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A PROSPECTIVE EVALUATION

INFORMED CONSENT IN INTERVENTIONAL SPINE PROCEDURES: HOW MUCH DO PATIENTS UNDERSTAND?

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Background: One of the most important issues that interventional physicians address during treatment is informing patients of their treatment options. Prior to beginning treatment, patients are given this information and allowed the opportunity to ask questions. Minimal qualitative information exists as to how much of this material patients retain and understand.

Objective: To determine the understanding and satisfaction patients have with the information provided through the informed consent process for interventional spine procedures.

Design: Prospective qualitative interview study.

Setting: University-based multidisciplinary spine practice.

Participants: Twenty-five consecutive patients undergoing spinal procedures who agreed to be interviewed about the informed consent process.

Interventions: Not applicable.

Main outcome measures: Domains of concern for patients undergoing spinal procedures were determined through a qualitative interview.

Results: Primary areas of concern for patients with the informed consent process centered on their desire for more information on the procedure and its risks, expectations of the procedure and benefits, and what treatments patients feel are effective. Patients had difficulty recalling the potential risks and alternatives to the procedure. The majority of patients had tried physical therapy and medications, without benefit. The most common suggestion patients gave for improving the process was to produce a video of the procedure. Common themes encountered during the interview are reviewed, with common phrases presented for each theme.

Conclusions: Despite discussion in the office, handouts, and pre-procedure instructions, patients felt that additional sources of information would be useful to fully understand the procedure and its risks, benefits, and alternatives. Moreover, informing patients' family members may enhance comprehension of all aspects of information provided within the informed consent process about interventional spine procedures.

Keywords: Chronic pain, spinal injections, informed consent, patient-physician relationship.

Over the last few decades, the manner in which medicine is practiced has changed dramatically. One remarkably notable change has occurred in the way physicians interact with their patients. In the past, it was accepted that a physician was well informed about medical options and was highly qualified to make decisions concerning patient care. Many doctors shared information with their patients based on their own judgment, a paternalistic approach that emphasized beneficence to the exclusion of other principles, particularly autonomy. This approach has been perpetuated by public attitudes reflected in statements like "doctor knows best." Unfortunately, physicians are not always able to determine their patients' best interests (1).The legal precedent for informed consent in the United States arises from a court case in 1914 in New York State in which a patient with a tumor underwent an operation to which he had not agreed. In his opinion, then New York Justice Benjamin Cardozo wrote that "every human being of adult years and sound mind has a right to determine what shall be done with his own body" (2).

In recent years, the public has become more knowledgeable about medical issues and many more individuals are showing interest in making decisions regarding their own health care (3). Patients expect to be "educated" by a physician about their medical issues so they can participate in the decision-making process (4). Moreover, patients have a right to know what may happen to them and what to expect from treatment, insofar as a physician can accurately foresee (5).

Informed consent is the process by which a person authorizes medical treatment after discussing with clinicians the nature, indications, benefits, and risks of treatment. Whereas in the past physicians did not routinely seek permission from patients to provide medical treatment, in current practice physicians are obliged to expect and encourage patient participation in decisions regarding their care (6).

Informed consent is predicated on the reasonable person standard, which states that physicians must provide the patient with all information that would be desired by a layperson to make a decision. This information includes discussion of the treatment, available alternatives, potential outcomes of each option, the costs, risks and benefits of each alternative, and the values of each potential outcome. An

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open discussion of the problem or diagnosis, procedure, the risks and benefits, prognosis, and alternative treatments and their risks and benefits, are considered a "standard of care" (7).

Therefore, informed consent has now become an essential part of the physician-patient relationship. It has been found that the process of obtaining informed consent can improve patient satisfaction and health outcomes as well as stimulate trust in the physician and observance of treatment recommendations (8). However, patients often have poor recall and understanding of medical information regarding the risks and benefits of procedures, even when considerable attempts are made to inform them (9). Several factors may preclude physicians' effective communication with patients. Lack of time during the consultation, lack of medical knowledge on the part of some patients, and disturbances such as anxiety, pain and fear of the unknown tend to contribute significantly to patient inability to learn and preserve information (10).

Recently, efforts have been made to enhance communication between physicians and their patients. It has been suggested that the consent giver must have satisfactory decision-making capacity, a sufficient comprehension of the procedures, and must unreservedly sanction the procedures (11).

The purpose of this study is to assess the level of patient understanding and recollection of the information provided to them by their practitioner regarding a spinal injection intervention. This information was used to develop a questionnaire to be given to patients prior to their procedure.

METHODS

Institutional review board approval for this study was granted. Twenty-five patients with a diagnosis of spinal stenosis or radiculopathy were chosen from a sample of convenience post spinal injection; all agreed to be interviewed in an anonymous manner. The patients were presented with nine broad-based and open-ended questions designed to elicit theirs views in each of the following areas: expectation, knowledge of risks and alternatives, and satisfaction (Table 1). Eligibility criteria for this study included a documented diagnosis of lumbar radiculopathy or spinal stenosis, and willingness to answer the questionnaire. Exclusion criteria were an inability to answer questions or a refusal to participate

RESULTS

Twenty-five patients were questioned immediately post spinal injection: 88% of them demonstrated satisfaction with the information provided by the physician; 56% of the patients felt that the procedure was consistent with their expectations. Patients had difficulty recalling the potential risks to the procedure: only 16% could recall more than five potential risks; 12% remembered zero to two potential risks; and 72% recalled from three to five potential risks.

Overall, 76% of the patients had tried physical therapy, 40% had tried chiropractice care, and 68% had tried medications. Some of the 40% of patients categorized under "other" had tried various treatments including acupuncture, massage therapy, herbal therapy, TENS, heating pads, and surgery. Four percent of the patients did not try any other type of treatment prior to the procedure. The majority of patients expected that the procedure would decrease pain (92%) and improve function (28%). Furthermore, patients feared that the procedure would fail to decrease pain (56%) and restore function (12%). Despite demonstrated satisfaction, patients felt that the delivery system for information needs to be improved (32%). The most common suggestion for improvement was to produce a video of the procedure (Table 2).

Table 1. *Patient interview questions*

1. Did you feel that with your office visit, pamphlet and discussions with the doctor that you were given sufficient information about the procedure?
2. Was the procedure consistent with what you were expecting?
3. What are the risks of this procedure? (Please list as many as you can remember.)
4. What treatments have been tried prior to the procedure?
5. What do you hope the procedure you are about to undergo will do for you?
6. What problems do you fear will not be helped by the procedure?
7. What other treatment options do you feel work for low back pain? (For treatments mentioned ask how well they think it works: Excellent, Very Good, Good, Fair, Poor)
8. Do you still have the ability to do all the activities that you want?
9. Do you have any suggestions for how to improve the system we currently use to give patients information on these procedures?

DISCUSSION

The heart of informed consent should be a discussion with the patient. However, the actual practice of obtaining informed consent demonstrates that certain problems exist in the process. Current studies indicate that patient ignorance and lack of understanding, along with failure to remember the information presented, make the practice of informed consent significantly less effective (12). Strong, deliberate attempts to obtain informed consent do not assure that a patient can retain pertinent information given to him for even one week. It may be that what appears to be memory deficit is a lack of initial comprehension. Evaluation of the readability of most informed consent forms has shown that the reading level required was so high that most Americans would not be able to understand the form (13). Indeed, many consent forms were found to be written at the level of graduate students (14).

Patient satisfaction with the information provided by their doctor in this study is higher than patient satisfaction reported in prior studies. Enlund et al (15) found that only 31% of respondents were satisfied with the information their physician gave them about the possible adverse affects of their medications.

Furthermore, patient understanding

Table 2. *Patient interview results with common responses.*

Question 1: *Did you feel that with your office visit, pamphlet, and discussions with your doctor that you were given sufficient information about the procedure?*

Yes: 88%
No: 12%

Comments: "Yes, he explained everything."
"I feel I was given all of the information that there is."
"No, I still felt in the dark. They don't fill you in on the procedure itself."

Question 2: *Was the procedure consistent with what you were expecting?*

Yes: 56%
No: 28%

Comments: Did not know what to expect: 16%
"Yes, but I didn't know it was going to be injected into the front of my body. The pain was right at expectation."
"No, I didn't expect it to be so painful."
"I didn't know what to expect even with all the information."

Question 3: *What are the risks of this procedure? (Please list as many as you can remember.)*

Recalled 0-2 risks: 12%
Recalled 3-5 risks: 72%
Recalled >5 risks: 16%

Note: According to the informed consent pamphlet given to patients, possible risks of this procedure include death, infection, swelling, paralysis, headaches, transient lightheadedness/fainting, nausea, increased pain, muscle soreness/redness, abscess, asphyxiation, fever, increased blood sugar, increased blood pressure, seizure, cardiovascular collapse, anaphylaxis, dural puncture, bleeding, stroke, allergic reaction, and nerve damage.

Question 4: *What treatments have been tried prior to the procedure?*

Physical Therapy: 76%
Chiropractics: 40%
Medication: 68%
Other: 40%
None: 4%

Note: Patients categorized under "other" tried treatments including acupuncture, massage therapy, herbal therapy, TENS, heating pads, and surgery.

Question 5: *What do you hope the procedure you are about to undergo will do for you?*

Decrease pain: 92%
Increase function: 28%
Decrease inflammation: 8%
Increase knowledge of condition: 4%

Note: Patients that responded with return to work, return to activities, increase flexibility and strength, and increase in mobility were grouped under "increase function."

Question 6: *What problems do you fear will NOT be helped by the procedure?*

Pain: 56%
Loss of function: 12%
Numbness: 8%
Stenosis: 4%
None: 8%
Unsure: 12%

Comments: "That the pain won't go away completely."
"I'm afraid it won't decrease my pain and I will be unable to gain more mobility."
"I don't know, today is the first treatment. I'm not sure where it will go from here."

Question 7: *What other treatment options do you feel work for low back pain? (For treatments mentioned, patient was asked to rank them on a scale as excellent, very good, good, fair or poor.)*

Physical Therapy (96%)	**Chiropractics** (60%)	**Medications** (60%)
Excellent: 0%	Excellent: 0%	Excellent: 0%
Very Good: 8%	Very Good: 0%	Very Good: 0%
Good: 42%	Good: 47%	Good: 13%
Fair: 33%	Fair: 20%	Fair: 60%
Poor: 17%	Poor: 33%	Poor: 27%
Acupuncture (44%)	**Surgery** (16%)	**Other** (40%)
Excellent: 0%	Excellent: 0%	Excellent: 0%
Very Good: 9%	Very Good: 0%	Very Good: 30%
Good: 27%	Good: 25%	Good: 10%
Fair: 55%	Fair: 0%	Fair: 40%
Poor: 9%	Poor: 75%	Poor: 20%

Question 8: *Do you still have the ability to do all the activities that you want?*

Yes: 48%
No: 52%

Yes response: *If yes, how long could you do your daily activities with your pain at its current level?*

Few days: 50%
Few weeks: 0%
Few months: 25%
Few years: 25%

Comments: "I still do my activities, pain or not. I could do it at this level for a few years."
"Just about, I still take care of my dogs and unload their feed. I could do this for a few days."
"No, I can't work, clean, drive, bend over, or sit."

Question 9: *Do you have any suggestions for how to improve the system we currently use to give patients information on these procedures?*

More information from the doctor: 20%
Informational video: 12%
None: 72%

Comments: "I would like to know my prognosis and possible prevention."
"A video may help the patients who want more information."
"No, everyone gave me the information I needed."

of the procedures in this study was significantly higher than previously reported. Byrne et al (16) noted that in a study of 100 patients who were questioned two to five days after surgery, 27% of the patients did not even know what organ had been operated on. In another study, Herz et al (17) found that 106 patients undergoing anterior cervical fusion or lumbar laminectomy had incomplete comprehension of the diagnosis, risks, and benefits immediately after disclosure. Additionally, Kekuchi et al (18) reported that at the time of their scheduled surgery, patients could answer fewer than 50% of the questions regarding the procedure.

Moreover, patient recollection of information about the risks and benefits of the procedures in our study was similar to previously reported results. In our study, zero to two potential risks were recalled by 12% of patients, three to five risks by 72% of patients, and more than five risks by 16% of the study participants. Hutson et al (19) reported the following results of risk factor recollection: death, 72%; infection, 82%; pain, 14%; loss of range of motion, 22%; loosening of prosthesis, 25%; damage to nerve or artery, 11%; and major medical complication, 61%.

The reason for low patient recollection of risks in our study is not clear. When informed of the risk factors of the interventional spine procedures, our patients demonstrated partial recollection. It is known that when people are exposed to a hazard, they may fail to remember some events surrounding that danger as a way of avoiding the most anxiety-producing details (20). Similarly, Hassar et al (21) found that anxiety might decrease patient ability to understand, retain, and recall information. In their study, two-thirds of the participants in a clinical trial of an anti-inflammatory medication did not recall being informed about possible gastrointestinal ulceration, an adverse affect that was an important risk.

However, most patients want to know what their treatment involves its risks and its benefits. Being anxious does not mean that they do not want information. It is well recognized that information helps people better cope with their anxieties. Understanding of the procedure can reduce patient anxiety and enable them to better comply with post treatment constraints as well as recognize and act appropriately should there be complications (22). Accordingly, future efforts to improve patient understanding of interventional spine procedures should be focused on development of new technological tools, such as videos or computerized interactive presentations.

Conclusion

Based on the results derived from interviews, we conclude that patients in our study felt that they received sufficient information regarding the procedure. Despite feeling adequately informed, only 16% of patients were able to recall more than five out of 24 possible side effects. A small majority of patients believed that the procedure was consistent with their expectations based on the information they received. Most patients were satisfied with the information they received, however some suggested alternate/complimentary methods of delivery.

Consequently, the effort to improve understanding of the interventional procedure could be based on alternate methods of information delivery such as videos or interactive computerized programs. We do not know which method of interaction is the best for facilitation of understanding. Therefore, a separate study on comparison of visual, interactive methods of information delivery should be performed.

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