DOI:10.4274/tnd.2019.41196
Turk J Neurol 2019;25:229-232

Original Article / Özgün Araştırma

Informed Consent in Diagnostic and Therapeutic Lumbar Puncture: Are Patients Aware of the Risks?

Tanısal ve Terapötik Lomber Ponksiyonda Bilgilendirilmiş Onam: Hastalar Risklerin Farkında mı?

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Abstract

Objective: To determine whether the type of informed consent (verbal or written and verbal) influenced the awareness of patients about the risks of lumbar puncture (LP).

Materials and Methods: An "informed consent form" was given to the patients in group 1 24 h before the procedure, and the patients were requested to read and sign the form. The informed consent form was given to patients in group 2, and then, a neurologist verbally explained the complications mentioned in the form to the patients. After the procedure, patients in both groups were asked whether they were aware of the complications mentioned in the consent form.

Results: We included 43 patients (group 1, n=23 and group 2, n=20) in the study; 14% (n=6) of the patients were university graduates, 18% (n=8) had completed high-school education, and 67% (n=29) had completed primary education. No significant difference was observed between the two groups in terms of age, sex, and education level. The mean value of the number of complications that the patients were aware of was 1.17±1.02 and 7.35±1.26 in groups 1 and 2, respectively. We observed a significant difference in the number of complications that the patients were aware of between both groups (p<0.001).

Conclusion: The responsibilities of physicians are not solely limited to giving the informed consent form to the patients before LP. Physicians should explain the contents of the form verbally to the patients.

Keywords: Awareness of patients, informed consent, lumbar puncture, risks of lumbar puncture

Öz

Amaç: Bu çalışmada, bilgilendirilmiş onam tipinin (yazılı veya yazılı ve sözlü), hastaların lomber ponksiyon (LP) işleminin riskleri konusundaki farkındalığı üzerine olan etkilerini araştırmayı amaçladık.

Gereç ve Yöntem: Grup 1'e işlemden 24 saat önce, "bilgilendirilmiş onam formu" verildi ve okuyup imzalamaları istendi. Grup 2'ye bilgilendirilmiş onam formu verildikten sonra, formda belirtilen komplikasyonlar bir nörolog tarafından sözlü olarak da ayrıca açıklandı. İşlem sonrası her iki gruba da onam formunda belirtilen komplikasyonlardan haberdar olup olmadıkları soruldu.

Bulgular: Çalışmaya 43 hasta (grup 1, n=23 ve grup 2, n=20) dahil edildi; hastaların %14'ü (n=6) üniversite mezunu, %18'i (n=8) lise mezunu, %67'si (n=29) ilköğretim mezunu idi. Her iki grup arasında yaş, cinsiyet ve eğitim düzeyi açısından anlamlı fark bulunmadı. Hastaların farkında olduğu komplikasyon sayısının ortalama değeri grup 1 ve 2'de sırasıyla 1,17±1,02 ve 7,35±1,26 idi. Her iki grupta da hastaların farkında oldukları komplikasyon sayısında anlamlı bir fark gözlendi (p<0,001).

Sonuç: Hekimlerin sorumlulukları LP öncesi hastalara yalnızca bilgilendirilmiş onam formu vermekle sınırlı değildir. Doktorlar, formun içeriğini hastalara sözlü olarak da açıklamalıdır.

Anahtar Kelimeler: Bilgilendirilmiş onam, hastaların farkındalığı, lomber ponksiyon, lomber ponksiyonun riskleri

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Received/Geliş Tarihi: 07.03.2019 **Accepted/Kabul Tarihi:** 16.07.2019

Introduction

Despite the potential complications associated with lumbar puncture (LP), this is the most commonly used method for obtaining cerebrospinal fluid for the diagnosis and treatment of neurologic diseases (1,2).

The known complications of LP are headache, local back pain, spinal cord bleeding, local infection, nausea and vomiting, ringing in the ears, hearing loss, urination problems, and double vision (3,4,5,6).

Documentation of medical records is important for protecting patients and physicians. The approach for obtaining consent for medical treatment has evolved in time. The current approach is completely different from that recommended by Hippocrates, that physicians should conceal medical information from their patients. Physicians have a legal and ethical responsibility to provide patients with all the necessary information to make informed decisions (7).

Informed consent is a legal, ethical, and regulatory requirement widely accepted for most research and healthcare procedures. The content of the informed consent form varies in clinical practice and is different from the ideal informed consent form (8).

Informed consent is required for diagnostic and therapeutic procedures such as LP. An adequate informed consent form provides sufficient information about the benefits, risks, necessity, and if available, alternatives to the procedure to the patient for making an informed decision. Many court decisions have underlined that efficient consent should be informed. If the patient is not informed about the benefits, risks, and possible alternatives, the consent is not effective. In the event of a complication, a malpractice lawsuit may focus on the presence of informed consent (9,10).

A consensus has been achieved about the scope of consent in that consent is not solely governed by signing a form; nonetheless, written consent forms are commonly used in clinical practice. The World Medical Association Declaration of Lisbon on the Rights of the Patient indicates that all patients have a right to self-determination and to information (8).

This study aimed to investigate as to whether the type of informed consent (written or written and verbal) influenced the awareness of patients about the risks of LP.

Materials and Methods

We included 52 patients who underwent diagnostic and/or elective therapeutic LP at our clinic between February 2017 and January 2018. This study was approved by the Ethics Committee of Bolu Abant Izzet Baysal University (no: 2017/140). All participants were informed about the study and written informed consent was obtained from each participant.

We included only those patients whose native language was Turkish, regardless of their age, sex, and level of education. Patients who had at least one of the contraindications for LP, such as an intracranial mass, ongoing anticoagulant use, thrombocytopenia, and coagulopathy, and patients with known cognitive dysfunction, and those who had previously undergone LP were excluded from the study. The patients were divided into two groups using the closed envelope technique. Cranial computed tomography/magnetic resonance imaging was performed to exclude the intracranial space-occupying lesion in both groups.

We gave an "informed consent form" 24 h before the LP procedure to patients in group 1 and requested them to read and sign the form. The informed consent form was also given to patients in group 2, and then a competent neurologist verbally explained the complications mentioned in the form to the patients.

The patients in both groups were explained in detail about the procedure. After the procedure, all patients were given a list of complications stated in the informed consent form, and the patients were asked to mark the checkbox next to the complication that they were already aware of. In addition, the patients were asked whether they were aware of all complications and whether they approved the procedure despite the complications. The complications stated in the informed consent form are shown in Figure 1.

Statistical Analysis

All statistical analyses were performed using the SPSS for Windows version 22.0 (SPSS Inc., Chicago, IL, USA) software package. The chi-square test was used to compare the distribution of sex and educational status. An independent sample t-test was used to compare the number complications that the patients were aware of between the two groups. Independent sample t-test was used to compare the difference between the groups in terms of age.

Results

Fifty-two patients who met the inclusion criteria were included in the study. Nine patients declined to participate. Thus, the study was performed with 43 patients (20 women and 23 men); group 1, n=23, and group 2, n=20 (Figure 2).

The mean age of the patients was 47.7±18.2 years. The educational status of the patients was as follows: 14.0% (n=6) were university graduates, 18.6% (n=8) were high-school graduates, and 67% (n=29) were primary school graduates.

We observed no significant difference in terms of age, sex, and level of education between the two groups. Our results showed that the mean number of complications that the patients were aware of was 1.17±1.02 and 7.35±1.26 in groups 1 and 2, respectively. There was a significant difference in the awareness of the number of complications between the groups (p<0.001, Table 1).

1.	Headache	**O**
2.	Local back pain	**O**
3.	Nausea and vomiting	**O**
4.	Ringing in the ears	**O**
5.	Spinal cord bleeding	**O**
6.	Local infection	**O**
7.	Hearing loss	**O**
8.	Urination problems	**O**
9.	Double vision	**O**
10.	Meningitis	**O**

Figure 1. The following complications may occur after the lumbar puncture procedure. Please tick (√) the checkbox next to the complication that you are already aware of. If you are not aware of the complication, leave the field blank

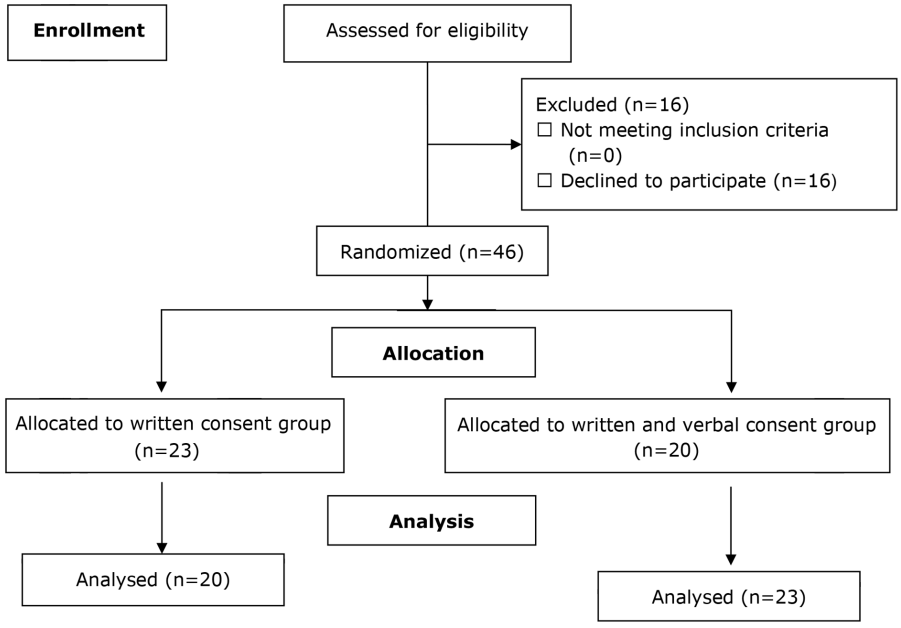

Figure 2. Design of the study

Table 1. Comparison of the general characteristics and the number of complications that the patients are aware of between the groups

	Group 1	Group 2	p value
Sex, n (%)			
Male	11 (47.8%)	12 (60%)	0.425
Female	12 (52.2%)	8 (40%)	
Educational status, n (%)			
Primary school	14 (39.1%)	15 (75%)	0.544
High-school and higher	9 (60.9%)	5 (25%)	
Age (mean±SD, years)	42.8±15.1	53.5±20.2	0.055
Number of complications that the patients are aware of	1.17±1.02	7.35±1.26	**<0.001**

SD: Standard deviation

Discussion

In clinical practice, physicians aim to protect themselves against possible legal sanctions by obtaining informed consent from patients undergoing LP. However, the presentation of the written consent form to the patient and obtaining the signature of the patient on this form alone may not be sufficient to protect the physician against legal actions. Our results showed a lack of awareness of the complications of LP among the patients, regardless of their educational status, and the patients had to be verbally informed about the complications.

In 1957, a patient claimed that he was not adequately informed about the risk of paralysis after a translumbar arteriogram, and the patient sued his physician. The court subsequently ruled that a more comprehensive consent should have been obtained. The decision of the court was a milestone for informed consent. Thus, simple consent implies that the patient approves the procedure and informed consent implies that the patient has been adequately informed about the procedure (7).

Our results showed that the patients signed the written consent form approving the procedure without sufficient knowledge. Only the patients who were scheduled for an elective procedure and were given a consent form 24 h before the procedure were included in the study. The fact that patients did not have sufficient information about the complications despite the 24 h period before an elective procedure indicates that a greater number of patients in emergency practice may not have sufficient information about the complications. Educational videos should be used as alternative methods for informing patients who are unaware of the complications mentioned in writing and have to be verbally informed about them (11).

A complainant may be justified in court despite the information in the informed and written consent forms if questions such as "are there any additional questions?" or "is there something you do not understand in these complications?" are not asked.

Although a patient who underwent an emergency coronary angiography in Turkey in December 2017 had been informed in a verbal and written manner that kidney failure might develop after the procedure, the physician was sued because the patient developed acute renal failure requiring dialysis after the procedure. The patient stated in court that "kidney failure could develop but hemodialysis was not mentioned". The court found the physician at fault and imposed a fine of $10,000 (12).

Despite all explanations, a patient may argue that they were not sufficiently informed, and these kinds of allegations can be justified in court. Thus, the standard informed consent form is not sufficient for protecting physicians. Therefore, every patient who has been given written consent must be informed verbally

and asked whether they want further information. In the case of patients undergoing elective procedures, the awareness of patients about complications can be determined using a checklist after the patient has read the form and has been informed about the complications.

Study Limitations

There are some limitations of this study. These include the small sample size, lack of educational videos about LP procedure, and lack of evaluation through the use of more objective methods. Future studies are recommended to address these limitations.

Conclusion

The responsibilities of the physicians are not limited to giving the informed consent form to patients before LP, they should also explain the content of the form. In addition, they should ask patients if they have any questions or require any detailed explanation. Various methods such as animated narrations of the procedure or educational videos should be used to educate patients about interventional procedures.

Ethics

Ethics Committee Approval: This study was approved by the Ethics Committee of Bolu Abant Izzet Baysal University (no: 2017/140).

Informed Consent: All participants were informed about the study and written informed consent was obtained from each participant.

Peer-review: Externally and internally peer-reviewed.

Authorship Contributions

Surgical and Medical Practices: M.N.Ö., M.Ö., Ş.A.T., Concept: M.N.Ö., Design: M.N.Ö., S.Y., Data Collection or Processing: M.N.Ö., M.Ö., Analysis or Interpretation: M.N.Ö., Ş.A.T., Literature Search: M.N.Ö., M.Ö., Writing: M.N.Ö., M.Ö.

Conflict of Interest: No conflict of interest was declared by the authors.

Financial Disclosure: The authors declared that this study received no financial support.

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