

Implantation of venous access devices under local anesthesia: patients' satisfaction with oral lorazepam

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Objective: The aim of the study reported here was to evaluate patients' satisfaction with implantation of venous access devices under local anesthesia (LA) with and without additional oral sedation.

Materials and methods: A total of 77 patients were enrolled in the prospective descriptive study over a period of 6 months. Subcutaneous implantable venous access devices through the subclavian vein were routinely implanted under LA. Patients were offered an additional oral sedative (lorazepam) before each procedure. The level of anxiety/tension, the intensity of pain, and patients' satisfaction were evaluated before and immediately after the procedure using a visual analog scale (ranging from 0 to 10) with a standardized questionnaire.

Results: Patients' satisfaction with the procedure was high (mean: 1.3 ± 2.0) with no significant difference between the group with premedication and the group with LA alone ($P=0.54$). However, seven out of 30 patients (23.3%) in the group that received premedication would not undergo the same procedure without general anesthesia. There was no significant influence of lorazepam on the intensity of pain ($P=0.88$). In 12 out of 30 patients (40%) in the premedication group, the level of tension was higher than 5 on the visual analog scale during the procedure. In 21 out of 77 patients (27.3%), the estimate of the level of tension differed between the interventionist and the patient by 3 or more points in 21 out of 77 patients (27.3%).

Conclusion: Overall patient satisfaction is high for implantation of venous access devices under LA. A combination of LA with lorazepam administered orally might not be adequate for patients with a high level of anxiety and tension. The level of tension is often underestimated by the interventionist. Pre-procedural standardized questionnaires could be used to identify patients for whom a gradual approach of individualized sedation may be more effective.

Keywords: patient satisfaction, pain, supportive care, chemotherapy, central venous port implantation

Introduction

Implantable venous access devices (IVADs; port-a-cath type) are of great importance for the systemic administration of chemotherapy and parenteral nutrition in oncological patients. It is still challenging to carry out port implantations with a minimum of pain and anxiety for outpatients. A previous retrospective study assessed 193 patients with ultrasound-guided port-catheter implantations over the subclavian vein.¹ Technical success, acute and long-term complications, and the patients' satisfaction were evaluated. It was shown that local anesthesia was not sufficient for pain relief in 25 out of 138 patients (18%). Given the well-known synergistic effect between mental tension and pain perception, in our institution, in addition to local anesthesia, all patients are currently offered premedication with an anxiolytic (lorazepam; 1–2 mg orally) before

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the procedure. The prospective descriptive study reported here evaluated the effectiveness of premedication with lorazepam in terms of sedation level and patients' satisfaction with port-catheter implantation under local anesthesia.

Methods and materials

The study was approved by the local ethics committee. All patients referred to us for a port-catheter implantation between November 2012 and April 2013 were included in the study, with the exception of patients complaining about intense pain already before the procedure (>4 of 10 points on the visual analog scale [VAS]). The port catheter was implanted in an outpatient procedure. The patients were routinely informed about possible complications and side effects of the port implantation in an informational consultation 24 hours prior to the procedure. Thirty minutes before the procedure, all patients were offered the additional administration of an oral sedative (lorazepam, 1 mg at <70 kg body weight, and 2 mg at >70 kg body weight).

For the purpose of evaluation, standardized questionnaires were used of which slightly different versions in a previous study.² Additionally, we implemented a VAS (range: 0–10) of specific factors that might be relevant to the procedure. The first questionnaire was filled in by the patient before the intervention and the administration of a premedication. This questionnaire contained questions about previous experience with port implantations or other outpatient procedures under local anesthesia. In addition, patients indicated on a VAS their level of comfort in narrow spaces (0= unproblematic; 10= extremely unpleasant), their level of tension regarding the upcoming intervention (0= no tension; 10= extreme tension) as well as their expectations regarding the procedure (0= no concerns, no pain anticipated; 10= great concerns, extreme pain anticipated).

The second and third questionnaires were filled in by the patient and the physician, respectively, immediately after the procedure. Using a VAS, the patients evaluated their sensation of pain (0= no pain; 10= extreme pain) and their level of tension during the procedure (0= no tension; 10= extreme tension) as well as their satisfaction with the procedure (0= highly satisfied; 10= highly dissatisfied). If patients were dissatisfied, they were asked to give a free-text response explaining the reasons for their dissatisfaction. In addition, patients were asked to indicate if they remembered the procedure completely, if their sensation of pain was as anticipated (0= same; 1= stronger; 2= weaker), and if they would undergo the same procedure again without general anesthesia. The patient's level of tension during the procedure was also evaluated by the physician (0= no tension, 10= extreme tension), so that a comparison with the patient's

own evaluation was possible. The physician evaluated the level of motor restlessness of patients on a VAS (range: 0–10) and, in case of motor restlessness, estimated to what extent the restlessness had interfered with the procedure (1= no to minimal; 2= slight; 3= strong interference with the intervention). Interventionists were distinguished in two groups: experienced physicians, having carried out 60 or more port implantations without supervision, and less experienced physicians in advanced training, having undertaken less than 60 port implantations. All procedures were technically carried out as described following.

Local anesthesia (mepivacaine hydrochloride 1%, 5 mL [AlleMan Pharma GmbH, Rimbach, Germany]) was introduced in sterile fashion into the skin and the access path to the lateral subclavian vein under ultrasound guidance (7 cm long, 18-gauge needle [PFM Medical AG, Cologne, Germany]). A small skin incision was made at the puncture site. Following this, the subclavian vein was punctured under ultrasound guidance and a guiding wire was introduced. An introducer sheath was passed via the guiding wire into the subclavian vein. The guiding wire was then removed and the IVAD could be introduced through the introducer sheath. Correct position was verified by fluoroscopy. A second local anesthesia (mepivacaine hydrochloride 1%, 10–15 mL) was introduced about 3 cm below the incision and a 3 cm wide skin incision was made parallel to the clavicle. A subcutaneous pocket was then prepared on the pectoral fascia. The port chamber (Bard PowerPort[®] isp MRI[®], Bard Access Systems, Inc, Salt Lake City, UT, USA) was fixed on the fascia of the pectoral muscle with two single nonabsorbable sutures. Correct flow for blood withdrawal and infusion was tested. The wound was closed with an absorbable subcutaneous suture and skin closed by a nonabsorbable intra-cutaneous suture. To complete the procedure the system was blocked with 5 mL heparinized saline (100 IE/mL).

Statistical methods

Parameters were described in terms of frequencies, percentages, means, minimums, maximums, and standard deviations (SDs). Categorical variables were analyzed using Fisher's exact test; for the analysis of continuous parameters, the Mann–Whitney *U*-test was used. The change of tension was examined using analysis of variance, including premedication as the fixed factor and tension before intervention as the covariate. Correlations between two continuous parameters were analyzed using Pearson's correlation coefficient. All of the tests for significance were two-sided; the significance level was $\alpha=0.05$. No adjustment for multiple testing was

applied. All analyses were computed with SPSS software (v 21; IBM Corporation, Armonk, NY, USA).

Results

A total of 77 patients (47 female, 30 male; age, mean \pm SD: 55 ± 14 years) participated in the study. The mean body mass index was 25.9 (minimum: 14.3; maximum: 44.1). The port system was implanted on the left side in 54 cases and on the right side in 23 cases. In 75 cases, the port was implanted to facilitate the administration of chemotherapeutic agents for the treatment of known malignant underlying diseases, in one case for parenteral nutrition, and in one other case for the purpose of long-term antibiotics. Thirty patients (18 female, 12 male) opted for premedication with lorazepam while 47 patients (29 female, 18 male) decided against this option. The decision to take the premedication was not influenced by sex ($P=0.881$). There were three minor complications (3.9%): a pneumothorax not requiring drainage and two cases in which the IVAD had to be moved to the other side during the intervention, because, in one case, of a previously undiagnosed ipsilateral central thrombosis, and, in the other case, because of a hematoma that had formed when the subclavian vein was punctured. The procedure took on average 39 minutes (mean \pm SD: 39.1 ± 14.5 minutes), and its duration did not differ significantly between the group that received premedication and the group that did not ($P=0.14$).

Level of tension with and without premedication

Patients who decided in favor of a premedication had a significantly higher level of tension before intervention (mean \pm SD: 2.0 ± 2.2 without premedication, mean \pm SD: 5.0 ± 2.8 with premedication; $P < 0.001$). Therefore, we included baseline values in the analysis. However, in the analysis-of-variance model for the change of tension before and at intervention, including the factors tension before intervention and premedication, premedication was the only significant factor ($P=0.001$). The change of tension was significantly better in patients who had been premedicated than in patients who had not (mean \pm SD: -0.40 ± 1.30 vs 0.47 ± 0.93 , with negative values indicating better outcome). The effect seems to be especially relevant for patients with lower baseline tension. Patients with a high degree of tension stayed on the same level during the intervention. Therefore, we categorized the patients into three groups regarding the tension before intervention (low: 0–3; medium: 4–7; high: 8–10) (Figure 1).

The level of tension as assessed by the physician was significantly higher in the group that received lorazepam

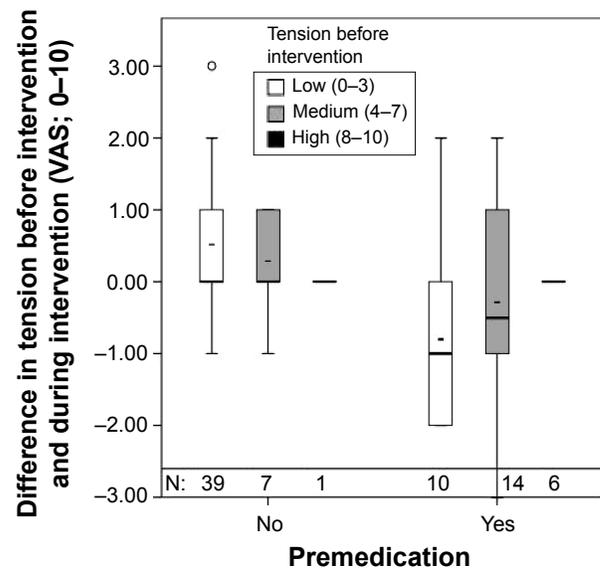


Figure 1 Difference in tension before intervention and during intervention, with and without premedication.

Notes: Patients were categorized in three groups depending on the tension level before the intervention (low: 0–3; medium: 4–7; high: 8–10). N is the number of patients; “No” indicates patients without premedication; “Yes” indicates patients with premedication. The short dashes within the boxes indicate the mean, and the broad lines indicate the median. Tension is measured by visual analog scale (VAS; 0–10). The circle indicates outlier ($> 1.5 \times$ IQR).

than in the group without premedication ($P=0.005$; mean \pm SD: 5.3 ± 2.5 vs 2.4 ± 1.6). Compared to the patients’ self-assessment, the level of tension in some patients was clearly under- or overestimated by the physician. In 21 patients (27.3%), the physician’s estimate differed by 3 or more points from that of the patients; in ten patients, (10.4%) the difference was 4 or more points (Figure 2).

The physicians considered the level of motor restlessness in the patients during the procedure to be low (mean \pm SD: 1.5 ± 0.7). The level of motor restlessness did not differ significantly between the group with and the group without premedication ($P=1.0$). In no case did restlessness interfere with the procedure.

There was a positive correlation between the level of tension and the level of pain ($r=0.456$, $P < 0.001$) as well as between the level of tension and patient satisfaction ($r=0.536$, $P < 0.001$). In a subgroup analysis, a value of > 5 on the 10-point VAS correlated with a significantly lower patient satisfaction both in patients with premedication ($P=0.019$) and in patients without ($P=0.003$) (Figure 3).

Sensation of pain with and without premedication

The analysis of the VAS with regard to the pain sensed during the procedure did not reveal a significant difference between the two groups ($P=0.88$; mean \pm SD with lorazepam: 2.4 ± 2.2 , and without lorazepam: 2.6 ± 2.5) with a high

degree of variability, including outliers with high scores of, in some cases, 10 out of 10 points on the scale (Figure 4). Thirty-six out of 77 patients (46.8%) reported that the pain sensed during the procedure corresponded to their expectations. Eight out of 77 patients (10.4%) stated that the pain sensed was stronger, and 33 patients (42.9%) reported that the pain was weaker than expected.

Patient satisfaction with and without premedication

Patient satisfaction as reported using the VAS was high for the entire patient collective (mean ± SD: 1.3±2.0). Satisfaction tended to be slightly higher in patients without premedication without significance ($P=0.542$; mean ± SD without lorazepam: 1.0±1.3 vs with lorazepam: 1.8±2.7). Retrospectively, eleven out of 77 patients (14.3%) would have preferred general anesthesia. Reasons for dissatisfaction were sensations of pain during the procedure in ten out of 22 cases (45.5%), intense tension in six out of 22 cases (27.2%), the length of the procedure in two out of 22 cases (9.1%), and uncomfortable positioning during the procedure in two out of 22 cases (9.1%). In two of the 22 patients, who had known claustrophobia, the reason was discomfort because of feeling confined (9.1%).

Other potentially predictive factors influencing patient satisfaction

The physician's level of experience had a significant influence on the length of the procedure ($P<0.001$) but no

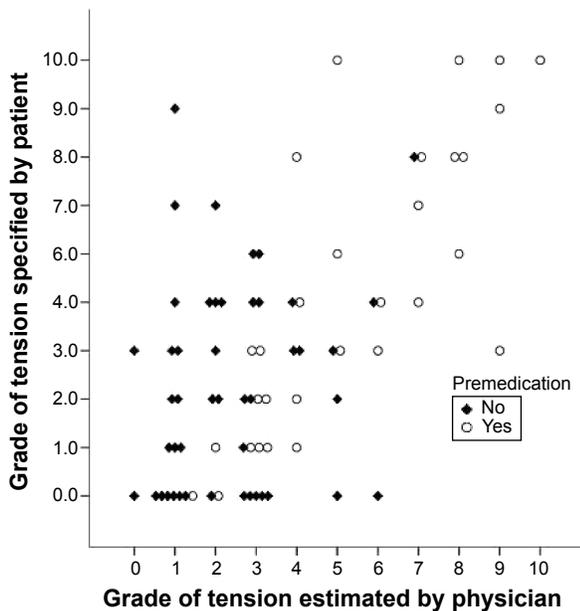


Figure 2 Patients' self-assessment of the level of tension compared with the estimation by the physician (with and without premedication, VAS: 0–10). **Abbreviation:** VAS, visual analog scale.

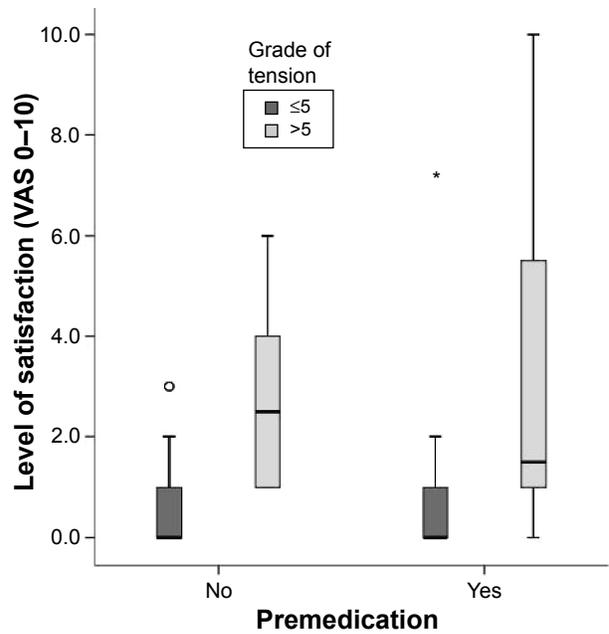


Figure 3 Patients' satisfaction (VAS 0–10) in respect of the grade of tension (VAS ≤5/10 or >5/10) with and without premedication. **Notes:** The circle indicates outlier (>1.5× IQR); the star indicates far outlier (>3× IQR). **Abbreviations:** IQR, interquartile range; VAS, visual analog scale.

significant influence on the level of tension ($P=0.926$), the sensation of pain during the procedure ($P=0.1$), or on patient satisfaction ($P=0.09$).

The expectation indicated on the VAS immediately after the informational consultation was rather heterogeneous (mean ± SD: 3.2±2.5). Patients with great concerns regarding the procedure ($n=11$ with VAS >5) tended to opt for the premedication ($n=7$; 63.6%), while patients with lesser concerns

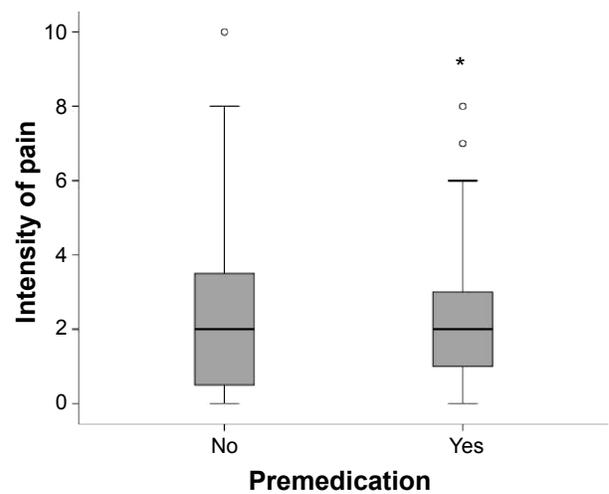


Figure 4 Intensity of pain during the procedure (VAS: 0–10) with and without premedication. **Notes:** The circles indicate outlier (>1.5× IQR); the star indicates far outlier (>3× IQR). **Abbreviations:** IQR, interquartile range; VAS, visual analog scale.

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Table 1 Summary of results dependent on premedication administration

Characteristic/evaluation	Premedication		Total (n=77)	P-value
	Yes (n=30)	No (n=47)		
Patient-specific data				
Age (years \pm SD)	52.8 \pm 14.1	56.9 \pm 14.2	55.3 \pm 14.2	0.200
Sex (male)	12 (40%)	18 (60%)	30 (100%)	
Sex (female)	18 (38.3%)	29 (61.7%)	47 (100%)	1.000
BMI (kg/m ² \pm SD)	26.3 \pm 5.4	25.7 \pm 5.7	25.9 \pm 5.6	0.650
Procedural characteristics				
Previous experience with port implantation (n)	5	3	8	
Duration of procedure (minutes \pm SD)	39.1 \pm 14.5	42.7 \pm 16.5	41.3 \pm 15.8	0.140
Experience of physician	9	25	34	0.060
<60 port implantations (n)				
\geq 60 port implantations (n)	21	22	43	
Complications (n)	1	2	3	0.780
Evaluation by the patient				
Expectation before procedure (VAS \pm SD)	3.9 \pm 3.1	2.7 \pm 2.0	3.2 \pm 2.5	0.130
Anxiety in narrow spaces (VAS \pm SD)	3.0 \pm 3.8	2.2 \pm 3.0	2.5 \pm 3.3	0.490
Level of tension during the procedure (VAS \pm SD)	4.6 \pm 3.4	2.4 \pm 2.4	3.3 \pm 3.0	0.005
Level of pain (VAS \pm SD)	2.6 \pm 2.5	2.4 \pm 2.2	2.5 \pm 2.3	0.880
Satisfaction (VAS \pm SD)	1.8 \pm 2.7	1.0 \pm 1.3	1.3 \pm 2.0	0.540
Would prefer general anesthesia in future procedure (n)	7	4	11	0.970
Evaluation by the physician				
Level of motor unrest (VAS \pm SD)	1.5 \pm 0.7	1.7 \pm 1.2	1.6 \pm 0.9	1.000
Level of tension in patient (VAS \pm SD)	5.3 \pm 2.5	2.4 \pm 1.6	3.5 \pm 2.5	0.005

Abbreviations: BMI, body mass index; SD, standard deviation.

(n=66 with VAS \leq 5) decided in only 23 cases (34.8%) to receive premedication. Patients with great concerns prior to the intervention also reported a higher level of tension during the procedure (VAS \leq 5: level of tension 2.8 \pm 2.7; VAS >5: level of tension 6.1 \pm 3.3) as well as a significantly lower satisfaction after the procedure (VAS \leq 5: satisfaction 1.0 \pm 1.5; VAS >5: satisfaction 3.4 \pm 3.2).

The level of patient satisfaction was independent of previous experience with minor procedures under local anesthesia ($P=0.304$; n=32; of those, n=8 outpatient port implantations).

There were no cases of temporary anterograde amnesia or memory dysfunction at the dosage used in our study.

Table 1 summarizes the results dependent on the administration of premedication

Discussion

The central venous administration of chemotherapeutics is of enormous importance in the treatment of oncological patients. Venous access devices implanted in the lateral subclavian vein have proved to be effective for the safe administering of chemotherapeutic agents. As yet, there is no general recommendation for analgosedation for such procedures. In a previous study, many patients found local infiltration

anesthesia insufficient for subduing pain.¹ Thus, 25 of 138 patients (18.1%) would not undergo the same procedure again without general anesthesia. The main reasons were pain during the procedure (17/25; 68%), the duration of the procedure (6/25; 24%), and anxiety about the procedure as such (2/25; 8%).

Different methods and strategies of sedation and pain management with relevance for other minor procedures are under discussion. There is evidence of a clearly improved tolerance by patients of gastroscopic and coloscopic examinations if a short-term general anesthesia is introduced with propofol.^{3,4} However, propofol poses the problem of a narrow therapeutic margin between the intended sedation on the one hand and unintended narcosis accompanied by apnea on the other hand, a problem that is aggravated by the lack of an antidote. Therefore, the guidelines of the German Society for Anesthesiology and Intensive Care Medicine require a second physician, who is not primarily responsible for the examination and who should be experienced in intensive care, to be involved in the administration of propofol.⁵ The same problem accompanies the use of all sedatives administered intravenously, such as midazolam. It is therefore difficult to create a deep analgosedation in an outpatient setting and

without the involvement of an anesthesiologist and the use of a monitored anesthetic recovery room.

Lorazepam is a benzodiazepine with anxiolytic, anticonvulsatory, sedating, and muscle-relaxing effects. The anxiolytic effect is the most dominant. Lorazepam is therefore mostly used as a sedative in cases of anxiety and panic disorders. Lorazepam differs from intravenously administered sedatives through its therapeutic index, which in general makes the involvement of an anesthesiologist unnecessary. Lorazepam appears to be an optimal choice for minor procedures in an outpatient setting. Against this background, the study reported here investigated the effectiveness of additional oral premedication with lorazepam in port-catheter implantations.

It has to be mentioned that this study was not randomized, as the evaluated groups were self-selected by the patients. This may have led to a sample bias resulting in limited assessability of the drug effect.

The results show an overall high degree of satisfaction with the procedure. However, eleven out of 77 patients would opt for general anesthesia retrospectively. The main reasons for their dissatisfaction were intense tension in 30% and intense pain during the procedure in 50% of patients.

If patients voted for a premedication in addition to local anesthetics, they were statistically not more satisfied with the procedure than those who denied the premedication ($P=0.54$). One possible explanation for this phenomenon is that the patients opted for premedication if they had already experienced a relatively high degree of tension before the procedure started ($P<0.001$). This assumption is supported by the fact that predominantly patients with negative expectations regarding the procedure (VAS >5) opted for premedication. Furthermore, the level of tension during the intervention was, on average, significantly higher in cases in which lorazepam was administered than in the other cases ($P=0.005$; 4.6 ± 3.4 vs 2.4 ± 2.4). Patients seemed to benefit from premedication especially when the baseline tension was low or medium (VAS: 0–6). However, we did not find an effect of premedication in patients with a high degree of tension before the intervention (VAS 7–10). It must be noted that this effect was not significant due to the small sample size in this group. This question could be answered only by a further study with a prospective-randomized design by comparing the effect of premedication on tension levels with that of placebo.

In a subgroup analysis, a value of >5 points on the 10-point VAS for the level of tension positively correlated with a significantly lower patient satisfaction, both in the group with premedication ($P=0.019$) and in the group without ($P=0.003$). The level of tension could not be lowered to <5 points on the

10-point VAS in 36.7% of patients. Lorazepam does not seem to have a sufficient effect at the dosage administered to these patients. It has to be mentioned that there is no recognized norm concerning the definition of a clinically significant level of tension using the VAS. Other authors showed, in accordance with our study, a marked differentiation in outcome between patients who scored <5 on the VAS and the remaining patients, all of whom scored >6 . The latter group might reasonably be classed as registering high tension.⁶

As in previous studies, sensation of pain appears to be one of the main factors influencing patient satisfaction with minor surgical procedures.^{7,8} Several studies have described a synergetic effect of sedative medication on analgesia.^{9–11} In our study, subjectively perceived pain was at an overall low level and it did not differ significantly between patients who did and did not receive premedication. The lack of evidence for an additive effect of lorazepam in conjunction with local anesthesia in our study may be due to the low dosage and the oral administration of the premedication.

Kramskay et al showed a significant reduction of pain during liver biopsies due to the administration of an analgesic agent (tramadol) in addition to lorazepam.¹² There were no unwanted interactions between the medications in this combination therapy. The authors therefore argue that the prophylactic administration of an analgesic should be considered in all patients. In contrast to Kramskay et al the observations in this study showed that the anticipated level of pain was overall low and equal to the level of pain actually experienced during the procedure in most of the patients (69/77 patients). Certainly, the use of an additive analgesic medication was not the aim of this study and should therefore be examined in further work.

The literature describes various technical options for port implantation.^{13–15} However, as far as we are aware, if jugular or transbrachial accesses are of advantage with regard to the level of pain has not been investigated up to now.

Thus, patients with a high baseline level of tension and sensitivity to pain should be identified prior to the procedure. These patients could electively undergo an adapted sedation including general anesthesia, possibly in conjunction with hospitalization for the purpose of postoperative observation. A pre-interventional questionnaire could help identifying the patients who meet the requirements for these measures. The use of such a specific questionnaire is particularly advisable because of the high rate of inaccurate estimates of patients' tension levels by the physicians conducting the procedure. The questionnaire used in this study showed that a high level of concern regarding the procedure and a high level

of tension of >5 points out of 10 on the VAS correlated with a higher intensity of perceived pain and a lower degree of satisfaction with the procedure. It has to be mentioned that this new questionnaire has not been validated yet and an evaluation of the implantation procedure might thus be limited.

Conclusion

Overall, we found that patient satisfaction with port implantations under local anesthesia was high, and the oral administration of lorazepam in addition to local anesthesia did not yield significant advantages. Patient satisfaction was mainly influenced by the level of pain and of tension during the procedure. In patients with a high level of tension (tension of >5 points out of 10 on the VAS), the administration of lorazepam was insufficient to improve the satisfaction with the procedure significantly. A standardized questionnaire administered in the informational consultation could aid in adapting an individual model of sedation and thus help to identify those patients who require a short general anesthesia. These measures could increase the level of patient satisfaction with the procedure.

Disclosure

The authors certify that they have no affiliations with or involvement in any organization or entity with any financial interest (such as honoraria; educational grants; participation in speakers' bureaus; membership, employment, consultancies, stock ownership, or other equity interest; and expert testimony or patent-licensing arrangements), or nonfinancial interest (such as personal or professional relationships, affiliations, knowledge, or beliefs) in the subject matter or materials discussed in this paper.

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