

Equivalence of apps and paper-based patient-reported outcome measures: From a multicenter observational study on CIPN prevention (KBCRNA004)

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ABSTRACT

Introduction

As the prognosis of breast cancer patients improves, the importance of evaluating side effects and QOL is increasing. App-based PROs has been introduced, however there is limited knowledge of the accuracy and characteristics of app-based PROs. We are conducting a prospective, multicenter observational study (KBCRNA004) on prevention of chemotherapy-induced peripheral neuropathy in breast cancer patients planning to receive paclitaxel or albumin-suspended paclitaxel. In this study, we evaluate PNQ using both paper and apps. Here, we report on a comparison of paper and

app data using data from first 50 cases registered in the study.

Methods

PNQ is collected using App weekly, while paperbased PNQ is collected for each of the left and right hands and foot at the time of outpatient visit (D1 of cycles 1, 4, 7, 10 and C12D8 for weekly paclitaxel therapy, and 6, 12, 18, and 24 months after the end of Taxanes. We evaluated the equivalence of PNQ scores using evaluation points within 4 days of the paper evaluation date and the app evaluation date.

Results

Thirty-five out of 50 patients use the app. The paper-based PNQ in 35 cases had total 833 points for both sensory and motor. The median difference between the scheduled evaluation date and the actual input date was 1.0 (IQR 0.6. 2.9) (days). When the evaluation date and input date were within 1 day, 2 days, and 3 days, the weighted k values, indicating the degree of agreement, were 0.797, 0.808, 0.721 (motor), 0.872, 0.875, and 0.834 (sensory), respectively,

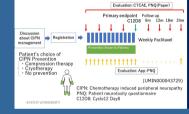
Conclusions

There was good equivalence between paper and app in CIPN evaluation. The app can be used as an alternative to paper, and if we are careful about recall bias we believe appbased PRO is highly useful because it allows us to collect information timely.

INTRODUCTION

- · As the prognosis of breast cancer patients improves the importance of evaluating side effects and OOL is increasing App-based PROs(Patient reported outcomes)has been introduced, however there is limited knowledge of the accuracy and characteristics of App-based PROs.
- · We are conducting a prospective, multicenter observational study (KBCRNA004) on prevention of chemotherapy-induced peripheral neuropathy in breast cancer natients planning to receive paclitaxel or albumin-suspended paclitaxel. In this study, we evaluate PNO using both paper and apps.
- · Here, we report on a comparison of paper and App data using data from first 50 cases registered in the study.

[Shema of KBCRNA04] Multicenter observational study on prevention of chemotherapy-induced peripheral neuropathy in breast cancer patients planning to receive paclitaxel or albumin-suspended paclitaxel



METHODS AND MATERIALS

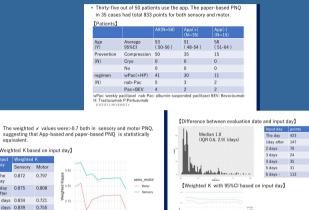
- PNO(Patient neurotoxity questionnaire) is an established natientreported outcome scale to evaluate CIPN
- In KBCRNA004, App-based PNQ is collected using App weekly. while naner-based PNO is collected for each of the left and right hands and foot at the time of outpatient visit (D1 of cycles 1, 4, 7 10 and C12D8 for weekly paclitaxel therapy, and 6, 12, 18, and 24 months after the end of Taxanes)
- A pair of App-based and paper-based PNO data of a part is defined as 1 point



 We evaluated the equivalence of PNO scores Chemotherapy using evaluation points within 4 days of the paper evaluation date and the app evaluation date. App-based (the weighted ĸ values>0.6 is considered as statistically equivalent) Paper-base



RESULTS



Summary of Results

- · Thirty-five out of 50 patients use the App.
- The weighted k values were>0.7 both in sensory and motor PNO, suggesting that App-based and paper-based PNO is statistically equivalent
- · When the evaluation date and input date were within 1 day, 2 days, and 3 days, the weighted κ values, indicating the degree of agreement, were 0.797, 0.808, 0.721 (motor), 0.872, 0.875, and 0.834 (sensory), respectively.

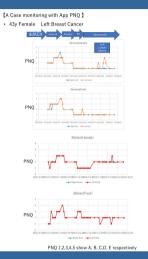
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CONCLUSIONS

- · There was good equivalence between paper and App in CIPN evaluation
- · The App can be used as an alternative to paper, and if we are careful about recall bias. We believe App-based PRO is highly useful because it allows us to collect information timely

COI

 Dr. Kawaguchi-Sakita reports personal fees from Chugai, personal fees from Dalichi-Sankyo, grants from Fuji Chemical Industrial, personal fees from Fujitsu, personal fees from Kyowa Kirin, personal fees from Meiji Seika Pharma, personal fees from Nippon Kayaku, personal fees from Pfizer, personal fees from Yakult, personal fees from NTT, personal fees from PRiME-R, personal fees from CANNON Medical, personal fees from HUG, personal fees from NTT-DATA, personal fees from IHC, grants from Kansai Medical Net, personal fees from Taiho, personal fees from Eisai, personal fees from Astra Zeneca, personal fees from Zene, outside the submitted work;

(Kuroi K, FH Hausheer et al,2008)

1 2 3 4 5 6 7 8 9 10 Dave

equivalent

The 0.872 0.797

1day 0.875 0.808

ofter

[PNQ]

2 days 0.834

3 days 0.839

4 days 0.819

5 days 0.824

All 0.763

[Weighted K based on input day]

Sensory Motor

0.721

0.755

0.761

0.769

0 714