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Impact of cornea recovery training and certification on ophthalmology residents

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ABSTRACT

Background: In Asian countries, such as Taiwan, social taboos regarding organ and tissue donation decreases the prevalence of organ and tissue transplants. This also applies to cornea recovery, which is a skill that requires precision and practice to perform well. In Taiwan, to ensure the maintenance of high-quality corneas, a comprehensive training program and certified examination has been implemented. This study aims to investigate the impact of these programs and examinations on cornea recovery.

Methods: Researchers evaluated the efficiency of the training and certified examination process by comparing the corneoscleral rim width, Descemet's membrane folds, endothelial layer stress lines, and endothelial cell density performed by ophthalmology residents in 2018 and 2019.

Results: After training and certification, the Descemet's membrane folds rate decreased from 14.3 % to 2.0 % and endothelial layer stress lines rate decreased from 22.5 % to 5.0 %. The endothelial cell density of donor grafts significantly improved from 2681.9 cells/mm^2 to 2869.7 cells/mm^2 ($p < 0.001$).

Conclusions: This study used objective data to evaluate cornea recovery quality after training and certification. The training and certified examination significantly improved the surgical skills of ophthalmology residents and could be applied in other tissue or organ recovery procedures to maintain and improve quality.

1. Background

The National Eye Bank of Taiwan (NEBT) was launched in 2014, and the standard operation procedures (SOPs) for cornea recovery were set up after its establishment. In 2017, NEBT signed a memorandum of understanding with SightLife and received a quality certificate by passing SightLife partner standards in 2020. In Taiwan, the cornea recovery process was mainly performed by ophthalmology residents or NEBT technicians; however, in Asian countries, social taboos regarding organ and tissue donation decreases the prevalence of organ and tissue transplants. Thus, the cornea recovery experiences of Taiwan ophthalmology residents or

List of abbreviations: NEBT, National Eye Bank of Taiwan; SOP, standard operation procedure; TOS, The Ophthalmological Society of Taiwan.

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NEBT technicians were impacted by a lack of donors [1,2].

Cornea recovery is a delicate procedure and damages may occur. Several evaluations can assess the quality of the cornea recovery, including the corneoscleral rim width, Descemet's membrane folding, endothelial layer stress lines and endothelial cell density [3,4]. These are performed after cornea recovery to maintain high cornea quality [5,6]. In the past decades, when eye banks were not available in Taiwan, ophthalmology residents typically learned the cornea recovery procedure through observation of experienced senior residents, fellows, or corneal specialists. To enhance the quality of corneal recovery, a training program was established, encompassing relevant knowledge, regulations, and wet lab simulation lectures, enabling residents to practice the entire cornea recovery procedure using pig eyes. Additionally, since 2018, an annual certified examination for ophthalmology residents has been conducted by The Ophthalmological Society of Taiwan (TOS). Following this examination, only qualified ophthalmology specialists and residents who passed the certification examination, along with eye bank technicians, are authorized to perform cornea recoveries.

After the establishment of NEBT, approximately half of the corneal tissue recovery procedures were carried out by ophthalmology residents, and the other half by eye bank technicians. Similar to eye banks in other countries, NEBT technicians underwent formal training to proficiently conduct the cornea recovery procedure. However, NEBT technicians faced challenging issues, including high turnover rates due to social taboos associated with performing procedures on cadavers, concerns about salaries, and work-related stress from being on call 24/7. These challenges resulted in unstable technician workforce. Consequently, Taiwan's healthcare institutions have maintained the practice of having ophthalmologists perform cornea recovery procedures instead of completely transferring the responsibility to NEBT technicians.

Given this context, our study aimed to evaluate the effectiveness of the training and certification process for ophthalmology residents. We compared the quality of cornea recovery before the implementation of the certification exam in 2018 with the results after its introduction in 2019. Our objective was to assess the efficiency of the training and examination processes, and, furthermore, to share our experiences with other tissue or organ recovery certifications.

2. Methods

The data presented here are derived from the analysis of secondary data routinely collected in conjunction with the cornea recovery process. Therefore, it did not require approval from the review board of the National Cheng Kung University Hospital. Informed consent was not obtained as the data were analyzed anonymously and de-identified. The ophthalmology residents involved in human cornea recovery process in 2018 were included as an analysis group, and the ophthalmology residents involved in human cornea recovery process in 2019 as a comparison group. All included ophthalmology residents underwent a residency training program in a tertiary referral teaching hospital in Taiwan. Residents were trained in 2018 ($n = 50$) and operated independently after passing the certified exam in 2019 ($n = 50$).

2.1. *In situ* donor cornea recovery procedure

According to the SOPs from the NEBT, the *in situ* donor cornea recovery was conducted following the guidelines outlined in Table 1. To begin, 5 % povidone-iodine was instilled in the donor eyes for 2 min, and BSS (Alcon Laboratories) was rinsed completely free from the povidone-iodine solution. The operation field was prepared with 10 % povidone-iodine and covered with a sterile drape. After placing an eyelid speculum, a 360-degree peritomy and tenotomy were performed with tissue forceps and scissors. The corneoscleral button was incised with Castroviejo scissors, leaving a distance of 3–4 mm from the limbus. The corneoscleral rim was removed by grasping the rim with a pair of forceps to pull down the ciliary body away from the cornea. After careful removal of corneoscleral button, the button was transferred to a preservation chamber. An eye cap was implanted and to replicate the corneal structure in the donor. The eyelids were gently closed over the eye caps.

2.2. Graft quality

According to the NEBT SOPs, there were several parameters for graft quality evaluation. The corneoscleral rim width was measured from the limbus to the cut edge by surgical ruler. The Descemet's membrane folding and endothelium layer stress lines were evaluated by slit lamp (Inami & Co, Ltd, Tokyo, Japan). Statistics of folding rate in Descemet's membrane included moderate and severe folding. Endothelial layer stress lines were defined as mild and numerous stress lines. Specular microscopy (Konan EKA-10; Konan Medical, Hyogo, Japan) was performed for endothelial cell density counting. All evaluated data were assessed through the medical director of

Table 1
Specific steps for *in situ* donor cornea recovery.

1. Instillation of 5 % povidone-iodine in the donor eyes for 2 min, followed by complete rinsing of balanced salt solution from the povidone-iodine solution.
2. Preparation of the operation field with 10 % povidone-iodine and covering it with a sterile drape.
3. Placement of an eyelid speculum, followed by a 360-degree peritomy and tenotomy performed using tissue forceps and scissors.
4. Incision of the corneoscleral button using Castroviejo scissors, leaving a distance of 3–4 mm from the limbus.
5. Removal of the corneoscleral rim by grasping the rim with forceps to pull down the ciliary body away from the cornea.
6. Careful extraction of the corneoscleral button, which is then transferred to a preservation chamber.
7. Implantation of an eye cap to replace the corneal structure in the donor.
8. Gently closing the eyelids over the eye caps.

the southern office of NEBT.

2.3. Statistical analysis

The data were presented as mean ± SEM (standard error of the mean). Prior to conducting the Student's t-test analysis of variance, we verified the parametrical distribution patterns through histograms. Graphpad Prism was used for the analysis. Statistical significance was considered non-significant (ns) for $p > 0.05$.

3. Results

In 2018, a total of 98 human cornea recovery procedures were completed by 50 uncertified ophthalmology residents. Subsequently, in 2019, 50 certified ophthalmology residents performed a total of 100 human cornea recovery procedures.

3.1. Certification examination

Since 2018, the corneal recovery technique became part of a regular training course for ophthalmology residents in Taiwan. At the beginning, ophthalmology residents were mentored by certified ophthalmologists, and then practiced cornea recovery procedures on pig eyes. After the training course, ophthalmology resident could apply for the certified examination (Fig. 1).

3.2. Examination conduction

Written and technical tests were included in the certification examination. The written test included SOPs of NEBT [7], Eye Bank Association of America Medical Standards [8], Eye Bank Association of America Procedures Manual [9], Regulations of Implementing Approval and Administration of Human Organ Transplantation [10], and recognition of corneal excision operative instruments. The technical test determined the completion rate for the items described in the evaluation form. The achievement rate was calculated by qualified/(qualified + unqualified) × 100 % (Fig. 2). All technical tests were performed on pig eyes (Fig. 3(A–D)). Residents who passed both tests received a certificate by TOS and were authorized for cornea recovery.

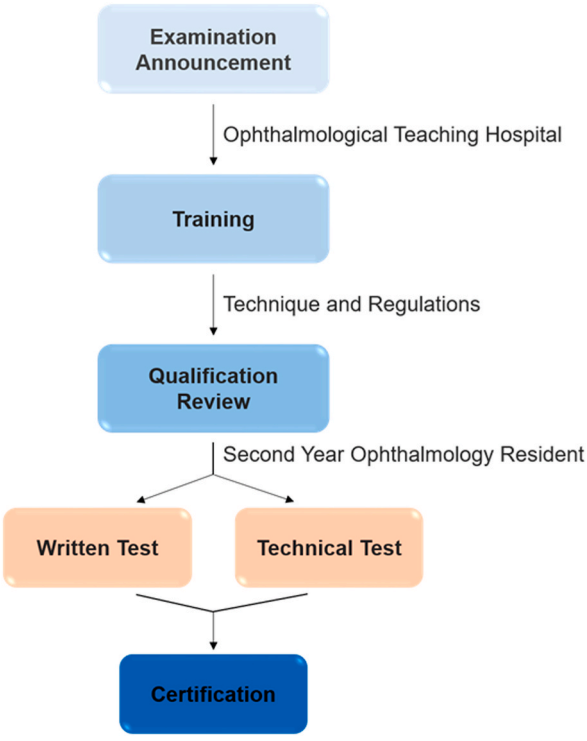

Fig. 1. Flow Diagram for conducting the corneal recovery examination by an ophthalmology resident. The examination was organized and announced by the Ophthalmology Society of Taiwan and co-organized by National Eye Bank of Taiwan.

Evaluation items	Qualified	Unqualified
To sterilize the surgical site and drape the sterile field		
To immerse the surgical eye with 5% povidone iodine solution		
To perform conjunctiva peritomy without tenon left		
Make 3~4mm marks from limbus with caliper		
To perform sclerotomy without perforating choroid		
To use non-repetitive instruments during sclerotomy		
Separate the corneo-scleral button with iris spatula and with no aqueous humor leakage		
To recover the graft without distortion		
Keep the surgical site to be sterile		
Know maintaining of donor's post-mortem appearance		
Know graft storage conditions		
Achievement rate = (Qualified / Total evaluation items) x 100% =		
Tutor (sign)		

Fig. 2. The technical test content of certificated examination. The test was invigilated by senior technicians at the National Eye Bank of Taiwan. All test results were reviewed by eye bank director and verified by Ophthalmology Society of Taiwan.

3.3. Excision in suitable size

The corneoscleral rim width depends on skillful excision. According to the NEBT SOPs, 3–4 mm would be marked from the limbus before the sclerotomy. This step was to make sure the recovery procedure would be performed within the pars plana area. Inadequate size of the corneoscleral bottom makes trephination more difficult and leads to more torsion or eversion to the donor tissue. Recovering the corneal tissue steadily in the target size depends on the operator's surgical skill. The corneoscleral rim width of grafts which were processed by ophthalmology residents in 2018 and 2019 were measured and analyzed in this study, which revealed no significant difference in comparison of the minimal ($p = 0.087$), maximum ($p = 0.232$) and average ($p = 0.118$) width of corneoscleral rim (Fig. 4A).

3.4. Prevention of endothelial damage and maintain corneoscleral button quality

After sclerotomy, the corneoscleral button must be separated from the globe and transferred to storage media. Different degrees of torsion or eversion damage the corneal endothelium. Even experienced, skillful operators created a few damages. In this step, the operator should be extremely gentle and careful to prevent any damages in the endothelium cell layer. If the endothelium damage occurred during the donor cornea recovery procedure, Descemet's membrane folding and low endothelial cell density could be observed. To evaluate donor cornea quality, we assessed several parameters of endothelium function. The statistics of Descemet's membrane folding rate of the grafts operated by residents was 14.3 % (14 of 98 corneas) in 2018 and that declined to 2.0 % (2 of 100 corneas) in 2019 after the certification process (Fig. 4B). A similar effect was presented in the comparison of endothelium cell layer stress lines rate between two years, which declined from 22.5 % (22 of 98 corneas) in 2018 to 5.0 % (5 of 100 corneas) in 2019 (Fig. 4C). The average endothelial cell density showed significant improvement from 2681.9 cells/mm^2 up to 2869.7 cells/mm^2 ($p < 0.001$) after certification (Fig. 4D). This data indicated that training and certified examination significantly improved surgical techniques and the quality of corneas recovered by ophthalmology residents.

4. Discussion

This study compared grafts quality between pre- and post-certification ophthalmology residents. The certification process was implemented by TOS in January 2019. *In situ* excision recovery of donor corneas was introduced to promote corneal donation by Vannas et al., in 1975 [11]. The technique offered attractive advantages such as a simplified protocol, earlier tissue placement in a storage medium, and an enhanced acceptance of eye donation. In fact, *in situ* excision recovery of donor corneas was much more acceptable than whole globe enucleation for corneal donation in Taiwan. However, corneal donation is a meticulous procedure that must avoid microbial contamination and damage to the endothelium [12]. Therefore, this study examined how training and certification exam improved the quality of the recovered corneas among ophthalmology residents.

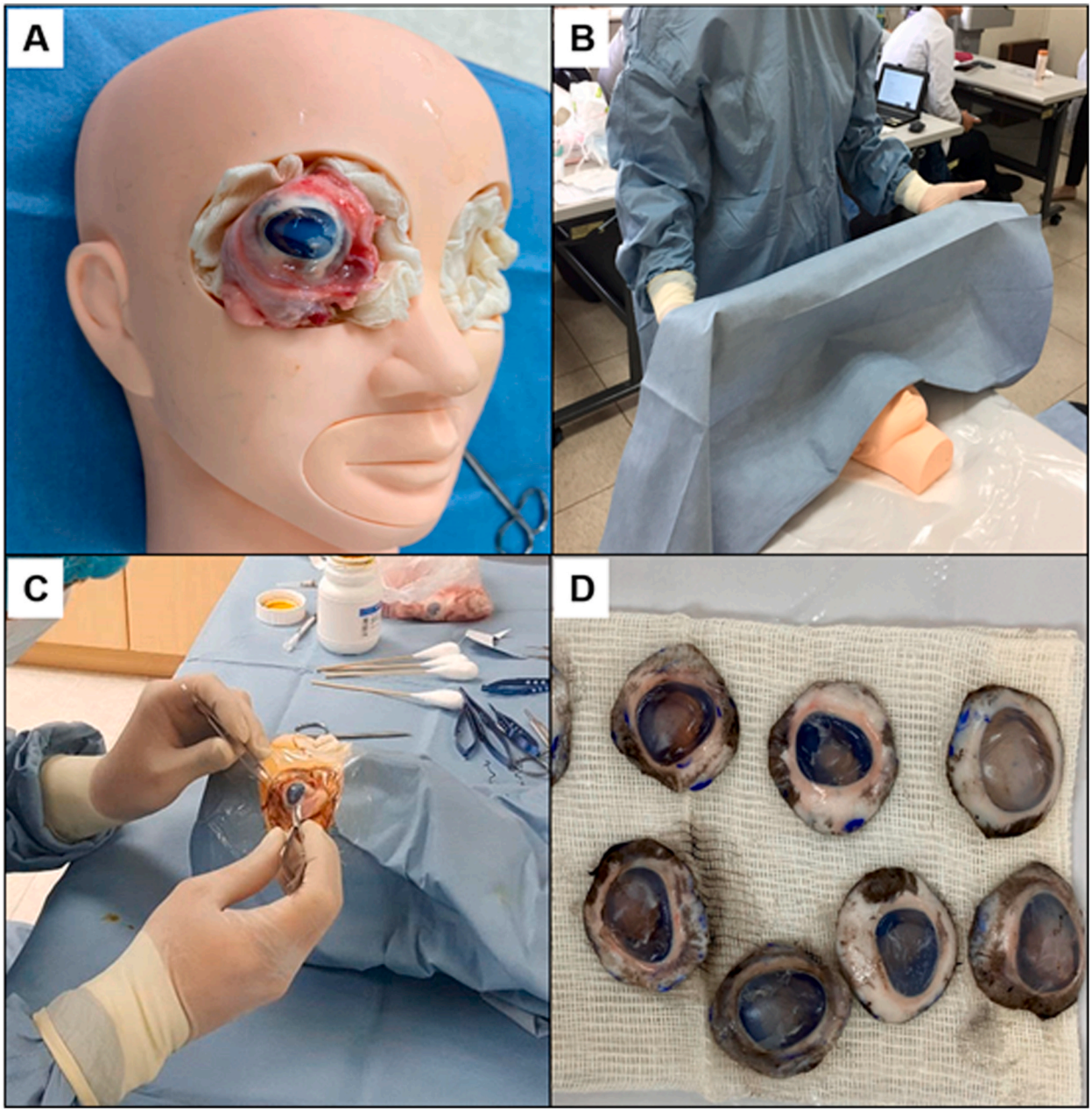

Fig. 3. Pig eyes model for training course and technical test. (A) Pig eyes were fixed with wet gauze and placed on a dummy to mimic the corneal donation procedure. (B) Sterilize the surgical site and drape the sterile field. (C) Peritomy performed on pig eye model. (D) Recovered pig corneoscleral rim. *Note: The person demonstrating is not a patient and were taken with the participants knowledge.

Due to limited amounts of donor corneas, an ophthalmology resident only performed an average of three donor corneas recovery procedures each year in Taiwan. To promote corneal recovery quality, the latest modification of "Regulations for Implementing Approval and Administration of Human Organ Transplantation" in April 2018 revealed that corneal recovery procedures were only permitted for qualified ophthalmology specialists, residents who passed certification examination conducted by TOS, and the eye bank technicians. Therefore, the TOS announced the standard corneal recovery training guideline to transplantation hospitals with teaching programs in Taiwan and conducted a periodic certification examination. The teaching hospital provided the corneal tissue recovery training program for each trainee. Wet lab simulation lecture instructed by a qualified corneal transplantation specialist was necessary for the trainee during the training program. The written test included regulations of the national act and the SOPs of Taiwan and the USA. The certification examination was also co-organized by NEBT, a national organization which was established through the project funding by Ministry of Health and Welfare of Taiwan.

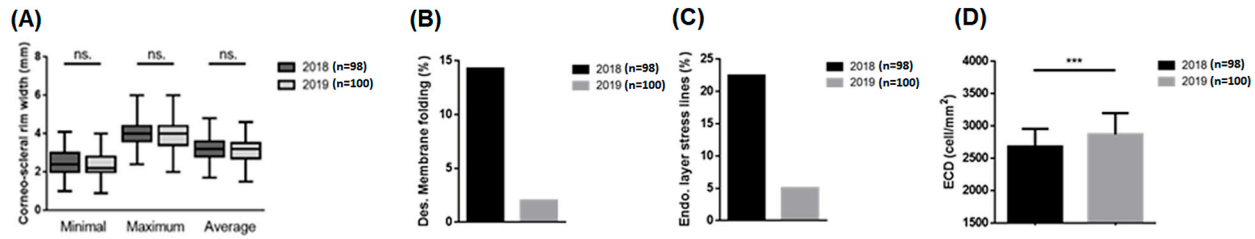

Fig. 4. The comparison of corneoscleral rim width and endothelial cell quality in grafts processed by ophthalmology residents (n = 50) in 2018 (with 98 cornea donations) and 2019 (with 100 cornea donations). (A) Statistical analysis of the residents' graft rim width between 2018 and 2019 revealed no significant difference in the minimal (p = 0.087), maximum (p = 0.232), and average (p = 0.118) width of the corneoscleral rim. (B) Descemet's membrane folding rate of residents' performed grafts in 2018 and 2019, respectively. (C) Endothelial layer stress lines rate of residents' performed grafts in 2018 and 2019, respectively. (D) Endothelial cell density (cells/mm^2) comparing 2018 and 2019 in residents' performed grafts, significance used Student's *t*-test, $p < 0.001$***.

In Taiwan, each donor cornea was examined at the NEBT. To evaluate the graft quality of the recovered corneal tissue, we first examined corneoscleral button width. During the cornea recovery procedure, the operators usually applied the ophthalmic calipers and marked the margin with marking device. Then the corneoscleral button was incised with Castroviejo scissors along the mark. The overall results of the corneoscleral button width, performed by ophthalmology residents, were similar between 2018 and 2019. Upon observation, we found that experienced technicians achieved better results in terms of the consistency of the corneoscleral rim width. Based on unpublished data, the percentage of abnormal corneoscleral rim widths (less than 1 mm or over 5 mm) was 1 % among experienced technicians, whereas it was 7 % among ophthalmology residents. Although the off-specification graft size has a limiting effect on tissue quality and transplantation outcome, the inconsistency of corneoscleral rim width may cause surgical difficulties for clinicians when preparing grafts for endothelial keratoplasty.

It is worth mentioning that separating the corneoscleral button from the globe is a critical step in cornea recovery, which was significantly improved for ophthalmology residents in our study. The corneal endothelium maintains corneal clarity through 2 functions: by acting as a barrier to the aqueous humor and by providing a metabolic pump. Increased permeability and insufficient pump sites occur with damaged endothelial cells [13,14]. The damages to the endothelial cells possibly occurred during the separation of the corneoscleral button from the globe. The certification process significantly improved the Descemet's membrane folding rate (14.9 %–2.0 %), endothelium layer stress lines rate (22.5 %–5.0 %), and corneal endothelial density (2681.9 cells/mm^2 to 2869.7 cells/mm^2). Taken together, the training course and cornea recovery certification significantly improve graft quality. In Asian countries, sociocultural beliefs frequently do not support recovering donor organs or tissue. Due to the limited source of tissue donors, ophthalmology residents must execute perfect recovery technique to ensure graft quality. The simulation of cornea recovery and certification examination for ophthalmology residents allowed the trainee to become more familiar with the detailed steps of the technique and associated regulations. Improved skills promoted recovered corneal graft quality and may contribute to better transplantation outcomes.

Our study demonstrated a positive impact on cornea recovery quality through a specialized training program with certified examination for ophthalmology residents. However, it is essential to acknowledge the limitations of our research, such as its retrospective nature and the restricted parameters for analysis. We specifically compared corneoscleral rim size, corneal endothelial density, Descemet's membrane folding rate, and stress line amounts. In the future, further investigations could explore additional aspects, such as corneal endothelial morphology, graft survival time, primary graft failure, and contamination rates. Moreover, it would be valuable to conduct a comparative analysis between ophthalmology residents and eye bank technicians. Such a study could contribute to the development of improved training courses for both residents and technicians, ultimately enhancing overall cornea recovery and transplantation procedures.

5. Conclusion

In conclusion, our study shows that a training course and certification examination contributes to higher quality of recovered grafts. Our results not only provide suggestions to future cornea recovery certifications but could be applied to other tissue or organ recovery certification programs.

Financial or commercial or proprietary interest

No.

Payment as a consultant/reviewer/evaluator

No.

Prior or repetitive publication

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Ethics approval and consent to participate

The reported data are results from an analysis of secondary data that are collected as part of standard procedures in relation to cornea donation, thus not requiring approval by the review board of the National Cheng Kung University Hospital. The informed consent was not obtained because the data were analyzed anonymously.

Data availability statement

Data included in article/supp. material/referenced in article.

CRediT authorship contribution statement

I-Huang Lin: Conceptualization, Data curation, Formal analysis, Investigation, Methodology, Project administration, Writing – original draft. **Yu-Jen Wang:** Data curation, Formal analysis, Investigation, Software, Writing – original draft. **Fu-Chin Huang:** Conceptualization, Supervision, Validation, Writing – review & editing. **Sung-Huei Tseng:** Resources, Supervision, Writing – review & editing. **Yi-Hsun Huang:** Conceptualization, Data curation, Formal analysis, Funding acquisition, Investigation, Methodology, Project administration, Resources, Software, Supervision, Validation, Visualization, Writing – review & editing.

Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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