Assessment of the effectiveness of SFCR patient information sheets before scheduled spinal surgery

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ABSTRACT

Introduction: Patient information is an essential component of any surgical procedure as it allows the surgeon to collect informed consent. This is a legal obligation in the civil code and a professional obligation in the code of medical ethics. As a result, the French spinal surgery society (SFCR) decided to make a model information sheet available on the Internet. The goal of this prospective study was to evaluate the impact of this information sheet when given to patients before scheduled spinal surgery.

Methods: This was a single-centre prospective study performed between November 2014 and February 2015. Seventy patients filled out two questionnaires. The first was about the quality of the medical information given orally by the surgeon; it was administered to patients after the preoperative consultation. The second was about the quality of the medical information contained in the information sheet; it was administered after patients had read this sheet. For each of the questions, patients could either select "yes" if they found the information to be correct/ useful (1 point) or "no" if not (0 point).

Results: The mean patient age was 56.7 years (range: 28–86). The average number of "yes" answers was 7.07 (out of 12) in the first questionnaire. The average number of "yes" answers was 10.3 (out of 12) after reading the information sheet. This indicates that patients were significantly better informed after reading the SFCR sheet. The written document was deemed to be understandable (mean: 8/10). It answered the patients’ questions (mean: 6.7/10) and helped them understand how the surgical procedure would be carried out (mean: 7.3/10). The patients’ level of education did not significantly alter these findings.

Conclusion: Adding a written SFCR information sheet to the preoperative consultation improved patients' understanding before scheduled spine surgery.

Level of evidence: Low-powered prospective study.

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1. Introduction

Patient information is an essential component of any surgical procedure as it allows the surgeon to collect informed consent. This is a legal obligation in the civil code and a professional obligation in the code of medical ethics. The French Code of Public Health states: “Doctors should give patients information about their condition that is understandable to them; when possible, information must also be provided about the treatment and care offered to them” [1]. The code of medical ethics states: “A physician shall provide the patient he is examining, treating or advising with complete, loyal and appropriate information” [2]. However, the laws do not set out the means for providing this information to the patient. The information can either be provided verbally or in written form, with the written document complementing the verbal information.

The French National Authority for Health (HAS) has produced a methodological guide to help validate information sheets: “… when written documents are available, they should be given to the patient to allow him to refer to it and/or discuss it with anyone that he wishes, in particular the physicians treating him…” [3]. This prompted the French Spinal Surgery Society (SFCR) to produce a model information sheet that is available on the Internet. The goal of this prospective study was to evaluate the impact of these SFCR patient information sheets before scheduled spinal surgery.

2. Material and methods

This was a single-centre prospective study performed between November 2014 and February 2015.

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Table 1
Demographic data.

<table>
<thead>
<tr>
<th>Questionnaires handed out (n)</th>
<th>78</th>
</tr>
</thead>
<tbody>
<tr>
<td>Returned (n)</td>
<td>70</td>
</tr>
<tr>
<td>Mean time between information sheet being handed out and the 2nd questionnaire (days)</td>
<td>35</td>
</tr>
</tbody>
</table>

2.1. Patients and information sheets

Seventy-eight patients were asked to fill out two questionnaires in succession. The first questionnaire evaluated how well patients understood the medical information given verbally by the surgeon (Appendix A); it was administered to patients at the end of the preoperative consultation. The patient was also given the SFCR information sheet during this visit. The second questionnaire evaluated how well the patient understood the medical information contained in this information sheet and the relevance of the document for the patient (Appendix B); it was administered on the day before the procedure, while the patient was in the hospital. A mean of 35 days elapsed between the time the patients read the information sheet and the time the second questionnaire was administered (Table 1). The goal was to compare the patients’ knowledge before and after reading the information sheet and to have patients evaluate the quality of this sheet.

All the patients had a preoperative consultation with the surgeon and received the document prepared by the SFCR. Patients received an information sheet that was appropriate for the specific procedure they were undergoing. The study population consisted of patients undergoing scheduled spinal surgery in the neurosurgery unit at the Dijon University Hospital. Patients were excluded if no SFCR information sheet was available for their condition, e.g., surgery on the cervical spine. The study was carried out by 3 surgeons in our unit. The French version of these sheets is available on the SFCR website: http://www.sfcr.fr/espaces-patients.

2.2. Materials

The first and second questionnaires were identical in that they assess the patients’ knowledge about the indication, surgical technique, benefits and potential complications of the surgery (Appendices A and B). For each question, the patient could select either “yes”, “no” or “I don’t know”. Patients always had the option of answering “I don’t know”, so as to not force them to answer a question. For each of the questions, patients could either select “yes” if they found the information to be useful or “no” if not. Each “yes” answer was given a score of 1 and each “no” or “I don’t know” answer was given a score of 0. The second questionnaire also included an evaluation of the information sheet (Appendix B). The answers to these items were scored using a 10-point Likert scale (1 = strongly disagree, 10 = strongly agree). Patients had to indicate whether they had read the document or not, and if they answered yes, how often they referred to it.

Table 2
Number of “yes” answers (in percentages) before and after reading the information sheet; this evaluates the patient’s overall understanding.

<table>
<thead>
<tr>
<th>Question</th>
<th>Before (%)</th>
<th>After (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Have you been informed about your medical condition?</td>
<td>97</td>
<td>98</td>
</tr>
<tr>
<td>Have you been informed about the progression of your condition?</td>
<td>53</td>
<td>74</td>
</tr>
<tr>
<td>Have you been informed about alternative treatment options?</td>
<td>61</td>
<td>94</td>
</tr>
<tr>
<td>Do you know the surgical procedures?</td>
<td>56</td>
<td>94</td>
</tr>
<tr>
<td>Do you know the risks associated with surgery?</td>
<td>77</td>
<td>96</td>
</tr>
<tr>
<td>Infection?</td>
<td>77</td>
<td>96</td>
</tr>
<tr>
<td>Haematoma?</td>
<td>60</td>
<td>91</td>
</tr>
<tr>
<td>Dural breach?</td>
<td>33</td>
<td>73</td>
</tr>
<tr>
<td>Neurological complications?</td>
<td>87</td>
<td>96</td>
</tr>
<tr>
<td>Have you been informed of the expected benefits of the surgery?</td>
<td>67</td>
<td>97</td>
</tr>
<tr>
<td>Have you been informed about the length of hospitalisation?</td>
<td>56</td>
<td>93</td>
</tr>
<tr>
<td>Have you been provided with postoperative instructions?</td>
<td>37</td>
<td>70</td>
</tr>
<tr>
<td>Have you been informed about your return to work or resumption of daily activities?</td>
<td>23</td>
<td>59</td>
</tr>
</tbody>
</table>

2.3. Statistics

The results are presented as average values (standard deviation) and/or percentages. An independent Student’s t-test or the Mann–Whitney test was used to compare the average values. The statistical analysis was carried out by the Biostatistics Department at the Dijon University Hospital.

3. Results

Of the 78 questionnaires administered, 70 could be analysed; 4 patients had not read the information sheet (and did not fill out the second questionnaire). 3 questionnaires were incomplete and one was not returned. The patients were 53% female and were between 28 and 86 years of age (average: 56.7 years). Each patient was given one of the 5 information sheets that corresponded to the procedure they were undergoing (Table 1).

3.1. Overall understanding

For both questionnaires, the overall comprehension of the medical information was evaluated based on the number of positive responses given by each patient. The average score was 7.07 (out of a possible 12) for the first questionnaire. The average score after reading the information sheet was 10.3 (out of a possible 12), which was significantly higher than the first questionnaire. This meant that patients had a significantly better understanding of the procedure after reading the SFCR sheet. Information about surgical complications was well retained by the patients, such as the possibility of neurological complications (96%) and the risk of infection (96%). In contrast, items related to return to work (or activities) and the postoperative instructions were more likely to have negative answers (70 and 59%, respectively) (Table 2). This improvement in the understanding of medical information after reading the sheet was independent of the patients’ age and education level (Mann–Whitney test).

3.2. Assessment of written document

Of the 70 patients who said that they had read the written document at least once: 33% said they referred to it often or very often,
51\% sometimes referred to it and 16\% rarely or very rarely referred to it.

For this assessment, each item was given a score between 1 and 10 by the patients (Likert-type scale). The overall layout of the information sheet was appreciated by the patients. The document was found to be understandable (average: 8/10) and the information was easy to find (average: 7.8/10) but the document was said to be too long (average: 2.2/10) (Table 3). Patients had a positive opinion of the usefulness and contents of the document. The information sheet provided patients with answers to their questions (average: 6.7/10). It helped patients understand how the surgical procedure would be carried out (average: 7.3/10). Patients judged that it corresponded to the information given by the surgeon during the preoperative consultation (average: 7.9/10) (Table 4). Lastly, patients found the information sheet to be reassuring (average: 7.4/10), but also reported being more anxious (average: 5.1/10) (Table 5).

3.3. Other sources of information

Of the 70 patients who filled out the questionnaires, 45\% stated that they received additional information from their family physician and 12\% receiving information from another surgeon. Forty-four percent said they had found information of the internet, but only 17\% of them had gone on the official SFCR website.

4. Discussion

4.1. Issues surrounding patient information

Patient information is essential to any medical or surgical procedure. The perception of this information is a subjective variable that partially depends on the strength of the patient–doctor relationship [4]. Unfortunately, this vital information can be misunderstood or not properly transmitted. Stanley et al. [5] found that 25\% of operated patients did not fully understand the risks and complications associated with the procedure. In neurosurgery, the average recall rate for potential surgical complications is 18\% for a scheduled surgical procedure [6]. This rate can vary from 15 to 50\% depending on the surgical specialty [7–11]. This is why we felt that an additional written document could be useful in reinforcing the information provided during the consultation. Our study provided evidence that it was. But published data are controversial. Several studies have shown that recall ability is better with a written document [12–15] (e.g. occurrence of facial palsy during otologic surgical procedures). However, other studies have shown no difference with and without a written document [5,7,16]. In particular, for orthopaedics surgery procedures, most patients did not recall more than 50\% of the verbal and written information that was provided [17]. In our prospective study, the information sheet provided in addition to the preoperative consultation helped patients understand the information provided by the surgeon.

4.2. Factors impacting how well the information is understood

Published studies have shown that a patient’s education level is an obstacle to deciphering written information sheets. Kubba [18] highlighted the importance of language and reading mastery. In our study, we found that the educational level did not seem to negatively impact the patients’ ability to understand the information, but all of the included patients knew how to read. For this reason, written documents should be reviewed by educational specialist and by representatives from patient associations [19].

Dufour et al. [20] emphasised that 16\% of patients who were given an information sheet found that the information provided was not targeted to them. A patient’s understanding is better when the information is presented in the form of simple, short questions and answers using plain, non-medical vocabulary [21,22]. This highlights the importance of the layout of the documents provided to the patients. The inconsistent findings can also be explained by the time elapsed between the information being given out and the information being recalled. Published data [23] indicates that information recall is best when this time interval is short (hours to weeks). Hutson found that 100\% recall was achieved when the information was given immediately before the procedure. This rate dropped to 25\% when the information was given 6 months before the procedure.

4.3. Anxiety

Several studies have shown that patients truly want to be informed, which is confirmed by the increased satisfaction rate [7,24,25]. But providing this information can also have negative consequence, such as increasing the patient’s anxiety [26–29]. Bowden et al. emphasised that information about surgical risks brought out anxiety, with a higher incidence associated with the risk of more severe complications [30]. Hoermann et al. studied information provided before total hip arthroplasty. They found that 11.7\% of patients wanted psychological support because of the stress induced by receiving information about the potential risks [27]. In our study, the anxiety induced by our information sheet varied greatly. Published data are also inconsistent relative to this matter. Some authors have shown that an information sheet does not increase anxiety in patients [31–33], while other authors have shown the opposite [34–36].

In our study, patients said the document reassured them. For the vast majority, this document helped them better understand the items discussed during the consultation and how the surgery will be conducted. Nevertheless, anxiety about the surgery itself persisted and did not seem to be altered because of the document.

4.4. Internet

The impact of having access to information on the Internet cannot be ignored. There are multiple information sources available, most of which have not been validated by scientific or academic institutions; unfortunately, the latter are likely difficult to read and access. In our study, 44\% of patients consulted the Internet, with only 17\% using the official SFCR website. The Internet should not be
perceived as a tool that brings medical competencies into question, but a way to supplement the information given.

5. Conclusion

Providing an information sheet after the preoperative consultation increases patients’ understanding and information. Verbally communicated information remains essential and can be optimised with patient-focused information sheets.

Disclosure of interest

The authors declare that they have no competing interest.

Appendix A. Questionnaire administered to patients following the consultation to evaluate their comprehension

1. Have you been informed about your medical condition? Yes/no/I don’t know
2. Have you been informed about the progression of your condition? Yes/no/I don’t know
3. Have you been informed about alternative treatment options? Yes/no/I don’t know
4. Do you know the surgical procedures? Yes/no/I don’t know
5. Do you know the risks associated with surgery? Yes/no/I don’t know

Haematoma?
Dural breach?
Neurological complications?

6. Have you been informed of the expected benefits of the surgery? Yes/no/I don’t know
7. Have you been informed about the length of hospitalisation? Yes/no/I don’t know
8. Have you been provided with postoperative instructions? Yes/no/I don’t know
9. Have you been informed about your return to work or resumption of daily activities? Yes/no/I don’t know

Appendix B. Questionnaire administered to patients the day before the procedure to evaluate their comprehension

10. Have you been informed about your medical condition? Yes/no/I don’t know
11. Have you been informed about the progression of your condition? Yes/no/I don’t know
12. Have you been informed about alternative treatment options? Yes/no/I don’t know
13. Do you know the surgical procedures? Yes/no/I don’t know
14. Do you know the risks associated with surgery? Yes/no/I don’t know

Infection?
Haematoma?
Dural breach?
Neurological complications?

15. Have you been informed of the expected benefits of the surgery? Yes/no/I don’t know
16. Have you been informed about the length of hospitalisation? Yes/no/I don’t know
17. Have you been provided with postoperative instructions? Yes/no/I don’t know
18. Have you been informed about your return to work or resumption of daily activities? Yes/no/I don’t know

Evaluation of written document

(1 = strongly disagree, 10 = strongly agree)
1. Was the document understandable?
2. Was the document too long?
3. Was the information easy to find in this document?
4. Did the document answer your questions?
5. Did the document help you better understand how the surgery will be carried out?
6. Did the document help you better understand the information provided during the consultation?
7. Did the document re-assure you about the surgical procedure?
8. Did the document make you feel less anxious?

References


