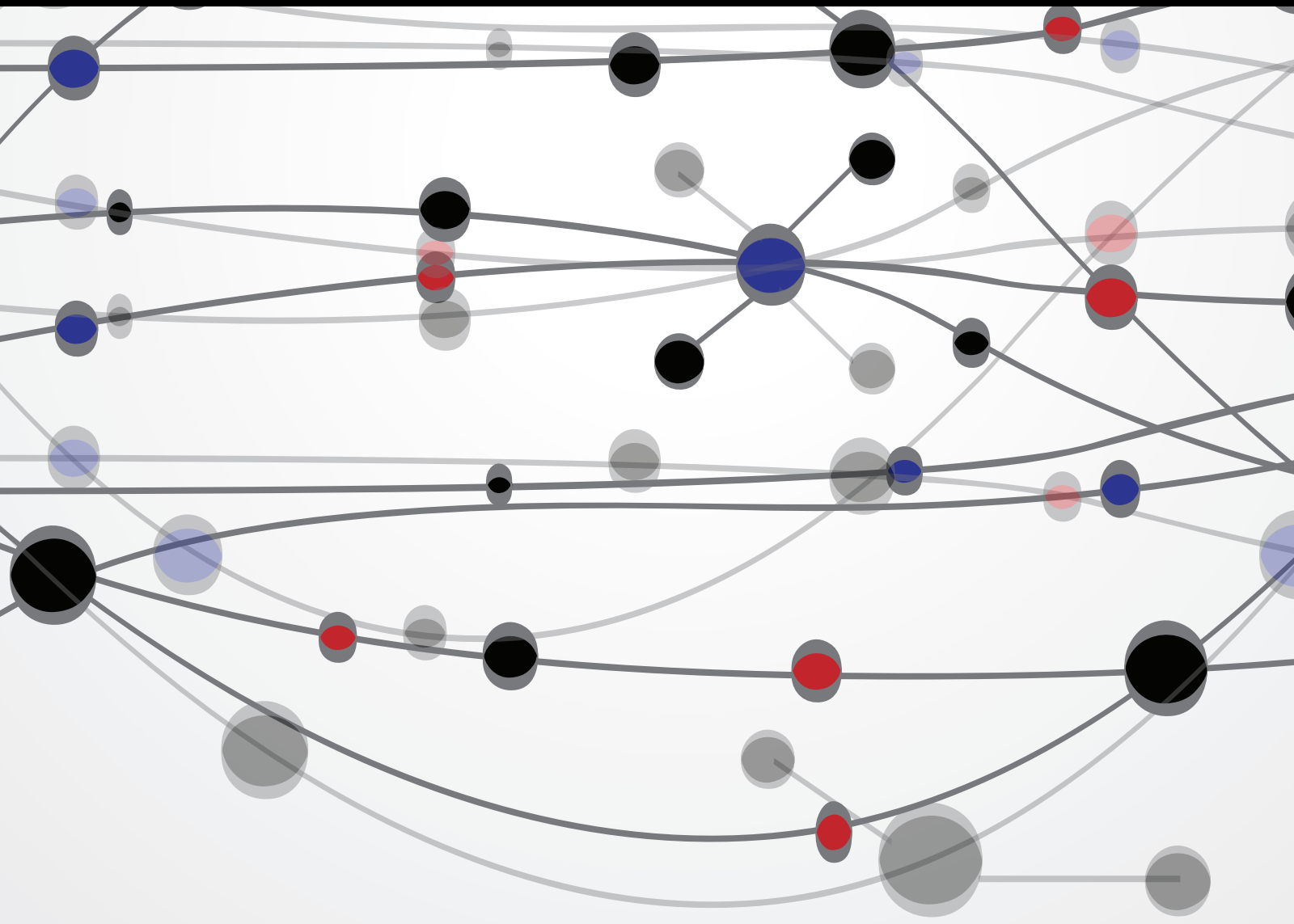
The Scientific World Journal

Comparison of the Anesthetic Techniques

Guest Editors: Ahmet Eroglu, Alparslan Apan, Engin Erturk, and Izhar Ben-Shlomo



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Contents

Editorial

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A great number of anesthetic techniques (general, regional, spinal, epidural, caudal, hypotensive, total intravenous, regional intravenous, inhalation, and nerve blocks) can be used for multiple surgical procedures [1–3]. The effect of anesthetic technique on perioperative outcomes is controversial.

Central neuraxial blocks including spinal, epidural, and caudal anesthesia are regional anesthesia techniques. Regional anesthesia techniques provide important advantages compared with general anesthesia in some surgical procedures [1, 3]. Regional anesthesia is not only performed for adequate anesthesia in the surgical procedures. There are other advantages for the use of regional anesthesia techniques including excellent pain control, reduced side effects, decreased blood loss, improved cardiac and pulmonary function, and shortened stay in the postanesthesia care unit [1–4]. Low doses of spinal anesthesia and intra-articularly administered analgesic provided a better pain relief, a shorter discharge time, and a higher satisfaction for outpatient arthroscopic knee surgery [2]. Epidural technique as a regional anesthesia is one of the important methods for multimodal postoperative pain control [1, 3]. Hypotensive epidural anesthesia is another technique that decreased blood loss in hip surgeries [1]. Caudal anesthesia is commonly performed in pediatric patients for surgical anesthesia and postoperative analgesia. Regional anesthesia would provide excellent pain control and improve outcomes such as decrease in side effects, improvement of pulmonary function, prevention of chronic pain, or reduction in hospital stay. Thus the regional anesthetic techniques and outcome using regional anesthesia for postoperative pain have becoming one of the important fields [4, 5].

Total intravenous anesthesia (TIVA) has been used in some surgeries and it has been compared with other anesthesia techniques. TIVA with propofol can make a positive contribution to preventing ischemia-reperfusion-associated increases in MDA and IMA in tourniquet-related ischemia reperfusion in arthroscopic knee surgery. In scoliosis surgery, the use of TIVA with propofol and remifentanil is associated with decreased neuroendocrine stress responses in the perioperative period when compared with inhalation anesthesia.

Regional intravenous anesthesia (RIVA) is generally preferred for patients who will have upper extremity surgery due to advantages such as providing a blood-free surgery site, rapid onset and termination of the anesthetic effect, lack of necessity of severe sedation, and general anesthesia and easy application. In addition some analgesic drugs to local anesthetics in intravenous regional anesthesia (IVRA) have been published. The addition of 3 mg/kg paracetamol and 50 mg dexketoprofen to lidocaine as adjuvant in RIVA applied for hand and/or forearm surgery created a significant difference clinically.

Nerve blocks are used for postoperative analgesia. Interscalene brachial plexus block (ISB) is used to provide both anesthesia and analgesia for shoulder surgery. In a study the authors showed that the same volume and concentration of bupivacaine and ropivacaine (30 mL of 0.5%) for interscalene brachial plexus block anesthesia produced similar surgical block. When continuing the block with a patient-controlled

interscalene analgesia infusion, 0.15% bupivacaine and ropivacaine provided adequate pain relief, similar side effects, and high patient satisfaction after shoulder surgery.

This special issue contains five clinical studies and a review article related to comparison of anesthetic techniques. In the review article the benefits and risks of hypotensive anesthesia during major maxillofacial surgery were compared to those of normotensive anesthesia. The authors reported that controlled hypotension during anesthesia or hypotensive anesthesia is often used in major maxillofacial operations. Reduced blood pressure is advantageous in some settings because it can contribute to a reduction in overall blood loss and improve the surgical field conditions. Since hypotensive anesthesia carries the risk of hypoperfusion to important organs and tissues, mainly the brain, heart, and kidneys, it cannot be applied safely in all patients.

In a clinical study, spinal and general anesthesia were compared for the impact of the surgical environment, especially the sounds of saw and hammer in the operating room, on patient's mood and anxiety after the operation in total knee arthroplasty (TKA). It was reported that sounds of hammer and saw had no evident negative effect on patient's mood and, in operations performed with spinal anesthesia, the patients were found to be more satisfied so that, with known advantages, regional anesthesia was advisable for TKA patients and appropriate sedation can be administered during the operation if needed.

Two clinical studies are related to the comparison of supraglottic airway devices. The aim of a clinical study was to compare the performance of recently released size 1 I-gel with size 1 ProSeal LMA, which is proven to be superior to the classical LMA for small infants and neonates. The study demonstrated that the size 1 I-gel provided an effective and satisfactory airway as the size 1 ProSeal LMA. It may be a good alternative supraglottic airway device for use in small infants and neonates. However, further studies are needed to determine whether it is reliable for aspiration because of the absence of a gastric drainage tube in this size. Another study compared ProSeal, Supreme, and I-gel supraglottic airway devices in terms of oropharyngeal leak pressures and airway morbidities in gynecological laparoscopic surgeries. It was reported that ProSeal, Supreme, and I-gel provided a safe airway in paralyzed and pressure-controlled ventilation administered gynecological laparoscopic surgeries. While initial oropharyngeal leak pressures obtained by I-gel were lower than ProSeal and Supreme, increased oropharyngeal leak pressures over time, ease of placement, and lower airway morbidity were favorable for I-gel.

The local anesthetics used in day-case spinal anesthesia should provide short recovery times. In a clinical study hyperbaric prilocaine and bupivacaine were compared in terms of sensory block resolution and time to home readiness in day-case spinal anesthesia. In the study it was reported that day-case spinal anesthesia with prilocaine 30 mg + 20 μg fentanyl provided faster sensory block resolution and home readiness compared to 7.5 mg bupivacaine + 20 μg fentanyl and the surgical conditions were comparable for perianal surgery.

Dislocation of epidural catheters (EC) may cause early termination of postoperative regional analgesia. In a clinical study the hypothesis that maximum effort in fixation by catheter tunneling and suture decreases the incidence of its dislocation was tested. It was reported that thorough tunneling and suture of thoracic epidural catheters significantly reduced incidence and extent of catheter dislocation and potentially that of bacterial contamination.

The outcomes of the comparison of anesthetic techniques are multifarious. In the future more researches are needed to explain the potential mechanisms for these outcomes.

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Review Article

Hypotensive Anesthesia versus Normotensive Anesthesia during Major Maxillofacial Surgery: A Review of the Literature

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Steady blood pressure within normal limits during surgery is one of the markers of the ideal and skillful anesthesia. Yet, reduced blood pressure is advantageous in some settings because it can contribute to a reduction in overall blood loss and improve the surgical field conditions. Controlled hypotension during anesthesia or hypotensive anesthesia is often used in major maxillofacial operations. Since hypotensive anesthesia carries the risk of hypoperfusion to important organs and tissues, mainly the brain, heart, and kidneys, it cannot be applied safely in all patients. In this paper we review the medical literature regarding hypotensive anesthesia during major maxillofacial surgery, the means to achieve it, and the risks and benefits of this technique, in comparison to normotensive anesthesia.

1. Introduction

Blood pressure is one of the essential vital signs that are monitored by health care professionals in modern medicine. In general, a normal blood pressure is an indicator of preserved cardiac output and good organ perfusion, and management of the patient often focuses on maintaining a normal blood pressure. Therefore, maintaining a patient's stable blood pressure within normal limits during surgery (normotensive anesthesia) is one of the indices of skillful anesthesia, and normotensive anesthesia is usually considered to be the gold standard for anesthesia.

The strategy of lowering the patient's blood pressure or controlled hypotension during anesthesia (hypotensive anesthesia) has been practiced for decades [1–5]. The physiological principle which underlies hypotensive anesthesia is a natural survival mechanism. When profuse bleeding occurs, the blood pressure drops. This drop leads to a reduction or cessation of the bleeding, blood pressure stabilization, and recovery. Accordingly, reducing the patient's blood pressure during surgery can potentially reduce overall bleeding. Since bleeding in the surgical field is also reduced, the surgical field operating conditions are improved.

The indications for hypotensive anesthesia are the surgical site, the course and extent of the surgery, and the patient's general condition. Hypotensive anesthesia is considered to be a suitable anesthetic technique for those patients who will be undergoing spinal surgery, hip or knee arthroplasty, craniosynostosis, hepatic resections, robotic surgery, and major maxillofacial operations [6–11]. However, the use of hypotensive anesthesia is associated with the risk of reduced perfusion to important organs and tissues, mainly the brain, heart, and kidneys [12, 13]. Thus, the hypotensive technique is potentially unsafe in some patients and is not suitable for all.

In this paper, we describe the means to achieve hypotensive anesthesia and compare the benefits and risks of hypotensive anesthesia and normotensive anesthesia during major maxillofacial operations.

2. Target Blood Pressure in Hypotensive Anesthesia

There are specific values that define normal blood pressure; nevertheless, "hypotension" is not an absolute term. Each individual has a range of blood pressures to which the individual's body is accustomed and within which it functions optimally. This range is considered "normal" for that individual. Thus, a patient whose blood pressure is usually at the lower range requires lower blood pressures than a hypertensive one. For normotensive anesthesia, the patient's blood pressure is maintained at levels that are within the range of blood pressure levels that were measured preoperatively. In hypotensive anesthesia, the patient's baseline mean arterial pressure (MAP) is reduced by 30% [14]. Consequently, the systolic blood pressure values are about 80–90 mm Hg and the MAP is reduced to 50–65 mm Hg [15].

3. Intraoperative Blood Loss in Normotensive and Hypotensive Anesthesia

Surgical procedures of the head and neck have a propensity to bleed profoundly because the region's blood supply is rich. These procedures are often extensive and prolonged thus inducing significant blood loss. The extent of intraoperative blood loss in normotensive and hypotensive anesthesia during maxillofacial operations has been compared in several clinical trials. Praveen et al. [16] conducted a prospective randomized clinical trial in which patients, who underwent orthognathic surgery, were randomly allocated to undergo these surgeries under normotensive or hypotensive anesthesia. They reported that the extent of intraoperative blood loss in those operations that were done under hypotensive anesthesia was substantially less than that in those operations that were done under normotensive anesthesia. These findings have been confirmed by others [10, 17–19]. Since intraoperative blood loss is reduced under hypotensive anesthesia, the need for allogeneic blood transfusion and its risks, namely, postoperative infection, acute lung injury, postoperative cardiac failure, tumor recurrence, perioperative myocardial infarction, and increased mortality [20], is also reduced.

4. Surgical Field Conditions in Normotensive and Hypotensive Anesthesia

Evaluation of the surgical field conditions is subjective and difficult to measure because the appraisal relies solely on the surgeon's assessment of the conditions. The duration of the surgery may be used as an objective indicator for surgical field conditions because the duration of an operation which is conducted under poor surgical field conditions may be longer than the one which is conducted under good surgical field conditions. The results of trials whose aim was to study the difference in surgical field conditions in major maxillofacial operations in hypotensive and normotensive anesthesia found that the surgical field conditions are better under hypotensive anesthesia than those under normotensive anesthesia despite the fact that there is no significant difference in the durations of the procedures [17, 21, 22].

5. Protocols for Hypotensive Anesthesia

Through the years, a multitude of drug combinations and protocols for hypotensive anesthesia have been suggested and compared. The two main strategies for achieving hypotensive anesthesia are (a) deep anesthesia and heavy analgesia and (b) standard anesthesia and administration of hypotensive drugs. By deepening the anesthetic plane and using high doses of analgesics, such as opioids, the recovery time may be prolonged. On the other hand, administering a hypotensive agent to a patient who is anesthetized using a standard anesthetic protocol may result in postoperative hypotension. In practice, the two strategies are used to achieve controlled hypotensive anesthesia. In the next section, we will discuss some of the anesthetic agents, analgesics, hypotensive drugs, and nonpharmacological methods that have been used for achieving hypotensive anesthesia.

5.1. Volatile Anesthetic Agents. Most anesthetic agents have a hypotensive effect: the blood pressure of a patient under general anesthesia is lower than that of same conscious patient. The volatile anesthetic agents, such as isoflurane, sevoflurane, and desflurane, have a potent vasodilator action, and this property can be exploited to reduce blood pressure by increasing the agent's concentration when administered to a patient. It has been reported that isoflurane, sevoflurane, and desflurane are each equal in their ability to reduce blood pressure [23, 24]. However, when volatile anesthetics are used alone, high concentrations are required to achieve a significant reduction in intraoperative bleeding, and these concentrations may lead to hepatic or renal injury. In addition, the volatile-mediated reduction in blood pressure is not meticulously controlled. The unwanted effects of these agents, such as nonthermoregulatory shivering and headaches, are to be expected during the postoperative period in patients recovering from isoflurane, sevoflurane, or desflurane anesthesia.

5.2. Propofol. Propofol, a widely used intravenous anesthetic agent, has a potent hypotensive capability. Accordingly, propofol has been used for achieving hypotensive anesthesia when administered as part of total intravenous anesthesia. Furthermore, normal blood pressure will be rapidly restored when the propofol infusion is discontinued. Although a short-term propofol infusion is safe, a long-term propofol infusion can cause propofol infusion syndrome in children [25, 26]. Ankichetty and colleagues compared using propofol to isoflurane for hypotensive anesthesia and found no significant difference in intraoperative blood loss and operative conditions [27]. Early postoperative complications following orthognathic operations that were conducted under hypotensive anesthesia were studied by Tabrizi and colleagues [28]. They found that total intravenous anesthesia using propofol offers no significant advantage over isoflurane-based anesthesia in terms of early postoperative complications, such as pain, nausea, vomiting, shivering, and agitation.

5.3. Alfentanil, Sufentanil, and Remifentanil. Alfentanil, sufentanil, and remifentanil are potent synthetic and short-acting opioid drugs of the anilidopiperidine family whose use has increased during the past three decades [29–32]. Alfentanil, a derivative of fentanyl, has a quicker onset and shorter duration of action than fentanyl and its vagomimetic properties are more intense than those of fentanyl and sufentanil. Sufentanil is a more potent analgesic than fentanyl and seems better than the other opioid analgesics, such as morphine or meperidine, in maintaining hemodynamic stability during surgery. Remifentanil is a potent mu-opioid receptor agonist that is rapidly metabolized by nonspecific blood and tissue esterases. According to its unique pharmacokinetic profile, remifentanil-based anesthesia combines high dose opioid intraoperative analgesia with a rapid and predictable postoperative awakening, which is independent of the duration of the infusion. When used for hypotensive anesthesia, each of these three drugs is equally effective in achieving hypotensive anesthesia for the required duration [33–35]. Since the recovery times from this type of anesthesia are also short, they are widely used for hypotensive anesthesia.

6. Hypotensive Drugs

Reducing blood pressure could be achieved in various ways that differ in the physiologic mechanism, duration, and side effects. The ideal hypotensive drug for inducing hypotensive anesthesia should be easy to administer, with a short onset time; its dose can be meticulously controlled; its effect disappears quickly when its administration is discontinued; it has a rapid elimination and causes no unwanted or adverse effects. In addition, it is important to match the drug with the patient's general condition, diseases, and daily medications.

Many hypotensive drugs with different mechanism and duration of action have been investigated for achieving hypotensive anesthesia [15]. These hypotensive drugs may be used alone or may be used in combination in order to limit the dose of each drug and minimize the occurrence of adverse effects of the other agents. The drugs that are used for hypotensive anesthesia include sodium nitroprusside (SNP), nitroglycerin (NTG), trimethaphan, calcium channel antagonists (e.g., nicardipine), β-adrenoceptor antagonists (e.g., propranolol and esmolol), angiotensin converting enzyme (ACE) inhibitors, and α_2- adrenoceptor agonists (e.g., clonidine and dexmedetomidine). In addition to these agents, fenoldopam, adenosine, and alprostadil are new hypotensive drugs, which are currently being evaluated in settings that are not related to hypotensive anesthesia and are not yet in widespread clinical use. In the next section, we will discuss some of the hypotensive drugs that are commonly used in the protocols for hypotensive anesthesia.

6.1. Nitrates. SNP and NTG are two very potent hypotensive agents that are commonly used for inducing hypotensive anesthesia [15, 36]. The mechanism of their hypotensive action is rapid onset vigorous vasodilatation, which is mediated by nitric oxide. The main difference between SNP and NTG lies in their effect on the coronary blood flow. In addition, SNP is arterio- and venodilator, while NTG is mainly venodilator. Yoshikawa et al. [37] compared SNP and NTG administration for hypotensive anesthesia in patients who underwent mandibular osteotomy and reported that the extent of intraoperative blood loss is similar.

Both SNP and NTG can cause blood pressure to plunge following their intravenous administration due to a lowering of total peripheral resistance and/or venous return. The administration of SNP and NTG should be titrated carefully using a syringe pump because of the risk for accidental severe hypotension. The hypotensive action of nitrates can be quickly stopped by discontinuing its infusion. Reflex tachycardia is an unwanted effect which often occurs with nitrates administration and can be prevented by a small dose of a β-adrenoceptor antagonist, such as esmolol [38] or propranolol premedication [39].

6.2. β-Adrenoceptor Antagonists. The β-adrenoceptor antagonists have been effectively used for inducing hypotensive anesthesia for maxillofacial operations when administered either as a single hypotensive agent or in combination with SNP [37, 38, 40]. There are several β-antagonists in clinical use, and they differ in their duration of action and their selectivity for β-adrenoreceptors. The less selective β-antagonists, such as labetalol, may cause bronchoconstriction and are to be avoided in asthmatic patients [15]. The hypotensive action of β-adrenoceptor antagonists is achieved by reducing cardiac output. Accordingly, these drugs are not suitable for patient with underlying heart failure. When administration of the drug is stopped, reflex tachycardia can occur.

6.3. Calcium Channel Antagonists. Calcium channel antagonists, such as nifedipine or nicardipine, are commonly used hypotensive drugs. Kim and others [41] tested the hypothesis that the adverse effects of hypotensive anesthesia on renal function can be prevented by a continuous nicardipine infusion. In order to test this hypothesis, they measured the blood levels of biomarkers for subclinical and reversible renal dysfunction that appear during hypotensive anesthesia for orthognathic surgery that was induced by either a continuous nicardipine infusion or a combination of desflurane-induced anesthesia and remifentanil. They found that both anesthetic protocols increased the blood levels of the biomarkers, though the increase was less in those patients to whom nicardipine was administered [41].

7. Nonpharmacological Means for Achieving Hypotension

7.1. The Anti-Trendelenburg Position. Hypotension in the anesthetized patient can be easily achieved by placing the patient in a head-up or anti-Trendelenburg position because of orthostatic or postural hypotension results. This positioning is frequently used for hypotensive anesthesia and normal blood pressure can be quickly restored by repositioning the patient [42]. When using this method, one should remember

that the patient's response to the head-up tilt is inconsistent and depends on the patient's cardiac output [43].

7.2. Acute Normovolemic Hemodilution (ANH). ANH is accomplished by drawing a unit or two of the patient's blood either immediately before or shortly after the induction of anesthesia and simultaneously replacing it with a cell-free fluid, preferably a synthetic colloid solution [44, 45]. In this setting, the patient bleeds "diluted" blood (the number of red blood cells in the blood is reduced), and upon completion of the surgery, the autologous blood is retransfused back to the patient. Consequently, when the patient bleeds during the operation, the volume of red blood cell loss is decreased. ANH is to be considered in patients who (a) are undergoing major elective surgery, (b) presenting with an initial hemoglobin concentration which is greater or equal to 12 g/dL, and (c) will have an anticipated blood loss of more than or equal to 1500 mL [43]. ANH has been used for decades in major operations [46–48] and is considered to be a part of a blood conservation strategy which reduces or limits the need for allogeneic blood transfusion during surgery [49, 50]. Adverse effects which can occur during ANH are hemodynamic changes, such as a decreased cardiac output [51, 52].

Although ANH can be a part of normotensive or hypotensive anesthesia, the procedure often results in a reduced blood pressure. Ervens et al. compared three anesthetic protocols, namely, normotensive anesthesia, hypotensive anesthesia, and hypotensive anesthesia combined with ANH, in a surgeon-blinded trial of 60 patients who required either a Le Fort I osteotomy or a bimaxillary surgery [18]. They reported that the extent of intraoperative blood loss and the requirements for an allogeneic blood transfusion were substantially reduced in those patients who underwent hypotensive anesthesia. They also reported that hypotensive anesthesia combined with ANH had no additional blood-sparing effects or surgical field quality improvement in orthognathic surgery.

8. Patient Selection for Hypotensive Anesthesia

Hypotensive anesthesia is not suitable for all patients because reducing the blood pressure is potentially unsafe in some patients. Patients with disseminated vascular disease, in whom atheromatous vessels provide perfusion to the organs, may suffer from hypoperfusion during hypotension, with the brain and heart at the highest danger to be injured. Patients with ischemic heart disease [53, 54] or carotid artery stenosis [55, 56] are at highest risk for clinically significant hypotension-induced injury following hypotensive anesthesia. These patients are candidates for normotensive anesthesia or, in selective cases, minor reduction in blood pressure, the so-called "modified hypotensive anesthesia", adjusted to their condition.

Another group of patients whose risks of hypotensive anesthesia are high are hypertensive patients, because the functions of their vital organs are adjusted to their usual high blood pressure. These patients are sensitive to reduced pressure and are at high risk for the occurrence of perioperative complications. In addition, hypertensive patients often have contracted blood volume and are extremely susceptible to vasodilatation [57]. If hypotensive anesthesia is to be used in a hypertensive patient, the patient should be closely monitored and managed with great caution because of the risk of a profound and rapid decrease in blood pressure due to the action of the hypotensive drugs. In addition, the patient should be given appropriate volume replacement prior to commencing hypotensive anesthesia.

Reduced blood pressure during surgery may result in transient tubular dysfunction in patients with normal preoperative renal function [35], and the use of hypotensive anesthesia may exacerbate renal function in patients with a known preoperative kidney disease. It is important to remember that the renal functions are affected mainly by the cardiac output and the blood flow in the splanchnic circulation and not by systemic arterial pressure. Thus, blood pressure measurements may not accurately indicate the actual renal perfusion pressure. In the study that we previously cited [41] the authors found that the use of nicardipine, a calcium channel antagonist, had a subtle protective effect on the kidneys during hypotensive anesthesia for maxillofacial surgery.

In the future, we anticipate studying new drugs which will induce hypotension without impairing the perfusion and function of vital organs.

9. Type of Maxillofacial Operation

Operations in the maxillofacial region require precise, accurate, and delicate surgery of the hard and soft tissues. The head and neck region is abundantly vascularized; this is a great advantage regarding healing and regeneration; yet it can be a major cause of severe life threatening bleeding during surgery. Several operations are at increased risk for extensive bleeding, including Le Fort osteotomies [58–60], maxillectomy for tumor resection, tumor resection from the tongue and floor of the mouth, and neck dissections [4, 5]. In all these procedures, hypotensive anesthesia is needed in order to reduce intraoperative bleeding in the surgical field, maintain the surgical plane, avoid unnecessary damage to the vital structures and tissues, and execute the required surgical procedure. It is important to identify procedures in which high blood loss is expected and restrict hypotensive anesthesia technique usage to these procedures and for the patients who are most likely to benefit by that.

9.1. Hypotensive Anesthesia and Maxillofacial Trauma. The use of hypotensive anesthesia in trauma patients is relatively new and controversial [61, 62]. In urgent or emergent operations of trauma patients, where there is major trauma to the face and neck, severe uncontrolled bleeding is possible, mostly in surgeries that involve more than two thirds of the face, panfacial trauma. Naturally, in a longer and more extensive procedure, the bleeding is more pronounced and controlling it is more difficult. In such cases the application

of hypotensive anesthesia may be useful. Nonetheless, trauma patients with facial injury often have other injuries, such as head trauma. A hypotensive approach may limit further bleeding but could aggravate any existing brain injury. The management of these patients, including their target blood pressure, should take into account all involved injuries. The ideal approach to these complex patients requires further investigation.

10. Conclusions

Patients who undergo major maxillofacial surgery are at risk of considerable intraoperative bleeding, and the outcome of the surgical procedure depends on the quality of the surgical field conditions. Since hypotensive anesthesia can reduce the extent of intraoperative bleeding and can potentially improve the quality of the surgical field conditions, hypotensive anesthesia is considered to be beneficial during these procedures. However, hypotension carries the risk of hypoperfusion in vital organs and is unsafe in certain patients. Thus, the magnitude of the blood pressure reduction should be adjusted to the patient's general condition, age, and existing diseases. Normotensive or modified hypotensive anesthesia should be used for patients with ischemic heart disease, carotid artery stenosis, disseminated vascular disease, kidney dysfunction, or severe hypertension who are scheduled to undergo a major maxillofacial operation.

Appropriate patient selection, careful monitoring, and adequate intraoperative volume replacement are mandatory in hypotensive anesthesia for its safe implementation in patients who are scheduled to undergo a major maxillofacial operation.

Conflict of Interests

The authors declare that there is no conflict of interests regarding the publication of this paper.

Authors' Contribution

All three authors contributed in the preparation of this paper.

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Clinical Study

Comparison of the Proseal, Supreme, and I-Gel SAD in Gynecological Laparoscopic Surgeries

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We compared proseal, supreme, and i-gel supraglottic airway devices in terms of oropharyngeal leak pressures and airway morbidities in gynecological laparoscopic surgeries. One hundred and five patients undergoing elective surgery were subjected to general anesthesia after which they were randomly distributed into three groups. Although the oropharyngeal leak pressure was lower in the i-gel group initially (mean ± standard deviation; 23.9 ± 2.4, 24.9 ± 2.9, and 20.9 ± 3.5, resp.), it was higher than the proseal group and supreme group at 30 min of surgery after the trendelenburg position (25.0 ± 2.3, 25.0 ± 1.9, and 28.3 ± 2.3, resp.) and at the 60 min of surgery (24.2 ± 2.1, 24.8 ± 2.2, and 29.5 ± 1.1, resp.). The time to apply the supraglottic airway devices was shorter in the i-gel group (12.2 (1.2), 12.9 (1.0), and 6.7 (1.2), resp., $P = 0.001$). There was no difference between the groups in terms of their fiber optic imaging levels. pH was measured at the anterior and posterior surfaces of the pharyngeal region after the supraglottic airway devices were removed; the lowest pH values were 5 in all groups. We concluded that initial oropharyngeal leak pressures obtained by i-gel were lower than proseal and supreme, but increased oropharyngeal leak pressures over time, ease of placement, and lower airway morbidity are favorable for i-gel.

1. Introduction

The use of supraglottic airway devices (SAD) with a gastric emptying tube in gynecological laparoscopic surgeries is growing. In addition to their ease of placement, they have low airway morbidity along with sufficient airway pressure in the trendelenburg position and so they have been determined as an alternative to endotracheal tube [1, 2].

The proseal SAD (LMA Proseal, Laryngeal Mask Company Ltd., Henley-on Thames, UK) is reusable, supraglottic airway device made of silicon and has a gastric emptying tube and inflatable pharyngeal cuff [3, 4]. The supreme SAD (LMA, Laryngeal Mask Company Ltd., Henley-on Thames, UK) is a single-use inflatable airway device with an ellipsoid semihard head made of medical silicon and gastric emptying tube in addition to the ventilation tube. The i-gel SAD (Intersurgical, Wokingham, UK) is a single-use, hard, supraglottic airway device with a mouth stabilizer resistant to biting, a gastric emptying tube, and a noninflatable elastomer structure head. Proseal SAD has an infection risk due to the fact that it can be used multiple times and therefore should be cleaned and sterilized after each use; this also poses a cost disadvantage. Supreme and i-gel, however, are single-use devices and therefore advantageous [5].

The number of studies comparing these techniques is scarce, and so we compared the three SADs with a gastric emptying tube on paralyzed patients who were to undergo gynecological laparoscopic surgery. Our primary objective was to compare the three SADs in terms of oropharyngeal leak pressure. In addition, we examined the safety of these airways by comparing their ease of placement and placement times, the degree to which vocal cords could be seen via fiberoptic bronchoscopy, pH values of secretion on SAD to determine aspiration or regurgitation, and postoperative airway complications.

2. Materials and Methods

The study was carried out at the Malatya Turgut Ozal Medical Center after the approval of the Malatya Clinical Studies Ethical Council (2011/188), and written and oral consents of the patients were taken. Clinical trial registration for this study can be found online (clinicaltrials.gov; registration identifier NCT01909297). One hundred and five ASA I-II patients between the ages of 18 and 60 who were to undergo elective gynecological laparoscopic surgery were included in the study. Physical examination of airway, including Mallampati class, thyromental distance, sternomental distance, inter-incisor distance, lower jaw movement, and head-neck movement, was evaluated prior to the operation as part of a routine preoperative clinical assessment. Exclusion criteria were patient with body weight below 30 kg and with a BMI over 40, SAD which was tried more than three times or when the SAD could not be placed in 120 s, the trial that was planned to deem a failure, those for whom difficult airway (Mallampati class ≥3, inter-incisor distance <3 cm) was expected, those with high gastric regurgitation and aspiration risk, respiratory system pathology, use of H_2 blockers, and planned operation time exceeding 2 h.

Patients were separated into three groups; proseal, supreme, and i-gel, via the randomized numbers table obtained from http://www.randomization.com/. The SAD dimension was selected according to patient weight without knowing which SAD would be used. For proseal and supreme SAD, 3 was used for weights of 30–50 kg, 4 was used for weights of 50–70 kg, and 5 was used for weights of 70–100 kg. For the i-gel, SAD number 3 was used for 30–60 kg, 4 was used for weights of 50–90 kg, and 5 was used for weights over 90 kg.

Pulse oximeter, electrocardiography, and noninvasive blood pressure, along with standard monitoring operations, were carried out prior to the surgery following a premedication of midazolam iv 0.03 mg kg^{-1}. Following a 3 min preoxygenation period, anesthetic induction was provided via intravenous fentanyl 1-2 μ kg^{-1}, propofol 2-3 mg kg^{-1}, and rocuronium 0.6 mg kg^{-1}. Mask ventilation was provided until sufficient muscle relaxation was attained. A prelubricated SAD was placed by an experienced anesthetist in accordance with the directions provided by the manufacturing company. Anesthesia maintenance was obtained by end tidal concentration of sevoflurane 2-3% MAC in a 50% oxygen and 50% air mixture. Pressure controlled ventilation (Drager Cato Edition, Lübeck, Germany) adjusted the airway pressure so that the tidal volume was 8–10 mL kg^{-1}, the respiratory frequency was 10–16 min^{-1}, and $EtCO_2$ was 35–45 cm H_2O. Proseal and supreme SAD cuffs were inflated via a manometer (Rüsch Endotest, Germany) such that the pressure was 60 cm H_2O. The time between lifting the mask from the face and placing the SAD until the first effective $EtCO_2$ graph occurred was recorded. We recorded the total number of insertion attempts. When the SAD was tried more than three times or when the SAD could not be placed in 120 s, the trial was planned to deem a failure and was excluded from the study.

Following the placement of the SAD, lubricant gel was applied 1 cm proximal to the gastric discharge outlet after which the suprasternal notch test [6] was performed (monitoring the pulsatile movement of the gel in the gastric discharge tube proximally when continuous pressure is applied at the cricoid cartilage level); the gastric discharge tube was placed when SAD location was identified to be correct. 14 French gastric discharge tubes were placed in the proseal and supreme SAD, whereas 12 French gastric discharge tubes were placed in the i-gel. The gastric content was aspirated, and the amount was recorded in milliliters. SAD placement was classified according to difficulty using a five-point scale (1 = easy, 2 = not so easy, 3 = difficulty, 4 = very difficult, and 5 = impossible) [7]. The success of the gastric discharge tube placement was also evaluated using a three-point scale (1 = easy, 2 = difficult, and 3 = impossible) [7].

Oropharyngeal leak pressure was measured three times for each patient, once initially just before the start of surgery, once 30 min after the start of surgery (in the trendelenburg position and intra-abdominal area inflated using CO_2), and once at 60 min of surgery. The auscultation method was used to measure the oropharyngeal leak pressure. The pressure value at the time when a leak sound occurred from the mouth of the patient was recorded, while 3 L of fresh gas flow was sent to the patient and the adjustable pressure valve was fully closed [7]. A maximum pressure of 40 cm H_2O was allowed during measurement.

A laryngeal image was recorded at 30 min in the trendelenburg position by using a 3.5 mm fiberoptic bronchoscope (Storz, Bavaria, Germany). The fiberoptic bronchoscope was inserted via ventilation tube of the SAD and a classification between 1 and 4 was made according to the visibility level of the vocal cords (1 = cords not seen; 2 = vocal cords and the anterior of the epiglottis seen; 3 = vocal cords and posterior of the epiglottis seen; and 4 = only vocal cords seen) [8].

Heart rate, mean arterial pressure, SpO_2, and $EtCO_2$ values were recorded at basal, after induction, and for every 5 min following placement of SAD. Airway pressure, inspiratory and expiratory tidal pressure difference, and respiratory rate were recorded prior to and after pneumoperitoneum formed.

At the end of surgery, the muscle relaxation effect was reversed using neostigmine 0.04 mg kg^{-1} and atropine 0.02 mg kg^{-1}; the SAD was removed when the patient started spontaneous respiration. pH measurement was made at the anterior and posterior surfaces of the pharyngeal region of SAD using a pH-meter (pH-fix 0–14; Macherey-Nagel GmbH & Co. KG, Düren, Germany). Recorded information included any laryngospasm, desaturation (SpO_2 < 95%), aspiration (fluid in the ventilation tube), bronchospasm, and blood on the SAD upon removal. Sore throat, pain on swallowing, and hoarseness were evaluated by an anesthetist who was independent of the study 1 h after the patient was taken to the recovery unit.

2.1. Statistical Analysis. Our primary comparison parameter was oropharyngeal leak pressure. Sample size was based on a pilot we conducted involving 20 SAD proseal insertions that

Table 1: Patients airway and surgery characteristics.

	Proseal ($n = 35$)	Supreme ($n = 35$)	I-gel ($n = 35$)
Age, years	31.9 ± 7.0	30.9 ± 7.1	31.1 ± 7.4
Height, cm	161.2 ± 4.8	161.9 ± 5.4	162.0 ± 5.6
Weight, kg	63.6 ± 8.8	67.9 ± 11.2	62.5 ± 10.3
BMI, $kg{\cdot}m^{-2}$	24.4 ± 2.9	25.8 ± 3.9	23.8 ± 4.1
ASA class I/II	29 (82.9)/6 (17.1)	26 (74.3)/9 (25.7)	33 (94.3)/2 (5.7)
Mallampati class 1, 2	27 (77.1)/8 (22.9)	24 (68.6)/11 (31.4)	28 (80.0)/7 (20.0)
Thyromental distance			
<6.5 cm	18 (51.4)	18 (51.4)	19 (54.3)
>6.5 cm	17 (48.6)	17 (48.6)	16 (45.7)
Sternomental distance			
<12.5 cm	18 (51.4)	18 (51.4)	18 (51.4)
>12.5 cm	17 (48.6)	17 (48.6)	17 (48.6)
Interincisor distance			
<4 cm	7 (20.6)	5 (14.3)	4 (11.4)
>4 cm	28 (80.0)	30 (85.7)	31 (88.6)
Lower jaw movement; yes/no	35 (100.0)	35 (100.0)	35 (100.0)
Head neck movement			
Normal >90°/abnormal <90°	35 (100.0)	35 (100.0)	35 (100.0)
Duration of surgery; min	65,3	64,8	66,1
Type of surgery; *n* (%)			
Laparoscopic hysterectomy	3 (8.6)	3 (8.6)	1 (2.9)
Laparoscopic cystectomy	5 (14.3)	4 (11.4)	1 (2.9)
Diagnostic laparoscopy	17 (48.6)	16 (45.7)	21 (60.0)
Laparoscopic tubal ligation	5 (14.3)	1 (2.9)	3 (8.6)
Laparoscopic myomectomy	5 (14.3)	9 (25.7)	7 (20.0)

Data are presented as number (proportion) or mean ± SD.

demonstrated a mean ± standard deviation oropharyngeal leak pressure of 25 (3.6) cm H_2O. To detect a difference of 10%, power analysis at 80% power and the 0.05 level of significance showed that a sample size of 31 patients would be required. We recruited 35 patients for each group.

Statistical analysis was performed using SPSS for Windows version 16.0 (SPSS Inc., Chicago, IL, USA). Continuous variables were reported as mean ± standard deviation. Categorical variables were reported as number (percent). Normality for continuous variables in groups was determined by the Shapiro-Wilk test. One-way analysis of variance (ANOVA), least significant difference test (LSD), Kruskal-Wallis analysis of variance, and Connover test were used for comparison of continuous variables among the studied groups. Pearson chi-square test was used for comparison of categorical variables among studied groups. A value of $P < 0.05$ was considered significant.

3. Results

The study was continued with 105 patients and no patients were excluded from the study. The demographic data and airway properties of the patients were given in Table 1. Whereas the initial oropharyngeal leak pressure was lower in the i-gel compared to the proseal and supreme, it was higher at 30 min in the trendelenburg position and at the 60 min of surgery ($P < 0.001$; Table 2). No cuff leak sound was heard outside of the measurement range. We did not allow the intra-abdominal pressure to exceed 15 cm H_2O. We did not detect an increase in airway pressure above 25 cm H_2O even at the maximum trendelenburg position.

Success rate in terms of insertion during the first attempt of proseal, supreme, and i-gel was 74.3%, 85.7%, and 94.3%, respectively. According to ease of placement, grade 1 (easy) ratios of proseal, supreme, and i-gel were 60%, 77.1%, and 91.4%, respectively. SAD placement time was shorter in the i-gel group compared to the proseal and supreme groups ($P < 0.001$) (Table 2). The gastric tube aspirate amounts were similar among the groups ($P = 0.843$) (Table 2).

The fiberoptic imaging is shown in Table 3; statistically no significant difference was found among the groups. There were no differences between the three SAD types in terms of airway pressure and ventilation parameters (Table 2).

In terms of hemodynamic values, the mean arterial pressure difference among the groups and the difference of the mean pulse rates were not statistically significant. The pH values of the anterior and posterior face of the SADs were in the range of 5–7 and the difference was not statistically significant ($P = 0.948$). In addition, the lowest pH values were 5 in all groups (Table 2).

Table 2: Airway insertion characteristics, oropharyngeal leak pressure, and ventilatory parameters of each group.

	Proseal ($n = 35$)	Supreme ($n = 35$)	I-gel ($n = 35$)	P value
SAD size number: 3/4/5	3/26/6	3/19/13	16/19/0	
SAD insertion attempts				
1	26 (74.3)	30 (85.7)	33 (94.3)	
2	8 (22.9)	4 (11.4)	2 (5.7)	
3	1 (2.9)	1 (2.9)	0 (0)	
Reported ease of placement				
1: easy	21 (60.0)	27 (77.1)	32 (91.4)	
2: not so easy	11 (31.4)	7 (20.0)	3 (8.6)	
3: difficult	3 (8.6)	1 (2.9)	0 (0)	
4: very difficult	0	0	0	
5: impossible	0	0	0	
Successful SAD placement time (sec)	12.2 ± 1.2	12.9 ± 1.0	6.7 ± 1.2	<0.001*
Ease of gastric tube insertion				
1: easy	27 (77.1)	31 (88.6)	32 (91.4)	0.195
2: difficult	8 (22.9)	4 (11.4)	3 (8.6)	0.208
3: impossible	0	0	0	
Gastric aspiration (mL)	4.0	3.2	3.2	
Oropharyngeal leak pressure (cmH_2O)				
Initial	23.9 ± 2.4	24.9 ± 2.9	21.0 ± 3.6	0.001*
At 30 min	25.0 ± 2.3	25.0 ± 1.9	28.3 ± 2.4	0.001*
At 60 min	24.2 ± 2.1	24.8 ± 2.2	29.5 ± 1.2	0.001*
Airway pressure: cmH_2O				
Before pneumoperitoneum	18.7 ± 0.8	18.9 ± 0.7	18.40 ± 0.7	0.106
After pneumoperitoneum	21.4 ± 0.9	21.3 ± 1.1	21.37 ± 1.1	0.081
Intra-abdominal pressure: cmH_2O	13.4 ± 0.7	13.4 ± 0.8	13.0 ± 0.7	0.051
respiratory rate: min	11.7 ± 0.5	11.6 ± 0.4	11.4 ± 0.5	0.106
Inspiration tidal volume: mL	510.1 ± 66.5	540.4 ± 94.0	500.5 ± 66.7	0.081
Expiration tidal volume: mL	525.7 ± 66.0	557.3 ± 102.5	513.8 ± 69.7	0.072
Inspiration-expiration tidal volume difference: mL	15.6 ± 6.6	14.2 ± 4.3	13.2 ± 4.6	0.163
pH of the anterior face SAD	6-7 (6.1)	5–7 (6.1)	5–7 (6.1)	0.948
pH of the posterior face SAD	5–7 (6.3)	5–7 (6.1)	5–7 (6.5)	0.043

Data are presented as number, number (proportion), mean ± SD, or min–max (mean). *(i-gel compared to proseal and supreme).

Table 3: Fiberoptic imaging classification.

	Proseal	Supreme	I-gel
FS ≤ 1	2 (5.7)	0	0
FS ≥ 2	33 (94.3)	35 (100)	35 (100)

Data are presented as number (proportion). Fiberoptic imaging classification ≥2 is a well-placed indicator.

Laryngospasm and desaturation were not observed in any patient. Whereas blood contamination was observed in 5 patients (14.3%) in proseal and 6 patients (17.1%) in supreme groups, none was observed in i-gel group. At 1 h postoperation evaluation, sore throat was not observed in the i-gel group but was observed in 9 (25.7%) and 6 (17.1%) patients, respectively, in proseal and supreme groups; this difference was statistically significant ($P = 0.007$). Hoarseness and pain on swallowing were not observed for the i-gel but were present for proseal [1 (2.9%) and 6 (17.1%), resp.] and supreme [4 (11.4%) and 8 (22.9%), resp.] groups; the values were not statistically significant ($P = 1.67$ and $P = 4.67$, resp.).

4. Discussion

In our study we found that insertion time was shorter in the i-gel than proseal and supreme SAD. Although the initial oropharyngeal leak pressure was lower in the i-gel, it was greater at 30 min of surgery and at 60 min of surgery than those of the proseal and supreme. Additionally postoperative sore throat, hoarseness, and pain on swallowing were not observed in the i-gel group.

High leak pressure of airway devices enables the safe of ventilation at high airway pressures, such as that occurs in laparoscopic surgery. In our study three measurements were obtained during the surgery; even though the initial oropharyngeal leak pressure was smaller for the i-gel, it was greater in the trendelenburg position and at 60 min of surgery. The

reason for this could be that the thermoplastic cuff of the i-gel expands over time due to body temperature, indicating that it has a better safety. In gynecological laparoscopic surgery, Teoh et al. [7] determined that the oropharyngeal leak pressure was 25.0 cm H_2O for the i-gel and 26.4 cm H_2O for the supreme. Shin at al. [9] compared i-gel, Proseal, and classical SAD techniques and oropharyngeal leak pressures were determined as 27 cm H_2O for the i-gel. In both studies, measurements were made only once after the insertion of the supraglottic airway device.

Although we found no difference among the groups in terms of insertion success, we determined that the insertion time was shorter with i-gel compared to both proseal and supreme. Bamgbade et al. [10] achieved first attempt insertion within 5 s in 290 patients and second attempt insertion within 10 s in 8 patients requiring jaw thrust. In another study i-gel was inserted in 4.4 s, while proseal was inserted in 16 s; i-gel is easy to insert because of its shape, contours, firm stem, bite guard, and buccal stabilizer [11]. In addition, we think that the noninflatable cuff of the i-gel leads to its shorter insertion time compared with the supreme and proseal.

Fiberoptic evaluation, which is an indicator of successful insertion of supraglottic airway devices, was carried out once and at the 30 min of the trendelenburg position. There was no difference among the groups in terms of imaging classification. Jun et al. [12] recorded the head position of patients and reported that the fiberoptic image does not change.

The important problems observed in the trendelenburg position are regurgitation and aspiration. One of the indicators of aspiration is the presence of gastric contents into the ventilation tube of the SAD. No patient in this study regurgitated gastric contents into the ventilation tube. Another method used for assessing the gastric regurgitation in the literature is pH measurement [13–15]. In the case series, Gibbison et al. [16] found 1 aspiration and 2 regurgitations among 280 patients with supine position, but they have not studied pH measurement. Gataure and Latto [13] measured the pH of the secretions at the tip of the SAD with pH paper after removal of the device and a value of ≤3 was defined as possible evidence of regurgitation. Similar to that study, we used pH paper following the removal of supraglottic devices. However, we assessed the two part of the device (the anterior and posterior surfaces) because the single measurement may not accurately reflect the actual incidence of regurgitation. For the reason that the lowest pH values were 5 in all groups, we concluded that there was no regurgitation. However, our measurements were done only following the removal of SAD.

Blood contamination, which is an indicator of airway complication, was observed in the proseal and supreme following the removal of the SAD (in 5 and 6 patients, resp.); there was no blood contamination in the i-gel group. Goyal et al. [17] did not find sore throat and hoarseness even though there was blood contamination in all three SADs (i-gel, proseal, and classical); however, they used these techniques on children and nonparalyzed patients, unlike our study. Similar to our findings, Shin et al. [9] did not determine any blood contamination or sore throat in the i-gel group who underwent orthopedic surgery in the supine position. Teoh et al. [7]. compared i-gel and supreme airways in gynecologic laparoscopic surgery and did not find any sore throat, pain on swallowing, and hoarseness but found one blood contamination in the i-gel group and two in the supreme group. The fact that Shin et al. and Teoh et al. obtained results very similar to ours might be due to their use of paralyzed patients. When Uppal et al. [18] compared the i-gel with a tracheal tube, they found 12% blood contamination in relation with the insertion method and ease. Ragazzi et al. [19] compared target-controlled anesthesia with the i-gel and supreme and found one blood contamination in the i-gel group and two in the supreme group. The gel-like cuff minimizes trauma of the airway and neurovascular compression [10].

Our study has some limitations. Fiberoptic bronchoscope was used only once at the 30 min of the trendelenburg position. We do not know whether there will be a change in the image at the end of surgery compared to the beginning of surgery. pH determination was made only once at the end of surgery, and we did not study whether there was any change when pH was monitored in the trendelenburg position.

In conclusion, we have demonstrated in this study that the proseal, supreme, and i-gel SAD provide a safe airway in paralyzed and pressure controlled ventilation administered gynecological laparoscopic surgeries. While initial oropharyngeal leak pressures obtained by i-gel were lower than proseal and supreme, increased oropharyngeal leak pressures over time, ease of placement, and lower airway morbidity are favorable for i-gel.

Conflict of Interests

The authors declare that there is no conflict of interests regarding the publication of this paper.

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Clinical Study

The Effect of Intraoperative Sounds of Saw and Hammer on Psychological Condition in Patients with Total Knee Arthroplasty: Prospective Randomized Study

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Purpose. Surgical procedures are likely to be stressful for patients and their families. Total knee arthroplasty (TKA) is a major surgical procedure used in the treatment of osteoarthritis. During this procedure the sounds of the saw and hammer may irritate the patient and adversely affect mood. The present study examines the effect of these intraoperative sounds during TKA on postoperative mood and anxiety, by comparing two different anesthetic procedures. *Methods*. A total of 40 patients who underwent TKA for grade IV gonarthrosis participated in the study. Patients were randomly divided into two groups: 20 patients in the general anesthesia group and 20 patients in the spinal anesthesia group. Mood and anxiety changes were evaluated using the Profile of Mood States (POMS) and State-Trait Anxiety Inventory (STAI) instruments, respectively. *Results*. The postoperative POMS value in the spinal anesthesia group was definitively higher than the general anesthesia group, though the difference in preoperative and postoperative POMS and STAI scores between the two groups was not significant. *Conclusion*. It would seem that sounds of hammer and saw have no evident negative effect on patient's mood. Regional anesthesia is advisable for TKA patients and appropriate sedation can be administered during the operation if needed.

1. Introduction

From beginning to end, surgical procedures can be very stressful for patients and for their families. Patients endure subjective feelings of risk and stress in order to regain their health. This may lead to high levels of anxiety in both the preoperative and postoperative periods [1]. These psychological problems may present as physical symptoms including headache, nausea, or confusion and may obscure the clinical tableau [2]. In relation to perception of pain anxiety in the preoperative and perioperative period, or presenting in the postoperative period, previous studies have shown that anxiety levels may lower the pain threshold, alter perceptions of pain, and increase postoperative analgesic consumption [3].

Total knee arthroplasty (TKA) is a commonly applied elective surgery which aims to enhance quality of life. The objective is to reduce pain and increase function. For a successful outcome, significant factors may include appropriate patient choice, careful and effective surgical procedure, and adequate rehabilitation [4]. For successful rehabilitation the level of patients' mood and anxiety is also significant [5]. Anxiety reduces patients' physical and emotional energy, causing fatigue and negatively affecting the healing process [6, 7]. In addition, it is ironic that TKA ranks first for noises, such as the sound of saws and hammers, which may alarm patients during the perioperative period. Many studies indicate that the highest anxiety is experienced by patients in the period before surgery [1]. However, there are relatively

few studies of mood changes in orthopedic patients during and after operations [6–8].

Previous studies have examined the effects of postoperative anxiety on patients observing their arthroscopic operations in real time. For operations with low noise levels, like arthroscopy, watching the procedure on live video has been determined to reduce patient's anxiety [9]. Another study reports that regional anesthetic administration changes postoperative mood [10]. Studies on this topic are controversial and for procedures with intense ambient noise, such as TKA, there are to date no studies evaluating effects on mood and anxiety.

There are a number of approaches toward testing of mood and anxiety. While the Profile of Mood States (POMS) is a psychological rating scale used to assess transient, distinct mood states, the State-Trait Anxiety Inventory (STAI) measures and discriminates two types of anxiety—state anxiety and trait anxiety [11, 12]. We used POMS and STAI (both state and trait forms) to measure mood and anxiety of the patients, respectively. POMS and STAI were used in many similar studies [13–19].

The present study investigates the impact of the surgical environment, especially the sounds of saw and hammer in the operating room, on patient's mood and anxiety after the operation. The design randomly divides patients into two groups: spinal anesthesia and general anesthesia groups and the hypothesis of this study is that regional anesthesia, administered without accompanying sedation, will not negatively affect the mood and anxiety in the postoperative period.

2. Materials and Methods

This study has received approval from the Institutional Ethics Committee and was conducted in accordance with the Declaration of Helsinki. Each participant received oral and written information about the study and signed a consent form.

Forty patients with planned elective TKA, and ranging in age from 55 to 80 years, participated in the study. Sampling criteria included advanced-stage gonarthrosis (Kellgren-Lawrence classification grade IV gonarthrosis), willingness to participate, and education to at least middle school standard [20]. Patients with previous hip and/or knee arthroplasty operations, known psychological disorders, or literacy problems were not included in the study. Patients were not given premedication before the procedure, and the Verbal Numeric Scale (VNS) was explained following the sequential order of sealed envelopes. In performing VNS, we asked the patient the following: "On a scale of 0 to 10, with 0 being "no pain" and 10 being "the most intense pain imaginable," how would you rate the severity of your pain right now?" The number verbalized by the patient is considered as VNS score [21]. There were 20 patients in each group.

Before the procedure each patient's basal hemodynamic parameters were recorded. The hemodynamic markers of heart rate (HR), systolic arterial pressure (SAP), diastolic arterial pressure (DAP), mean arterial pressure (MAP), and SpO_2 values were recorded throughout surgery.

In the spinal anesthesia group, patients were administered spinal anesthesia while held in a sitting position by an assistant, in the L3-4 or L4-5 interspinous interval. Spinal anesthesia was administered using 2.5 mL of hyperbaric bupivacaine (12.5 mg). When the sensory block level reached T8, the operating table was brought to a neutral position, and permission was given to start the operation. Control values for MAP falling by more than 20% or below 60 mm Hg were evaluated as hypotension, and fast fluid replacement (50 mL/min) was initiated. If no response was seen within 3 minutes, treatment was IV bolus of 5 mg ephedrine. HR less than 50 bpm was evaluated as bradycardia, and IV bolus of 0.5 mg atropine was administered for treatment.

In the total intravenous anesthesia (general anesthesia) group, patients were given 1 μg/kg remifentanil for 30 to 60 seconds, IV bolus for induction, and 0.05 to 0.25 μg/kg/min infusion after anesthesia deepened or shallowed. In the 2 minutes after administration of propofol 1.5 mg/kg and vecuronium bromide 0.1 mg/kg IV, endotracheal intubation was completed after 100% oxygen ventilation through a mask. For maintenance, 4 to 6 mg/kg/hr propofol infusion was initiated. Mechanical ventilation with tidal volume of 8 mL/kg, respiration count of 10 breaths per minute, 50% O_2, and 50% air was administered. MAP falling by more than 20% or below 60 mmHg was evaluated as hypotension, and fast fluid replacement (50 mL/min) was initiated. If the patient did not respond, the remifentanil dose was reduced by 50%. If levels did not improve, the speed of propofol infusion was reduced by 50%. If no improvement was seen within three minutes, treatment was IV bolus of 5 mg ephedrine. HR below 50 bpm was evaluated as bradycardia and IV bolus of 0.5 mg atropine was administered for treatment.

During surgery all patients were monitored for side effects: blood and blood product transfusions, any complications, and total surgical duration were recorded. After operation, 2 L/min oxygen therapy was administered with mask to prevent postoperative respiratory depression, heating was administered to prevent shivering, and antiemetic therapy was administered to prevent nausea and vomiting in all patients if required. In the recovery room HR, SAP, DAP, MAP, and SpO_2 monitoring parameters were recorded every 10 minutes. After eliminating the risk of early postoperative complications, patients with normal values for at least 60 minutes were sent to the orthopedic service. While the same surgeon performed all surgical procedures, exposure to the same brand and system of prosthetic was ensured.

The State-Trait Anxiety Inventory can be used in clinical settings to diagnose anxiety and to distinguish it from depressive syndromes. The inventory contains separate self-report scales to measure two distinct anxiety concepts: state anxiety (A-State) and trait anxiety (A-Trait). The STAI consists of two scales containing 20 items of 4 options each on a standard Likert scale coded from 0 to 3. The total score indicates which type of anxiety is prevalent [12]. POMS is a self-rating scale which consisted of 65 adjectives that were rated on a 5-point scale. POMS measures 6 identifiable mood or affective states: "tension-anxiety," "depression-dejection," "anger-hostility," "vigor-activity," "fatigue-inertia," and "confusion-bewilderment." To obtain a score for each mood factor,

Table 1: Demographical parameters of all patients.

	General anesthesia (Group 1) $n = 20$	Spinal anesthesia (Group 2) $n = 20$	x^2/t	P
Women (n/%)	13/32.5	15/37.5	0.476	**0.49**[*]
Men (n/%)	7/17.5	5/12.5	*0.476*	*0.49*[*]
Age (M ± SD)	65.6 ± 7.2	65.2 ± 5.6	*0.197*	*0.85*[#]
Weight (M ± SD) kg	86.9 ± 14.9	82.8 ± 13.1	*0.948*	*0.35*[#]
Height (M ± SD) cm	161.3 ± 8.4	159.1 ± 5.9	*0.956*	*0.35*[#]
ASA-score (M ± SD)	2 ± 0.3	2.2 ± 0.4	*−1.710*	*0.96*[#]

[*] Chi-square test, [#] independent samples test, $P < 0.05$, ASA-score: American Society of Anesthesiologists' score, M: mean, and SD: standard deviation.

the sum of the responses is obtained for the adjectives defining the mood factor. A seventh score of total mood disturbance is also calculated by subtracting the score on the one positively scored subscale, vigoractivity, from the sum of the other five subscales [22].

The patients completed forms in the preoperative period and in the twelfth hour after operation for psychometric evaluation using the POMS [11] and STAI [12]. Also patient and doctor satisfactions were evaluated by the test of satisfaction that measured the satisfaction from grade 0 to grade 4 (0: not satisfied–4: fully satisfied).

3. Statistical Methods

Statistical analysis was performed with the Statistical Package for Social Sciences version 19.0 (IBM Corp. Released 2010. IBM SPSS Statistics for Windows, Version 19.0. Armonk, NY: IBM Corp.). Descriptive statistics were used to define sociodemographic and basic clinical variables. The chi-square test was used to compare the categorical variables. Normality of continuous data was determined by the Kolmogorov-Smirnov test. When normality of the distribution of variables was acceptable, Student's t-test and the paired samples t-test were used to analyze differences in scale between preoperative and postoperative data. Differences were considered significant at $P < 0.05$ for all tests (two-tailed).

4. Results

The demographic characteristics of the 40 patients (28 female, 12 male) included in the study showed no statistical difference between the two groups and had a homogeneous distribution (Table 1).

The anesthetic parameters and hemodynamic findings of both groups are shown in Table 2. In relation to anesthesia and surgical procedure duration, there was no significant statistical difference between the groups. In the general anesthesia and spinal anesthesia groups the average fluids given were 2100 ± 536.6 mL and 2512.0 ± 642.6 mL, respectively ($P = 0.04$). The heart rate in the spinal anesthesia group before and during the operation was higher, and this was also statistically significant ($P < 0.05$) (Table 2).

The required blood transfusions in the general and spinal anesthesia patients were 1.9 ± 0.6 and 2.1 ± 0.5 units, respectively ($P = 0.378$, independent samples test, $P < 0.050$). No difference was found between the groups in relation to blood transfusions.

In the postoperative period, shivering severe enough to cause discomfort to the patient occurred in three patients in the general anesthesia (7.5%) and one patient in the spinal anesthesia group (2.5%). In the postoperative period, nausea and respiratory depression were observed in three patients (7.5%) in the general group and one patient (2.5%) in the spinal anesthesia group. In both the perioperative and postoperative periods no additional complications were observed.

In general and spinal anesthesia administration, the preoperative and postoperative POMS and STAI measurement values showed no statistically significant difference ($P = 0.179$ and $P = 0.893$, resp., for general anesthesia; $P = 0.266$ and $P = 0.203$ for spinal anesthesia, paired samples t-test, $P < 0.05$). But in the postoperative period, the POMS value in the spinal anesthesia group was definitively higher than the general anesthesia group, although statistically not significant (Table 3).

According to genders, when the change in postoperative and preoperative POMS is investigated, the averages were −7.8 ± 29.2 in men and 2.9 ± 24.9 in women, and these were not statistically significant ($P = 0.251$, independent samples test, $P < 0.05$). The changes in postoperative and preoperative STAI averages for men and women were 3.5 ± 12.4 and 0.8 ± 15.6, respectively, and again this was not statistically significant ($P = 0.597$, independent samples test, $P < 0.05$).

Both general and spinal anesthesia patients showed a statistically significant correlation between preoperative and postoperative POMS results ($r = 0.536$, $P = 0.015$ and $r = 0.656$, $P = 0.002$, resp., paired samples t-test, $P < 0.05$), but there was no correlation between STAI results ($r = 0.157$, $P = 0.509$ and $r = 0.261$, $P = 0.266$, resp., paired samples t-test, $P < 0.05$).

While patients with operations completed with spinal anesthesia appeared to be more satisfied ($P = 0.09$, chi-square test, $P < 0.05$), there was no difference between general and spinal anesthesia groups in terms of doctor satisfaction ($P = 0.537$, chi-square test, $P < 0.05$).

Table 2: Comparison of anesthetic parameters.

	General anesthesia (Group 1) $n = 20$	Spinal anesthesia (Group 2) $n = 20$	t	P
Duration of anesthesia (min)	157.0 ± 30.0	156.1 ± 30.5	0.089	0.93*
Duration of surgery (min)	123.1 ± 26.1	126.6 ± 30.1	−0.393	0.70*
Total iv fluid (mL)	2100.0 ± 563.6	2515.0 ± 642.6	−2.171	**0.04***
HR (pre-op)	74.4 ± 10.6	83.9 ± 13.0	−2.516	**0.02***
HR (1. min)	70.8 ± 10.3	83.2 ± 12.3	−3.475	< **0.01***
HR (30. min)	62.8 ± 8.2	75.3 ± 9.3	−4.525	< **0.01***
HR (60. min)	65.7 ± 12.8	73.2 ± 2.0	−2.142	**0.04***
HR (90. min)	64.2 ± 7.7	76.2 ± 5.9	−5.516	< **0.01***
HR (120. min)	69.0 ± 10.4	78.0 ± 8.0	−2.400	**0.03***
MAP (pre-op)	107.0 ± 18.8	107.8 ± 12.1	−0.150	0.88*
MAP (1. min)	92.0 ± 29.1	102.7 ± 15.0	−1.462	0.16*
MAP (30. min)	90.7 ± 17.5	94.1 ± 13.4	−0.691	0.49*
MAP (60. min)	94.3 ± 16.5	93.9 ± 12.6	0.86	0.93*
MAP (90. min)	90.9 ± 14.4	95.0 ± 15.8	−0.858	0.40*
MAP (120. min)	93.8 ± 22.0	100.2 ± 15.5	−0.825	0.42*
SpO_2 (30. min)	99.1 ± 1.1	99.2 ± 0.7	−0.327	0.75*
SpO_2 (60. min)	99.0 ± 1.2	99.0 ± 0.9	0.152	0.88*
SpO_2 (90. min)	99.2 ± 0.9	99.3 ± 0.7	−0.380	0.71*
SpO_2 (120. min)	99.1 ± 1.8	99.1 ± 0.6	0.027	0.98*

*Independent samples test, $P < 0.05$, HR: heart rate, MAP: mean arterial pressure, pre-op: preoperative, min: minute.

Table 3: Comparison of anesthetic procedures on psychological condition.

	General anesthesia (Group 1) $n = 20$	Spinal anesthesia (Group 2) $n = 20$	t value	P value
Preoperative POMS	63.6 ± 28.2	65.7 ± 33.9	*−0.208*	*0.836**
Postoperative POMS	56.0 ± 20.2	72.7 ± 31.9	*−1.977*	***0.055****
Preoperative STAI	89.9 ± 12.3	90.7 ± 8.0	*−0.259*	*0.797**
Postoperative STAI	89.4 ± 13.0	94.4 ± 12.0	*−1.276*	*0.210**
Postop-preop POMS	−7.6 ± 24.4	7.0 ± 27.3	*−1.784*	*0.082**
Postop-preop STAI	−0.5 ± 16.5	3.7 ± 12.5	*−0.908*	*0.370**

*Independent samples test, $P < 0.05$.

5. Discussion

Total knee arthroplasty (TKA) is an effective treatment method for advanced knee osteoarthritis patients and is becoming more common. During TKA surgery, the sound of the cutting motor used for femoral and tibial osteotomy, the hammering sounds during placement of the prosthesis, and even the smell of cement can make this a frightening and stress-inducing situation for patients. There is cause for concern that this exposure to stress in the operating room may adversely affect a patient's emotional state in the postoperative period. To our knowledge, the effect of these sounds on mood states in patients undergoing TKA has not previously been studied.

Factors including youth, low educational attainment, and no prior experience of surgical intervention are predictors of higher subjective anxiety in the period before surgery [2, 23]. Studies by Nickinson and Szekely determined that, in the postoperative period, mood is more likely to be affected in women than in men [6, 24]. The present study, however, finds no difference in mood between the genders in preoperative and postoperative periods.

It is known that patients who have previously had hip or knee arthroplasty are more prone to depression in the postoperative period of the second surgery, by comparison with patients having their first arthroplasty operation [6]. For this reason the present study does not include patients who had previously undergone hip and knee arthroplasty operations.

Karanci and Dirik predicted that preoperative anxiety will show a significant decrease when measured in the postoperative period [2]. The present study, however, finds

no significant change in mood and anxiety between the preoperative and postoperative periods. Contrary to the findings that postoperative distress levels may be predicted by preoperative distress levels [25, 26], the present study finds that preoperative and postoperative anxiety levels are not correlated and postoperative anxiety level could not be predicted by assessing the preoperative anxiety level. On the other hand, mood state showed a correlation between preoperative and postoperative periods in both groups. This may relate to the more dynamic and variable nature of anxiety itself and the possible impact of environmental conditions; mood changes do appear to be more stable.

Regional anesthesia methods are often the preferred choice for orthopedic surgery. This form of anesthesia reduces perioperative bleeding, postoperative embolic complications, postoperative nausea and vomiting, risk of aspiration, and postoperative pain. It has also been found to make rehabilitation easier. Disadvantages of spinal anesthesia include slower onset, spinal headaches, and micturition dysfunction [27–29].

Tanaka et al. asked patients to watch live video of their arthroscopic surgery and reported that these patients had greater levels of satisfaction after surgery [25]. Similarly, just as the cold and stressful environment of the operating room increased both perioperative and postoperative anxiety in patients, they concluded that, in the perioperative period, distracting interventions reduced patients' anxiety and improved postoperative results. These distractions included watching live video of the arthroscopy (non-TKA) and listening to music [1, 3, 30]. Bayar et al. found that the patients with spinal anesthesia watching their images of arthroscopic operation had lower postoperative STAI scores and visual feedback was effective in reducing anxiety, in both the perioperative and postoperative periods [9]. Adversely, in another study investigating the effect on mood of spinal anesthesia and laryngeal mask anesthesia in 46 patients undergoing hemorrhoidectomy, the evidence suggests that mood in the spinal anesthesia group disimproved in the postoperative period [10].

In the present study it was aimed to investigate the effects of intraoperative sounds of hammer and saw on the patients' mood and anxiety. Although it can be thought that the sounds of hammer and saw used in arthroplasty operations may be frightening and stress inducing, the preoperative and postoperative POMS and STAI measurement values showed no statistically significant difference in the present study. POMS value in the spinal anesthesia group was definitively higher than the general anesthesia group. Also patients with operations completed with spinal anesthesia appeared to be more satisfied. In light of this, it would seem that sounds of hammer and saw have no evident negative effect on patient's mood. One possible explanation for the satisfaction might be that spinal anesthesia lessens postoperative pain, allowing the early postoperative period, when pain is most strongly felt, to pass painlessly.

The present study also found differences between groups in the relation between anesthetic parameters of total fluid amounts given and heart rate. We consider that similarity on other parameters did not affect anxiety and mood data. The higher heart rate in the spinal anesthesia group may not be due to anxiety but due to the higher amount of fluids given to spinal anesthesia patients.

There is considerable evidence that anxiety and depression in patients adversely affect outcomes of surgery and increase length of hospital stay [6, 31, 32]. High levels of preoperative and perioperative anxiety and depression may cause serious pain or phantom pain and impact seriously on postoperative results [33, 34]. Mossey et al. found a relationship between the quality of patients' recovery and postoperative mood and also found that postoperative anxiety and depression adversely affected functional recovery [35].

In our view, mood during the postoperative period is a factor in achieving a successful outcome. TKA is an elective surgical procedure intended to enhance the patient's daily quality of life. In light of this, we believe that any factor that can be shown to affect postoperative results must be considered important.

In conclusion, it would seem that sounds of hammer and saw have no evident negative effect on patient's mood and in operations performed with spinal anesthesia, the patients were found to be more satisfied so that, with known advantages, regional anesthesia is advisable for TKA patients and appropriate sedation can be administered during the operation if needed.

Conflict of Interests

There is no conflict of interests related to the paper.

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Clinical Study

Performance of Size 1 I-Gel Compared with Size 1 ProSeal Laryngeal Mask in Anesthetized Infants and Neonates

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Purpose. The size 1 I-gel, recommended for small infants and neonates weighing 2–5 kg, has recently been released. There are no prospective studies available that assess the insertion conditions, sealing pressures, or ventilation quality of it. This study was designed to compare the performance of recently released size 1 I-gel with size 1 ProSeal LMA. *Methods*. Fifty infants and neonates, ASA I-II were included in this prospective, randomized, and controlled study. Patients were divided into two groups for placing I-gel or ProSeal LMA. The primary outcome was airway leak pressure, and secondary outcomes included insertion time, insertion success and conditions, initial airway quality, fiberoptic view of the larynx, and complications. *Results*. There were no significant differences in terms of airway leak pressure between the I-gel (27.44 ± 5.67) and ProSeal LMA (23.52 ± 8.15) ($P = 0.054$). The insertion time for the I-gel was shorter (12.6 ± 2.19 s) than for the ProSeal LMA (24.2 ± 6.059 s) ($P = 0.0001$). Insertion success and conditions were similar in groups. We encountered few complications. *Conclusion*. Our study demonstrates that the size 1 I-gel provided an effective and satisfactory airway as the size 1 ProSeal LMA. It may be a good alternative supraglottic airway device for use in small infants and neonates. This trial is registered with: ClinicalTrials.gov NCT01704118.

1. Introduction

The I-gel (Intersurgical Ltd., Wokingham, Berkshire, UK) is a disposable supraglottic airway device with noninflatable cuff and is made from thermoplastic elastomer, which is unlike other laryngeal masks [1]. The manufacturer states that I-gel is suitable for hypopharyngeal anatomy, provides good perilaryngeal sealing, and reduces the risk of airway obstruction by preventing intraoral trauma and folding of epiglottis, due to the device's soft and gel-like structure [2]. Studies assessing I-gels of different pediatric sizes, except size 1 (without gastric drainage tube), have shown that the I-gel is an efficient and safe airway device with easy insertion, a high rate of successful insertion, sufficient ventilation, and few complications [1, 3–5]. The size 1 I-gel, recommended for small infants and neonates weighing 2–5 kg, has recently been released for use. There are no prospective studies available that assess the insertion conditions, sealing pressures, or ventilation quality of it.

The ProSeal laryngeal mask (PLMA) (LMA North America, Inc., San Diego, USA) is a modified type of LMA (larger and deeper bowl, enlarged and softer cuff) with a gastric drainage tube. Unlike the PLMA for adults, the size 1 PLMA for infants and neonates below 5 kg has no additional cuffs on its dorsal side similar to other pediatric sizes. There are several studies comparing the size 1 PLMA with size 1 classic LMA and showing its superiority [6, 7].

The objective of this prospective, randomized, and controlled study is to compare the performance of the recently released size 1 I-gel and the size 1 PLMA, which has been proven to be superior to the classical LMA in prospective studies. In this study, the primary endpoint was the airway leak pressure, and the secondary endpoints were the insertion time, insertion success and conditions, initial airway quality, fiberoptic view, and complications.

2. Materials and Methods

This study was carried out after obtaining approval from the Local Ethical Committee of the Faculty of Medicine, Inonu University (Acceptance No. 2011/89), Malatya, Turkey

(Chairperson Professor M. Genc), on 5 July 2011. Informed consent was obtained from parents of infants and neonates. Fifty infants and neonates, ASA I-II, and weighing 2–5 kg were included into the study. Infants who required a supraglottic airway device and were scheduled for elective surgery under general anesthesia were chosen for the study. Infants who had a history of pulmonary disease, expected to have aspiration (gastroesophageal reflux, gastrointestinal stenosis, or stricture) and a difficult airway, were excluded from the study.

Infants were administered rectal 30 mg/kg paracetamol 1 hour before the operation and taken into operating room after a peripheral venous cannulation and began hourly fluid infusion on the Pediatric Surgery Services. Routine monitoring (ECG, pulse oximetry, blood pressure, and temperature) was performed while the infants were on the operating table that was covered by a heating blanket. The randomization was performed by sealed envelope method. An anesthesiologist who was blinded to the study opened a sealed envelope and prepared the device. Lidocaine 1 mg/kg, remifentanil 1 mcg/kg (slow bolus in approximately 1 min), and 3 mg/kg propofol were administered on anesthesia induction; no muscle relaxant was administered. The infants were ventilated with a facemask until conditions were suitable for laryngeal mask insertion (loss of eyelash reflex, jaw relaxation, and the absence of movement). If sufficient anesthetic depth was not achieved, an additional 1 mg/kg propofol was administered. In Group P, a PLMA with fully deflated cuff and applied water-based lubricant was inserted using a metal introducer. After insertion, the cuff was inflated with the recommended volume of air and the cuff pressure was adjusted to 60 cmH_2O using a manometer (Endotest pressure manometer, Rüsch, Germany). In Group I, the I-gel with its lubricated cuff was orally inserted along the hard palate until resistance was felt, as recommended by the manufacturer. Afterwards, patients in both groups were connected to the circle system of anesthesia machine and were ventilated manually. Anesthesia was maintained with 4 L/min fresh gases, consisting of 2.5%–3% sevoflurane and 50%/50% O_2/N_2O. An experienced and same anesthesiologist performed the insertion procedures in all patients.

The time between picking up the prepared PLMA (with introducer and deflated cuff) or the I-gel and the appearance of the first stable capnographic trace was recorded as the insertion time. As previously described, the conditions for insertion were scored according to mouth opening (1: full; 2: partial; 3: nil), gagging or coughing (1: nil; 2: slight; 3: gross), swallowing (1: nil; 2: slight; 3: gross), head or limb movement (1: nil; 2: slight; 3: gross), laryngospasm (1: nil; 2: slight; 3: complete), and ease of insertion (1: easy; 2: difficult; 3: impossible) [8, 9]. A summed score was obtained by adding the scores collected for each patient. The initial airway quality was evaluated with manual ventilation by adjusting APL valve to 20 cmH_2O. The evaluation was performed by listening to the lungs, epigastrium, and perilaryngeal field and observing the expansion of thorax. The following scale was used: excellent (no leaks heard), good/acceptable (a slight, clinically insignificant leak and sufficient ventilation), and poor/unacceptable (significant leak and insufficient ventilation which requires reposition or relocation of the device). Next, the airway device was taped, and the head was fixed in a neutral position. In the event of unsuccessful insertion of the device or insufficient ventilation despite two attempts, a muscle relaxant was administered, and endotracheal intubation was performed. The number of attempts required to position the device was recorded.

Fresh gas flow was adjusted to 3 L/min, and after closing the expiratory valve, the airway pressure at which an audible leak in the mouth was heard was recorded as the "P_{leak}". If P_{leak} reached 35 cmH_2O, the expiratory valve was opened [6]. After adjusting the APL valve to 35 cmH_2O, the maximum tidal volume (TV_{max}) was measured by squeezing the balloon of anesthesia circuit until an audible leak occurred [6]. The presence of gastric insufflation was detected by auscultation of the stomach.

To evaluate the anatomic position of the supraglottic device, a fiberoptic evaluation was performed. Before fiberoptic evaluation, 1 mcg/kg of additional fentanil was administered to the patients. The breathing system was disconnected and the fiberoptic bronchoscope (11302BD2, diameter 3,7 mm; length 65 cm; Karl Storz, Tuttlingen, Germany) was inserted through the ventilation tube to evaluate the glottic view. Fiberoptic images were recorded using a digital camera and stored on a personal computer for grading by an independent anesthetist. The images were graded with a score from 1 to 5, which has been defined and proposed previously [10, 11] (grade 1-only larynx seen; grade 2-larynx and epiglottis posterior surface seen; grade 3-larynx and epiglottis tip of anterior surface seen, <50% visual obstruction of epiglottis to larynx; grade 4-epiglottis downfolded and its anterior surface seen, >50% visual obstruction of epiglottis to larynx; and grade 5-epiglottis downfolded and larynx cannot be seen directly).

Additionally, the heart rate and mean blood pressure values were recorded. In Group P, a lubricated 8 F gastric tube was inserted through the gastric drainage tube. The position of the gastric tube was verified by air injection and aspiration of gastric contents. After assessments and evaluations, mechanical ventilation using pressure-controlled ventilation was started (peak pressure 10–14 mmHg and respiratory rate 35–40/min to obtain a tidal volume 8–10 mL/kg).

At the end of the operation, wound infiltration was done with 1 mg/kg 0.25% bupivacaine. The inhalation agent was stopped, and the airway device was removed, upon observing sufficient spontaneous ventilation and protective reflexes. Complications encountered during or at the end of the operation, such as desaturation (SpO_2 less than 90%), gastric insufflations, aspiration, laryngospasm, bronchospasm, and blood stain on the airway device during removal, were recorded.

The null hypothesis was that there was no difference in P_{leak} between the size 1 I-gel and the size 1 PLMA. We did a pilot study of 10 patients to detect a difference of 10% between the groups with a standard deviation of 4. Therefore, for a power of 0.8 and $\alpha = 0.05$, a sample size of 24 patients in each group was required. Twenty-five patients in each group were recruited because of the possibility of dropouts. Statistical analyses were performed using SPSS for windows, version

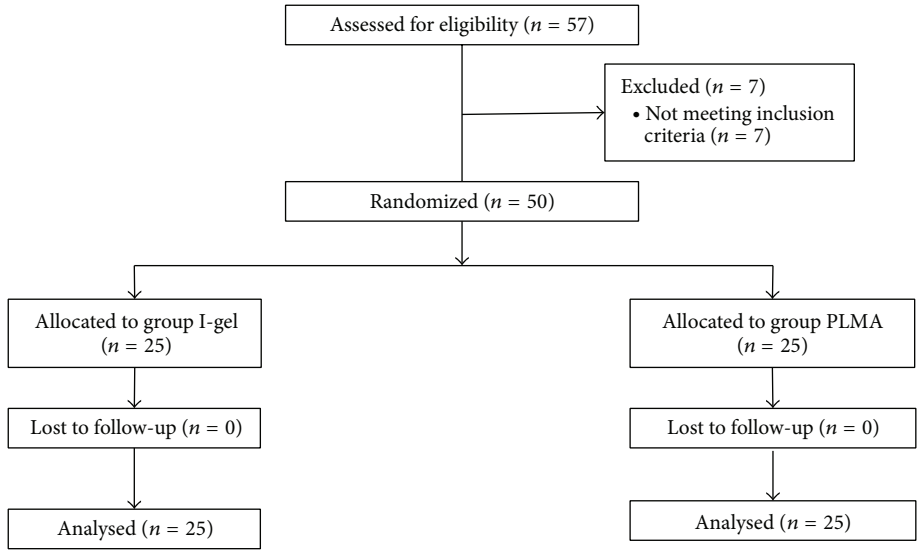

Figure 1

Table 1: Demographic data and additional doses of propofol. Values are mean ± standard deviation or number.

Patients	Group I ($n = 25$)	Group P ($n = 25$)	P value
Gender (F/M)	5/20	6/19	1.000
Age (month)	2.1 ± 0.7	2.3 ± 1.1	0.448
Weight (kg)	4.2 ± 0.7	4.4 ± 0.9	0.400
ASA status I/II	22/3	20/5	0.700
Additional propofol (mg)	1.7 ± 2.95	3.08 ± 3.46	0.136

ASA Status: American Society of Anesthesiologists Physical Status.

13.0 program. Continuous data were reported as mean ± SD. Categorical data were reported as number and proportion. Normality for continuous variables in groups was determined by the Shapiro Wilk test. The variables showed a normal distribution ($P > 0.05$). Therefore, an unpaired t test was used for comparison of variables between the groups. A paired t test was used for variables within the groups. Pearson chi-square and Fisher's exact tests were used for the categorical data. A value of $P < 0.05$ was considered to be significant.

3. Results

Fifty-seven patients were eligible for the study. Seven of the patients were excluded from the study because they did not meet the inclusion criteria. Fifty patients completed the study, and no patients were excluded from the analysis (Figure 1). There were no significant differences between the two groups in terms of demographic data, ASA status, and the need for additional doses of propofol (Table 1). The types of surgery consisted of 41 unilateral inguinal hernia repairs, 7 bilateral inguinal hernia repairs, 1 rectal biopsy, and 1 cystoscopy.

The mean P_{leak} values were 27.44 ± 5.67 cmH_2O in Group I and 23.52 ± 8.15 cmH_2O in Group P. There were no statistical differences between the groups ($P = 0.054$) (Table 2). The TV_{max} values were 90 ± 45.91 mL and 69.13 ± 36.79 mL in Group I and in Group P, respectively ($P = 0.091$) (Table 2). The expiratory valves were opened in 6 patients in Group I and 4 patients in Group P when the P_{leak} value exceeded 35 cmH_2O. While insertion time was shorter in Group I (12.6 ± 2.19 sec) than in Group P (24.2 ± 6.059 sec) ($P = 0.0001$), insertion success rates and insertion conditions were similar in both groups. First-attempt insertion success and overall success rates were 92% (23 patients) and 96% (24 patients) in Group I, and 88% (22 patients) and 100% (25 patients) in Group P. In a patient for whom insertion failed in Group I, despite suitable insertion conditions and sufficient initial airway quality, a decrease in the ventilation quality (decrease in capnograph trace, low tidal volume) was observed during the operation. Upon failing to achieve sufficient ventilation on the second attempt, the I-gel was removed, and endotracheal intubation was performed. Initial data were recorded for this patient and therefore included in the results.

The initial airway quality was detected to be better in Group I than in Group P ($P = 0.006$). The fiberoptic view scores are shown in Table 2. There were no statistical differences between groups ($P = 0.085$). Grade 1 (only the larynx) was seen in 12 and 5 patients in Group I and Group P, respectively ($P = 0.036$). The number of patients whose larynx was not seen (grade 5) was 0 in Group I and 5 in Group P ($P = 0.025$). It was recorded that the epiglottis could not be seen in 2 of these 5 patients due to downfolding of the PLMA.

Comparisons between groups showed no statistical differences in heart rates and mean blood pressures. Preoperative desaturation developed in 3 patients. Desaturation was observed in 1 patient in Group I due to laryngospasm developed during fiberoptic evaluation, in 1 patient in Group P due to impairment in ventilation after surgery was started, and in 1 patient in Group P due to laryngospasm after removal of PLMA at the end of the operation. Desaturation was quickly eliminated by manual ventilation with 100% O_2 and

Table 2: Conditions during insertion, quality of initial airway, airway leak pressure, maximum tidal volume, and fiberoptic view of size 1 I-gel and PLMA and complications during surgery and emergence. Values are mean ± standard deviation or number (proportion).

	Group I ($n = 25$)	Group P ($n = 25$)	P value
Insertion time (s)	12.6 ± 2.19	24.2 ± 6.05	0.0001[†]
First-attempt insertion success n (%)	23 (92%)	22 (88%)	0.609[#]
Overall insertion success	24 (96%)	25 (100%)	
Insertion condition summed score	6.2 ± 0.5	6.4 ± 0.5	0.197[†]
Mouth opening (full/partial/nil)	25/0/0	25/0/0	
Gagging or coughing (nil/slight/gross)	25/0/0	25/0/0	
Swallowing (nil/slight/gross)	24/1/0	24/1/0	
Movement (nil/slight/gross)	24/1/0	19/5/1	
Laryngospasm (nil/partial/complete)	25/0/0	25/0/0	
Ease of insertion (easy/difficult/impossible)	23/1/1	22/3/0	
Quality of initial airway (n)			0.006[#]
Excellent	19	9	
Good/acceptable	4	15	
Poor/unacceptable	2	1	
Airway leak pressure (P_{leak}) (cmH_2O)	27.44 ± 5.67	23.52 ± 8.15	0.054[†]
Maximum tidal volume (TV_{max}) (mL)	90 ± 45.91	69.13 ± 36.79	0.091[†]
Fiberoptic view (1/2/3/4/5[*])	12/4/2/7/0	5/5/3/7/5	0.085[#]
Grade 1 (only larynx seen)	12 (48%)	5 (20%)	0.036[#]
Grade 5 (epiglottis downfolded and larynx cannot be seen directly)	0 (0%)	5 (20%)	0.025[#]

[†]Unpaired t test was used for comparison of variables between two groups.
[#]Pearson chi-square and Fisher's exact test were used for comparison of variables between the categorical data.
[*](1) Only larynx seen; (2) larynx and epiglottis posterior surface seen; (3) larynx and epiglottis tip of anterior surface seen, 50% visual obstruction of epiglottis to larynx; (4) epiglottis downfolded and its anterior surface seen, 50% visual obstruction of epiglottis to larynx; (5) epiglottis downfolded and larynx cannot be seen directly.

increasing the anesthetic depth in the first and second patient. Again, positive pressure manual ventilation with 100% O_2 administration was sufficient in the third patient and there was no need to succinylcholine for laryngospasm. Gastric insufflations developed in 1 patient in Group I. In Group P, blood stain was detected on the LMA in 2 patients. No aspiration or bronchospasm was observed in any of the patients (Table 3).

Table 3: Complications during surgery and emergence. Values are number (proportion).

	Group I ($n = 25$)	Group P ($n = 25$)	P value
Desaturation ($SpO_2 < 90\%$)	3 (12%)	2 (8%)	1.000
Gastric insufflations	1 (4%)	0 (0%)	1.000
Aspiration	0 (0%)	0 (0%)	—
Laryngospasm	1 (4%)	1 (4%)	1.000
Bronchospasm	0 (0%)	0 (0%)	—
Blood stain	0 (0%)	2 (8%)	0.490

4. Discussion

In this prospective study, the size 1 I-gel and the size 1 PLMA exhibited similar performances in terms of P_{leak} and TV_{max} values, insertion conditions, insertion success, and larynx visibility. However, the size 1 I-gel has advantages over PLMA in terms of insertion time and initial airway quality.

There are few clinical studies on supraglottic airway devices manufactured for small infants and neonates below 5 kg. In comparative studies of the size 1 PLMA and classic LMA, it was reported that P_{leak} was higher, the initial airway quality was better, and there was less gastric insufflations with the PLMA [6, 7, 12, 13]. Because of the proven effectiveness and safety of the PLMA in the infants and neonates, we preferred to compare the I-gel with PLMA only.

It was reported that the I-gel, with its different physical characteristics, is an advantageous device for pediatric patients above 5 kg because of its ease of insertion, sufficient ventilation, and ease of gastric tube insertion [1, 3–5, 14–16]. Hughes et al. [14] compared size 2 I-gel with PLMA and classic LMA, in spontaneously breathing children, and they found that size 2 I-gel was easy to insert and provides higher oropharyngeal sealing pressure (OSP) than the others. The detected values of OSP were 26 ± 2.6 cmH_2O and 23 ± 1.2 cmH_2O with the size 2 I-gel and size 2 PLMA, respectively. Their values were similar to our study that obtained

a sufficient and acceptable P_{leak} value (27.44 cmH_2O) with the size 1 I-gel. Jagannathan et al. suggested that I-gel had higher P_{leak} value than the Supreme device in infants and children. The selected sizes of the airway devices were 1.5, 2, 2.5, and 3 in their study and the median P_{leak} value was 20 (18–25) cmH_2O with the I-gel [15]. In a similar manner, Lee et al. detected the mean P_{leak} value of size 1.5, 2, and 2.5 I-gels 22 (20–25) cmH_2O [17]. In these studies, the researchers did not report each P_{leak} measurements for the different sizes used in their study. However, Theiler et al., in their study on children from different age groups weighing 5–50 kg, found the average P_{leak} value to be 22 ± 5 cmH_2O with the I-gel and they obtained a significantly higher P_{leak} value (27 cmH_2O) with the size 1.5 I-gel [5]. Similarly, Beringer et al. found the average P_{leak} value to be 20 cmH_2O with sizes 1.5, 2, and 2.5 I-gels; the value obtained with size 1.5 I-gel was higher (26 cmH_2O) [3]. Furthermore, in our study, the initial airway quality was better and we obtained a sufficient TV_{max} value with the I-gel. As a result, it can be concluded that the small size (size 1 and 1.5) I-gels are suitable for the anatomical structure of infants and neonates and provide satisfactory airway.

The P_{leak} for the size 1 PLMA was higher than the P_{leak} found by several clinical studies [18] and lower than others [6, 7]. This was caused by the differences in standardization of anesthetic depth and different measuring techniques, such as the maximum airway pressure allowed during measurement or the amount of fresh gas flow [1, 18]. Additionally, different head-neck positions may affect P_{leak} values, as well [19, 20].

In our study, we inserted the size 1 PLMA using an introducer because of more flexibility than other sizes of the PLMAs and because of a small introducer strap, and the absence of an integral bite block, as recommended by the manufacturer. We think that removal of the introducer and inflation of the cuff significantly increases the time required for achieving an effective airway. Although times obtained in various studies may be different, the general conclusion is that the I-gel has a short insertion time and is inserted easily [3, 14, 17]. As in many other studies, the insertion time required with the I-gel in our study was quite short. So, I-gel may be advantageous for emergency airway management in infants.

In our study, the larynx could not be seen in 5 patients in the PLMA group, and it was found that the PLMA was downfolded in 2 patients. P_{leak} values (15 and 9 cmH_2O) and leak volumes in these patients were quite low, and the PLMA was inserted twice in one patient due to failure to maintain sufficient ventilation. It was reported that the PLMA might cause upper airway obstruction in pediatric patients and infants due to supraglottic bulging and laryngeal compression. Thus, pediatric PLMA users were recommended to be awake [20, 21]. Hyperinflation of the LMA cuff may cause airway morbidity by increasing the pressure on perilaryngeal structures. Therefore, routine monitoring of the cuff pressure is recommended in pediatric patients [21]. In studies on pediatric patients, low levels of airway trauma were observed with I-gel [1, 3–5]. In our study, blood stain was detected in 2 patients in the PLMA group while no blood was detected in the I-gel group. Absence of a cuff in the I-gel may, as suggested by Lee et al. [17], be thought of as an advantage to avoid these problems.

Previous researchers have warned that pediatric size I-gels are likely to dislodge and should be taped well [3–5, 14]. Although we had no objective data, we agreed with this opinion based on our clinical observations.

The absence of a gastric drainage tube in the size 1 I-gel may be a disadvantage because it may increase the risk of gastric regurgitation or aspiration. Although no aspiration events were observed in any of the patients, the number of patients in our study is quite low, and we think that more clinical studies with larger patient populations are needed to understand whether the size 1 I-gel provides protection against aspiration.

Our study has a number of limitations. One of these limitations is that our data collection was unblinded with the exception of the fiberoptic evaluation. Second, ventilation quality and the P_{leak} values were evaluated only in the beginning of the operation. I-gel may provide better sealing of the perilaryngeal area over time by warming with body temperature, due to its thermoplastic characteristic. Third, an anesthesia specialist who had more experience with the size 1 PLMA carried out the insertion procedures. It may be assumed that this affected the results related to insertion. However, the insertion time was found to be shorter for I-gel in our study, despite this disadvantage. Another limitation is that this study had only power for airway leak pressure, not for the other variables.

In conclusion, our study demonstrates that the size 1 I-gel is an effective supraglottic airway device for use in small infants and neonates. In comparison with size 1 PLMA, I-gel is quicker to insert and provides better initial airway quality. Although we encountered few complications, further studies are needed to determine whether size 1 I-gel is reliable for regurgitation and aspiration.

Conflict of Interests

The authors declare that there is no conflict of interests regarding the publication of this paper.

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Clinical Study

Spinal Anaesthesia with Hyperbaric Prilocaine in Day-Case Perianal Surgery: Randomised Controlled Trial

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Background. The local anaesthetics used in day-case spinal anaesthesia should provide short recovery times. We aimed to compare hyperbaric prilocaine and bupivacaine in terms of sensory block resolution and time to home readiness in day-case spinal anaesthesia. *Methods*. Fifty patients undergoing perianal surgery were randomized into two groups. The bupivacaine-fentanyl group (Group B) received 7.5 mg, 0.5% hyperbaric bupivacaine + 20 μg fentanyl in total 1.9 mL. The prilocaine-fentanyl group (Group P) received 30 mg, 0.5% hyperbaric prilocaine + 20 μg fentanyl in the same volume. *Results*. Time to L1 block and maximum block was shorter in Group P than in Group B (Group P 4.6 ± 1.3 min versus Group B 5.9 ± 01.9 min, $P = 0.017$, and Group P 13.2 ± 7.5 min versus Group B 15.3 ± 6.6 min, $P = 0.04$). The time to L1 regression and S3 regression of the sensorial block was significantly shorter in Group P than in Group B (45.7 ± 21.9 min versus 59.7 ± 20.9 min, $P = 0.024$, and 133.8 ± 41.4 min versus 200.4 ± 64.8 min, $P < 0.001$). The mean time to home readiness was shorter for Group P than for Group B (155 ± 100.2 min versus 207.2 ± 62.7 min ($P < 0.001$)). *Conclusion*. Day-case spinal anaesthesia with hyperbaric prilocaine + fentanyl is superior to hyperbaric bupivacaine in terms of earlier sensory block resolution and home readiness and the surgical conditions are comparable for perianal surgery.

1. Introduction

The incidence of perianal surgery varies among institutions, accounting for up to 10% of general surgical procedures [1]. The procedure is suitable to perform on a day-case basis with spinal anaesthesia [2, 3]. However, prolonged sensory and motor block and urinary retention can cause a delay in discharge [4, 5].

Day-case spinal anaesthesia with short-acting local anaesthetics such as lidocaine and chloroprocaine can provide short times to discharge [6, 7]. However the association of lidocaine with transient neurologic symptoms (TNS) and chloroprocaine with neurologic injury has limited the use of these agents in spinal anaesthesia [8, 9]. Bupivacaine is safe with a very low incidence of associated TNS, but the prolonged sensory and motor block are a disadvantage for day-case spinal anaesthesia [10]. The use of small doses of bupivacaine with the addition of opioids is proposed to enhance the recovery of the spinal block [11].

The recently introduced local anaesthetic agent, hyperbaric prilocaine, has a short duration of action and the TNS incidence is low [12, 13]. Hyperbaric prilocaine provides faster spinal block onset and earlier patient recovery in ambulatory surgery compared to plain prilocaine [14]. Plain prilocaine was also compared to bupivacaine in day-case surgery and the authors concluded that bupivacaine provided shorter block duration [15]. The baricity of the local anaesthetic agent is the major factor that influences the distribution of the local anaesthetic in the subarachnoid space [16]. Scientific evidence regarding the differences of spinal block characteristics of hyperbaric prilocaine and hyperbaric bupivacaine is lacking.

This study compared 2% hyperbaric prilocaine 30 mg + fentanyl 20 μg to 0.5% hyperbaric bupivacaine 7.5 mg + fentanyl 20 μg for day-case spinal anaesthesia. The outcome measures were anaesthetic recovery as evaluated with the time to sensory block resolution to S3 dermatome and time to

home readiness and the efficacy of the spinal block in perianal surgery.

2. Methods

The ethical approval for this study was provided by the Erciyes University, Faculty of Medicine Ethics Committee, Kayseri, Turkey (03.01.2012, number 2012/74, Chairperson Professor K. Kose) (Clinicaltrials.gov identifier: NCT01880775). Fifty consenting patients scheduled for perianal surgery were enrolled in this prospective randomized trial. Patients with contraindications for outpatient surgery or spinal anaesthesia, known sensitivity to the study drugs, or previous voiding difficulty, patients taking anticholinergic medications, and emergency cases were excluded from the study. The following patient parameters were recorded: gender, age, body mass index (BMI), concomitant diseases, and the American Society of Anesthesiologists (ASA) physiologic state. The patients were asked to void before surgery.

A peripheral intravenous (IV) catheter was inserted and a 7 mL kg^{-1} crystalloid infusion was initiated. The patients were premedicated with 0.03 mg kg^{-1} midazolam IV. Heart rate and peripheral oxygen saturation (SpO_2) were monitored continuously; systolic, diastolic, and mean arterial pressure (MAP) were measured noninvasively at 5 min intervals during the procedure and at 15 min intervals during the postanaesthesia care unit (PACU) stay. The baseline values were recorded. Nasal oxygen 2 L min^{-1} was administered during the whole procedure.

The patients were randomized into two groups using a computer-generated sequence of numbers, and sealed envelopes were used for allocation. The bupivacaine-fentanyl group (Group B) ($n = 25$) received 1.5 mL (7.5 mg) 0.5% hyperbaric bupivacaine (Marcaine, heavy bupivacaine 5 mg mL 0.5%, glucose 8%, Astra Zeneca, Sweden) and 0.4 mL fentanyl (Fentanyl citrate, Abbott Pharmaceuticals, IL, USA) (20 μg) in a total 1.9 mL. The prilocaine-fentanyl group (Group P) ($n = 25$) received 1.5 mL (30 mg) 0.5% hyperbaric prilocaine (Prilotekal, prilocaine 20 mg mL 2%, glucose 6%, Mercury Pharma, UK) and 0.4 mL fentanyl (20 μg) in the same volume.

Spinal anaesthesia was performed at the L4-5 intervertebral space with the patient in the sitting position with a midline approach and a 25 G needle. After verifying free flow of clear cerebrospinal fluid, the prepared solution was injected into the intrathecal space in 15 seconds. The patients remained in this position for 2 minutes after the injection and were placed in the lithotomy position thereafter.

2.1. Intraoperative Assessment and Treatments. The sensorial block was measured at the midclavicular line with a pinprick test (via a 22 gauge hypodermic needle) at 1 min intervals until the maximum block was achieved and at 15 min intervals thereafter until the block resolved to S3 dermatome. The motor block was measured when the maximum dermatomal spread was achieved using the modified Bromage scale (0: no motor block, 1: hip blocked, 2: hip and knee blocked, and 3: hip, knee, and ankle blocked). The sensorial and motor block were evaluated by an anaesthesiologist blinded to group allocation. Motor block assessment was not done during surgery. Fentanyl (50 μg), midazolam (1–5 mg), and propofol (10–20 mg incremental boluses) were used for rescue analgesia and sedation.

The time of subarachnoid injection, the onset of sensorial block (block at L1 dermatome), and the readiness for surgery (block at T10 dermatome), as well as the maximum block level and time to reach the maximum block level were recorded. Hypotension (defined as a ≥30% decrease in the systolic blood pressure in comparison with the baseline values or a systolic blood pressure of less than 80 mmHg) was treated with 250 mL crystalloid fluid boluses or 5 mg ephedrine IV. The total amount of fluid was registered. Bradycardia (defined as a heart rate ≤50 beats/min) was treated with 0.5 mg atropine IV. The periods of desaturation ($SpO_2 < 95$) were recorded. The duration of surgery was defined as the time between surgical incision and wound closure.

2.2. Postoperative Assessment and Treatments. At the end of surgery, the patients were transferred to the PACU. Resolution of the spinal block was assessed by the time to two-segment L1 and S3 regression of the sensory block. The regression of motor block was also determined. Pain was measured with a visual analogue scale (VAS) (0: no pain; 10: maximum pain) at rest and during mobilization. Postoperative analgesia was provided with 50 mg tramadol and it was first administered when the pain score was greater than 3.

The first analgesic intake and total analgesic consumption were determined. The patients left the PACU after achieving an Aldrete score of at least 9, and the time spent in the PACU was recorded [17]. The patients were assessed for their ability to sit, stand, walk, and urinate at 15-minute intervals. The postoperative urinary retention (POUR) was evaluated at hourly intervals in the PACU and ward; ultrasonic bladder scanning was used for this purpose. If the bladder volume exceeded 500 mL and the patient had not voided spontaneously, urinary catheterization was planned. The time to home readiness was assessed as the time from the end of surgery until the patients reached a postanaesthesia discharge score (PADS) ≥9 and were able to void spontaneously or received a urinary catheter and the sensory block resolved to S3 dermatome. Any adverse events were recorded before discharge, including postoperative nausea and vomiting (PONV) or voiding difficulty. All of the patients were contacted the next day by telephone and questioned regarding pain, headache, use of analgesics, and complaints of TNS, which were defined as pain, dysesthesia, or both in the buttocks and/or lower extremities. During their control visit at the hospital 3 days after the surgery, patients also completed a questionnaire regarding headaches, TNS, and their rating of the anaesthetic method (unsatisfied, satisfied, or very satisfied).

2.3. Statistical Analysis. The relation between the independent parameters and the onset and recovery of the spinal block was statistically determined. SPSS for Windows version 11.5 (SPSS Inc., Chicago, IL, USA) was used. The Kolmogrov

Table 1: Patient characteristics and surgical data.

	Group P ($n = 25$)	Group B ($n = 25$)	P value
Age (years)	37.8 ± 12.4	38.4 ± 13.3	0.878
Gender (n)			
Male	12 (48.0%)	16 (64.0%)	0.254
Female	13 (52.0%)	9 (36.0%)	
BMI (kg/m^2)	26.4 ± 5.2	27.3 ± 5.2	0.541
ASA (n)			
I	15 (60.0%)	13 (52.0%)	0.569
II	10 (40.0%)	12 (48.0%)	
Operation (n)			0.483
Haemorrhoid	14 (56.0%)	13 (52.0%)	
Perianal fissure	10 (40.0%)	11 (44.0%)	
Perianal fistula	3 (12.0%)	1 (4.0%)	
Duration of surgery (min)	18 ± 9.4	20 ± 10	0.387

BMI: body mass index, ASA: American Society of Anaesthesiologists physiologic state. Results are presented as mean ± standard deviation, numbers, and percentages.

Smirnov test was used to test the normality of the distribution for continuous variables. These data were expressed as the mean ± standard deviation or median (minimum-maximum), where applicable. The mean differences were compared using an unpaired Student's t-test, and the Mann-Whitney U test was used to compare median values. The hemodynamic parameters (i.e., systolic, diastolic, and mean blood pressure, pulse rate, and oxygen saturation) were evaluated by repeated measures of ANOVA. The Greenhouse-Geisser test was applied to test the significance of the interaction term (i.e., time × group). The nominal data were analysed using Fisher's exact test or the Pearson's chi-squared test, where applicable. A P value less than 0.05 was considered statistically significant. For all possible multiple comparisons, the Bonferroni correction was applied to control for type I errors.

A sample size of 25 per group was required to detect at least a 30-minute difference (SD = 35.2) in S3 regression time and a 45-minute difference (SD = 38.9) in S1 regression time with a power of 90% at the 5% significance level. The differences of 30 minutes and 45 minutes were taken from literature [12, 18]. The primary outcome variables were the sensory block resolution to S3 block and time to home readiness. Other outcome variables included the onset time of the block, maximum dermatomal spread of the block, degree and motor block resolution time, length of stay in the PACU, hemodynamic parameters, and adverse events.

3. Results

3.1. Patient Characteristics. Fifty patients were enrolled in the study; none of the enrolled patients was excluded. There was no difference between treatment groups regarding age, weight, height, BMI, or gender. (Table 1). All of the operations were completed with the planned spinal anaesthesia method.

3.2. Onset of the Spinal Block. The mean time to L1 block was shorter for Group P than for Group B (4.6 ± 1.3 min versus 5.9 ± 01.9 min, $P = 0.017$). The mean time to maximum sensory block was shorter for Group P than for Group B (13.2 ± 7.5 min versus 15.3 ± 6.6 min, $P = 0.04$). Maximum dermatomal spread of the block was T9 (6–12) in Group B and T9 (6–12) in Group P ($P = 0.657$). The groups were similar regarding the degree of motor block at the time that each group reached maximum sensory block (Figure 1) (Table 2).

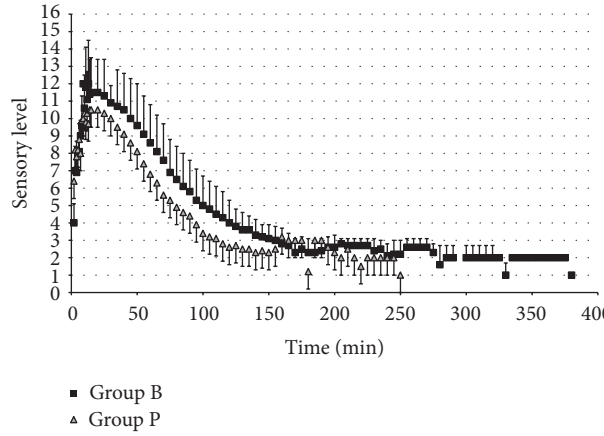

Figure 1: Onset and resolution of the sensory block.

3.3. Intraoperative Events and Treatments. The blood pressures and heart rates of all of the patients were stable throughout the study period. The mean MAP at the time that each group reached maximum sensory block was similar. One patient in each group experienced hypotension that needed treatment with additional fluid and ephedrine, and 1 patient in Group B experienced bradycardia and required treatment with atropine. Oxygen desaturation was not observed in any group. The groups were similar regarding intraoperative adverse events and treatments. One patient in each group required sedation. The maximum midazolam dose was 5 mg.

Table 2: Recovery and motor block characteristics.

	Group P	Group B	*P*
PACU time (min)	63 ± 28	99 ± 37	<0.001*
Time to sit unassisted (min)	30.6 ± 11	36.1 ± 13.7	0.109
Time to stand unassisted (min)	138.7 ± 55.9	172.2 ± 85.2	0.002*
Time to walk unassisted (min)	136.9 ± 53.6	172.0 ± 82.5	0.002*
Time to void (min)	152.8 ± 104.8	172.4 ± 130.8	0.682
Recovery time (time to S3 resolution of sensory block) (min)	133.8 ± 41.4	200.4 ± 64.8	<0.001*
Time to home readiness (min)	155 ± 100.2	207.2 ± 62.7	<0.001*
Bromage score at max. block 0/1/2/3 (*n*)	13/6/3/3	8/1/12/4	0.152
Bromage score at 1 hour 0/1/2/3 (*n*)	22/2/1/0	11/9/4/1	<0.001*
Bromage score at 2 hours 0/1/2/3 (*n*)	25/0/0/0	22/3/0/0	0.235

Bromage score: 0: no motor block, 1: hip blocked, 2: hip and knee blocked, 3: hip, knee, and ankle blocked, and *n*: number of patients with each degree of motor block at the corresponding time. Data are presented as mean ± standard deviation and numbers.
*Significant difference between groups.

The mean duration of surgery was similar in both groups (18 ± 28 min for Group *P* versus 20 ± 10 min for Group B).

3.4. Resolution of the Spinal Block. The mean time to two-segment resolution was similar between the groups (19 ± 12.4 min for Group P versus 23 ± 12.5 min for Group B ($P = 0.214$)). The mean times to L1 regression and S3 regression of the sensorial block were significantly shorter for Group P than for Group B (45.7 ± 21.9 min versus 59.7 ± 20.9 min, $P = 0.024$ (time to L1 regression), and 133.8 ± 41.4 min versus 200.4 ± 64.8 min, $P < 0.001$ (time to S3 regression)). The motor block resolved in both groups by the time the block resolved to the S3 dermatome. The length of stay in the PACU and the time required to stand and walk without assistance were different between groups, but no difference was found in the mean time to sit. The mean PACU stay was 63.2 ± 28 min for Group P and 98.8 ± 37 min for Group B ($P < 0.001$) (Figure 1) (Table 2).

3.5. Postoperative Events and Treatments. The postoperative VAS scores for Groups P and B were similar. The mean time to first analgesic intake was 192 min for group P versus 277 min for Group B; the difference was not statistically significant (Figure 2).

The time to spontaneous voiding was also similar between the two groups. The mean time to S3 resolution of sensory block was shorter for Group P than for Group B (133.8 ± 41.4 and 200.4 ± 64.8 min, resp.) (Table 2). The groups were also similar regarding postoperative adverse events. One patient in each group had urinary retention; these patients were treated with urinary catheterization. The acceptance of the anaesthesia technique was rated as either satisfied or very satisfied by the patients; none of the patients reported to be unsatisfied. TNS were not observed in either spinal anaesthesia group at the 3-day postoperative follow-up.

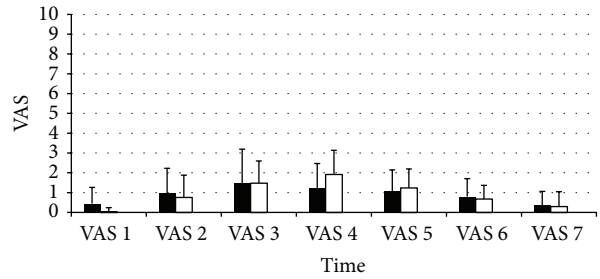

Figure 2: Postoperative VAS pain scores. VAS: visual analog scale.

4. Discussion

Discharge delay is a major concern in day-case spinal anaesthesia [4, 5]. This study demonstrated that spinal anaesthesia with 2% hyperbaric prilocaine 30 mg + 20 μg fentanyl provides faster sensorial block resolution and earlier home readiness compared with 0.5% hyperbaric bupivacaine 7.5 mg + 20 μg fentanyl. Time to block onset was also faster with the hyperbaric prilocaine-fentanyl combination and the surgical conditions were comparable to the hyperbaric bupivacaine-fentanyl combination.

Bupivacaine has been widely studied in day-case spinal anaesthesia. Lacasse et al. used 0.75% 7.5 mg bupivacaine in

anorectal surgery and reported the time to S2 regression as 329 min [19]. In another study comparing different bupivacaine doses, the time to the resolution of the spinal block to the S2 dermatome with 15 mg bupivacaine was 343 min [10]. The long recovery times reported in these studies may be explained by the high concentration of bupivacaine used in the first study and the high dose bupivacaine in the second. Ben David et al. also compared different doses of bupivacaine and reported that 0.5%, 7.5 mg bupivacaine is the optimum dose for day-case anaesthesia, whereas 5 mg bupivacaine is associated with intraoperative pain [20]. Inadequate anaesthesia with low doses of bupivacaine has been reported, and the addition of an opioid seems to overcome this problem [21, 22]. Fentanyl is suitable for this purpose as it has a quick onset, medium-length lasting effect, and low risk of late-onset respiratory depression. Intrathecal 10–25 μg fentanyl is safe and increases the quality of the sensory block without prolonging motor block [23, 24].

In the present study, a bupivacaine-opioid mixture, as an active control of proven efficacy, was used to evaluate the effectiveness of 30 mg hyperbaric prilocaine in day-case spinal anaesthesia for perianal surgery. Different doses of either plain or hyperbaric prilocaine have been studied in day-case spinal anaesthesia. Camponovo et al. compared the use of 40 mg and 60 mg hyperbaric prilocaine doses with 60 mg plain prilocaine in ambulatory surgery. The authors reported that hyperbaric prilocaine is superior to plain prilocaine in the ambulatory setting in terms of faster time to motor block resolution and shorter durations of surgical block [14]. The time to home discharge was reported to be 256 min with 60 mg and 208 min with 40 mg hyperbaric prilocaine; the time to home readiness was longer compared to our results but the doses used were higher and the maximum spread of the sensory block was not reported in this study. Black et al. reported that the use of 20 mg plain prilocaine and 20 μg fentanyl was comparable to the use of 7.5 mg bupivacaine and 20 μg fentanyl, and prilocaine provided shorter times to recovery [23]. This study defined the recovery of spinal block as the time to sensory block regression to the L4 dermatome. Further regression of the sensory block is unclear. The resolution of the sensory block to S3 must be evaluated, especially in surgery with high risk of urinary retention. As perianal surgery is associated with a high risk of urinary retention, we consider time to sensory block resolution to S3 dermatome as a better outcome.

A recent study by Gebhardt et al. compared 3 different doses of hyperbaric prilocaine in perianal surgery [18]. They reported 199, 219, and 229 minutes discharge times with 10, 20, and 30 mg hyperbaric prilocaine, respectively. The discharge time as well as the time to void with 30 mg hyperbaric prilocaine was longer compared with our results. In that study, the patients waited in the sitting position for 10 minutes after the spinal injection, this might have limited the spread of the sensory block. In our method, the patients waited in the sitting position for only 2 minutes, and the wider spread of the local anaesthetic probably resulted in a lower concentration of local anaesthetic per segment and faster elimination from the intrathecal space [25, 26]. The authors recommended 10 mg hyperbaric prilocaine for perianal outpatient surgery; however, they also noted that the procedures should be limited to the perianal skin. Despite this recommendation and since our series included perianal fistulas and surgical interventions that involved deeper tissues we preferred to use 30 mg prilocaine.

In addition to the advantage of faster block regression and early home readiness, we showed that the block quality with 30 mg hyperbaric prilocaine + 20 μg fentanyl was similar to 7.5 mg hyperbaric bupivacaine + 20 μg fentanyl. The maximum block height was similar with both prilocaine and bupivacaine in our study. The block height is determined by the baricity of the local anaesthetic solutions as well as the position of the patient. The hyperbaric solutions of bupivacaine and prilocaine are identical in their glucose concentration. The motor block intensity of intrathecal 7.5 mg bupivacaine is well defined. Bromage grade 2 block was reported in 53% of the patients with 7.5 mg bupivacaine and the time to complete resolution of motor block was 119 minutes [19, 20]. However data concerning 30 mg prilocaine is lacking. In the present study Bromage grade 2 motor block was observed in 48% of the patients in Group B and in 12% of the patients in Group P. Patients in Group P were significantly earlier able to walk unassisted.

Along with prolonged sensory and motor block, pain is an important cause for discharge delay [5]. Despite the shorter block duration in Group P, the postoperative VAS pain scores and the time to first analgesic intake were comparable between the groups in our study.

A recovery difference of 35 minutes is significant in the day-case setting. Decreasing the time to discharge from the PACU by more than 10% can decrease PACU congestion by 20%. Shorter PACU stays should enable PACUs to increase the number of patients served and also increase the quality of care and reduce the risk of postanaesthesia complications [27]. Hyperbaric prilocaine is more economical than bupivacaine if the PACU stay is shorter than at least 130 minutes [28].

TNS were not observed in our study population; however the study was powered to compare the recovery times of the spinal block between groups so we are not able to comment on adverse events and this is a limitation of this study.

In conclusion, day-case spinal anaesthesia with prilocaine 30 mg + 20 μg fentanyl provides faster sensory block resolution and home readiness compared to 7.5 mg bupivacaine + 20 μg fentanyl and the surgical conditions are comparable for perianal surgery.

Conflict of Interests

The authors declare that there is no conflict of interests regarding the publication of this paper.

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Clinical Study

Tunneling and Suture of Thoracic Epidural Catheters Decrease the Incidence of Catheter Dislodgement

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Background. Dislocation of epidural catheters (EC) is associated with early termination of regional analgesia and rare complications like epidural bleeding. We tested the hypothesis that maximum effort in fixation by tunneling and suture decreases the incidence of catheter dislocation. *Methods.* Patients scheduled for major surgery ($n = 121$) were prospectively randomized in 2 groups. Thoracic EC were subcutaneously tunneled and sutured (tunneled) or fixed with adhesive tape (taped). The difference of EC length at skin surface level immediately after insertion and before removal was determined and the absolute values were averaged. Postoperative pain was evaluated by numeric rating scale twice daily and EC tips were screened microbiologically after removal. *Results.* Both groups did not differ with respect to treatment duration (tunneled: 109 hours ±46, taped: 97 ± 37) and postoperative pain scores. Tunneling significantly reduced average extent (tunneled: 3 mm ±7, taped: 10±18) and incidence of clinically relevant EC dislocation (>20 mm, tunneled: 1/60, taped: 9/61). Bacterial contamination showed a tendency to be lower in patients with tunneled catheters (8/59, taped: 14/54, $P = 0.08$). *Conclusion.* Thorough fixation of EC by tunneling and suturing decreases the incidence and extent of dislocation and potentially even that of bacterial contamination.

1. Introduction

Dislocation of epidural catheters (EC) may cause early termination of postoperative regional analgesia. Moreover, accidental removal shortly after anticoagulant administration, such as prophylaxis of deep vein thrombosis, may increase the risk of epidural hematoma and neurologic complications [1, 2]. Finally, it is speculated that catheter movement within the skin may potentially contribute to bacterial contamination possibly linked to catheter-related infective complications with colonization rates as high as 12% [3].

At our institution, EC had been traditionally attached to the skin using adhesive tape (taped). Regarding institutional data, dislocation occurred in up to 30 percent of our patients during the first postoperative days, which is within previously reported limits [4]. Accordingly, we tested the hypothesis that maximum effort to secure EC by subcutaneous tunneling and suture decreases the incidence of dislocation and the extent of movement. Postoperative analgesia during EC treatment as quantified by numeric rating scale and bacterial contamination was defined as secondary study endpoints.

2. Material and Methods

2.1. Ethics. Ethical approval for this study (Ethical Committee ID number 3433) was provided by the Ethical Committee of the Medical Faculty of the University of Düsseldorf, Düsseldorf (Chairperson Professor Dr. H.-G. Lenhard), on July 28, 2010. Additionally the study was registered at clinicialtrials.gov (http://www.clinicaltrials.gov/, NCT01402778).

After informed consent, 158 patients older than 18 years and scheduled for major abdominal or thoracic surgery under combined general and thoracic epidural anesthesia were assessed for eligibility (Figure 1). Patients were allocated to

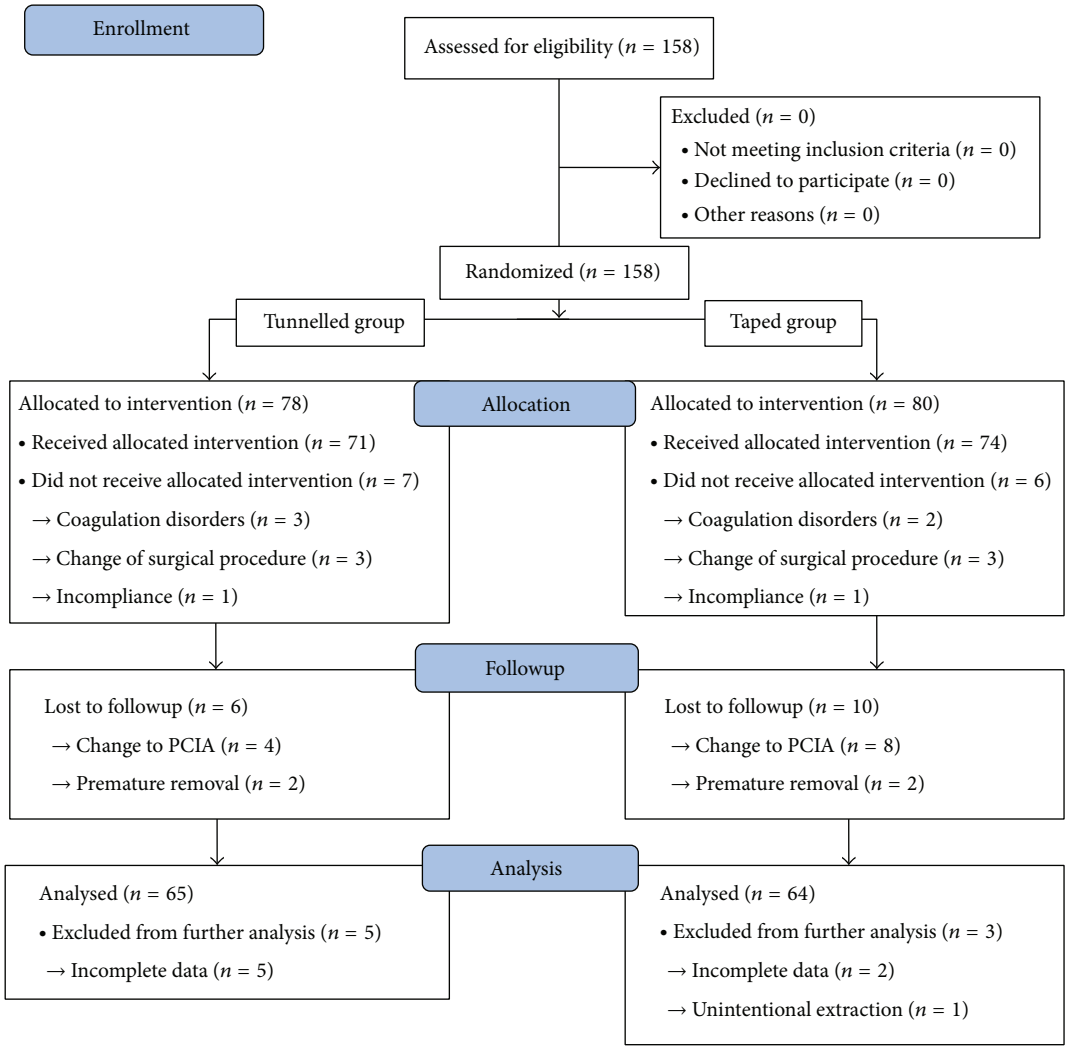


Figure 1: Flow chart according to CONSORT guidelines. PCIA patient controlled intravenous anesthesia.

treatment groups by means of randomization (block formation with 10 patients each).

2.2. Treatment Groups. Thoracic EC were inserted preoperatively before induction of anesthesia using the "loss of resistance technique" under sterile conditions using gloves, surgical caps, gown, and facial mask.

Patients were placed in sitting position and their backs were prepped with a propanol-based solution (Kodan tincture forte, Schuelke & Mayr GmbH, Norderstedt, Germany) for 2 minutes and covered with a fenestrated self-adhesive drape [5]. A skin wheal was induced using lidocaine 1%, followed by the insertion of a 17-gauge Tuohy needle. After loss of resistance to saline, an EC (Perifix Catheter, B. Braun, Germany) was inserted 3–5 cm into the epidural space and connected to a Perifix bacterial filter (0.2 μm; B. Braun, Germany). EC were either fixated by steri-strips (Steri-Strip, 3M, St. Paul, MN, USA) or subcutaneously tunneled (>2 cm) using a 16-gauge i.v. line as a control structure followed by suturing to the skin using a synthetic, monofilament, nonabsorbable polyester suture. Steri-strips were taped leaving the puncture site uncovered. Thus, the position of the catheter could be assessed without movement likely induced by removal of the sterile tapes. Fixation techniques are presented in Figure 2. Afterwards, all EC were covered at the puncture site with a sterile tape (Tegaderm 3M, St. Paul, MN, USA). The distance between epidural tip and skin surface was recorded in each patient.

Postoperative analgesia was accomplished using epidural ropivacaine 0.2% (4–10 mL/h, depending on NRS score). Comedication consisted of intravenous metamizole (1 g every 6 h). In case of intolerance intravenous paracetamol (1 g every 6 h) was given. Intravenous piritramide (7.5 mg) was allowed as rescue medication.

2.3. Postoperative Followup. A physician of the Acute Pain Service (APS) daily visited all patients twice until 24 hours after catheter removal. No systematic change of drapes was undertaken. There was no specific nurse protocol for EC maintenance.

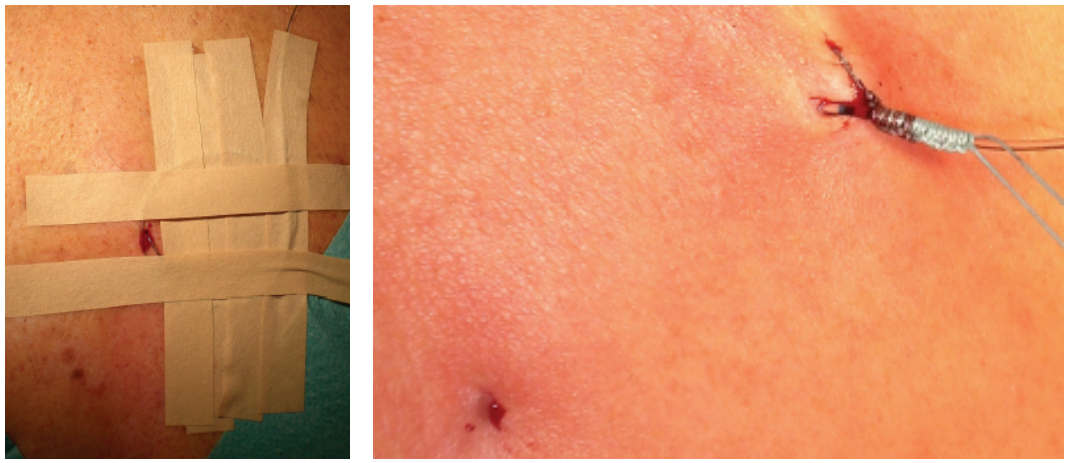


Figure 2: Different fixation techniques. Fixation by taping (left) and tunneling and suturing (right). For further information please refer to the text.

Pain intensity (numeric rating scale, NRS) at rest and during movement, use of analgesic adjunct, systemic antibiotic medications, and signs of catheter-related local complications were assessed during follow-up visits. Duration of treatment and time point of sterile catheter removal were determined by an anesthesiologist not involved in the study. The catheter tip was transferred to a polypropylene screw-cap tube with internal conical shape filled with 1 mL of liquid Amies medium (Copan Innovation, Brescia, Italy) for microbiological evaluation.

2.4. Study Endpoints

2.4.1. Epidural Catheter Dislocation. The distance between catheter tip and the skin was recorded a second time at removal and compared to the preoperative value directly after catheter insertion. Absolute values for catheter length were determined in millimeters using a ruler. Data collection and catheter removal were performed by an anesthesiologist who was blinded to the initial value at catheter insertion. According to previous definitions [4, 6] and the type of multiorifice catheters used, we considered dislocation to be clinical relevant when in- or outward movement greater than 20 mm occurred.

2.4.2. Quality of Postoperative Analgesia. The extent of postoperative analgesia was recorded after interviewing the patients using NRS at rest and during movement. After catheter removal, overall subjective contentment with the procedure was assessed retrospectively, using notes from 1 (excellent) to 5 (insufficient).

2.4.3. Clinical Signs of Infection. Clinical signs of site inflammation followed the classification recommended by the German Society of Anesthesiologists and were defined as mild (two or more of the following: redness, swelling, pressure pain at catheter insertion, or tunneling site), moderate (two or more of the following: rise of C-reactive protein, pus secretion from puncture site, leukocytosis, fever, or necessity for antibiotics after exclusion of other causes), or severe (need for surgical intervention) [6–10].

2.4.4. Bacterial Contamination. The catheter tip was cut into roughly 5 mm pieces that were incubated in thioglycolate bouillon for 48 hours. The cultures were assessed at 24 and 48 hours and if growth was detected a Gram stain was performed and 10 μL aliquot of the bouillon was plated onto MaConkey, blood, and chocolate agar, respectively. If yeasts were seen on Gram staining Sabouraud agar was inoculated. The agar plates were incubated for 24 hours and microbiological methods were used to identify the bacteria. Bacteria were then tested for antibiotic sensitivity.

2.5. Statistical Analysis. Sample size calculation: assuming an incidence of clinical relevant EC migration (>20 mm) at our institution in 27% of patients (±10%) with traditional EC fixation a 15% difference (incidence greater than 31% or lower than 23%) can be determined by inclusion of 60 patients per group ($\alpha < 0.05$, $1 - \beta < 0.2$).

Data are expressed as mean (SD) except ordinal data (median, interquartile range). Statistical analysis was performed using Fisher's exact test, student's t-test, Mann-Whitney test, or Friedman's test when appropriate. P values less than 0.05 were considered to be statistically significant.

3. Results

Sixteen patients (10 taped and 6 tunneled) were lost to followup, 7 had incomplete data, and 1 was extracted unintentionally. This means that the degree of dislodgement was not assessed in 24 of 145 patients that received their allocated intervention (and 158 randomized) (Figure 1). One hundred twenty-one patients were included into the final analysis (Figure 1). Both groups were comparable with respect to age and gender. There were no significant differences between groups regarding puncture site, duration, access (midline

Table 1: General data of study groups (tunneled versus taped).

	Tunneled	Taped	
Age [years]	57	58	$P = 0.34$
Gender [male : female]	35 : 25	35 : 26	$P = 0.61$
Duration of catheterization [hours]	109 (±46)	97 (±37)	$< P = 0.06$
Access of puncture (n=)			$P = 0.2$
Midline	38	44	
Paramedian	22	17	
Level of puncture (n=)			$P = 0.2$
High thoracic ($T_{3/4}$–$T_{6/7}$)	7	10	
Mid thoracic ($T_{7/8}$–$T_{8/9}$)	40	41	
Low thoracic ($T_{9/10}$–$T_{11/12}$)	13	10	
Type of surgery (n=)			$P = 0.31$
Thoracic	7	9	
Abdominal	44	37	
Urological	8	15	
Combined	1	0	

General data revealed no intergroup difference. Student's t-test, Fisher's exact test, and Mann-Whitney U test were used for statistical analysis.

versus paramedian), level (high, mid, and low thoracic) of catheterization, and type of surgery (Table 1).

3.1. Epidural Catheter Dislocation. Tunneling and suture significantly decreased the incidence of catheter dislocation considered clinically relevant (>20 mm) from 9/61 (taped) to 1/60 (tunneled), respectively, ($P < 0.01$, Figure 3). Of all dislocations >20 mm, five epidurals of the taped group moved inwards; all other catheters moved outwards. Major displacement occurred mainly after day 2. No complications occurred by tunneling of the catheters. Particularly, we did not observe subcutaneous hematoma, bleeding, or occlusion of the catheter lumen by sutures placed too tight.

3.2. Quality of Postoperative Analgesia. Frequency of analgesic comedication as well as analgesic quality of both techniques was comparable between groups at rest as well as during movement over the course of time. When interviewed retrospectively, both groups showed no difference in satisfaction with the procedure, $P = 0.26$, (Figure 4).

3.3. Clinical Signs of Infection. All patients received systemic antibiotic medications as single shot surgical prophylaxis that was repeated once in patients with duration of surgery greater than 6 hours. No patient received antibiotics for EC-related infections. Overall, three patients presented with mild

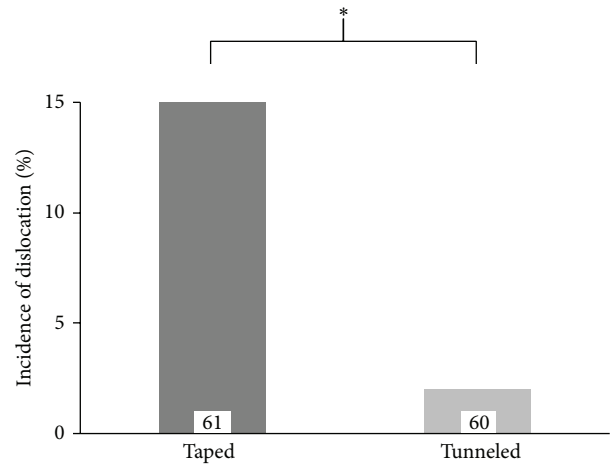


Figure 3: Incidence of catheter dislocation >20 mm. Data was available for $n = 121$ patients (61 taped/60 tunneled). Fisher's exact test was used to calculate statistical significance ($^*P < 0.01$). Relative risk was 0.3389 [95% CI 0.1158–0.9920].

clinical signs of infection. One patient had a positive bacterial contaminated catheter (taped) and two patients had EC that were microbiologically sterile (tunneled). No patient showed signs of moderate or severe infection. Therefore, no extended diagnostics (blood cultures, MRI) were performed. There was no difference between the study groups.

3.4. Bacterial Contamination. Of 121 enrolled patients, 113 catheter tips (59 tunneled, 54 taped) were available for microbiological screening (Figure 5). Eight catheters were lost to followup. A total of 22 pathogens (8 tunneled, 14 taped EC) were detected. Tunneling and suture of EC tended to decrease bacterial contamination ($P = 0.08$). Coagulase-negative staphylococci (CoNS) were the predominant pathogens, exclusively found in the tunneled group and in the majority of the taped group, whereas *Staphylococcus aureus* and *Enterococcus faecalis* were isolated in two patients with catheters taped. Data with respect to contaminated EC are summarized in Table 2.

4. Discussion

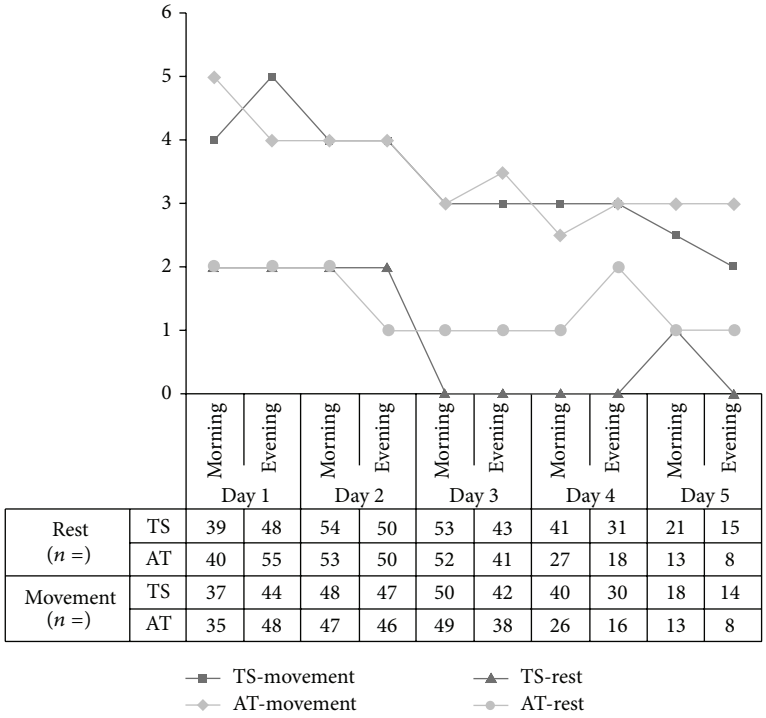
Epidural catheter dislocation is a common phenomenon. Overall dislocation rate in this study was 37 percent (45/121), which is previously reported, though at the very high part of the range [4, 11–14]. The major achievement of our study is that we were able to demonstrate a more than 90 percent decrease of incidence of dislocation as compared to standard plain adhesive tape fixation. Furthermore, incidence of bacterial contamination tended to be decreased as well.

Premature catheter dislodgement bears relevant objective (economic) and subjective (patient) burden and may potentially lead to prolonged and more expensive inpatient stay [6]. In addition, unplanned catheter movement may be associated with rare, but clinically most relevant, complications such as spinal hematoma when occurring shortly after anticoagulant administration [14].

Table 2: Data concerning contaminated epidural catheters.

	Age	Sex	Site	Level	Duration (h)	Dislocation	Pathogen	Comorbidities				Perioperative antibiotics	Punctures	Signs of infection
								MG	DM	CS	CT			
Group 1 (tunneled)	47	M	Paramedian	Mid	147		CoNS*	Yes	No	No	Yes	CPZ¶ (2 g)	1 x	Ø
	61	M	Midline	High	294		CoNS*	Yes	No	No	No	CPZ¶ (2 g) + METRO** (0.5 g)	2 x (os)	Ø
	62	F	Midline	Mid	99		CoNS*	Yes	No	No	No	CPZ¶ (2 g) + METRO** (0.5 g)	1 x	Ø
	76	F	Midline	Mid	100		CoNS*	Yes	No	No	No	CPZ¶ (2 g) + METRO** (0.5 g)	1 x	Ø
	79	F	Midline	Mid	74	10 mm out	CoNS*	Yes	No	No	Yes	CPZ¶ (2 g) + METRO** (0.5 g)	2 x (os)	Ø
	44	M	Midline	Low	48		CoNS*	No	No	No	No	CPZ¶ (2 g)	1 x	Ø
	36	M	Midline	Low	124		CoNS*	Yes	No	No	No	CFTX†† (2 g)	1 x	Ø
	61	M	Midline	High	101		STAEPI†	Yes	No	No	No	CPZ¶ (2 g)	1 x	Ø
Group 2 (taped)	55	M	Midline	Mid	76		CoNS*	Yes	No	No	No	CPZ¶ (2 g)	1 x	Ø
	68	M	Paramedian	Mid	124		CoNS*	Yes	No	No	No	CPZ¶ (2 g) + METRO** (0.5 g)	1 x	Ø
	78	F	Midline	Mid	93	30 mm in	CoNS*	Yes	Yes	No	No	CPZ¶ (2 g) + METRO** (0.5 g)	2 x	Ø
	66	M	Midline	Mid	96		CoNS*	Yes	No	No	No	CPZ¶ (2 g) + METRO** (0.5 g)	1 x	Ø
	53	M	Midline	Mid	194		CoNS*	Yes	No	No	No	CPZ¶ (2 g) + METRO** (0.5 g)	1 x	Ø
	75	F	Midline	Mid	76	10 mm out	CoNS*	Yes	Yes	No	No	CPZ¶ (2 g)	1 x	Ø
	71	M	Midline	Low	70		CoNS*	Yes	No	No	No	CPZ¶ (2 g) + METRO** (0.5 g)	1 x	Ø
	53	M	Midline	High	99	20 mm out	STAAUR‡	Yes	No	No	Yes	CPZ¶ (2 g) + METRO** (0.5 g)	1 x	Redness, swelling
	76	M	Midline	Mid	190		CoNS*	Yes	Yes	No	No	CPZ¶ (2 g) + METRO** (0.5 g)	1 x	Ø
	83	F	Paramedian	Low	148		CoNS*	Yes	No	No	No	CPZ¶ (2 g) + METRO** (0.5 g)	1 x	Ø
	66	F	Midline	Low	100		CoNS*	Yes	No	Yes	No	CFTX†† (2 g)	1 x	Ø
	61	M	Paramedian	High	96	90 mm out	CoNS* + ENCFIS§	Yes	No	No	No	CPZ¶ (2 g)	1 x	Ø
	37	M	Midline	Mid	167		CoNS*	No	No	No	No	CPZ¶ (2 g) + METRO** (0.5 g)	1 x	Ø
	53	M	Midline	Mid	95	20 mm in	CoNS*	No	No	Yes	No	CPZ¶ (2 g) + METRO** (0.5 g)	1 x	Ø
P=	**0.2**	**0.5**	**0.9**	**0.4**	**0.4**									

MG: malignancy; DM: diabetes mellitus; CS: corticosteroids; CT: chemotherapy; *CoNS: coagulase-neg. staphylococci; †STAEPI: *Staphylococcus epidermidis*; ‡STAAUR: *Staphylococcus aureus*; §ENCFIS: *Enterococcus faecalis*; ¶CPZ: cephazoline; **METRO: metronidazole; ††CFTX: ceftriaxone; antibiotics were administered exclusively in the perioperative period. Note that none of the contaminated epidural catheters in the tunneled and only one epidural catheter *n* the taped group showed clinical signs of infection. Student's *t*-test, Fisher's exact test, and Mann-Whitney *U* test were used for statistical testing. Of note, the patient of the taped group with a 90 mm catheter dislodgment showed no signs of insufficient analgesia during rest; however, his visual analogue scale was 5-6 on movement for the first three days.



		Day 1		Day 2		Day 3		Day 4		Day 5	
		Morning	Evening	Morning	Evening	Morning	Evening	Morning	Evening	Morning	Evening
Rest (n =)	TS	39	48	54	50	53	43	41	31	21	15
	AT	40	55	53	50	52	41	27	18	13	8
Movement (n =)	TS	37	44	48	47	50	42	40	30	18	14
	AT	35	48	47	46	49	38	26	16	13	8

Figure 4: Comparison of analgesic quality by means of NRS (numeric rating scale). TS tunneled and sutured ("tunneled"); AT adhesive tape ("taped"). All data are presented as median. The total number of interviewed patients at different times is presented at the bottom of the graph. Not all patients were present at the time of the ward round.

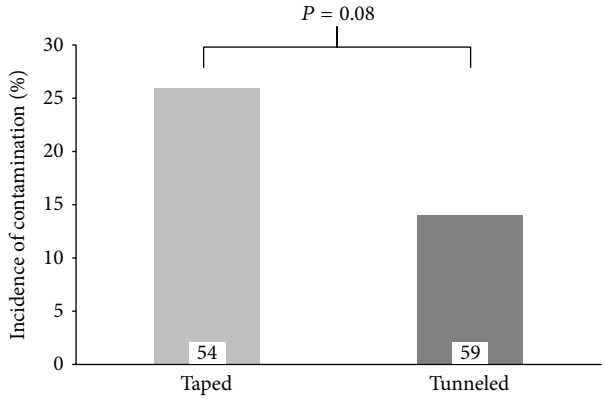


Figure 5: Overall incidence of bacterial contamination. 113 epidural catheter tips (59 tunneled, 54 taped) were available for microbiological screening. Fisher's exact test showed no statistical significance (P = 0.08).

Epidural catheters in our institution are routinely inserted 3–5 cm into the epidural space in order to allow minor catheter movements without immediate loss of analgesic effect combined with lowest rates of catheter insertion-related problems (e.g., unilateral spread of anesthesia, neural root affection) [15, 16]. We routinely use multiorifice catheters with the most proximal orifice located 14 mm from catheter tip. If epidurals are inserted 30 mm a dislocation of 20 mm would consecutively lead more or less to procedural failure, as the proximal orifice would be out of the epidural space. Thus, we have chosen to adopt dislocation definitions introduced by Bougher et al. in 1996 [4], though a variety of other definitions exist [3, 11, 14, 17]. Dislocation rates in the tunneled group of our study were considerably lower in comparison to available literature [11, 13]. Only Tripathi and Pandey found comparable dislocation rates for tunneled EC of 3 percent [12]. There seems to be a tendency towards higher overall movement rates of thoracic in comparison to lumbar epidural catheters [4, 11]. As inward migration may lead to ascending levels of blockade or accidental dural perforation with consecutive spinal drug infusion, an even more stringent definition for clinically significant movement, usually 10 mm, has been suggested [3, 11, 13]. In our study, all patients had a thoracic epidural and received early daily physiotherapy; however, no case of secondary, accidental spinal drug infusion was reported. This study, to our knowledge, is the first to demonstrate the impact of using maximum effort of catheter fixation by a combination of techniques each described as independently reducing dislocation [3, 13].

Dislocation frequently occurs during treatment course (from day 2 on) and not directly after insertion [4, 11]. Table 2 shows that catheter dislodgment > 20 mm emerged around day four in the majority of cases. Clinically, day four of epidural treatment is distinguished by a nonsignificant accretion of pain intensity as expressed by NRS in the taped group only. We may speculate that reasons for late displacement may be postoperative recovery and increasing mobilization. Thus, tunneling and suture may be particularly

beneficial if EC are planned to be used for more than a couple of days.

Bougher et al. did not report on any relation between catheter dislodgement and analgesia quality [4]. Bishton et al. in contrast found a 100 percent relation between catheter migration (≥25 mm) and failed epidural block [17]. Mourisse et al. observed that inward movement was accompanied by a higher level of sensory blockade but did not report on loss of analgesic quality [18]. We believe that routine use of analgetic comedication with NSAID (metamizole), paracetamol, and/or piritramide was sufficient enough to compensate the putative loss of late catheter function.

4.1. Clinical Signs of Infection. Tunneling and suture of epidurals may lead to local inflammatory reactions of the skin restricting a more prolonged use [12]. On the other hand, plain tape fixation theoretically allows less restricted in- and outward movement of catheters, thus potentially promoting infectious complications. Overall, three patients presented with signs of local infection (2.5%), which is comparable to earlier data from a German network [6]. As could be expected, no patient in our study suffered from moderate or severe infection and no catheter had to be removed in face of infectious complications. It was interesting to see a higher, though microbiologically unobtrusive, incidence with clinical signs of infection contamination in tunneled in comparison to taped epidurals, where *Staphylococcus aureus* was isolated. Factors presumably increasing the risk of infectious complications include age, gender, immunosuppression, duration of catheterization, and multiple punctures or puncture sites [6, 19]. In our study, these factors showed no statistical significant intergroup difference. It remains interesting that despite potential protective effects the rate of clinical signs of infection was twice as high for tunneled epidurals in this study, lending no support to the thesis that firm fixation is associated with less signs of infection. In contrast, the increased site inflammation can be readily explained by the increased number of skin punctures associated with tunneling and suturing. Given the extremely low incidence of severe, potentially fatal infectious complications like deep epidural infections, which varies from 0.007 percent (USA) to 0.025 percent (Sweden) [20, 21], it would be difficult to conduct a trial with sufficient power to detect any significant difference [10].

4.2. Bacterial Contamination. The total rate of pathogen findings in our study was 19% (22/113), with lower incidence for tunneled EC by trend ($P = 0.08$). Contamination rates found in literature vary from 4 percent to 53 percent [22, 23]. One possible explanation might be the use of propanol, an alcohol-based highly potent disinfectant, prior to catheter insertion. Positive microbiological cultures were defined as "bacterial contamination," as accidental contamination during catheter removal could not be ruled out. Of note, blood cultures to confirm or exclude bacteremia were not taken. Yuan et al. suggested that bacterial migration along the epidural catheter track is the most common route of EC colonization [23]. But is there also relation between bacterial contamination and infectious complications?

The effect of subcutaneous tunneling for potentially preventing intravascular device-related infections has been shown [24]; however, its role in regional anesthesia is still a matter of scientific discussion. Bubeck et al. described a reduction of colonization of caudal catheters in children if tunneled, whereas Morin et al. could not observe any correlation between colonization and tunneling in regional anesthesia [25, 26]. At present there is no clear evidence for subcutaneous tunneling to prevent infections in regional anaesthesia [4]. Actual data from Germany stated tunneling rates in regional anesthesia of 21 percent unfortunately not discriminating between peripheral and central nerve blockades [6]. All of the pathogens identified in our study were Gram-positive and potentially capable of causing deep epidural infections (e.g., abscesses) [19]. It is difficult to assess the clinical impact of these findings, particularly, as contamination rarely leads to potentially life-threatening deep epidural infection [24] and the overall incidence of severe infectious complications is low [20, 21].

4.3. Limitations of the Study. As mentioned before, the degree of dislodgement was not assessed in 24 of 145 patients that received their allocated intervention, which may influence the true results. Specifically, premature removal, unintentional extraction, and change to PCIA are relevant outcomes because they may reflect dislodgement. The a priori power analysis was accomplished using the primary end-point of catheter dislocation considered to be clinically relevant. As infectious complications such as contamination are a rare event, this study is underpowered to detect statistical significant infectious complications of these secondary endpoints of the study. Despite this lack of power with respect to infectious complications, a clear trend towards reduced bacterial contaminations using tunneling and suture was noted. Additionally, analgesia was achieved by epidural ropivacaine according to individual pain scores and not at a fixed per protocol rate. This might be considered another limit for the interpretation of analgesia between patient groups that cannot be resolved. Finally, both fixation techniques had been standardized and taught prior to inclusion of the first patient and photo illustrations of both techniques were available in each induction room. However, since the physician inserting the epidural catheter could not be blinded to the fixation technique we cannot completely exclude a "less cared" fixation contributing to the observed inferiority of taping epidural catheters.

5. Conclusions

Thorough tunneling and suture of thoracic epidural catheters significantly reduce incidence and extent of catheter dislocation and potentially that of bacterial contamination. Based on these results, we changed standards for patient care at our institution requiring catheter fixation by tunneling and suture in all patients receiving epidural catheters.

Disclosure

Preliminary data for this study were presented as poster presentations at the Deutsche Anaesthesie Congress (DAC) on May 5–7, 2012, Leipzig, and at the European Society of Anaesthesiology (ESA) Euroanaesthesia on June 9–12, 2012, Paris.

Conflict of Interests

Peter Kienbaum has received lecture fees from Baxter and Air Liquide. For the remaining authors no conflict of interests was declared.

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