

Pattern of informed consent acquisition in patients undergoing emergent endovascular treatment for acute ischemic stroke

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Abstract

Background—Telephone consent and two physician consents based on medical necessity are alternate strategies for time sensitive medical decisions but are not uniformly accepted for clinical practice or recruitment into clinical trials. We determined the rate of and associated outcomes with alternate consenting strategies in consecutive acute ischemic stroke patients receiving emergent endovascular treatment.

Methods—We divided patients into those treated based on in-person consent and those based on alternate strategies. We identified clinical and procedural differences and differences in hospital outcomes: symptomatic ICH and favorable outcome (defined by modified Rankin Scale of 0–2 at discharge) based on consenting methodology.

Results—Of a total of 159 patients treated, 119 were treated based on in-person consent (by the patient in 27 and legally authorized representative in 92 procedures). Another 40 patients were treated using alternate strategies (20 telephone consents and 20 two physician consents based on medical necessity). There was no difference in the mean ages and proportion of men among the two groups based on consenting methodology. There was a significantly greater time interval incurred between CT scan and initiation of endovascular procedure in those in whom in-person consent was obtained (117 ± 65 min versus 101 ± 45 min, $p = 0.01$). There was no significant difference in rates of ICH (9% versus 8%, $p = 0.9$), or favorable outcome at discharge (28% versus 30%, $p = 0.8$).

Conclusions—Consent through alternate strategies does not adversely affect procedural characteristics or outcome of patients and may be more time efficient than in-person consenting process.

Keywords

Informed consent; endovascular treatment; thrombolytics; ischemic stroke; procedure time

Introduction

Complying with the surgical informed consent requirements for surgical and endovascular treatments is a mandatory component for hospitals to participate in the Medicare program. The “conditions of participation for hospitals” document¹ states: “a properly executed informed consent form for the operation must be in the patient’s chart before surgery, except in emergencies.”² In emergent situations, when the patient is unable to provide informed consent, and a surrogate decision maker is not available onsite, the law acknowledges that imposing the duty of written informed consent may become detrimental if immediate treatment is indicated to prevent death or serious harm.^{3,4} If a written consent

cannot be obtained, an informed consent by telephone is permissible in some settings. Consent via telephone requires the signature of the person obtaining the consent and a third party (usually a health care professional preferably a nurse or physician).^{5,6} If the surrogate decision maker cannot be contacted, the procedure can be performed without consent if the health care provider presumes that the patient would have chosen the care others would have chosen under similar circumstances, unless the provider has information to the contrary.⁷ The two physician consent is a modification of the aforementioned concept which requires concurrence of two licensed physicians that emergent surgery should be per-

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formed without the consent of the patient because delay in obtaining consent would be detrimental to the health of a patient.⁸ Endovascular treatment of acute ischemic stroke is considered an emergent treatment which may often require consent via telephone or two physician consent. The prevalence of such practice and impact upon procedural outcomes have not been studied previously.

Methods

Identification of cases and data collection

Cases were identified from a cohort of consecutive acute ischemic stroke patients treated with endovascular treatment performed between February 2007 to March 2011 at a University affiliated comprehensive stroke center. The institution maintained a prospective endovascular procedure database which recorded information regarding the procedural components, devices used, and intra-procedural medication with doses. The database was supplemented by chart review using a protocol approved by the IRB at the institution as part of a standardized database. The details of this database have been published previously.^{9–11} The presence of cardiovascular risk factors (active cigarette smoking, hypertension, atrial fibrillation, coronary artery disease, hyperlipidemia, diabetes mellitus, prior TIA, or ischemic stroke), various time intervals between symptom onset and endovascular treatment, and use of IV rtPA were recorded.

The endovascular treatment consisted of a combination of pharmacological agents and/or mechanical thrombus disruption and/or retrieval used in varying paradigms. The procedure was performed after written-informed consent is obtained either from patient or legally authorized representative (LAR) if patient was unable to provide consent. Two physician consent and obtaining consent by telephone witnessed by another medical professional were an acceptable option at both institutions. A single investigator reviewed the medical records and copy of written informed consent to identify the consenting party and whether the consent was in-person or via telephone. Pre-procedural documentation was also reviewed to provide independent confirmation of methodology used to acquire consent. The techniques for administration of thrombolytics and thrombectomy through the microcatheter are described in detail in previous publications.^{9–11} Angiographic occlusion and recanalization were classified by the treating physician using either the TIMI grading scale or the Qureshi grading scale¹² as described in previous publications.^{9,13} Two investigators (AEH, JTM) reviewed the medical

records and angiographic images to determine the time interval between symptom onset and CT scan acquisition and interval between CT scan acquisition to initiation of procedure (time of femoral puncture) as described in a previous publication.¹¹

We also recorded admission, 24 h post-treatment, and discharge NIHSS scores. Outcome at time of discharge was assessed using modified Rankin Scale (mRS) determined by review of detailed descriptions provided by the vascular neurology team, and occupational, speech, and physical therapists in the medical records. We also ascertained early neurological improvement events defined by a reduction in NIHSS score of 4 points or greater at 24 h compared with admission NIHSS score. Symptomatic ICH was defined as noncontrast CT scan-documented ICH resulting in neurological deterioration (greater than or equal to 4-point worsening on a NIHSS score compared with previous clinical assessment). “Favorable outcome” was defined by a mRS of 0-2 at discharge.

Statistical analysis

All data was descriptively presented using mean \pm standard deviation for continuous data and frequencies for categorical data. The frequency of baseline demographic and clinical characteristics, and outcome measures were compared between patients treated using in-person consent and those treated based on alternate strategies. The outcomes of interest included rates of symptomatic ICHs, early neurological improvement, favorable outcome at discharge, and in-hospital mortality. The time intervals between ED arrival to CT scan and from CT scan to initiation of procedure were also compared between the two groups. Means and frequencies were compared using ANOVA and chi-square, respectively. A *p* value < 0.05 was considered significant. All analyses were performed by using SAS statistical software (SAS, Cary, NC).

Results

Of a total of 159 patients treated, 119 were treated based on in-person acquisition of consent; the consent was provided by the patient in 27 and LAR in 92 procedures. Another 40 patients were treated using alternate consenting strategies (20 telephone consents and 20 two physician consents based on medical necessity). There was no difference in the mean ages (66 ± 15 versus 65 ± 17) and proportion of men (versus women, 40% versus 49%) among the two groups based on consenting methodology (see Table 1). The proportion of patients with hypertension, diabetes mellitus, atrial fibrillation, or

Table 1. Demographic and clinical characteristics of patients who underwent endovascular treatment for acute ischemic stroke according to consenting methodology used.

Overall number (%)	In person consent (n=119)	Consent by alternate methodology(n=40)	P-value
Age: mean (\pm standard deviation)	65 \pm 17	66 \pm 15	0.5
Women	58 (49)	16 (40)	0.3
Race/ethnicity			
White	92 (77)	35 (87)	
African Americans	20 (17)	4 (10)	
Others	7 (6)	1 (3)	0.5
Co-morbid conditions			
Hypertension	76 (64)	27(67)	0.7
Diabetes mellitus	25 (21)	6(15)	0.5
Atrial fibrillation	32 (27)	10 (25)	0.9
History of stroke/TIA	20 (17)	11 (27)	0.1
Coronary artery disease	29 (24)	7 (18)	0.5
Congestive heart failure			
Dyslipidemia	40 (34)	12 (30)	0.8
Cigarette smoking			
Time intervals: mean (\pm standard deviation)			
ED arrival to CT scan	21 \pm 12	18 \pm 9	0.08
CT scan to initiation of endovascular procedure	117 \pm 65	101 \pm 45	0.01
Procedure initiation to microcatheter placement	34 \pm 25	33 \pm 23	0.4
Microcatheter placement to recanalization	61 \pm 38	64 \pm 34	0.4
Admission NIHSS score			
NIHSS score 0–10	37 (31)	7 (18)	
NIHSS score 11–19	51 (43)	18 (45)	
NIHSS score 20–42	31 (26)	15 (37)	0.1
Discharge NIHSS score			
NIHSS score 0–10	66 (55)	27 (68)	
NIHSS score 11–19	27 (23)	5 (12)	
NIHSS score 20–42	26 (22)	8 (20)	0.3
Type of treatment			
Intra-arterial thrombolytic	93 (78)	31 (77)	0.9
Mechanical thrombectomy	61 (51)	21 (52)	0.9
Stent placement	7 (6)	4 (10)	0.4
Angiographic recanalization			
Partial/complete	87 (73)	33 (82)	0.3
Intravenous thrombolytic administered	54 (45)	21 (52)	0.4
Length of stay: mean (\pm standard deviation)	8 \pm 7	7 \pm 6	0.2
In hospital events			
Any ICH	19 (16)	8 (20)	0.6
ICH [symptomatic]	11 (9)	3 (8)	0.9
In hospital mortality	24 (20)	6 (15)	0.6
Discharge outcome			
Favorable (mRS < 3)	33 (28)	12 (30)	
Unfavorable (mRS \geq 3)	86 (72)	28 (70)	0.8

hyperlipidemia was similar between the two groups. There was a nonsignificantly higher proportion of patients with a history of previous stroke/TIA among those in whom alternate consenting methodology was used (27% versus 17%, $p = 0.1$). The proportion of patients with NIHSS score <10 was lower and those with NIHSS score \geq 20 was higher among those in whom alternate consenting strategy was used ($p = 0.1$).

There was a trend toward longer time interval between ED arrival and CT scan among those in whom in person consenting was used ($p=0.08$). There was a significantly greater time interval incurred between CT scan and initiation of endovascular procedure in those in whom in-person consent was obtained (117 \pm 65 min versus 101 \pm 45 min, $p = 0.01$). There was no difference in the total procedure time between the two groups. The proportions of patients who received intra-arterial thrombolytics, mechanical thrombectomy, and/or stent placement were similar in the two groups (see Table 1). There was no difference in rate of partial or complete angio-

graphic recanalization (82% versus 73%) between the two groups. There was no significant difference in rates of symptomatic ICH (9% versus 8%, $p = 0.9$), or favorable outcome at discharge (28% versus 30%, $p = 0.8$). The rates of in-hospital mortality ($p=0.6$) and length of stay ($p=0.2$) were also similar between the two groups.

Discussion

There has been a sixfold increase in acute ischemic stroke patients who undergo endovascular treatment from 2004 to 2009.¹⁴ In our study, only 17% of the patients treated provided their own consent prior to the endovascular procedure. Due to the relatively low rate of patient's ability to consent and increasing utilization of endovascular treatment, alternate consenting strategies are gaining more importance in acute ischemic stroke settings. Previous studies have identified challenges in acquisition of consent prior to administration of IV rtPA in acute ischemic stroke patients. A retrospective

study¹⁵ involving 10 Connecticut hospitals (1996–1998) found that, 53 (84%) of 63 rtPA-treated patients had informed consent documented; 30% gave their own consent. However, the study found prominent deficiencies in explicit consent documentation and determination of incapacitation during the urgent decision regarding rtPA administration. The low rate of self-consent in patients undergoing endovascular treatment for acute ischemic stroke is probably attributable to greater severity of neurological deficits among patients selected for endovascular treatment.¹⁶ Therefore, the necessity of a consent (or waiver of) is a more important issue in patients undergoing endovascular treatment compared with those receiving IV rtPA. Endovascular treatment has higher risk of post-treatment ICH and additional risk associated with pre-procedural intubation and anesthesia, and femoral artery catheterization.^{16–18} Endovascular treatment is not uniformly accepted as standard of care unlike IV rtPA, increasing the liability associated with the procedure.¹⁹ Therefore, the use of alternate strategies to acquire consent (or waiver of) requires greater consideration prior to application.

Consent acquired through telephone with or without a third party witness is one method to acquire consent from LAR who is not physically available in the hospital. Such an approach expands the consenting procedure to involve LAR who are not residing within the same city or township. Such consenting methodology is not accepted by certain federal regulatory authorities due to inability of the consenting party to read the actual consent document. For example, the FDA policy states “informed consent shall be documented by the use of a written consent form approved by the IRB and signed and dated by the subject or the subject’s LAR at the time of consent.”²⁰ However, there is some data that supports alternate methodologies as a possible effective means of communicating the risks and benefits of the procedure. A study found that acquisition of consent through televideo consultation resulted in adequate understanding of risks and benefits of rtPA in 80% of the consenting encounters.²¹ Two-physician consent is another option in the event that patient is incapacitated and no LAR is available. This option has been used and studied in withdrawal of life-sustaining treatments within the ICU settings. In one study,²² 37 decisions were made without patient or LAR consent in seven ICUs. In 30 patients, the decision was made by the ICU team alone or by the ICU team plus another attending physician. In another seven patients, there was prospective hospital or court reviews prior to decision making. However, the time sensitive nature of decision making in acute ischemic stroke makes the use of prospective hospital or court reviews impractical.

Our study was not designed to determine the adequacy of communicating risks and benefits of the procedure through alternate strategies for acquisition of consents. Our study demonstrated that use of alternate consenting methodologies resulted in outcomes similar to those in which in person consent was acquired. Overall, 25% of acute ischemic patients underwent endovascular treatment after consent was acquired using alternate consenting methodology. Alternatively, in the absence of alternate consenting methodologies, these patients would not have been treated with endovascular treatment. Whether such practice would have resulted in suboptimal outcomes in these patients can be supported by previous studies demonstrating effectiveness of endovascular treatment.²³ However, the retrospective design without a control group in whom treatment was withheld does not allow a direct assessment. There is another aspect of patient/LAR satisfaction with such a process and whether patient/LAR would prefer proceeding with alternate consenting methodologies rather than risk withholding or delaying of endovascular treatment.

Our study is one of the first to assess patterns of methodologies used to acquire (or waive) informed consent. The time efficient aspect of alternate consenting methodology with similar rates of angiographic recanalization and favorable outcomes supports the use of such methodology to avoid withholding treatment in appropriate candidates.

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