Research Article

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Combined Double-Segment Spinal-Epidural Anesthesia With Fixation of the Epidural Catheter in the Subcutaneous Canal Using a Modified Spinal Needle

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AIM OF STUDY To develop a new safe and reliable method of fixing an epidural catheter (EC), to study and compare the results of this method of fixing EC in the subcutaneous canal using a modified spinal needle (MSN) and an adhesive tape with a standard method of fixing an EC using only an adhesive tape when performing the combined double-segment spinal-epidural anesthesia (CDSEA) in the surgical treatment of fractures of the bones of the lower limb.

MATERIAL AND METHODS A comparative study of two methods of EC fixation was carried out in patients undergoing CDSEA during the surgical treatment of fractures of the bones of the lower limb. The patients were divided into two groups. The Group 1 (comparison, n=65), where EC was fixed at the site of epidural access with adhesive tape and the Group 2 (study, n=65), where EC was fixed in the subcutaneous canal using MSN and adhesive tape at the site of EC exit on the skin.

RESULTS In the study group, where EC was fixed in the subcutaneous canal using MSN and adhesive tape at the site of EC exit to the skin, there were 32.3% fewer cases with clinically significant dislocation (more than 15 to 30 mm) than in the comparison group, where EC was fixed at the site of epidural access only with adhesive tape.

CONCLUSIONS A used spinal needle in a modified version can be used to perform EC in the subcutaneous canal. The dimensions of the MSN allow tunneling of the EC less traumatic and at a great distance from the site of the epidural access, which provides more reliable fixation of the EC, the number of cases with clinically significant + dislocation decreases, this allows for a longer and better postoperative epidural analgesia. This method does not solve all the problems of EC fixation; it is required to develop new methods of EC fixation, including fixation in the subcutaneous canal.

Keywords: combined double-segment spinal-epidural anesthesia, dislocation of the epidural catheter, fixation of the epidural catheter in the subcutaneous canal, tunneling epidural catheter, modified spinal needle

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CDSEA – combined double-segment spinal-epidural anesthesia
CSEA – combined spinal epidural anesthesia
CSSEA – combined single-segment spinal-epidural anesthesia
EC – epidural catheter
EN – epidural needle
EP – epidural space
MSN – modified spinal needle

INTRODUCTION

Combined spinal epidural anesthesia (CSEA) is widely used in anesthetic practice. The advantages of CSEA over spinal and epidural anesthesia are known: “It is a fast onset, long-term anesthesia effect, practically unlimited in time, with the possibility of extending the block to several anatomical regions” [1]. CSEA is used in general surgery, orthopedics, lower extremity trauma surgery, urological and gynecological operations, and in obstetric practice. The combination of spinal and epidural blocks provides excellent operating conditions as quickly as with a single subarachnoid block, which is better than using only an epidural block. Anesthesia occurs quickly, saving 15–20 minutes. It becomes possible to supplement subarachnoid anesthesia, which may be insufficient when used alone [2]. Also, CSEA makes it possible to perform postoperative analgesia, the incidence of post-puncture headache decreases to 1.3% [3] and unsuccessful anesthesia compared to epidural blockade, it becomes possible to perform sequential CSEA with the introduction of subarachnoidally low doses of local anesthetics, which allows achieving hemodynamic stability in high-risk patients. The most widely used combined single-level spinal-epidural anesthesia (CSEA) is associated with the fact that this technique requires one puncture in one intervertebral space and takes less time — 12.9 minutes versus 15 minutes with the “separate needles” technique [4, 5] . Despite this, the technique of "separate needles" — combined double-segment spinal-epidural anesthesia (CDSEA) has not lost its relevance and is also widely used in anesthesiology practice. It has a number of undeniable advantages over the needle-through-needle technique (CCSEA). CDSEA can reduce the risk of neurological damage, since the epidural catheter (EC) is installed before the start of the subarachnoid block and the symptoms of damage to the nervous tissue are not masked, and in case of an unsuccessful attempt to catheterize the epidural space (ES), the possibility of repeated catheterization remains. In addition, the rate of unsuccessful anesthesia is reduced compared to the “needle through the needle” technique [5], fewer transitions to general anesthesia are made [6]; the technique, among other things, is 40% cheaper [7]. The quality of the epidural analgesia performed depends on whether the EC is installed correctly, whether the local anesthetic dose is correctly selected, and also on the absence/presence of a clinically significant EC dislocation. EC dislocation can lead to intravascular injection of local anesthetic, dural perforation and total spinal block, EC migration through the intervertebral foramen and unilateral block. Also, EC can leave ES, which will lead to the termination of the ongoing anesthesia [8].

N. Kumar et al. consider that internal and external migration of EC can contribute to bacterial contamination and lead to infectious complications associated with EC, with a frequency of up to 12% [9]. *Kost-Byerly S. et al*. concluded that tunneling reduces the risk of neuraxial catheter infection in infants and children [10]. *Bubeck J. et al*. in their study, they found a 3-fold decrease in the incidence of infection in tunneled ECs compared to non-tunneled ones [11]. One of the most reliable ways to fix EC is the use of special fixing devices. Fixation with adhesive tape is the least reliable method, in which, according to some authors, EC dislocation occurs in 36% of

cases [12], according to others, in 75%, and in 20–25% of patients, dislocation exceeds 2 cm [13]. When fixing EC in the subcutaneous canal, dislocation occurs only in 10% of cases [14].

Tunneling of the EC provides a number of advantages: a) the inner part of the EC is lengthened, which is from 80-100 mm without tunneling, and with tunneling it lengthens by 70–80 mm (the entrance gate for infection is located further); b) more reliable fixation due to the subcutaneous location of the EC and the appearance of another bend at an angle of 900; c) 60–80 mm laterally from the medial line, there is always a flat skin surface, which is an ideal platform for fixing the EC (in the region of the medial line, there will not always be good conditions for fixing the EC); d) we get the opportunity to change the adhesive sticker daily or if necessary (when fixing with special devices, this will not be possible, due to the laboriousness of changing the fixing device, the danger of dislocation when replacing the device and the high cost of fixing devices; e) tunneling of the EC prevents its internal dislocation [15].

There are several ways to fix EC in the subcutaneous canal. The first method is with an unmodified epidural needle (EN) S.A. Ilyin and others, whose peculiarity is that the longer the subcutaneous canal is, the more difficult it is to conduct EN to the epidural access site and the greater the risk of damaging the EC [16]. The second method is a modified EN by V.V. Kuzmina and others. With this method, there is no risk of damaging the EC at the site of the epidural access. Modified EN is conducted from the epidural access site, and not towards the location of the EC, but there is a risk of damaging the EC when it is passed through the lumen of the EN, since an uneven sharp inner edge may form at the proximal end during the modification of the EN [17]. The third way belongs to A.V. Nikolayev, which uses a three-component device with an external cylinder diameter of 2.7 mm (the larger the diameter of the tunneling device, the more aggressive the EC in the subcutaneous canal) [18]. The fourth method is the use of EN with a metal mandrel, according to which EN is first carried out to the epidural access site, through the lumen of which EC is then performed [19]. The fifth method, using a special tunnel when installing an epidural port, which is not used independently, but is performed through the lumen of a special splitting needle. *Tripathi M. et al*. consider EC tunneling to be an aggressive and dangerous method, leading to a pronounced inflammatory reaction in 25–30% of cases [20]. In order for EC tunneling to be less aggressive and not lead to the development of severe inflammatory reactions and infectious complications, the tunneling device must meet certain requirements. It should be sharp, thin and long. Its outer diameter must be less than or equal to the outer diameter of the EC (0.85 mm). The device should be at least 88–90 mm long to allow for EC and exit to the skin in a convenient place for fixation. The location of the EC exit site on the skin lateral to the medial line will provide convenient access and care for the EC. Also, in order not to increase the cost of anesthesia, it is desirable that EC tunneling takes place within the framework of the ongoing anesthesia technique, without the use of additional devices.

Aim of study: to develop a safe and reliable method for fixing EC in the subcutaneous canal using MSN and adhesive tape, to study and compare the results of EC fixation by this method with the standard method of EC fixation using only adhesive tape when performing CDSEA in the surgical treatment of fractures of the bones of the lower limb.

MATERIAL AND METHODS

We have developed a method for fixing EC in the subcutaneous canal using MSI during CDSEA. A patent for the invention was obtained for this method [21]. In our study, there were two groups of patients who underwent CDSEA during the surgical treatment of fractures of the bones of the lower limb in the period from 2018 to 2021. These were mainly patients of elderly and senile age. A total of 130 patients were divided into two groups. The first group consisted of a comparison group, 65 patients who underwent CDEA with EC fixation on the skin of the lumbar region with only adhesive tape. The second group of the study included 65 patients who underwent CDEA with EC placement and fixation in the subcutaneous canal using MSN. When comparing patients in the study groups by gender, age, presence of concomitant pathology and physical status on the ASA scale, as well as by the complexity of the surgical intervention, no statistically significant differences were found (Tables 1, 2, 3).

Table 1

Distribution of patients by gender and age

Indicators, years	Comparison group *n* (%)	Study group *n* (%)	Total *n* (%)	*R*
Men	22 (33.8%)	21 (32.3%)	43 (33.1%)	0.853
Women	43 (66.2%)	44 (67.7%)	87 (66.9%)	0.853
Young 18–44	3 (4.6%)	3 (4.6%)	6 (4.6%)	1,000
Medium 45–59	4 (6.2%)	6 (9.2%)	10 (7.7%)	0.511
Elderly 60–74	27 (41.5%)	18 (27.7%)	45 (34.6%)	0.098
Senile 75–90	30 (46.2%)	33 (50.8%)	63 (48.5%)	0.599
Longevity >90	1 (1.5%)	5 (7.7%)	6 (4.6%)	0.095
Average age	72.52±1.42	73.32±1.84	72.92±1.16	0.731264

Table 2

Co-morbidity in patients in the study groups

Related pathology	Comparison group *n* (%)	Study group *n* (%)	Total patients *n* (%)	*p*
Diseases of the cardiovascular system	57 (87.7%)	57 (87.7%)	114 (87.7%)	1,000
Cerebrovascular diseases	6 (9.2%)	11 (16.9%)	17 (13.1%)	0.194
Respiratory diseases	13 (20%)	14 (21.5%)	27 (20.1%)	0.829
Diseases of the gastrointestinal tract	3 (4.6%)	3 (4.6%)	6 (4.6%)	1,000
Diseases of the endocrine system	8 (12.3%)	9 (13.8%)	17 (13.1%)	0.795
Anemia (hemoglobin content less than 120 g/l)	14 (21.5%)	21 (32.3%)	35 (26.9%)	0.167
Body mass index over 30	11 (16.9%)	9 (13.8%)	20 (15.4%)	0.627
Chronic kidney disease	8 (12.3%)	5 (7.7%)	13 (10%)	0.381
Chronic liver disease	0 (0.0%)	2 (3.1%)	2 (1.5%)	0.155
Oncologic disease	7 (10.8%)	2 (3.1%)	9 (6.9%)	0.085

Table 3

The physical status of patients according to the ASA scale

Physical status by *ASA*	Comparison group *n* (%)	Study group *n* (%)	Total patients n (%)	p
1	0	0	0	
2	23 (35.4%)	23 (35.4%)	46 (35.4%)	1,000
3	40 (61.5%)	41 (63.1%)	81 (62.3%)	0.857
4	2 (3.1%)	1 (1.5%)	3 (2.3%)	0.560

As can be seen from Table 1, in the studied groups, female patients and patients of elderly and senile age predominated. There were no statistically significant differences in gender and age in the study groups.

In the comparison group, the age of patients ranged from 37 to 90 years. The mean age was 72.52±1.42 years, Me — 74, σ =11.45. In the study group, the age of patients ranged from 18 to 95 years. The mean age of the patients was 73.32±1.84 years, Me — 79, σ =14.85. The differences are not statistically significant: $p = 0.731264$. The critical value of Student's *t*-test, equal to 1.98 at a significance level $\alpha = 0.05$. During the preoperative examination, comorbidity was detected in all (100%) patients in both groups.

Table 2 shows that in the study groups, 100% of patients had comorbidities, in which cardiovascular diseases, anemia, respiratory diseases and obesity predominated. The physical status of the 2nd and 3rd class was in the vast majority of patients in both groups. There were no statistically significant differences in the presence of comorbidity and physical status (Table 3).

Surgical interventions were performed for a fracture of the proximal femur in the comparison group in 58 cases (89.2%), in the study group — in 47 (72.3%); for the fracture of the femoral diaphysis in the comparison group — in 4 (6.3%), in the study group — in 15 (23.2%); for the fracture of the distal femur in the comparison group and the study group, there was one case each (1.5%); for the fracture of the bones of the lower leg in the comparison group and the study group — 2 cases (3%). Surgical interventions in the studied groups were of medium degree of trauma.

All patients were given antibiotic prophylaxis for infectious complications before surgery. A broad-spectrum antibiotic was administered intravenously 40 minutes before the start of the operation. Pre-infusion was 250-300 ml of 0.9% sodium chloride solution. The position of the patient on the operating table: sitting with a bent back. All patients underwent CDSEA. In the comparison group, EC tunneling was not performed. EC was fixed on the skin only with adhesive tape at the site of epidural access. In the study group, EC was fixed by tunneling with MSN and adhesive tape at the site of EC exit to the skin.

Description of the CDSEA technique with conducting and fixing EC in the subcutaneous canal using MSN.

First stage: catheterization of the EP in the L_3-L_4 interval with a *G 20* catheter (outer diameter — 0.85 mm, inner diameter — 0.45 mm) (Fig. 1). The catheter was passed in the cranial direction in the ES at a distance of 45 mm. A distance of 45–50 mm is considered optimal for catheters with three lateral holes at the distal end [22]. In the comparison group, spinal anesthesia was performed at the second stage after extraction of EN with the introduction of a hyperbaric solution of bupivacaine, 15–17.5 mg, into the subarachnoid space in the interval L_2–L_3 (Fig. 2). EC was fixed on the skin with adhesive tape. In the study group, before removing the EN below its standing, a skin incision of 3–4 mm was performed and its expansion with a surgical clamp to create access to the subcutaneous canal, after which the EN was removed (Fig. 3).

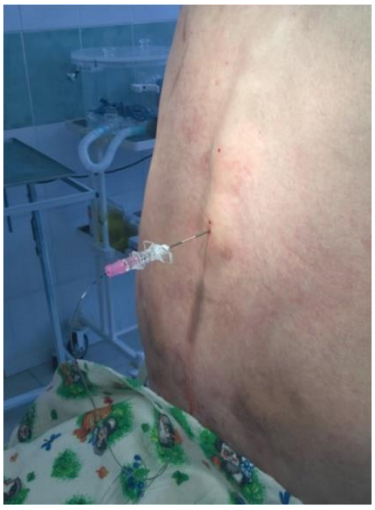


Fig. 1. Catheterization of the epidural space in L_3–L_4. The G 20 catheter was passed into the epidural space at a distance of 45 mm in the cranial direction

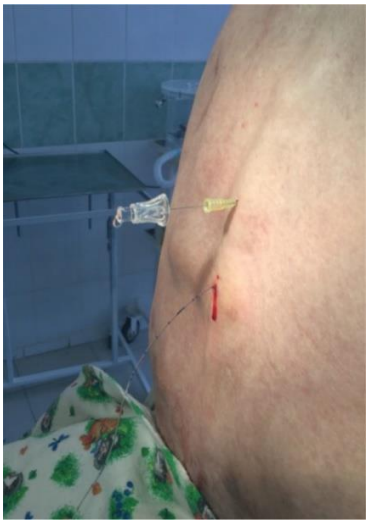


Fig. 2. Spinal anesthesia one segment higher in L_3–L_4

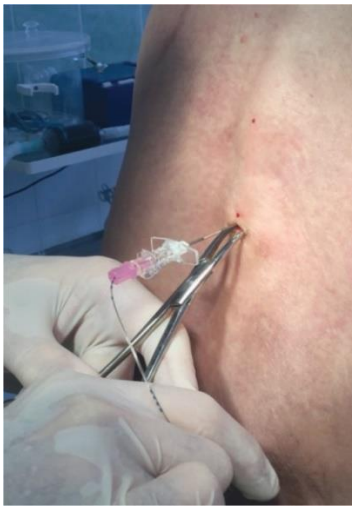


Fig. 3. A skin incision was made below the epidural needle and access to the subcutaneous canal was created

The second stage was the puncture of the subarachnoid space in the interval L_2-L_3 with a *G* 26 or *G 25* needle (the outer diameter of which is 0.45 mm and 0.52 mm, respectively, the length is 88 mm or 120 mm). A hyperbaric solution of bupivacaine, 15–17.5 mg, was injected into the subarachnoid space. The spinal needle was removed and modified, breaking off the pavilion (Fig. 4) and fixing the EC on the MSN (Fig. 5). After EC, using MSN, it was performed in the subcutaneous canal (Fig. 6, 7) and fixed at the point of exit to the skin of the lumbar region with an adhesive tape. After that, the patient was transferred to a horizontal position. The time it took to modify the spinal needle and tunnel the EC was 5 to 9 minutes. The T_{10} level of anesthesia was achieved by placing the patient in Trendelenburg or anti-Trendelenburg positions. The onset of sufficient anesthesia for surgical intervention was from 7 to 15 minutes. Postoperative epidural analgesia was started after regression of sensory and motor block and test dose and its evaluation. A solution of ropivacaine 2 mg/ml at a dose of 10 to 16 mg/hour was injected into ES using a syringe pump. The change of the aseptic sticker, the treatment of the site of exit of EC on the skin and the site of epidural access was carried out after 24 hours without fail, on the next day of the postoperative period, if necessary.

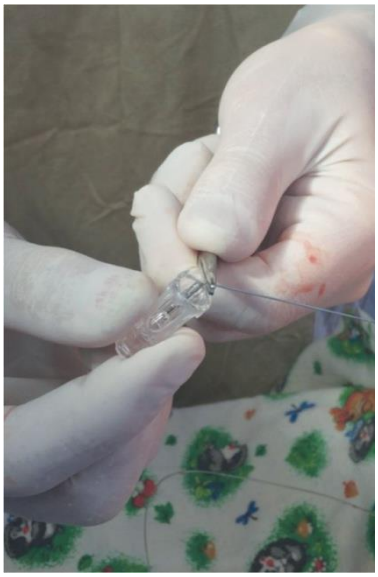


Fig. 4. The modification of the spinal needle was carried out, the hub of the needle was broken off

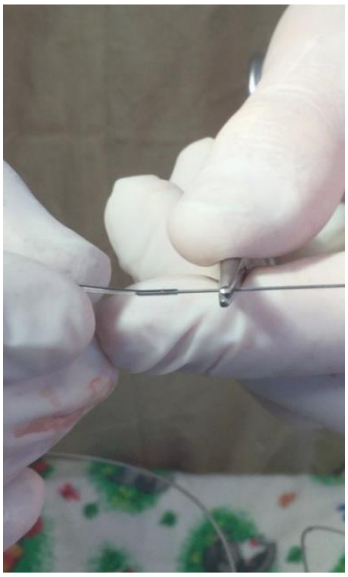


Fig. 5. An epidural catheter was fixed on a modified spinal needle

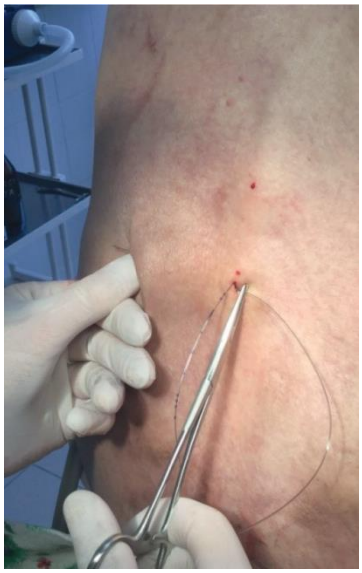
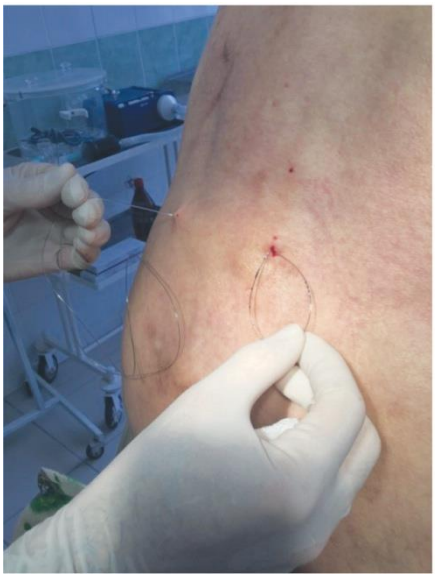


Fig. 6. Insertion of an epidural catheter into the subcutaneous canal using a modified spinal needle



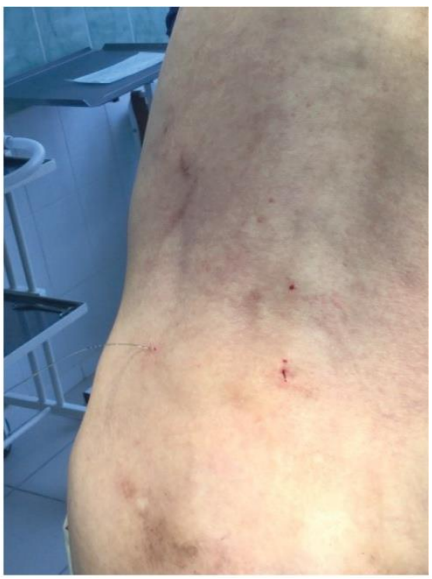


Fig. 7. An epidural catheter was inserted and fixed in the subcutaneous canal

RESULTS AND DISCUSSION

The degree of external dislocation was assessed at the time of EC extraction. For this, the method for assessing the degree of external dislocation of the EC was used (an application for the invention "Method for assessing the degree of external dislocation of the epidural catheter" dated February 17, 2021, registration number 2021104089/14 (008901)) was applied (Table 4).

Table 4

Method for assessing the degree of external dislocation of epidural catheter

Degree of dislocation	Value, mm	Dislocation characteristic
1	0 to 5	No dislocation
2	5–10	Minor dislocation
3	10–15	Moderate dislocation
4	15–20	Pronounced dislocation
5	20–30	Threat of catheter loss
6	over 30	Complete dislocation or loss

The results of the study are presented in Table 5. Statistically significant differences were found in the dislocation of the epidural catheter of the 1st, 2nd, 4th and 5th degree. In the study group, there are more cases with dislocation of the 1st and 2nd degree (no dislocation and minor dislocation) and fewer cases with dislocation of the 4th and 5th degree (significant dislocation and the threat of loss) than in the comparison group.

Table 5

The comparison of the degree of external dislocation of epidural catheter in the study groups

Degrees of dislocation	Comparison group *n* (%)	Study group *n* (%)	Total *n* (%)	*R*
Internal dislocation from 0 mm to 10 mm	1 (1.5%)	0 (0%)	1 (0.8%)	0.316
1st degree: no dislocation (0–5 mm)	3 (4.6%)	11 (16.9%)	14 (10.8%)	0.024
2nd degree: minor dislocation (5–10 mm)	11 (16.9%)	22 (33.85%)	33 (25.4%)	0.027
3rd degree: moderate dislocation (10–15 mm)	17 (26.2%)	22 (33.85%)	39 (30%)	0.339
4th degree: significant dislocation (15–20 mm)	18 (27.7%)	5 (7.7%)	23 (17.7%)	0.003
5th degree: threat of loss (20–30 mm)	12 (18.5%)	4 (6.2%)	16 (12.3%)	0.033
6th degree: more than 30 mm. Lost epidural catheter	3 (4.6%)	1 (1.5%)	4 (3%)	0.310

When comparing the degree of dislocation in the study groups, statistically significant differences were revealed with dislocation of the 1st degree (0–5 mm) — in the study group it was 12.3% more than in the comparison group, with dislocation of the 2nd degree (5–10 mm) — in the study group by 16.95% more than in the comparison group, with a dislocation of the 4th degree (15–20 mm) — in the study group by 20% less than in the comparison group and with a dislocation of the 5th degree (20-30 mm) — in the study group it is 12.3% less than in the comparison group (Fig. 8).

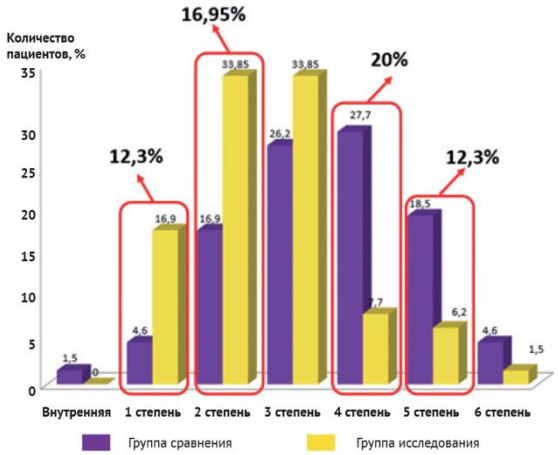


Fig. 8. Statistically significant differences when comparing the degree of external dislocation of epidural catheter in the studied groups

If a catheter with lateral holes is inserted into the ES at a distance of less than 30 mm, there is a high probability of inadequate analgesia [23]. When the catheter is inserted into the ES at a distance of 45 mm, the external dislocation of the EC no more than 15 mm (grade 2 and 3) will be clinically insignificant. Such a dislocation will not lead to a deterioration in the quality of anesthesia. External dislocation of the EC at a distance of 15 to 30 mm (grade 4 and 5) will be clinically significant. Such a dislocation can lead to a decrease in the level of epidural analgesia and, accordingly, to a decrease in the quality of anesthesia provided (Table 6). Statistically significant differences were found in the dislocation of the group of degrees 2-3 (clinically insignificant dislocation) — the number of cases in the study group is more by 24.6% and in the group of degrees 4-5 (clinically significant dislocation) — the number of cases in the study group is less by 32, 3%.

Table 6

The comparison of the degree of epidural catheter dislocation taking into account their clinical significance in the study groups

Degrees of dislocation	Comparison group *n* (%)	Study group *n* (%)	Total *n* (%)	*R*
Internal dislocation (0–10 mm)	1 (1.5%)	0 (0%)	1 (0.8%)	0.316
1st degree: no dislocation (0–5 mm)	3 (4.6%)	11 (16.9%)	14 (10.8%)	0.024
2–3rd degree (5–15 mm)	28 (43.1%)	44 (67.7%)	72 (55.4%)	0.005
4–5th degree (15–30 mm)	30 (46.2%)	9 (13.9%)	39 (30%)	<0.001
6th degree (more than 30 mm). Lost epidural catheter	3 (4.6%)	1 (1.5%)	4 (3%)	0.310

When comparing the degree of external dislocation in the study groups, taking into account their clinical significance, the following results were obtained. The number of cases with clinically insignificant external dislocation of the EC in the study group was 24.6% more than in the comparison group ($p = 0.005$), and with a clinically significant external dislocation of the EC in the study group was 32.3% less than in the group comparisons ($p < 0.001$). The differences turned out to be statistically significant and are shown in Fig. 9.

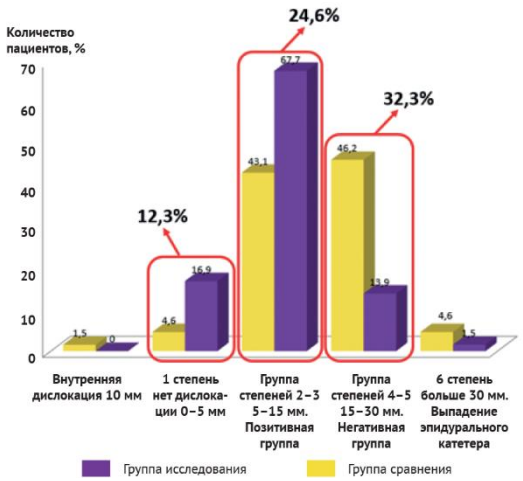


Fig. 9. Comparison of the degree of external dislocation of the epidural catheter, taking into account their clinical significance in the study groups and statistically significant differences

The duration of postoperative epidural analgesia was from 1 to 5 days (Table 7, Fig. 10). Longer epidural postoperative analgesia was performed in patients in the study group. A statistically significant difference was found at the duration of anesthesia for 2 days. In the study group, the number of patients with a duration of anesthesia of 2 days was 20.7% less than in the comparison group, and with a duration of 3, 4, and 5 days more, but the difference was not statistically significant.

Table 7

The duration of postoperative epidural analgesia in the study groups

Duration in days *n* (%)	Comparison group *n* (%)	Study group *n* (%)	Total *n* (%)	*p*
1 day	1 (1.4%)	0 (0%)	1 (0.7%)	0.316
2 days	19 (26.4%)	4 (5.7%)	23 (16.2%)	0.001
3 days	37 (59.7%)	45 (67,1%)	82 (63,4%)	0,146
4 days	6 (9,7%)	12 (21,5%)	18 (15,5%)	0,128
5 days	2 (2,8%)	4 (5,7%)	6 (4,2%)	0,404

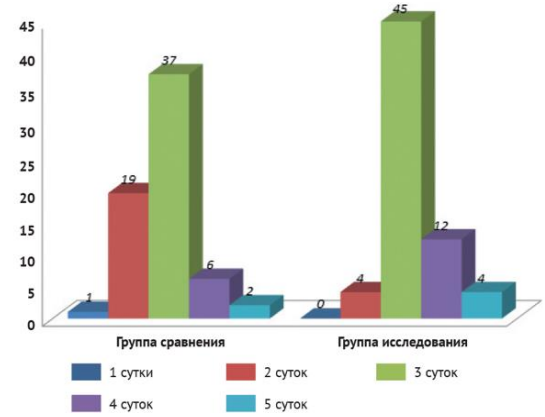


Fig. 10. The duration of postoperative epidural analgesia in the study groups

The average duration of postoperative epidural analgesia in the comparison group was 2.83±0.09 days (67.92 h), in the study group — 3.26±0.08 days (78.24 h). The average duration of postoperative analgesia in the study group was 0.43 days (10.32 hours) longer than in the comparison group. When comparing the average duration of postoperative epidural analgesia in the study groups, the differences were statistically significant (p = 0.000503). The value of Student's t-test was 3.57. At the same time, the critical value of Student's t-test is 1.98 at a significance level of $\alpha = 0.05$.

As a result of the study, it was proved that the method of fixing EC in the subcutaneous canal using MSN is more reliable than fixing EC only with adhesive tape. With this method of fixation, the number of cases with clinically significant external dislocation of the EC is significantly less than with fixation with only adhesive tape. Also, with this method of EC fixation, tunneling is less traumatic, the cost of anesthesia does not increase, since in the modified version, an already used spinal needle is used and there is no need for special fixing devices. Reliable fixation of the EC in this way allows the daily change of the aseptic adhesive sticker or the change of the sticker as needed. We believe that it is necessary to change the aseptic label after 24 hours without fail, and in the following days, if necessary. On the 2nd day after ES catheterization, in most cases, blood or other wound discharge accumulates at the site of epidural access, which is an ideal nutrient medium for the development of an infectious process, which will increase the risk of developing neurological infectious complications.

However, this method does not solve all the problems of EC fixation, which is why it is necessary to develop new methods of its fixation, including the subcutaneous canal.

CONCLUSION

1. Used in the framework of combined double-segment spinal-epidural anesthesia, the spinal needle in a modified version can be used to guide and fix the epidural catheter in the subcutaneous canal.

2. The dimensions of the modified spinal needle (88–120 × 0.45–0.52 mm) make it possible to tunnel the epidural catheter less traumatically, at a distance of 70–80 mm from the epidural access, which provides more reliable fixation of the epidural catheter.

3. When fixing the epidural catheter in the subcutaneous canal with a modified spinal needle, the number of cases with clinically significant dislocation of the epidural catheter (from 15 mm to 30 mm) is 32.3% less than when fixing it only with adhesive tape (p = 0.005).

4. Reliable fixation of the epidural catheter allows to achieve long-term postoperative epidural analgesia, which is especially important in elderly and senile patients, as it makes possible early verticalization and activation of patients, thereby reducing the risk of postoperative complications.

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