What Label Design of Ampule for Injection, Do You Want?

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1 Background

Since “To Err Is Human: Building a Safer Health System (Institute of Medicine publication, USA, 1999)” has published, the interest to accidents which happened in medical institutions has spread to the general public in Japan. And over half number of incident reports in medical institutions is related to medication. The factors which induce medication error are look-alike of the preparations, sound-alike of preparation’s trade name, calculation error of dosage and so on.

The healthcare professionals generally recognize the pharmaceutical preparations visually. So, to identify a preparation correctly, the design of the preparation label is important. In the small size preparations like the ampule and the vial for injection. the lots of information are required to write by regulation in the limited narrow space. As a result, the preparation’s trade name on the label should be written in small font size, and the medical staff have a potential for the mistaking the preparations and the misunderstanding pharmacological action (therapeutic purpose).

In Japan, some safety measures have been done to the high concentrated potassium preparation for injection which is high risk pharmaceutical agent. One example is to change the label design of high concentrated potassium named "ASPARA KALIUM ™ (Tanabemitsubishi Co. ,Ltd)" and “ASPARAGINSAN KALIUM ™ (Terumo Co. ,Ltd)”, which are potassium aspartate preparation for injection widely used in Japan. The part of “ASPARA” is strong product image of nutritional drink "ASPARA (Tanabemitsubishi Co. ,Ltd)" available commercially at the drug stores in Japan, and not few health care professionals misunderstand the pharmacological action of "ASPARA KALIUM ™" .

Therefore, we have made the proposal of changing the font size of the "ASPARA " part and “ASPARAGINSAN” part (smaller) and the "KALIUM" part (larger) to the pharmaceutical company for preventing medication errors of the healthcare providers. And about 2 years after, our proposal has accepted and released the new printed preparation in Nov., 2008 and Mar., 2009, respectively (Fig. 1,2).

2 Purpose

After the preparation of new label design available in the market, we tried to compare the understanding the therapeutic purpose before and after the label design change with the healthcare providers (physician, nurse and pharmacist) and their students as the survey subjects and to evaluate the effect of the label design change.

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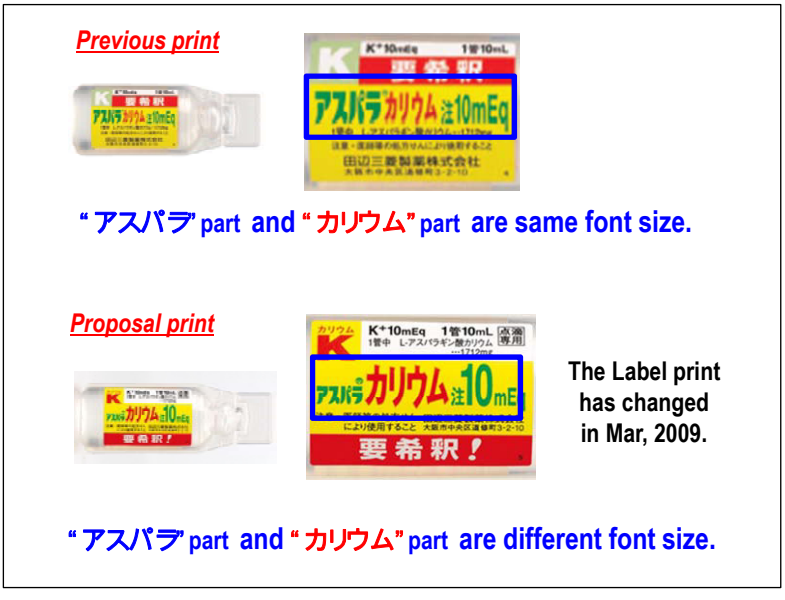

Fig. 1. Previous and new preparation label design of “ASPARA Kalium™ (potassium aspartate)

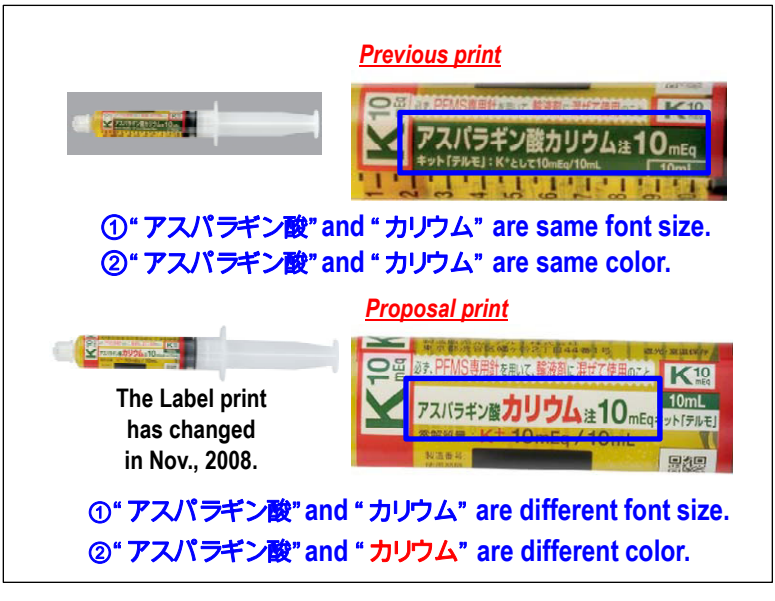

Fig. 2. Previous and new preparation label design of “ASPARAGINSAN Kalium™ (potassium aspartate)

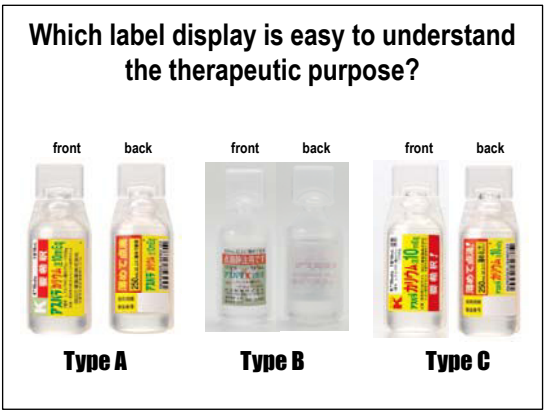

Fig. 3. Survey sheet of ASPARA Kalium ™ (potassium aspartate) for the healthcare providers

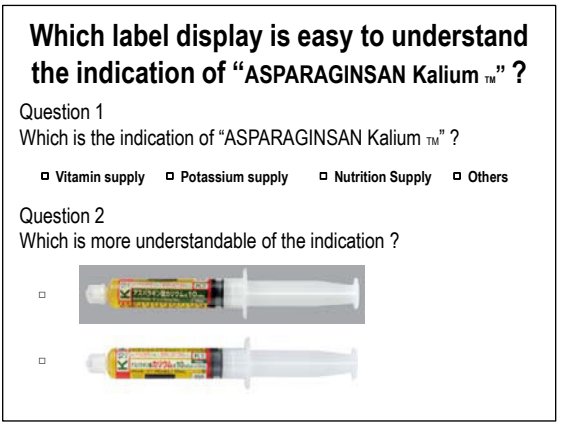

Fig. 4. Survey sheet of ASPARAGINSAN Kalium ™ (potassium aspartate) for nurses and pharmacists

3 Methods

The survey sheets of the picture image of preparation (Fig. 3-6) are showed to the subjects, and the answers were collected on a voluntary basis. The results are analyzed statistically.

4 Results

The survey sheets were collected from physician (n=64), nurses(n=413) and pharmacist (n=328)., and 3 0f 64 physicians, 33 of 413 nurses and 1 of 328 pharmacists did not understand the therapeutic purpose of "ASPARA Kalium ™". (Fig. 7).

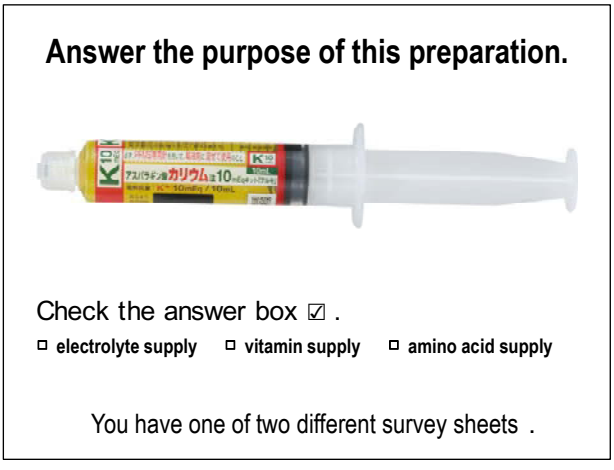

Fig. 5. Survey sheet of ASPARAGINSAN Kalium ™ (potassium aspartate)'s new label design for the medical students

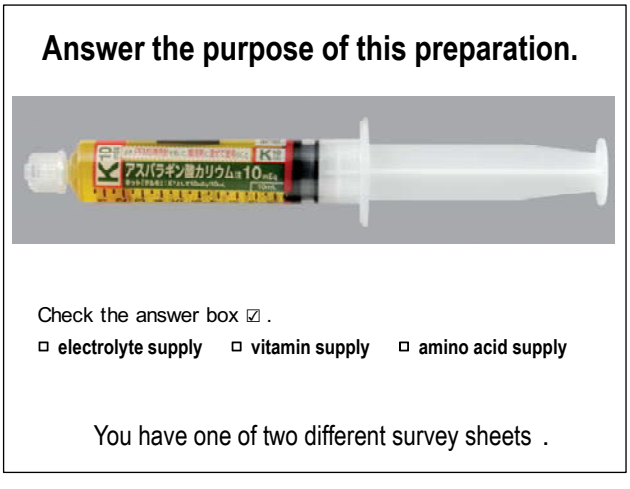

Fig. 6. Survey sheet of ASPARAGINSAN Kalium ™ (potassium aspartate)'s previous label design for the medical students

As for "ASPARA Kalium™", our proposal design "Type C" was the most understandable in all three subject groups which are 61 physicians, 380 nurses and 327 pharmacists except the respondents of the therapeutic purpose misunderstanding (fig. 8). And our proposal design was more understandable in the medical students (n=78), but not significant statistically (fig. 9).

As for "ASPARAGINSAN Kalium™", our proposal design was more understandable than the previous design in both the pharmacists (n = 158) .and the nurses (n = 159), and also in the medical students (n=66), statistically significantly ($p<0.05$, chi-square test) (fig. 10, 11).

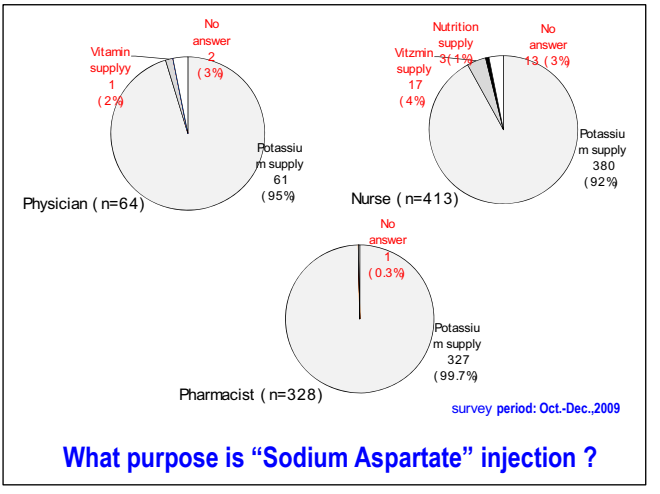

Fig. 7. Understanding of the therapeutic purpose of "ASPARA Kalium ™". (subjects= 64 physicians, 413 nurses and 328 pharmacists. survey period: Oct.-Dec.,2009).

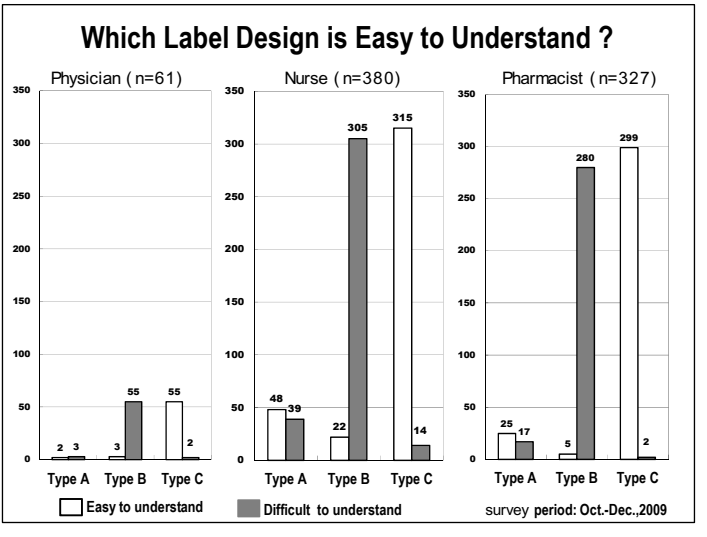

Fig. 8. Comparison of understanding of the therapeutic purpose of "ASPARA Kalium ™" in three label designs. (subjects = 61 physicians, 380 nurses and 327 pharmacists. survey period: Oct.-Dec.,2009).

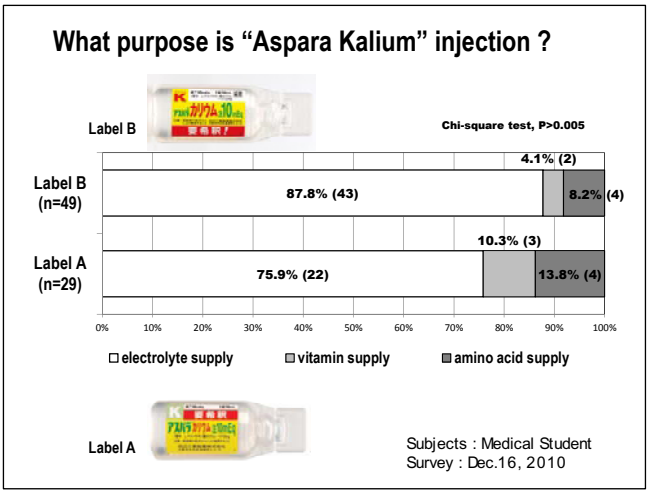

Fig. 9. Comparison of understanding of the therapeutic purpose of “ASPARA Kalium ™” in two label designs. (subjects = 78 medical students. survey period: Dec.,2010).

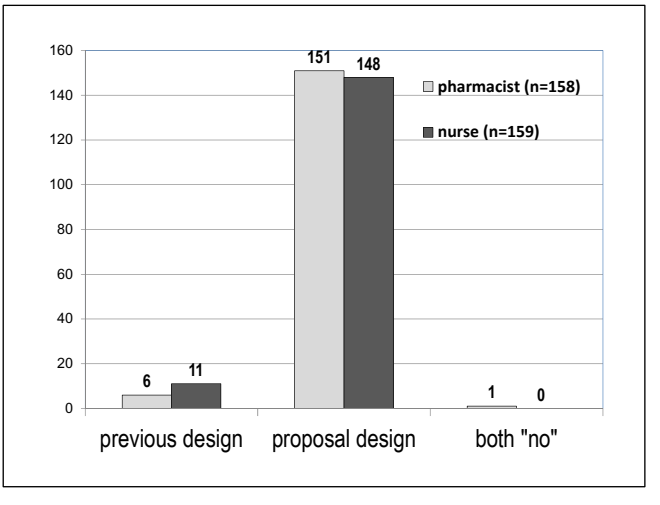

Fig. 10. Comparison of understanding of the therapeutic purpose of “ASPARAGINSAN Kalium ™” in two label designs. (subjects= 158 pharmacists and 159 nurses. survey period: Jan.,2010).

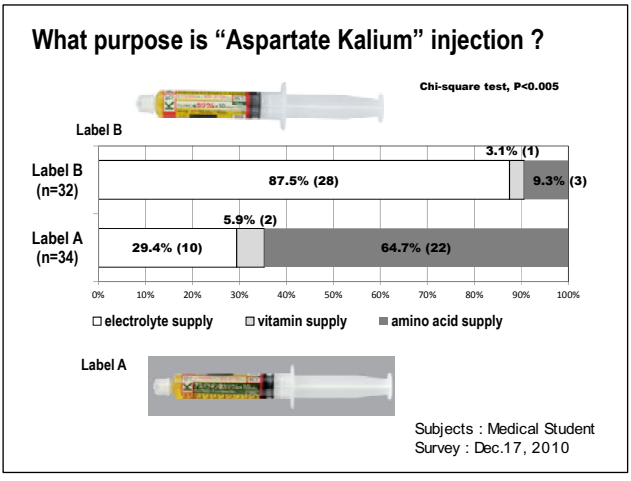

Fig. 11. Comparison of understanding of the therapeutic purpose of “ASPARAGINSAN Kalium ™” in two label designs. (subjects= 66 medical students. survey period: Dec.,2010).

5 Discussion

The injectable preparation of high concentration potassium is high risk when administered rapid intravenously, because it induces cardiac arrest. So the several improvements of the preparation form and design have been tried over the past decade in Japan (fig. 12).

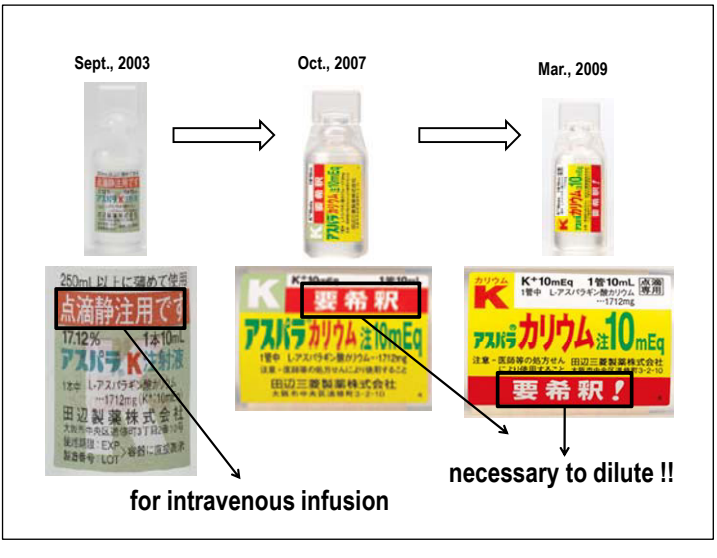

Fig. 12. Change of the label design of “ASPARA Kalium ™”

But therapeutic purpose of some preparations like “ASPARA Kalium ™,” and “ASPARAGINSAN Kalium ™,” were misunderstood in the healthcare providers and medical students. Especially, a Japanese translation of “aspartate” is “ASPARAGINSAN”, so many healthcare providers understand as amino acid supply preparation. And many medical students misunderstand the therapeutic purpose of “ASPARAGINSAN Kalium ™,”.

So we were proposing the change of the preparation label design, which were the font size and color change of two parts (“ASPARA” or “ASPARAGINSAN” and “Kakium”) to the pharmaceutical companies (Fig. 1,2). Our proposes have been accepted and the new designed preparations hav released in Nov., 2008 and Mar., 2009,respectively.

After the change of the preparation design, we tried to evaluate the change of understanding of therapeutic purpose in the healthcare providers. And the all results of survey showed understanding of therapeutic purpose increased by changing the label design. The change of the label design in “ASPARA Kalium ™,” and “ASPARAGINSAN Kalium ™,” is expected to decrease human error.

6 Conclusion

Changing font size and color of two parts (“ASPARA” or “ASPARAGINSAN” and “Kakium”) increased understanding of the therapeutic purpose. And visual improvement in the label design of pharmaceutical preparation is expected to decrease human error.

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