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BENEFITS OF MEDICAL-MEDIATION IN INFORMED CONSENT: EVALUATING CLINICIANS' PERSPECTIVES

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Abstract

Ensuring shared decision-making processes between physicians and patients/families through informed consent (IC) is essential. However, information gaps and time constraints can make it difficult to achieve satisfactory IC. Therefore, medical-mediation by “a mediator” was conceived to address these issues. Medical-mediation solves problems by visualizing reasons for cognitive conflicts during dialogue. We investigated its usefulness in five IC settings conducted by five clinicians in Japan. Semi-structured interviews were conducted using five questionnaires after the same mediator-mediated IC. Data were qualitatively analyzed using KH Coder 3 developed by Koichi Higuchi. Clinicians’ ages ranged from 30 to 65 years, and the

time required for IC was 7 to 15 minutes. In all the questions, none of the participants rejected medical-mediation. The co-occurrence network analysis showed a connection between “mediator” and "ease of explanation," "facilitating questions," and "sharing and obtaining information." In terms of IC time, characteristic words were "explanation" and "patient" for less than 10 minutes, and “family” for more than 10 minutes. In terms of clinicians’ years of experience, the characteristic words were "explanation" and "ease" for less than 9 years, and "family," "concrete," and "feelings" for more than 9 years. During medical-mediation, the mediator can be close to both parties, making it easier for both parties to ask questions and disclose more information spontaneously, such as addressing the patient's questions and concerns. The patients expressed their satisfaction with the IC. This study showed that clinicians' assessment by medical mediation is beneficial in the shared decision-making process of IC.

Keywords: clinician; decision-making process; facilitation; informed consent; medical-mediation

1. Introduction

The ethical and legal basis for Informed consent (IC) is autonomy, which is achieved by providing information that enables patients to understand their treatments, so they can make informed decisions about whether or not to accept them [1]. In Japan as in other countries, standard IC forms include the proposed medical treatment (name and condition/stage of the disease), an explanation of IC in terms of the patient’s needs, admission period, risks (side effects and complications), benefits (expected results), available alternative treatments, expected results if proposed treatments are not performed, and standard clinical paths [2-3].

Although IC procedures are always used in practice, the reality is that patients do not fully engage with the IC process because the clinician-patient dialogue is not sufficient, and the necessary decision-making information is not well conveyed [4]. Previous research has pointed out the barriers to good IC practice [5]. Patient barriers include a lack of medical knowledge, differences in individuals’ needs, and anxieties about the treatments [6]. Clinician barriers include lack of patients’ understanding, excessive use of technical medical

terms, lack of clinical experience, lack of understanding of IC procedures, and time pressure [7-9]. Time pressure is a particularly important barrier to good implementation of IC [10-11].

In Japan, hospitals expect clinicians to treat a high number of patients to achieve their expected revenue. As patient numbers increase, the amount of time that clinicians can allocate to each patient decreases [12-14]. Clinicians understand that time is essence in IC sessions. Shortened IC delivery time risks undermining the trust relationship between clinicians and patients and sometimes leads to litigation. An effective solution has not yet been found [15-17]; therefore, in this study, we shifted the perspective to try to solve this problem. Previous studies have proposed the use of audiovisual, online, and computer-based tools in the implementation of standard IC documentation [18-19], but the present study adopted the use of people power, that is, medical-mediation [20]. We conducted a qualitative study to ascertain the effectiveness of medical-mediation by a professional mediator, to promote dialogue between the patient and clinician during the IC session.

2. Materials and Methods

2.1 Ethical approval and Subjects

This study was approved by the Research Ethics Committee of Yamagata University School of Medicine (Approval No. 306, 2017) and by the study site. Informed consent was obtained from the participants prior to each study. All procedures were performed in compliance with relevant laws and hospital guidelines.

Five clinicians in a Japanese public hospital consented to participate in the study over a three-month period from November 2019 to January 2020. The clinicians had no previous medical-mediation training. The clinicians carried out their IC sessions as usual. The mediator was accredited by the Ministry of Health, Labour and Welfare (MHLW) for medical dialogue facilitation and had five years of medical-mediation experience. She intervened in the IC session at her own initiative as needed to promote dialogue [21]. The duration of each IC was timed and recorded.

2.2 Design

An exploratory study using text analysis was employed.

2.3 Definition of terms

Mediator

A mediator is a person who acts as a bridge between the patient and the medical provider, empathically accepts each person's thoughts and background, and supports dialogue through questions so that both parties can share information and promote mutual understanding [21-22].

Medical-mediation

Medical-mediation is a relationship adjustment model that supports the prevention and adjustment of cognitive conflicts by promoting information sharing through the facilitation of dialogue between patients and medical professionals [21-22].

2.4 Process of Survey

Semi-structured interviews were conducted after each IC session. After the completion of the IC session, the clinician in charge of the IC was asked to evaluate the medical-mediation based on the following five questions.

Question 1 (Q1): Did you feel reassured by the presence of a medical mediator during the IC explanation? If you felt secure, what changed between the times you did not have a medical mediator present and this time?

Question 2 (Q2): Did you feel that you were able to sufficiently speak (or not) with the medical mediator present, and what areas of the explanation were affected?

Question 3 (Q3): Did you feel that the medical mediator's presence made it easier for you to explain things to the patient?

Question 4 (Q4): Did you feel (or not) that the medical mediator's presence helped you explain how you and the patient could fight the disease together?

Question 5 (Q5): Did you feel (or not) that the presence of a medical mediator helped you to understand the true intentions of the patient and family and that they understood your explanation?

Responses to these questions were recorded, and verbatim transcripts were converted into text.

After the IC was over, we asked the level of satisfaction whether the presence of the medical mediator facilitated the dialogue between the patient/family and the doctor in another room.

2.5 Data analysis

Quantitative text analysis was conducted using KH Coder 3, a free software package by Koichi Higuchi(2004)[23].

(1) Word frequency

This is an analysis method in which the number of times a word appears in a sentence is visualized in a graph, and the occurrence frequency is recorded for each question.

(2) Co-occurrence network of words

Co-occurrence network analysis using the Jaccard index is a method of analysis in which the frequency of word co-occurrences is diagrammed. Five questions were combined into a single text containing 863 words and analyzed.

(3) Characteristic words

Characteristic word analysis is used to find words that represent the characteristics of certain attributes. The external variables for feature word analysis were IC time and years of physician experience. The IC time was defined as 10 minutes or more [13-14], and experience was 9 years or more. Nine years was set for experience, as it takes nine years for clinicians to achieve specialist status in Japan [24-25].

3. Results

Table 1 shows the IC content, time, and attributes of the clinicians who performed the IC procedures. The IC contents in Table 1 were broadly divided into two categories: terminal care and medical treatment of the disease. The IC sessions lasted 7–15 minutes. During each IC session, the mediator intervened to facilitate clinician-patient IC interaction at least once and for a maximum of 3 times, and the average intervention time ranged from 30 seconds to 2 minutes. The intervention times taken by the mediator to speak to both the parties in the 5 IC sessions were as follows: 2 minutes for Case 1, 30 seconds for Case 2, 1 minute for Case 3, 1.5 minutes for Case 4, and 15 seconds for Case 5.

Table 1. Characteristics of Informed Consent

Case	Contents of informed consent	Doctors	Sex	Specialty	Age	Years of medical practice	Time required for IC (minutes)
1	Explanations of medical condition and post-discharge care plan for the patient with terminal lung cancer	A	Male	Respiratory Medicine	65	39	15
2	How to proceed with the treatment of the patient who refused a notice of lung cancer	B	Male	Respiratory Medicine	31	5	9
3	Explanation for tongue cancer surgery to the patient and his family who concerned about complications (functional impairment, change in appearance)	C	Male	Otolaryngology	33	6	9
4	How to proceed with medical treatment at home for the patient with terminal breast cancer and the worry of her daughter about the burden of the care	D	Female	Breast Surgery	30	7	12
5	Explanation for progress of the patient with terminal cardiac arrest who transported on the day of discharge to allay his family who concerned with the doctor's response	E	Male	Orthopedic Surgery	32	9	7

The number of clinicians' positive responses to the five questions were as follows: Five for Q1, two for Q2, four for Q3, three for Q4, and five for Q5.

The verbatim transcripts of the interviews yielded 863 words.

3.1 Word frequency.

The most frequent words in each question were "listen" and "good" for Q1; "can do" and "remain the same" for Q2; "understand" and "ease" for Q3; "plan" for Q4; and "patient" for Q5.

3.2 Co-occurrence network of words

A co-occurrence network analysis was conducted based on 863 words (Fig. 1). The seven subgraphs that suggest characteristic topics were as follows: 01-satisfaction with explanation; 02-ease of explanation; 03-facilitating questions; 04-feeling secure; 05-sharing and obtaining information; 06-facilitating interactive dialogue; and 07-collaborative decision making. Among the subgraphs, the words "could say" and "specific" were found in subgraph 02 (ease of explanation), "question" in 03 (facilitating questions), and "observe," "feel," and "speak" in 05 (sharing and obtaining information). The word "mediator" was found in subgraph 04 (feeling secure) and was linked with subgraphs 02, 03, and 05.

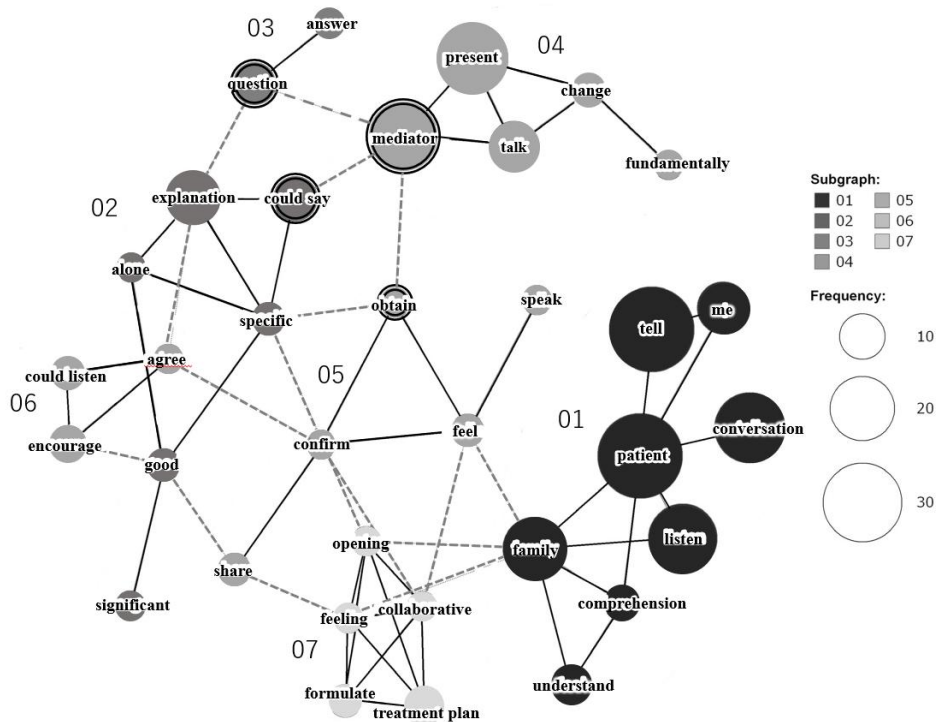


Figure 1. Co-occurrence network evaluation of medical-mediation. The size of each node indicates the frequency of words. The lines between nodes indicate a co-occurrence relationship, and the thickness of the lines shows the strength of the relationship. The solid lines represent a connection within a subgraph, while the dotted lines represent a connection between subgraphs. The distance between nodes is not meaningful. A subgraph is a collection of nodes with strong links between nodes (high Jaccard coefficient values). Seven subgraphs were detected as follows: 01, satisfaction with explanation; 02, ease of explanation; 03, facilitating questions; 04, feeling secure; 05, sharing and obtaining information; 06, facilitating interactive dialogue; and 07, collaborative decision-making. As indicated by double circles, the word “mediator” was found in subgraph 04. In addition, it was linked with “could say” from subgraph 02, “question” from subgraph 03 and “obtain” from subgraph 05 by dotted lines. These connections suggest that the clinicians felt the presence of medical-mediator-promoted interactive dialogue compared to the usual informed consent process

3.3 Characteristic words

The characteristic words for IC procedure time were as follows: “Explanation” and “patient” for less than 10 minutes and “family” for more than 10 minutes. The feature words for clinicians’ years of medical experience were as follows: “Explanation” and “ease” for less than nine years and “family,” “concrete,” and “feelings” for more than nine years. Regardless of the number of years of experience, all the clinicians mentioned “acceptance of the patient/family’s ideas”

3.4 Patients’ evaluation

The age of patients ranged from 40s to 60s. All of the patients were male in gender, while their family members were female. They and their families answered that they were satisfied with the following four questions; (1) ease of interaction with the doctor, (2) ease choice of

the therapies, (3) clarity of reasons of the therapies, and (4) understanding of the medical condition of the patient.

4. Discussion

The shared decision-making process is a very important element in building trust between clinicians and patients. Through this shared decision-making process, patients should be supported to gain sufficient information and to deliberate and express their preferences and views [26]. The clinicians' ratings for Q1 through Q5 and the word frequency of words such as "understand" and "ease" suggest that medical-mediation is useful for determining patients' feelings, and thus, promoting this communication process.

As [1] have stated, physicians are expected to help patients make informed choices during IC sessions and to share responsibility for the decision-making processes and outcomes with patients. This requires sufficient time for the IC session and a shared understanding of the IC content [10-11]. However, in clinical practice, there is often not enough time [8, 12]. For this reason, many short IC sessions focus on written explanations, consent, and obtaining signatures [27]. As shown in Table 1, the IC sessions took only 7–15 min. In this short period of time, the mediator provided support for the patient's IC using medical-mediation. In Fig. 1, in subgraph 04, the word "mediator" is linked with subgraph 02-ease of explanation, subgraph 03-facilitating questions, and subgraph 05-sharing and obtaining information, which confirms that the mediator was involved in promoting dialogue. The clinicians commented that the explanation process promoted interactive dialogue, which was different from their usual experience. This dialogue facilitation is suggested in subgraphs 02, 03, 04, and 05, where the clinicians used words such as "could say" and "specific" in subgraph 02 (ease of explanation), and "obtain" and "share" in subgraph 05 (sharing and obtaining information) (Fig. 1). However, the most negative evaluation of the mediator was found in answers to Q2 (enough talking). This indicated that they were not fully satisfied with the dialogue process, which indicated a procedural issue for medical-mediation.

Another reason for promoting medical-mediation interaction is the difference in the conversation structure. In other words, the usual conversation structure in the medical field is bipolar between the clinician and patient. In the study cases, it is noted that the conversation structure changed from a bipolar to a tri-polar structure with the intervention of the mediator; that is, an interactive format consisting of a clinician, patient/family, and mediator. The

changed dialogue structure made it possible to realize the role of the clinician in the IC procedure, as described by [1]. From a different point of view, when IC is conducted within a limited time frame, it is suggested that IC with the intervention of the mediator enables a more proactive, lengthier, and effective dialogue between the clinician and the patient/family.

The number of years of clinical experience of the clinician is an important factor for effective IC [28]. In our results, there was a difference in the characteristic words depending on the number of years of clinical experience. We speculated that the less experienced clinicians (B, C, and D) in Table 1, whose characteristic words were “explanation” and “ease,” would want patients to gain an understanding of their treatment proposals through active explanations. Simultaneously, they understood that there is a limit to patients’ and families’ acceptance of explanations in the usual IC procedure. The reason for this duality may be that shared decision-making between clinicians and patients requires a longer time to establish than the limited clinical time that is usually available [10-11]. In addition, it is especially difficult to communicate with dying patients, and providing a good IC session requires experience [9, 29]. In this regard, we believe that by asking both parties questions during medical-mediation, mediators can extract more information from patients such their concerns and anxieties, and they can make it clear that clinicians truly care. Clinicians can explain treatments while confirming patients’ and families’ state of understanding, which leads to a reduction in clinicians’ burden.

The limitation of this study is that the total number of words analyzed was small due to the small number of subjects and the limited content of the IC and the years of experience of the clinicians. In addition, in the evaluation of IC from the patient/family side, it would be necessary to evaluate both quantity and quality regarding the ease of asking questions, the clarity of selection, the clarity of the rationale for suggestions, and the ease of understanding the medical condition. Therefore, the results cannot be generalized to all mediators who promote dialogue between clinicians and patients/families during IC sessions. In the future, we would like to confirm this result by increasing the number of clinicians and patients.

In the current situation where clinicians are not educated about IC and IC is largely based on clinicians’ experience, the use of mediators during IC sessions is expected to contribute to assuaging patients’ anxieties associated with treatment, enhancing understanding among patients and their families, improving interactions between physicians and patients, and encouraging shared decisions in acceptance of treatments.

We used medical-mediation to assist clinicians in obtaining IC. As a result, the participating clinicians positively evaluated the usefulness of medical-mediation in promoting shared decision-making processes during IC.

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