Development and Validation of a Questionnaire on Knowledge, Attitude, and Perception Towards Allergic Reactions of Paracetamol

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ABSTRACT

Introduction: National Pharmaceutical Regulatory Agency, Ministry of Health Malaysia has received 1018 adverse drug reaction reports related to paracetamol with 1972 adverse events from the year 2000 to February 2015. Serious skin reactions including Stevens–Johnson syndrome (SJS), toxic epidermal necrolysis, and acute generalized exanthematous pustulosis may develop as a result of allergic reactions of paracetamol. This study aimed to develop and validate a questionnaire regarding Knowledge, Attitude, and Perception towards Allergic Reactions of Paracetamol (KAP-ARP) among the general population.

Materials and Methods: Content and face validity of the KAP-ARP were determined by four experts and 20 respondents, respectively. A questionnaire with 36 items, consisting of 16 Knowledge, 9 Attitude, and 11 Perception items, was distributed to 177 respondents. Exploratory factor analysis (EFA) was performed for construct validity. Cronbach’s alpha was used to determine the reliability of the questionnaire.

Results: EFA constructed 13 Knowledge, 8 Attitude, and 8 Perception items. The final KAP-ARP questionnaire is reliable based on its internal consistency reliability (Knowledge: α = 0.78; Attitude: α = 0.63; Perception: α = 0.70). Conclusion: A valid and reliable questionnaire that is useful for measuring KAP-ARP among the general population has been developed.

Keywords: Allergic reaction, development, paracetamol, questionnaire, validation

INTRODUCTION

Paracetamol is a common nonopioid analgesic and it is also well-known as nonsteroidal antiinflammatory drugs (NSAIDs) with a favorable safety profile. It is a drug of choice and is available worldwide as an analgesic and antipyretic.[1]

In the Adverse Drug Reactions report 2014, paracetamol is one of the top analgesics as suspected drugs with 213 reports that cause adverse effects like urticarial, itching, and rash maculo-papular.[2] Paracetamol has been associated with the risk of rare but serious skin reactions. Examples of serious skin reactions are Stevens-Johnson syndrome (SJS), toxic epidermal necrolysis (TEN),[3] and acute generalized exanthematous pustulosis (AGEP).[4]

Based on a review done by the US FDA, there were 107 reports of serious skin reactions.[8] It mostly involved single active ingredient paracetamol product. Three cases reported positive rechallenge, where the patients developed relapse of serious skin reactions after consuming paracetamol over again.[9] National Pharmaceutical Regulatory Agency (NPRA) had received 1018 adverse drug reaction reports related to paracetamol with 1972 adverse events from the year 2000 to February 2015.[9] Seventy-eight percent of the total 790 reports involved showed at least one skin reaction, like pruritus, rash, urticaria, and angioedema.

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Serious skin reactions involved 18 reports on SJS, five on erythema multiforme, four on TEN, two on SJS-TEN overlap, and one AGEP. A rare or uncommon case of SJS-TEN overlap syndrome was reported after a formerly healthy child ingest three 500 mg paracetamol tablets given at an interval of 8 h.\(^\text{[4]}\)

According to Nuttall \textit{et al.},\(^\text{[6]}\) asthma seems to be connected with paracetamol consumption and that those patients with more severe asthma consumed paracetamol more frequently. The most reasonable explanation, which was extensively discussed by Shaheen \textit{et al.},\(^\text{[7]}\) is that paracetamol decreases the availability of glutathione, which is an essential antioxidant. The lack of antioxidants renders the asthmatics susceptible to free radical damage, inflammatory responses, and bronchospasm.

Several cases of allergic reactions to paracetamol have been reported in the literature including a recent report in Japan, which described an anaphylaxis to paracetamol diagnosed by skin prick test (SPT).\(^\text{[8]}\) The patient developed urticarial and dyspnea and exhibited positive reaction to SPT after a few minutes of administering paracetamol. Based on the SPT results, IgE-mediated anaphylaxis due to paracetamol was diagnosed.\(^\text{[8]}\) In Turkey, a 51-year-old woman developed swelling and redness reactions more than 3 mm to prick test.\(^\text{[9]}\) An allergic reaction associated with paracetamol was diagnosed as a result of the prick test.\(^\text{[9]}\) Misirlioglu \textit{et al.}\(^\text{[10]}\) reported a 3-year-old boy diagnosed with multiple fixed drug eruption (FDE) induced by paracetamol as a result of developing same-site skin lesions after each intake of paracetamol to treat fever.

Paracetamol hypersensitivity is thought to be immunologically or non-immunologically mediated. Skin tests, oral challenges, and serum IgE results with paracetamol suggested that an IgE-mediated mechanism was responsible for these reactions.\(^\text{[11]}\) Non-immunologically, the drug functions as a weak inhibitor of cyclooxygenase-1 and increased leukotriene synthesis may be the mechanism of paracetamol hypersensitivity.\(^\text{[12]}\)

There is a need to conduct more research that may help to identify the knowledge, attitude, and perception towards allergic reactions of paracetamol among the general population. Knowledge is defined as what a person knows and what is stored in the human brain. It is not called as knowledge if none individuals do not recognize it.\(^\text{[3]}\) Attitude is defined as a mental or neutral state of readiness, organized through experience, exerting a directive or dynamic influence on an individual’s response to all objects and situations to which it is related.\(^\text{[13]}\) Perception is defined as receiving sensory patterns that come from mental processes. It produces an interpretation of sensation.\(^\text{[13]}\)

A questionnaire is a common and well-established tool for gathering information related to the concern of interest from individuals.\(^\text{[3]}\) The development of a questionnaire consists of six steps: conceptualization and research design, questionnaire design, testing, revision, data collection as well as process monitoring and evaluation.\(^\text{[3]}\) Reliability is the consistency of measurements or tests.\(^\text{[14]}\) It refers to the degree to which measurements or tests can be repeated. In order to consider results produced from a study as valid, the measurement procedure must first be reliable. There is a need to develop a validated questionnaire that assesses the knowledge, attitude, and perception towards allergic reactions of paracetamol. Thus, this study sought to develop and validate a questionnaire regarding Knowledge, Attitude, and Perception towards Allergic Reactions of Paracetamol (KAP-ARP) among the general population.

**MATERIALS AND METHODS**

**Study design**

A cross-sectional study was conducted from August 1 to September 1, 2016 at public congregation around Pasar Siti Khadijah, Kota Bharu to examine the validity and reliability of the English-version KAP-ARP questionnaire. Individuals older than 18 years were enrolled in this study. This study applied convenience sampling, in which the respondents were approached conveniently to participate in the study. The respondents were given a brief explanation about the study. All respondents gave written informed consent. Ethical approval was obtained from the Cyberjaya University of Medical Sciences (CUCMS) Research Ethics Review Committee (CRERC) (Reference number: CUCMS/CRERC/ER/020).

**Development of questionnaire**

Items for the preliminary questionnaire were developed based on the literature searches, because there was obviously no validated questionnaire available regarding the study of knowledge, attitude, and perception towards allergic reactions of paracetamol yet. As for this research, all information regarding paracetamol allergic reactions from either locally or internationally has been taken into account based on the reports, case studies, and bulletins from NPRA Malaysia.

The questionnaire consisted of three main domains, namely Knowledge, Attitude, and Perception.
Knowledge was defined as the respondents’ knowledge about paracetamol, including the brand name of paracetamol, indications, possible development of allergic reactions towards paracetamol, and symptoms of allergic reactions of paracetamol. A total of 16 Knowledge items were developed for the preliminary questionnaire, including three negatively structured items, K 4, K 6, and K 8.

The final questionnaire contained 13 Knowledge items. This domain was divided into two sections, which were general knowledge regarding paracetamol (3 items) and knowledge towards allergic reactions on paracetamol (10 items). A correct response scored as “1,” whereas a wrong and a “do not know” answer scored as “0.” Reverse scoring was used for negatively structured items. Only items in the knowledge towards allergic reactions on paracetamol section were evaluated during data analysis. Thus, the possible score range for the Knowledge domain was 0–10 scores. Scores were converted to a percentage, ranging from 0 to 100%. A score of ≥60% was considered “Positive Perception” while a score of <60% was considered “Negative Perception.”

Validation process
Three types of validities were determined for the KAP-ARP questionnaire. These included content validity, face validity, and construct validity. For content validity, the first draft of the questionnaire (51 items) was reviewed by an expert panel, comprising a quantitative researcher, a pharmacist, an endocrinologist, a medical doctor, and an English language expert with many years of research and clinical experience. They reviewed the questionnaire individually and rated based on content relevance, clarity, simplicity, and ambiguity of each item in the questionnaire. The items were remained, paraphrased, or removed based on the comments and opinions from the experts involved. Of the 51 items in the first draft of the questionnaire, two items were removed.

After the determination of content validity by the expert panel, the questionnaire (49 items) was pretested among 20 respondents for face validity. Their comments and suggestions were taken into consideration, which were later thoroughly discussed and streamlined by the expert panel and the research team. Of the 49 items in the second draft of the questionnaire, 13 items were removed. The questionnaire was then made available for construct validity and reliability study.

One hundred and seventy-seven respondents were recruited in order to examine the construct validity and reliability of the KAP-ARP questionnaire. Five respondents to one variable ratio (5:1) was used for sample size calculation. This study needed a minimum of 175 respondents to validate the final version of the questionnaire because there were 35 items in the preliminary questionnaire.

Statistical analysis
Descriptive statistics were used to describe the demographic characteristics. For construct validity study of the KAP-ARP questionnaire, an exploratory factor analysis (EFA) with principle component analysis and varimax rotation were performed to determine the number of factors influencing the variables and to analyze the variables that belong together. Sample adequacy and factorability of an intercorrelation matrix were measured using the Kaiser–Meyer–Okin (KMO) test and Barlett’s test of sphericity, respectively. Eigenvalue (>1) rule method was used to determine the number of factors to retain. Internal consistency reliability of the KAP-ARP questionnaire was assessed.
using Cronbach’s alpha. Cronbach’s alpha statistic was conducted separately for Knowledge, Attitude, and Perception domain. Cronbach’s alpha value of 0.8 was considered reliable and 0.7 was considered as minimal acceptable. Statistical analysis was done using Statistical Package for the Social Sciences SPSS/Win software (Version 21.0, SPSS, Inc., Chicago, IL, USA).

Results

Demographic characteristics
One hundred and seventy-seven respondents completed the questionnaire. A majority of them (n = 121, 68.4%) were female. Most of them (n = 167, 94.4%) were Malay, while others were non-Malay which included Chinese, Indian, and others [Table 1].

Content and face validity
A total of 51 items were developed for the first draft of the questionnaire. Based on the comments provided by the expert panel, few items were paraphrased and removed. The items in the second draft of the questionnaire (49 items) were grouped into domains of Knowledge, Attitude, and Perception. Based on the comments and suggestions from 20 respondents and on further discussion with the expert panel, some items were found to be too technical for the general population, were repetitive of similar items in the literature reviews, and had insufficient explanation of SJS/TEN. Thus, 13 items were deleted and the definition was improved.

The process of content and face validity retained 36 items that consisted of 16 Knowledge items, 9 Attitude items, and 11 Perception items.

Construct validity
Kaiser–Meyer–Olkin and Bartlett’s test of sphericity results showed that Knowledge, Attitude, and Perception items met the criteria required for EFA. Table 2 shows the results of EFA for the Knowledge domain of the KAP-ARP questionnaire. In the final Knowledge domain, two components were identified with 13 items retained from the initial 16 items. The deleted items were K 4, K 5, and K 6. Items K 1, K 2, and K 3 were classified as general knowledge of paracetamol and the other 10 items were classified as knowledge towards allergic reactions to paracetamol.

In the Attitude domain, eight items were retained from the initial nine items. Table 3 shows the results of EFA for the Attitude domain of the KAP-ARP questionnaire.

Table 1: Demographic data of respondents (n = 177)

| Variable                   | N  | %  |
|----------------------------|----|----|
| Gender                     |    |    |
| Female                     | 121| 68.4|
| Male                       | 56 | 31.6|
| Age, years                 |    |    |
| <25                        | 75 | 42.4|
| 26–35                      | 56 | 31.6|
| 36–45                      | 24 | 13.6|
| 46–55                      | 17 | 9.6 |
| >56                        | 5  | 2.8 |
| Race                       |    |    |
| Malay                      | 167| 94.4|
| Non-Malay                  | 10 | 5.7 |
| Highest academic qualification |    |    |
| Masters/PhD                | 2  | 1.10|
| Bachelors degree           | 54 | 31.5|
| Pre-university/diploma     | 72 | 40.7|
| High school                | 45 | 25.4|
| Others                     | 4  | 2.3 |
| Employment status          |    |    |
| Student                    | 53 | 29.9|
| Employed                   | 96 | 54.2|
| Unemployed                 | 19 | 10.7|
| Others                     | 9  | 5.1 |
Table 4 shows the results of EFA for the Perception domain of the KAP-ARP questionnaire. Two groups were identified: items P 5, P 7, and P 8 were grouped in component 1 and the other 11 items were grouped in component 2. After discussion with the expert panel, the items P 5, P 7, and P 8 were deleted.

**Internal consistency reliability**

Cronbach’s alpha coefficient for the Knowledge domain increased when the items K 4 and K 5 were deleted. The Cronbach’s alpha coefficient for the Attitude domain did not increase when the items other than item A 4 were deleted. For the Perception domain, the items P 5, P 7, and P 8 were not strong enough as their Cronbach’s alpha coefficient was less than 0.6 and, hence, these items were considered to be deleted. The Cronbach’s alpha for the final Knowledge, Attitude, and Perception domains of the KAP-ARP questionnaire were 0.78, 0.63, and 0.70, respectively.

**Discussion**

Surveys are primarily used to collect quantitative information to measure people’s knowledge, attitudes, and perceptions by using close-ended questions. The main benefits of data gathering methods by using questionnaires are standardization and ease of interpretation. The main objective of this paper was to report the validity and reliability of the newly developed English-version questionnaire on the KAP-ARP. This study was the first to systematically develop and validate the KAP-ARP questionnaire. To the best of our knowledge, there are no other studies conducted to develop and validate the KAP-ARP questionnaire. The results of this study are important because it fulfilled the need for a reliable and valid questionnaire to assess the knowledge, attitude, and perception towards allergic reactions of paracetamol.

In this study, the pre-tested questionnaire underwent judgment stage, where all the professional opinions of the expert panel were evaluated. The content of the questionnaire was assessed based on its accurateness, clinical terminology, comprehensiveness, and significance of all statements. Besides, spelling and English grammar was also checked by an English expert.

In the determination of face validity, 20 samples of respondents were approached. The samples had the same criterion for the target population. This phase is needed to check on the readability, feasibility, and
general formatting of the instrument.\textsuperscript{[24]} Besides, Hiew et al.\textsuperscript{[23]} revealed that face validity is used to determine the pertinence of the test based on the respondents’ perception. All suggestions for the improvement of the questionnaire in this study were taken into consideration and amendments were done as required.

For construct validity of the KAP-ARP, all data collected from 177 respondents were subjected to EFA. Yong and Pearce\textsuperscript{[26]} stated that EFA is used to determine the number of factors influencing the variables and to analyze the variables that belong together. As for this study, both KMO and Bartlett’s test of sphericity results showed adequate sample and appropriateness. This is based on KMO value more than 0.5.\textsuperscript{[27]} Meanwhile, the Barlett’s test of sphericity result was based on P-value < 0.05, which is considered to be significant.\textsuperscript{[29]}

For knowledge factor, two subsections were developed as the K 1, K 2, and K 3 items with factor loading of 0.86, 0.79, and 0.74, respectively, were independently strong together in a component that was excluded from other items. These items were then classified under general knowledge of paracetamol and were not evaluated during data analysis. Item K 8 was a negatively worded question which required reverse scoring. Negatively worded question increases cognitive process and is useful to disrupt unwanted answer sets.\textsuperscript{[29]} Besides, items were reverse phrased to minimize biased answer and acquiescent bias from respondents.\textsuperscript{[30]}

For attitude factor, following the factor analysis based on fixed number of two and reliability test, only item A 4 was deleted because it had a low factor loading and it did not belong to any component in the rotated component matrix. Thus, only eight items remained in the attitude factor.

For perception factor, item P 1 was excluded in factor analysis as it was a “dummy question.” Following factor analysis based on fixed value of two and reliability test, three items P 5, P 7, and P 8 were deleted. These three items belong together in a component and the other items were grouped together in another component. However, items P 5, P 7, and P 8 were not strong enough as their Cronbach’s alpha coefficient was less than 0.6. Hence, after expert advice, these three items were deleted as it they would not give much influence to this research study.

One way to determine the reliability of the instrument is by using the internal consistency reliability.\textsuperscript{[25]} Most articles accept a value of 0.7–0.8 for Cronbach’s alpha.\textsuperscript{[31]} However, the lower acceptable Cronbach’s alpha values are 0.6–0.65 which might probably be clarified by considering at the specific items.\textsuperscript{[32]} Saiful and Yusof\textsuperscript{[33]} accepted Cronbach’s alpha value more than 0.6 for internal consistency. Poor alpha value is between 0.5 and 0.6 and unacceptable alpha value is below than 0.5.\textsuperscript{[34]} For internal consistency reliability, knowledge, attitude, and perception domains of the KAP-ARP questionnaire have obtained Cronbach’s alpha coefficients of more than 0.6. The Cronbach’s alpha coefficients comply with the recommendations for exploratory research. This study reported that the English-version questionnaire on the KAP-ARP had good reliability.

Following EFA and reliability test, further discussions with the expert panel were conducted. The final questionnaire consisted of 29 items all together (available upon request). These items were divided into three domains which are Knowledge (13 items), Attitude (eight items), and Perception (eight items). Only Knowledge domain had two subsections which entitled as general knowledge of paracetamol and knowledge towards allergic reactions of paracetamol.

Scales for the final questionnaire in this research were “yes,” “no,” and “do not know” for Knowledge domain, while a five-point Likert scale with “strongly disagree,” “disagree,” “neutral,” “agree,” and “strongly agree” were used for both attitude and perception domains. Most internationally published journals used Likert scales for attitude and perception domains. This Likert technique was used by at least 21 articles that were published in the Journal of Extension.\textsuperscript{[35]} Boone and Boone\textsuperscript{[36]} concluded that Likert method is easy to be interpreted.

There is a limitation of this study. This study was conducted using an English-version questionnaire. Nevertheless, it is still possible to translate the questionnaires into Malay version.

The findings of our current study have a number of practical implications for future research. It is appropriate to further continue this study by translating the English-version questionnaire on the KAP-ARP into Malay version as most of the general population in Malaysia use Malay as their communication language. As the translated questionnaire is established, later it can be used to further investigate the knowledge, attitude, and perception towards allergic reactions of paracetamol among Malaysian population in larger numbers. Further actions such as the education of the general population about allergic reactions of paracetamol could be planned. Besides, making the English-version questionnaire on the KAP-ARP available to researchers all over the world increases the possibility for other researchers to further the
CONCLUSION
As a conclusion, a newly developed questionnaire on Knowledge, Attitude, and Perception towards Allergic Reactions of Paracetamol (KAP-ARP) has been developed and validated. This instrument can serve as an important tool to evaluate knowledge, attitude, and perception towards allergic reactions of paracetamol among the general population.

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Conflicts of interest
There are no conflicts of interest.

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