Development of the knowledge test of medical instruments and materials for cancer chemotherapy

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Abstract

Background

Focusing on medical instruments and materials used for high-risk medicines for cancer treatments, a test on knowledge of medical instruments requiring acquisition of basic knowledge and materials was developed for students in pharmacy school. The aim of the study is to investigate the reliability and validity of the test (medical instruments and materials for cancer treatment-Questionnaire 45; MIMCT-Q45) we developed.

Methods

Focus group discussion was performed by participants consisting of medical staff considered to have abundant experience of cancer chemotherapy. Content analysis was performed and a list of extracted medical instruments and materials was prepared. A questionnaire survey was performed twice in pharmacy students to confirm reliability employing the retest method. Responses were also collected from nurses and pharmacists to investigate discriminative validity on comparison with the students. Furthermore, difficulty and discrimination were estimated using the item response theory (IRT).

Results

Thirteen types of medical instruments and materials were extracted and listed in the knowledge test. In the questionnaire survey, the overall Cronbach's α and interclass correlation coefficient were high, but Cronbach's α was slightly low (0.56-0.58) in some categories. The range of discrimination estimated based on IRT was 0.98-3.09, and that of difficulty was -0.91-3.00.

Conclusions

A knowledge test on cancer chemotherapy-related medical instruments and materials including palliative care at home (MIMCT-Q45) was prepared, and its reliability and validity were confirmed. MIMCT-Q45 might serve as a guidance on basic knowledge to be acquired by students and resident pharmacists and be useful to confirm the level of acquired knowledge.

Background

Reduction of incidents and medical errors involving drugs is an important medical issue [1] because it has been clarified that drugs are involved in about half of incidents and medical errors at medical practice sites [2,3], and prevention of these and minimizing negative influences of these on patients are likely to contribute to medical safety. Especially, many medicine used for cancer treatment, such as

anticancer drugs, psychotropic drugs, and narcotics for medical use, have a high risk [4-6], for which concentrated measures should be taken.

Measures to improve the safety and quality of cancer treatment, such as regimen registration system, intervention of wards and outpatient chemotherapy rooms by pharmacists, and certification system of pharmacists specialized in the oncology field, have recently penetrated clinical practice in Japan, with which the previous assignment to pharmacists, which are dispensing and drugs based on prescriptions and delivery within the occupational range, has been shifting to a new form being in charge of following patients from before and after drugs administration to outpatient treatment and treatment at home.

However, previous education concerning medical instruments and materials used to administer drugs was weak, and education concerning dealing with problems with equipment during drug administration, selection of medical materials used for drug administration, and medical devices frequently used in home health care (especially palliative care at home) and instruction of patients inevitably depended on physicians and nurses. Since physicians and nurses are not experts of medical instruments, further involvement of pharmacists in handling medical instruments and materials to administer drugs are needed, and educational targets to promote close involvement of pharmacists in medical instruments and materials were set in the revised core curriculum of pharmaceutical education enforced in 2015. However, the specific medical instruments and materials requiring acquisition of basic knowledge are not stated and no scale to measure whether the knowledge is presented.

Thus, in this study, focusing on medical instruments and materials used for high-risk treatment for cancer, we developed a knowledge test concerning medical instruments and materials requiring acquisition of basic knowledge for students.

Methods

1. Preparation of questionnaire and knowledge test

Focus group discussion was performed by participants consisting of one surgical oncologist (MD), 3 nurses with cancer-related certification, 2 pharmacists, one clinical engineer, and one well experienced and trained researcher (phD) assumed to have abundant experience of cancer treatment, in which specific medical instruments and materials requiring acquisition of basic knowledge and related knowledge were discussed. The discussion facilitated in accordance with the interview guide. The content of the discussion was entirely recorded. The tape was transcribed and converted to text which was returned to and confirmed by participants and subjected to content analysis.

A list of the medical instruments and materials extracted on content analysis was prepared and defined as ‘medical instruments and materials requiring acquisition of basic knowledge’. In addition, parts in which basic knowledge to be acquired were spoken by the medical instruments and materials were extracted by meaning and classified by the medical instruments and materials to prepare categories. In

addition to ‘correct’ and ‘false’, ‘I do not know’ was set as a choice to exclude unanswered and accidental correct answers as much as possible, and responses to a knowledge test were collected. Students in the 6th year of Faculty of Pharmacy and Pharmaceutical Sciences, University of Toyama, took the prepared pilot knowledge test as a pretest, and a complete version was prepared after discussion among several researchers. In addition, a questionnaire was prepared by adding questions concerning background of respondents.

2. Evaluation of validity and reliability of the knowledge test

To investigate reliability of the knowledge test, the questionnaire survey was performed in students twice with a 2-week interval to confirm reliability using the retest method. For the indices of reliability, the interclass correlation coefficient and Cronbach’s α were calculated. In addition, using a 2-parameter logistic model of item response theory (IRT) analysis, difficulty and discrimination of each item were estimated [7].

The surveys were performed in 4-5th year pharmacy school students of nationwide national, public, and private universities in Japan between January 2015 and March 2015. To verify discriminative validity of the knowledge test [8], the questionnaire survey was similarly performed in nurses and pharmacists (medical staff) belonging to cancer treatment base hospitals in Toyama, Japan to investigate whether the total score of medical staff is higher than that of students. The questionnaire survey was performed using the anonymous mailing method.

3. Statistics and analysis

1) Statistical analysis

For between-group comparison, the student *t*-test was used setting the significance level at <0.05. For the correlation coefficient, Pearson’s product-moment correlation coefficient was used. IRT analysis was performed using EasyEstimation version 2.00 [9], and the other analyses were performed using IBM SPSS version 22 (IBM Japan Ltd., Tokyo).

2) Content analysis

Content analysis was performed based on the method reported by Krippendorff et al [10]. Names of medical instruments and materials and related knowledge stated as those ‘requiring acquisition of knowledge’ and existing reports and their experience (incident reports, etc.) told by the participants of the discussion were extracted regarding a sematic content as one unit. The extracted sematic contents were inductively classified and abstracted following similarity, and several categories (names of medical instruments and materials/ basic knowledge to be acquired) were prepared. The above process was

performed independently by several researchers. Discussion was repeated until the results became consistent and the final conclusion was reached.

4. Ethical considerations

This study plan was approved by the Ethics Committee of University of Toyama (RIN26-11). All subjects (medical staff and students) were adults requiring no legal representative, and consent to participation in the focus group discussion was obtained after oral explanation of the content using documents. For the questionnaire survey, a consent form was sent with the questionnaire by postal mail to the subjects, and sending back responses to the questionnaire was regarded as consent to the study.

Results

1) Preparation of the knowledge test

The 13 types of medical instruments and materials shown in Table 1 were extracted from the focus group discussion by content analysis and listed in the knowledge test.

Table 1

Name of extracted medical instrument and material	Number of statements
Pump (common subjects)	20
Infusion pump	20
PCA* pump	11
Infusion line	9
Syringe pump	7
Infuser pump	7
Filter	5
Injection needle	3
Central venous port	2
Syringe	2
Drip Eye®	2
Catheter	1
Cufftee Pump®	1

*PCA: Patient Controlled Analgesia

2) Questionnaire survey

A total of 2,331 questionnaire forms were distributed to 36 universities per survey, and 14 universities replied (1st: 1,289 forms, 2nd: 1,201 forms). One university replied only once. The overall questionnaire collection rate was 53.4%. The background of the respondents is shown in Table 2.

Table 2 Characteristics of Participants

Item	Student	Medical personnel
Age (years, mean±standard deviation)	22.4±0.5	41.2±5.3
Sex (n, male/female)	1139/2568	28/417
Type of university (n, national & public/private)	841/2865	
Year of school (n, 4th/5th)	1883/1824	
Experience of practical training at hospital (n, no/yes)	2355/1351	
Years of clinical experience		12.2±8.7
Years of cancer treatment experience		4.9±4.6
Occupation (n, nurse/pharmacist)		362/83

3) Reliability and validity of the knowledge test (Table 3)

Overall, both Cronbach's α and the interclass correlation coefficient were high, but Cronbach's α of 'PCA pump' and 'other medical materials' was slightly low (0.56-0.58).

The mean score of the medical personnel (nurses and pharmacists) widely varied and biases of knowledge were present, whereas the score of the students was consistently lower significantly than that of the medical staff, and the overall effect size was 0.56 (medium).

The discrimination estimated by IRT ranged from 0.98 to 3.09, and that of difficulty ragged from -0.91 to 3.00. The total score tended to be higher in respondents who could correctly answer to questions with high discrimination.

Discussion

A knowledge test concerning medical instruments and materials of cancer treatment (medical instruments and materials for cancer treatment- Questionnaire 45 (MIMCT-Q45)) was prepared and its reliability and validity were confirmed. MIMCT-Q45, prepared focusing on medical instruments and materials used for high-risk cancer treatment including palliative care at home, may serve as a guidance on basic knowledge to be acquired by students and resident pharmacists and be useful to confirm the level of acquired knowledge.

In the responses from medical personnel collected as a positive control, the percentage of the score was high in items frequently used in routine practice, such as infusion pumps and syringe pumps, but it was low in some domains of items less frequently used, such as home health care-specific devices and materials, and the rate of correct answer was lower than 10% in 3 questions in the medical staff. Since MIMCT-Q45 is comprised of items considered important by experts of cancer treatment, it was concluded that a low percentage of the score in the medical staff does not indicate that the knowledge is

unnecessary. In particular, it might be useful to incorporate it into the educational curriculum of physicians.

The reason for the bias and variation in knowledge among the medical professionals was presumably due to the differences in the types of work they had experienced. The average age of the medical professionals in this study was about 40 years old, but the medical education that these people had received in Japan did not include a curriculum for learning about medical instrument and materials. Hence, they had to acquire the knowledge through hands-on experience. In particular, it is only recently that pharmacists have become involved in cancer chemotherapy and palliative medicine. In addition, the work involved in these areas is subdivided (e.g., those in charge of compounding anticancer drugs, those in charge of giving medication guidance in the wards, those in charge of giving medication guidance in outpatient clinics, and those in charge of home care), and the division of work is clearly defined, and the work assignment is hardly ever changed. It is suggested that this background of the medical field might have influenced the bias in knowledge.

In contrast, the percentage of the score in the students was lower than that in the medical staff in most items, suggesting that discriminative validity was verified. The percentage of the score was higher in the students than in the medical staff in a few items. These may have been unfamiliar medical instruments and materials even for medical staff, suggesting the necessity of on the-job-education.

The importance of knowledge related to infusion devices for home health care requiring close involvement of medical staff has also been pointed out [11, 12], but it was discussed from viewpoints of physicians and nurses in many cases, in which greater importance is attached to training and knowledge concerning administration of transfusion and drugs [13]. In Japan, pharmacists do not have a right to prescribe or directly administer drugs in response to instruction from physicians, for which required knowledge and training programs (interactions between infusion devices and drugs and troubleshooting) may be different. Accordingly, the systematically constructed knowledge required for resident pharmacists and pharmacy students may be the important first step toward providing safe medical care.

There were several limitations of this study. Since MIMCT-Q45 was prepared aiming at widely measuring knowledge concerning several medical instruments and materials, important education items may have been overlooked. However, the amount of required knowledge concerning only infusion devices is too large to cover entire knowledge. Therefore, this knowledge test on limited targets may be useful to measure the educational effect. Since MIMCT-Q45 was developed mainly targeting Japanese pharmacy school students, it was prepared so as to match the medical state in Japan. Accordingly, to apply it to other countries and occupations, modification may be necessary in several items.

Conclusion

In conclusion, MIMCT-Q45 targeting pharmacy students and resident pharmacists was developed. Development of educational materials concerning ‘medical instruments and materials requiring acquisition of knowledge’ and measurement of its educational effect using MIMCT-Q45 remain as tasks.

Abbreviations

MIMCT-Q45
medical instruments and materials for cancer treatment-Questionnaire 45
IRT
item response theory

Declarations

Acknowledgements

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Authors’ contributions

KT and KH made a substantial contribution to the concept or design of the work; or acquisition, analysis or interpretation of data. KT, AN, HO, and HY drafted the article or revised it critically for important intellectual content. KT, HO, and KH have participated. All authors approved the version to be published.

Availability of data and materials

The datasets used in the study are available from the corresponding author on reasonable request.

Ethic approval and consent to participate

This study plan was approved by the Ethics Committee of University of Toyama (RIN26-11).

Competing interests

The authors declare no competing interests.

References

1. Kawamura H. 2002. The analysis of Hiyari-Hatto reports for prevention of medication errors and falls. J Jpn Soc Health Care Manage. 2002;2:265-9.
2. Funakoshi S, Nakamura M, Yamasaki M, Ohno S, Waki H, Matsuda S, Takeda K, et al. The Effect of Grasp and Consideration of Medication-related incidents on Medical Safety by Pharmacists in the Ward. J Jpn Soc Hosp Pharm. 2014;50:853–7.
3. Ministry of Health, Labour and Welfare. In: Medical Council Meeting Report, June 26, 2000. Analysis of Hiyari-Hatto episodes. 2000. http://www1.mhlw.go.jp/houdou/1206/h0626-1_10.html. Accessed 10 Nov 2017.
4. Sugiura S, Gohma H, Hamajima N. Measures of Preventing Occupational Exposure to Hazardous Drugs - Based on New Insights. Jpn J Cancer Chemother. 2014;41:923–5.
5. Amino Y, Oi T, Fukuda Y, Michishita K, Tatsuno M, Tatsumi M. The Management of Chemotherapy Regimen on the Electronic Medical Record. Jpn J Cancer Chemother. 2014;41:1135–8.
6. Yamamot H, Kitada N, Shibatani N, Hirabatake M, and Hashida T. Role of Pharmacists in Introduction of New Drugs for the Minimization of Risk - In Case of Denosumab. Jpn J Drug Inform. 2014;16:28–32.
7. Streiner DJ. Health Measurement Scales: A Practical Guide to Their Development and Use. 4th ed. New York: Oxford University Press; 2008.
8. Murayama K. Validity. Historical and Psychometric Perspectives. The Annual Report of Educational Psychology in Japan. 2012;51:118-30.
9. Kumagai R. 2009. GUI Development of IRT analysis programs for beginners: EasyEstimation series. Jpn J Res Testing. 2009;5:107-18.
10. Krippendorff K. Content Analysis: an Introduction to Its Methodology. Beverly Hills: Sage Publications; 1980.
11. Beer JM, McBride SE, Mitzner TL, Rogers WA. Understanding challenges in the front lines of home health care: a human-systems approach. Appl Ergon. 2014;45:1687–99.
12. Lyons I, Blandford A. Safer healthcare at home: Detecting, correcting and learning from incidents involving infusion devices. Appl Ergon. 2018;67:104–14.
13. Kim UR, Peterfreund RA, Lovich MA. Drug Infusion Systems: Technologies, Performance, and Pitfalls. Anesth Analg. 2017;124:1493–505.

Table 3

Table 3 Item analysis and item response theory of MIMCT-Q45

Question	T/F	Correct answer				IRT		ICC	Cronbach's α
		Students	Medical stuff	P value	ES	discrimination	difficulty		
Common subjects of electric echanical) pumps used to minister drugs		39.0	51.7	<0.001	0.42			0.86	0.68
q1 Generally, electric pumps ve alarm function against ockade and bubbles.	T	47.9	91.0			1.74	0.12		
q2 Setting 2 of variables: the low rate, administration time, and planned dose, subsequently set the remaining one variable.	T	42.5	49.2			0.98	0.38		
q3 Most episodes in nursing by e field are related to injection d infusion.	T	37.5	44.3			1.33	0.56		
q4 Incidents caused by mistakes n setting and operation of electric pumps account for less than half of episodes.	F	27.4	19.1			1.48	0.89		
q5 Normally, electric pumps are uipped with a free-flow evention device.	T	39.8	55.1			1.88	0.40		
Infusion pump		41.3	61.8	<0.001	0.69			0.89	0.69
q6 There are dripping- and volume-control types of flow rate control system of infusion pump	T	35.2	37.1			2.15	0.56		
q7 There are stationary and portable types corresponding to the use condition of infusion pump.	T	49.0	58.4			1.95	0.05		
q8 Infusion pumps send solution pressing the tube set in the it.	T	15.9	58.7			1.02	1.88		
q9 Uncleanness in the pump unit has a negative influence on the accuracy of flow rate.	T	72.4	87.6			1.80	-0.91		
q10 The cover of infusion pumps equipped with a free-flow prevention device can be opened while the clamp is open.	F	34.1	67.2			2.03	0.51		
Syringe pump		38.0	64.4	<0.001	0.87			0.86	0.64
q11 Generally, the injection accuracy of syringe pumps is higher than that of infusion pumps.	T	39.5	81.8			1.19	0.46		
q12 Syringe pumps are suitable injection of a large volume of usion solution.	F	57.7	93.0			1.39	-0.34		
q13 Drug solution is not injected less the plunger is completely .	F	18.7	29.2			1.06	1.54		
q14 Solution is continuously njected by setting a rigid syringe and pressing the plunger at a constant speed.	T	36.1	53.5			1.98	0.54		
4. Infuser pump		33.1	48.3	<0.001	0.45			0.88	0.75
q15 Infuser pumps continuously administer drug solution using a balloon, atmosphere, or spring as a driving force.	T	41.8	59.3			2.55	0.34		
q16 Infuser pumps are used for continuous administration of anticancer drugs and narcotics for medial use.	T	43.3	67.6			2.14	0.29		
q17 Since infuser pumps are	F	41.0	52.1			2.30	0.35		

equipped with a flow rate-control system, the viscosity and temperature of drug solutions do not influence the flow rate.								
q18 Flow rate-control systems have a function to remove a trace amount of bubbles to prevent them from entering the patient's body.	F	6.4	14.2		1.15	2.69		
PCA pump		24.0	34.3	<0.0010.39			0.89	0.58
q19 PCA is an abbreviation of Pain Care Adjustment Method representing a method for physicians to flexibly adjust the dose of analgesics.	F	7.1	6.5		1.02	3.00		
q20 Using a PCA pump, patients can administer injection (analgesics) in their judgment when they feel pain.	T	37.3	72.4		1.45	0.65		
q21 In electric PCA pumps, complex administration methods can be programmed and history of administration can be recorded.	T	33.4	31.5		2.11	0.61		
q22 In balloon-type PCA pumps, the lockout time and flow rate can be freely changed.	F	18.2	27.0		1.80	1.33		
Drug injection controller (Drip Me®)		16.1	12.1	0.004 0.16			0.92	0.68
q23 Drug injection controller is a dripping control-type infusion pump.	F	5.6	3.6		1.57	2.30		
q24 Similar to volume control-type infusion pumps, it has an alarm function against blockade and free flow-preventive function.	T	24.8	16.0		3.09	0.80		
q25 Compared with volume control-type infusion pumps, it reduces the risk of extravasation.	T	22.6	15.7		2.75	0.89		
q26 Drug injection controller can also be used for precision microinjection, arterial administration, and blood transfusion.	F	11.6	13.0		2.18	1.50		
Infusion line (infusion set/drip infusion line)		36.4	54.2	<0.0010.69			0.90	0.81
q27 Infusion lines represent medical instruments to inject infusion solution into patients.	T	63.4	90.3		1.54	-0.54		
q28 Infusion lines are comprised of bottle needles, drip tubes, clamps, and connecting parts.	T	53.2	79.3		2.05	-0.07		
q29 A bottle needle is connected to the end of the infusion line and inserted into patients to fix the line.	F	15.1	57.1		1.19	1.76		
q30 There are various types of infusion line, such as those for general use, adults, and blood transfusion.	T	34.3	59.8		1.29	0.59		
q31 The same infusion line can be used for infusion by natural dropping and using an infusion pump.	F	36.0	61.6		1.78	0.52		
q32 A metal needle is used in a drip tube of a 1-mL =20 drops	F	7.1	40.9		1.48	2.25		

ype infusion line, for which ıttention should be paid to ıydrophilization.								
ı33 Plasticizer is added to soften he tube material for easy nolding.	T	35.5	29.0		1.53	0.61		
ı34 Regarding inscription of ube materials, the meanings of VC-Free and DEHP-Free are he same.	F	31.8	33.5		1.89	0.68		
ı35 Joints of an infusion line orming a dead space cause nfection.	T	55.7	68.1		2.46	-0.13		
ı36 Products in which olycarbonate is used for the oints may get cracked lepending on the drug infusion ıdministered.	T	32.0	22.2		2.55	0.62		
Filter		27.6	22.1	<0.0010.21			0.86	0.63
ı37 A filter incorporated in an usion line is termed in-line filter.	T	48.6	61.3		2.11	0.09		
ı38 To remove bacteria, a 0.45- ı filter with a homogeneous pore e is used.	F	21.4	10.6		1.18	1.49		
ı39 To remove glass fragments oduced by cutting an ampule, a 3-µm filter is used.	T	25.2	14.8		1.64	1.01		
ı40 When clogging of filters by changes in compounding of nfusion solution is concerned, ıo filter is used.	F	23.2	17.8		1.20	1.36		
ı41 Filters with a function to emove air mixed in infusion solution comprised of only a ıydrophobic membrane.	F	19.6	5.8		2.22	1.10		
Other medical supplies jection needle, injection syringe, port, catheter etc.)		23.2	29.6	<0.0010.24			0.90	0.56
ı42 When drug solution is emoved from an anticancer lrug vial, a regular bevel needle s used.	F	12.6	5.8		1.31	1.87		
ı43 For puncture into the port of the central vein, a Huber- ointed needle is used.	T	19.2	40.7		2.81	1.04		
ı44 When an anticancer drug is ıandled, a slip tip-type syringe is ısed.	F	13.0	13.7		1.35	1.77		
ı45 To prevent exposure to ınticancer drugs, it is desirable o use closed adjustment nstruments and exclusive nfusion line.	T	48.1	58.0		2.02	0.17		
erall		32.0	43.9	<0.0010.56			0.90	0.94

IRT: Item response theory, ICC: Interclass correlation coefficient