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2013年度ホスピス緩和ケアに関する研究助成

研 究 報 告 書

研究課題

Palliative care Outcome Scale (POS) 日本語版の開発および信頼性・妥当性の検証

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1 研究の目的

がん患者においては、その治療経過のなかでさまざまな身体・精神症状が出現する。国内外の研究によると、疼痛をはじめとする身体症状、抑うつ・不安などの精神症状は治療のあらゆる段階をとおして 60-80%の患者が経験する(文献 1-4)。患者に適切な緩和ケアを提供するには診断時からの全体像を見据えた包括的なアプローチが必要である。

緩和ケアの主な目的は、患者が最期を迎えるまで最善の Quality of Life(QOL)を追求することにある。これを達成するにはケアの質を高く保つことが重要で、それにはその質を評価する仕組み(オーディット)が必要である。ケアの質を定期的に評価することで日常診療、教育、人的・物的資源の配置状況などを改善することが出来る。しかしこれまで日本の緩和ケアの現場において医療の質の評価は日常的に行われているものではなかった。その理由としては緩和ケア介入の成果(アウトカム)を評価する尺度でゴールドスタンダードとなるツール自体がなかったこと、また尺度の主なもの英語で開発されており、英語を母国語としない患者にそれを使用するには、文化の違いを考慮して翻訳し、妥当性を検証するという作業が必要で、日本語で使用できるものは少なかったことが挙げられる。

緩和ケアにおけるアウトカム測定尺度は、生活の質のほか、死にかたの質、家族支援、ケアの満足度、場合によっては超越した存在に関する認識や生きる意味などを反映するものであることが望まれる。これまで開発されてきたものとして、Edmonton Symptom Assessment System (ESAS) (文献 5)、European Organization for Research and Treatment of Cancer (EORTC) QLQ-C30 (文献 6) およびその短縮版である QLQ-C15 PAL (文献 7)、The McGill Quality of Life Questionnaire (MQOL) (文献 8)、Support Team Assessment Schedule (STAS) (文献 9)、Functional Assessment of Chronic Illness Therapy-Palliative Care (FACIT-PAL) (文献 10) などがある。数ある尺度の中で Palliative care Outcome Scale (POS)はそれらを適切に反映していると考えられている。

POSはSTASやMQOLなどのツールを発展させて1999年にHearn, Higginsonらによって作成された(文献 11)。直近3日間の身体症状・感情・心理状態・スピリチュアルな欲求・医療情報やさまざまな援助の提供状況について査定する。10の質問項目から構成され、各項目は0(最良)-4(最悪)のリッカートスケールとなっており、それに加えて、最後にある自由記載欄で患者が最も気にしている問題を扱うことが出来る。またPOSは患者用、介護者用、スタッフ用があり、患者の主観的評価のみではなく、観察者評価としても使用できる。POS各項目とEORTC-C30の関連項目との相関係数は0.43-0.80で妥当性が確立されている。各項目のテスト・再テストのκ係数は0.74-1.00で信頼性が確立されている(文献 11)。加えて患者用、介護者用、スタッフ用ともに10分以内での評価が可能であり簡便性にも優れている。以上からこれまでドイツ語(文献 12)、スペイン語(文献 13)などに翻訳されているが現在のところ日本語版はない。今回は作成したPOSの日本語版の信頼性・妥当性を検証することを目的に研究を行う。

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II 研究の内容・実施経過

(1) POS日本語版（パイロット版）の開発

POS原版をもとに、double back translation法によりPOS日本語版（パイロット版）を開発する。

① 概念の整理、これまでの文献の整理

(ア) 研究者間でこれまで日本語で作成された健康関連QOL測定尺度をレビュー

(イ) 緩和ケアを専門とする医療者5名程度でPOSの各項目の示す概念を定義する

(ウ) これらの概念が日本において通用するかどうか緩和ケアを受けている5名程度の患者グループ2グループ、計10名程度にたいしてインタビューを行う

② 順翻訳(Forward Translation)

日本語を母国語とする2名の翻訳者が独立にPOSを日本語に翻訳する。翻訳者の一人は緩和医療を専門とする医師で、英語に精通している者とする。

③ 逆翻訳(Back Translation)

順翻訳を行った翻訳者とは別で、英語に精通する者2名が、パイロット版をそれぞれ独立して英語に翻訳し、順翻訳と同様の手順で一つの訳にまとめる。逆翻訳者の一人は医療を専門とするものとする。逆翻訳された内容を原作者に渡し、承認が得られるまで①-③を繰り返す。

④ 原作者に承認をえられたパイロット版を、研究チーム、POSについて熟知している医療関係者、4人の翻訳者で、原版と同等であるかをレビューする。

(2)パイロットテスト

作成したパイロット版を、今後使用することが想定される外来・入院患者を対象に実施し、その結果をもって日本語訳を最終調整して原作者に承認を得る。

目標患者数 患者20名

(3)実施経過

2012年4月1日から組織の立ち上げ、研究計画書作成を始め、本研究助成決定後から研究を開始した。

①概念の整理 助成決定後-2013年6月30日

②順翻訳 2013年7月完成

③逆翻訳 2013年8月完成

④医療関係者でのレビュー 2013年8月14日-9月30日

④パイロットテスト 2013年10月1日-12月31日

⑤翻訳の最終調整 2014年1月1日から1月30日

III 研究の成果

研究経過・成果は英国の POS 版権元に下記の通り英語で報告した。

① Conceptual definition

【Step1】 Health-related Quality of Life (HR-QOL) Research in Japan

1. History

Since the 1970s, there has been increasing recognition of the importance of QOL assessment as a qualitative indicator of medical care, in addition to the established quantitative indicators. Publication of clinical research articles in Japanese regarding HR-QOL was first observed in the 1980s, followed by a rapid increase in publication in the 1990s.

According to Nakane¹⁾, 1390 QOL-related papers were published in 1995. Of them, 41% were cancer-related, 24% were on digestive diseases, and 13% were on cardiovascular diseases. The contents of these included 18% therapy-related, followed by topics related to the elderly and nursing. Only 15% of these studies were conducted with a primary intention to evaluate QOL. They concluded that very few QOL studies are currently internationally recognized. There have been no systematic reviews on this topic published subsequently.

2. HR-QOL scales in Japanese palliative care (Table 1)

Since the field of palliative care in Japan has developed concurrently with cancer treatment, the Japanese health insurance for palliative care only covers cancer and acquired immune deficiency syndrome. QOL scales for cancer patients are used frequently in the clinical setting.

Valid HR-QOL scales available in Japanese are as follows:

2-1. Generic Scales

EuroQol-5 Dimension²⁾, MOS 36-Item Short Form Health Survey³⁾

2-2. Disease Specific Scales

McGill QOL Questionnaire⁴⁾, MD Anderson Symptom Inventory⁵⁾, Support Team Assessment Schedule⁶⁾, European Organization for Research and Treatment of Cancer QOL Questionnaire Core 30⁷⁾, Functional Assessment of Cancer Therapy-General⁸⁾, QOL Questionnaire for Cancer Patients Treated with Anticancer Drugs⁹⁾¹⁰⁾, Care Notebook¹¹⁾¹²⁾. The last two were developed in Japan.

The Edmonton Symptom Assessment System¹³⁾, Memorial Symptom Assessment Scale¹⁴⁾ and POS¹⁵⁾ are used worldwide, but are neither translated into Japanese nor validated. Therefore, translation of POS will contribute to quality improvement efforts and clinical audit in the Japanese medical practice.

【Step2】 Conceptual Definition (Appendix A)

Among our group members consisting of 5 palliative care physicians, 1 family practice physician with special interest in palliative care, and 1 nurse, we reviewed the POS items and discussed potential issues related to its contents. As all members are native speakers of Japanese, a tentative brief translation was initially prepared by the study coordinator and was used for our discussion. We commented on the POS items based on the following: 1. Understandability of the questions and answer options for Japanese people, 2. Concepts of the questions and the answer options, and our definition if confusing or difficult to understand.

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	Scale		P.I.	Publish year	Validated Japanese version
Generic Scale	EQ-5D	EuroQol-5 Dimension	The EuroQOL Group	1990	✓
	SF-36	MOS 36-Item Short Form Health Survey.	Ware JE	1992	✓
Disease Specific Scale	ESAS	Edmonton Symptom Assessment System	Bruera E	1991	
	STAS	Support Team Assessment Schedule	Higginson I	1993	✓
	FACT	Functional Assessment of Cancer Therapy	Cella DF	1993	✓
	EORTC-C30	European Organization for Research and Treatment of Cancer QOL-C30	Aaronson NK	1993	✓
	QOL-ACD	QOL Questionnaire for Cancer Patients Treated with Anticancer Drugs	Kurihara M	1993	✓
	MSAS	Memorial Symptom Assessment Scale	Portenoy RK	1994	
	MQOL	McGill Quality of Life Questionnaire	Cohen SR	1995	✓
	Care Note	Care Notebook.	Ando M	1997	✓
	POS	Palliative care Outcome Scale	Higginson IJ	1999	
	MDASI	M.D. Anderson Symptom Inventory	Cleeland CS	2000	✓

Table 1

Appendix A : Conceptual Definition

Original questionnaire:	Conceptual Definitions
<p>Please answer the following questions by ticking the box next to the answer that is most true for you. Your answers will help us to keep improving your care and the care of others. Thank you.</p>	<p>How to answer. Meaning of questionnaire and thanks to cooperation.</p>
<p>1. Over the past 3 days, have you been affected by pain?</p> <p>0 Not at all, no effect 1 Slightly - but not bothered to be rid of it 2 Moderately - pain limits some activity 3 Severely - activities or concentration markedly affected 4 Overwhelmingly - unable to think of anything else</p>	<p>Presence and extent of pain. The difference between “Severely” and “Overwhelmingly” seems confusing for Japanese. In order to distinguish, the Japanese POS project members define “severely” as seriously, and “overwhelmingly” as very seriously or unbearably.</p>
<p>2. Over the past 3 days, have other symptoms e.g. nausea, coughing or constipation seemed to be affecting how you feel?</p> <p>0 No, not at all 1 Slightly 2 Moderately 3 Severely 4 Overwhelmingly</p>	<p>Presence and extent of symptoms other than pain. Defined “severely” as seriously, and “overwhelmingly” as very seriously or unbearably.</p>
<p>3. Over the past 3 days, have you been feeling anxious or worried about your illness or treatment?</p> <p>0 No, not at all 1 Occasionally 2 Sometimes - affects my concentration now and then 3 Most of the time - often affects my concentration 4 Can't think of anything else - completely pre-occupied by worry and anxiety</p>	<p>Presence and extent of patient’s anxiety or worry resulting from health problem.</p>
<p>4. Over the past 3 days, have any of your family or friends been anxious or worried about you?</p> <p>0 No, not at all 1 Occasionally 2 Sometimes – it seems to affect their concentration 3 Most of the time</p>	<p>Perspective of patient on anxiety or worry of relatives or loved ones.</p>

<p>4 Yes, always preoccupied with worry about me</p>	
<p>5. Over the past 3 days, how much information have you and your family or friends been given?</p> <p>0 Full information or as much as wanted – always feel free to ask</p> <p>1 Information given but hard to understand</p> <p>2 Information given on request but would have liked more</p> <p>3 Very little given and some questions were avoided</p> <p>4 None at all – when we wanted information</p>	<p>The quality and quantity of information and account given by medical personnel.</p> <p>Box 1 describes patient accepts the quantity but is partially unsatisfied with the quality.</p> <p>Box 2 describes the quality and quantity is partially unsatisfactory.</p> <p>Box 4 describes the quality and quantity is totally unsatisfactory.</p> <p>Box 3 is intermediate between 2 and 4.</p>
<p>6. Over the past 3 days, have you been able to share how you are feeling with your family or friends?</p> <p>0 Yes, as much as I wanted to</p> <p>1 Most of the time</p> <p>2 Sometimes</p> <p>3 Occasionally</p> <p>4 No, not at all with anyone</p>	<p>How much patient can tell family their feeling, think family supportive and reliable.</p> <p>Concept of 'sufficient as needed' is added to box0.</p>
<p>7. Version 1 - Over the past 3 days, have you felt that life was worthwhile?</p> <p>0 Yes, all the time</p> <p>1 Most of the time</p> <p>2 Sometimes</p> <p>3 Occasionally</p> <p>4 No, not at all</p>	<p>How much patient can feel the meaning of their life and think their life valuable.</p>
<p>7. Version 2 - Over the past 3 days, have you been feeling depressed?</p> <p>0 No, not at all</p> <p>1 Occasionally</p> <p>2 Sometimes</p> <p>3 Most of the time</p> <p>4 Yes, all the time</p>	<p>Presence and extent of depressive mood. Question 3 and 7-ver2 supplement each other to assess psychological distress.</p>
<p>8. Over the past 3 days, have you felt good about yourself as person?</p> <p>0 Yes, all the time</p> <p>1 Most of the time</p>	<p>The word 'Peace', or 'quiet in mind' is more popular among Japanese than literal translation when asked mental and spiritual well-being. Contains the concept</p>

2 Sometimes 3 Occasionally 4 No, not at all	of 'Life-worthy'. The answer options are comprehensible.
9. Over the past 3 days, how much time do you feel has been wasted on appointments relating to your healthcare, e.g. waiting around for transport or repeating tests? 0 None at all 2 Up to half a day wasted 4 More than half a day wasted	Patient's perception of the meaning of the time for medical care.
10. Over the past 3 days, have any practical matters resulting from your illness, either financial or personal, been addressed? 0 Practical problems have been addressed and my affairs are as up to date as I would wish 2 Practical problems are in the process of being addressed 4 Practical problems exist which were not addressed 0 I have had had no practical problems	How the actual events in daily life are managed by anyone other than patient.
11. If any, what have been your main problems in the last 3 days?	Patient's concern.
12. How did you complete this questionnaire? 0 On my own 1 With the help of a friend or relative 2 With the help from a member of staff	Assistance to complete the questions.

With regards to the conceptual definitions, the Japanese palliative care experts agreed on the translation and validation of the POS. They also suggested using POS ver2 rather than ver1 in the Japanese palliative care setting, because the question of 'Depression' is important and the 'Feeling good' question can more appropriately address the concept of 'Life-worthy' among Japanese.

【Step3】

Two focused-group discussions among patients and family members were held using the tentative brief translation.

One consisted of 5 patients, and the other consisted of 3 patients and 2 family members.

A semi-structured interview was performed on each item addressing issues of understandability, ambiguity, and level of burden to answer. In addition, free comments were welcomed. Findings from these focus-group discussions are summarized below.

Summary

- Description : understandable, unambiguous, no burden
- Pain : understandable, unambiguous, no burden
- Other Symptoms: understandable, unambiguous, no burden
- Anxiety : understandable, unambiguous, no burden
- Family Anxiety : understandable, easy to mistake whether patient or family should answer, no burden
- Information : understandable, unambiguous, no burden
- Share Feelings : understandable, unambiguous, no burden
- Life-worthy : Incomprehensible when literally translated. Difficult to decide own life is valuable or not, because the answer comes after death. Easy to say we have something to live for rather than valuable. May be burden for the dying.
- Depression : understandable, unambiguous, no burden.
- Feeling Good : 'Being like themselves' is hard to understand. 'Satisfaction' is obscure, because they cannot make quick answer with what they are satisfied. 'Peace' is understandable and no burden.
- Wasted Time : understandable, unambiguous, no burden.
- Personal Affairs : understandable, unambiguous, no burden.
- Answer Assist : understandable, unambiguous, no burden.

② Forward Translation

③ Backward Translation

④ Expert Review

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(2) Pilot test

Semi-structured interviews were held among the patients

Surveillance period: October 2013 to December 2013

Patient Demographics

n = 20

Age	mean 64.3 (Median 65, range 39-83)	
	Under 65	9
	65 or over	11
Sex	Male	10
	Female	10
Care Setting	Outpatient clinic	10
	Inpatients	10
Diagnosis	Gastrointestinal	6
	Liver, Gallbladder, Pancreas	4
	Lung	2
	Breast	5
	Genitourinary	2
	Soft tumor	1
Stage	I	0
	II	2
	III	1
	IV	8
	Recurrent	8
	Unknown	1
Period since diagnosis	1-6 months	2

7-60 months	10
61 or more months	8

Comorbidity (multiple answer allowed)

Cancer (other than one on current treatment)	1
Hypertension	2
Diabetes	4
Osteoporosis	1
Hepatitis	3
None	13

Treatment

Follow-up, Planned	1
Chemotherapy	3
Radiation	0
Chemo-Radiation	1
Completed, Discontinuation	15

Performance Status

0	2
1	4
2	3
3	9
4	2

Result

- Time required to complete
Average 8.25 min, range 4-30 min
- Recognition of length to complete
Too long; n=0, Appropriate; n=18 (90%), Too short; n=2 (10%)
- Overall understandability (1: very easy, 5: very difficult)
Average 2.0
1: n=6 (30%), 2: n=8 (40%), 3: n=6 (30%), 4: n=0, 5: n=0

Comments:

- I wonder whether I should report the average or maximum of the 3 days.
- All questions do not sit well.
- Some questions are confusing, so overall rating is 3.

4. Overall ease of fill-in (1: very easy, 5: very difficult)

Average: 1.6

1: n=10 (50%), 2: n=8 (40%), 3: n=2 (10%), 4: n=0, 5: n=0

Comments:

- Characters are small
- Boxes are small

5. Understandability of question. If confusing, its content

6. Clarity of response alternatives. If unclear, its content

7. Unpleasant or inappropriate question. If not appropriate, its content

8. Alternative wording

Questions not issued: Description, Q3, 7-2, 11, and 12.

Q1: Pain

Confused: n=1

- I could not understand this question asking the extent of “*Eikyou*”.

Alternative wording: “*Eikyou no doai ha doredesu ka?*” (To what extent are you affected) or “*Shishou arimasita ka?*” (Do you have some trouble in....)

*translators note: *Shishou* : trouble, interference, negative effect

Q2: Other Symptoms

Confused: n=1

- I could not understand this question asking the extent of “*Eikyou*”.

Alternative wording: “*Eikyou no doai ha doredesu ka?*” (To what extent are you affected) or “*Shishou arimasita ka?*” (Do you have some trouble in ...)

Q4: Family and friends anxiety

Confused: n=2

- I have no friends
- Unclear how ‘friends’ should be defined.

Q5: Explanation

Confused: n=4

- Who do you intend to ask for an explanation? Doctor? Facility staff? Subject is needed (n=3)
- I have not been seen by doctors in the last 3 days.

Alternative wording: "*Iryousha karano setumei ha arimasita ka?*" (Was explanation given by medical staff?)

Q6: Telling feelings

Upset: n=1

- Telling my feeling is my "own" challenge; there is no suggestion.

Q7-1: Worth living

Upset: n=1

- Too straightforward

Alternative wording: "*Ikiru yorokobi ha kannjiraremasita ka?*" (Can you feel the joy of living?)

Q8: Feel at peace

Confused: n=1

- I put 3 on question 7, so I mistakenly thought that question 8 should be answered after reporting to nurse

Q9: Wasted time

Confused: n=1

- I spent a lot of time, however, I do not think it was a waste. So it was difficult to decide which box I should check.

Q10: Personal affairs

Confused: n=1

- Which do you intend to ask, the problem addressed by family or by medical staff? Subject is needed.
- What does "personal affairs" mean?

Alternative wording: "*Sigoto ya kaji no mondai*" (job or home affairs)

B. focused group discussion among palliative care professionals

A focused group discussion among palliative care professionals was held. Participants were 3 palliative care nurses and 1 palliative care doctor (facilitator).

Questions not issued: Description, Q2, 4, 7-2, 8, 11, and 12.

Q1

- We commonly say “*Shishou*”, not “*Eikyou*”, to an effect by illness.

Q3

- Some people may waver between “*Tamani*” and “*Tokidoki*”, however, being arranged in order of frequency makes the responses clear.

Q5

- My impression was that the patient is more satisfied with the situation A2 than A1.
- A1 appears to deny whole explanation, so “*wakaririkui tokoro ga atta*” (could not understand certain places) is better.
- It is preferable to sandwich “*aruiha*” (or) between “*setsumei site moraezu*” (very little given) and “*situmon niyotteha*” (some questions were avoided), because we cannot ask questions without explanation.

Q6

- Japanese place more emphasis on getting what others feels, rather than speaking one’s own feelings. Telling needs language, so telling does not sit well for Japanese. But I have no idea about alternative wording.
- If I do not see someone in 3 days, which box should I choose? A4 or leave a blank?

Q7-1

- The value of life is an idea I never thought of before; I think this is not a straightforward question.

Q9

- The sum over 3 days should be underscored.

Q10

- Are you asking about the concern addressed by family or by medical staff?

C. Expert review

Result of the pilot study was shared with the project members through e-mail.

Q1, 2

"*Shishou*" fits in best.

Q6

As the BT2 described that telling feelings is less valued in Japanese culture, "Share feeling" is difficult to translate. According to Appendix B, it asks patient whether they think their family is supportive. It may be better to ask about the outcome (the feelings is understood), not action (tell).

Q7

"Next examination" should be underscored

Q9

"Waiting around for transport" in the original does not indicate the time spent in hospital. However, the waiting time to see doctors is a burden to many Japanese patients, not transport time itself. This is the difference in health care system.

Conclusion

Q1, 2

"*Eikyou*" is changed to "*Shishou*"

Q6

"*Tsutaerukoto ga dekimashita ka*" is changed to "*Wakatte morae masita ka*"

Q9

"Machi jikan" (times for waiting in hospitals) is added.

Q10

"Mondai" is changed to "Kigakari" (soft expression of *Mondai*)

Based on the pilot study, the final POS in Japanese for psychometric testing was produced. Members of the project team reached an agreement.

【以下は仮翻訳で妥当性信頼性の検証がなされておりませんので、患者さんへのご使用はお控えください。】

The final POS in Japanese

緩和ケア アウトカムスケール (バージョン1)

患者 アウトカムスケール (バージョン2)

患者さん用 アンケート

www.pos-pal.org

下記の質問の答えとして最も当てはまるところにチェックを入れてください。この回答は、あなたと他の患者さんのケアの向上のために役立てられます。ご協力ありがとうございます。

- 1 この3日間、痛みによる支障がありましたか？
 - 0 全くなかった、支障はなかった
 - 1 少しあった - しかし、気にならなかった
 - 2 中くらいあった - 痛みでいくらか生活に支障がでた
 - 3 とてもあった - 生活や集中力に大きな支障がでた
 - 4 耐えられないくらいあった - 他のことを考えられなかった

- 2 この3日間、痛み以外の症状、例えばはき気、せき、便秘などによる支障がありましたか？
 - 0 いいえ、全くなかった
 - 1 少しあった
 - 2 中くらいあった
 - 3 とてもあった
 - 4 耐えられないくらいあった

- 3 この3日間、あなたは、病気や治療のことで不安や心配を感じていましたか？
 - 0 いいえ、全く感じていなかった
 - 1 たまに感じていた
 - 2 ときどき感じていた - 他のことに集中できないときがあった
 - 3 よく感じていた - 他のことに集中できないときがよくあった
 - 4 他のことを全く考えられなかった - 不安と心配で頭がいっぱいだった

- 4 この3日間、家族や友人は、あなたのことで不安や心配を感じていた様子でしたか？
 - 0 いいえ、全く感じていた様子はなかった
 - 1 たまに感じていたようだ
 - 2 ときどき感じていたようだ - 他のことに集中できない様子があった
 - 3 よく感じていたようだ
 - 4 はい、いつも私のことが心配で、頭がいっぱいのようなようだった

【以下は仮翻訳で妥当性信頼性の検証がなされておりませんので、患者さんへのご使用はお控えください。】

- 5 この3日間、治療や病気について、あなたと家族や友人にどれくらい説明がされましたか？
- 0 知りたいことは全て説明してもらえた - いつも遠慮なく質問できた
 - 1 説明はしてもらえたが、分かりにくかった
 - 2 希望すれば説明してもらえたが、もっと説明して欲しかった
 - 3 ほとんど説明してもらえず、質問によっては答えてもらえなかった
 - 4 全く説明がなかった - 説明を希望したときでさえもなかった
- 6 この3日間、あなたの気持ちを家族や友人に分かってもらえましたか？
- 0 はい、十分に分かってもらえた
 - 1 たいてい分かってもらえた
 - 2 ときどき分かってもらえた
 - 3 たまに分かってもらえた
 - 4 いいえ、全く分かってもらえなかった
- 7 7-1 この3日間、生きていることに価値を感じられましたか？
- 0 はい、いつも感じられた
 - 1 よく感じられた
 - 2 ときどき感じられた
 - 3 たまに感じられた
 - 4 いいえ、全く感じられなかった
- 7-2 この3日間、気分が落ち込むことはありましたか？
- 0 いいえ、全くなかった
 - 1 たまにあった
 - 2 ときどきあった
 - 3 よくあった
 - 4 はい、いつもあった

上記(7-1,7-2)の□3もしくは□4にチェックされた方は、次の診察の際に看護師か医師にそのことを伝えてください。

- 8 この3日間、気持ちは穏やかでいられましたか？
- 0 はい、いつもいられた
 - 1 たいていいられた
 - 2 ときどきいられた
 - 3 たまにいられた
 - 4 いいえ、全くいられなかった

【以下は仮翻訳で妥当性信頼性の検証がなされておられませんので、患者さんへのご使用はお控えください。】

- 9 この3日間、診療に関わることでどれくらいの時間を無駄にしたと感じましたか？
例えば待ち時間や通院、検査の繰り返しに費やした時間など
- 0 全く無駄にしなかった
 - 2 (3日間のうち)多くて半日くらい無駄にした
 - 4 (3日間のうち)半日以上無駄にした
- 10 この3日間、病気のために生じた、経済的な心配や個人的に気がかりなことに対応してもらえましたか？
- 0 すでに対応してもらい、いまのところ希望した通りになっている
 - 2 いま対応してもらっているところだ
 - 4 対応してもらいたいことがあるが、対応してもらえなかった
 - 0 対応してもらいたいことが特になかった
- 11 この3日間で大変だったことがあれば、それは主に何でしたか？
1.
2.
- 12 どのようにしてこの質問票に答えましたか？
- 0 自分一人で答えた
 - 1 友人や家族に手伝ってもらって答えた
 - 2 スタッフに手伝ってもらって答えた

IV 今後の課題

全計画のうち本研究助成期間中に第一段階のみ達成した。

これは本邦の緩和医療関係者で最終翻訳に合意を得ることを慎重に行ったことと、パイロットテストの対象が緩和ケアを受けている患者という特性上、インタビューに耐えうる患者の登録に時間がかかったことが予定よりも遅れた原因と考えられた。

現在出来上がったPOSの信頼性・妥当性の検証を多施設で行う準備を進めており、来年度かけて下記方法で行う予定である。

1 観察・検査項目と方法

1.1 観察・検査項目

(1)医学的社会的患者背景

(2)POS

(3)European Organization for Research and Treatment for Cancer QLQ-C 30 (EORTC QLQ-C-30) (文献1)

(4)Functional Assessment of Chronic Illness Therapy – Spiritualのうち、Spiritualityに関する12項目 (FACIT-Sp12) (文献2)

(5)Support Team Assessment Schedule日本語版 (STAS-J) (文献3)

1.2 観察・検査方法

観察・検査スケジュール

	1回目	2回目
日程	評価初日	翌日
(ア)医学的社会的患者背景 (加行)	○	
(イ)POS日本語版患者用 (患者)	○	○
(ウ)EORTC-QLQ-C-30日本語版 (患者)	○	
(エ)FACIT-Sp12 日本語版 (患者)	○	
(オ)POS日本語版家族用 (家族)	○	○
(カ)POS日本語版スタッフ用 (スタッフA)	○	○
(カ)POS日本語版スタッフ用 (スタッフB)	○	
(キ)STAS-J (スタッフB)	○	
研究実施場所	緩和ケア病棟 一般病棟 緩和ケア外来 一般外来	緩和ケア病棟 一般病棟 緩和ケア外来 一般外来

2 患者数と研究期間

2.1 患者数

目標患者数 150名。そのうち再テストを実施するのは目標50名。家族用・スタッフ用もそれと並行するので、目標数は同じとする。スタッフは複数の患者について評価するので延べ数とする。

2.3 研究期間

研究許可日から平成27年3月31日までとする。

3 統計解析

(1)研究対象者の背景要因を記述する。

(2)POS日本語版の信頼性・妥当性を計量的評価に基づき検討する。

① 項目分析

欠損値解析

② 信頼性の検討

test-retest法による再現性の検討。

評価者間の再現性の検討
内的整合性(internal consistency)の検討

③ 妥当性の検討

併存的妥当性(concurrent validity)の検討

弁別的妥当性(discriminant validity)の検討

構成概念妥当性(construct validity)の検討

IV章の引用文献

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2. Noguchi W, Ohno T, Morita S, et al. Reliability and validity of the Functional Assessment Chronic Illness Therapy-Spiritual (FACIT-Sp) for Japanese patients with cancer. *Supportive Care in Cancer*. 2004;12:204-245

3. Miyashita M, Matoba K, Sasahara T, et al. Reliability and validity of the Japanese version of the Support Team Assessment Schedule(STAS-J). *Palliat Support Care* 2004;2(4):379-85.

V 研究の成果等の公表予定(学会、雑誌)

平成27年3月31日まで患者登録を行なったのち、英語論文にして公表予定である。