AMBULATORY SURGERY

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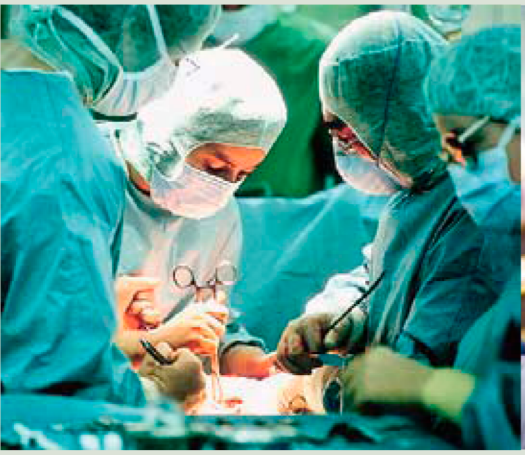
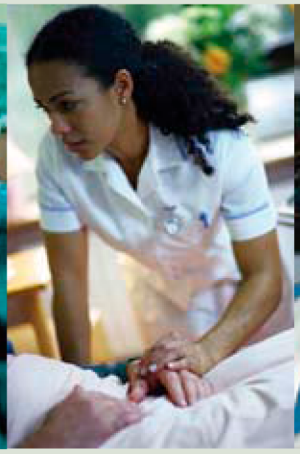

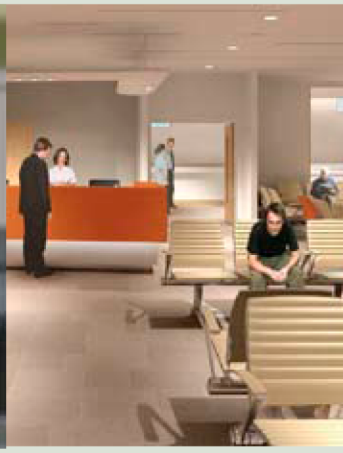

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Editorial

Mark Skues, Editor-in-Chief

This quarter's edition of the *Journal* contains a pot-pourri of articles from a number of international ambulatory surgery centres that I hope will be of interest to all. Mark Coppens and colleagues have provided a review of patient controlled sedation, describing in some detail the history of the technique, suitable drugs for use, and suggested protocols to employ. While the method appears potentially time consuming with the patient explanations required, the review provides insight into a different technique for which both patient satisfaction and outcomes are high.

Greenstein and co-workers submit a paper with a similar theme evaluating the safety and effectiveness of sedation of patients undergoing transurethral procedures using midazolam with or without ketamine by the urologist. They found that in a cohort of 77 patients, use of the drugs together with lidocaine gel infiltration, resulted in successful outcomes with low levels of peri-procedural pain.

Eskander and colleagues have written a case report and review of a patient requiring transfer to another hospital for ongoing surgery after complications arose during a gynaecological operation. While the subject matter doesn't strictly embrace ambulatory care, given that there is a prevalence of need to transfer such patients should complications arise, I hope that the review provides some insight into the equipment, drugs and personnel required, should transfer and admission be required for ongoing care.

In the fourth paper, Mads Moxness provides a personal commentary of his view that Ambulatory Surgery Centres are well suited for clinical research. He cites the reliability of pre-operative assessment and the timeliness of the procedure as an incentive for conducting research in comparison with inpatient facilities, as well as the high volume of similar surgical procedures that are carried out in a centre or department, thereby facilitating the ease with which patients can be recruited.

Finally, a date for your diary: Preparations are underway for the 2nd IAAS European Congress to be held in Budapest, Hungary, between 10th and 12th May, 2018. The website to keep an eye on is http://www.iaaseuropeancongress2018.com/, where further details will be published in due course. Book your study leave now.

Mark Skues
Editor-in-Chief

Patient–Controlled Sedation: A Narrative Review

Sam Schelfout, Kristine Fonck, Marc Coppens

Abstract

Patient-controlled sedation (PCS) was first described in the early nineties for third molar extraction. The concept of PCS resembles the one of PCA. If a patient desires a deeper level of sedation they can push a button and a pre-set amount of hypnotics/opioids are delivered. Because every patient and procedure has its own level of anxiety and discomfort, it is an attempt to eliminate the interindividual pharmacokinetic and pharmacodynamic differences. It has been used since the 1990s for a wide variety of procedures and many different drug regimens have been used. This narrative review describes the procedures, contra-indications and drugs used in PCS. At the end of this article a PCS protocol used for third molar extraction in our institution can be found.

Keywords: Sedation, Patient controlled.

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Introduction

A variety of procedures are performed under local or loco-regional anaesthesia in the ambulatory setting. For example, orthopaedic surgery under spinal anaesthesia or nerve block, eye surgery, third molar extraction and many more.

Until recently, in our institution third molar extraction was performed under local or general anaesthesia. An alternative technique is the use of sedation. Sedation should produce a relaxed, comfortable, co-operative, cardiovascularly stable patient able to maintain his airway [1]. Sedation could alleviate the painful injection of local anaesthetics and make the procedure more easily tolerated.

Pharmacokinetic and pharmacodynamic variability and varying levels of pre-operative fear and intra-operative stress can make it difficult to titrate to an optimal level of sedation. The level of discomfort may change over the course of a long procedure and furthermore, every patient has individual preferences about the degree of sedation [1–3].

Encouraging patient participation can lead to increased patient satisfaction and improved operating conditions [2, 3]. For surgical third molar extraction, intra-operative patient-controlled sedation (PCS) was described in 1991 by Rudkin and coworkers [1]. This technique allows the patient to take control of their own desired level of sedation [3]. The idea is the same as in patient-controlled analgesia; if patients would like to be more sedated they can press a button and a preset amount of sedative/analgesic drugs are administered.

Different sedation protocols and sedative drugs have been used in different kinds of procedures, which makes it very difficult to compare. We conducted a brief literature enquiry in our search for the optimal protocol for patient controlled sedation for extraction of third molars.

Procedures and patients

An overview of different procedures performed with PCS can be found in Table 1. Most studies were performed in dental surgery and colonoscopy procedures, but PCS has been successfully described in awake craniotomy [4], changing of dressing in burn patients [5] and flexible fiberoptic bronchoscopy [6].

Most studies are performed in ASA I-III patients. In earlier studies, mainly younger patients were included, but PCS can be safely used in elderly patients. It was observed that total dose is inversely related to age and it is recommended to lower the dose [3, 7–9]. Lee et al. (2002) concluded that PCS appeared to be even safer than classic intravenous sedation, with comparable effectiveness and acceptance, in elderly patients undergoing colonoscopy [10].

Contra-indications

The use of patient-controlled sedation requires some form of cooperation. Any condition that influences cognition and understanding of controlling the button is a real contra-indication. Relative contra-indications are age less than 14 years, ASA IV patients and history of severe impairment of cardiac or respiratory function. The main reason to exclude these patients is lack of evidence. An

Table 1 Procedures Suitable for Patient Controlled Sedation.

Dental Surgery [1-3, 11-17]	Cataract surgery [8, 9]
Transvaginal oocyte retrieval [18]	Colonoscopy [10, 26–33]
Lower extremity surgery [7, 19, 20]	Endoscopic retrograde cholangiopancreatography [33]
Outpatient gynaecologic surgery [21–23]	Awake craniotomy [4]
Endoscopic sinus surgery [21]	Flexible fiberoptic bronchoscopy [6]
Lymph node biopsy [21]	Dress changing burns [5]
Extracorporeal shock wave lithotripsy [24, 25]	Procedural sedation [34]

ASA-IV patient with coronary disease might experience less cardiac instability when slightly sedated. More contra-indications can be found in Table 2.

Table 2 Contraindications to Patient Controlled Sedation.

Absolute contra-indications
- Inability to understand or use the equipment
- Allergic reaction to one of the medications
- Patient refusal
- Surgery too difficult or excessive for sedation
- Severe impairment of respiratory function
Relative contra-indications
- History of difficult intubation
- History of anaesthetic problems
- Severe impairment of cardiac function
- History of drug or alcohol abuse
- Patients taking sedatives, hypnotics or other psychoactive drugs
- Patients with pre-existing cognitive impairment
- Pregnancy and breast feeding
- Hepatic impairment

Material and Monitoring

Patient-controlled sedation can be performed in an operating room or as office based anaesthesia. Either way, all safety material like emergency medication and monitoring should be present. In particular, for PCS, there must be a modified syringe pump with a patient control button. The anaesthetist should be able to program all settings of the pump, for example the bolus dose, lockout time, and rate of administration. To use a true patient-controlled sedation lockout time should be zero and there should not be a limitation on the maximum dose [18].

The ASA Standards for basic anaesthetic monitoring needs to be applied to PCS; this includes the presence of qualified anaesthetic personnel in the operating room at all times during the procedure. Although some PCS studies suggested the presence of an anaesthesiologist or anaesthesia nurse is no longer necessary, in Belgium it is an absolute requirement that the anaesthesiologist remains present [35].

Oxygenation and ventilation can be observed in different ways. The patient should be able to answer questions at all times (Conscious Sedation, according to ASA [36]), if not the sedation is too deep and indicates the anaesthetist must intervene by physical stimulation, bag and mask ventilation or even urgent intubation. In most studies patients were given additional oxygen by nasal prongs. There is a possibility to use nasal prongs with end tidal capnography, which provides feedback about ventilation. This can be of interest in dental surgery in which verbal feedback is not always obvious. While monitoring end tidal capnography with nasal prongs it's the trend rather than the absolute value that is important. Electrocardiogram and blood pressure should be evaluated every 5 minutes.

It is not necessary to monitor patient temperature, but the room temperature should be comfortable. During all sedation procedures and particularly in PCS, the environment must be one of serenity. Disturbing music, or too many people walking in and out of the operating room and unnecessary conversation should be avoided.

Products and administration

Administration method

Numerous combinations of drugs and methods of administration have been described and compared to each other. To date, it is very difficult to decide which combination is the best. The main principle is described below.

Premedication can be given, demonstrated by Park et al (1991) using diazepam PO/IM and/or morphine IM 1 hour before surgery. Hwang et al. (2005) administering 0.03mg midazolam IV [6, 19].

The anaesthetist can give an initial bolus dose. It is though that when an initial bolus dose is given, the desired level of sedation is reached earlier [37]. Normally the loading dose is a combination of one or more drugs used in the PCA-pump and is weight-based. Usta et al. (2011) used an initial bolus dose of 0.03mg/kg midazolam IV in combination with an IV loading dose of alfentanil or fentanyl depending on study group [31].

A background infusion may be set as studied by Herrick et al (1997) who used a continuous basal infusion of propofol or fentanyl [4]. In 2005 Hwang et al. [6] and Esen et al. [15] used a background infusion for respectively flexible fiberoptic bronchoscopy and third molar surgery.

The most obvious settings of the PCS-pump are bolus dose, lockout time, maximum dosage and rate of bolus infusion. If lockout is set to zero, the maximum rate of infusion determines the lockout time. For example if the rate of infusion is set to 300mL/h, it will take 30 seconds to deliver a bolus dose of 2.5mL.

Products: Sedatives

The main principle is the administration of a sedative like propofol or midazolam whether or not in combination with an opioid.

Propofol has relatively few side effects, has a rapid onset and recovery due to rapid redistribution and metabolism and less to none postoperative amnesia. [1, 14, 20] In 1991, the first PCS study described propofol as the preferred agent for intra-operative PCS [1]. Propofol has also been used as an anxiolytic [20]. Other advantages are its antiemetic properties, positive euphoric effect on mood and anticonvulsive properties [4].

Intravenous weight based initial and demand bolus doses of propofol are found between 0.2mg/kg [25] and 0.7-0.75 mg/kg [20, 34].

Among benzodiazepines, midazolam is the first choice because its rapid onset, short elimination half-life and it is devoid of significant pharmacologically active metabolites. With therapeutic doses, there is minimal respiratory or cardiovascular depression and it decreases analgesic requirements [24]. Midazolam gives excellent anterograde amnesia, which slowly decreases with time, but sedative effects often last longer than desired [16]. Kelly found amnesia if operation duration did not exceed 25 minutes [17]. There is profound and often prolonged psychomotor depression that requires close supervision [16].

Intravenous weight based initial and demand bolus doses are found to be between 0.025mg/kg [24] and 0.05mg/kg [26], with the usually used bolus dose of 0.03mg/kg [17, 31].

In 1992 Rudkin et al concluded that propofol was more suitable than midazolam for PCS because of its more rapid response to fluctuating patient requirements and because the recovery of memory and mental performance was faster in patients who received propofol [2].

Cook et al (1993) showed no difference in time to mobilisation between propofol and midazolam when used in PCS, but the psychometric tests showed a greater residual effect on cognitive function in the midazolam group [18].

Opioids

Opioids alone or in combination with sedatives are used in PCS, but with mixed results. Grattidge et al (1992) concluded that propofol was sufficient as a single agent and removed the need to use intravenous analgesics with their attendant potential for undesirable side effects [20]. Fentanyl, alfentanil or remifentanil are used in patient-controlled sedation. Alfentanil may be preferred because its shorter duration in comparison to fentanyl. The use of alfentanil as a sole agent in PCS resulted in significantly more nausea and a significantly longer time to discharge compared to propofol or midazolam PCS [21].

Nillson et al. concluded that the addition of alfentanil to propofol in PCS can make the treatment easier, but alfentanil contributed to an increased need for attention and intervention [22]. In contrast, Uyar et al (1996) found that the combination of alfentanil with midazolam and propofol provides safe, effective analgesia and sedation during lithotripsy [24].

It may be advantageous to exclude alfentanil from the PCS pump and give it before start of the procedure, as a titrated reduced single dose, adjusted to age, weight, or other variables of importance [22]. The same author stated alfentanil should not be added to propofol in the same syringe, because of different pharmacodynamic profiles. The alfentanil effect became predominant during the time course of sedation and increased the risk of early and late respiratory depression [38].

The reason to choose remifentanil is because it has the shortest working duration of all clinically used opioids. Combining propofol to PCS instead of remifentanil alone provides a better overall satisfaction level [23].

Esen et al. (2005) concluded that PCS with remifentanil in combination with midazolam seems to be a safe and reliable method, which effectively eliminates the pain and discomfort associated with third molar surgery and provides a satisfactory sedation level, without any severe side effects [15]. In contrast Fong et al (2005) concluded that the addition of remifentanil PCS did not result in a reduction of pain scores and is not useful as additive to local anaesthesia for treating pain and discomfort associated with dental extraction [16]. In 2010 Mandel et al. warned that the mixture of propofol and remifentanil has the potential for profound respiratory depression and should be used cautiously. They noted that respiratory depression occurs significantly less frequently when used in PCS compared to sedation by anaesthesiologist, but there was still an intervention rate of 10% in PCS group [30].

Ketamine has been described as adjuvant in PCS. Ketamine reduces levels of hypnotic and anaesthetic doses of propofol. Ketamine preserves airway patency and respiratory function and would decrease desaturation, but no significant difference was found between alfentanil and ketamine in combination with propofol [6, 39]. A commonly described adverse event of ketamine is the emergent delirium or hallucinations. In the study of Hwang et al., no patients reported these side effects, but some patients reported dreaming during the procedure [6].

In conclusion, irrespective of which drugs were used for patient-controlled sedation, the main characteristics must be a rapid onset, rapid recovery, few side effects and rapid clear headedness immediately post-operative. In many painful procedures, and especially in dental surgery, the administration of local anaesthesia is of utmost importance for the success of PCS. If, during a procedure, a patient experiences pain, it is the surgeon who must administer more local anaesthetics and not the anaesthesiologist who has to deepen the sedation. Possible reasons for procedural pain are a short interval time between injection and start of surgery. An inflammatory reaction may increase the need of local anaesthetic as well as insufficient dosing or suboptimal location of infiltration.

Tokumine et al. studied whether a high/low loading dose and demand dose should be used. Their results indicated that the most appropriate method for administering propofol/fentanyl/ketamine was to use a high loading dose and a low patient demand bolus, because of lower incidence of oversedation and desaturation [39]. In literature many different dose schemes can be found. The protocol used in our institution for the extraction of third molars can be found below.

Advantages and disadvantages of PCS

It is very difficult to compare the advantages and disadvantages of patient-controlled sedation because the wide variety of procedures, drugs and protocols used. Below a general idea of advantages and disadvantages of PCS can be found.

Satisfaction

There is a very high satisfaction rate among patients using patient-controlled sedation [1, 2, 7, 14, 16, 18, 20, 21, 28, 31]. Not only the satisfaction but also the willingness to repeat the procedure using the same technique was very high [6, 14, 21, 33]. In some studies there was no significant difference between PCS and sedation by anaesthesiologist in terms of willingness to repeat, preference or satisfaction [4, 10, 13, 33, 34] in others PCS was in favour of non-PCS sedation [3, 26, 27].

Herrick at al showed that satisfaction maintains high on the fifth day after procedure [4].

Some patients described a feeling of well-being and relaxation during the PCS procedure [20]. One of the reasons of this high satisfaction rate is the positive psychological effect of allowing the patients to feel that they are in control of their level of sedation [19].

Furthermore, surgeons and/or anaesthesiologists judged PCS to be good or excellent during ESWL and colonoscopy procedures [9, 24, 26]. Only one study described a higher satisfaction rate of patients and surgeons in the classic anaesthesiologist controlled sedation [25]. Surgeons reported a higher difficulty during ERCP procedures in PCS-patients, but satisfaction was not significantly different between groups [33].

Sedation

Different studies describe the deepest level of sedation with PCS as full eye closure with response on verbal stimulus [1, 2, 11]. According to the continuum of depth of sedation defined by the American Society of Anesthesiologists, this corresponds to moderate sedation which is a drug-induced depression of consciousness during which patients respond purposefully to verbal commands, either alone or accompanied by light tactile stimulation. No interventions are required to maintain a patent airway, and spontaneous ventilation is adequate. Cardiovascular function is usually maintained [36].

In comparison to classic sedation using propofol with or without opioid, some studies concluded that patient-controlled sedation has a lighter level of sedation [3, 12, 33, 34].

Comparing propofol PCS to midazolam-alfentanil PCS, sedation scores were significantly higher in the midazolam-alfentanil group [24]. As described earlier midazolam PCS might have a greater residual effect on cognitive function post-operatively [18].

Propofol PCS compared to midazolam administration by nurse/anaesthetist, had a deeper level of sedation, but even though patients were more sedated initially, recovery time was faster in patients received PCS with earlier discharge [26].

One of the main advantages of PCS is the "Fail safe": the administration of an overdose is prevented by the inability to activate the button when asleep from heavy sedation [19].

Amnesia
In dental surgery, Zacharias et al. (1998) reported complete or partial amnesia for local anaesthetic injections being 79% as well with PCS as with anaesthetist sedation [13]. Rudkin et al reported amnesia for the extractions in 70% of patients [1]. Girdler et al. reported only 38-50% having amnesia of local anaesthetic injection and dental treatment [3]. A similar result was published by Rodrigo et al. where 19% were totally amnesic and 42% partially amnesic to surgical events in dental surgery, it was postulated that this incidence is lower than with midazolam [14].

Side effects
The main side effect described with the administration of propofol is pain on infusion [1, 7, 12, 21].

Cardiorespiratory stability
Overall, patient-controlled sedation is assumed to be safe. Many studies would like to convince that an anaesthesiologist is no longer needed to perform PCS because of its unique safety profile. A specific population group is the elderly population, because they are considered more fragile to cardiac and respiratory events.

Ganapathy et al. described a transient depression of respiratory rate in patients who received propofol PCS for hip or knee arthroplasty under spinal or epidural anesthesia. These episodes were of short duration and were not associated with pulse oximetric desaturation and did not require intervention [7]. Herrick et al noted in cataract surgery more patients in the non-PCS group with increased systolic blood pressure but without a statistically significant result. There was however 1 of 28 PCS patients that experienced a transient episode of apnoea and excessive sedation, but this was solved by stimulation [8]. Lee et al. included 100 patients over 65 years for colonoscopy and their results showed 2 patient in PCS group with transient hypotension compared to 14 patients (28%) in the standard intravenous sedation group (diazemuls and meperidine) [10].

Overall, patient controlled sedation with propofol/midazolam even in combination with opioids, can be considered safe. It is however recommended to reduce the dosage in patients with co-morbidities and elderly patients, as described above.

No case of aspiration during PCS was found in literature.

Example protocol
The authors of this article cannot be held responsible for the use of the protocol described below.

Operating room and equipment
In our institution patients are admitted in the surgical day-care unit and surgery is performed in a common operating room of the hospital. A small gauge cannula is placed and every necessary monitoring is used.

Medication
PONV
- Dexamethasone 0.15mg/kg, max 10 mg in adult patient is administered as soon as the cannula is sited. Dexamethasone not only has anti-emetic properties, but it is advantageous because of analgesic and euphoric action.
- Ondansetron 0.1mg/kg max 4mg in adult patient if there are risk factors of PONV.

Pain killers
- NSAID as soon as possible
- Paracetamol 0.2mg/kg max 2g (IV)

Patient-controlled sedation
- ***Initial loading dose***
  - Midazolam 0.03mg/kg IV (usually 2mg)
  - Alfentanil 3-4mcg/kg IV (usually 250mcg)
- ***PCS-infuser pump***
  - Propofol 1% IV

  Settings:
  - Bolus dose: 0.3mg/kg (usually 2-2.5mL) in elderly reduced dose of 0.15mg/kg
  - Lockout time: 1 minute
  - Continuous infusion rate: 0mL/h
  - Rate of administration: 800mL/h

Post-operative course
After surgery, most patients stand up from the operating table and walk to their seat.

We use the White and Song fast tracking criteria to determine whether outpatients can be transferred directly from the operating room to the step-down unit [40]. If patients meet Post-Anaesthesia Discharge Scoring System criteria, described by Chung et al. they can leave the hospital [41].

Conclusion

Patient-controlled Sedation is a technique used in many outpatient ambulatory procedures. In general there is a high satisfaction rate, with minimal cardiorespiratory events. Patient turnover is high and discharge times are short. Because of the many different procedures and medication regimens used, it is difficult to find the ideal protocol. A literature review was performed and a protocol for third molar extraction was developed in our institution.

Almost all studies compare patient-controlled sedation with one medication to another or they compare patient-controlled sedation to the standard sedation protocol.

In our institution however we changed from general anaesthesia to a sedation protocol. We believe that more studies have to focus on changing from a general anaesthesia plan to a sedation protocol. This can be done not only in dental surgery, but also in lower extremity surgery under spinal anaesthesia and many more. Patients who would otherwise not tolerate the idea of being awake and who are too anxious can now determine their own level of sedation. Up to date there is no study that compares turnover time and waiting lists or compare cost-benefit ratio of introducing patient-controlled sedation versus general anaesthesia. In our belief, further research is necessary.

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Safety and efficacy of sedation/analgesia administered by the urologist for minimally invasive transurethral procedures

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Abstract

Aim: To evaluate the safety and efficacy of sedation/analgesia administered solely by the treating urologist during minimally invasive transurethral procedures.

Methods: All patients who underwent minimally invasive transurethral procedures under sedation/analgesia delivered solely by the treating urologist were analyzed. They all received intravenous midazolam, and some also received ketamine according to the discretion of the urologist.

Results: The 77 study patients uneventfully underwent insertion of an internal ureteral stent (n=30), cystoscopy (n=26), cold cup biopsies of bladder tumors (n=19), and urethral dilations (n=2).

Conclusion: Sedation/analgesia administered solely by the treating urologist during minimally invasive transurethral procedures is safe and effective.

Keywords: transurethral procedures, sedation, safety, efficacy.

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Introduction

Minimally invasive transurethral procedures, such as cystoscopy, insertion of indwelling ureteral stents, bladder biopsies, and fulguration of superficial bladder tumors may be associated with pain and discomfort for patients. Performing them on an outpatient basis would have significant implications on conserving financial and workforce resources, but they must be tolerable [1]. The pain, restlessness and movements of the patient that may lead to complications and the necessity to abort the procedure can be resolved by providing sedation combined with analgesia/anesthesia, usually induced by an anesthesiologist. The aim of the present study was to evaluate the safety and efficacy of sedation/analgesia administered solely by the treating urologist to patients undergoing minimally invasive transurethral procedures.

Materials and Methods

This study was approved by the Ethics Committee (Helsinki) of the Tel Aviv Sourasky Medical Center.

Patients

Seventy-seven patients age between 18-85 years who were referred for bladder biopsy, insertion of indwelling ureteral catheters, or fulguration of small bladder tumors comprised the study group. They were classified according The American Society of Anesthesiologists (ASA) Physical Status system, and those with a score > 3 were excluded. They all received sedation/analgesia delivered by the treating urologist in our institution between 2014 and 2016.

Qualifications of the Medical Staff

One urologist and one nurse assistant who both completed the Advanced Cardiovascular Life Support (ACLS) Provider Course and a one-day instructional course for providing analgesia and sedative medications as well as for evaluating patients before a procedure were in attendance. The ACLS course is designed for healthcare providers who either direct or participate in the management of cardiopulmonary arrest or other cardiovascular emergencies. Evaluation and monitoring of patients before and following the procedures was carried out by the urological nurse and by the urologist according to LEMON criteria (Look externally, Evaluate the 3-3-2 rule, Mallampati, Obstruction, Neck mobility) for assessing airway competence [2,3].

Sedation/analgesia administration

All patients with ASA classification less than IV who underwent either bladder biopsy, insertion of an indwelling ureteral catheter, fulguration of small bladder tumors, or cystoscopy were evaluated by the urologist and the nurse. They received an explanation about the urological and the sedation/analgesia procedures and signed an informed consent for both sedation/analgesia and the urological intervention. They were instructed to arrive with an adult escort and to refrain from driving during the 24 hours following sedation/analgesia. Patients who were reluctant to undergo the procedure while awake or whose procedure was estimated to take more than 60 minutes were scheduled for a formal operating room session. These procedures usually take between 15 and 50 minutes in our hands.

An intravenous (IV) cannula was inserted by the urologist or the nurse in all complying patients, and sedation/analgesia were administrated by the urologist performing the transurethral procedure. All the patients received IV midazolam 3–5 mg, and the addition of ketamine dose was left to the discretion of the urologist and based on the scheduled urological procedure and the patient's tolerance. Both the midazolam and ketamine were administered until minor or moderate level of sedation was achieved. A minor level of sedation was defined when the patient was able to respond to instructions without cardiac and/or respiratory compromise but with mild mental and cognitive short-term decline. A moderate level of sedation was defined as the patient being awake but not responding to instructions, and depression of cardiac and/or respiratory reflexes without airway

or respiratory compromise [3]. A designated cardiopulmonary resuscitation (CPR) cart that included antidotes (e.g., flumazenil, a selective benzodiazepine receptor antagonist) was available in the room.

Lidocaine gel 2% was installed into the urethra of the male patients. Blood pressure was monitored with arm cuffs, continuous heart activity was monitored with ECG screen monitor and blood oxygen saturation was monitored with a pulse oximeter. Monitoring continued throughout and following the procedures, and the data were recorded by the nurse every five minutes during the procedure and every 15 minutes during the recovery period up to at least 30 minutes until the patient was discharged from the ambulatory urological suite by the treating urologist. A formal cardiopulmonary resuscitation cart was available in the room with antidotes such as Flumazenil which is a selective benzodiazepine receptor antagonist.

Safety

Safety was defined as the absence of any of the following: a reason to provide CPR, an oxygen saturation <90%, an emergency call for anesthesia team, and hospitalization of the patient due to a complication attributed to the sedation/analgesia. The highest and the lowest blood pressure and heart rate measurements recorded during the procedure and throughout the recovery period were included in the analysis.

Efficacy

Efficacy was defined as the uneventful completion of the planned urological procedures. Reasons for stopping the procedures due to failed sedation/analgesia, such as pain, patient movement, etc., were recorded.

Clinical data collection

The compiled patient characteristics included age, sex, type of transurethral procedure and whether the procedure was performed in ambulatory or operating room settings. The documented procedure-related measures included the ASA score, the lowest and highest blood pressure and pulse rates, as well as the lowest oxygen saturation level during the sedation.

Patient's Self-Report of Pain/Discomfort

Following the recovery period and before discharge home or to the ward, the patients were asked to grade their pain level during the procedure using a Likert visual analog scale (VAS) where 0 = no pain and 10 = unbearable pain.

Statistics

Descriptive statistics of the study sample were used to summarize participant characteristics. ANOVA was used for comparison of two means between the two groups of sedation, i.e., midazolam alone and midazolam + ketamine. All tests were two-tailed, and statistical significance was defined as a p-level < 0.05.

Results

Data of 77 patients (51 men and 26 women) undergoing urological transurethral procedures with sedation/analgesia were analyzed. Five patients received 3-4 mg midazolam and the remaining 72 received 5 mg midazolam. 28 patients also received ketamine with dose range 10-25 mg. Table 1 summarizes the clinical characteristics of all the study patients. Table 2 summarizes the procedure-related measurements, and Table 3 displays the results of the midazolam alone group (n =49) compared to those of the midazolam + ketamine group (n = 28).

None of the patients indicated that they wanted to stop the procedure, and only six reported that it had been painful (level 1 = 4 patients, level 2 = 1 and level 4 =1).

Table 1 Procedures Suitable for Patient Controlled Sedation.

Characteristic	Patients, n
Age (yr)	
Mean (SD)	58.4 (17.1)
Median (IQR)	61 (50–73)
Gender	
Males	51
Females	26
Transurethral procedure	
Bladder biopsy	19
Cystoscopy	26
DJ stent insertion or replacement	30
Endoscopic urethral dilation	2
Patient status	
Hospitalized	30
Ambulatory	47

SD = standard deviation; IQR = interquartile range; DJ = double J.

Table 2 Procedure-related measures (n = 77).

Measure	Patients, n
ASA grading	
I	58.4 (17.1)
II	61 (50–73)
III	
Self-report pain score (0–10) (n=71)	
1	4
2	1
4	1
Highest blood pressure (mmHg)	
Mean (SD)	152.4 (20.6)
Median (IQR)	151 (140–168)
Lowest blood pressure (mmHg)	
Mean (SD)	123.5 (18.5)
Median (IQR)	124 (110–134)
Highest pulse (bpm)	
Mean (SD)	82.7 (15)
Median (IQR)	81 (72–91)
Lowest pulse (bpm)	
Mean (SD)	67.7 (10.1)
Median (IQR)	65 (60–74)
Lowest oxygen saturation (%)	
Mean (SD)	94.2 (2)
Median (IQR)	94 (93–96)

SD = standard deviation; IQR = interquartile range.

Table 3 Comparison between the midazolam alone group (n = 49) and the midazolam + ketamine group (n = 28).

	Midazolam alone	Midazolam + ketamine	p value
Age (yr) mean ± SD	59.1 ± 17.8	57.2 ± 15.9	0.647
Gender (n)			0.466
Males	31	20	
Female	18	8	
Transurethral procedure (n)			0.229
Bladder biopsy	9	10	
Cystoscopy	20	6	
DJ stent insertion or replacement	19	11	
Endoscopic urethral dilation	1	1	
Patient's status (n)			0.158
Hospitalized	27	20	
Ambulatory	22	8	
ASA grading (n)			0.261
1	17	14	
2	27	10	
3	5	4	
Pain score (0–5) (n)			0.122
0	45	26	
1	4	0	
2	0	1	
4	0	1	
Highest blood pressure (mmHg) mean ± SD	152.7 ± 21.2	151.8 ± 18.8	0.853
Lowest blood pressure (mmHg) mean ± SD	123.5 ± 18.8	123.4 ± 18.4	0.989
Highest pulse (bpm) mean ± SD	80.3 ± 15.1	87 ± 14.1	0.058
Lowest pulse (bpm) mean ± SD	67.5 ± 10.8	68.2 ± 8.8	0.762
Lowest oxygen saturation (%) mean ± SD	94.1 ± 2.1	94.4 ± 1.9	0.625

SD = standard deviation; DJ = double J; yr = year; *n* = number.

Discussion

Minimally invasive transurethral procedures may be associated with pain and discomfort for patients, particularly among younger ones [4]. Due to patients' lack of understanding of the details of cystoscopy, the procedure is commonly considered as being associated with anxiety and pain. Some patients may therefore be reluctant to undergo the procedure due to the fear and concern about the pain associated with transurethral insertion of instruments. Pain is a physiologic response to tissue irritation, but a patient's reaction to pain is also emotional and related to any number of psychological influences, among them the level of pre-procedural anxiety and recall of an unpleasant experience associated with cystoscopy in the past. As a result, a patient's behavior during a transurethral procedure is essentially unpredictable. In colonoscopy, for example, it is common practice to administer sedation [5].

Intravenous sedation/analgesia is considered safe and a cost-effective alternative to other forms of anesthesia. Birch et al. reviewed 1020 endourologic cases involving the use of midazolam as a premedication combined with local anesthesia, before various urological procedures. They considered that the preference of 93% of patients over conventional general anesthesia was a testimony to its high degree of acceptability. They went on to suggest that it may eliminate the need for the nursing and anesthesia team along with anesthetic equipment and, as such, reduce the cost of selected urologic procedures [6]. Gastroenterologists routinely sedate their patients for endoscopic evaluations [3], and our experience is that urologists can safely and efficaciously administer sedative analgesia when needed without the presence of an anesthesiologist.

Ketamine has been in medical use for more than four decades due to its dissociative sedation and analgesics effects, and it is recommended for day care ambulatory short anesthesia [7]. Midazolam is a short-acting, water-soluble benzodiazepine, with anxiolytic properties and limited cardiovascular effects that allows for speedy recovery, without post-procedural sequelae, such as nausea and vomiting [2]. The benefits of combining midazolam and ketamine make it especially attractive for children undergoing various procedures [8].

All the procedures performed on our study patients were accomplished as planned with no need for interruption due to complications. Specifically, none of the patients required CPR, the administration of an antidote, an emergency call for anesthesia team, or unscheduled hospitalization due to complications of the sedation/analgesia. Our results are in accordance with the results reported by Froehlich et al. in their study on patients undergoing colonoscopy [5]. They noted that the combination of low-dose midazolam and pethidine does not improve patient tolerance and pain perception during colonoscopy compared with either drug given alone, and concluded that the mode of sedation and analgesia should be based on the endoscopist's judgment. Hanno and Wein reported that the addition of meperidine does not augment significant analgesia or sedation to intravenous midazolam in men undergoing cystoscopy [9]. Contrary to our results, Kose et al reported their experience in 60 patients scheduled to outpatient transurethral procedures and were randomly assigned to receive midazolam-dexmedetomidine or ketamine-dexmedetomidine. Those authors concluded that while both combinations provided satisfactory sedation levels, the dexmedetomidine-ketamine combination provided better analgesia and hemodynamic stability, with less nausea and vomiting and shorter recovery time [10]. Similar to our results, the beneficial effects of combined ketamine and midazolam for transurethral procedures were reported by Attalah et al. in 1993 [11]. They conducted a double-blind study on 30 patients and concluded that ketamine produced satisfactory anesthesia and that the addition of midazolam did not change the cardiovascular parameters [11].

Our findings on the efficacy and safety of sedation/analgesia in our older patients were similar to those for our younger patients. Briggs et al. evaluated one hundred patients with a mean age of 78 years (range 59-97) and compared those under and over the age of 75 years and those with an ASA status of I and an ASA status of III or IV and concluded that elderly and medically unfit patients may be treated safely with no serious complications using sedation/analgesia [12].

The limitations of the present study are that our sample size is relatively small and the study was neither randomized nor blinded for patients and physicians. The choice of medication was made by the same team which administered the sedation/anesthesia, and no information on post-procedural analgesia requirement, if any, was available. We also did not have an untreated (no sedation) control group because we strongly believe that it is unethical to perform these procedures without some sedation/analgesia, although the level of pain experienced during diagnostic cystoscopy is reportedly low [4].

Conclusions

Sedation/anesthesia using midazolam and ketamine administered solely by the urologist without the involvement of an anesthesia crew is safe and effective for minimally invasive transurethral procedures in an ambulatory setting.

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Emergent Inter-Hospital, Direct Operating Room-to-Operating Room Transport of an Anesthetized Patient: A Case Report and Discussion

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Abstract

A 37-year-old healthy woman developed an intraoperative complication while undergoing a laparoscopic-assisted vaginal hysterectomy at a Women and Children's Hospital. Her external iliac artery was nicked, requiring emergent repair consisting of lateral wall suture-ligation to control hemorrhage. The artery was suture-ligated, and the patient was stabilized. The patient was then transferred under anesthesia to a nearby hospital equipped with a surgical intensive care unit and in-house vascular surgeon for comprehensive repair of the iliac artery. In preparation for transport, EMS was contacted, and the patient was given midazolam 2 mg IV and rocuronium 40 mg IV. An infusion of propofol 75 mcg/kg/min was administered under the supervision of an anesthesiology resident who remained with the patient during transport, and a portable mechanical ventilator provided by EMS was utilized. Standard ASA monitors were used throughout the ambulance transfer. In addition to standard emergency drugs, 2 units of packed red blood cells (pRBC), additional anesthetics (rocuronium, propofol & fentanyl), a laryngoscope and blades, an i-STAT® handheld blood analyzer, and a warming blanket were taken for transport. The patient was moved directly to the operating room upon arrival to the receiving hospital.

Keywords: emergency transport, critical care anesthesia, inter-hospital transfer, anesthesia transport guidelines, operating room-to-operating room transport.

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Introduction

The medical literature is rich with articles pertaining to the transport of critically ill patients from rural hospitals to larger, more-specialized medical centers [4,5]. These reports focus on basic transport guidelines [3,6], triaging [7], helicopter transport [8,9], and regulations [10]. Notably absent from current literature is a description of inter-hospital transport of an anesthetized patient to complete an emergency operation at a more specialized medical centre.

The incidence of inter-hospital transport of critically ill patients has increased during the past ten years [1,2]. This trend can be explained by the increasing numbers of ambulatory surgery centers located outside of urban centers, where advanced medical technology and specialized services are concentrated. Even with proper pre-operative management and careful selection of surgical candidates, unstable and life-threatening situations cannot be fully avoided. There are numerous instances of patients with unexpected complications who require transport to higher-level centers for specialized care (e.g. septic shock after elective intra-abdominal surgery, acute respiratory distress syndrome after blunt thorax trauma, lacerated artery requiring emergent graft repair). The following case outlines our approach to inter-hospital patient transport, with an emphasis on anesthetic considerations for a patient requiring emergent transfer intraoperatively due to a surgical complication.

Case Report

A 37-year-old healthy woman presented to a Hospital for Women and Children for a scheduled laparoscopic-assisted vaginal hysterectomy secondary to endometriosis and fibroids. Midazolam 1 mg IV was administered 15 minutes before the start of the case and anesthesia was induced without incident using propofol 140 mg IV. Following successful oro-tracheal intubation with direct laryngoscopy, mechanical ventilation was set, and the laparoscopic surgery proceeded as planned. After identification of the fibroid, a tenaculum was used to grasp the fibroid; however, the tenaculum clamp was noted to dislodge immediately. Upon visualization, the tooth of the clamp was noted retroperitoneally along with profuse bleeding in the left pelvis. Immediate intraoperative consult was made to a general surgeon and the case was converted to an open surgery. The general surgeon was able to identify the laceration of the left external iliac artery and repair the vessel while the gynecologist applied finger pressure to the laceration. At this time the patient was transfused with two units of packed red blood cells (pRBC's) due to blood loss estimated at 750 ml. Hemostasis was achieved and pulses were palpated above and below the repair site initially. At this point the surgery was continued with an open abdominal supracervical hysterectomy with right salpingo-oophorectomy. Upon reexamination of external iliac artery below the repair site, pulses were notably absent in the dorsalis pedis and posterior tibial artery. Biphasic doppler confirmed limited blood flow to the lower left leg and the patient was administered 5,000 units of heparin. A vascular surgeon was consulted at a specialized medical center and the surgeon agreed to accept the urgent transfer of care. Following the hysterectomy, the incision sites were closed and the patient was transported approximately 15 miles under general anesthesia for further evaluation by the vascular surgeon.

In preparation for transport, EMS was contacted, the patient was given rocuronium 40 mg IV, and midazolam 2 mg IV. An infusion of

propofol 75 mcg/kg/min was administered under the supervision of an anesthesiology resident who remained with the patient and monitored her throughout the ambulance transfer to the downtown hospital. In preparation for potential obstacles during transport, supplies were carried onto the ambulance, including four units of packed red blood cells on ice, phenylephrine, ephedrine, epinephrine, rocuronium, propofol, fentanyl, laryngoscopes and extra blades, empty syringes, an I-STAT, and a warming blanket. Additionally, there was a mechanical ventilator and standard ASA monitors provided by the EMS technicians. After arrival at the downtown hospital, handoff commenced in operating room between both anesthesia teams. Anesthesia was continued with the receiving medical team and the remainder of procedure – an interposition saphenous vein graft from the distal common iliac artery to the mid external iliac artery – commenced without incident. Postoperatively, the patient received one more unit of packed red blood cells and was transferred to the Surgical Intensive Care Unit (SICU) and eventually the floor. Post-op course was three days and unremarkable.

Discussion

The most recent guidelines for inter-hospital transport, published in Critical Care Medicine in 2004, have remained unchanged for the past decade [3]. These guidelines focus on patient transport from an emergency medicine perspective – discussing personnel, equipment and the decision to transfer. To our knowledge there exists no literature that documents patient transfer from an anesthesiologist's perspective. As noted earlier, we believe the need to transfer patients between operating rooms at different hospitals could see an upswing in the future with the centralization of specialized critical care.

The first step to inter-hospital transfer is performing a careful risk-benefit analysis of the situation. Obviously, certain life-saving surgeries can only be performed with specific equipment at a specialized medical center. However, in some cases, it may be safer from a patient perspective for a specialized surgeon to travel to the ambulatory surgery center to avoid patient transport. Before this happens though, a careful review of equipment at the ambulatory surgery needs to be evaluated. In addition, it is important to consider the post-op needs of the patient. In our case above, the decision to transport downtown was not only based on equipment but also the presence of a surgical intensive care unit at the specialized medical center where the patient could be monitored post-operatively. The hospital for women and children hospital does not contain an intensive care unit and thus the medical care team felt it was unsafe to perform the vascular repair.

In weighing the option to transfer a patient it also important to be cognizant of risks associated with transport. Although emergency transport services and equipment have improved over the past decade, the risks associated with both inter- and intra-hospital transport is well documented. The earliest study in patient transport from 1970 demonstrated arrhythmias in 84% patients transported with high-risk cardiac disease [11]. Another study in 1975 showed bleeding and hypotension in 7/33 patients undergoing intra-hospital transport [12] and a more recent study of 127 patients being transported to ICU showed mishaps (ECG lead disconnection, monitor power failure, IV disconnection, ventilator malfunction) occurring in 34% transports to ICU [13]. Wallen et al compared vital signs of patients 1 hour before transport and during transport to ICU and noted vital sign changes: most commonly blood pressure change (21.3%), heart rate change (15.7%), and hypothermia (11.2%) [14].

After determining the need to transport, the next step is acquiring the proper equipment, medications and personnel to transport the patient. The critical care guidelines for patient transport documents a list of the minimum equipment needed to transport [15]: cardiac monitor with defibrillator, airway management equipment, resuscitation bag (to allow for emergency intubation, coniotomy, and manual ventilation via mask and tube), sufficient gas supplies, battery operated infusion pump, and a portable ventilator for patients receiving mechanical ventilation. We support these recommendations with the addition of a portable clinical analyzer (e.g. i-STAT®) for rapid interpretation of electrolytes, blood gases, and blood cell counts, and warming blankets for the patient.

In terms of medications, Warren et al recommends 40 medications to be carried during emergency transport. While this list is certainly detailed, we have condensed this list to 21 essential medications to be carried by an anesthesiologist (Table 1). Considering the acute timing

Table 1 Our recommendations for anesthesia transport medications.

Warren Critical Care Guidelines [3]	Our essential anesthesia list
Adenosine, Albuterol, Amiodarone	Atropine, Dextrose (if diabetic), Diphenhydramine
Atropine, Calcium Chloride, Cetacaine/Hurricaine spray,	Ephedrine, Epinephrine, Fentanyl
Dextrose, Digoxin, Diltiazem	Glucagon (if diabetic and on insulin drip)
Diphenhydramine, Dopamine	Heparin, Labetalol, Midazolam or Lorazepam
Epinephrine, Fosphenytoin, Furosemide	Metroprolol, Morphine or Hydromorphone
Glucagon, Heparin, Isoproterenol	Normal Saline, Naloxone
Labetalol, Lidocaine, Mannitol	Nitroglycerine or Nitroprusside or Nicardipine
Magnesium Sulfate, Methyl Prednisolone	Packed RBC's (one unit per every 15 minutes of anticipated transport time)
Metoprolol, Naloxone, Nitroglycerin	Phenylephrine, Potassium Chloride
Nitroprusside, Normal Saline, Phenobarbital	Propofol or Dexmetomidine, Sodium Bicarbonate
Potassium Chloride, Procainamide, Sodium Bicarbonate	Succinylcholine
Terbutaline, Verapamil	Vecuronium or Rocuronium or Cisatracurium
To be added immediately before transport: narcotics (morphine, fentanyl), sedatives/hypnotics (lorazepam, midazolam, propofol, etomidate, ketamine), Neuromuscalar blocking (succinylcholine, rocuronium, atracurium), Prostaglandin E1, Pulmonary surfactant	

The left column is adapted from Table 1 of Warren et. al. 'Guidelines for the inter- and intrahospital transport of critically ill patients', *Critical Care Medicine*, 2004 [3]. The right column is our proposed list of essential medications needed by an anesthesia provider with the caveat that extra medications may be needed for certain comorbidities.

of such an emergency transport, we feel these 21 medications will cover a majority of situations encountered during transport under anesthesia. Additionally, we would like to make the recommendation to carry one standard 300mL packed red blood cell unit for every 15 minutes of anticipated transport in a patient at risk for blood loss.

Finally, in deciding whether an anesthesia provider is needed for direct transport of a patient under anesthesia it is important to consider limitations to EMT scope of practice. We have determined eight areas and skills where the presence of an anesthesia provider would be safer for the patient (Table 2) In reviewing current protocol for EMT delivery of medications there are a limited number of pre-approved medications that advanced EMT staff can deliver while medical direction is missing or off-line. This includes naloxone, glucose, bronchodilators using pre-measured or metered doses, epinephrine, and nitroglycerine [16]. These medications cover only a limited number of medical situations. Therefore, it is our belief that a licensed anesthesia provider should accompany patients with cardiopulmonary instability, those requiring blood products, or those with an increased risk of acute blood loss.

Table 2 Limits to EMT Scope of Practice.

Initiating or titrating infusions
Dosing mediations (EMT personnel must use auto-injectors or pre-dosed medications)
Starting blood product transfusions
Administering vasopressors (except for pre-dosed epinephrine)
Starting I.V. sedatives (i.e. midazolam)
Administering neuromuscular blocking agents
Gaining central intravenous or arterial access
Interpretation and management of blood chemistry, ABG, or ECG changes

Conclusion

Operating room-to-operating room transport of intubated patients under anesthesia carries many potential risks that may be better managed by anesthesia personnel. These events are underreported in the literature but may represent a growing trend due to the increasing number of ambulatory surgery centers and hospitals lacking specialized surgical services. We strongly recommended that a physician trained in airway management and ACLS accompany transfers of potentially unstable patients.

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Commentary: Ambulatory Surgery Centres are Well Suited for Clinical Research

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Introduction

The health care industry has witnessed a substantial rise in the volume of surgeries and medical procedures being performed in ambulatory surgical centres [1]. While this shift in surgical management often has been linked to technological improvements and an enhancement of administration of anaesthetic drugs, as well as the need to reduce the overall costs of medical treatment, it has also brought forward a shift in patient management and the possibility of monitoring patient progress in clinical trials.

Traditionally we are used to clinical trials in an in-patient setting with volunteers often waiting days or weeks for the approval and implementation of a planned procedure. The planned activities will be subject to delays due to a multitude of reasons; emergency cases taking priority in the OR, lack of OR staff members, hospital policy or a depletion of hospital funding. In addition, there will be a variety of medical professionals involved. This implies that people with different sets of surgical skills and medical know how to perform the actual treatment. Unless the number of patients treated in the trial is substantially high, this will create a bias in the measured outcome. Chowdhury and co-workers reflect on this in a systematic review in the British Journal of Surgery in 2007, in which over 55000 articles were reviewed between 1957 and 2003, where they conclude that high surgeon volume and specialization are associated with improvement in patient outcome [2]. In addition to this ambiguous setting, the cancellation of elective surgery in tertiary level hospitals may still be high in a global perspective with up to one fifth of scheduled cases being postponed on the day of surgery [3].

Why are ambulatory surgery centres well adapted to clinical research?

In the ambulatory surgery centre the elective surgery is made a priority, and scheduled surgery will usually go as planned due to reliable patient pre-assessment plans [4] and a minimum of interference from outside the operating room. The benefit of treating otherwise "healthy" patients with little or no co-morbidities is an obvious cause of controlling research confounding.

This creates an ideal environment for real life clinical research trials. In contrast to large hospital based trials that need to single out certain traits or construct a specific scenario in which two or more treatments are compared, the ambulatory surgery trials will focus on quality assessments and clinical parameters that are not constructed for the sake of a research project. In this regard, ambulatory research has an aura of quality assessment about it and the results are usually very reliable due to small teams with one or two specialized surgeons, a dedicated staff in both the OR and the recovery room that has extensive experience in the procedures that are performed. Furthermore, the ambulatory centres have made elective surgery a clear priority with few unexpected procedure dropouts or cancellations on the day of the surgery [5].

What types of research are suitable in such a setting? I think it is fair to say that interventions that are time consuming or revolves around patients with rare diseases that generate extra hours of labour for the staff at hand are less suited for ambulatory research. Large observational case-control studies and time consuming prospective cohort studies are probably difficult to conduct due to the amount of follow up time required by such studies. The ambulatory setting will rather attract those type of studies where the intimate relationship between the patient population and the researchers facilitates a better coordination than what can be achieved in a large scale hospital setting. Put simply, the ambulatory setting offers a more streamlined approach to clinical real life research due to greater control over procedures and patient logistics. Experimental interventional studies that involve pre- and postoperative medical interventions, randomized prospective trials involving medical or surgical interventions or trials of new technology/innovations within the pre-, per- or postoperative phase can be done reliably, relatively quickly and without spending the entire department budget in doing so.

In my department there are a total of four operating rooms, and the recovery unit can handle around fifteen patients when all the ORs are in use. There are three research projects currently running. Two prospective trials within ENT [6, 7] and one randomized controlled and prospective trial on hypothermia during surgery (data not yet published). Up to this point, all patients have had their procedures done without prolonging the pre- or postoperative time spent at the daycare unit. The main reason for the seemingly effortlessly patient logistics is in my opinion the less institutionalized environment and the high volume of same surgery procedures that keep the staff well prepared and trained at all times.

Future concerns?

Are there any concerns that should be addressed? Of course there is the matter of financing. There is no shortage of funding institutions, but so far there seems to be a tendency to give credits to the already established research communities affiliated with university clinics, making it harder for smaller ambulatory centres to get grants. Some private ambulatory hospitals have solved this by setting aside part of their revenue to establish their own research fund in accordance with the rules of good clinical research practice (GCP). Aleris Hospital, Scandinavia's largest chain of private health care companies, made a trial research fund of 1 million pounds from 2013-16 which became an instant success. This year the fund was made permanent, donating 250 000 pounds a year to applicants that fulfil the guidelines of GCP.

Another concern is the time the researchers themselves spend on documenting the projects. The researchers are usually members of the staff, doctors or nurses that spend some of their free time on their projects. Even though some clinics have established grants enabling their staff to do research, there is still a lack of standardized protocols within the ICT systems that can facilitate outcome measures and make it easier to collect biometric information.

Conclusion

Ambulatory surgery centres are ideal for real life clinical research given that the funding of the research is established. Experimental studies, both non-randomized and randomized, can be performed due to high surgeon volume and smaller settings that are key to improved efficacy and good clinical trials.

Key points

- Experimental studies suitable for ambulatory surgery centers, less suited for large scale observational studies on rare diseases
- High surgeon volumes and specialized staff of key importance
- There is a lack of reliable funding for researchers as well as reliable ICT systems for research purposes

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