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Comparison of the techniques for the identification of the epidural space using the loss-of-resistance technique or an automated syringe — results of a randomized double-blind study

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Abstract

Background: The conventional, loss of resistance technique for identification of the epidural space is highly dependent on the anaesthetist's personal experience and is susceptible to technical errors. Therefore, an alternative, automated technique was devised to overcome the drawbacks of the traditional method. The aim of the study was to compare the efficacy of epidural space identification and the complication rate between the two groups — the automatic syringe and conventional loss of resistance methods.

Methods: 47 patients scheduled for orthopaedic and gynaecology procedures under epidural anaesthesia were enrolled into the study. The number of attempts, ease of epidural space identification, complication rate and the patients' acceptance regarding the two techniques were evaluated.

Results: The majority of blocks were performed by trainee anaesthetists (91.5%). No statistical difference was found between the number of needle insertion attempts (1 vs. 2), the efficacy of epidural anaesthesia or the number of complications between the groups. The ease of epidural space identification, as assessed by an anaesthetist, was significantly better ($P = 0.011$) in the automated group (87.5% vs. 52.4%). A similar number of patients (92% vs. 94%) in both groups stated they would accept epidural anaesthesia in the future.

Conclusion: The automated and loss of resistance methods of epidural space identification were proved to be equivalent in terms of efficacy and safety. Since the use of the automated technique may facilitate epidural space identification, it may be regarded as useful technique for anaesthetists inexperienced in epidural anaesthesia, or for trainees.

Key words: epidural anaesthesia; epidural space, automatic identification; epidural space, identification, loss-of-resistance technique

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Epidural anaesthesia is well known procedure, which has been used for many years for pain relief [1, 2]. Effective epidural space identification (ES) is a crucial element of an effective block. The traditional method of ES identification is subjective and prone to error. The efficacy of ES identification depends on the anaesthetist's experience with the technique [3, 4]. Researchers have sought more objective methods of epidural space localization [5–9]. All methods are based on the difference in pressure between the epidural space and the surrounding structures [3].

One of the alternative techniques of ES identification is the use of an automated syringe, whose structure enables the maintenance of a constant pressure on the syringe plunger. When the needle reaches the epidural space, the plunger depresses automatically, which can be readily observed by the operator. Its key advantage is an increased

objectivity, reducing both the subjective element of the loss of resistance technique and dependence on the experience of the anaesthetist. This should result in greater success in accurate ES identification. The method could translate into lower incidences of failed epidurals, a reduced complication rate and a reduction in patient discomfort during insertion.

The key aim of the study was to compare the ease of epidural space identification using the automated syringe and compare this with the traditional loss of resistance technique. The additional objectives were to compare the pain relief obtained, the incidence of complications and the acceptability of both techniques to the patient.

METHODS

The research was approved by the Bioethics Committee of the Medical University of Warsaw. Forty-eight consecutive patients undergoing surgery of the lower limbs or minor pelvic procedures (orthopaedic and gynaecological) and who were scheduled for epidural anaesthesia were enrolled. The exclusion criteria were as follows: lack of consent, pregnancy and breast-feeding, ASA score > III, skin changes at the site of needle insertion and coagulation disorders.

The patients gave informed, written consent for epidural anaesthesia, as well as for participation in the study, and were randomly assigned to one of two groups: the study group in which an automated syringe was used (Group Auto) and the control group (group C).

The epidurals were performed in the operating theatre. Standard monitoring and iv access were established prior to commencement. The epidural blocks were performed in the lumbar region in the sitting or lateral decubitus position, according to the preferences of the attending anaesthetist and taking the patient`s comfort into consideration.

In group C patients epidural anaesthesia was carried out using a Perifix set (B. Braun Melsungen AG, Melsungen, Germany) containing an 18 G epidural Tuohy needle Perican®, 1.3 mm in diameter and 80 mm in length, a Perifix syringe® LOR, in which the anaesthetist exerts continuous pressure on the air-filled plunger with the thumb. In the automatic syringe group, the same Tuohy needle was used with a different air-filled syringe (Epimatic –Vygon, Ecouen, France), in which continuous pressure was applied by stretching an elastic strip over the plunger. A loss-of-resistance to air technique rather than saline was chosen as this is the technique preferred by the anaesthetists taking part in the study.

In both groups, after preparation of the operative field and selection of an appropriate intervertebral space, the skin and the subcutaneous tissue were anaesthetized using 1% lidocaine. The Tuohy needle was inserted and the automated syringe or traditional air-filled syringe was attached to it. The needle was advanced into the epidural space until loss of resistance was detected. In both groups, once loss of resistance was achieved, a catheter was inserted through the needle to a depth of 4 cm in a cephalad direction (Perifix® 20G with a closed tip and three lateral openings). Having checked that there was no blood aspiration through the catheter, a test dose of 2% lidocaine (4 mL) was injected with 40 µg of epinephrine. Subsequently, 0.25% bupivacaine with epinephrine was administered. After 30 minutes, the attending anaesthetist determined the extent of sensory block checking for a loss of sensation to cold. When the block was ineffective or its extent was insufficient, general anaesthesia was performed. Patients with satisfactory epidural blocks were sedated intraoperatively with midazolam in fractionated doses to achieve Ramsey`s scale 3 (the patient is drowsy and responds to commands).

Postoperative analgesia was carried out using a continuous infusion of 0.25% bupivacaine into the epidural space, 3–8 mL h^{-1} depending on the degree of pain intensity and the extent of the block.

After 6–8 hours, a blinded investigator evaluated the intensity of pain (using a numerical rating scale — NRS). On the second day, the same investigator evaluated the site of Tuohy needle insertion and recorded complications, if any. Before discharge, the patients were asked to complete a questionnaire assessing their discomfort during anaesthesia (completely acceptable/rather acceptable/unacceptable at times/completely unacceptable), the maximum intensity of pain in the immediate postoperative period (NRS) and possible consent to the same anaesthesia in the future (yes/rather yes/no/rather not).

The following criteria were applied to compare both techniques of ES identification, namely: the visible movement of the plunger (study group) or a detectable loss of resistance (control group) after possibly reaching the epidural space (the 3-point scale: 1 — a distinct decrease, 2 — barely detectable, 3 — none); a lack of signs of subarachnoid anaesthesia after the test dose; the duration of the procedure; the number of attempts at ES identification (calculated as the number of attempts of Tuohy needle insertion through the skin); the degree of discomfort during the procedure declared by the patient evaluated immediately after the anaesthesia and during the next postoperative day; as well as the presence/absence of blood aspiration from the catheter after insertion.

STATISTICAL ANALYSIS

STATA 14 (StataCorp LP, College Station, USA) was used for the calculations. The normality of distribution was verified by the Jarque-Bera test, while a homogeneity of variance by the Fisher test. The difference in characteristics that may be numerically expressed was compared using the Student's t test or the Mann-Whitney U test. Moreover, distributions of categorical data were compared applying the

Pearson's chi-squared test and the Fisher`s exact test [10]. $P < 0.05$ was considered significant.

RESULTS

Forty-nine patients (32 women and 17 men) were included in the study; the data of 47 anaesthetic procedures were analysed (1 case was excluded — loss of the patient`s record, 1 case- the exclusion criterion fulfilled during data verification).

The demographic data of groups were comparable (Table 1).

Table 2 includes the characteristics of both groups according to the method of ES localization.

There were no intergroup differences in the depth at which the loss of resistance was achieved, simplicity of catheter insertion, number of injections and the time required to achieve anaesthesia. According to the anaesthetists, the loss of resistance was more commonly defined as distinctly noticeable in the automatic syringe group, as compared to group C. The simplicity of catheter introduction (evaluated as easy or with slight resistance) was comparable in both groups.

The efficacy of epidurals in the postoperative period was defined as a lack of pain or mild pain only (completely effective). The findings were comparable in both groups (Table 3).

There were no cases with evidence of unintended injection of local anaesthetic (LA) into the subarachnoid or intravascular space.

The degree of discomfort experienced during anaesthesia was not statistically different between the two groups (Table 4).

During the first postoperative day, the patients completed a questionnaire in which they were asked whether they would consent to another anaesthetic procedure using the method applied. Forty-one patients filled-in the questionnaire; 23 (92%) from the automatic syringe group and 15 (94%) from group C would give their consent for another anaesthesia performed according to the same method; 2 patients (8%) from group Auto and 1 patient (8%) from group C would not consent to the same kind of anaesthesia in the future; the reasons were not specified. There was no statistical significance found between the groups.

The most common anaesthesia-associated complications were redness and pain at the site of injection. No

Table 1. Demographic data of the study population. Data expressed as means ± SD

Parameter	Group AUTO (n = 25)	Group C (n = 22)	*P*-value
Body mass (kg)	77 ± 18	73 ± 18	0.23
Age (years)	45 ± 16	53 ± 20	0.06
Height (cm)	169 ± 11	167 ± 8.0	0.24
BMI (kg m^{-2})	26.8 ± 5.4	26.0 ± 5.5	0.31

Table 2. Data regarding ES anaesthesia in both groups (expressed as means ± SD, n (%), unless specified otherwise)

Parameter		Group Auto (n = 25)	Group C (n = 22)	*P*-value
Depth at which loss of resistance was achieved (cm)		5.8 ± 0.6	5.5 ± 0.9	0.19
Depth of catheter insertion (cm)		4.6 ± 1.0	4.4 ± 0.6	0.55
Number of injections required for anaesthesia*		1 ± 1	2 ± 0.5	0.82
Time needed to perform anaesthesia (sec.)		166 ± 113.7	208 ± 242.6	0.95
Loss of resistance	Distinct	21 (87.50%)	11 (52.38%)	0.011*
	Barely noticeable	3 (12.50%)	10 (47.62%)	
	None	0 (0%)	0 (0%)	
	No data	1	1	
Simplicity of catheter insertion	Easy	12 (48%)	7 (33.33%)	0.604
	With slight resistance	10 (40%)	11 (52.38%)	
	With considerable resistance	3 (12%)	3 (14.29%)	
	No data	0	1	

*median ± interquartile range

Table 3. Efficacy of epidural anaesthesia in the immediate postoperative period. Percentages were calculated for complete observations

Parameter	Group Auto (n = 24)	Group C (n = 20)	*P*-value
Completely effective	17 (89.47%)	12 (92.31%)	1.00
Partially effective (asymmetry, patchy anaesthesia)	1 (5.26%)	0 (0%)	
Completely ineffective	1 (5.26%)	1 (7.69%)	
No data	5	7	

Table 4. Discomfort of patients during anaesthesia. Percentages were calculated for complete observations

Discomfort	Group Auto (n = 24)	Group C (n = 22)	*P*-value
None	16 (66.67%)	8 (47.06 %)	0.335
Slight	8(33.33%)	9 (52.94%)	
Considerable	0 (0%)	0 (0%)	
No data	1	5	

Table 5. Anaesthesia-related complications

Parameter	Group Auto (n = 25)	Group C (n = 22)	*P*-value
None	12 (48%)	9 (56%)	0.751
Local pain	8 (32%)	5 (31%)	1.0
Redness (irritation) at the site of injection	5 (20%)	1 (6%)	0.376
Bruised site of injection	2 (8%)	0 (0%)	0.512
Purulent secretion	0	0	–
Feeling of a foreign body in the back	0	1 (6%)	0.390
Failed anaesthesia	0	1 (6%)	0.390
Unintended punctures of the dura mater	2 (8%)	3 (14%)	0.654
Blood aspiration through the epidural catheter	4 (16%)	5 (23%)	0.715
No data	0	6	

infections occurred. The incidence of various complications did not significantly differ between the groups (Table 5).

In 91.7% of patients (43/47 cases), the identification of ES was performed by trainee anaesthetists, whereas in 8.5% (4 cases) by specialists in anaesthesiology and intensive care.

DISCUSSION

Failed epidural anaesthetic procedures predominantly result from improper identification of the epidural space, which is more common amongst inexperienced anaesthetists [3, 4]. Since traditional identification is performed blindly, research has been carried out to find new methods of facilitating ES identification [5, 9].

The most popular technique of epidural space identification is the manual method of loss of resistance, in which, during the insertion of the needle towards the epidural space, the anaesthetist presses the plunger of a low-resistance syringe with the thumb. An alternative method is the use of the automated Epimatic syringe, i.e. a low-resistance syringe in which a constant pressure is generated by an elastic strip. When the Tuohy needle reaches the epidural space, the plunger distinctly moves forward (depression of the plunger). To our knowledge, there have been no reports in the literature analyzing the use of Epimatic syringes. Several available studies concern Episure™ AutoDetect™ syringes (Indigo Orb, Inc., Santa Clara, USA), which are similar but use a different mechanism used for identification of the space, i.e. the constant pressure is generated by a spring located inside the syringe. Two of these mentioned studies were carried out in parturients [11, 12], the third in patients undergoing urological procedures [13] and the fourth in paediatric patients [14]. The study by Riley *et al.* [11] was performed without the controlled group being subjected to the traditional method of identification.

In our study, the median number of attempts to introduce the needle into the epidural space in the automatic

syringe group, was 1 while in group C this was 2. The difference was not statistically significant. In the studies mentioned above [11, 13], the mean number of identification attempts was 1 in both groups; moreover, there were no cases of unintended punctures of the dura mater.

In the study involving a smaller population [12, 13], although the time required to perform epidural anaesthesia was found to be shorter in the study group, the difference was not statistically significant, which is likely to be associated with the small size of the study group. In studies by Habib *et al.* [12] Gulen *et al.* [13], the identification time was significantly shorter in the Episure group as compared to the control group — 20 and 40 sec. and 29 and 45 sec., respectively. In the Riley study [11], the time was not determined. In the available papers [11–14], the ease of catheter placement was not evaluated.

In our study, there were no significant intergroup differences in the efficacy of postoperative pain relief using a continuous infusion of local anaesthetic through the epidural catheter, a fact which corresponds with the findings of other studies in which the efficacy of epidural anaesthesia was 100% in the study group versus 97% in the control group [9, 10].

According to our findings, the percentage of unintended dural puncture was higher than that in other studies (8% for Epimatic and 13.64% for Perifix); however, the intergroup difference was not statistically significant. In a study published by Habib *et al.* [12], no cases of unintended dural puncture were observed in the study group while 4 cases were found (2.6%) in the control group. Likewise, Riley *et al.* [11] did not observe any cases of unintended dural puncture. In their study, the majority of anaesthetic procedures were carried out by the trainees, hence a high percentage of unintended dural puncture. In our study, blood aspiration through the epidural catheter was observed in 4 cases (16%) in the study group and in 5 cases (22.73%) in the control group. Habib *et al.* observed intravascular catheter location in 9 cases (5.4% — the study group) compared to 7 cases (4.5% — the control group) [12].

The most common remote complications included local pain and irritation (redness) of the injection site. The distribution of complications between the two methods of epidural space identification was not found to be statistically significant.

The results of the anonymous questionnaire revealed that the vast majority of patients (above 90%) would consent to the method of anaesthesia being used; the data were comparable in both groups, which proves a high acceptance of epidural anaesthesia, irrespective of the technique of epidural space identification.

LIMITATIONS OF THE STUDY

The major limitation was the small sample size. To increase the strength of the study, the number of patients included should be larger. Due to the nature of the study, the anaesthetist performing the technique was not blinded. The investigators evaluating the efficacy of epidural anaesthesia and the occurrence of complications were group-blinded.

CONCLUSIONS

1. Identification of the epidural space using an automated syringe identifying loss of resistance was comparable to the method with standard low-resistance syringes in terms of safety and efficacy. The efficacy of ES identification, the quality of analgesia, the time needed to identify the epidural space, as well as the number of complications, were comparable in the groups. In cases of automatic identification, the moment the needle reaches the epidural space was more easily noticeable compared to the traditional technique.
2. Our study findings demonstrate a high acceptance of epidural anaesthesia expressed as patients' consent for further epidural anaesthesia, irrespective of the identification method used.

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2. Conflict of interest: none.

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