

ANALYSIS OF THE HIGH COURT DECISIONS ON INFORMED CONSENT CASES IN TURKEY FROM A FORENSIC POINT OF VIEW

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ARTICLE INFO	ABSTRACT
<p>Article History: Received:07July2018 Accepted:17July 2018</p> <p>Keywords:<i>inadequate informed consent, malpractice, physician</i></p> <p>DOI: 10.26900/jsp.2018342251</p>	<p><i>Informed consent is linked to the principle of patient autonomy and has an important place in common medical codes of conduct and legislative regulations. The aim of this study is to determine the judgments and reviews of the high court (Yargıtay) related to informed consent and to discuss them from a medicolegal aspect within Turkish jurisprudence. In the search engine of the website publishing high court decisions, the keywords “informed consent”, “information”, “consent” and “assent” were used without any date limitation. In this study, N=32 high court judgments were investigated. The data obtained were analyzed in light of the literature and guidelines. In 23 of the cases (71.9%) surgical interventions requiring general anesthesia were performed. In the other 9 cases (28.1%) surgical interventions not requiring general anesthesia and medical interventions with diagnostic and/or treatment purposes were performed. There was a statistically significant difference between the groups with informed consent and without informed consent for “surgical interventions not requiring general anesthesia and medical interventions with diagnostic and/or treatment purposes”. The high court identified that in 17 of the cases (53.1%) informed consent was not present while in 15 (46.9%) informed consent was obtained. The court could not prove that informed consent was obtained in 15/17 cases in the group without consent, while in 7/15 cases in the consent group inadequate informed consent was obtained. The high court interrogated the extent and adequacy of informed consent for all types of surgical interventions both requiring and not requiring general anesthesia and medical interventions with diagnostic and/or treatment purposes. The types of surgical and medical interventions that require written informed consent and the aims of informed consent should be re-evaluated.</i></p>

1. INTRODUCTION

Patients have the right to make decisions related to surgical and medical interventions to be performed on them and this right has an important place in common medical codes of conduct and legislative regulations (Williams, World Medical Association-WMA-Medical Ethics Manual, 2005). The Biomedicine (Oviedo) Convention approved by Turkey in 2003 gives the following general rule related to consent: *any intervention in the area of health shall be performed after consent is given by the relevant individual freely and after being informed about the intervention* (Council of Europe, Oviedo/Biomedicine Convention, 1997; Yılmaz, 2015). In fact, the topic of “consent” is not a new one in Turkey. Pertaining to the

Performance of the Art of Medicine and its Branches Law dated to 1928 states that: *Doctors shall obtain consent from the patient for all medical interventions. For large surgical interventions this consent must be written* (Art of Medicine Law, 1928). Currently the Professional Ethics Rules of the Turkish Medical Association (TMA) and the Ministry of Health Patient Rights Regulations include basic regulations related to obtaining informed consent from patients (TMA-Professional Ethics Rules of Medicine 1999; Patient Rights Regulation 1998/2014).

Informed consent may result in accepting or rejecting medical interventions or choice between treatment options (Williams, WMA Medical Ethics Manual, 2005). The information process basically involves informing the patient sufficiently about their disease and possible treatment options so they can make decisions related to treatment (Turla *et al.*, 2005). When examined from this aspect, the informed consent process is defined as sufficiently informing the patient, letting them consider the situation within the bounds of possibility and freely making a decision (TMA Informed Consent Guide, 2010). Consent obtained after inadequate information is accepted as legally void (Türker *et al.*, 2019). In the literature, there are many cases of doctors being sued for malpractice due to obtaining inadequate consent, or not obtaining written informed consent or not obtaining informed consent (Küçüker, 2012; Tümer and Dener, 2006). These cases related to informed consent are not only relevant to surgical branches. For example, according to a research, the rate of inadequate informed consent in dermatology is 20% (Ogawa *et al.*, 2008). In recent years in Turkey, there are many high court decisions related to informed consent known (Oral, 2011; Gülel, 2011). In the literature there are researches investigating court decisions related to malpractice (Can *et al.*, 2011, Cakmak *et al.*, 2017); but there is no research discussing the medicolegal dimension of cases related to informed consent. This research will contribute to remedy this deficiency in the literature. The aim of this study is to discuss decisions and criticisms of the high court related to informed consent from a medicolegal aspect.

2. MATERIAL AND METHODS

2.1. Research design and population

This research is a descriptive, cross-sectional study and retrospectively screened decisions by the high court that represent a precedent about informed consent. The investigated decisions were accessed using the search engine on the high court website (Court of Cassation/Yargıtay, 2018). This website included the decision summaries of cases heard by the high court. While screening the decisions there was no date limitation. In this research, cases related to informed consent where the verdict of the local courts was overturned or upheld were investigated. The inclusion criteria for the cases were: i) whether informed consent was obtained or not obtained, ii) whether information and documents related to informed consent were present in the files or not, iii) whether the local court or expert reports investigated the topic of informed consent or not, iv) whether informed consent for performed medical interventions were adequate or not, and v) the Biomedicine (Oviedo) Convention, TMA Professional Ethics Rules for Medicine or other relevant legal regulations were cited.

2.2. Application of the Research

In this research, court decisions open to the public and published on the internet by the Court of Cassation were investigated with no ethics committee permission obtained. The decisions were accessed from the high court website (Court of Cassation/Yargıtay, 2018). In the search engine, the keywords “informed consent”, “information”, “consent” and “assent” were used without any date limitation. The screening accessed 34 decisions. There were 32 cases abiding by the inclusion criteria for the study which were investigated with the aid of a

data collection form. The descriptive characteristics of the research group, surgical and medical interventions, criticisms related to informed consent and data belonging to the legal basis for these criticisms of the Biomedicine (Oviedo) Convention and TMA Professional Ethics Rules for Medicine and other legal regulations were analyzed.

2.3. Data collection tools

Data belonging to the study group were obtained based on variables included in the data collection form and all data was transferred to a statistical analysis program. The variables analyzed in this study of sociodemographic data, event and court dates, court type, surgical and medical interventions, content of expert reports, criticisms and judgments of the high court related to informed consent, and variables belonging to relevant international and national legal regulations varied according to the features of the event.

2.4. Statistical analysis

Analysis of data obtained in this research used the Statistical Product and Service Solutions (SPSS) (version 20.0; SPSS /IBM Inc., Chicago, IL, USA) program. Descriptive data of number, percentage, mean, standard deviation, median, minimum and maximum values are presented. The correlations between variables were assessed with the Pearson Chi-square test and significance was assessed with the T test. Statistical significance was accepted as $p < 0.05$.

2.5. Limitations of the Research

This research to reveal the deficiencies and errors related to informed consent attracts attention to the importance of applying standards in medical interventions but may increase the possibility of other medical errors being missed. With the aid of the investigated sample, an important perspective on the legal approach to informed consent in Turkey is revealed; however, the small size of the sample may prevent generalization of the results. It was determined that some descriptive characteristics were missing in the cases of the high court. For example, the ages and genders of all cases could not be determined. Using the available data and characteristics of the case, an attempt was made to determine the approach of the high court to scope and adequacy of informed consent.

3. RESULTS

In this research, N=32 high court judgments were investigated. According to the accessible data, 10 cases were female (76.9%), 3 were male (23.1%) and mean age was 30.0 ± 10.0 (n:5, min:13-max:39) years. The mean duration of cases was 6.7 ± 10.0 (n:32, min:2.6-max:11.8) years. When the legal basis cited in the cases are investigated, 19 (59.4%) cited the Biomedicine (Oviedo) Convention, 19 (59.4%) cited the TMA Professional Ethics Rules of Medicine, 1 (3.1%) cited the Patient Rights Regulation and 1 (3.1%) cited the Pertaining to the Performance of the Art of Medicine and its Branches Law (Table 1). Of the 32 cases investigated, 3 (9.4%) were determined to involve death, 8 (25%) life-threatening event, and 19 (59.4%) permanent functional disorder or loss. There was no statistically significant difference in terms of case duration between cases involving death, life-threatening event, and permanent functional disorder or loss ($p > 0.05$). Of interventions performed, 23 (71.9%) were surgery requiring general anesthesia (Table 1) and these included 4 nose operations, 3 births, 3 laser eye surgeries, 2 spinal surgeries, 2 breast reductions and abdominoplasty, 1 liposuction and abdominoplasty, 1 breast enlargement, 1 laparoscopic appendectomy, 1 knee operation, 1 triple arthrodesis (ankle) surgery, 1 tonsillectomy, 1 thyroidectomy, 1 surgery and 1 teratoma-linked retroperitoneal cyst excision. Of cases, 9 (28.1%) were surgical interventions not requiring general anesthesia and medical interventions with diagnostic and/or treatment purposes (Table 1); these included 2

colonoscopies, 1 angiography, 1 hemorrhoidal electrocoagulation, 1 filler material injection, 3 injections and 1 laboratory test (beta HCG). According to expert reports, for 26 cases (81.3%) the results were determined to be complications, with no assessment on this topic for the other 6 cases. Expert reports stated there was no medical intervention error in 23 cases (71.9%), with 2 cases (6.3%) obtaining signed informed consent and 1 case (3.1%) with no informed consent obtained. Of the investigated cases, 17 (53.1%) did not have informed consent obtained and 15 (46.9%) did have informed consent obtained. Between the groups with and without informed consent, there was a statistically significant difference identified in terms of “surgical interventions not requiring general anesthesia and medical interventions with diagnostic and/or treatment purposes” ($p < 0.05$). When the decisions and criticisms of the high court about the 15 consent cases (46.9%) are investigated, 8 cases (25.0%) were assessed as adequate informed consent while 7 (21.9%) were determined to be inadequate informed consent (Table 1).

Table 1. Descriptive characteristics, medical expert reports and high court judgments of investigated cases	
Investigated high court judgments (%)*	32 (100.0%)
Age (mean \pm SD*)(of cases with age stated)	30.0 \pm 10.0
Gender(female), n (%)* (of cases with gender stated)	10 (76.9%)
Gender(male), n (%)*(of cases with gender stated)	3 (23.1%)
Case duration (mean \pm SD*)	6.7 \pm 10.0
Legal basis cited by court	
Biomedicine (Oviedo) Convention	19 (59.4%)
TMA Professional Ethics Rules for Medicine	19 (59.4%)
Patient Rights Regulation	1 (3.1%)
Pertaining to the Performance of the Art of Medicine and its Branches Law	1 (3.1%)
Types of intervention	
Surgical interventions requiring general anesthesia	23 (71.9%)
Surgical interventions not requiring general anesthesia and medical interventions with diagnostic and/or treatment purposes	9 (28.1%)
Results of medical expert reports	
Result occurring was complication	26 (81.3%)
No surgical or medical intervention error	23 (71.9%)
Signed informed consent given	2 (6.3%)
Lack of informed consent as deficiency	1 (3.1%)
Informed consent procedure according to high court	
Informed consent not present**	17 (53.1%)
Informed consent obtained	15 (46.9%)
Adequate informed consent	8 (25.0%)
Inadequate informed consent	7 (21.9%)
*: SD: standard deviation; n: number; %: percentage.**:consent not obtained, no information/documentary proof and fake consent	

The decisions of the court related to the 17 cases (54.8%) without informed consent were that in 1 case informed consent was not obtained and in 10 cases there were no information or documents showing informed consent was obtained. For 5 cases it could not be proven that informed consent was obtained and in 1 case fake informed consent documents were created. The criticisms and decisions of the high court related to informed consent are shown in Table 2.

Table 2. Decisions and criticisms related to informed consent of the high court according to types of intervention		
Decision and Criticism of the high court		Types of intervention
IC*not obtained		Hemorrhoidal electrocoagulation
No IC document in file, no discussion of whether IC was obtained or not in expert reports		Breast enlargement
IC document present. In the form of printed consent form. IC document insufficient as evidence		Laser eye surgery
Not proven that IC was organized		Laser eye surgery
		Injection Knee surgery
No information or document about information in the file.		Colonoscopy Beta HCG test
		Spinal surgery
IC document present. Treatment, success rates and duration, risks, medical results and possible complications explained		Laser eye surgery
Written IC document present. Medical results and possible complications explained. However, no explanation (inadequate) of treatment, success rates and duration, risks, medical results and possible complications		Nose surgery
		Thyroidectomy
Not sufficiently informed**		Breast reduction and abdominoplasty
		Nose surgery
		Breast reduction and abdominoplasty
Whether IC was obtained should be investigated		Written IC document present. Medical results and possible complications explained. However, no explanation of treatment, success rates and duration, risks, medical results and possible complications
		Written IC document present. Medical results and possible complications explained. However, not sufficiently informed about health problems experienced
No IC document in file		Injection Spinal surgery
		Birth Triple arthrodesis
Information about complications could not be proven with written document		Filler material injection
No IC document in file. Firstly IC form signed by patient should be obtained		Injection Angiography
Fake IC form created		Surgery
Consent on patient's admission paper. Necessary information about the quality and probable risks of surgery not given (inadequate).		Nose surgery
IC document present. Diagnosis, surgery and possible risks should be explained and IC obtained.		Retroperitoneal cyst excision
IC document present. Diagnosis, procedure and possible risks clearly explained.		Colonoscopy Birth
IC document present. IC obtained for selection of surgical technique		Laparoscopic appendectomy
IC document present. Informed consent form including possible complications arranged.		Birth
IC document present. However, proof of information about risks of surgery inadequate .		Liposuction and abdominoplasty
*IC: informed consent, **: Scope of informed consent inadequate.		

4. DISCUSSION

In this research, the judgments of the high court in Turkey related to informed consent were investigated from the medicolegal aspect. In this study, 23 cases (71.9%) were surgical interventions requiring general anesthesia and 9 (28.1%) were surgical interventions not requiring general anesthesia and medical interventions with diagnostic and/or treatment purposes. There was a statistically significant difference identified between the groups with and without informed consent in terms of “surgical interventions not requiring general anesthesia and medical interventions with diagnostic and/or treatment purposes”. According to high court judgments, 17 cases (53.1%) did not involve informed consent and 15 (46.9%) did involve informed consent. Of the group without consent, the court stated that in 15/17 cases there was no information or document proving informed consent was obtained. Of the group with consent, the court found adequate informed consent was obtained in 8/15 cases and inadequate informed consent was obtained in 7/15 cases. According to the results of this research, the high court in Turkey interrogated “whether informed consent was obtained or not” and “the extent and adequacy of the consent” for all cases including those with surgical interventions not requiring general anesthesia and medical interventions with diagnostic and/or treatment purposes.

The literature related to informed consent reports that inadequacy of informed consent is common in Turkey (Gündoğmuş et al., 2005). In 93 surgical malpractice cases informed consent was not obtained from the majority of patients (Tümer and Dener, 2006). A group surgical malpractice case found 31.9% developed thyroid pathology and 44.7% had laryngeal nerve injury and informed consent was not obtained from the majority of these cases (Eş et al., 2017). Informed consent was not obtained in 19% (4 cases) of eye surgery cases (Özdemir et al., 2014). In this research, the high court found informed consent was not obtained for 17 cases (53.1%) and identified that 15 of these 17 cases did not have any information and documents proving informed consent existed in the case file. For some cases, the court stated it was necessary to firstly research whether the patient was informed or not and then obtain the informed consent document. In medical malpractice cases insufficient and unreliable records are an important argument used by plaintiffs (Altun and Yorulmaz, 2010). For cases related to plastic surgery interventions (Vila-Nova da Silva et al., 2015; Hwang et al. 2018), the main factors severely affecting court judgments were stated to be the quality of medical records and informed consent, and photographs from before and after surgery. In this research analyzing high court judgments in Turkey, the majority of interventions were surgical; however, among these there were several plastic surgery interventions and 9 (28.1%) were surgical interventions not requiring general anesthesia and medical interventions with diagnostic and/or treatment purposes. In the whole group analyzed, though expert reports stated that the majority of negative results harming the patients’ health were complications, the high court questioned whether informed consent was obtained or not for all medical applications including injections. In 15 cases (46.9%) informed consent was identified and nearly half of these were determined to be inadequate informed consent. These results reveal the importance of the quality of medical records and informed consent in terms of the courts.

According to legal regulations in Turkey, written informed consent is required for large surgical interventions, organ transplants, curettages and sterilizations, situations where reproductive-assisting treatments are applied and researches using human subjects (Gülel, 2011; Tümer et al., 2011; Demir, 2017). However, written consent is not requested for applications like injections, vaccinations and wound dressing (Tümer et al., 2011). There are different approaches among countries in relation to the written informed consent procedure. For example, while there is no written informed consent obligation for any medical practice in Denmark, this is a legal requirement in Portugal (Tümer et al., 2011). Minor procedures may

only require verbal consent in Australia (Australian Commission on Safety and Quality in Health Care, 2012). In the present study, the high court identified that for some surgical interventions requiring general anesthesia, there was no information or documents about whether informed consent was obtained in the case files. Additionally, patient informed consent was not obtained for “surgical interventions not requiring general anesthesia and medical interventions with diagnostic and/or treatment purposes” and this was statistically significant. Cases not requiring general anesthesia included 2 colonoscopies, 1 angiography, 1 hemorrhoidal electrocoagulation, 1 filler material injection, 3 injections and 1 laboratory test (beta HCG). According to the high court in Turkey the doctor or the hospital should prove that the patient was informed. One of the noteworthy results identified in this research is that for injections and any biochemical testing, informed consent was interrogated. The Patient Rights Regulation, updated in recent years, mentions that written consent should be obtained for medical interventions predicted to cause disputes, apart from the situations stated in law (Patient Rights Regulation, 1998/2014). The consent form should state that information has been verbally explained to the patient and two consent forms are signed with one given to the patient (Patient Rights Regulation, 1998/2014; Türker et al.,2019). In some clinics in Turkey, doctors avoid legal disputes by obtaining written informed consent for even the simplest procedures and this type of approach is stated to negatively affect the functioning and coverage of medical practice (Tümer et al., 2011). According to these results, it is considered necessary to re-evaluate which types of intervention require written informed consent and the aim of informed consent.

In the literature, some studies have discussed the topic and limits of giving sufficient information in relation to the adequacy and quality of informed consent (Turla et al., 2005; Turla et al. 2006; Oral, 2011). Different results from research of patients are noteworthy; one research found 22.7% of patients were not given information about surgery, 18.3% were not informed of disease diagnosis, 52.3% were not informed of the name of the surgery, 12.5% were not informed about possible complications during surgery and 13.7% were not informed about postoperative complications (Kurt et al., 2016). Another study reported that all patients signed informed consent forms, 80% received important information about disease, 62% received information about the surgery, 56% were informed in writing (in person or with the aid of a relative), 28% received information about possible complications of surgery and 85% did not receive information about alternative treatments (Ekmekçi et al., 2016). Another research reported 85% of patients did not know how long they would stay in hospital after surgery, while 83% were not given information about possible changes to their lives after surgery (Turla et al., 2005). A research investigating informed consent forms found 81.3% had the risks of treatment in writing, while 33.1% had alternative treatment methods in writing (Küçükler, 2012). The judgments and reviews of the high court (Yargıtay) about inadequate informed consent were as follows in the present study: “necessary information about the quality of the surgery and possible risks were not given; patients not sufficiently informed about health problems experienced; side effects and complications reported in general statements but the type of complications of this type of surgery not explained in detail; and no explanation of treatment, chance of success and duration, risks, medical results and possible complications”.

5. CONCLUSIONS

These results reveal the importance of the informed consent process. It appears necessary to assess recommendations related to the consent process, like the right of the patient not to be informed, noting patient benefit from all medical interventions, effect of diagnosis and information on the patient’s health, use of short and understandable language for informing the patient, developing multi-media resources, use of visual material like videos

and photographs, and inclusion of patients in the informed consent form development process (Art of Medicine Law 1928; TMA Professional Ethics Rules in Medicine 1999; Patient Rights Regulation 1998/2014; TMA Informed Consent Guide, 2010; Council of Europe, Oviedo/Biomedicine Convention, 1997; Williams, WMA Medical Ethics Manual, 2005; Turla et al., 2005; Tümer et al., 2011; Kurt et al., 2016; Ekmekçi et al., 2016).

In conclusion, it is considered necessary to rethink the aim of informed consent of the patient and to consider this question: is the basic aim of informed consent to protect doctors from malpractice cases or to ensure participation in the decision-making process by observing principles of patient benefit and autonomy?

Acknowledgment

The author would like to thank İrem Doğa Akgül for her criticism and final revision.

Abbreviations

Art of medicine law: Pertaining to the Performance of the Art of Medicine and its Branches Law (Tababet ve Şuabatı San'atlarının Tarzı İcrasına Dair Kanun, No.1219).

Biomedicine (Oviedo) Convention: Convention for the protection of human rights and dignity of the human being with regard to the application of biology and medicine: convention on human rights and biomedicine (CETS No. 164), Oviedo.

TMA: Turkish Medical Association.

WMA: World Medical Association.

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