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Understanding Patient Acceptance of Written and Verbal Consent in Clinical Settings

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Abstract

Conducting research in acute myocardial infarction (AMI) is challenging because patients are acutely ill and often in a suboptimal state to provide informed consent. The extent to which patients understand verbal assents in AMI research has not been previously studied. The Patients Acceptance and Comprehension to Written and Verbal Consent (PAC–VC) study aimed to compare patients' understanding and attitudes toward verbal versus written consent in AMI randomized controlled trials (RCTs). PAC–VC enrolled patients from three AMI trials, including those who provided verbal consent (N = 12) and written consent (N = 6). Patients' understanding was assessed using two survey tools. The first included open-ended questions with multiple-choice answers, and the second used a 5-point Likert scale to evaluate understanding and attitudes toward the consent process. Overall scores were categorized as Adequate understanding (71–100%), Partial understanding (41–70%), and Inadequate understanding (0–40%). Patients who gave verbal assent demonstrated adequate understanding of most informed consent components, comparable to those who provided written consent. Many patients did not fully read written information and felt it was not essential for making a final decision. While patients preferred having written information available as part of the consent process, they did not consider it necessary during the initial consent discussion. Participants in the verbal assent group reported feeling less pressured compared with those in the written consent group. Patients exhibited adequate understanding of verbal assent, similar to written consent. Verbal assent in acute care settings warrants further evaluation in larger trials.

Keywords: Informed consent, Verbal assent, Acute myocardial infarction, Written consent, Clinical trials

Background

The concept of informed consent dates back to 1767, when an English court prohibited experimenting on patients without their consent [1]. Since then, the concept has evolved to its current definition. According to the International Council for Harmonization (ICH), informed consent is a process in which participants voluntarily confirm their willingness to take part in a study after receiving all information relevant to their decision. Informed consent is grounded in three key principles: providing adequate information, ensuring participant comprehension, and securing voluntary agreement [2].

Randomized clinical trials (RCTs) are critical for developing new treatments and refining existing ones for both acute and chronic conditions. Research in acute myocardial infarction (AMI) presents particular challenges, as it involves enrolling critically ill patients who are often distressed and require urgent interventions to reduce morbidity and mortality. Studies suggest that patients in this context may struggle to understand or retain information about their condition and proposed interventions [3–5]. While patients often recall the main

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points, their actual comprehension and perceived understanding are frequently limited [6]. Many patients in the acute phase of AMI find reading written materials impractical, relying instead on oral explanations [4, 7, 8]. Despite this, verbal assent has not been formally evaluated or compared to conventional written consent. Prior studies often measured comprehension subjectively or used recall as a surrogate. The Patients Acceptance and Comprehension to Written and Verbal Consent (PAC–VC) study was designed to compare patients' understanding and perspectives on verbal versus written consent in AMI trials.

Methods

Study design

PAC–VC was a descriptive, questionnaire-based survey conducted at the Mazankowski Alberta Heart Institute between April 2014 and June 2015. The study included patients enrolled in three ongoing AMI RCTs: REMCON-STEMI (Remote Ischemic Conditioning in STEMI), COMPLETE (Complete versus Culprit-only Revascularization for Multi-vessel Disease after Early PCI in STEMI), and TOTAL (Routine Aspiration Thrombectomy with PCI versus PCI Alone in STEMI).

The COMPLETE and TOTAL trials used conventional written consent, providing patients with materials to review prior to enrollment. REMCON-STEMI employed a different approach: patients were given verbal assent via a script read by Emergency Medical Services (EMS) personnel during ambulance transport to the hospital, with no written materials at that stage. Once patients were stable post-treatment, formal written consent was obtained within 72 hours by a research nurse, including supplementary written information. The primary distinction between REMCON-STEMI and the other trials was the absence of initial written materials. Ethics approval was obtained before recruitment. Written materials had a readability level of 10–13 on the Flesch–Kincaid Grade Level test.

Recruitment

Following randomization to one of the three AMI trials, patients were screened for eligibility by the research team. No formal sample size calculation was performed; based on the principal investigator's experience, approximately 40 participants were considered ideal, with adjustments anticipated based on data and recruitment feasibility. Of 21 patients approached, 18 consented to participate.

Participants were divided into two arms: verbal and written. The verbal arm included patients from REMCON-STEMI who had provided verbal assent but not yet written consent. The written arm included patients from COMPLETE and TOTAL. All patients were approached within 72 hours of trial randomization, once medically stable, and invited to join PAC–VC. Those who agreed completed a survey to assess their comprehension, as illustrated in **Figure 1**.

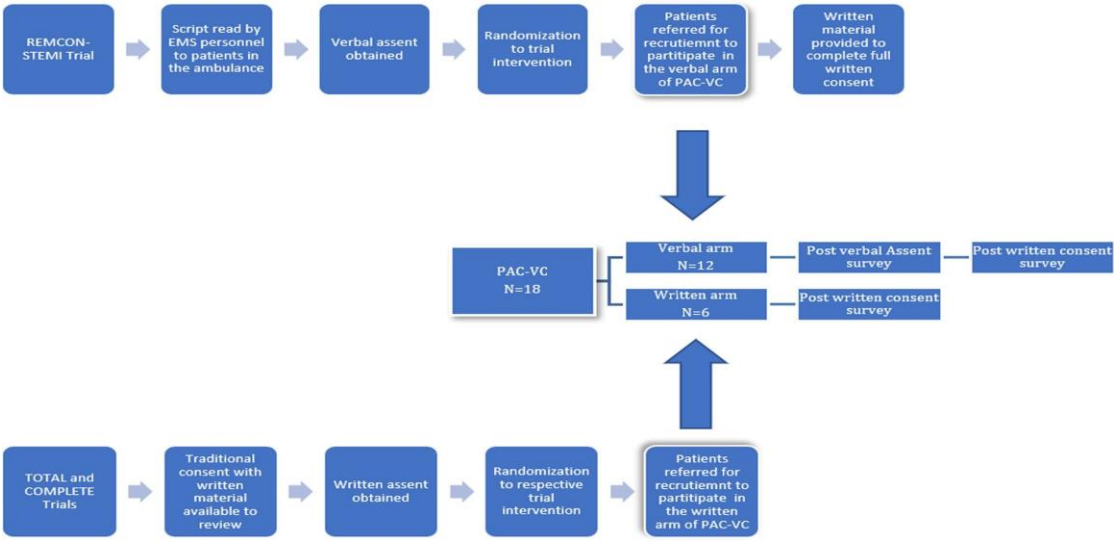

Figure 1. PAC–VC methods flow chart

Study population

Participants for the PAC–VC study were recruited from individuals already enrolled in the REMCON, COMPLETE, or TOTAL acute myocardial infarction (AMI) trials. All patients were screened for eligibility, and those unable to provide informed consent themselves were excluded. Specifically, patients were ineligible if they were unconscious, hemodynamically unstable, or had cognitive impairments such as dementia or other psychiatric conditions. Patients who provided consent via a proxy or substitute decision-maker were also excluded to ensure that responses reflected personal understanding and perspectives.

Assessment tools and data collection

The study employed two survey instruments designed to evaluate both objective comprehension and subjective perspectives on the consent process. The first instrument consisted of open-ended questions combined with multiple-choice answers, assessing understanding of essential elements of informed consent, including study purpose, procedures, risks, and voluntary participation. This component was intended to measure comprehension in a structured and objective manner. The second instrument utilized a 5-point Likert scale to capture participants' perceived understanding, attitudes, and satisfaction with the consent process, providing a qualitative measure of how patients experienced verbal versus written consent. Both survey instruments were reviewed by the research team and an external expert to confirm clarity, relevance, and validity. Once patients agreed to participate in PAC–VC and provided written consent, surveys were administered in paper format. Participants completed the questionnaires at their own pace, and completed surveys were collected the same day to ensure immediate reflection of comprehension and perceptions.

Scoring and analysis

For the objective component of the survey, responses were scored as follows: correct answers received 100%, incorrect answers received 0%, and "do not know" responses were scored 50% to reflect partial awareness. Scores were then averaged across all consent components to produce an overall comprehension score for each participant. Overall scores were categorized into three levels: Adequate understanding (71–100%), Partial understanding (41–70%), and Inadequate understanding (0–40%). These thresholds were selected for this study as no standardized benchmark currently exists to define adequate understanding in acute care research settings. Descriptive statistics were calculated using SPSS to summarize patient responses, including percentages and mean scores per question and per consent type. Although the study was not primarily designed for inferential statistics, independent t-tests were applied to compare mean comprehension scores between verbal and written consent groups, using a significance threshold of $P = 0.5$.

Patient characteristics

Eighteen patients were enrolled in PAC–VC, divided into two groups according to the type of consent initially received in the parent AMI trials: 12 patients provided verbal assent in the REMCON-STEMI trial, and 6 patients had completed written consent in the COMPLETE or TOTAL trials. The cohort was predominantly male (83.3%), with a median age of 54 years. The majority of participants (72.2%) spoke English as their first language, and half had attained college-level education. Only one participant had a prior history of myocardial infarction, while 24% reported previous involvement in clinical research studies. Past exposure to emergency services was common, with 52.9% having experienced ambulance transport and 70.6% having previous hospital admissions. During the consent process, participants rated their levels of attention, stress, pain, and anxiety on a scale from 1 to 10 **(Table 1)**, providing context for their cognitive and emotional state while providing consent.

Recruitment process

Once patients were randomized in one of the three parent trials, the research team was notified to screen them for eligibility in PAC–VC. No formal sample size calculation was performed; the target of approximately 40 patients was based on the principal investigator's clinical experience and feasibility considerations. Of the 21 patients initially approached, 18 consented to participate. Patients were then assigned to one of two parallel arms: the verbal assent arm, consisting of REMCON-STEMI patients who had not yet provided written consent, and the written consent arm, composed of patients from the COMPLETE and TOTAL trials. All participants were approached within 72 hours of

enrollment in their respective trials and after medical stabilization, ensuring that patients were physically and cognitively capable of engaging in the survey assessment.

Table 1. Baseline characteristics (consent type)

	Verbal	Written	Total
N (%)	12 (66.7)	6 (33.3)	18
Males	11 (91.7)	4 (66.7)	15(83.3)
Age	60.83 (Median 57.5)	48.83 (Median 51.5)	56.83 (M = 54)
1st language is english	7 (58.3)	6 (100)	13 (72.2)
College education	6 (50)	3 (50)	9 (50)
Previous history			
MI	1 (9)	0	1(6)
Research	3 (27.3)	1 (16.7)	4 (24)
Hosp. admission	9 (81.8)	3 (50)	12 (70.6)
Ambulance transport	6 (54.5)	3 (50)	9 (52.9)
Physcal symptoms (Mean out of 10)			
Attention	5.73	6.17	5.88
Stress	7.18	6.67	7
Pain	5.27	5	5.18
Anxiety	6.91	6.83	6.88

Patients' degree of understanding and comprehension

Responses showed that patients had adequate understanding of most core components of the verbal assent and was comparable to the understanding of written consents as shown in **Figure 2**.

Participants in both the verbal and written consent groups demonstrated adequate comprehension regarding the overall purpose of the consent process, with mean scores of 91.7% for the verbal group and 100% for the written group. However, when asked more specifically about the detailed objectives of the study, their understanding was only partial, reflected by average scores of 41.7% for the verbal consent group and 66.7% for the written consent group. These findings aligned with participants' self-reported perspectives captured in the second questionnaire, which similarly indicated a general grasp of the consent purpose but limited understanding of finer study details **(Tables 2 and 3)**.

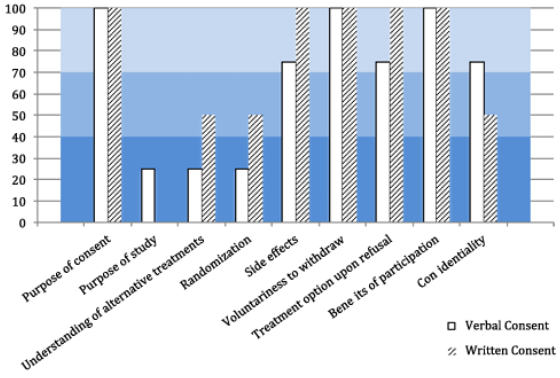

Figure 2. Total score of patients' understanding to the components of consent

Table 2. Objective questionnaire scores described in means out

Consent component	Consent type	
	Verbal assent	Written consent
Purpose of consent	91.67	100.00
Purpose of study	41.67	66.67
Duration of study	45.83	25.00
Nature of study intervention	50.00	66.67
Number of study groups	50.00	75.00

Understanding of alternative treatments	33.33	33.33
Randomization	37.50	50.00
Blindness	25.00	25.00
Side effects	70.83	33.33
Contacts in case of side effects	62.50	25.00
Compensation in case of harm	58.33	75.00
Voluntariness of withdraw	83.33	91.67
Treatment options if refused to participate	75.00	83.33
Benefits of participation	70.00	100.00
Financial benefits of participation	83.33	91.67
Confidentiality	83.33	83.33
Whom to contact for any complaints	83.33	75.00
Total Score	61.47	64.71

Table 3. Patients Subjective Understanding

Items examined	**Consent type**			
	Verbal assent		**Written consent**	
	Count	**N %**	**Count**	**N %**
You understand the purpose of study				
Agree	1	8.3	0	0.0
Cannot decide	2	16.7	0	0.0
Disagree	9	75.0	6	100.0
You know how long you will be enrolled in this study				
Agree	3	25.0	3	50.0
Cannot decide	4	33.3	0	0.0
Disagree	5	41.7	3	50.0
You understand what will be done in this study and what you are being asked to do				
Agree	1	8.3	1	20.0
Cannot decide	3	25.0	0	0.0
Disagree	8	66.7	4	80.0
You recognize the experimental part that may be used in your treatment. (Study intervention)				
Agree	1	8.3	0	0.0
Cannot decide	2	16.7	0	0.0
Disagree	9	75.0	6	100.0
You recognize the possible risks or discomforts that may result due to participation in this study				
Agree	0	0.0	0	0.0
Cannot decide	2	16.7	1	16.7
Disagree	10	83.3	5	83.3
You recognize the possible benefits you may gain from participation				
Agree	0	0.0	0	0.0
Cannot decide	2	16.7	0	0.0
Disagree	10	83.3	6	100.0
You recognize the possible benefits that may help future patients				
Agree	0	0.0	0	0.0
Cannot decide	0	0.0	0	0.0
Disagree	12	100.0	6	100.0
*You know alternative options/treatments you may have if you had chosen to **NOT** participate*				
Agree	2	16.7	1	16.7
Cannot decide	1	8.3	1	16.7

Disagree	9	75.0	4	66.7
You understand that your information is being kept confidential and disclosed only to authorized personnel				
Agree	0	0.0	0	0.0
Cannot decide	0	0.0	0	0.0
Disagree	12	100.0	6	100.0
You know whom you should contact in case of side effects or injuries that may result due to participation in the study				
Agree	1	8.3	2	33.3
Cannot decide	2	16.7	0	0.0
Disagree	9	75.0	4	66.7
You know what compensation or treatment is available for you in case of side effects or injury				
Agree	3	25.0	3	50.0
Cannot decide	3	25.0	0	0.0
Disagree	6	50.0	3	50.0
You understand that your participation is completely voluntary and it is not going to affect your treatment if you choose to withdraw				
Agree	0	0.0	0	0.0
Cannot decide	0	0.0	0	0.0
Disagree	12	100.0	6	100.0
You understand that you can withdraw from this study at any time you wish to do so				
Agree	0	0.0	0	0.0
Cannot decide	0	0.0	0	0.0
Disagree	12	100.0	6	100.0
You know whom you should contact in case you have questions, comments, concerns or complaints about the study				
Agree	2	16.7	2	33.3
Cannot decide	2	16.7	0	0.0
Disagree	8	66.7	4	66.7

Participants in both groups found the concept of randomization difficult to grasp, demonstrating inadequate to partial understanding, with average scores of 37.5% in the verbal consent group and 50% in the written consent group. The difference between the two groups was not statistically significant. Regarding comprehension of risks, participants in the verbal consent arm showed adequate understanding (70.8%), whereas those in the written consent group scored lower (33.3%). Conversely, both groups demonstrated adequate understanding of the potential benefits, with mean scores of 70% for the verbal group and 100% for the written group.

Participants also showed sufficient understanding of key ethical concepts, including autonomy and treatment alternatives, with average scores of 83.3% in the verbal arm and 91.7% in the written arm. Comprehension of confidentiality was similarly adequate in both groups, with an average score of 83.3%.

Regarding patient perspectives and attitudes, only one-third of participants read the written study information. The majority of patients—75% in the verbal consent group and 100% in the written consent group—felt that written information was not essential for making their final decision about participation. Nevertheless, 75% of patients in the verbal consent group expressed a preference to have written information included in the consent process, although only 25% of the verbal group and 16.7% of the written group wanted it presented at the time of initial consent. Furthermore, 83.3% of participants in the written consent group and 50% in the verbal consent group reported feeling pressured during the consent process. Most participants also indicated that the consent procedure was unsatisfactory, with 75% of the verbal group and 100% of the written group expressing this view **(Table 4)**.

Table 4. Patients perspectives

	Consent type	
	Verbal assent	**Written consent**

	N %	N %
I would prefer only verbal information presented during the consent process		
Agree	2 (16.7%)	2 (33.3%)
Cannot decide	1 (8.3%)	2 (33.3%)
Disagree	9 (75.0%)	2 (33.3%)
I would prefer written information presented during the consent process		
Agree	3 (25.0%)	1 (16.7%)
Cannot decide	3 (25.0%)	3 (50.0%)
Disagree	6 (50.0%)	2 (33.3%)
I read the written information about the research study before making my decision		
Agree	2 (16.7%)	2 (33.3%)
Cannot decide	2 (16.7%)	0 (0.0%)
Disagree	8 (66.7%)	4 (66.7%)
I believe written information is very important in making my final decision to participate		
Agree	2 (16.7%)	0 (0.0%)
Cannot decide	1 (8.3%)	0 (0.0%)
Disagree	9 (75.0%)	6 (100.0%)
I feel satisfied and comfortable with the consent process		
Agree	0 (0.0%)	0 (0.0%)
Cannot decide	3 (25.0%)	0 (0.0%)
Disagree	9 (75.0%)	6 (100.0%)
I felt pressured by time when I made my decision during the consent process		
Agree	6 (50.0%)	5 (83.3%)
Cannot decide	3 (25.0%)	1 (16.7%)
Disagree	3 (25.0%)	0 (0.0%)

Post-consent interviews

Patients from the REMCON-STEMI trial in the verbal consent arm were invited to complete the questionnaire a second time after they had provided formal written consent. Out of 12 patients, only 2 agreed to participate in this follow-up. The responses indicated some improvement in knowledge in certain areas **(Figure 3)**. Notably, patients' attitudes and perspectives toward the consent process remained unchanged after reviewing the written consent.

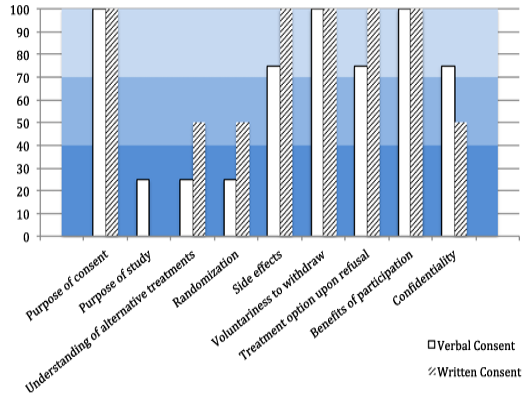

Figure 3. Post-verbal/post-written consent interviews responses

Discussion

Clinical trials in acute myocardial infarction (AMI) are essential for improving treatment strategies and refining existing guidelines. However, the urgent and critical nature of AMI creates unique challenges for obtaining informed consent, as patients are often acutely ill and under significant stress.

To our knowledge, PAC–VC represents the first study to objectively compare patients' comprehension and attitudes toward verbal assent versus traditional written consent in AMI trials. The results demonstrate that patients' understanding of verbal assent was generally comparable to that of written consent, with adequate comprehension of most core elements, including the purpose of consent, autonomy, potential benefits, treatment alternatives, the option to decline participation, and confidentiality. Yet, participants showed only partial to inadequate understanding when details were more complex, such as randomization, blinding, alternative treatments, and potential side effects. These findings

align with prior research showing that patients often retain general information about clinical trials but struggle with specific details. This challenge may reflect the cognitive demands of abstract reasoning, which are difficult for severely ill patients during an acute medical event. Additionally, previous studies suggest that poor recall of side effects may also relate to patients' reluctance to confront potentially unpleasant information. Interestingly, participants in the verbal assent arm demonstrated adequate understanding of treatment side effects, suggesting that verbal communication may be more accessible and effective in conveying complex or sensitive information.

Most participants did not read the provided written materials and did not consider them essential for making the final decision about participation. Nonetheless, patients supported the availability of written information, though not necessarily during the acute phase. This preference aligns with prior findings indicating that patients often rely on verbal explanations rather than reading detailed materials before deciding to participate in trials. Notably, 75% of verbal assent participants and 100% of written consent participants reported dissatisfaction with the consent process, warranting further investigation into patient expectations and perceptions.

Given the time-sensitive nature of AMI treatment, delaying interventions to obtain written consent may increase risks of adverse outcomes or mortality. Patients in the written consent group reported feeling more pressured (83.3%) compared to the verbal assent group (50%), highlighting that written consents may impose additional cognitive load and stress during an acute event. In contrast, verbal assent allows patients to process information more quickly and make decisions without feeling rushed.

These findings support the potential use of verbal assent in research involving vulnerable, acutely ill populations, including stroke, trauma, and AMI patients. In such contexts, patients may be unable to process written information adequately, and verbal assent can facilitate quicker, yet informed, enrollment. Proper implementation requires trained personnel to ensure consistent and accurate information delivery, along with mechanisms to confirm patient understanding through interactive discussion.

Strengths and Limitations

PAC–VC is, to our knowledge, the first study to compare patients' comprehension of verbal assent and written consent in AMI trials using an objective assessment rather than self-reported measures. The study employed multiple-choice questionnaires to quantify understanding, rather than relying solely on subjective impressions. However, no standardized instruments exist to define or grade adequate comprehension, requiring the creation of study-specific scoring thresholds. While this approach enables interpretation, it remains subjective and highlights the need for standardized measures of comprehension in future research.

The study also included participants from multiple AMI trials with varying protocols and complexities. For example, patients in the COMPLETE trial were generally more stable compared to those in REMCON-STEMI and TOTAL trials, introducing variability. Furthermore, the study was small, non-randomized, and involved a heterogeneous population in terms of age, gender, and education level, limiting generalizability and the strength of conclusions. Thus, findings should be interpreted cautiously as preliminary evidence rather than definitive outcomes.

Conclusion

PAC–VC is a small, prospective study evaluating patients' comprehension of verbal assent versus written consent in AMI research. Results indicate that patients adequately understood most elements of verbal assent, comparable to written consent. Although patients value the availability of written materials, most do not read them or require them during the acute phase. These findings suggest that verbal assent could serve as a viable alternative to written consent in time-sensitive, acute care research. Further studies with larger, more diverse populations are needed to confirm these findings and explore broader applications in acute clinical trials.

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