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Comparison of Postoperative Pain between Infiltrative Local Anesthesia plus Paracetamol and Total Intravenous Anesthesia plus Paracetamol in Ambulatory Breast Surgery

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ABSTRACT

Background: Acute postoperative pain is an important surgical side effect that may delay patient discharge in ambulatory operations; moreover, the strategies used to alleviate pain may cause side effects that require longer hospitalization to recover. In this clinical trial, we compared two current anesthetic methods with special concerns about postoperative pain intensity beside other important components of ambulatory anesthesia.

Methods: This clinical trial was conducted on two age-matched groups of 75 members who underwent ambulatory breast surgery. Patients in the first group (GA) underwent general anesthesia with propofol plus remifentanyl by employing a laryngeal mask airway. In the second group (LA), the surgeon used infiltration of 2% lidocaine in the breast tissue and midazolam was applied as premedication. At the end of surgery, paracetamol was administered to all patients in both groups. The pain score was evaluated when the patients were fully awake using a numerical pain rating scale. Patients with severe pain received analgesia. The length of postanesthesia care unit (PACU) stay was recorded for each patient.

Results: None of the patients in the LA group were satisfied because of the experience of needle insertion into their breast tissue ($P = 0.001$). The patients in the LA group experienced more pain in PACU requiring adjuvant analgesia ($P = 0.001$). Patients in the LA group had longer PACU admission ($P = 0.001$).

Conclusions: Patients in the LA group had higher pain scores and were dissatisfied with the plan of their anesthesia. This may confirm the role of preemptive analgesia or the effect of emotional stress of breast tissue needling in wakeful patient.

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Introduction

Ambulatory breast surgery for diagnostic or therapeutic approaches is widely used in recent years.¹⁻⁶ Because of the high turnover rate of patients in these ambulatory procedures, the aim of anesthesiologists is to provide an anesthesia technique with acceptable conditions during the procedure and short term postanesthetic care unit (PACU) admission beside early ambulation.^{4,7-9} To



achieve this goal, anesthesiologists employ different techniques of anesthesia and postoperative analgesia to provide patients with safety and comfort.⁷⁻¹³ When the patients are discharged from these ambulatory centers, they should have stable hemodynamic conditions with no significant complaint of nausea, vomiting, and pain.^{4,5,8,9} Acute postoperative pain is an important surgical side effect that may delay patient discharge in ambulatory surgery and also the strategies used to alleviate the pain may cause side effects that require longer hospitalization to recover.¹⁴⁻¹⁶ So, pain management is one of the important aspects of ambulatory breast surgery.

A common method of anesthesia for this purpose is infiltration of local anesthetics in the breast tissue with or without sedation.^{4,5,7} Another popular method is employing total intravenous anesthesia with short acting anesthetic drugs.^{8,9} Available short acting drugs like propofol, remifentanyl, and midazolam have facilitated the use of this method of anesthesia in ambulatory surgical centers in recent years.^{8,9} Furthermore, anesthesiologists prefer to use these short acting drugs in sedative doses when they choose the local infiltration technique.⁴

In this clinical trial, we compared these two anesthetic methods with special concerns about postoperative pain intensity beside other important components of ambulatory anesthesia.

Methods

This clinical trial was conducted on 150 middle aged women who underwent ambulatory breast surgery in breast surgery operating room of an Iranian general hospital during one year from March 2014 up to March 2015. The patients were between 25 to 55 years old. Patients with any comorbidity or addiction to cigar or cigarette, alcoholic drinks, or any drug were excluded from the study. All the patients were admitted in day surgery unit at the same day of the surgery. They were fasting for 8 hours as they were asked to on their last visit before the procedure. The patients were informed about the clinical trial and all of them consented to participation. The details of the methods in the two groups and the principles of infiltrative anesthesia and general anesthesia were not discussed with the patients because the study was double blinded. Their surgery plan was excisional breast biopsy, lumpectomy or cosmetic repair of the breast lesion. The patients were randomly divided into two age-matched groups of 75 patients. The reason for age matching was to remove any senile impression of pain perception in the two groups. The study was double blinded because neither the patients nor the anesthetic nurse who collected the data in PACU was aware of the anesthetic technique employed for each patient.

Patients in the first group (GA) received the

induction dose of propofol (2mg/kg) and general anesthesia was maintained with continuous infusion of 50 mcg/kg/min propofol plus 0.05 mcg/kg/min remifentanyl. The ventilatory support was achieved by using a classic laryngeal mask airway (LMA). Since the patients in this group did not receive any muscle relaxants in their GA regimen, they were able to move their hands in response to painful stimulants. Moreover, any rise in heart rate and blood pressure more than 20% of baseline was also considered as pain in this group.

In the second group (LA), the surgeon used about 150 mg of lidocaine 2% in the site of surgery in the breast tissue; if the patients had pain, the surgeon considered more local anesthetic infiltration up to about 100 mg. The patients were informed that they could ask for more analgesia during the operation by raising their hand. All the cases in this group received 2mg midazolam intravenously as premedication. They had face masks for oxygen supplementation during the procedure.

All the patients in both groups received 1 gr paracetamol intravenously during 30 minutes which started in the final 10 minutes of the surgery and continued in the first twenty minutes in the PACU.

Standard hemodynamic monitoring was applied for all patients during the procedure and in the PACU. At the end of the procedure, the surgeon was asked about the quality of anesthetic technique and his satisfaction was recorded in each case.

An anesthetic nurse who was unaware of the method of the anesthesia visited the patients in PACU when they were fully awake and completed the data collection form designed for the study. The data collection form included hemodynamic components, nausea and vomiting, and patient satisfaction. She also evaluated the pain intensity once after finishing the infusion of paracetamol in each patient by using an 11-point numerical pain rating scale (0: no pain, 1-3: mild pain, 4-6: moderate pain and 7-10: severe pain).¹⁷ The patients with scores more than 6, received adjuvant analgesia and stayed in the PACU for a longer period of time while others were discharged with oral analgesic medication. We used the Aldrete scoring system for discharging the patients from PACU and the length of PACU stay was recorded for each patient.¹⁸

Collected data were analyzed by employing Chi-square test and independent t-test and the results were compared between two groups. Statistical analyses were performed using SPSS software version 16 and P value of less 0.05 were considered as statistically significant.

Results

The duration of procedure was 35.00±8.05 min in the GA and 26.33±7.58 min in the LA group. (P=0.001)

Hemodynamic stability was similar in both



groups. The incidence of bradycardia and hypotension after the induction of anesthesia was 5 (6.7%) in the GA group vs. 1 (1.3%) in the LA group ($P = 0.09$) and the incidence of tachycardia and hypertension was 2 (2.7%) in the GA group vs. 6 (8%) in the LA group ($P = 0.1$) with no significant difference.

No case of desaturation was recorded in the participants and they received O₂ supplementation in PACU for 5 minutes using the face mask; after discontinuing oxygen supplementation, they all had SpO₂ > 95% (97.41 ± 1.74 vs 97.05 ± 1.64). ($P = 0.1$)

Patients in both groups were completely awake few minutes after the procedure when transferring to PACU. None of the patients experienced nausea and vomiting and orthostatic hypotension in PACU.

All the patients in the LA group experienced pain when infiltration of local anesthetic was performed and they were not satisfied because of the experience of needle insertion into their breast tissue. The patients in the GA group were more satisfied with their anesthetic technique compared to LA group (100% vs 0%, respectively) ($P = 0.001$).

During the procedure, 32 (42.7%) patients in the LA group experienced pain. Twenty-five patients (33.3%) in this group raised their hands in response to pain that interrupted the procedure. There were no surgical interruptions in the GA group ($P = 0.001$).

The patients in the GA group had no complaint of pain on their assessment in PACU and they were discharged with an oral analgesic agent if they met other criteria of the Aldrete scoring system. Patients in the LA group experienced pain in PACU about 20 minutes after their PACU admission; the pain was severe in 51 (68.0%) patients requiring adjuvant analgesia. ($P = 0.001$)

The length of PACU stay was 26.92 ± 6.53 min in the GA and 34.84 ± 9.20 min in the LA group. Longer PACU admissions were recorded in the patients with severe pain who needed further treatment, the mean duration of PACU admission was 43.21 ± 5.14 min in these patients ($P = 0.001$).

Discussion

Due to recent advances in the diagnosis of breast diseases, ambulatory breast surgery is performed much more than the past.¹⁻⁵ The aim of medical team is to provide satisfactory medical services with minimal hospital stay for each patient.³⁻⁵ Because of the high turnover rate of patients in these ambulatory procedures, the goal of anesthesiologists is to provide anesthesia technique with acceptable conditions during the procedure and short term PACU admission beside early ambulation.^{4,7-9} To achieve this goal, anesthesiologists employ different techniques of anesthesia and postoperative analgesia to provide the patients with safety and comfort.⁷⁻¹³ When the patients are discharged from these ambulatory centers, they should have stable hemodynamic

conditions with no significant complaints of nausea, vomiting, and pain.^{4,5,8,9} Acute postoperative pain is an important surgical side effect that may delay patient discharge in ambulatory surgery and also the strategies used to alleviate pain may cause side effects that require longer hospitalization to recover.¹⁴⁻¹⁶ Also, pain is an important fearful component of the surgery that makes the patients avoid or delay the surgical plan in non-emergency situations. Therefore, pain management is one of the important aspects of ambulatory breast surgery.^{14, 15} Another important issue that should be considered is that pain management strategies in an ambulatory setting should include methods with no significant side effects that may delay patient discharge.¹⁴ For example, nausea and vomiting and sedation are common side effects of opioids and prolonged sensory or motor block may be noted following regional anesthesia.^{8-12,14-16} In recent years, different methods of anesthesia and analgesia have been studied in different centers to find out which might be a better method to provide all these suitable conditions beside patient comfort and satisfaction.⁷⁻¹³

In this study, we compared two common methods of anesthesia employed in ambulatory breast surgery by focusing on pain management advantages of each method.

In the LA group, we used lidocaine 2% as the local anesthetic agent and midazolam as premedication. This method is employed in many ambulatory surgical centers without the need for the presence of an anesthesiologist since it is done by the surgeon himself.^{4,5,7} The patients in this group experienced a shorter procedure time and were fully awake at the end of the procedure as in other similar studies.^{4,5,7} None of them experienced nausea and vomiting or significant hemodynamic instability during the procedure and in PACU like other similar study.^{4,5,7} The disadvantage of this method was that the patients were not satisfied with the method of anesthesia; they feared needle insertion into their breast tissue and all of them experienced the pain of insertion. Also, the quality of surgical procedure was affected because of the interruptions due to pain or movement.^{4,5} Despite using the same dose of paracetamol which is a well-known analgesic agent for the management of mild to moderate pain, at the end of the procedure, the patients in this group experienced pain requiring adjuvant analgesia administration in PACU.^{4,19-21} In this group, the patients had a longer PACU stay due to pain and adjuvant analgesia administration like other similar study.⁴

In The GA group, the patients received short acting drugs and experienced a longer duration of surgery because of the induction of anesthesia, inserting LMA, and extubation at the end of the procedure. This longer duration of surgery was compensated by the shorter length of PACU

**Table 1.** Comparing O2 saturation, PACU admission length and operation duration between two groups

	Total	GA group	LA group	P-value
SpO2	97.23±1.70	97.41±1.74	97.05±1.64	0.1
Length of PACU admission	30.88±8.89	26.92±6.53	34.84±9.20	0.001
Operation duration	30.67±8.92	35.00±8.05	26.33±7.58	0.001

Table 2. Comparing the frequency of complications between two arms of trial

	GA group	LA group	P-value
Early Awakening			1.0
Yes	75 (100%)	75 (100%)	
No	0 (0%)	0 (0%)	
Nausea & Vomiting			1.0
Yes	0 (0%)	0 (0%)	
No	75 (100%)	75 (100%)	
Bradycardia / hypotension			0.09
Yes	5 (6.7%)	1 (1.3%)	
No	70 (93.3%)	74 (98.7%)	
Tachycardia / hypertension			0.1
Yes	2 (2.7%)	6 (8.0%)	
No	73 (97.3%)	69 (92.0%)	
Patients' Satisfaction			0.001
Yes	75 (100%)	0 (0%)	
No	0 (0%)	75 (100%)	
Surgeons' Satisfaction			0.001
Yes	75 (100%)	0 (0%)	
No	0 (0%)	75 (100%)	
Pain in operating room			0.001
Yes	0 (0%)	32 (42.7%)	
No	75 (100%)	43 (57.3%)	
Interruption			0.001
Yes	0 (0%)	25 (33.3%)	
No	75 (100%)	50 (66.7%)	
Pain in PACU			0.001
No pain	75 (100%)	0 (0%)	
Mild pain	0 (0%)	4 (5.3%)	
moderate	0 (0%)	20 (26.7%)	
Severe	0 (0%)	51 (68.0%)	

admission. None of the patients experienced nausea, vomiting, or significant hemodynamic instability during the procedure or in PACU. Patients in this group had no complaints of significant pain in PACU, and all of them were satisfied with the plan of their anesthesia. Moreover, the surgeon preferred this method of anesthesia because of better surgical condition. These results were achieved in a previous similar study, as well.⁴

The remarkable result of this study considering the pain management strategy is an important claim that may confirm the importance of preemptive analgesia in surgical interventions.²²⁻²⁵ Moreover, the emotional stress of inserting the needle into the breast tissue and being awake during the surgical plan may have significant effects on postoperative pain.^{22,26} As we know, anxiety and emotional stress have significant impacts on postoperative pain (26-30); therefore, in wakeful patients who underwent the procedure under local anesthesia, this important factor was not managed appropriately.²⁶⁻³⁰ They felt the incision of their breast tissue and despite being

pain free due to the local anesthetic agent, they suffered from the surgical procedure. This acute stress state may be the cause of higher pain scores in the postoperative period in comparison with the GA group. Other studies are needed to clarify and confirm this important result in the future.

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