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Original article

The concept of a waiting period for preoperative patient consent: Prospective study of 51 shoulder arthroscopy cases

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ABSTRACT

Introduction: The French Code of Public Health (CSP) does not explicitly require that patients should be given a certain amount of time to think about a procedure, except for cosmetic surgery, where 15 days is required (Art. L 6322-2 CSP). We hypothesized that patients require a waiting period during their decision-making process for scheduled shoulder arthroscopy procedure.

Materials and methods: This prospective observational study of 51 patients analysed the concept of a waiting period based on a 10-item questionnaire. A comparative statistical approach was used and the P values were calculated using a paired Wilcoxon rank-sum test.

Results: Of the 51 patients, 42 (82%) rejected the concept of a waiting period before the procedure and 37 patients (73%) did not want a mandatory waiting period imposed by law.

Discussion: This study looked at the decision-making process during scheduled orthopaedic surgery and differentiated between the conscious and unconscious approach corresponding to an active and passive waiting period. A waiting period does not allow patients to make a conceptually deliberative decision that conforms to the criteria defined by the French Health Authority. This study rejects the need for a mandatory waiting period imposed on surgeons and patients as it does not integrate itself into the informative model of ethical decision-making for scheduled shoulder arthroscopy.

Type of study: Prospective, observational; level of evidence IV.

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1. Introduction

The French Code of Public Health (CSP) does not explicitly require that patients be given a certain amount of time to think about a procedure, except for cosmetic surgery, where 15 days is required (Art. L 6322-2 CSP). The primary objective of this study

was to study the concept of a mandatory waiting period within the patient's decision-making process before scheduled shoulder arthroscopy. The secondary objectives were to look for factors (age, sex, socioprofessional categories) that play a part in the patient's decision-making process and that could modify the waiting period. We hypothesized that patients require a waiting period during their decision-making process for a scheduled shoulder arthroscopy procedure.

2. Materials and methods

This prospective, observational study enrolled a cohort of continuous patients eligible for shoulder arthroscopy. The patients' occupation was placed in one of the eight groups of the 2003 professions and socioprofessional classification (PCS) of the INSEE [1].

Abbreviations: Art, article; CC, Court of Cassation; CSP, French Code of Public Health; HAS, French Health Authority; INSEE, French National Institute of Statistical and Economic Studies; MRI, magnetic resonance imaging; PCS, professions and socioprofessional categories; L, law; R, regulation.

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Patients were excluded if they were placed under legal protection measures, or had cognitive disorders or psychiatric treatments that could modify their ability to provide consent.

The patients were treated during a standard hospital stay in the day surgery unit of the Remiremont Hospital Centre (France) between December 1, 2015 and February 29, 2016. Information was given to the patients before the surgical procedure during a preoperative consultation that consisted of a clinical evaluation (Constant score), standard radiographs and an MRI or MR arthrography. An information document in the form of a 14-page booklet that included 8 diagrams was given to all patients during this preoperative consultation. The consultation with the anaesthesiologist was a few weeks after the preoperative surgical consultation.

The surgical protocol was the same for all patients: general anaesthesia, lateral decubitus and three surgical approaches (posterior, anterior, lateral).

The patients filled out a 10-item questionnaire designed in a multichotomic, progressive and dynamic manner using the filter-question method (Appendix 1). It pertained to the moment of the decision, the potential waiting time, any influential people (physician, surgeon, appointed representative, supports, etc.) and ended with a question on the need for a mandatory waiting period, in accordance with regulations. These data were collected by one of the co-authors during a semi-structured interview with the patient before discharge. Since this study did not alter standard treatment practices, ethics committee approval was not needed. However, all enrolled patients received verbal and written information about this study in accordance with article L. 1122-1-1 of the CSP (Appendix 2).

The patients were reviewed postoperatively with a clinical evaluation (Constant score) and radiographs (A/P and lateral views of the operated shoulder).

The statistical analysis was done using StatView software with Yates correction as needed. A comparative approach was used and the *P* values were calculated using a paired Wilcoxon rank-sum test. A *p*-value below 0.05 was considered statistically significant. The sample size could only be estimated based on two prior studies [2,3] with no reference being found before this study was initiated.

3. Result

Of the 55 eligible patients, 51 were included in the study and 4 were excluded (questionnaire incompletely or not filled out, withdrawal request). The overall cohort data (51 patients) are summarized in Tables 1–3. Forty patients (78.4%) had a single preoperative consultation and 11 patients (21.6%) had two preoperative consultations (5 to analyse imaging assessment and 6 to discuss subacromial corticosteroid injection). The pre-anaesthesia visit occurred an average of 27 days (11–81) after the first consultation. The surgical procedure was done an average of 34 days

Table 1
General data (*n* = 51).

Sex	Men/Women	30/21
Mean age (min, max) (years)	57.1	19/80
Operated side	Right/left shoulder	34/17

Table 2
Surgical procedures.

Procedure done	<i>n</i> = 51
Rotator cuff repair	28
Acromioplasty ± LHB tenotomy	12
Osteophyte removal	5
SLAP lesion	6

Table 3
Occupational categories (INSEE PCS 2003).

Socio-professional categories	<i>n</i> = 51
Farmers	0
Craftsmen, shopkeepers, head of company	3
Managers and professionals	0
Middle managers	3
Employees	11
Laborers	7
Retired	22
Other persons without an occupation	5

Table 4
Desire to have a waiting period (*n* = 51).

Desire to have a waiting period	Yes	No
Number (%)	9 (18%)	42 (82%)

(13–103) after the first preoperative consultation. Among the 51 patients enrolled initially, 5 were lost to follow-up, thus 46 were reviewed postoperatively at 64 days (42–82).

Primary objective: 42 patients (82%) did not want a waiting period before the procedure (Table 4) and 37 patients (73%) were against the concept of a mandatory waiting period (Table 5).

Secondary objectives: The “decisional moment” characterized by the instant where the patient voluntarily and consciously agrees to the surgical procedure occurred before the surgical consultation in 21 patients, at the time of this consultation in 20 patients and after the surgical consultation in 10 patients (Table 6). No patient sought a second opinion.

Of the 42 patients (82%) who did not want a waiting period, there was no effect of an appointed representative, the time between the consultation and procedure, sex, type of procedure, age and information support on the patients’ decision-making process (*P* < 0.001) and the concept of a mandatory waiting period (*P* < 0.001). Thirty-two patients (62.7%) considered the orthopaedic surgeon as the most important person in the decision-making process (*P* < 0.001) relative to the other elements (attending physician, appointed representative, information supports). The disparity in socioprofessional categories made it impossible to draw any conclusions about their impact on the decision-making process.

Of the 9 patients (18%) who initially wanted some time to think about the procedure, 4 talked with an appointed representative, 3 had a discussion with their family physician, and 2 consulted other information sources (internet, specialized journals). The mean duration of the proposed waiting period was 64 days (7–240).

All 46 patients reviewed postoperatively (100%) said they had read the information given to them during the first preoperative consultation. Thirteen of these patients (28.2%) felt this support was “useful” in their decision-making approach and 33 (71.8%) felt that it had not interfered in their decision-making or on their choice to more request time to think about the procedure (*P* < 0.01). The quality of the outcome in the 46 reviewed patients (15 very good, 20 good, 6 fair, 5 poor) did not change their initial impression of the need for a mandatory waiting period (*P* < 0.01).

Table 5
Opinion on mandatory waiting period (*n* = 51).

Mandatory waiting period	In favour	Against
Number (%)	14 (27%)	37 (73%)

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