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ORIGINAL SCIENTIFIC REPORT

Insight in Information Provision Prior to Obtaining Surgical Informed Consent—by Audiotaping Outpatient Consultations

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Abstract

Background Literature suggests that patient-informing process prior to obtaining surgical informed consent (SIC) does not function well. This study aimed to provide insight into the current practice of SIC in the Netherlands.

Methods This is a prospective, observational, and multicenter study, conducted in one academic and two non-academic teaching hospitals in the Netherlands. Audio recordings were made during outpatient consultations with patients presenting with Dupuytren Disease. The recorded informing process was scored according to a checklist. Written documentation of the SIC process in the patient's chart was compared to these scored checklists. Time spent on SIC during the consultations was also recorded.

Results A total of 41 outpatient consultations were included in the study. Consultations were conducted by 25 plastic surgeons and their residents. Average time spent on SIC was 55.6% of the total consultation time. Considerable variation was observed concerning the amount and type of information given and discussed. In 59% of the consultations, discrepancies were observed between written documentation of consultations and audio recordings. Information on treatment risks, the postoperative period, and the operating surgeon was addressed the least.

Conclusion Despite a relatively large part of the consultation time being spent on SIC, patients received scarce information concerning treatment risks, postoperative period, and who their operating surgeon would be. Discrepancies were observed between the written documentation of SIC and information recorded on the audio recordings. This occurred predominantly in one hospital that used a pre-made list of 'discussed information' in its digital patient chart.

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Introduction

The term 'surgical informed consent' (SIC) refers to the patient's consent to a surgical treatment. The patient needs to comprehend all aspects of treatment which might influence his or her arrival at a well-considered decision. The responsibility for the patient's comprehension lies with the treating surgeon [1, 2].

In the Netherlands, SIC is regulated by law in the Dutch Medical Treatment Contracts Act (MTCA). Besides being legally required [1, 3], SIC is beneficial to patients. This is because patients with a proper understanding of their diagnosis, treatment, and their respective implications on lifestyle have been found to show lower levels of illness concerns, higher patient satisfaction, and better perceived control over the situation [4–6].

Since SIC is an important part of medical treatment, it is surprising that most of the literature we have consulted suggests that SIC is not adequately conducted in current practice [3, 7]. For example, surgeons seem not to be aware of every aspect of informed consent. Surgeons also underestimate the patient's desire to receive extensive information prior to a surgical procedure [8, 9]. Audio recordings of outpatient consultations show that patients are informed inconsistently. Only a minority of patients receives information on all aspects of treatment [10].

Despite the issues that arise from these studies, there have only been a few studies that have aimed to analyze the actual practice of SIC today. Therefore, the purpose of the present study was to provide insight into the current practice of SIC in the Netherlands. We investigated the patient-informing process, the written documentation of the SIC process in the patient's chart, and time spent on SIC.

Materials and methods

Setting

This prospective, observational study was conducted at the plastic surgery outpatient clinics of one academic and two non-academic teaching hospitals in the Netherlands. Audio recordings were made of consultations of patients referred with Dupuytren Disease. The consultations were carried out by plastic surgeons and their residents. The obtained recordings were analyzed after the consultation. The doctor and the patient were the only people present in the consultation room. A digital audio recorder was installed prior to the consultation. Participating doctors and patients were aware that SIC was the subject of the research and that they were being recorded. However, they had no knowledge about what specific content would be analyzed. We obtained written and verbal informed consent from both patients and doctors for participation in this study. The need for ethical approval of this study was waived by the local medical ethics committee.

Inclusion in this study was limited to patients that were both presenting with Dupuytren Disease and being counseled for the surgical treatment option of a limited fasciectomy. This treatment usually requires only a single preoperative consultation, in which the entire SIC information exchange takes place. Exclusion criteria were: (1) Consultations that did not directly lead to a scheduling for limited fasciectomy. (2) Consultations with patients who had an earlier healthcare consultation about Dupuytren Disease during the past one-and-a-half years and patients who had a surgical correction for Dupuytren Disease in the past 10 years. (3) Consultations with patients under 18 years of age. (4) Consultations with patients with a language barrier.

Analysis

The information discussed on the audiotapes was scored on a checklist by one of the investigators (BBB). This checklist contained a range of information items that might be addressed during the process of SIC. The items were sourced from the 2004 report by the Royal Dutch Medical Association (KNMG). This report stipulates how to perform the MTCA in practice [2]. Information items on the list were specified to Dupuytren Disease using the Dutch guidelines on Dupuytren Disease established by the Dutch Society for Plastic Surgery in 2012 [11]. The checklist consisted of 33 different information items and divided into the following eight categories: diagnosis, treatment characteristics, purpose, risks, postoperative period, operating surgeon, alternatives, and prognosis. An overview of scored checklist results was made.

For every item on the checklist, we calculated the percentage of consultations in which the item was addressed. Per information category, the mean of these percentages was determined.

The doctors' documentation of SIC in the patients' chart was examined and compared to the outcomes of the checklists. The total consultation time (TCT) and the time spent specifically on SIC [surgical informed consent time (SIT)] were recorded. The percentage SIT to TCT was calculated.

Internal validation

The reliability of the scoring process, performed by the first author (BBB), was tested by the second author (MMV), by re-scoring almost all of the consultations. The second researcher was blinded to the results of the first researcher.

Table 1 Consultation characteristics

Patient (n = 41)	
Median age in years (range)	62 (46–85)
Male	29 (71%)
Education level*	
Low	1 (2%)
Intermediate	28 (68%)
High	11 (27%)
Competent in Dutch language	41
Doctors (n = 25)	
Median age in years (range)	34 (30–61)
Male**	14 (56%)
Function	
Plastic surgeon	11 (44%)
Resident	14 (56%)

*Educational levels included low (none or primary school), intermediate (completed high school or vocational education), and high (completed pre-university education or university). One patient refused to share his level of education, **Male doctors conducted a total of 24 consultations (59%)

The inter-rater agreement was calculated using Cohen's kappa coefficient.

Results

Between March and October of 2015, a total of 41 consultations, conducted by 25 different plastic surgeons and residents, were included in the study (Table 1).

Within these consultations, an inconsistency was found concerning the number and choice of consultation items that were discussed. This inconsistency can be deduced from the irregular distribution of black rectangles in the overview of scored checklist items per consultation (Table 2).

The information categories that were less often discussed were treatment risks, postoperative period, and operating surgeon. These had the lowest mean percentage of the discussed information items, respectively: 44%, 33%, and 18% (Table 2).

In 90% of the consultations, the patient chart contained documentation about the SIC. In 59% of consultations, the written documentation of SIC contained in the patient charts stated that certain information had been discussed, while the audio recordings of the verbal exchange did not confirm these claims. In six of these consultations, five or more information items were erroneously described as having been discussed (Table 2). This discrepancy between written record and the actual verbally discussed information was mainly observed in one specific hospital in which the list of items to be discussed was prelisted in the electronic patient file. Thirteen out of 23 consultations that contained this discrepancy and all six consultations that erroneously mentioned five or more information items in the patient chart were from this hospital.

The mean TCT was 15.91 min (σ = 7.4 min), and the mean SIT was 8.85 min (σ = 3.5 min). The percentage of TCT that was spent on SIC was 55.6% (Fig. 1).

Almost all consultations (n = 37) were retested by the second author. A kappa coefficient of 0.63 (95% CI, 0.59–0.66) was calculated, which corresponds to the second best kappa coefficient category. This means that the scored results of both authors were similar to a high degree.

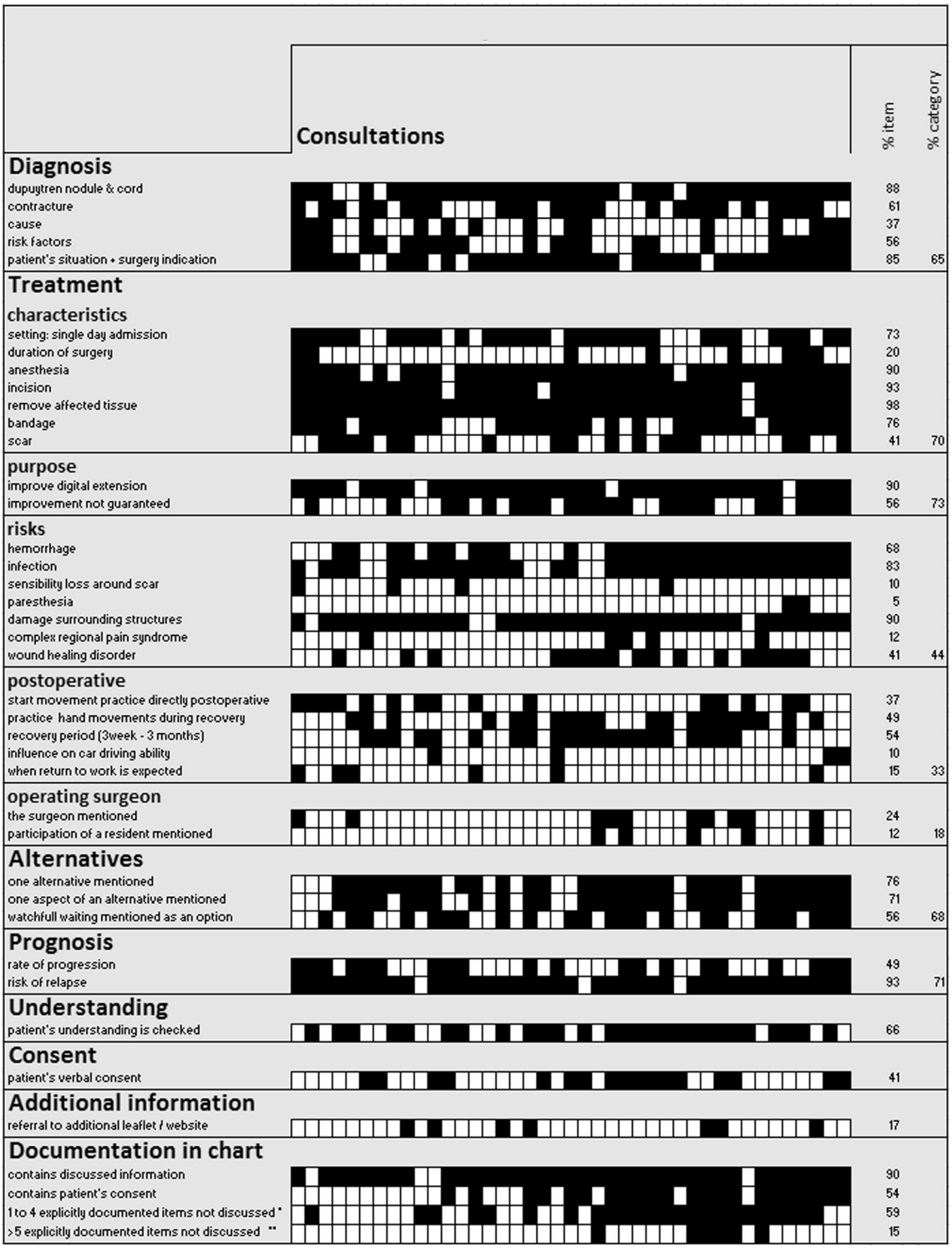
Discussion

This study aimed to provide insight into the current practice of SIC in the Netherlands. The results show that, despite more than half of total consultation time being spent on SIC, several information categories were hardly mentioned. In many cases, the written documentation of the SIC process did not match the actual information discussed with the patient.

This is one of few studies that has analyzed what SIC information is actually discussed during patient consultations. Most of the previous studies that aimed to analyze the current practice of SIC either endeavored to describe the patient's understanding of discussed information or the surgeon's knowledge of SIC [8, 12, 13]. From the few that studied the actual patient-informing process [10, 14, 15], only Knops et al. focused on the *surgical* part of informed consent. As with our study, Knobs et al. used audiotapes and a checklist to analyze consultations. Our main findings are in line with their results, as they show a considerable variation concerning the information received by patients, as well as the neglect of certain information categories (treatment purpose, treatment risks, and alternative treatments). The combined results of these studies suggest that, in current practice, no unambiguous way of informing exists and certain information is less well covered.

The checklist items are unproven when it comes to their value for the patient's decision-making process concerning their consent to treatment. This is because we did not ask the patients about their opinion concerning the relevance of the items. Therefore, the relevance of the relatively less discussed categories is unclear. However, other studies suggest that, in general, patients seem to value extensive information on treatment risks and the postoperative period [9, 16]. Moreover, patients from a former study liked to know who would be their operating surgeon, and they have opined to be informed about the level of resident participation during surgery. This kind of information could have

Table 2 Overview of scored checklist items per consultation



Overview of the results of the scored checklist items per consultation. The vertical columns represent the 41 different consultations. The horizontal rows display the different checklist items grouped by information category. Items mentioned and scored are marked as a black small rectangle. Items not mentioned and not scored are marked as a white small rectangle. The two columns on the right display the percentage of consultations in which a checklist item was addressed and the mean of these percentages per information category

*Consultations in which 1–4 items were noted as being discussed while they actually were not, **Consultations in which five or more items were noted as being discussed while they actually were not

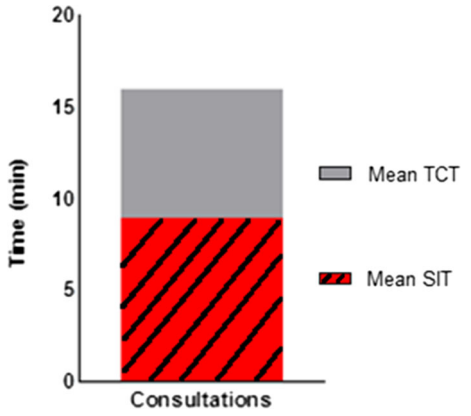


Fig. 1 Graphical view of the mean SIT as a part of the mean TCT, which corresponds to 55.6%

changed their decision for consent [9, 17]. This suggests that, despite the fact that these information categories are relatively less well covered, they might still be relevant to the patient's consent.

In the case of a malpractice claim or lawsuit, sufficient documentation of the discussed information aids the doctor in proving that certain information was given before the start of treatment [18, 19]. Not surprisingly, adequate documentation has been associated with a decreased indemnity risk [20]. It is particularly remarkable that, since this documentation can be used as evidence in court, a discrepancy between documented and actually discussed information was found. This discrepancy was found in all of the three hospitals, but mainly seen in one hospital that used a pre-made list of possibly discussed information items in the digital patient chart. Doctors had to actively delete the items that they did not discuss before saving their final note. Probably, this kind of pre-made list contributes to these mistakes in the patient chart documentation.

One of the strengths of this study is that inclusion was limited to cases with only one preoperative consultation. Therefore, the entire SIC process took place in the consultation studied, allowing us to fully capture the discussed information. Still, a couple of limitations merit a mention. The plastic surgeons and their residents were aware of the audio recorder's presence and of the fact that SIC was the object of study. Though the doctors were not aware of the study's methods, the above limitations might have led to a considerable performance bias. It can be assumed that the doctors will have tried to conduct SIC more thoroughly than usual. In regular practice, less information is probably transferred. Besides that, this study solely focused on patients with Dupuytren Disease. Therefore, the results of this study only describe SIC concerning Dupuytren Disease and not SIC in general. Nevertheless, when interpreted with care, these results might be used as an indication for the current practice of SIC in the Netherlands in general.

Since this study and previous studies indicate that current SIC has several shortcomings, we believe that there is room for improvement. Digital and multimedia educative software might serve to aid the patient-informing process [21, 22], as it can facilitate the process of addressing all aspects of information. Perhaps, when used before or after the consultation, the system can free up time in the consultation room.

In conclusion, despite the fact that a rather large part of the consultation time was spent on SIC, patients were only partially informed about treatment risks, the postoperative period, and who will be their operating surgeon. A discrepancy exists between noted and actually discussed information. This discrepancy was mainly seen in one hospital that used a pre-made SIC information list in its digital patient chart.

Compliance with ethical standards

Conflict of interest The authors declare that they have no competing interests

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