

Pain as an outcome measure in various anesthesia and analgesia techniques

OBJECTIVE To compare the effectiveness of the most commonly used surgical anesthesia and post-operative analgesia techniques in Greek hospitals in terms of patients' reported subjective pain assessment, measured via a visual analogue scale (VAS). **METHOD** A prospective, open label, multicenter study in three major general hospitals in Athens. During a period of one calendar year ending on 25/12/1998 308 patients were studied. All patients were eligible for all anesthesia techniques and participating anesthesiologists conducted their routine anesthesia and analgesia techniques. Effectiveness was measured in terms of units of pain relief via a linear VAS. The clinical significance of these scores was first tested, based on an expert opinion of a 5% clinically meaningful difference. Next, the statistical significance of the results was tested using one-way analysis of variance tests. Sensitivity analysis was carried out with particular emphasis on the extent of clinically meaningful difference. **RESULTS** Combined general-epidural, combined spinal-epidural and epidural anesthesia techniques seem to result in lower early post-operative pain levels. In terms of lower achievable absolute pain levels, combined general-epidural technique was the most preferable technique with the lowest pain levels at the first pain measurement immediately after surgery. The superiority of the epidural technique was also shown in the period of post-operative analgesia. The results revealed that the absolute pain levels in the analgesia period of the patients with continuous epidural infusion were significantly lower than those with the per os and intra-muscular technique. **CONCLUSIONS** Pain measurement via a linear VAS is a reliable measure of pain which can be easily incorporated into routine pain management processes. Combined general epidural and epidural alone surgical and post-operative analgesia techniques lead to lower absolute post-operative pain levels.

Pain is a devastating state and may have a significant negative impact on the quality of life of patients. The pain following surgery is frequently severe and it may be the most unpleasant aspect of a hospital stay, and the reason for remaining in hospital after surgery. Poorly treated pain contributes to post-operative complications and psychological morbidity, and may lead to future problems with persistent pain. Many studies have shown that post-operative pain is generally poorly managed.¹ Up to 75% of

patients feel moderate or severe pain in the first 24 hours after surgery; almost 90% can expect to feel a lot of pain at some point in the first 7 days postoperatively.

For the clinician, the aim of post-operative pain relief is to provide subjective comfort, to inhibit trauma induced nociceptive impulses and to enhance restoration of function by allowing the patient to breathe, cough and move more easily.² Effective operative and post-operative pain management may present the potential to reverse

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Ο πόνος ως παράμετρος έκβασης
διαφόρων αναισθησιολογικών
και αναλγητικών τεχνικών

Περίληψη στο τέλος του άρθρου

Key words

General anesthesia
Pain
Post-operative analgesia
Regional anesthesia
Visual analogue scale

the adverse physiological effects of pain and to improve the patient's psychological condition. This may lead to fewer postoperative complications, earlier recovery and improved patient outcome.¹

It is probable that a combination of pre-emptive analgesia followed by multi-modal post-operative pain therapy may lead to the best possible results in terms of efficacy but research is needed on the issues of side effects, post-operative outcomes, need for surveillance etc. As the choice of available pharmacological treatments and techniques is widening it is important to study the efficacy of these techniques in terms of perception both of the clinician and the patient.³

As the clinician seeks to achieve sufficient pain relief for the patients in order to restore normal function it is important to take patients' subjective assessment of pain into account. Subjective pain can be measured via either simple methods such as rating or visual analogue scales (VAS) or more refined instruments such as the McGill pain questionnaire (MPQ).⁴ Visual analogue scales are simple, easy to use and possess high discriminant validity. Their use in routine clinical practice can provide useful insights into the efficacy of various pharmacological treatments or anesthetic or analgesic techniques.

Nevertheless the issue of pain management both intra- and postoperatively from the patients' perspective has not been studied adequately. This is particularly the case in Greece where post-operative pain management processes are not in place in the majority of the public hospitals. Moreover very few studies have been performed comparing the effectiveness of anesthetic or analgesic techniques.

The purpose of this study was to assess the effectiveness of the most commonly used anesthesia and analgesia techniques in Greek hospitals under everyday clinical practice conditions in terms of the patients' subjective assessment of pain intensity.

MATERIAL AND METHOD

Patients

A multicenter, open label, prospective study was conducted in the Anesthesiology Departments of three major hospitals in the Metropolitan area of Athens, Greece (the Evangelismos Hospital, the 251 Airforce General Hospital, and the Nikea District Hospital) from January 1st 1998 until December 25th 1998. The aim was to evaluate the level of pain relief of patients undergoing hip replacement. The study included a comparison between different techniques of regional anesthesia, such as epidural, spinal and combined epidural and spinal, general anesthesia combined general and epidural anesthesia. Different post-operative analgesia techniques were also compared,

specifically, intra-muscular combined with per os administration and continuous epidural infusion. The study was not randomised; rather it attempted to be a depiction of the current situation in the hospitals studied. For this reason all patients undergoing hip arthroplasty surgical procedures in the participating hospitals during the study calendar year were included.

Data were collected by trained investigators (nursing students). Training lasting two months took place in one of the three study hospitals before the beginning of the study following which the investigators were randomly assigned to one of the three hospitals. With the assistance of the staff doctors and nurses, the investigators kept a detailed report of the data. The sensitivity of the questionnaire and the reliability and accuracy of data collection were evaluated through an analysis of ten completed questionnaires from each hospital. These questionnaires were not used in the final analysis of the data.

In all, 315 questionnaires were collected from which 308 were eligible for analysis. The remaining 7 questionnaires were not included in the analysis due to missing data. Approximately 80% of participating patients were female and 20% male.

The inclusion criteria required that, firstly, all patients be eligible for administration of both general and regional anesthesia, and secondly, their American Society of Anesthesiologists (ASA) status be I, II or III, according to the preoperative evaluation by the investigators.

Techniques compared

Each anesthesiologist conducted his/her standard practice of anesthesia, while the analgesia drug regimens were determined by the standard practice of each individual hospital.

The distribution of techniques is depicted in table 1. It was observed that the 251 Airforce General Hospital (Hospital 2) performed mainly epidural anesthesia or some combination of epidural anesthesia, whereas the Evangelismos Hospital (Hospital 1) and Nikea District Hospital (Hospital 3) performed spinal or general anesthesia (fig. 1). Patients' consent for the relevant technique was obtained in all cases.

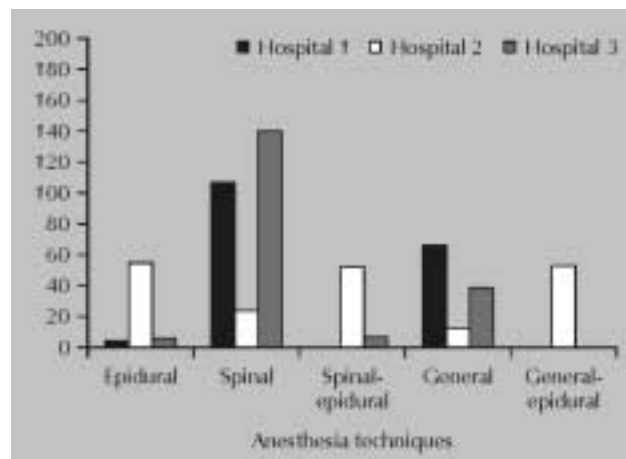


Figure 1. Type of anesthesia according to hospital.

Table 1. Anesthesia and analgesia techniques used for patients undergoing total hip replacement.

Anesthesia techniques	Analgesia techniques	No of patients
Epidural	Continuous epidural infusion	41
Spinal	Intra-muscular and per os	141
Combined epidural-spinal	Continuous epidural infusion	23
General	Intra-muscular and per os	73
Combined general-epidural	Continuous epidural infusion	30
Total		308

Two different practices of post-operative analgesia were commonly used: intra-muscular combined with per os, and continuous epidural infusion. The second method of post-operative analgesia was the standard method of analgesia in Hospital 2, whereas the first method was the standard practice of Hospitals 1 and 3.

Descriptive statistics depict the distribution of anesthetic technique according to sex (fig. 2), according to age (fig. 3) and according to ASA status (fig. 4).

Outcome measures

The main effectiveness measure employed in the study was the level of pain intensity experienced by patients. The patients' pain levels were recorded by the use of a VAS which involved the use of a 10 cm line similar to a thermometer, provid-

ing a continuous scale of the degree of pain intensity. On the one side of the VAS, the patient is asked to indicate the level of pain, where the one end of the line indicates "no pain at all" while the other end indicates "worst pain ever". The reverse side of the scale is a line divided in millimetres for the investigators' reading. Pain scores recorded with the aid of the VAS ranged between 0 (no pain at all) and 100 (worst pain ever). The VAS instrument in this study measured absolute levels of pain intensity and not relative (i.e. comparison of pain levels with the previous pain measurement).

The VAS is considered to be one of the best methods available for the estimation of the intensity of pain.⁴⁻⁶ Its main advantage has been claimed to be a high degree of sensitivity, in other words, a discriminating capacity superior to that of other scales, such as verbal and numerical rating scales.⁵ Because of its subjective nature, pain is most effectively assessed by means of self-reporting.¹ Nevertheless it has been argued that the VAS seems to involve a high rate of individual biases, as the data are not the result of measurement procedures and do not qualify as interval level scores.⁵ The subjectivity of the VAS scale may also rely on the fact that it yields a unidimensional measure, usually estimates of pain intensity. Several authors have argued in favor of a multidimensional method for the measurement of pain, such as the MPQ.⁵ However, being a verbal questionnaire, the MPQ requires translation and adaptation to other languages in order to be useful outside English speaking countries, and it has not been translated or validated in Greek. Also verbal multidimensional questionnaires have not been tested in measuring pain in surgical anesthesia and post-operative analgesia, for the comparison of which a unidimensional pain measure such as the VAS can be sufficient. As a result, despite the above men-

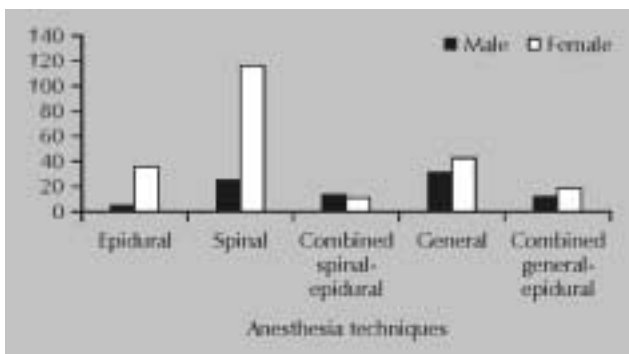


Figure 2. Type of anesthesia according to sex.

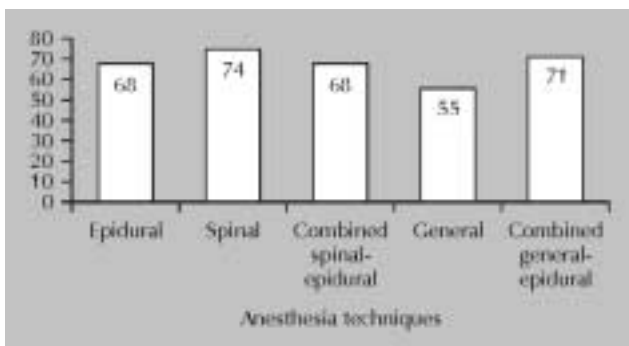


Figure 3. Age according to anesthesia techniques.

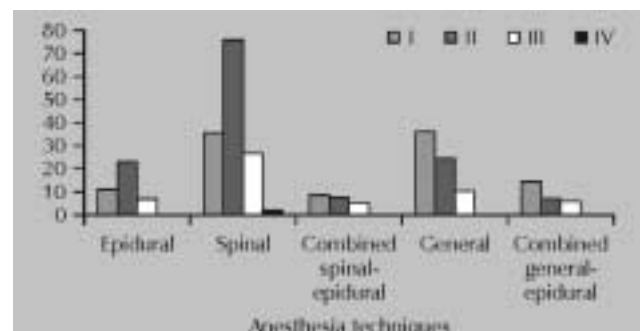


Figure 4. ASA status according to anesthesia techniques.

tioned disadvantages, the VAS, one of the most frequently used methods for the measurement of clinical pain,⁵ was employed in this study.

With the aid of the VAS, patients' assessments of their absolute pain intensity levels were recorded at 2–3 hours after the end of the surgical procedure and then twice daily (8 a.m., 8 p.m.) over a period of 72 hours. Patients were asked to report pain at rest (at the time of interview) as well as the worst pain experienced within the time since the last interview. The average pain level recorded in each interview (pain at rest and worst experienced pain before the interview) was the measure of pain intensity used for the comparison of the various techniques.

In addition, the analysis also took into account possible adverse events that could occur during the 72-hour post-operative period as additional outcome measures. These adverse events included nausea, vomiting, severe hypotension, pulmonary embolism or insufficiency, neurological complications, fever.

Analysis

The study was divided into two stages of analysis in order to present the results in more detail. The first stage involved analysis of the clinical significance of the measurements. The second stage involved statistical analysis of the measurements of the levels of pain relief. The statistical significance of the results was tested using one-way analysis of variance tests at a 5% level of significance.

The two stages of analysis were carried out for three time periods: the first period involved the first 4 hours after surgery. The use of the first pain measurement is explained by the fact that the patients' first pain is closely related to the technique of anesthesia used since this measurement takes place a few hours after the operation, whereas the post-operative analgesia technique corresponds to all the remaining measurements. The second and third periods of analysis involved the analgesia period. The second period included the second to fifth pain measurements (48 hours), whereas the third period included all the measurements in the span of 72 hours post-operatively (second to eighth measurements). The choice of the second period is explained by the fact that the analysis of measurements up to 48 hours of post-operatively analgesia is the standard point of observation of Greek anesthesiologists. The third time period, the total measurements during over 72 hours, includes all the measurements over the study.

RESULTS

Anesthesia and analgesia techniques

The local anesthetics used varied between the three hospitals. In the Evangelismos Hospital (Hospital 1) xylocaine spinal 5% (2 mL) was used in approximately 82% of the patients and bupivacaine spinal 0.5% (2–4 mL) in 18% of the patients. In the 251 Airforce General Hospital (Hospital 2) bupivacaine spinal 0.5% (2–3 mL) was used in 29% of the patients and a mixture of xylocaine 2%, adrenaline with bupivacaine, 6–7 mL of each, for epidural analgesia in 71% of the patients. Xylocaine spinal 5% (2–3 mL) was used in 98% of the patients in the Nikea District Hospital (Hospital 3).

The post-operative analgesic techniques also varied according to the hospital. The post-operative analgesia technique used in Hospital 2 was mainly continuous infusion of a mixture of local anesthetic and morphine via epidural catheter, whereas per os and intra-muscular administered analgesic drugs on patient demand was the main post-operative analgesic method in Hospitals 1 and 3.

Adverse side-effects of anesthesia and post-operative analgesia during the study period were found to be significant, therefore, no further analysis on the adverse events was considered in the study. The results are shown in table 2.

Levels of pain relief

The results of the three periods of analysis are shown diagrammatically in figures 5, 6, and 7 respectively. In the first period, from a clinical point of view, all five anesthesia techniques were found to present significant differences from each other in pain level at a 5% level. Statistical significance tests were performed and the results of the P-values are shown in table 3.

In the first period of the analysis, differences between all anesthesia techniques were statistically significant (P-value ≤ 0.020), except for spinal versus general anesthesia (P-value=0.214) and epidural versus spinal-epidural (P-value=0.552).

Table 2. Adverse events during anesthesia and analgesia.

Anesthesia techniques	Adverse events (%)					
	Nausea	Vomiting	Severe hypotension	Respiratory depression	Paresis	Pulmonary embolism
Epidural	7.13	3.55	0.50	0.50	8.68	0
Spinal	10.15	7.23	0.70	2.35	2.95	0.10
Spinal-epidural	24.13	11.83	2.63	7.90	11.83	0.45
General	10.75	3.95	0.70	3.50	11.48	0
General-epidural	17.38	9.85	0	10.55	6.13	

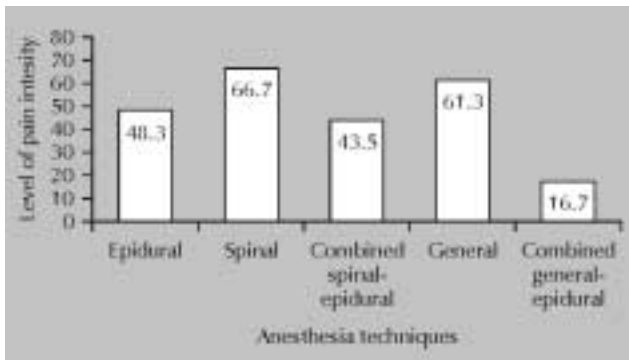


Figure 5. Mean level of pain intensity at first pain measurement.

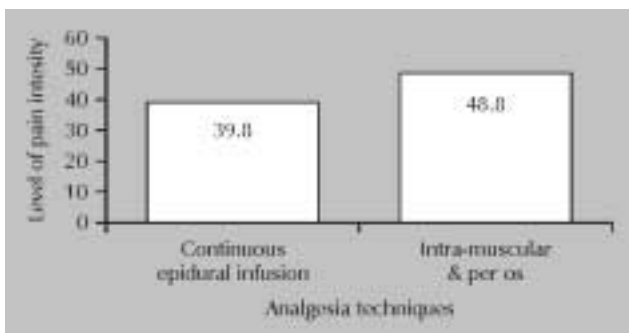


Figure 6. Mean level of pain intensity at 2nd-5th measurements.

Similarly, clinical and statistical significance tests were performed for the effectiveness measures of the second and third periods, the mean VAS scores of the second to fifth measurements and the mean VAS scores of the second to eighth measurements. The two postoperative analgesia techniques were found to be significantly different at a 5% clinically meaningful difference. The difference between the two analgesia techniques in the second period of the analysis was found to be statistically significant. In the third period, the two analgesia tech-

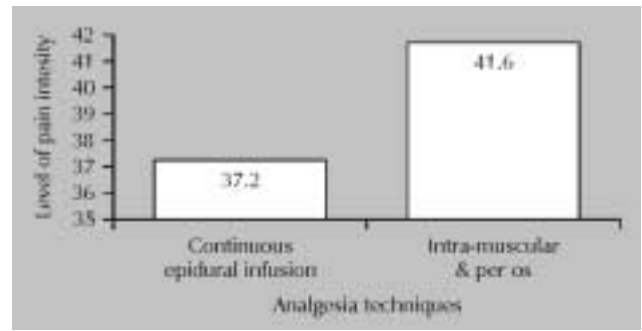


Figure 7. Level of pain intensity at 2nd-8th measurements.

niques were not found to have a statistically significant difference. All statistical tests were performed at a 95% confidence interval (tbl. 4).

Sensitivity analysis was conducted on the 5% clinically meaningful difference concerning the VAS score measurements. Instead of a 5% clinically meaningful difference, a 10% difference was considered in order to evaluate any changes in the interpretation of the differences in the levels of pain intensity in the anesthesia and the analgesia periods. The first period of analysis, the anesthesia period, was considered initially. The results showed no difference in the 10% clinically meaningful difference. Similar findings resulted in the examination of the other two periods of analysis.

The statistical significance was tested of the results of the three periods at a 10% level of significance. In the first period, all the results remained the same as in the 5% level of significance analysis, except for the comparison between spinal and general anesthesia techniques, which were found in this case to be statistically different. In addition, in the second period of the analysis a statistically significant difference between the two analgesia techniques continued to exist. Differences in

Table 3. Differences in pain level according to anesthesia techniques.

Anesthesia techniques	Epidural	Spinal	Combined spinal-epidural	General	Combined general-epidural
Epidural	-	0.000	0.552	0.003	0.000
Spinal		-	0.006	0.214	0.000
Combined spinal-epidural			-	0.020	0.005
General				-	0.000
Combined general-epidural					-

Table 4. Differences in pain level according to analgesia techniques.

Analgesia techniques	2nd period (2nd-5th measurements)	3rd period (2nd-8th measurements)
Continuous epidural infusion	P-value=0.002	NS
Intra-muscular & per os		

Table 5. Mean levels of pain intensity according to anesthesia and analgesia techniques.

Anesthesia techniques	Mean level of pain intensity at 1st pain measurement	
Epidural	48.3	
Spinal	66.7	
Combined spinal-epidural	43.5	
General	61.3	
Combined general-epidural	16.7	

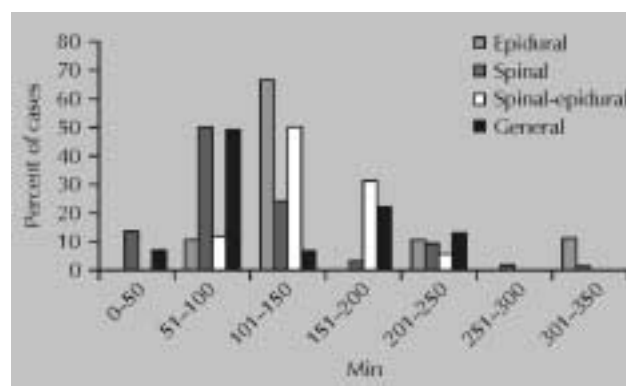
Analgnesia techniques	Mean level of pain intensity at 2nd-5th pain measurements	Mean level of pain intensity at 2nd-5th pain measurements
Continuous epidural infusion	39.8	37.2
Intra-muscular & per os	48.8	41.6

the statistical significance in the two analgesia techniques were found at the third period of analysis where the two techniques were found to be statistically different at the 10% level and not statistically significant at the 5% level of significance.

DISCUSSION

Combined general-epidural, combined spinal-epidural and epidural anesthesia techniques seem to result in lower early post-operative pain levels. More specifically, the VAS scores of the first pain measurement are at their lowest after the use of the epidural techniques. In terms of reduced pain, combined general-epidural technique is the most preferable technique, giving the lowest pain levels at the first pain measurement.

On the other hand, the results reveal high levels of pain in both spinal anesthetic and in general anesthetic, which can be attributed to two factors. First, the high levels of pain might be due to the increased use of xylocaine as the main anesthetic in spinal and general anesthesia. Specifically, in Hospitals 1 and 3, where the current practices are spinal and general anesthesia, Hospital 1 used xylocaine in approximately 82% of its patients and Hospital 3 used xylocaine in 98% of the patients. The length of action of xylocaine is in some cases shorter than the actual length of the operation itself. Consequently, some patients may already be in pain, even before they leave the operation room (fig. 8). A second explanation for the increased levels of spinal and general anesthesia and analgesia techniques lies in the analgesia treatment. The main post-operative analgesic method used in Hospitals 1 and 3 is per os and intra-muscularly administered drugs on patient demand. A significant difference in the post-operative analgesia period is presented in Hospital 2 where a continuous administration of a mixture of local anesthetic and morphine via epidural

**Figure 8.** Time in surgery with spinal and general anesthesia.

catheter is used. From these factors, it can be concluded that continuous pain management of the patients results in lower pain levels during the analgesia period.

The superiority of the epidural technique is also demonstrated by the period of post-operative analgesia. The pain levels of the patients in the analgesia period with continuous epidural infusion were significantly lower than the levels of pain with the per os and intra-muscular technique.

It can be observed from the results that the level of pain in the anesthesia and analgesia techniques decreases through time. Even though the first pain measurement reveals a very low level of pain, the second measurement presents an increase in pain but still at a low level. After this measurement, relatively constant slow decrease of pain levels towards the last measurements is observed. This pattern can be explained by the fact that the first pain measurement is a result of the effect of both the general and the epidural anesthetics. As the influence of the general anesthesia decreases after the operation, the continuous infusion of epidural anesthetic keeps the patients in low levels of pain.

The interpretation of the study posed several limitations. First, the measurement of outcome with the use of the VAS might have been biased. A common problem in anesthesia is to assess the effect of certain interventions on levels of pain.⁷ "Pain is difficult to measure, partly because it is usually accompanied by other sensations, and partly because the reaction component affects the judgment of the pain, regardless of the intensity of the stimulus".⁴ The subjective nature of the VAS might have biased the measurements and, as a consequence, the results of the study.

A second limitation was that, although the study was a depiction of the current practice in the three hospitals, it was not randomised. Thus, biases may exist from the non-randomisation of patients. Finally, despite the levels of significance of the results, an important limitation is the small number of patients assigned to each anesthesia and analgesia technique.

Subjective measurement of pain should be an important aspect of routine clinical practice. It was evident in this study that on some occasions patients experienced relatively high levels of pain especially immediately after surgery with spinal and general anesthesia techniques. Furthermore, post-operative pain levels were also high

in certain hospitals and especially in patients receiving per os and intra-muscular analgesia regimes.

These findings highlight the need for the incorporation of pain management processes in Greek hospitals. In most cases, responsibility for post-operative pain management lay with the attending physician and nurses in the orthopedic clinics, without no co-operation with the anesthesiology department. In the hospital where post-operative pain management was the responsibility of the anesthesiologists, the patients reported pain levels were significantly lower.

The use of the VAS showed that simple instruments can provide useful insight regarding patients' outcomes and thus lead to improved clinical management. The VAS scores effectively discriminated patients' assessments regarding different anesthetic and analgesic techniques and clearly helped to underline areas for improvement. More research is needed on the efficacy comparison of various therapeutic agents and techniques regarding intra and post-operative pain management especially in the Greek context. Continuous medical education and robust evaluation of the newly introduced multi-modal analgesia techniques may significantly improve patients' outcomes as far as post-operative pain is concerned.

ΠΕΡΙΛΗΨΗ

Ο πόνος ως παράμετρος έκβασης διαφόρων αναισθησιολογικών και αναλγητικών τεχνικών

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ΣΚΟΠΟΣ Σκοπός της μελέτης είναι η σύγκριση των συχνότερων, μεταξύ των Ελληνικών νοσοκομείων, τεχνικών χειρουργικής αναισθησίας και μετεγχειρητικής αναλγησίας ως προς την υποκειμενική αξιολόγηση επιπέδων πόνου των ασθενών, μετρούμενης μέσω οπτικής αναλογικής κλίμακας. **ΥΛΙΚΟ-ΜΕΘΟΔΟΣ** Ανοικτή, προοπτική, πολυκεντρική μελέτη σε τρία μεγάλα γενικά νοσοκομεία των Αθηνών, στην οποία συμμετείχαν 308 ασθενείς, οι οποίοι υποβλήθηκαν σε ολική ή μερική αρθροπλαστική χειρουργική επέμβαση κατά τη διάρκεια ενός ημερολογιακού έτους (1.1.98-25.12.98). Όλοι οι ασθενείς ήταν κατάλληλοι για όλες τις τεχνικές χειρουργικής αναισθησίας και μετεγχειρητικής αναλγησίας, ενώ οι αναισθησιολόγοι-ερευνητές ακολούθησαν τη συνήθη αναισθητική και αναλγητική μέθοδο της κλινικής τους. Η αποτελεσματικότητα μετρήθηκε σε επίπεδα υποκειμενικής εκτίμησης του πόνου από τους ασθενείς, μετρούμενη με οπτική αναλογική κλίμακα. Ελέγχθηκε αρχικά η κλινική σημαντικότητα της διαφοράς αποτελεσματικότητας των διαφόρων τεχνικών αναισθησίας και μετεγχειρητικής αναλγησίας, με όριο 5% για την αναγνώριση κλινικής σημαντικής διαφοράς. Ακολούθως, η στατιστική σημαντικότητα της διαφοράς αποτελεσματικότητας ελέγχθηκε με τη χρήση τεχνικών ανάλυσης δια-

κύμανσης. Διενεργήθηκε ανάλυση ευαισθησίας, με ιδιαίτερη έμφαση στη διακύμανση του κατώτερου επιπέδου κλινικά σημαντικής διαφοράς. **ΑΠΟΤΕΛΕΣΜΑΤΑ** Η συνδυασμένη γενική-επισκληρίδια, ραχιαία-επισκληρίδια και επισκληρίδια τεχνική αναισθησίας οδηγεί σε κατώτερα επίπεδα πόνου στο χρονικό διάστημα αμέσως μετά την εγχειρητική επέμβαση. Σε όρους απόλυτης υποκειμενικής εκτίμησης του επιπέδου πόνου, η συνδυασμένη γενική-επισκληρίδια τεχνική αναισθησίας παρουσίασε τα κατώτερα επίπεδα πόνου στην πρώτη μέτρηση μετά την εγχειρητική επέμβαση. Κατά τη διάρκεια της περιόδου χορήγησης μετεγχειρητικής αναλγησίας, η επισκληρίδια τεχνική παρουσίασε την καλύτερη αποτελεσματικότητα, καθώς τα απόλυτα επίπεδα πόνου ήταν σημαντικά χαμηλότερα για τους ασθενείς που δέχθηκαν επισκληρίδια αναλγησία με συνεχή έγχυση, από αυτούς που δέχθηκαν ενδομυϊκή ή από του στόματος μετεγχειρητική αναλγησία. **ΣΥΜΠΕΡΑΣΜΑΤΑ** Η χρήση μιας οπτικής αναλογικής κλίμακας μέτρησης της υποκειμενικής εκτίμησης του πόνου μπορεί κάλλιστα να ενσωματωθεί στην καθημερινή κλινική πρακτική. Οι συνδυασμένες τεχνικές χειρουργικής αναισθησίας και η επισκληρίδια τεχνική μετεγχειρητικής αναλγησίας οδηγούν σε χαμηλότερα απόλυτα επίπεδα πόνου των ασθενών κατά τη μετεγχειρητική περίοδο.

Λέξεις ευρετηρίου: Αναλογική οπτική κλίμακα, Γενική αναισθησία, Μετεγχειρητική αναισθησία, Περιφερική αναισθησία, Πόνος

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