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OPTIMIZED METHOD OF UNILATERAL SPINAL ANESTHESIA, PRELIMINARY RESULTS

Yernar D. Mamyrov [1], https://orcid.org/0000-0003-4070-2165
Daulet U. Mamyrov [2], https://orcid.org/0000-0001-7887-1736
Marat K. Syzdykbayev [1], https://orcid.org/0000-0002-0561-4111
Yoshihiro Noso [3], https://orcid.org/0000-0003-3477-1260

[1] Anesthesiology and intensive care department,
Semey medical university,
Semey city, Republic of Kazakhstan;
[2] Anesthesiology and intensive care department,
Pavlodar branch of Semey medical university,
Pavlodar city, Republic of Kazakhstan;
[3] Department of surgery, Faculty of Medicine, Shimane University,
Izumo city, Shimane, Japan

Summary

Introduction: Unilateral, or otherwise, monolateral spinal anesthesia (USA /MSA), is one of the methods of spinal anesthesia in one side operations on the lower limbs. However, this kind of anesthesia is not without flaws. One of the main criteria for evaluating this type of anesthesia is the frequency of successful monolateral blocks, which, according to different authors, varies from 13% to 94%. Such a spread is, without any doubts, is not the criterion of a "reliable" method of anesthesia and in many cases is explained by the technique of its implementation. In recent years, by Mamyrov D.U. et al., a new original technique of monolateral spinal anesthesia with the use of electroneurostimulation (MCA + ENS) has been proposed, reg №26023 ((19) KZ(13)A4(11)26023), but its effectiveness and safety have not been studied enough.

The aim of the study: To conduct the comparative evaluation of the efficacy and safety of the methods of conventional monolateral spinal anesthesia (MSA) and monolateral spinal anesthesia using electroneurostimulation (MSA + ENS).

Materials and methods: This work was carried out within the frames of the PhD doctoral education program. On the basis of Pavlodar city hospital №1, in the period from July to September 2018, 18 patients operated on for varicose disease of the lower limbs, deep vein thrombosis of the lower extremities, as well as amputations of one of the extremities were examined. 7 patients underwent MSA + ENS (main group), 11 patients had traditional MSA (comparison group).

The study design is a blind, randomized, clinically-controlled study.

During the processing of statistical data, the following criteria were applied: the Shapiro – Wilk criterion, the Levene criterion, Student's t-test for independent samples, the U-Mann Whitney test with the Moses amendment and the Chi-square test was used to analyze dichotomous variables.

Results: Both study groups were comparable to gender M = 1.56 (SD = 0.5), age M = 50.7 (SD = 8.7), BMI = 25 (SD = 5.2) and ASA status M = 2.4 (SD = 0.5). In both groups there were no statistically significant differences in hemodynamic parameters, so in main group M_{SAP} = 103 (SD = 4.6), t = 1.43 df = 16 p> 0.05; in comparison group M_{SAP} = 99 (SD = 6.6), t = 1.55 df = 15.7 p> 0.05. At the same time, the parameters of the sensor and motor block are different. Thus, the adequacy of anesthesia in the main group was observed in all patients, in the comparison group, 4 (36%) patients required additional administration of analgesics. Bilateral anesthesia was in 2 (18.1%) patients in the comparison group. Also, 2 (18.1%) patients of the comparison group had nausea, without vomiting. In the postoperative period 2 (18.1%) patients of the comparison group there were post-puncture headaches, that had been treated after 2 days, in patients of the main group headaches were not observed

Conclusions: The obtained results, despite the small amount of observations, confirm the expediency of applying the MSA + ENS method, since this technique gives an objective control of the puncture of the dura mater process by obtaining a motor response. The MSA + ENS technique allows to stop pushing the spinal needle into the subarachnoid space, thereby reducing the incidence of injury of the spinal cord roots and cauda equina with a needle, also significantly increases the chance of obtaining an adequate one-sided spinal block. Thus, this method seems to us more effective and safe in comparison with the usual monolateral spinal anesthesia.

Keywords: *unilateral spinal anesthesia, monolateral, unilateral, Quincke, electroneurostimulator, post-dural puncture headache, dura mater, bupivacaine, hyperbaric solution.*

Резюме

УСОВЕРШЕНСТВОВАННЫЙ МЕТОД ОДНОСТОРОННЕЙ СПИНАЛЬНОЙ АНЕСТЕЗИИ, ПРЕДВАРИТЕЛЬНЫЕ РЕЗУЛЬТАТЫ

Ернар Д. Мамыров [1], https://orcid.org/0000-0003-4070-2165
Даулет У. Мамыров [2], https://orcid.org/0000-0001-7887-1736
Марат К. Сыздыкбаев [1], https://orcid.org/0000-0002-0561-4111
Йошихиро Носо [3], https://orcid.org/0000-0003-3477-1260

[1] **Кафедра анестезиологии и реаниматологии,**
НАО «Медицинский университет Семей»,
г. Семей, республика Казахстан;
[2] **Курс анестезиологии и реаниматологии кафедры неотложной медицины,**
Павлодарский филиал НАО «Медицинский университет Семей»,
г. Павлодар, Республика Казахстан;
[3] **Кафедра хирургии медицинского факультета университета Шимане,**
город Идзумо, Шимане, Япония

Введение. Односторонняя, или по-другому, монолатеральная спинальная анестезия (ОСА/MCA), это один из методов обезболивания при односторонних операциях на нижних конечностях. Однако данный вид обезболивания не лишен недостатков. Одним из главных критериев при оценке данного вида анестезии является частота удачных монолатеральных блокад, которая по данным разных авторов, варьирует от 13% до 94%. Такой разброс, несомненно, не является критерием «надежного» метода анестезии и во многих случаях объясняется техникой ее выполнения. В последние годы, Мамыров Д.У. с соавторами, была предложена новая оригинальная техника монолатеральной спинальной анестезии с применением электронейростимуляции (МСА+ЭНС), рег №26023 ((19)KZ(13)A4(11)26023), однако эффективность и безопасность ее недостаточно изучена.

Цель. В клинических условиях провести сравнительное исследование эффективности и безопасности методов общепринятой монолатеральной спинальной анестезии (МСА) и монолатеральной спинальной анестезии с применением электронейростимуляции (МСА+ЭНС).

Материалы и методы. В период с июля по сентябрь 2018 года, на базе Городской больницы №1 города Павлодара, было исследовано 18 пациентов, оперированных по поводу варикозной болезни нижних конечностей, тромбоза глубоких вен нижних конечностей, также ампутаций одной из конечностей. Из них у 7 пациентов проведена МСА+ЭНС (основная группа), у 11 пациентов традиционная МСА (группа сравнения). Дизайн исследования - слепое рандомизированное клинически-контролируемое исследование.

При статистической обработке данных, применялись критерии Шапиро-Уилка, Ливиня, t-критерий Стьюдента для независимых выборок, U-Манна Уитни с поправкой Мозеса и критерий Хи-квадрат для анализа дихотомических переменных.

Результаты: Исследуемые группы были сопоставимы относительно пола M=1,56(SD=0,5), возраста M=50,7(SD=8,7), ИМТ M=25(SD=5,2) и класса риска по ASA M=2,4(SD=0,5). В обеих группах не было статистически значимых различий в показателях гемодинамики, так $M_{САД1}$=103(SD=4,6), t=1,43 df=16 p>0,05; $M_{САД2}$=99(SD=6,6), t=1,55 df=15,7 p>0,05. В то же время, показатели сенсорного и моторного блока разнятся. Так, адекватность анестезии в основной группе наблюдалась у всех пациентов, в группе сравнения у 4 (36%) пациентов потребовалось дополнительное введение анальгетиков. Билатеральная анестезия была у 2(18,1%) пациентов группы сравнения. Также у 2(18,1%) пациентов группы сравнения наблюдалась тошнота, без рвоты. В послеоперационном периоде у больных основной группы головных болей не было отмечено, а у 2(18,1%) пациентов группы сравнения наблюдались постпункционные головные боли, купированные на 2 сутки.

Выводы: Полученные результаты, несмотря на малый объем наблюдений, подтверждают целесообразность применения метода МСА+ЭНС, так как эта техника дает возможность объективного контроля процесса пункции твердой мозговой оболочки путем получения двигательного ответа. Данная методика МСА+ЭНС позволяет остановить продвижение иглы в субарахноидальное пространство, что тем самым позволяет уменьшить частоту травм корешков спинного мозга иглой и значительно повышает шанс получения адекватного одностороннего спинального блока. Таким образом, данная методика нам представляется более эффективной и безопасной в сравнении с обычной монолатеральной спинальной анестезией.

Ключевые слова: *односторонняя спинальная анестезия, монолатеральная, унилатеральная, Квинке, электронейростимулятор, постпункционная головная боль, твердая мозговая оболочка, бупивакаин, гипербарический раствор.*

Түйіндеме

БІР ЖАҚТЫ ЖҰЛЫН АНЕСТЕЗИЯ ӘДІСІН ЖЕТІЛДІРУ, АЛДЫН АЛА НӘТИЖЕЛЕРІ

Ернар Д. Мамыров [1], https://orcid.org/0000-0003-4070-2165
Даулет У. Мамыров [2], https://orcid.org/0000-0001-7887-1736
Марат К. Сыздыкбаев [1], https://orcid.org/0000-0002-0561-4111
Йошихиро Носо [3], https://orcid.org/0000-0003-3477-1260

[1]**Анестезиология және реаниматология кафедрасы,**
Семей медициналық университеті,
Семей қаласы, Қазақстан Республикасы
[2]**Анестезиология және реаниматология курсы жедел медицина кафедрасының,**
Семей медициналық университетінің Павлодар филиалы,
Павлодар қаласы, Қазақстан Республикасы
[3] **Хирургия кафедрасы, Шимане университетінің медицина факультеті,**
Идзумо қаласы, Шимане, Жапония

Кіріспе. Бір жақты немесе басқаша, монолатеральды жұлын анестезиясы (БЖЖА /МЖА) аяққа жасалынатын біржақты операциялар үшін анестезия әдістерінің бірі болып табылады. Алайда, бұланестезияның кемшіліктері де бар. Анестезияның осы түрін бағалауда негізгі критерийлерінің бірі- эффективті монолатеральды блокадалардың жиілігі,әртүрлі авторлардың пікірінше, 13% -дан 94% -ға дейін өзгереді. Мұндай айырмашылық, әрине, анестезияның «сенімді» әдісінің өлшемі емес және көптеген жағдайларда оны жүзеге асыру әдісімен түсіндіріледі. Соңғы жылдары Мамыров Д.У. авторларымен, электронейростимуляцияны қолдану арқылы (МСА + ЭНС) монолатеральды жұлын анестезиясының жаңа бірегей әдістемесі ұсынылған, рег №26023 ((19)KZ(13)A4(11)26023), бірақ оның тиімділігі мен қауіпсіздігі толығымен зерттелмеген.

Мақсаты. Клиникалық жағдайларда қарапайым монолатеральды жұлын анестезиясының (МСА) тиімділігі мен қауіпсіздігін және электронейростимуляция қолдануымен (МСА + ЭНС) монолатеральды жұлын анестезиясын салыстырмалы зерттеу жүргізу.

Материалдар мен әдістер. Бұл жұмыс PhD диссертация аясында жүзеге асырылды. Павлодар қаласының №1 қалалық ауруханасының жағдайында, шілде айынан қыркүйек айына дейін 18 науқасқа ота жасалды, варикоз ауруына, аяқтардың терең тамырларындағы тромбоздарында және аяқтардың біреуінің ампутациясына байланысты жүргізілді. Олардың ішінде 7 науқасқа МСА + ЭНС (негізгі топ), 11 науқаста жалпы МСА (салыстырмалы топ) болды.

Зерттеу дизайны - соқыр, рандомизацияланған, клиникалық бақылаулы зерттеу. Статистикалық деректерді өңдеу үшін, Шапиро-Уилк, Ливиня критерийі, тәуелсіз үлгілер үшін Стьюдент t-критерийі, Мозес түзетуімен U-Манн Уитни және Хи-квадрат тесті дихотомдық деректерді талдау үшін пайдаланылды.

Нәтижелері: Зерттелген топтар M = 1.56 (SD = 0.5), M = 50.7 (SD = 8.7), ДСИ M = 25 (SD = 5.2) ASA M = 2.4 (SD = 0.5). Екі топта да гемодинамикалық параметрлерде статистикалық маңызды айырмашылықтар болмады, сондықтан MCAD1 = 103 (SD = 4.6), t = 1.43 df = 16 p> 0,05; MCAD2 = 99 (SD = 6.6), t = 1.55 df = 15.7 p> 0,05. Сонымен қатар сенсорлық және моторлы блоктың көрсеткіштері әр түрлі. Осылайша, негізгі топтағы анестезия барлық науқастарда науқастарда эффективті болды, салыстыру тобында 4 (36%) науқасқа анальгетиктерді қосымша енгізу қажет болды. Салыстыру тобында 2 (18,1%) науқаста екі жақты анестезия байқалды. Сонымен қатар салыстырмалы топтағы 2 (18,1%) науқаста жүрек айнуы, құсу болған жоқ. Операциядан кейінгі кезеңде негізгі топтағы науқастарда бас ауруы байқалған жоқ, салыстырмалы топтағы 2 (18,1%) науқаста, 2 күннің ішінде пункция кейінгі бас ауруы байқалды.

Қорытындылар: Алынған нәтижелер МСА + ЭНС әдісін қолдану орындылығын растайды, себебі бұл әдіс қозғалтқыш реакциясы арқылы ұзақ уақыттық пункцияны объективті бақылауға мүмкіндік береді. МСА + ЭНС әдісі инелерді субарахноидальды кеңістікте қозғалуын тоқтатуға мүмкіндік беріп, осылайша жұлын миын жарақат алу жиілігін азайтады, ол бастапқыда бір жақты омыртқаның блоктарын алу мүмкіндігін арттырады. Осылайша, бұл әдіс дәстүрлі монолатеральды жұлын анестезиясымен салыстырғанда бізге тиімді және қауіпсіз болып табылады.

Негізгі сөздер: бір жақты жұлын анестезиясы, монолатеральды, унилатеральды, Квинке, электронейростимулятор, пункциядан кейінгі бас ауруы, бупивакаин, гипербарикалық ерітінді

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Introduction

The positive impact of regional anesthesia on the pathophysiology of operative trauma, the rapid development of the block, the high quality of sensory and motor block, ease of implementation, reliability of muscle relaxation, low risk of systemic toxic reactions and cost effectiveness, led to a significant increase of the number of spinal anesthesia in the overall structure of pain management methods [6, 7].

On the other hand, high applicability of spinal anesthesia throughout the world, as well as popularity among anesthesiologists [13], due to the high efficiency and reliability of the spinal block, like any other methods of anesthesia, has its pitfalls.

One of these drawbacks is the development of hypotension during the operation upon the occurrence of spinal anesthesia, which, according to different authors, reaches 33% in general surgical patients, up to 70-80% of obstetric patients [12, 19].

Another important complication of spinal anesthesia is post-puncture headache (PGB), characterized by the appearance of headache within three days in 91% of cases and in 66% of cases within 48 hours after lumbar puncture. The frequency of this complication varies from 1 to 40% depending on the diameter of the needle, direction of needle, the competence of the anesthesiologist and the presence of associated risk factors [2].

In 1961, the technique of monolateral (unilateral) spinal anesthesia was described, in which the authors noted that monolateral spinal anesthesia (MSA) was accompanied by fewer central hemodynamic and respiratory impairments due to sympathetic blockade on only one side [20]. A large role in achieving the aforementioned is played by the rate of injection of a local anesthetic, its volume, type and caliber of spinal needles [25, 26]. This type of anesthesia has proven itself in both conventional medical institutions and one-day surgery clinics [22], due to its advantages, in particular: achieving an asymmetric spread of spinal anesthesia between the operated and non-operated parties [9]. However, strict monolateral distribution of anesthetic in the subarachnoid space and, as a consequence, unilateral anesthesia is not always an achievable indicator [17], which according to different authors varies from 68% to 94.5%. If the introduction of low doses of anesthetic, during the monolateral spinal anesthesia is performed with errors, superficial, poor-quality anesthesia may occur that will require additional systemic administration of analgesics, and failure of such anesthesia will result in conversion to total intravenous anesthesia(TIVA). On the other hand, there are a number of contraindications associated with anatomy, features of the spinal column pathology, obesity, which make it difficult and precluding the use of this type of anesthesia due to the high probability of unsuccessful puncture of the subarachnoid space, or requiring repeated attempts of the anesthesiologist, which increases the risk of complications. The consequence of the above is that researches of different authors continue to improve the selectivity of monolateral spinal anesthesia. For example, in the study of Yakup Tomak et al., the method of cooling the solution of Bupivacaine 0.5% to 5 ° C, in order to increase the density of solution to hyperbaric is described, which according to the authors increased the frequency and improved the quality of the monolateral block [21].

Other authors compared the injection rate of anesthetic into the spinal space, and proved the effectiveness of slow introduction of anesthetic [10]. Also, these studies provide controversial data on the patient's side position, since it is known that the time required to fix anesthetic on the axons of the nervous structures of spinal cord varies from 10 to 25 minutes, which in some cases delays a surgical team and not every patient can lie so much time in the lateral decubitus position.

At the same time, a high interest in MSA is mainly caused by hemodynamic advantages, namely, a decrease in blood pressure after the onset of anesthesia was recorded much less frequently, compared to bilateral SA, and according to the data of various authors was from 5 to 18% [1, 11, 24, 28, 29]. Also, the use of MSA causes greater adherence in both patients and surgeons, due to the spread of sympathetic block only on the operated side, and as a consequence, comfort in postoperative period due to the preservation of motor activity in the non-operated limb, also when applying MSA for short-term operations, the recovery rate of sensory and motor sensitivities are significantly higher in comparison with traditional bilateral spinal anesthesia [23, 24].

Monolateral spinal anesthesia, in terms of safety, has significant advantages over bilateral. Thus, the incidence of acute urinary retention in the postoperative period is significantly lower compared with bilateral anesthesia [28, 30].

However, along with all the advantages of the MSA, there are some drawbacks: to properly perform this type of anesthesia, high qualifications and experience of an anesthesiologist are required, strict adherence to an anesthesia algorithm is necessary, since during the manipulation the patient is in lateral decubitus position with the legs, brought to the body and as a result, there is a high probability of injury of spinal cord and cauda equine [14]. Also there can be needle deviations from the median line, failure of the puncture of subarachnoid space, and no leakage of cerebrospinal fluid from the needle cannula [1]. As the confirmation of the above, we can assume the data of different authors, showing that the frequency of successful monolateral blocks varies from 13% to 94% [3, 5–7, 10, 11], which undoubtedly is not a criterion of the “reliable” method of anesthesia.

Repeated attempts of puncture can provoke the appearance of post-dural puncture headaches [21], due to the multiple damage of dura mater, and as a result, the outflow of cerebrospinal fluid into epidural space [29].

The aforementioned is confirmed by data, presented in a meta-analysis conducted in 2017 by Chambers D.J. et al., where 41 papers were investigated, including 43 clinical cases of cerebral nerve palsy, where the authors found that the main etiological factor of such a terrible complication is intracranial hypotension [8].

With regard to the economic component of the MSA, a number of authors noted a higher profitability due to a reduction in the dose of injected anesthetic from 25 to 50% [16], a decrease in the patient's stay in clinic and a decrease in the number of bed-days, which significantly reduces the costs of medical institutions, as well as patients for treatment [4, 15, 18].

It follows that taking into account the advantages and disadvantages of monolateral spinal anesthesia, there is an obvious need for further study of this method of anesthesia, as well as its improvement. In recent years, a new original technique of monolateral spinal anesthesia with the use of electroneurostimulation has been proposed (MSA + ENS) [27] however, its effectiveness and safety is not studied well.

Thus**, the purpose of this work** was to conduct in clinical conditions a comparison of the efficacy and safety of methods of conventional monolateral spinal anesthesia (MSA) and monolateral spinal anesthesia using electroneurostimulation (MSA + ENS).

Materials and methods of research.

The design of this study is a blind, randomized, clinically-controlled study. *The inclusion criteria were:* upcoming surgery on the vessels of one lower limb; age from 25 to 65 years; ASA risk – I-III degree; informed consent of the patient. *Exclusion criteria were:* refusal to participate in the study; ASA risk IV-V degree; coagulopathy of various etiologies; acute heart and / or respiratory failure; hypovolemia; intolerance to local anesthetics; infection of skin and soft tissues in the area of intended puncture; peripheral neuropathy; cognitive / mental disorders or alcohol / drug dependence, causing inability to adhere to the study protocol, as well as the patient's refusal of regional anesthesia.

The aforementioned means, that patients with an upcoming vascular operation on the lower limb, who suits the inclusion / exclusion criteria, receive information about the methods and extent of the upcoming anesthesia in oral and written form. Then they are included in the study after an informed consent to anesthesia is obtained.

Randomization in this study was carried out by the method of opaque, sealed and consecutively numbered envelopes, which were opened just before the anesthesia, and then entered into the table of accounting of distributed patients.

Evaluation of the level of sensory block was carried out using the “pin-prick” test (loss of pain sensitivity of the skin in response to needle irritation), which implies a score of 0 - maintaining pain sensitivity; feeling of dull touch in response to stimulation with a sharp needle - 1 point (analgesia); no sensations during needle stimulation - 2 points (anesthesia).

Evaluation of the level of motor block was carried out using a modified “Bromage” scale, where Bromage 0 - the patient can lift a straight leg; Bromage 1 - the patient can lift a leg bent at the knee; Bromage 2 - movements only in the ankle joint; Bromage 3 - full motor block, movements in the hip, knee, ankle joints are absent.

The assessment of the level of pain - by the visual analogue scale (VAS); Intra / postoperative monitoring of hemodynamics and respiration was also carried out until sensitive and motor activity fully restored. Within 3 days, the complications of anesthesia were monitored.

Spinal anesthesia was considered as one-sided in case of sensory block at the 20th minute was at the level of Th12 and the modified Bromage scale was at the level of> 2 on the operated limb, and also in case of the absence of sensory and motor sensitivity on the healthy non-operated limb.

The adequacy of anesthesia was determined by the absence of the need for additional administration of analgesics and anesthetics, i.e. adequate — no need for analgesic administration, inadequate — only analgesics were required, failure of anesthesia — if there was a conversion to general anesthesia(TIVA).

We investigated 18 patients operated for varicose disease of lower extremities, deep vein thrombosis of lower extremities, and amputations of one of the extremities. 7 patients underwent MSA + ENS (main group), 11 patients had usual MSA (comparison group).

The anesthesia technique of the MCA + ENS was as follows: before surgery, 6-10 ml / kg of crystalloid solution 0.9% of sodium chloride/Ringer's solution were administered intravenously in 15-20 minutes. Then the patient was positioned in the lateral decubitus position on the side of the upcoming surgery. Under strict aseptic conditions, the puncture of subarachnoid space was performed at the LIII-LIV level with a Stimuplex 22G (B.Braun) needle connected to the Stimuplex-HNS 12 electroneurostimulation apparatus (B.Braun). A 4 ma current, with frequency of 2 Herz and pulse duration of 0.1 msec was conducted through the needle. After the puncture of dura mater, if the patient received a motor response and sensations of electric stimulation on the side of the forthcoming surgery, the needle bevel was turned down and the estimated dose of hyperbaric Bupivacaine (Grindex) was slowly injected, making up 7.5 mg 0.5% solution for 60-120 seconds, without aspiration of cerebrospinal fluid. After the injection, the patients were in lateral decubitus position for 15–20 minutes to fix a local anesthetic on nerve structures. On the other hand, if the aforementioned sensations of electrical irritation and motor response were not received on the dependent side, this meant that the needle tip is placed wrong. In this case, the needle was removed and re-inserted to get the effect on the side of upcoming operation. Thus, for the first time, we used the needle for electroneurostimulation of the Stimuplex brand from B.Braun (Germany), which allows to localize the location of the needle tip in the subarachnoid space in relation to the midline and more precisely introducing a local anesthetic into the subarachnoid space.

Monolateral spinal anesthesia according to the standard technique (MSA) was carried out as follows: similar to the

MSA + ENS method, before surgery, 6-10 ml / kg of crystalloid solution of 0.9% sodium chloride/Ringer's solutions were administered intravenously. Then the patient also was positioned in the lateral decubitus position on the side of the upcoming surgery. Under strict aseptic conditions, the puncture of subarachnoid space was performed at the LIII-LIV level with a standard spinal needle of size 22G of the B.Braun company (Germany) with a Quincke cut. After the puncture of dura mater and obtaining cerebrospinal fluid in the needle cannula, which was evidence of falling into the subarachnoid space, the needle bevel was turned down and the estimated dose of hyperbaric Bupivacaine (Grindex) was slowly injected, making up 7.5 mg 0.5% solution for 60-120 seconds, without aspiration of cerebrospinal fluid. After the injection, the patients were in lateral decubitus position for 15–20 minutes to fix a local anesthetic on nerve structures.

Hemodynamic monitoring in both groups was started 15 minutes prior to anesthesia on admission to the operating room, blood pressure, heart rate, and SpO2 were measured. Further, intraoperative monitoring was carried out every 5 minutes after administration of local anesthetic for 20 minutes, then every 15 minutes until the end of the operation, the above-mentioned central hemodynamic parameters were measured, as well as anesthesia quality indicators (pin-prick, Bromage scale, pain level according to VAS). The degree of anesthesia adequacy and the need for additional administration of analgesics / hypnotics, the achievement of one-sidedness of anesthesia, as well as the regression time of the motor block were also recorded. Complications of spinal anesthesia, such as nausea, vomiting, hypotension, were recorded. Hypotension was considered as a decrease in blood pressure more than 30% from the baseline, and bradycardia was considered as decrease in heart rate below 50 beats / min. Hemodynamics were corrected if necessary. In the postoperative period, the regression time of motor and sensory block was recorded, as well as the need for the introduction of analgesics.

The information described above is filled in by the anaesthesiologist, who performed the appropriate type of anesthesia in the framework of this study, into a special patient's condition assessment card, where he encodes the performed type of anesthesia (for example, MSA-4, MSA + ENS-7). Further, another researcher transfers the received information to the statistical editor and carries out statistical processing, which is described below.

If we take into account the use of pre-prepared, numbered and sealed envelopes with written type of anesthesia, that is opened in the operation room right before the anesthesia, as well as the encoding of the results of intraoperative patient's condition - thus we achieved double blinding in this study, which certainly improves the quality of research and reduce the risk of the impact of human factor.

Statistical processing was performed using the IBM SPS Statistics program (version 20.0.0.02). The confidence interval was 95%, the 2-sided significance was 0.05 with a power of 0.8. The normality of the distribution was checked using the Shapiro – Wilk criterion, the equality of dispersion was checked using the Levene criterion. Patient characteristics as well as differences in hemodynamics were analyzed using Student's t-test for independent samples with normal distribution and equality of variances. The sensory and motor blockade characteristics were analyzed using the U-Mann Whitney test with the Moses amendment for independent samples. The Chi-square test was used to analyze dichotomous variables. Quantitative data were presented as mean (M) ± standard deviation (SD). Ordinal data are presented as Median.

This study was carried out in frames of PhD doctoral program, in the period from July to September 2018.

The study was approved by the Local Institutional Ethical Committee (protocol №1, 28.09.2017) and written, informed consent was obtained from all patients before anesthesia.

The results of the study

There were no statistically significant differences in the studied groups regarding age, gender, body mass index, class of anesthetic risk for ASA (table 1). In most cases, surgery was completed without the additional administration of analgesics / anesthetics. In the comparison group, one patient required the administration of 150 mg of Ketamine hydrochloride, three patients were given 2 to 4 ml of 0.005% Fentanyl by the end of the operation.

Table 1.

Patient characteristics (Mean ± standard deviation).

	MSA+ENS	MSA
Age	51 ± 11	50 ± 7
Height	165 ± 6	165 ± 7
Weight	71 ± 18	69 ± 16
Gender	1,57 ± 0,5	1,55 ± 0,5
BMI	26 ± 6	25 ± 5
ASA risk	2,57 ± 0,5	2,36 ± 0,5

There were no statistically significant differences in hemodynamic parameters in the compared groups. So, SBP in patients who underwent MSA + ENS was on average 4 mm Hg. higher (with a normal distribution and equality of dispersions) than in patients who underwent standard MSA ($t = 1.464$; $df = 16$; $p = 0.162$).

Pulse rate in patients who underwent MSA + ENS were on average 15 units lower (with a normal distribution and equality of variances) than in patients who underwent a standard MSA ($t = -2.096$; $df = 16$; $p = 0.052$).

Hemodynamic correction was required in 3 patients of the comparison group, using either crystalloid solutions from 500 to 1000 ml, in more severe cases, hydroxyethyl starch (HES) solutions 500 ml intravenously were used.

Also, the duration of surgery and the regression time of motor block were relatively equal: the duration of surgery in patients undergoing MSA + ENS was, on average, 5 minutes shorter (with normal distribution and equality of dispersions) than in patients who underwent standard MSA ($t = -0.579$; $df = 16$; $p = 0.571$).

The regression time of motor block of anesthetized lower limb in patients who underwent an MSA + ENS was, on average, 13 minutes shorter (with a normal distribution and equality of dispersions) than in patients who underwent a standard MSA ($t = -1,358$; $df = 16$; $p = 0.193$).

The ratio between the sensory and motor blocks among the groups is summarized in Table 2. Thus, the quality of

the sensory and motor blocks in the main group (Bromage> 2 and Pin-prick = 2) in most cases exceeded that in the comparison group, but according to the Mann-Whitney test, significant differences in the above indicators were not observed, and the null hypothesis of p = 0.211 was adopted for the Pin-prick test and p = 0.056 for the Bromage test.

Table 2.

Characteristics of anesthesia and other data.

	MSA+ENS	MSA
SBP	103 ± 5	99 ± 7
Pulse rate	69 ± 30	85 ± 19
Anesthesia adequacy 1/2/3	7/0/0	7/5/0
Additional analgesic administration	0	4 (36%)
Sensory block pinprick) Th12 (after 15 min) 0/1/2	0/0/7	0/4/8
Motor block (Bromage scale) 0/1/2/3	0/0/0/7	0/1/5/5
Surgery duration	85 ± 19	90 ± 20
Motor block recovery (min)	116 ± 21	130 ± 21
MSA on the 15th minute monolateral / bilateral	7/0	9/2
Nausea yes / no	0/7	3/8
Vomit yes / no	0	0
PDPH yes/no	0/7	1/10

Strictly unilateral anesthesia was achieved in 100% of cases in the main group and in 9 out of 11 cases (81.8%) in the comparison group x2 = 1.432, df. = 1, p = 0.231.

Concerning early complications of anesthesia, such as nausea and vomiting, it can be said that in the main group 100% of patients did not have nausea, in the comparison group in 3 out of 11 patients (27.3%) nausea was recorded (x2 = 2.291, df. = 1, p = 0.130). Vomiting was not recorded in both groups.

In the postoperative period, 1 (5.6%) patient of the comparison group showed post-dural puncture headache, cured on the 2nd day; no such complication was detected in the main group.

Discussion

In the medical scientific literature, no similar studies were found where monolateral spinal anesthesia (MSA) and monolateral spinal anesthesia with the use of electroneurostimulation (MSA+ENS) were compared. In general, the authors compared bilateral spinal anesthesia with monolateral spinal anesthesia, where MSA has obvious, distinct advantages due to more stable hemodynamics [9][11]. As an example, closest to ours, we can cite the study of the authors Moosavi Tekye S.M. and Alipour M., where they conducted a comparative assessment of the effects and complications of unilateral and bilateral spinal anesthesia in orthopedic surgery of the lower extremities [17], for example, in this study, almost all of the indicators were similar to the indicators used in our study.

Of the main ones, we can provide an assessment on the Bromage and Pin-prick scales, an assessment of hemodynamic parameters, the adequacy of anesthesia and the need for additional analgesics as well as an assessment of complications associated with one or another type of anesthesia.

It is also necessary to note the frequency of post dural puncture headaches (PDPH) - one of the most important indicators that interests the scientific community and practical anesthesiologists most strongly, so in our study, with a sample size of just 17 patients versus 72 patients, the frequency of PDPH is 1 patient in the control group in the absence of such a complication in the main group, against 2 cases of PDPH in the control group in the study of the authors Moosavi Tekye SM et al., which undoubtedly requires a further expansion of the sample size and research of these complications.

In other studies, authors compare monolateral spinal anesthesia with sciatic nerve block [22], paravertebral blocks, continuous epidural or spinal anesthesia, epidural anesthesia in pure form, a comparison of different types of needles with monolateral spinal anesthesia, various types and doses of local anesthetics, and adding various drugs as an adjuvants to the main local anesthetic [5][7][15][21].

However, there is almost no study has adequately described the topic of the number of successful punctures, as well as the use of MSA in critical patients, patients with obesity, spinal column deformities in which the use of MSA may be contraindicated.

Thus, the comparison of two methodologically similar types of anesthesia, can be considered as one of the main advantages of this study, and we couldn't find any information about such comparisons, provided by other authors in the form of scientific articles or abstracts, which indicates that there is no such comparison has been made before us. The use of randomization, double blind design of study, and conducting research in two different medical centers contributes to an increase in the quality of research and a more objective and correct assessment of the results obtained.

From a technical point of view, objectification of the dura mater puncture as a result of the use of electroneurostimulation should be noted, and the possibility of using this type of anesthesia in critical patients and patients in whom the use of a conventional MSA may be accompanied by technical difficulties and which may require multiple puncture attempts with all resulting consequences.

Statistical processing of the results showed that there were no significant differences in the main assessment criteria. In our opinion, there were no differences due to the fact that a small number of observations were taken as a basis, therefore there is an increase in statistical error and a high risk of obtaining a statistical error of the 1st type. However, the study showed that the presence of objective criteria for the tip of the needle in the subarachnoid space improved the quality of the anesthesia obtained and reduced the number of postoperative nausea and PDPH in MSA + ENS. In our opinion, further studies and an increase of sample size will provide statistically significant results for the benefits of the MSA + ENS, compared to the usual MSA.

Hemodynamic parameters were not significantly different, since two similar methods were compared and the same doses of local anesthetic were used.

Conclusions

The obtained results confirm the expediency of using the MSA + ENS method, since the technique developed by us allows objective monitoring of the dura mater puncture process by obtaining a motor response. This method of MSA + ENS allows to stop moving the needle into the subarachnoid space, thereby reducing the incidence of injuries to the roots of the spinal cord and cauda equina with a needle. Also this technique increases the chance of obtaining an adequate one-sided spinal anesthesia. Thus, this technique seems to us more effective and safe compared to conventional monolateral spinal anesthesia.

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Corresponding Author:
Syzdykbayev Marat Kelissovich - Head of Department Anesthesiology and Resuscitation Doctor of Medical Sciences, anesthesiologist-resuscitator of highest qualification category, assistant at chair of anesthesiology and resuscitation at State Medical University of Semey city.
Address: 071400, The Republic of Kazakhstan, The East Kazakhstan region, Semey city, Abay Kunanbaev street, 103.
Phone: +7(777)-633-47-57.
e-mail: fortunato74@mail.ru