatory surgery results in less wound infections, although there is little good evidence for this. *Objective*: To obtain evidence of the influence of ambulatory surgery on the post-operative wound infection results in pediatric day-surgery. *Methods*: A total of 753 patients underwent 812 ambulatory surgery operations; elective general, vascular, and urological minor surgery included. No operations involving infected patients were reviewed in our study, and all operations were performed in the operating room with the patient under general anesthesia at Teresópolis School of Medicine Hospital, Hospital das Clinicas de Teresópolis Constantino Otaviano (HCTCO). Hematoma, wound infection, and recurrence rates were analyzed. *Results*: The wound infection incidence rate was 2.2% in pediatric ambulatory patients. *Conclusion*: Pediatric ambulatory surgery reduces the post-operative morbidity of incidence of wound infection rates, and increases the pediatric quality care.

Keywords: Pediatric ambulatory surgery; Outpatient surgery; Day-hospital; Wound infection; Hospital infection

1. Introduction

Ambulatory surgery is one of those rare socio-economic political movements in which all participants have benefited as demonstrated by public interest and demand, surgeon satisfaction, patient participation and most importantly, payer encouragement and mandate [1].

During the last two decades, many different countries have experienced a dramatic switch from inpatient to day-surgery [2]. To determine the surgical wound infection (WI) incidence rate associated with pediatric day-surgery, a retrospective study of all electively operated pediatric surgery day-cases was carried out, during an 8-year-period from a university hospital in Rio de Janeiro, Brazil, between January 1993 and June 2001. The study included gastroenterological, vascular, and urological surgery.

2. Materials and methods

This study involved the retrospective analysis of all infants admission records treated with day-surgery by our staff consecutively during the period between January 1993 and June 2001. A total of 753 patients underwent 812 operations requiring a skin incision. No operation involving infected patients was reviewed in our study, and all operations were performed in the operating room with the patient under general anesthesia at Teresópolis School of Medicine Hospital, Hospital das Clínicas de Teresópolis Constantino Otaviano (HCTCO). Our method included: (a) a parent or a responsible adult accompany all children following the invitation to go into the operating room with the child; (b) children inhale anesthetic gases as they go to sleep; (c) once the child is asleep, doctors insert an i.v. and begin the surgical procedure; (d) the day-surgery patients generally spent 8–10 h at the pediatric surgery unit (including reception, surgery room visitation with parents, procedure per se and anesthesia recovery); and (e) patients were seen after discharge in both the pediatric surgery hospital unit or a private clinic. Patients were seen 1 week and 2 weeks after discharge, and periodically thereafter, until they were well.

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Table 1
Grøgaard, Kimsas e Ræder criteria

1	Discharge of pus from the wound
2	Microorganisms present in swabs taken from any discharge from the wound
3	Surgical revision and drainage of the wound with positive bacteriology
4	Antibiotic treatment due to clinically suspect infection

The definition of wound infection was based on fulfillment of one from following Grøgaard, Kimsas e Ræder criteria [3] (Table 1). The collection of data included the factors associated with the procedures which were documented for each patient at the time of the operation. Such factors included the name of the surgeon, name of the scrub- and assisting nurse, type and duration of the procedure, location of the incision, and ASA-class of anesthesia risk. Following the Wilson scoring system for WI's [4] in our service, we defined nosocomial infection as any infection acquired in the hospital, i.e. not present or incubating prior to hospitalization. The patients' ages were grouped into: neonates (0–30 days), infants (31 days to 18 months), and children (19 months to 12 years). Patients' nutritional status was assessed using the Marcondes weight-for-height anthropometrical method for protein-energy nutrition state. [5] Additional clinical data included: primary diagnosis, sex, coexisting disease process or anomaly, duration of operative procedure, number of operations for each patient, and time interval in days from operation to onset of infection. A rate of infection was calculated for the entire population as well as for each procedure possible risk-factor. The data were analyzed with Student's *t*-test, and $P < 0.05$ was considered statistically significant.

3. Results

The day-surgery pediatric patients admitted between January 1993 and June 2001 were reviewed. A total of 753 patients underwent 812 operations. The total WI infection rate was 2.2%. In addition 1% of the patients had healing disturbance (usually consisting of transient erythema without any exudate). The median time from operation to diagnosis of WI was 7 days (range 2–7). According to age group (Table 2), the infection rate was higher for neonates (3.6%) than for infants (2.8%) or children (1.1%). When we had a new element in the operative team—a resident or an intern—there was a relative total incidence risk of 15% over procedures performed by experienced surgeon over 3 years.

4. Discussion

Day-surgery is effective and useful [2] and ambulatory surgery is the best for healthy children undergoing minor procedures. It has been claimed that ambulatory surgery results in less wound infections compared with inpatient

Table 2
Wound infections by operation and age

	Neonates	Infants	Children
Operation no.	186/753	211/753	365/753
Inguinal herniorraphy (421)	3	1	2
Umbilical hernioplasty (60)	–	2	–
Testis operation (e.g. orchidopexy) (109)	2	–	–
Orthophalloplasty (different procedures) (38)	–	–	1
Excision of small lipoma (10)	–	–	–
Circumcision (119)	–	1	–
Others (55)	2	2	1
Total no. of patients with WI	7 (3.6%)	6 (2.8%)	4 (1.1%)

treatment [3]. Ambulatory surgery is increasingly accepted and encouraged throughout the world by both government and private agencies [6]. In the long history of surgery, hospital-based operations have been well-accepted in medical and social policy, but as yet, the ambulatory surgery is not accepted everywhere [7,8]. The ambulatory surgery patient may be sent home immediately after an operation and doesn't need a hospital bed [9].

During the last decades, 'quality care' has been used to describe physician–patient relationships evolved into 'cost-effective quality care', and consumers, payers, and providers have differing perspectives [10]. Distribution of health care—mainly "the quality care distribution" according to need—is perhaps the most widely discussed rationing principle in both academic and non-academic debates [11]. In the private hospitals, the situation is totally different. In these hospitals, which prima facie should have an "ambulatory surgery", has taken root exactly in the manner in which it has in developed countries [12].

The medical ethics typically recommend that medico–moral decisions should be guided by four basic philosophical principles [11]—respect for autonomy, beneficence (the patient's interests come first), non-maleficence (above all do no harm), and justice. This position can be referring to as "ambulatory surgery definition". An ambulatory surgery is very safe, with a low incidence of complications, and refers to elective surgery in which people undergoing surgery arrive and return home on the same day [13–15]. The technologic progress related to medical invasive proceedings, diagnostics, and therapeutics conducts a "new" oldest public health problem—nosocomial cost [16]. The virtually absence of cost from post-operative complications has been claimed because ambulatory surgery results less than inpatient treatment [17–19]. This low cost must be include in the absence of post-operative wound infection, ever an important part of the successful outcome of any operative procedure [3]. In Brazil, the epidemiological data on nosocomial infections are little published [20], and it's "hard" to define a right Brazilian rate. Few data exist on post-operative WI in pediatric patients in contrast to numerous reports in adults [21]. Adjustment for variables known to confound rate esti-

Table 3
Wound infection rates reported

Authors	Year	Location	Operations	Wound infection (%)
Davis et al. (31)	1984	Milwaukee, USA	1045	4.2
Sharma and Sharma (40)	1986	Rohtak, India	1325	5.4
Bhattacharya and Koloske (26)	1990	Albuquerque, USA	676	2.5
Davenport and Doig (41)	1993	London, England	1433	16.6
Tiryaki, Baskin, and Bulut (39)	1998	Istanbul, Turkey	1131	1.9
This report	2003	Rio de Janeiro, Brazil	812	2.2

mates is critical if valid comparisons of WI rates are to be made between surgeons or hospitals [22,23] (Table 3).

Our overall WI rate of 2.2% was medium compared to those reported in previous series of pediatric patients (Table 3), and generally accepted as comparable to rates in the United States [21]. However, that study [21] included laparoscopic operations, which generally have a lower risk of WI compared to open operations [24,25]. In our review, when there was a new element in the operative team—a resident or an intern—there was a relative total incidence risk of 15% over procedures performed by 3 years experienced surgeon.

Risk-factor analysis should be used to identify steps to reduce the infection rate, which still occurs despite control practices, including improved sterilization methods and barriers, surgical technique, and availability of personal prophylaxis [26]. The day-surgery at HCTCO is not physically separated from the rest of the hospital. It includes five operating theatres, four post-operative beds, and a step-down area. The unit is located in an old building with no controlled ventilation.

5. Conclusion

The prevention of WIs remains an important aspect of patient care. Educational programs covering both WI prevention and control may increase benefits for the patients, reduce expenses at institutions, and address other underlying issues by improving the working conditions. Pediatric day-surgery provides adequate treatment [27,28], and may improve the quality of hospital care for children in many developing countries. It should be provided not only by public insurance institutes, like SUS (the Brazilian system of public health) but also by both private physicians and services around the world. Our results in pediatric ambulatory surgery support our intents—ambulatory surgery makes sense when it can maintain or improve the quality of care, here defined as the low incidence of WIs [6,28]. The low incidence of wound infections reported here support the safety of ambulatory surgery, and should encourage its continued growth.

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Operating room nitrous oxide trace concentrations: a clinical study in ambulatory surgery

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Abstract

Purpose: This blinded study evaluates the N_2O concentration variations in an ambulatory surgery centre using a small, simple on-line trace gas concentration monitor (GasFinder^{TM} [Medair AB, Delsbo, Sweden]).
Scope: Thirty-seven day surgical sessions using standardised anaesthesia with propofol/fentanyl induction and sevoflurane/N_2O with larynx mask. Five of 37 time-weighted averages (TWA) were greater than 25 ppm but less than 100. Peak registered concentrations reached 2000 ppm. Eleven sessions showed peak values higher than 100 ppm (range 13–1693).
Conclusions: This simple, on-line N_2O monitor is a useful tool for detecting deviations from strict gas hygiene.

Keywords: Ambulatory surgery; Nitrous oxide; Occupational environment and health

1. Introduction

The risks associated with chronic exposure to trace concentrations of anaesthetic gases are not established [1]. Due to potential health risks that cannot fully be foreseen, most countries have established national guidelines for safe exposure limits based on a time-weighed average (TWA) over an 8 h period. As the dose–safety relationship is not well-defined, the maximum accepted TWA value varies with country among which the United States' National Institute for Occupational Safety Health (NIOSH) is one of the more conservative and sets the limit for nitrous oxide at 25 ppm [2]. Most European countries have a 100 ppm limit for nitrous oxide.

The aim of the present investigation was to blindly monitor nitrous oxide TWA values during routine anaesthesia in an ambulatory centre with strict gas hygiene routines and fixed anaesthetic protocols. A simple, trace concentration monitor based on infrared technique was used.

2. Methods

Gasfinder^{TM} trace nitrous oxide concentration monitors (Medair AB, Delsbo, Sweden) were placed on the top-front of the anaesthetic machines in two random operating theatres for ambulatory surgery. Measurements were started at the start of the first case and continued throughout the typically 8 h day (range 6–9 h) with an average of seven cases per theatre day. The Gasfinder^{TM} is a small (125 g), commercially available, relatively simple indicator of nitrous oxide in trace concentrations. Gasfinder^{TM} uses an infrared gas sensor and sampling is done through gas diffusion. It is intended to detect both chronic and acute leaks by providing both instantaneous and cumulative TWA nitrous oxide concentrations in parts per million with an updating time of about 20 s.

All personnel were blinded, unaware of the monitoring. Anaesthesia followed departmental routines consisting of co-administration of propofol and fentanyl (20–50 mg and 0.05 mg, i.v., respectively) for sedation and anxiolysis when patients were on the operating table. Preparation, washing and dressing were done while patients were awake but sedated. Induction with propofol and fentanyl (0.05 mg, i.v.) after

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2–4 min preoxygenation with a facemask. An ordinary laryngeal mask was placed immediately after induction without prior ventilation with inhaled anaesthetics. When the laryngeal mask was in place and tightened, a fresh gas flow of 1 L/min oxygen, 2 L/min nitrous oxide and sevoflurane 1–2% (dialled) was initiated with assisted ventilation until spontaneous breathing resumed. Semi-closed anaesthetic circuits were used, and sevoflurane was titrated according to clinical needs. No muscle relaxants were used. At the end of surgery all anaesthetic gases were turned off and fresh gas flow was resumed (oxygen 6 L/min and 2–3 L/min air). The laryngeal mask was not removed until patients were so awake they showed discomfort from the mask. All operating theatres have an ordinary climate ventilation system (approximately 25 changes/h) and all anaesthetic machines are connected to a standard scavenging system (−20 cm H_2O or about 5 L/min).

3. Statistics

Nitrous oxide concentrations are given as average and range.

4. Results

Thirty-seven ambulatory surgery sessions (approximately 8 h days) were monitored. Five TWAs were above the NIOSH limit of 25 ppm (26, 40, 58, 79 and 85 ppm, respectively). In 11 recordings, peak levels were above 100 ppm and 3 were above 500 ppm. The mean TWA for all 37 recordings was below 25 ppm (range 1–85 ppm). Figs. 1–3 show nitrous oxide concentrations for a session using laryngeal mask per department routine, another where an anaesthetic mask was used instead of larynx mask, and one for an operating theatre when the exhaust suction was accidentally forgotten.

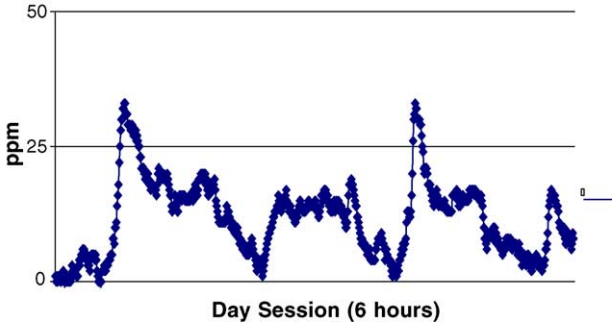

Fig. 1. Nitrous oxide concentration (ppm) vs. session time for a session using laryngeal mask per department routine.

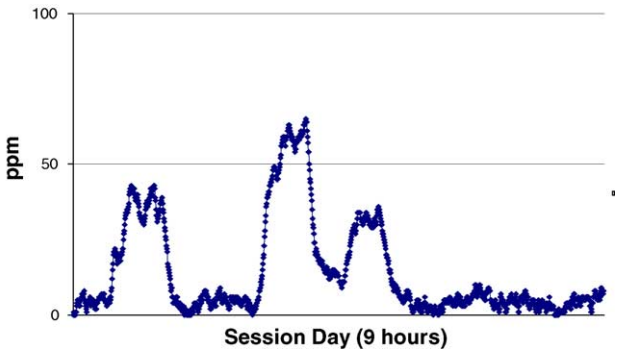

Fig. 2. Nitrous oxide concentration (ppm) vs. session time for a surgical theatre day when facemask was used.

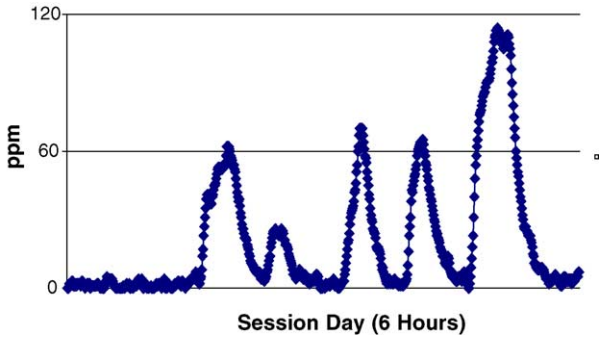

Fig. 3. Nitrous oxide concentration (ppm) vs. session time for a surgical theatre day when exhaust system was forgotten.

5. Discussion

This study investigated workplace nitrous oxide exposure in the surgical theatre using a simple, on-line trace gas concentration monitor. In the type of ambulatory surgery theatres studied where proactive gas hygiene anaesthetic techniques and equipment are used, the day averages of nitrous oxide concentrations were generally reassuringly low. Incidents with unnecessarily high peak and daylong averages of nitrous oxide concentrations were observed. This study indicates the potential value of a simple on-line monitor or dosimeter of the ambient air nitrous oxide trace concentration to reassure adequate work place air quality even when a stringent anaesthetic technique is used.

Long-term occupational exposure to trace concentrations of volatile anaesthetics has been considered to have adverse health effects on the exposed personnel [3,4]. Both halogenated inhaled anaesthetics and nitrous oxide have been associated with potential negative health effects [5,6]. Whether these potential health hazards are associated with environmental trace concentrations of nitrous oxide, halogenated inhaled anaesthetics or a combination of factors is not fully established [3,7].

Even on the basis of present knowledge a reduction of work exposure levels of nitrous oxide to the lowest possible levels is motivated by the well-described inactivation of methionine synthase from experimental studies with nitrous

oxide and secondarily the potential change in production of DNA precursors [8,9]. Experimental studies use higher nitrous oxide concentrations than occur typically in hospital environments, but the clinical implication of impaired methionine turnover is also well-known with potential effects on bone marrow and neurological symptoms [3]. The potential negative effects from more extensive chronic exposure to trace concentrations such as spontaneous abortions and impaired fertility have been shown in dental assistants [10]. Unfortunately, specific concentrations or amount of exposure were not determined in that study. The exact safe level is difficult to define, if indeed there is a threshold value, and it may vary with other factors such as Vitamin B12 and folate status. This range of uncertainty is reflected by the range of national limits: Most European health authorities have a TWA nitrous oxide limit of 100 ppm while in the USA the NIOSH has set a more conservative level of 25 ppm [2].

This study has shown that the more conservative limit of 25 ppm is generally not difficult to achieve if optimal anaesthetic techniques are used. The vast majority of measurements in the present study were well below the NIOSH limit of 25 ppm but during a handful of sessions TWA values above 25 ppm were recorded, indicating that inattention to stringent anaesthetic practice will result in unacceptably high levels. A number of peak readings were clearly higher than recommended levels. The blinding of the measurements prevented identifying the cause of TWA readings higher than 25 ppm in most cases. On one occasion, however, one of the investigators noticed gas leakage during a session when an ordinary mask was used instead of the clinical routine with laryngeal mask. In another case the gas exhaust system had not been turned on. As baseline instantaneous concentrations are low in this study, increased TWA values can be concluded to arise from personnel errors and not background leakage. These errors are most likely to occur at the beginning and end of each case.

Both economic and health considerations have resulted in a modern anaesthetic practice which generally employs closed circle systems with minimal gas leakage and waste scavengers attached to all anaesthetic machines. Forced ventilation in operating theatres, principally for infection prevention, further promotes low anaesthetic gas trace concentrations in the surrounding air. All these technical improvements may not be potent enough to guarantee acceptable workplace environments if guidelines for gas and equipment use are not followed.

The present study corroborates the reassuring results observed in other recent studies on operating room concentrations of anaesthetics [11,12]. There are, however, papers showing that nitrous oxide exposure is still a problem [13]. The results presented here must be interpreted in the context of an ambulatory centre which consistently employs anaesthetic protocols, a semi-closed anaesthetic circuit and equipment associated with optimal gas hygiene. The use of intravenous induction, lack of muscle relaxants, and not starting the use of inhaled anaesthetics until a laryngeal mask airway is in place and tightened has been shown to minimize environmental gas concentrations [14,15]. Higher concentrations have been found repeatedly during mask induction and ventilation [13,16]. Even the technique used during emergence has an impact [17]. Finally, not only ventilation technique but also accidentally de-activated scavenging systems and leaking anaesthetic equipment have been shown to contribute to high operating room nitrous oxide concentrations [16,17].

Some may argue that nitrous oxide is no longer appropriate for ambulatory anaesthesia [18]. The use of nitrous oxide has, however, been shown to promote spontaneous breathing, improve emergence, shorten the time to resumption of spontaneous breathing, time to extubation or removal of the laryngeal mask as well as time to orientation [19–21]. Nitrous oxide has been shown to be cost-effective in day surgery [22].

This study employed a simple gas detector that makes continuous nitrous oxide trace monitoring available to normal anaesthetic units. The technique used in the Gasfinder™ is simplified by depending on gas diffusion and detection using infrared technique. Ambient gas is not actively brought into the device. Its calibration guarantees to indicate when nitrous oxide levels are lower than the lowest accepted limits (25 ppm), but it does not give the exact values at those low concentrations. The accuracy for the Gasfinder™ has been confirmed for concentrations 100 ppm, 300 ppm and 1000 ppm.

In summary, during routine ambulatory anaesthesia with intravenous induction and spontaneous breathing with a laryngeal mask inhaled anaesthetic maintenance, trace concentrations of nitrous oxide are generally not a major concern. Surgical sessions with unnecessarily high nitrous oxide concentrations do occur, however, even in centres with stringent anaesthetic techniques. The Gasfinder™, measuring real-time nitrous oxide concentrations in ambient air, has an educational effect and could help to maintain a high degree of awareness for optimal gas hygiene in addition to detecting other technical errors.

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Early bioavailability in day surgery: a comparison between orally, rectally, and intravenously administered paracetamol

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Abstract

Purpose: Compare early bioavailability of rectal, effervescent oral, and i.v. paracetamol.
Scope: Five groups of $N = 7$ patients received 1 or 2 g paracetamol orally or rectally or 1 g i.v. immediately after day surgery. Paracetamol concentrations taken after 20, 40 and 80 min. Median plasma paracetamol concentrations for 1 versus 2 g effervescents were 78 (25–114) versus 108 (95–146) μmol L^{-1} at 80 min and 16 (9–30) versus 17 (10–30) μmol L^{-1} for 1 versus 2 g suppositories. Paracetamol i.v. gave median 97 (77–135) μmol L^{-1} after 40 min.
Conclusion: Only intravenously and 2 g effervescent paracetamol gave therapeutic concentrations during the period studied.

Keywords: Day surgery; Postoperative analgesia; Paracetamol; Suppositories; Effervescent tablets

1. Introduction

Pain is still one of the most common complaints after day surgery [1]. Multi-modal pain management, the gold standard for ambulatory surgery, is based on a combination of local anaesthetics, orally administered paracetamol and non-steroid anti-inflammatory drugs (NSAID), When necessary weak opioids are added with the potent classical opioids reserved as rescue medication [2,3]. The optimal drug form, route of administration and dose for the non-opioid paracetamol has not been adequately determined in day surgery [4]. The optimal drug formulation has been discussed ever since Prescott wrote one of the first articles on paracetamol kinetics [5,6].

The primary aim of the present study was to investigate early bioavailability for two different fixed doses of rectal, oral effervescent and one fixed dose of the recently introduced intravenous paracetamol formulation, Perfalgan®. All drugs were given immediately after day surgery in general anaesthesia.

2. Materials and methods

Thirty-five ASA I–II day surgical patients participated in the study after ethical committee approval and written informed patient consent. The patients were divided into five groups, seven patients in each group. Patients were excluded if they had any liver disease or any contraindication for paracetamol. The patients, 20 women and 15 men, were scheduled for ordinary day surgery and had a median age of 49 (20–72) years and weight 74 (57–105) kg. They were randomly assigned using sealed envelopes to receive paracetamol as either 1 or 2 g suppositories or effervescent tablet or 1 g intravenous paracetamol (Perfalgan®; Bristol-Myer-Squibb AB; Stockholm, Sweden).

All patients were anaesthetised according to standard departmental routines. No premedication was given apart from cyclozine 50 mg orally. Anaesthesia was induced with propo-

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Table 1
Patient characteristics, age, weight and the amount of paracetamol administered (mg kg^{-1})

	1 g rectally	2 g rectally	1 g i.v.	1 g orally	2 g orally
Male/female	1/6	3/4	4/3	4/3	3/4
Age (years)	46 (20–54)	56 (36–68)	46 (25–61)	54 (29–72)	51 (32–64)
Weight (kg)	62 (59–86)	72 (65–90)	75 (57–90)	76 (66–105)	80 (62–104)
Paracetamol (mg kg^{-1})	16 (12–17)	28 (22–31)	13 (11–18)	13 (10–15)	25 (19–32)

All values shown as median (range).

fol and fentanyl (0.1 mg) followed by the placement of a laryngeal mask airway. Anaesthesia was maintained with oxygen in nitrous oxide (1:2), and sevoflurane was titrated to clinical needs. At the end of surgery anaesthetic gases were discontinued and replaced by oxygen 100% until patients regained consciousness.

Patients randomised to rectal paracetamol received the suppository just prior to removal of the laryngeal mask while the patients randomised to the oral or intravenous paracetamol received their medication just after entry in the recovery room. All patients were also given an NSAID orally (lornoxican) and were encouraged to drink and eat as soon as possible.

VAS-values were noted and documented at the same time as the blood samples were taken and rescue analgesia, dextropropoxyphene 100 mg, was given orally whenever VAS > 4. Side effects such as nausea and vomiting were also noted and treated accordingly (metoclopramide).

Blood samples (5 ml) for analysis of plasma paracetamol concentrations were taken prior to paracetamol administration (baseline) and at 20, 40 and 80 min after administration. Serum was separated by centrifugation and stored at −20 °C plasma paracetamol concentration determination using fluorescent polarisation immunoassay (AxSym from Abbott Scandinavia AB; Stockholm, Sweden). The assay dynamic range is 6.6–1320 μmol L^{-1}. The lower limit of detection is 6.6 μmol L^{-1} and the coefficient of variation is 6% at 100 μmol L^{-1}.

2.1. Statistics

Data are shown as median and range. For differences within groups Friedman ANOVA was used.

3. Results

Patient characteristics and the amount of paracetamol per kilogram given are shown in Table 1. Surgery and postoperative course was uneventful and all patients were discharged after fulfilling departmental routines criteria.

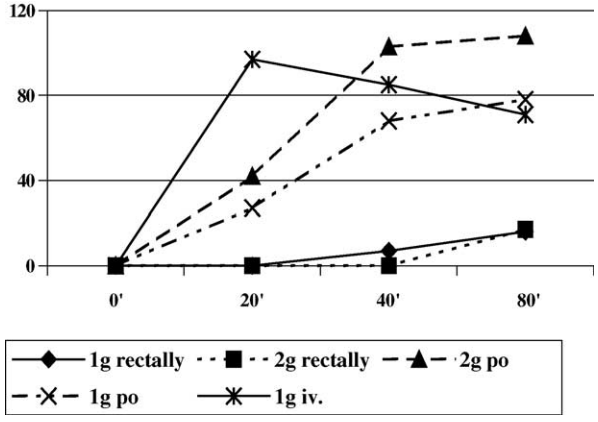

Fig. 1. Maximal plasma paracetamol concentration μmol L^{-1} (median) at any of the three time points (20, 40 and 80 min) after 1 and 2 g of rectally administered paracetamol, 1 g as intravenous paracetamol and 2 g of paracetamol administered orally as an effervescent tablet after minor surgery.

One and 2 g effervescent paracetamol plasma concentrations increased during the 80-min study period to a median value in the same range as intravenous paracetamol at 20 min. Rectally administered paracetamol plasma concentrations increased slowly with time but without any obvious dose effect. The overall plasma concentrations reached after rectal administration remained low during the entire study period. Plasma concentrations after intravenous paracetamol peaked within 40 min. The patients given i.v. or effervescent tablets had higher plasma concentrations at all time points compared to the patients receiving paracetamol rectally (Table 2, Fig. 1).

There were no differences in pain ratings. Six patients needed rescue analgesia, one each in the i.v., one and 2 g effervescent groups and three in the 2 g rectal group. One patient in each of the 1 and 2 g effervescent paracetamol groups as well as the rectal groups and three patients in the i.v. group

Table 2
Plasma concentrations of paracetamol (μmol L^{-1} median and range) when administered after ambulatory surgery as 1 g or 2 g rectally, 1 g intravenously (i.v.) or 2 g effervescent tablets (orally) and the number of patients who reached the therapeutic paracetamol concentration

	1 g rectally	2 g rectally	1 g i.v.	1 g orally	2 g orally
Baseline	0	0	0	0	0
20 min	0 (0–13)	0 (0–8)	97 (77–135)	27 (20–82)	42 (0–150)
40 min	7 (0–17)	0 (0–14)	85 (61–107)	68 (21–102)	103 (10–121)
80 min	16 (9–30)	17 (10–30)	71 (53–81)	78 (25–114)	108 (95–146)
No. of patients (>66 μmol L^{-1})	0	0	7	4	7

experienced a short period of nausea that responded to metoclopramide.

All patients given 2 g effervescent tablets and intravenous paracetamol and 4/7 patients given 1 g effervescent reached a plasma concentration >66 μmol L^{-1}. No patient given a suppository showed a plasma concentration greater than 66 μmol L^{-1} at any time point studied (Table 2). Doubling the suppository dose did not significantly improve measured concentrations.

4. Discussion

The main finding of the present study was a pronounced difference in early plasma concentrations for the different routes of postoperatively administered paracetamol. The newly introduced i.v. paracetamol gave rise to a fast and predictable plasma concentration similar to that seen with a 2 g effervescent dose after 80 min. Rectally administered paracetamol did not create seemingly adequate concentrations and a doubling of suppository dose gave no significant improvement.

The therapeutic antipyretic plasma concentration for paracetamol is considered to be 66–132 μmol L^{-1} or 10–20 mg L^{-1} [4]. The minimum plasma concentration for paracetamol's analgesic effect is not well described, but it is not likely to be lower than the concentration for the antipyretic effect [7,8]. Both lower and higher concentrations have been suggested for paracetamol's analgesic effect [9–11].

Patients receiving intravenous paracetamol showed sufficient (i.e. what is considered therapeutic) plasma concentrations after only 20 min in all seven patients studied. It is not possible from the present study to state whether the peak concentration after i.v. administration was reached even earlier.

The orally treated group was given paracetamol as an effervescent formulation as they are known to be absorbed significantly faster than ordinary commercial paracetamol tablets [12,13]. We found that the effervescent formulation had a quite rapid onset and the majority of patients reached "therapeutic" plasma levels in all patients within 80 min. This favourable bioavailability for the effervescent formula has also been shown by others [14,15]. It is, however, of importance to notice that three out of seven patients did not reach the desired plasma concentration within 80 min among the 1 g group.

Orally administered analgesics may not always be an option in post-surgical patients, especially not after more extensive surgery and or in patients at risk for PONV. The rectal route for administration in adults is slower and more erratic than the oral route and the usefulness of rectally administered paracetamol has been discussed for several years [4,6,16]. The rectal route is, however, still frequently used in many institutions as it is considered safer than early oral administration in the perioperative period [4,10]. The subtherapeutic concentrations achieved here with the 1-g rectal dose are in good agreement with a recent study by Kvalsvik et al. [17]. Higher rectal doses have been suggested based on kinetic simulations [11]. Doubling the rectally administered paracetamol dose did not increase the maximal plasma paracetamol concentrations at any time point studied. Overall plasma concentrations following rectal administration were low and never approached those considered therapeutic during the 80 min studied, a finding similar to that found by others [9,18].

It is important to consider the limitations of the present study. Registered nurses familiar with the use of the rectal route gave all suppositories. Nevertheless a full guarantee for optimal placement cannot be given. We did not intend to perform a full classical pharmacokinetic study of paracetamol uptake but merely to study the early plasma concentrations following postoperative administration in the clinical setting. We are therefore not able to say anything about peak plasma concentrations following rectally administered paracetamol, only those within the early postoperative period. Both Hahn and Stocker followed paracetamol plasma concentrations for up to 4 h after rectal administration without being able to detect therapeutic plasma concentrations from doses lower than 35 mg kg^{-1} [9,18]. We consider it important to reach a therapeutic concentration within about an hour if the clinical strategy is to have pharmacological impact during the early phase of postoperative pain management. Rectal administration of paracetamol is not an optimal route.

None of our patients had eaten within at least 6 h prior to anaesthesia and had had nothing to drink for at least 2 h prior to anaesthetic induction. No patient received muscle relaxants and all remained normothermic. Patients were encouraged to drink within 30 min after surgery and to eat a sandwich when adequately awake. Intake of food has been shown to potentially delay absorption of oral paracetamol [12], but all patients receiving the oral effervescent paracetamol reached levels above 66 μmol L^{-1} in less than 80 min.

We studied a relatively small number of patients, but the groups' results in terms of plasma concentrations differed distinctly with potentially significant clinical relevance. The number of patients studied in combination with the fact that different surgical procedures were included precludes making any concentration–effect relations.

When given postoperatively, maximal plasma paracetamol concentrations were achieved within 40 min after intravenous administration, and similar concentrations were reached within 80 min after a 2 g effervescent paracetamol while 1 g still may not guarantee adequate plasma concentrations within 80 min. Paracetamol plasma concentrations achieved after rectal paracetamol administration were low and did not improve significantly by doubling the dose. The current comparison clearly demonstrates that the intravenous route is superior by far in terms of speed and predictability followed by the effervescent formulation and that these two formulations are a far better choice with respect to the plasma concentrations than the rectal route regardless of dose. Paracetamol suppositories appear to be a poor choice for early postoperative pain treatment in day surgery.

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Low-cost pain infusion catheter for the control of postoperative pain in ambulatory foot surgery

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Abstract

The authors report the use of a low-cost method of providing prolonged patient controlled anesthesia at the surgical site following elective forefoot surgery performed in ambulatory surgical settings. In this series of 54 patients there were no postoperative complications and 95.92% of patients believed the device helped to control their post-operative pain.

Keywords: Elective surgical procedures; Postoperative pain; Patient-controlled analgesia; Hallux valgus

1. Introduction

When considering elective foot surgery, postoperative pain has been cited as one of the primary concerns expressed by patients [1]. An obvious goal of patient care in the perioperative period is to adequately control pain. It has been noted that patient perception of control and participation in the pain reduction process may positively affect patient satisfaction post-operatively [2].

Continuous peripheral nerve blocks have been utilized by a variety of surgical specialties to decrease postoperative pain. Clinical trials have shown these to be effective in both reducing the amount of pain experienced and in decreasing the oral and intravenous use of narcotics following cardiac [3,4], obstetric [5], plastic [6,7], maxillofacial [7], and orthopedic surgical procedures [7,8]. Similar successes following lower extremity surgery have been reported in the form of continuous sciatic and popliteal blocks [9–13]. Additionally, disposable pain pumps have been successfully utilized for more distal nerve blockade following foot surgery [14].

Although a variety of pain pumps are commercially produced, in some ambulatory settings these pain pumps may not be available or may prove cost-prohibitive to the patient [15]. The authors report the use of a low-cost method of providing prolonged anesthesia at the surgical site following elective forefoot surgery.

2. Technique

The device consists of a multi-hole, thin (20-gauge) epidural catheter, 3 cm^3 needleless syringes, and 0.5% bupivicaine without epinephrine. At the time of surgery, the catheter is placed in the subcutaneous layer of the surgical wound following closure of the deep fascia (Fig. 1). The catheter exits the skin proximally through a separate puncture site and is secured in place with mastisol and steri-strips (Fig. 2). The remainder of the surgical closure is performed and the dressing applied. The dressing incorporates the catheter into the bandages with only the last 2–4 cm visible as it exits the dressing proximally. This allows the patient to connect a sterile syringe to the catheter and self-administer local anesthetic directly blocking any post-operative pain (Fig. 3).

Patient education is undertaken explaining use of the pain infusion catheter. Patients are directed to administer one 3 cm^3 syringe at the first indication of pain in the operative site. Patients are also directed to observe for adverse effects

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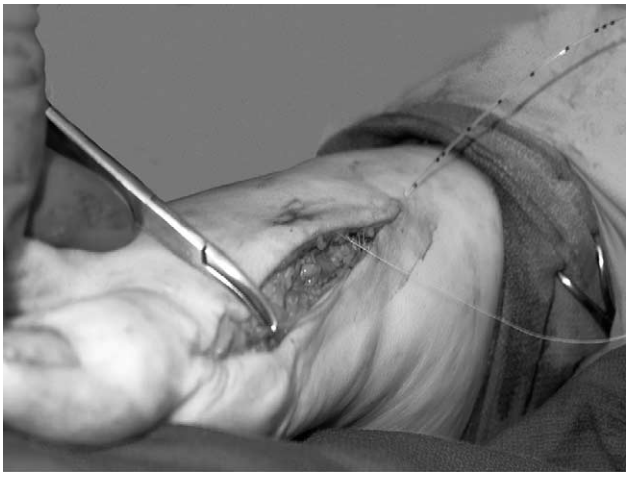

Fig. 1. Placement of the catheter in the subcutaneous layer at the surgical site.

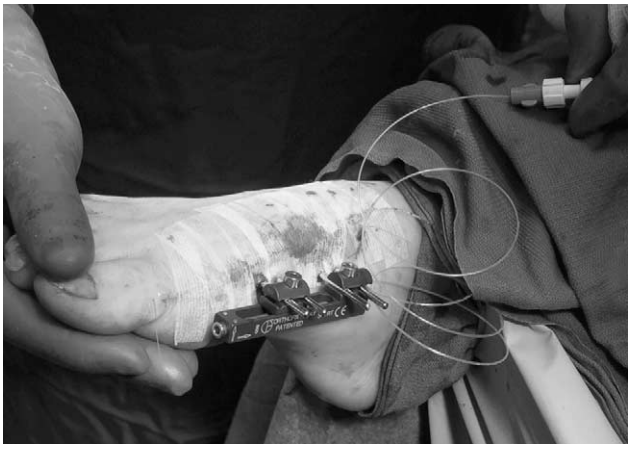

Fig. 2. The catheter exiting the skin proximally and secured with steri-strips.

such as numbness of the tongue or tinnitus. The telephone number of the surgeon is included on the instruction sheet so that any questions or concerns can be promptly answered in such events. The patient is discharged with alcohol wipes and eight 3 cm^3 needleless syringes filled with 0.5% bupivicaine without epinephrine and is given a written copy of the following directions:

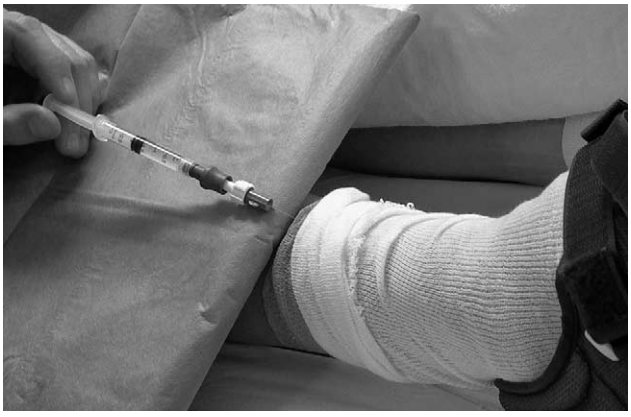

Fig. 3. The syringe attached to the catheter to self-administer local anesthetic.

Contents of pain kit:
- alcohol wipes;
- eight 3 cm^3 needleless syringes with 0.5% bupivicaine.

Frequency of administration:
- One 3 cm^3 syringe of 0.5% bupivicaine may be administered no more than every 4 h.

Instructions for step-wise administration of local anesthetic:
- *Step* 1: Clean the end of the catheter with an alcohol wipe.
- *Step* 2: Remove cap from tip of syringe. Do not touch the uncovered end of the syringe; it is sterile.
- *Step* 3: Connect the syringe to the catheter by simply pressing the two together and turning the syringe in a clockwise direction.
- *Step* 4: Apply pressure to the plunger of the syringe slowly infiltrating the skin with local anesthetic over a 1–2 min period.

Removal of catheter:

The catheter must be removed by the end of the third day. This is accomplished by simply pulling the catheter from the bandages. The catheter is secured by a small piece of adhesive tape to the skin under the bandage so removal may require a small tug to free the catheter.

3. Discussion

At the authors' institution the total cost of the apparatus is approximately $15. The senior author (JBD) has utilized this pain infusion catheter for the control of post-operative pain following surgical correction of hallux abductovalgus in 54 cases. To date there have been no cases of postoperative infection or wound dehiscence.

An attempt was made to contact all 54 patients by telephone. Forty-nine patients were interviewed, one had died of causes unrelated to the surgery, and four were lost to follow-up. Forty-seven patients (95.92%) stated that they believed the device helped to control their post-operative pain and would use the pain infusion catheter again if faced with elective outpatient forefoot surgery.

One patient (2.04%) stated she would not use the pain infusion catheter again, expressing an overall dissatisfaction with the surgical outcome. Another patient (2.04%) did not feel the pain pump was necessary citing very limited post-surgical pain. All 49 patients (100%) stated they experienced no pain or difficulty in removing the catheter from the surgical site.

This method of delivering patient-controlled repeated bolus local anesthesia offers several advantages over other methods. First, the patient is afforded the perception of control and participation in the pain reduction process that has been shown to enhance post-operative patient satisfaction [2]. Secondly, commercially available elastomeric, spring loaded and electronic infusers have been shown to have substantial vari-

ations in rate and duration of infusion related to ambient temperature and power source [16]. One might speculate that these variations in administration might lead to over-infiltration of the subcutaneous tissue with subsequent wound dehiscence. Because the present method involves only small sequential infusions, there is little risk of over infiltration. Additionally, the prolonged presence of local anesthetics has a reported antimicrobial benefit [17–19]. Lastly, the device as presented can be assembled from materials readily available at most hospitals and surgery centers at a very low cost to the patient.

4. Conclusion

The pain infusion catheter as described is a low-cost adjunct to controlling postoperative pain in patients undergoing elective forefoot surgery. Additional prospective clinical validation is needed to compare this and other methods of infusion for peripheral anesthesia following elective outpatient forefoot surgery.

Conflict of interest

The authors have no financial interest in the products mentioned in this article.

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A double blind, randomised trial to compare the analgesic effect of oral premedication with paracetamol, diclofenac, or diclofenac and paracetamol, on postoperative pain following surgical suction termination of pregnancy

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Abstract

Objectives: The aim of this study was to determine whether a combination of paracetamol and diclofenac provided a more effective analgesic premedication than paracetamol, or diclofenac alone for the treatment of postoperative pain following surgical suction termination of early pregnancy.
Methods: A double blind, prospective trial, involving 60 patients randomized to receive either paracetamol (1 g) and placebo, diclofenac (50 mg) and placebo, or diclofenac (50 mg) and paracetamol (1 g) orally, prior to surgical termination of pregnancy. Intraoperative management was standardized. Peak pain was the primary end point. Pain scores were recorded immediately postoperatively, and at 2 and 4 h. Secondary end points were nausea, sedation, intraoperative blood loss, supplementary postoperative analgesic use, and delayed hospital discharge.
Results: There was no statistically significant difference in peak pain between the three groups ($P = 0.6$).
Discussion: The co-administration of prophylactic oral analgesic premedication with diclofenac and paracetamol did not result in a reduction in pain scores when compared to either diclofenac or paracetamol administered alone.

Keywords: Paracetamol; Diclofenac; Analgesia; Postoperative pain; Prevention and control

1. Introduction

Suction termination of pregnancy is a commonly performed day-case surgical procedure, often resulting in mild to moderate lower abdominal postoperative pain. Persistent postoperative pain is both unpleasant for the patient, and may lead to delayed discharge.

Analgesic premedication with paracetamol in combination with diclofenac or diclofenac alone is routine practice in our hospital, and in many other centers. The evidence for the analgesic efficacy of paracetamol and NSAIDs administered alone is poor, but no evidence exists to determine the relative efficacy of a combination of NSAIDs and paracetamol in this common clinical situation. Our hypothesis was that the combination of diclofenac and paracetamol would produce a clinically significant reduction in analogue pain scores.

2. Materials and methods

Approval was obtained from the Local Research Ethics Committee. Written informed consent was gained preoperatively from 60 consecutive female patients scheduled for elective surgical termination of pregnancy (STOP) over a 6-month period in a large teaching hospital. Inclusion criteria

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Table 1
Patient demographics

	Group A: paracetamol ($n = 20$)	Group B: diclofenac ($n = 20$)	Group C: both ($n = 18$)
Age (year)	27 (8)	27 (8)	24 (6)
Weight (kg)	66 (11.3)	67 (10.7)	67 (6.3)
Time from premed to surgery (min)	79 (37)	89 (35)	76 (36)
Duration of surgery (min)	12 (4)	11 (5)	11 (4)
Had misoprostil (*n*)	10 (50%)	12 (60%)	10 (56%)
IUCD implanted (*n*)	7 (35%)	8 (40%)	4 (22%)

Data expressed as mean (standard deviation) or number (percentage of total).

were age 16–35 years and American Society of Anesthesiologists (ASA) class I or II. Exclusion criteria were a history of allergy to any of the medications used in the study, asthma, peptic ulcer disease, chronic analgesic use, or necessity for tracheal intubation.

A computer-generated randomization list with three groups was drawn up by the hospital pharmacy department, who prepared sealed, numbered packages based upon this list. Each paper package contained an opaque plastic container, containing three tablets, with Vitamin C being used as a placebo. Tablet preparations were chosen for their similar appearance. The packages contained paracetamol 1 g and placebo (Group A), diclofenac 50 mg and placebo (Group B), and paracetamol 1 g and diclofenac 50 mg (Group C). Women were allocated the next available number on entry to the trial, and prior to surgery the ward nurse gave the package to the patient with a small glass of water. The code was revealed to the researchers only once recruitment and data collection were complete.

Anaesthesia was induced with propofol 2–4 mg kg^{-1}, following intravenous fentanyl 100 μg and ondansetron 4 mg. A laryngeal mask was inserted, and anaesthesia maintained with isoflurane in nitrous oxide and oxygen, with spontaneous respiration. Duration of surgery, blood loss, and the volume of intravenous fluid given were recorded. Nursing staff administered misoprostol gel vaginally, 1 h preoperatively, to patients who had not previously delivered vaginally. Patients who requested an intrauterine contraceptive device (IUCD) preoperatively had a Mirena coil (Schering Health, Berlin, Germany) placed after the evacuation of the uterus. No oxytocic drugs were administered to any patient during the study.

Analogue pain scores from 0 (no pain) to 10 (worst pain imaginable), and the incidence of nausea and vomiting were assessed immediately postoperatively, and after 2 and 4 h. Tramadol 50 mg and dihydrocodeine 30 mg were prescribed for all patients as required for postoperative analgesia. These were administered at the discretion of the nursing staff to patients with pain scores of three or greater. Patients who reported nausea or vomited postoperatively were administered prochlorperazine 12.5 mg intramuscularly. Patients were allowed tea and toast postoperatively in the recovery ward. The majority of patients were discharged at 4 h following surgery, but if discharge was delayed, then the reason for this was recorded. Potential confounding variables, such as age, weight, use of misoprostol gel, or insertion of an IUCD were recorded.

Prior to starting the study, we considered that a difference in pain scores of two or more would be clinically significant. Power calculation demonstrated that in order to detect a difference of this magnitude, with an α-error of 0.05 and a power of 0.85, we would require 20 patients in each group. Subsequent analysis confirmed that the study was powered to detect this difference.

3. Results

Two patients were excluded from the analysis. One vomited several minutes after swallowing the tablets, and one declined the procedure after administration of the tablets. Table 1 contains the remaining 58 patients' characteristics, and Table 2 contains the results. The highest pain score reported by each patient during the postoperative period was recorded as the 'peak pain', and this data was regarded as not being normally distributed. The data were analyzed using the Kruskal–Wallace test, analysis of variance, or the Chi-square method as appropriate. Patient characteristics were well matched between treatment groups. Analysis of two potential confounding variables revealed no significant difference in peak pain scores between those patients who received misoprostol and those who did not (median 2.0 versus 3.0, respectively, $P = 0.21$) and those patients who received an IUCD and those who did not (median 2.0 versus 3.0, $P = 0.91$).

There was no statistically significant difference in peak pain scores or requirement for rescue analgesia between the three treatment groups ($P = 0.6$). A non-significant association was noted between premedication with diclofenac, and nausea and requirement for supplementary anti-emetics. Delayed discharge was only noted in one patient, a Group C patient, as a result of nausea.

4. Discussion

The existing literature contains little evidence for the efficacy of NSAIDs used as analgesic prophylaxis in minor gynecological surgery. Jacobsson et al. [1] demonstrated significantly reduced pain with intramuscular diclofenac 75 mg, but not oral diclofenac 50 mg. This result may have been affected by the use of retrospective assessment of pain, insufficient time for absorption of the oral preparation prior to

Table 2
Primary and secondary endpoints

	Group A: paracetamol ($n = 20$)	Group B: diclofenac ($n = 20$)	Group C: both ($n = 18$)	*P*-value
Peak pain				
Mean	3.2	3	2.6	
Median	2.5	3	2	0.60
25th–75th centiles	1–5.0	2.0–4.5	0–5.0	
Range	0–8.0	0–7.0	0–8.0	
Rescue analgesia required				
(*n*)	13 (65%)	10 (50%)	9 (50%)	0.63
Nausea (*n*)	2 (10%)	4 (20%)	4 (22%)	0.56
Anti-emetics required (*n*)	0 (0%)	2 (10%)	3 (17%)	0.18
Blood loss (mL)	210 (118)	277 (211)	249 (135)	0.44

Number of patients (percentage of total) for 'rescue analgesia', anti-emetics, and nausea, and mean (standard deviation) for blood loss.

surgery, and lack of blinding. Hein et al. [2] demonstrated a reduction in pain with oral lornoxicam 8 mg. However, in this study, rescue analgesic requirement was no different from placebo and the unorthodox method of analyzing pain could have amplified a small clinically insignificant difference.

A literature search revealed no evidence for the efficacy of prophylaxis with paracetamol in these circumstances. Two studies were unable to demonstrate any statistically significant benefit from the use of paracetamol [3,4]. However, Cade et al. utilized an insensitive measure of pain (i.e. pain or no pain) and Hein et al. administered the paracetamol rectally at the end of surgery, resulting in an inadequate time for absorption and reduced bioavailability. We utilized the oral route, which has greater bioavailability and less variability than the rectal route [5], and we allowed adequate time for absorption [6]. In our study, premedication with diclofenac resulted in no significant reduction in postoperative pain, when used either in place of, or in addition to paracetamol. This result is perhaps surprising, given the accepted efficacy of NSAIDs in treating moderate pain [7]. Possible explanations for this lack of effect include drug pharmacokinetics, dosage, and severity of pain. We would expect from the available literature on the pharmacokinetics of diclofenac [8], that its analgesic effect would be near its peak immediately postoperatively, having been administered 1–2 h previously. Diclofenac 50 mg has been shown by systematic review to be an effective dose for the treatment of moderate to severe postoperative pain [7] and increasing the dose to 100 mg only minimally increases efficacy (number needed to treat 2.3 versus 1.8, respectively). In addition, systematic review has shown a lack of evidence for differences in analgesic efficacy between routes of administration for NSAIDs [9]. It is possible that the lack of demonstrable effect of diclofenac used as prophylaxis is due to the fact that only 18 (31%) of the patients reported moderate to severe pain [10], while most experienced only mild discomfort which was self-resolving and did not require analgesic treatment.

Given the lack of positive findings, it would be prudent to consider the sensitivity of the experimental model, and in particular whether the use of fentanyl at induction may have affected the results. It is common practice to utilize a short acting opioid to achieve balanced anaesthesia, and we administered fentanyl 100 μg to reflect this, thereby allowing the results to be applicable to routine anaesthetic practice. In addition, the available evidence suggests that an intraoperative bolus dose of fentanyl has no effect on postoperative pain scores or postoperative analgesic requirements [11,12]. Given the routine use of paracetamol as an analgesic premedication in our hospital, it was considered unethical to use a placebo control in this study. In summary, we utilized a well-validated measure of acute pain, and an adequate number of patients and no clinically or statistically significant difference was found between the treatment groups.

The routine use of prophylactic analgesia for surgical termination of pregnancy is widespread. We have demonstrated that there was no clinically significant difference between the treatment groups with respect to the primary outcome. The results of this study do not support the prophylactic co-administration of oral analgesic premedication with diclofenac and paracetamol as the combination confers no significant clinical benefit over either paracetamol or diclofenac alone.

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A comparison of local intraarticular anesthesia versus general anesthesia for ambulatory arthroscopic knee surgery

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Abstract

Various anesthetic techniques including local, regional, and general anesthesia have been utilized for ambulatory arthroscopic knee surgery. The choice of anesthetic technique for this surgical procedure can have a significant impact on postoperative recovery, side effects, and patient satisfaction. The objective of this randomized, prospective study is to evaluate the efficacy of utilizing either intraarticular (IA) local anesthesia or general anesthesia (GA) for patients undergoing outpatient arthroscopic knee surgery. Patients assigned to the local anesthesia group were administered an IA injection of 30 mL of bupivacaine 0.25% approximately 20–30 min before surgery. Intraoperative sedation was provided with the administration of propofol. Patients assigned to the GA group were administered propofol and fentanyl for induction and maintained with sevoflurane combined with nitrous oxide in oxygen by laryngeal mask airway. The surgeon injected 30 mL of bupivacaine 0.25% through the arthroscope at the completion of the surgical procedure. This study demonstrates that IA anesthesia provides for improved pain relief, decreased postoperative opioid use, postoperative nausea and vomiting (PONV), time spent in the recovery room, and improved patient satisfaction with similar operating conditions comparable to general anesthesia in patients undergoing outpatient arthroscopic knee surgery. Although both groups received a similar dose of IA bupivacaine, administering the local anesthetic prior to surgery resulted in more effective analgesia. We currently believe that intraarticular local anesthesia fulfills all the criteria for the optimal anesthetic technique for outpatient arthroscopic knee surgery.

Keywords: Knee arthroscopy; Intraarticular; Ambulatory surgery; Local anesthesia; Outcomes

1. Introduction

The optimal anesthetic technique for ambulatory arthroscopic knee surgery should be technically simple to administer, have minimal side effects, provide for rapid onset with a high success rate, allow for a timely discharge, be inexpensive, and provide postoperative analgesia [1–3]. General anesthesia (GA) may be associated with a higher incidence of side effects and unanticipated hospital admissions after outpatient surgery [4]. Regional anesthesia may be more preferable for ambulatory surgical patients because of the potential for improved postoperative analgesia, faster recovery times, and decreased incidence of side effects [4–6]. A variety of regional anesthetic techniques have been described for outpatient arthroscopic knee surgery. Peripheral regional techniques have included instillation of intraarticular (IA) local anesthetics [2,3,7–23], combined psoas compartment and sciatic nerve blocks [24], and femoral three-in-one nerve blocks [2,14,25]. Central neuraxial nerve blocks have included spinal, epidural, and combined spinal–epidural anesthetic techniques [1,22,26–28]. Due to concerns about possible back pain, spinal headache, transient radicular irritation, and prolonged hospital discharge, we no longer perform spinal or epidural anesthesia for outpatient knee arthroscopy. Although femoral three-in-one nerve blocks may provide ad-

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equate anesthesia, they take considerable time to perform, have a high failure rate, and many anesthesiologists are not familiar or comfortable performing them [29]. Furthermore, the use of a femoral three-in-one block was shown to be no more efficacious than the IA administration of local anesthesia following outpatient knee arthroscopy [2]. At our institution, arthroscopic knee surgery has been successfully performed with IA local anesthesia (LA) for over a decade. For those patients refusing an IA local anesthetic block, we currently offer the option of general anesthesia. This study was designed to prospectively evaluate general and IA local anesthesia in patients scheduled for outpatient knee arthroscopy by comparing postoperative pain, incidence of side effects, surgical operating conditions, discharge times, and patient satisfaction.

2. Materials and methods

Following approval by our local Institutional Review Board, written informed consent was obtained from 104 patients scheduled to undergo elective diagnostic or operative arthroscopic surgery of the knee by a single surgeon (JS). By the use of a computer-generated table of random numbers, patients were allocated to receive either GA or IA local anesthesia.

All patients were premedicated with intravenous (IV) midazolam 0.035 mg kg^{-1}. A standard three-portal arthroscopic technique was used for surgery. Before incision, 10–15 mL of 1.0% lidocaine was used to infiltrate the skin, subcutaneous tissue, and capsule at the portal sites (3–5 mL in each of the three portals) in both study groups. A tourniquet was not used for any of the surgical procedures.

Patients assigned to the local anesthesia group were administered an IA injection of bupivacaine by one of two anesthesiologists (SSR or SBG) in the preoperative holding room approximately 20–30 min before surgery. After a sterile preparation was performed, an 18-gauge needle was used to inject 30 mL of bupivacaine 0.25% with 1:200,000 epinephrine through the superolateral portion of the knee. Presence of anesthetic solution within the knee joint was confirmed by one of several methods. If an effusion was present, it was aspirated, ensuring correct IA placement of the needle. If no effusion was present, free flow of local anesthetic was sought by palpating the flow of fluid along the medial gutter. If resistance was felt, the injection was identified as going into the fat pad or IA soft tissues, and the needle was redirected. After IA injection, the knee was flexed three or four times to achieve an even distribution of the local anesthetic. Intraoperatively, intravenous sedation was titrated throughout the procedure in accordance to the patients' wishes and comfort. Some patients preferred to be awake enough to watch the video monitor, whereas others preferred to be more sedated. Propofol was administered in a bolus dose of 20 mg immediately prior to insertion of the trochar and then as an IV infusion at a rate of 10–100 μg kg^{-1} min^{-1}. Opioids were not a component of the intraoperative sedation. During the surgical procedure, patients were asked to rate their pain on an 11-point verbal rating scale (VRS) pain score, with 0 corresponding to no pain and 10 the worst imaginable pain. Intraoperative assessment of pain was performed every 10 min or when the patient experienced a painful event. If the intraoperative VRS was ≥3, 5 mL of lidocaine 1.0% was injected through the arthroscope. If the pain persisted, IV fentanyl 25 μg could be titrated to a total dose of 2 μg/kg. If pain persisted despite these measures, patients were converted to general anesthesia.

Patients assigned to the GA group were administered IV propofol 2 mg/kg and fentanyl 1.5 μg/kg for induction. General anesthesia was maintained with 0.5–2% sevoflurane (end-tidal concentration) combined with 60% nitrous oxide in oxygen by laryngeal mask airway. The surgeon injected 30 mL of 0.25% bupivacaine with 1:200,000 epinephrine through the arthroscope at the completion of the surgical procedure.

After surgery, patients were admitted to the Phase I postanesthesia care unit (PACU). Patients were transferred to the Phase II ambulatory surgical unit (ASU), after achieving a modified Aldrete score [30] of 10. If patients achieved a modified Aldrete score of 10 before leaving the operating room, they were admitted directly to the Phase II ASU. Patients were discharged home from the ASU after achieving a postanesthetic discharge scoring system (PADSS) [31] score ≥9. While in the PACU, patients received incremental doses of fentanyl 25 μg IV every 5 min for a VRS ≥3. Side effects including postoperative nausea and vomiting (PONV) were recorded. Odansetron 4 mg IV was administered for nausea lasting longer than 5 min, on patient request, or when vomiting occurred. All assessments (pain, time to oral intake, nausea, vomiting, Aldrete, and PADSS scores) were recorded by an independent nurse-observer (HM) blinded to the analgesic treatment group.

At the completion of surgery, the primary surgeon (JS) was asked to assess surgical operating conditions on a five-point scale (1: excellent, 2: very good, 3: good, 4: moderate, 5: unacceptable). Postoperative pain scores, both at rest and with movement, were assessed using an 11-point VRS at 30 min, 60 min, and 24 h after surgery. Pain scores with movement were recorded immediately after the patient actively flexed the operative knee to 90°.

Patients were instructed to take 1–2 acetaminophen 325 mg/oxycodone 5 mg tablets, every 3 h as needed for a VRS ≥ 3 while at home. Patients were contacted by telephone 24 h after surgery by the same blinded investigator (HM), and were asked about their pain score, time to first analgesic use, 24-h total use of analgesic tablets, incidence of nausea and vomiting, and to estimate their overall satisfaction with the entire perioperative experience on a five-point scale (1: very satisfied, 2: satisfied, 3: somewhat satisfied, 4: unsatisfied, 5: very unsatisfied). Analgesic duration was defined as the time

from completion of surgery until the first postoperative use of fentanyl or acetaminophen/oxycodone.

2.1. Statistical analysis

Demographic data and times (duration of procedure, time to discharge, time to oral intake, and analgesic duration) were assessed by analysis of the variance. Pain scores, patient satisfaction, surgical operating conditions, amount of postoperative analgesics, and odansetron use were analyzed by the Kruskal–Wallis test. The incidence of nausea and vomiting were evaluated by contingency analysis and the chi-square test. If a significant result was obtained, the Mann–Whitney *U*-test was performed to determine between which groups there was significance; a Bonferroni adjustment was made for multiple comparisons. Significance was determined at the $P < 0.05$ level.

3. Results

Of the 104 patients accepting randomization, four were excluded from analysis (one required open arthrotomy, one required overnight admission because of IA bleeding, and two for protocol violations). There were no significant differences among the two study groups with respect to age, sex, weight, duration of surgery, or surgical procedures (Table 1). There were no differences in the surgeon rating of intraoperative surgical conditions (Table 2) between the two groups. No patient in the IA local anesthesia group required intraoperative fentanyl or conversion to general anesthesia. Fourteen patients (28%) in the IA local anesthesia group required an additional IA injection of local anesthetic because of an intraoperative VRS pain score ≥3. Pain scores in the immediate postoperative period were significantly lower, both at rest and with movement in the IA group (Table 2). There were no differences in pain scores 24 h after surgery. Significantly, more patients required the administration of fentanyl in the PACU or acetaminophen/oxycodone use in the 24 h following surgery (Table 2). Patients in the GA group had a higher incidence of PONV, antiemetic use, and longer time to first oral intake compared to the IA group (Table 2). All patients in the IA local anesthesia group achieved a modified Aldrete score of 10 after leaving the operating room and were admitted directly to the ASU (Table 2). These patients spent less time in both the ASU and were discharged from the hospital sooner than patients receiving GA (Table 2). Analgesic duration in the IA local anesthesia group was significantly longer compared to patients in the GA group (Table 2). More patients in the IA group reported higher satisfaction scores with their entire perioperative care compared to the GA group (Table 2).

Table 1
Patient demographics and surgical data

	IA local anesthesia	General anesthesia
Number	50	50
Gender (M/F)	29/21	33/17
Age (year)	41 ± 12	44 ± 16
Weight (kg)	79 ± 15	81 ± 16
Type of surgery (*n*)		
Partial medial meniscectomy	19	16
Partial lateral meniscectomy	6	5
Chondroplasties	5	7
Loose body removal	5	6
Diagnostic arthroscopy	4	2
Lateral release	3	4
Medial meniscal repair	3	5
Lateral meniscal tear	2	3
Synovectomy	2	2
Plica excision	1	0
Duration of surgery (min)	21 ± 7	24 ± 6
Propofol use (mg)	58.8 ± 20.1	170.3 ± 69.8*
Fentanyl (μg)	0 ± 0	127.5 ± 52.3*

Data are presented as mean ± S.D.; *n*, number in each group.
* $P < 0.001$.

Table 2
Surgical outcomes

	IA local anesthesia	General anesthesia	*P*-value
Number	50	50	
Intraoperative VRS[a]	2 (0–4)	0 (0)	<0.05
Postoperative VRS[a]			
30 min (rest)	1 (0–2)	3 (2–5)	<0.05
30 min (movement)	2 (1–4)	4 (3–8)	<0.05
60 min (rest)	1 (0–2)	3 (2–6)	<0.05
60 min (movement)	2 (1–4)	5 (3–9)	<0.05
24 h (rest)	2 (1–3)	2 (1–4)	NS
24 h (movement)	3 (2–5)	3 (2–6)	NS
PACU fentanyl use (μg)[b]	0 ± 0	25.5 ± 36.2	<0.001
24 h Percocet use (tabs)[b]	4.6 ± 1.2	6.1 ± 1.1	<0.05
Nausea[c]	1 (2)	19 (38)	<0.01
Vomiting[c]	0 (0)	8 (16)	<0.05
Odansetron use[c]	0 (0)	10 (20)	<0.05
Time to oral intake (min)[b]	9.2 ± 2.1	59.1 ± 12.6	<0.01
Phase I PACU stay (min)[b]	0 ± 0	48.7 ± 11.3	<0.001
Phase II ASU stay (min)[b]	58.1 ± 12.2	138.5 ± 24.1	<0.01
Actual discharge time (min)[b]	112 ± 22	198 ± 36	<0.01
Analgesic duration (min)[b]	310 ± 42	64 ± 12	<0.001
Surgical conditions[c,d]			NS
Excellent	41 (82)	45 (90)	
Very good	7 (14)	5 (10)	
Good	2 (4)	0 (0)	
Patient satisfaction[c,e]			<0.05
Very satisfied	35 (70)	16 (32)	<0.01
Satisfied	12 (24)	15 (30)	NS
Somewhat satisfied	3 (6)	19 (38)	<0.01

[a] Data are presented as median (range).
[b] Data are presented as mean ± S.D.
[c] Values are numbers and percentages [*n* (%)]; IA, intraarticular; PACU, postanesthesia care unit; ASU, ambulatory surgical unit.
[d] Graded from 1 (excellent) to 5 (unacceptable).
[e] Graded from 1 (very satisfied) to 5 (very unsatisfied).

4. Discussion

Arthroscopy of the knee joint is one of the most commonly performed orthopedic surgical procedures performed in the United States. In an attempt to decrease cost, an increasing number of these procedures have been performed over the past decade on an outpatient basis. The choice of anesthetic technique for outpatient arthroscopy can have a significant impact on postoperative recovery, side effects, and patient satisfaction. Local anesthetic techniques fulfill many of the requirements for the ideal ambulatory anesthetic technique [32]. Although IA local anesthesia is a more cost-effective technique [19–21], many institutions continue to utilize general, spinal, or epidural anesthesia for arthroscopic knee surgery. Some physicians have expressed concerns about adequacy of surgical conditions for operative arthroscopy or certain patient populations [14,22,33]. Our present study revealed that a wide variety of knee procedures could be successfully performed utilizing local anesthesia with sedation. We found this to be a safe, practical, and reliable technique that resulted in high patient satisfaction. Operative surgical conditions were rated very good to excellent in the majority of patients and similar to those patients receiving general anesthesia. The majority of patients in the local anesthesia group reported either no or mild (VAS ≤ 3) intraoperative pain.

In contrast to our findings, Swedish surgeons assessed "technical difficulties" and patients' pain as "more intense" with the use of local anesthesia compared to spinal or general anesthesia for arthroscopic knee surgery [22]. The reasons for the improved surgical conditions observed in our study may be several-fold. Firstly, it has been observed that the "success of local anesthesia/sedation techniques is also dependent upon the skills of the surgeon" [5]. Some orthopedic surgeons believe that there is a larger "learning curve" [18] and that a greater degree of expertise with more "meticulous attention to technical details" [16] is required when local anesthesia is used. Excessive varus and valgus manipulation of the knee under local anesthesia should be avoided since this can produce significant intraoperative pain [34]. In contrast to our surgeon (JS), the Swedish surgeons [22] had varying experience from the resident to consulting level. Secondly, the two prospective studies [14,22] that revealed better surgical conditions under general anesthesia, failed to administer intraoperative sedatives for those patients assigned to receive local anesthesia. The use of sedation with local anesthesia has been shown to improve both patient satisfaction and arthroscopic operating conditions (reduces anxiety and muscle spasm) compared to local anesthesia alone [16]. Although intraoperative sedation is beneficial, we are in agreement with other investigators [16,17,19] that the patient should not be oversedated. Our study utilized minimal intraoperative doses of propofol (< 60 mg) for the duration of the surgical procedure. This provided for optimal surgical conditions while still allowing patients the opportunity to view the video monitor. We have found that allowing patients to view their surgery is beneficial in facilitating the explanation and understanding of their pathology. In addition, since functional performance of the knee is not altered after IA anesthesia [34], the retained ability of the patient to voluntary move his or her knee during the procedure allows for dynamic evaluation of the knee and patellofemoral joints [20].

Another factor, which may affect surgical conditions, is the injection technique utilized for the IA administration of local anesthetics for arthroscopic knee surgery. We have observed that a minimum IA volume of 20–30 mL of bupivacaine injected at least 20 min before surgery is necessary to produce adequate surgical conditions. This wait is necessary to insure that the local anesthetic is well absorbed by the synovium and capsule and will not be leached out by the irrigating fluids later. Further, the knee is then flexed three or four times to achieve an even distribution of the local anesthetic as described by other investigators [11]. Alternatively, others recommend ambulating the patient with assistance to the operating room table to allow for adequate distribution of the local anesthetic prior to surgery [11,18,21]. In addition, providing for a supplemental injection of IA local anesthetic during the operative period may provide for additional comfort [9,11,23]. We found that 14 (28%) of patients in the local anesthesia group required an additional IA injection of local anesthetic to improve intraoperative analgesia and avoid the use of either intraoperative opioids or general anesthesia. Similarly, Eriksson et al. [11] reported that 22% of patients undergoing arthroscopic knee surgery required an additional IA injection of local anesthesia and none required conversion to general anesthesia.

IA anesthesia also provided for enhanced perioperative analgesia while obviating the need for intraoperative administration of opioids or general anesthesia. Utilizing a non-opioid analgesic technique for ambulatory surgical procedures may be associated with an improvement in outcomes and patient satisfaction [35]. The use of large doses of opioids during ambulatory surgery can be associated with an increased incidence of postoperative complications (e.g., PONV, ileus, pruritus, urinary retention, sedation, and respiratory depression), which in turn, contribute to a prolonged stay in the same-day surgery facility or to unanticipated hospital admissions [35]. Further, the intraoperative use of large bolus doses or continuous infusions of short-acting opioid analgesics may actually increase postoperative pain as a result of their rapid elimination and the development of acute tolerance and hyperalgesia [36–38].

We believe the use of IA local anesthesia for arthroscopic knee surgery provides for the ideal non-opioid analgesic technique. This technique provided for enhanced postoperative analgesia, decreased PONV and recovery times, and higher patient satisfaction when compared to general anesthesia. None of the patients in the IA group required either parenteral or oral opioids in the PACU compared to 100% of patients in the GA group. Although both groups received a similar dose of IA bupivacaine, the timing of local anesthetic administration may have contributed to the difference in analgesic

efficacy. Patients in the IA group were administered bupivacaine 20–30 min before surgery, whereas those in the GA group received an IA injection at the conclusion of the arthroscopic procedure. The enhanced analgesic effect in the IA group may be related to a preemptive analgesic effect of IA bupivacaine [39]. We have previously demonstrated that IA bupivacaine is a more effective analgesic when administered prior to rather than at the conclusion of arthroscopic knee surgery [40]. Alternatively, the IA administration of bupivacaine at the conclusion of arthroscopic knee surgery may have not provided sufficient analgesia until well after the patients were admitted to the PACU. It has been demonstrated that the optimal analgesic effect derived from bupivacaine is not observed until at least 20 min after its IA injection [39].

In addition to an improved analgesic effect, patients in the IA group demonstrated a significantly lower incidence of PONV. This decreased incidence of PONV may been due to the reduction in postoperative pain or perioperative use of opioids, both of which are known to be independent risk factors for PONV [41]. The improved perioperative analgesia and decreased PONV may have contributed to the earlier discharge times and improved satisfaction scores observed in the IA group. Inadequate pain management and PONV are two of the most common reasons for delayed discharge, unanticipated admission, and hospital readmission following ambulatory surgery [4]. Further, increased PONV has been associated with significantly decreased patient satisfaction following surgery [42].

In conclusion, IA anesthesia provides for improved pain relief, decreased postoperative opioid use, PONV, time spent in the recovery room, and improved patient satisfaction with similar operating conditions comparable to general anesthesia in patients undergoing outpatient arthroscopic knee surgery. Although both groups received a similar dose of IA bupivacaine, administering the local anesthetic prior to surgery resulted in more effective analgesia. We currently believe that intraarticular local anesthesia fulfills all the criteria for the optimal anesthetic technique for outpatient arthroscopic knee surgery.

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Preoperative predictive factors of ambulatory laparoscopic cholecystectomy

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Abstract

Background: The aim of our study was to review our experience and to determine preoperative predictive factors for ambulatorization of laparoscopic cholecystectomy (LC).
Methods: Between January 1999 and June 2002, 305 consecutive LC were performed as outpatient procedures. We performed univariant and multivariant analysis of preoperative clinical, analytical and ultrasonographic variables. The preoperative scoring system developed allowed us to calculate the ambulatorization probability of LC in each individual patient.
Results: 265 patients were strictly ambulatory (86.8%). Thirty-five patients required overnight admission (11.4%), most of them due to social factors, and five patients were admitted. Preoperative factors related to overnight stay or admission were: age over 65 years ($p = 0.011$), past history of biliary complications ($p = 0.001$), previous admission due to complicated biliary disease ($p = 0.001$), previous supramesocholic abdominal surgery ($p = 0.011$) and ultrasonographic findings of gallbladder thickened wall and/or shrunken gallbladder ($p = 0.041$). Right classification index of the predictive system was 87.5% reaching a sensibility of 87.8% and specificity of 56.6%.
Conclusions: Outpatient LC is safe and feasible. Age, previous biliary history and ultrasonographic findings are independent preoperative factors influencing ambulatorization rate.

Keywords: Predictive factors; Cholelithiasis; Laparoscopic cholecystectomy; Outpatient surgery

1. Introduction

Laparoscopic cholecystectomy (LC) is the gold standard technique for symptomatic cholelithiasis and one of the most frequently performed procedures in surgery. LC has substituted traditional cholecystectomy due to a more comfortable postoperative period than the open approach [1,2]. Many authors have evaluated the safety and the initial results of LC in the ambulatory setting. However, ambulatory LC remains controversial. In the USA, LC is regularly performed as an outpatient procedure in patients with uncomplicated gallstone disease [5,6]. The results of LC in day-care facilities are promising, but outpatient treatment is not generally accepted in Europe, being performed only in some hospitals [3,4]. Previous publications on ambulatory LC have focussed on the need for selection criteria and in the safety of the ambulatory management.

The aim of our study was to analyze preoperative variables related to ambulatorization and to develop a scoring system to predict the individual probability of patients undergoing successful outpatient LC.

2. Methods

We prospectively analyzed 305 consecutive patients undergoing elective LC for symptomatic gallbladder disease

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during the period January 1999 and June 2002. Patients with suspicion of choledocolithiasis, unstable ASA III or ASA IV classification, were excluded from the study. Surgical technique, postoperative management in a fast track way, and admission criteria have been previously described [3,7]. Variables included in the analysis were clinical, ultrasonographic and analytical. Clinical variables included: age, sex, obesity, previous abdominal surgery, ASA and POSSUM classification, past history of biliary complications and previous hospital admission due to biliary complications. Analytical variables included: WBC count, total bilirubin, alkaline phosphatase, GOT and GPT values. Ultrasonographic variables analyzed were: multiple or simple cholelithiasis, wall size, common bile duct diameter and gallbladder distension (distended versus shrunken gallbladder). Patients were considered ambulatory if hospital stay was less than 8 h, while overnight patients were those staying in hospital less than 23 h. Patients considered for analysis in the admitted or over night stay group included only patients with a medical or surgical reason. Social factors for unexpected stay were excluded from the analysis as these are not predictable. Statistical analysis was performed with SPSS program. The scoring system was obtained by multivariate analysis through discriminant analysis and variables were only included if $p < 0.05$.

3. Results

Demographics and past history are shown in Table 1. Of 305 consecutive patients, 265 were strictly ambulatory (86.8%), with a median postoperative in hospital stay of 5.3 ± 1.24 h. In contrast 35 patients required overnight admission, which represents an 11.4% of global series. Most of these were due to social causes: refusal of the patient or relatives, nearest hospital over 100 kms, or conclusion of the operation after 17:00 h. Only five patients (1.6%) were admitted, with a median postoperative in hospital stay of 1.6 days (Table 2).

Fifty (13.1%) postoperative complications were observed, reaching in the ambulatory group 11.6%, most of them managed on an outpatient basis. Four patients were readmitted to our hospital: two due to repeated episodes of vomiting, one due to biliary acute pancreatitis episode, and one due to a subphrenic collection. A fifth patient was readmitted to another institution due to intestinal obstruction that required surgical treatment (Table 2).

Univariant analysis results are shown in Table 3. The discriminant multivariate study found that independent variables influencing the ambulatorization rate were: age over 65 years ($p = 0.011$; $F = 6.515$), complicated biliary disease and previous admission due to biliary complications ($p = 0.001$; $F = 11.17$), previous supramesocholic abdominal surgery ($p = 0.011$; $F = 4.92$) and ultrasonographic findings of thickened wall and/or shrunken gallbladder ($p = 0.041$; $F = 4.20$). The predictive equation derived from discriminant analysis was able to classify correctly 87.5% of cases.

Table 1
Demographics and clinical findings

	Outpatient (%)	Global (%)
Gender		
Male	60 (22.6)	71 (23.3)
Female	205 (77.4)	234 (76.7)
Obesity		
Thin (BMI < 20)	17 (6.5)	19 (6.3)
Normal (BMI: 20–25)	124 (46.8)	139 (45.6)
Obese (BMI > 25)	124 (46.7)	147 (48.1)
ASA		
I	157 (59.2)	179 (58.7)
II	101 (38.1)	116 (38)
III estable	7 (2.7)	10 (3.3)
POSSUM		
20–21	129 (48.6)	148 (48.5)
22–23	118 (44.5)	134 (43.9)
24–25	18 (6.8)	23 (7.6)
Age (years)		
Median (S.D.)	53.74 (14.1)	54.35 (13.9)
Antecedents		
Biliary dyspepsia	59 (22.3)	64 (21)
Biliary cholic	175 (66)	198 (64.9)
Acute cholecystitis	16 (6)	23 (7.5)
Biliary pancreatitis	11 (4.2)	14 (4.6)
Jaundice	4 (1.5)	6 (2)
Previous hospital admission[a]	34 (12.8)	41 (13.1)

[a] Due to complicated past biliar history.

Table 2
Causes of overnight stay, admission and readmission after LC

	No.	Treatment
Outpatients	265 (86.8%)	
Overnight admission	35 (11.4%)	
"Social" cause	21	
Refusal of the patient or relatives	12	
Nearest hospital over 100 kms	5	
Conclusion of the operation after 17.00 h	4	
"Medical" cause	14	
Extended curarization	1	
Acute respiratory insufficiency	3	Symptomatic therapy
Help needed for ambulation	2	
Postoperative pain	1	NSAIDs
Thoracic pain	1	
Umbilical wound haematoma	1	Symptomatic therapy
Vomiting	2	Ondansetron
Technical complexity of operation	3	
Admission	5 (1.6%)	
Conversion to open procedure	2	
Congestive cardiac failure	1	ICU
Esquizophrenic psicosis	1	Psicotropal medication
Intraoperative pneumothorax	1	Thoracic drainage
Readmission	5 (1.6%)	
Vomiting	2	Symptomatic therapy
Subphrenic collection	1	Antibiotics
Acute biliary pancreatitis	1	Conservative
Postoperative intestinal obstruction	1	Surgery
Total	305 (100%)	

ICU: intesive care unit.

Table 3
Outpatient LC: univariant analysis

Variables	Outpatient ($n = 265$)	No outpatient ($n = 40$)	p
Clinical			
Age			
Over or equal 65 years	68 (25.7)	18 (45)	0.011*
Younger 65 years	197 (74.3)	22 (55)	
Gender			
Male	60 (22.6)	11 (27.5)	0.498
Female	205 (77.4)	29 (72.5)	
Previous abdominal surgery			
Supramesocholic	11 (4.2)	5 (12.5)	0.027*
No supramesocholic	254 (95.8)	35 (87.5)	
Obesity			
BMI > 30	124 (46.8)	22 (55)	0.333
BMI < 30	141 (53.2)	18 (45)	
ASA			
I	157 (59.2)	22 (55)	0.271
II	101 (38.1)	15 (37.5)	
III	10 (3.3)	7 (7.5)	
POSSUM score	21.8 ± 1.1	21.9 ± 1.3	0.503
Past history of biliary complications (acute cholecystitis, acute pancreatitis, jaundice)			
Yes	29 (10.9)	12 (30)	0.001*
No	236 (89.1)	28 (70)	
Previous admission due to biliary complications			
Yes	28 (10.5)	13 (32.5)	0.001*
No	237 (90.5)	27 (67.5)	
Analitical			
WBC count (/ml)	7242 ± 2224	6975 ± 2625	0.490
Total bilirrubine (mg/dl)	0.53 ± 0.26	0.51 ± 0.263	0.655
Alkaline phosphatase (mg/dl)	104.9 ± 62.2	114 ± 78.1	0.380
GOT (U/L)	25.4 ± 22.6	25.5 ± 17.1	0.983
GPT (U/L)	28.9 ± 28.4	28.8 ± 25.1	0.977
Ultrasonographic			
Cholelithiasis			
Simple	71 (26.8)	9 (22.5)	0.658
Multiple	162 (61.1)	28 (70)	
Biliary sludge	4 (1.5)	0	
Chronic acalculous Cholecystittis/gallbladder dysfunction	28 (10.6)	3 (7.5)	
Gallbladder volume			
Normal	238 (89.8)	32 (80)	0.100
Hydrops	14 (5.3)	2 (5)	
Shrunken	13 (4.9)	6 (15)	
Gallbladder wall			
Normal	231 (87.2)	30 (75)	0.041*
Thickened and/or shrunken	34 (12.8)	10 (25)	
Common bile duct size			
Normal	257 (97)	40 (100)	0.265
Increased	8 (3)	0	

Due to a low number of patients with previous supramesocholic surgery (16 patients) the variable was excluded from final classification as its inclusion would have produced two population subgroups. The definitive predictive equation, $Y = 11X^0 + 20X^1 + 11X^2 - 79$, allows easy and quick estimation of the individual probability of outpatient management; where Y represents the probability of ambulatorization of the patient; X^0, age greater of 65 years; X^1, past history of complicated biliary disease; X^2, sonographic findings of thickened or shrunken gallbladder. A cut off value over -3 achieved the higher classification index and was related to a probability of ambulatorization up to 74% (Tables 4–6) accounting for a

Table 4
Coefficients according to equation values in discriminant analysis, after removing "previous supramesocholic abdominal surgery" factor

Variable	Corrected coefficient (X10)
Age over 65 years	11
Past history of biliary complications	20
Positive sonographic findings	11
Constant	−79

Equation $p(\text{CLA}) = 11X^0 + 20X^1 + 11X^2 - 79$; ($X^0$ = age over 65 years; X^1 = past history of biliary complications; X^2 = positive; sonography findings; constant = −79).

Table 5
Scoring values and ambulatory probability

Patients	Age	Antecedents	US	N/AMB	Score	Outpatient (%)
$N = 305$	Age over 65 years 86	PHBC+ 17	US+	1/5	−37	20
			US−	8/12	−26	66.6
		PHBC− 69	US+	7/10	−17	70
			US−	52/59	−6	88.1
	Age minor 65 years 219	PHBC+24	US+	2/4	−26	50
			US−	18/20	−15	90
		PHBC−195	US+	24/25	−6	96
			US−	153/170	5	90

PHBC: past history of biliary complications; US+: sonographic findings of shrunken or thickened gallbladder wall; amb: ambulatory.

Table 6
Scoring system cut off value and outpatient probability, after removing social admission

Scoring value	Outpatient		Total
	Yes	No	
≥−3 (−3, 7)	224	13	237
%Total	73.4%	7.5%	81.0%
<−3 (−3, −39)	41	17	58
%Total	13.4%	5.6%	19.0%
Total	265	30	295

Right classification index: 87.2% of cases. Sensitivity 87.8%, specificity 56.6%, positive predictive value 94.5%, negative predictive value 29.3%.

87.8% sensitivity and 56.6% specificity (positive predictive value: 94.5; negative predictive value: 29.3).

4. Discussion

The ambulatory approach of LC has been facilitated fundamentally by use of opiate-free anaesthesia, pre-emptive analgesia and the use of intraperitoneal anesthetics [8–10]. This method results in an improvement in quality, a substantial economic saving and an increase in the availability of hospital resources [4].

The rate of unexpected admissions represents a quality index that measures the success or failure of this kind of surgery. The percentage of failure of outpatient LC in selected patients in some series varies between 2 and 19%, due mainly to uncontrolled postoperative symptoms like nausea and vomiting or abdominal pain, conversion to open surgery and patients or relatives feeling of lack of safety [6–8,11–12]. Several studies have identified preoperative factors (Table 7) that could predict unsuccessful outpatient LC [6,11–24]. Our group (18) reported the term “technically difficult LC”, in a prospective study with overnight LC patients identifying predictive factors for potentially outpatient patients (female, normal gallbladder wall). Some authors [23,24] have argued like essentials: social factors as acceptance and motivation of patients, need of preoperative detailed information with comprehensible instructions, right selection of patients, experienced laparoscopic team and successful management of postoperative symptoms, as important keys for outpatient management. In our study, age of the patient, suprameso-

Table 7
Factors predicting unsuccessful outpatient LC

Author	*N*	Preoperative factors
Reddick (1990)	83	Ancient age
		Previous abdominal surgery
Saunders (1995)	506	Associated serious illness
Sikora (1995)	150	Female gender
		Gallbladder wall thickness
Voitk (1995)	100	Ancient age
		Associated serious illness
		Acute cholecystitis
Fiorillo (1996)	149	Patient’s motivation
Jansen (1997)	738	Age > 70 years
		Cholelithiasis > 20 mm
		Gallbladder wall > 4 mm
		Common bile duct diameter > 6 mm
		Shrunken gallbladder
Voyles (1997)	605	Age > 65 years
		Previous abdominal surgery
		Acute cholecystitis
		Choledocolithiasis signs
Alponat (1997)	783	Acute cholecystitis
		Gallbladder wall inflammation in sonographic images
		Seric alkaline phosphatase elevation
		Serum WBC count elevation
Keulemans (1998)	80	Age > 60 years
		Past history of jaundice and biliar cholic
Planells (1999)		Male gender
		Past history of acute cholecystitis
Simpson (2000)	126	ASA > II
		Past history of acute pancreatitis or cholecystitis
Fatás (2000)	265	Previous abdominal surgery
		ASA III/IV
		Serum GOT, GPT and GGT elevation
		Gallbladder wall thickness > 4 mm
Lau (2001)	731	Sonographic and surgical gallbladder wall thickness
Richardson (2001)	847	Patient’s preoperative information
		Patient’s acceptation
Robinson (2002)	387	Age > 50 years
		ASA III/IV

cholic abdominal previous surgery, previous complicated biliary history (admission due to acute cholecystitis, acute pancreatitis or obstructive jaundice) and ultrasonography findings of thickened or shrunken gallbladder wall were the most important preoperative factors that determined failure in outpatient LC. We did not find significant differences with respect to admission or overnight stay in male patients, with overweight or high score of ASA or POSSUM classification. Analytical values like WBC count, liver serum parameters, and sonographic findings of increased common bile duct diameter, number of stones (multiple versus isolated) or gallbladder hydrops due to stone impactation at gallbladder neck, did not reach statistical significance in univariate analysis. The inclusion of the variable "previous supramesocholic abdominal surgery" in the predictive system, originated several sub-groups with equal score to zero, so we decided to eliminate this variable in the discriminant study although it should always be taken into account as an independent factor. Social factors that influenced overnight admission rate were mainly due to refusal of the patient or relatives based on feeling of insecurity feeling about discharge on the same day of surgery. As there is no possibility of preoperative estimation of the development of social factors in the postoperative period this outcome was not considered in the analysis.

In conclusion, age, previous abdominal surgery, past history of complicated biliary history with or without previous hospital admission and thickened or shrunken gallbladder wall in sonographic studies are independent preoperative factors that predict success or failure of outpatient LC. The preoperative scoring system developed is of clinical value, and allows discarding previously non-subsidiary patients for outpatient LC. Social factors developing mainly in the early postoperative period would be only avoidable by extensive information with patients and relatives and will remain as a non predictable factor in relation to ambulatorization.

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