Educational intervention with serial album about pregnant women positioning for spinal anesthesia: randomized clinical trial

Intervenção educativa com álbum seriado sobre posicionamento de gestantes para raquianestesia: ensaio clínico randomizado

Intervención educativa con álbum seriado sobre posicionamiento de gestantes para raquianestesia: ensayo clínico randomizado

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ABSTRACT

Objective: To evaluate effectiveness of using educational intervention serial album to positioning pregnant women for spinal anesthesia. **Method:** Randomized clinical trial with 90 women casually assigned to control (CG) and intervention group (IG), in a maternity hospital located in Northeast region of Brazil. The primary endpoint was "achieve correct positioning to perform spinal anesthesia"; and secondary, "how number of spinal cord puncture attempts". Effectiveness was verified using the chi-square test, Fisher's exact test and likelihood ratio. **Results:** The positioning was correct in 37 women in each group. There was an association between women in control group remaining still, relaxing shoulders and flexing the spine; and women in intervention group should remain still and relax the shoulders; furthermore there was a statistical association achieved by correct positioning and the number of attempts to access the lumbar puncture. **Conclusion:** Educational intervention with serial album was effective and contributed to immobility and positioning of pregnant women. Brazilian Registry of Clinical Trials (RBR-3Z7SRD).

Descriptors: Anesthesia Spinal; Patient Positioning; Pregnant Women; Health Education; Clinical Trial.

RESUMO

Objetivo: Avaliar o efeito de intervenção educativa com álbum seriado no posicionamento de gestantes para raquianestesia. **Método:** Ensaio clínico randomizado, realizado com 90 mulheres alocadas aleatoriamente nos grupos de controle e intervenção, em maternidade do Nordeste brasileiro. O desfecho primário foi "posição correta para a raquianestesia"; e o secundário, "quantidade de tentativas de punção medular". A efetividade foi verificada a partir do teste qui-quadrado, exato de Fisher e razão de verossimilhança. **Resultados:** O posicionamento foi correto em 37 mulheres de cada grupo. Houve associação entre ser do grupo-controle e ficar imóvel, relaxar os ombros e flexionar a coluna; e ser do grupo-intervenção e ficar imóvel e relaxar os ombros; além de associação estatística entre o posicionamento correto e a quantidade de tentativas de punção lombar. **Conclusão:** A intervenção educativa com álbum seriado foi efetiva e contribuiu para imobilidade e posicionamento das gestantes. Registro Brasileiro de Ensaios Clínicos (RBR-3Z7SRD).

Descritores: Raquianestesia; Posicionamento do Paciente; Gestantes; Educação em Saúde; Ensaio Clínico.

RESUMEN

Objetivo: Evaluar el efecto de intervención educativa con álbum seriado sobre el posicionamiento de gestantes para raquianestesia. Método: Ensayo clínico randomizado, realizado con 90 mujeres alocadas aleatoriamente en os grupos de control e intervención, en maternidad del Nordeste brasileño. El resultado primario ha sido "posición correcta para la raquianestesia"; y el secundario, "cantidad de tentativas de punción medular". La efectividad ha sido verificada a partir del test chi-cuadrado, exacto de Fisher y razón de verosimilitud. Resultados: El posicionamiento ha sido correcto en 37 mujeres de cada grupo. Hubo relación estadística entre estar en el grupo control y quedar inmóvil, relajar los hombros y flexionar la columna lumbar y estar en el grupo de intervención y quedar inmóvil y relajar los hombros. Conclusión: educativa con álbum seriado ha sido efectiva y contribuyó para inmovilidad y posicionamiento de las gestantes. Registro Brasileño de Ensayos Clínicos (RBR-3Z7SRD) Descriptores: Raquianestesia; Posicionamiento del Paciente; Gestantes; Educación en Salud; Ensayo Clínico.



INTRODUCTION

Success of anesthetic procedure suffers influence of the correct positioning of the patient⁽¹⁾. Precisely, in obstetrics, the correct positioning of the pregnant woman in the spinal anesthesia has more relevance to achieve the desirable anesthesia, due to the existence of factors inherent to pregnancy, such as increase in the size and weight of the abdomen, which affects hemodynamic changes⁽²⁾.

Health education during the preoperative period, as well as access to information and explanations regarding the anesthesia, may be possible to increase understanding in patients who will be submitted to surgical intervention. The main goal must be obtained their collaboration to perform the procedure, if effectiveness on the part of the strategy educational.is used⁽³⁾.

Educational interventions, patient guidance and assistance to anesthetic positioning are part of the perioperative nursing duties, which have used technological resources to contribute to the communication process⁽⁴⁾.

In Brazil, there is already a technological resource able to be used in pre-operative health education for cesarean sections, to guide pregnant women about the correct position for spinal anesthesia: it is a serial number, built from a literature review, with its content validated by specialists (education professionals, nurses and anesthesiologists) and considered comprehensible to pregnant women⁽⁵⁾.

When contemplating the need for evidence-based practice, it is believed that pertinent and relevant research results support the decision-making when it comes to choose the educational strategy that proves to be more effective to guide pregnant women on spinal anesthesia positioning. In view of the importance of correct positioning of pregnant women to assure the success of the anesthetic procedure, the relevance of health education for the process of guiding patients and usage of technology as a facilitator to the educational process, the need for research on this object is justified the need to investigate the effectiveness of the previous mentioned serial number. Thus, the following research question has surfaced: "Educational intervention using serial number is effective to be adopted as the correct positioning of pregnant women during spinal anesthesia?"

The conduct of a study to answer that question corroborates the World Health Organization's Safe Surgery Saves Lives Program which recommends the usage of strategies to decrease harm during the anesthetic procedure⁽⁶⁾. Besides, it includes safety during childbirth established by Rede Cegonha, a public health policy, provided by the Brazilian Unified Health System⁽⁷⁾, and helps the professional exercise of health education by nursing professionals.

Given the above, it is believed that there will be a contribution to the practice of obstetric and perioperative nursing.

OBJECTIVE

To evaluate the efficacy of educational intervention using serial number into pregnant women positioning undergoing spinal anesthesia positioning.

METHODS

Ethical aspects

The research has been approved by the Research Ethics Committee of the Regional University of Cariri. The participants accepted to join the research and signed a Free and Informed Consent Form. The clinical trial was registered with the Brazilian Clinical Trials Registry (RBR-3Z7SRD).

Study design, location and period

Controlled and randomized clinical trial (RCT), carried out in a maternity hospital in a medium-sized public hospital, in Juazeiro do Norte, State of Ceará, Brazil, from June to August 2017. The recommendations to guide the study design were followed according to the Consolidated Standards of Reporting (CONSORT).

Sample, inclusion and exclusion criteria

The sample was calculated by establishing a significance level of 95%, power of the test was 80%, standard deviation of 5% and difference between groups of resulting in 70 participants joining the study. Due to consideration of losing participants, 90 pregnant women were recruited: 45 for the control group (CG) and 45 for the intervention group (IG).

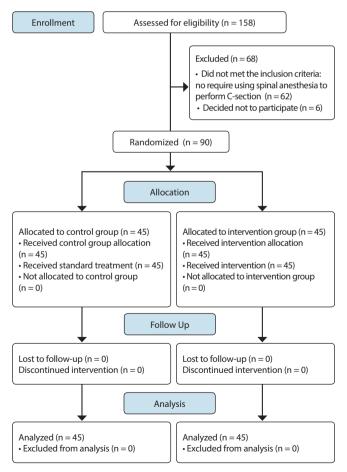


Figure 1 - Flowchart of recruitment and allocation of study participants, Juazeiro do Norte, Ceará, Brazil

Inclusion criteria were: 18 years of age or older; current medic indication for C-section because of topical pregnancy, single fetus and spinal anesthesia. Exclusion criteria appeared due to clinical or obstetric complications, and then the participants would be unavailable for the study.

From a total of 158 women evaluated for eligibility, 68 were excluded, either for giving up (6) or for not meeting inclusion criteria (62). Ninety women were randomized and following the sample calculation, 45 women were assigned to each group. Enrollment ended when estimated sample size was achieved as shown in Figure 1.

Study protocol

Randomization was chosen and based simple random draws organized in the beginning of each week, shown where the participants should be allocated, in a proportion 1: 1 ratio in CG and IG. The draws were conducted using thick and sealed envelopes, which contained the number 1 to determine the IG or the number 2 for the CG.

Blinding or masking were drawn by a hospital employee, unrelated to the research, to decide to which group the pregnant women would be allocated. Even participants did not know to which group they were allocated. Furthermore, observation of anesthetic procedure and analysis of the outcome variable were performed by the chief researcher, who, at the time of observation, was unaware of which group each participant belonged to.

Applicants considered eligible to take part in the sample were approached individually during the preoperative consultation and invited to join the study; they were also asked to sign the Free and Informed Consent Form. At that same time, women in the CG received nursing guidelines provided by a service routine (nurse on duty at the institution), while members of the IG were subjected to preoperative education intervention using serial number (flipchart).

The intervention mentioned above was performed by an auxiliary researcher -- sitting in a chair in front of the patient's bed – providing 20 minutes guidelines using serial number (flipchart), to explain what spinal anesthesia is, its advantages and disadvantages in cesarean delivery, detailed and graphic explanation of the pregnant woman position to undergoing this procedure and the upmost importance to stay still in the appropriate position during the anesthetic puncture. After initiating the procedure there were no other changes during the intervention.

After preoperative consultation, pregnant women were being transferred to a surgical center. During spinal anesthesia in the operating room the chief researcher (a licensed nurse professor with vast experience in surgical nursing) observed the anesthetic procedure without interfering in the positioning process.

The primary result (correct position for spinal anesthesia) and the secondary result (number of punctures performed) were evaluated at that moment using a checklist created and validated by the Study and Research Group on the Promotion of Health in Critical Situations, at the Federal University of Ceará.

The content to support the structure of the referred instrument was compiled by reviewing bibliographical references, and contemplated characteristics regarding the appropriate positioning the patient needs to adopt during the spinal anesthesia - sitting

position: immobility, flexing lumbar and cervical spine, dorsal muscle relaxing, including shoulders, extending hands over the legs; for lateral decubitus position: flexion of the lumbar spine without flexion of the cervical spine, immobility, relaxation of the shoulders and flexion of the lower limbs directed towards the abdomen.

In terms of content the instrument was validated by five anesthetists, with 80% of minimum acceptance to consider the item valid. and to consider the positioning as correct it was established that the pregnant woman presented a correct position at least of 70% of the instrument items.

Analysis of results and statistics

The data were entered into the Microsoft Excel 2016 software and analyzed using the Statistical Package for the Social Sciences (SPSS) software, version 20.0 (license No. 10101131007). Pearson's chi-square test was used and, in cases it did not fit, Fisher's exact test or likelihood ratio was used adopting a significance level of 5% and confidence interval of 95%.

RESULTS

Pregnant women in control and intervention groups were evaluated and compared accordingly to socioeconomic, obstetric and types of positioning during spinal anesthesia. In terms of socioeconomic variables both groups presented homogeneity regarding age, religion, education, marital status, occupation and income (Table 1).

Table 1 – Characteristics of pregnant women according to socioeconomic variables, Juazeiro do Norte, State of Ceará, Brazil, 2017

Sociodemographic variables	Control Group		Interve Grou		<i>p</i> value	
variables	n	%	n	%	value	
Age (years)						
18-20	10	22.2	14	31.1	0.597*	
21-30	24	53.4	20	44.5		
31-42	11	24.4	11	24.4		
Statistical average ± Standard deviation	25.67 ± 5.99) :	25.91 ± 6.61		25.78 ± 6.28	
Religion						
Catholic	38	84.4	33	73.3	0.162**	
Evangelical	3	6.7	9	20.0		
Other	4	8.9	3	6.7		
Years of study						
Up to 8	7	15.6	10	22.2	0.645*	
9 to 11	9	20.0	10	22.2		
12 to 16	29	64.4	25	55.6		
Statistical average ± Standard deviation	11.26 ± 2.54		10.69 ± 2.25		10.97 ± 2.40	
Marital status						
No partner	6	13.3	9	20.0	0.646*	
Partner	39	86.7	36	80.0		
Occupation						
Housewife	30	66.7	28	62.2	0.660*	
Other	15	33.3	17	37.8		
Income (Minimum wage))					
<1	7	15.6	10	22.2	0.548*	
1	28	62.2	23	51.1		
2-4	10	22.2	12	26.7		
Statistical average ± Standard deviation	1.56 ± 0.76		1.10 ± 0.83		1.12 ± 0.79	
Total	90	100	90	100		

In respect to the obstetric history, the groups were similar regarding the number of pregnancies, births, abortions and live children, gestational age in the moment of collection, motives to indicate C-section and nutritional assessment. There was a difference among the groups, regarding the kind of previous delivery: C-section prevailed in the control group; and vaginal delivery in the intervention group (Table 2).

Table 2 – Characteristics of pregnant women according to obstetric variables, Juazeiro do Norte, State of Ceará, Brazil, 2017

Obstetric variables	Control Group		Intervention Group		p value
	n	%	n	%	value
Number of pregnancies					
1	14	31.1	19	42.1	0.531*
2	17	37.8	12	26.7	
3	9	20.0	7	15.6	
4 to 9	5	11.1	7	15.6	
Number of childbirths					
0	16	35.6	22	48.9	0.196*
1	19	42.2	11	24.4	
2 to 7	10	22.2	12	26.7	
Number of abortions					
0	38	84.5	36	80.0	0.823**
1	5	11.1	7	15.6	
2 to 3	2	4.4	2	4.4	
Number of born alive					
0	16	35.6	21	46.6	0.296*
1	19	42.2	12	26.7	
2 to 7	10	22.2	12	26.7	
Previous types of childbirth					
Vaginal	8	27.6	8	34.8	0.000*
C-section	21	72.4	15	65.2	
Gestation period at time of collection					
Premature	4	9	3	7	0.693**
Full gestation	41	91	42	93	
Reason to indicate C-section					
Previous C-section scars	18	30	13	25	0.267*
Fail of labor progression	7	11	8	15	0.777*
Preeclampsia	8	13	6	12	0.561*
Labor podromos	6	10	1	2	0.039**
Elective	4	6	3	6	0.693**
Other	18	30	20	40	0.576*
Nutritional assessment					
Low weight	9	20	9	20	0.330*
Normal weight	13	29	11	24	
Overweight	7	15	14	32	
Obesity	16	36	11	24	
Total	45	100	45	100	

 $Note: {\it *Pearson's chi-square test.} \ {\it **Likelihood-Ratio Test.}$

Regarding the groups' assessment as to the primary outcome (correct positioning for spinal anesthesia), it was significant that there were no statistical association in any group with age, religion, years of study, marital status, occupation or income; and the two groups were statistically similar according to these variables.

Neither was found a statistical association between correct positioning and obstetric variables. However, it is worth noting that in the control group (G1) regarding the number of pregnancies, the highest frequency of women who had a correct position was among those who were in the second pregnancy (40.5%). When compared to the intervention group (G2), a higher frequency of correct positioning was observed in primiparous women (43.2%), although no statistical significance was found.

It is also noteworthy that, in the control group, there was a higher frequency of correct positioning among women who had had a previous birth (43.2%), while in the intervention group there were no women having previous birth (51.3%). The greatest number of women who had a correct position occurred among pregnant women with previous cesarean section (72.4% in the CG and 65.2% in the IG).

Observing pregnant women position during anesthetic procedure, all participants maintained the hands on their legs; there was a statistical association between being in the control group and standing still, relaxing the shoulders and flexing the lumbar spine; and being in the intervention group, staying still and relaxing the shoulders. Table 3 presents items which integrate the correct positioning variable distributed by group.

Table 3 - Correct positioning of pregnant women from control and intervention groups while under spinal anesthesia, - Juazeiro do Norte, State of Ceará, Brazil, 2017

Variables	Control Group n (%)	<i>p</i> value*	Intervention Group n (%)	<i>p</i> value*
Immobility	37 (82.2)	< 0.001	37 (82.2)	< 0.001
Relaxed shoulders	37 (82.2)	< 0.001	34 (75.5)	0.013
Lumbar spine flexion	37 (82.2)	< 0.001	36 (80.0)	0.077
Cervical spine flexion	37 (82.2)	0.178	37 (82.2)	0.178

Note: *Fisher's exact test

The positioning was considered correct (fulfilling at least 70% of the items) in 74 pregnant women (37 in each group). In 46 (62.2%) there was a single puncture attempt (achieved in the first attempt); in 18 (24.3%), occurred two attempts (because of failure in the first attempt) and in 10 (13.5%), three or more punctures were performed for the procedure to be successful. Thus, as for the likelihood ratio, a statistical association was found between correct positioning and the number of attempts at PL (p = 0.010).

DISCUSSION

Health education is a valid strategy to promote health in different scenarios of nursing care, including the operating room. In the context of perioperative care, educational actions play an important role by positively influencing patients' psychological condition, reducing anxiety levels and impacting their health⁽⁸⁾.

However, few aspects need to be examined before application, to guarantee better accomplishment, such as: the ideal moment to apply the educational intervention (preoperative, transoperative or postoperative), years studying the target audience, professional skills, among other factors. Regarding the ideal moment to carry out the educational intervention, studies point out the importance of creating/passing the guidelines in the preoperative period⁽⁸⁾, to be easily apprehended and put into place.

Particularly, when it comes to educational activity mediated by the serial number already discussed, some guidance must be necessary in the preoperative moment, considering that there has an action to be taken during the anesthetic procedure, which occurs in the transoperative period.

As to participants socioeconomic characteristics, the results showed similar information amongst the two groups. Such

characteristics are comparable to those findings in a demographic study carried out in Brazil, from 2011 to 2012⁽⁹⁾, considering the average age and the variable "years of study". The report of the National Survey of Demography and Health of Children and Women (PNDS) indicated a significant increase in the education of Brazilian women of reproductive age⁽¹⁰⁾. Furthermore, it is believed that the number of years studying was a relevant variable for the effectiveness of an educational intervention. That information had a positive influence to better understand the correct position during spinal anesthesia. That fact was endorsed by a study linking educational intervention with cardiac surgery patients, making clear why the level of education was decisive in adhering to educational guidelines⁽¹¹⁾.

The educational material to clarify the correct positioning in spinal anesthesia, when used properly, would promote health in pregnant women who experience the anesthetic procedure for the first time. When compared to a group that already experienced this procedure, as observed in this study, a higher frequency of correct positioning was observed in primiparous women among the intervention group.

In the history of obstetric an issue of equivalence stands out, which revealed that more than half of the number of women with history of previous childbirth, experienced surgical delivery. That information reveals that a great number of women had previous experience with anesthetic procedure. Especially in the control group, where the percentage of C-section was 72.4%, while in the intervention group, it was 65.2%. In all those cases women were submitted to spinal anesthesia.

The assumption is previous experience with surgical deliveries promoted in research participants some level of prior knowledge about how they should position themselves during anesthesia. Previous knowledge on that subject (addressed in educational activities) should always be valued by professionals who conduct such activity and incorporated into the new knowledge that is intended to be addressed. Another important point to consider is the number of previous unsuccessful puncture attempts, since this leads to dissatisfaction and fear, even increasing the risk of refusing the procedure in the future (12).

Educational practice, as a tool to health promotion, must start from the principle of respect for people's cultural universe. In this concept, there must be considered the acquired experience, which consists of their knowledge⁽¹³⁾.

Based on the research discoveries, it is possible to infer an interconnection between lower number of attempts at lumbar punction, precision on the first attempt and correct position of the patient. And considering that the correct position was favored by the educational material applied. And, considering that the correct position was favored by the educational material, there is a relevant data for obstetric surgical practice; signs that using educational technologies help the correct positioning of the patient may have an impact on saving time material, reducing surgical risk and increasing the number of safe surgeries.

Confirming those findings result of randomized study carried out in Australia point out that graphic demonstration with images was effective to contribute a better positioning during spinal anesthesia, reducing time and a lot numbers of perforations required to perform the procedure and provides greater satisfaction to patients⁽¹⁾.

The sitting position with both feet downwards was the most used method to perform anesthetic procedures. This position offers a faster start course of action. Compared to sitting position with legs elevated on the operating table, the first one offers women more comfort, due to the increased abdominal volume.

It is noteworthy mentioning that anesthesiologists perform neuraxial block using techniques based on surface anatomy, whereas the most significant predictor at the time of blockade would be the quality of these reference points and the patient's position⁽¹⁴⁾. Although some studies⁽¹⁴⁻¹⁵⁾ discuss the predictors of difficult axial block, few studies analyze techniques to minimize those difficulties. Some mention using ultrasound, although it would require expertise on sonoanatomy, will cost time and money to be executed, and technical limitations because it needs an operator.

Therefore, the relevance of correct patient positioning for spinal anesthesia is reinforced, which can be optimized through the performance of perioperative nursing. In this context, it is up to the nurse and his team to guide and assist patients in the correct positioning during the anesthetic procedure.

Relevant characteristics to pursue a correct positioning were observed, such as immobilization, shoulder relaxation and flexion of the lumbar spine (concerning the control group, are directly linked to correct positioning. It is considered that the applied series album (flipchart) aimed to inform the importance of those characteristics for success in the correct positioning, which reinforces the idea of positive influence of its use on the variable outcome.

Other characteristics identified in the present study - which also showed a statistically significant association with correct positioning, such as immobility and dorsal relaxation, observed by the relaxed shoulders, did not appear as variables in studies mentioned before.

The importance of preparing women for surgical delivery must be emphasized, which should include preparation for anesthesia, which is almost always feared by the patients who live the surgical experience. The notion of what is to be experienced can help women to remain calmer and more relaxed, as well as contribute to adoption a correct position, which includes immobility and dorsal muscle relaxation. Thus, prenatal consultations, carried out by nurses, are both an opportunity to address issues related to childbirth and important for the surgical preparation.

Study limitations

The research has its limitations since investigates a specific population (pregnant women attended by Brazil's public funded care health system [SUS] in the Northeast region). The practice of using other surgical populations, doing research in private health care institutions or in other regions in Brazil may present different results from those identified in this study.

Contributions to Nursing, Health and Public Policies

Pregnant women submitted to C-section may have difficulty to positioning themselves during spinal anesthesia, due to increased abdominal volume, in addition to other factors. Preoperative guidance promotes correct positioning to increase the success

of the procedure and prevents other complications. that the educational intervention with a serial number

Nursing can contribute by guiding and assisting women during the spinal anesthesia positioning. Results of the current study indicate that it could be used by perioperative nursing professionals or by those involved with women's health, since it has shown to be effective.

In this sense, the relevance of this clinical trial has been proven, serial number might contribute to a greater chance of pregnant women adopting the correct position during spinal anesthesia and being less exposed to numerous attempts at lumbar puncture.

CONCLUSION

The educational intervention with serial number (flipchart) to position pregnant women to perform spinal anesthesia was able to identify effectiveness just as the preoperative guidelines performed by nursing. There was no difference among groups

regarding number of pregnant women whose position was considered correct (37 in the CG and 37 in the IG). There was a statistical association between being in the CG and holding still, relaxing the shoulders and flexing the lumbar spine; and being an IG and standing still and relaxing your shoulders. In addition, a statistical association was found between correct positioning and the number of lumbar puncture attempts

The results hereby presented showed the efficacy of both strategies while preparing pregnant women who will submitted to spinal anesthesia, so that they will be correctly positioned during the anesthetic procedure.

Future research should contemplate the construction and validation of other technologies that can be added and / or compared with the serial album. Furthermore, it is pertinent to investigate both the variables that influence the correct positioning of the pregnant woman for spinal anesthesia and the effectiveness of educational intervention with other non-pregnant populations, in the surgical / spinal anesthetic context.

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