

ABSTRACT

□ Introduction

1. Background

A recent SNS (Social Networking Service) analysis on the interest regarding healthcare safety from the healthcare consumers' perspective indicated that cosmetic services and out-of-pocket money services took high priority (Kim S et al, 2014). The services included double-jaw surgery, dental implants, laser eye surgery, orthodontic treatment, non-surgical rhinoplasty with botulinum toxin, propofol anesthesia, filler injection, liftings, and tattooing. Cosmetic surgery is a typical example of health care not covered by national health insurance. In addition, cosmetic surgery adverse events including injuries and death of patients are frequently reported by the media and it made the social concern high. Accordingly, in September 2014, Korean Ministry of Health and Welfare conducted a survey of clinics that perform cosmetic surgery and proposed measures to enhance surgery safety in clinics.

Compared to the degree of controversy in society surrounding safety associated with cosmetic surgery, the safety mechanisms regarding this issue are relatively weak. In particular, because plastic surgery conducted for cosmetic purposes is categorized as uninsured medical procedures that are not treated as essential either for disease treatment or improved physical function; therefore, proper management within the health care system has not been achieved adequately. Furthermore, while it is estimated that the majority of such procedures are performed at clinics, the limited amount of accessible data sources has caused difficulties in identifying the status and the side effects of cosmetic surgery. Therefore, in order to enhance the safety of cosmetic surgeries that typically occur in clinics, reviewing the relevant standards and providing criteria for a safe procedure remain essential tasks. Especially, the need to explore management measures for

patient safety regarding medical practices that are typically conducted at general clinics is significant at this point as the Patient Safety Act is being enacted. In addition, efforts need to be implemented that strengthen the establishment of a basic safety measures foundation regarding cosmetic surgery cases performed in medical institutions.

2. Research Objectives and Methods

Our goal in this study was to establish a foundation to improve patient safety by providing standards and guidelines for the surgeries conducted in medical institutions, starting with cosmetic surgeries, addressing specific issues have been raised by public concern. To ensure safety for users of cosmetic surgery, we identified possible safety issues expected to exist throughout the overall surgery process.

To achieve this goal, this study collected data on guidelines and policy measures related to the management of cosmetic surgery from different countries and conducted interviews with relevant officials. The analysis was conducted around the same categories as much as possible in consideration of the differences among national systems to increase data comparability. The categories included the following: the workforce related to cosmetic surgery (qualifications, etc.), facilities (standards for the operating room, etc.), patients (minors, providing information, and consent), medical advertising, and compensation for damages.

The World Health Organization (WHO) guidelines for safe surgery (2009) were used to develop the cosmetic surgery safety guidelines. Moreover, the methods for the guideline-based development of quality indicators (Thomas et al, 2012) were referenced for details during each stage, as was the protocol development method for clinical safety management (Lee, 2011). Furthermore, the surgical procedures details were based on the patient safety advisory for plastic surgery patients provided by the Korean Society of Plastic and Reconstructive Surgeons (2009).

A search of preceding literature related to the guidelines was conducted

by the researchers, and the proposed guideline based on the collected data was written under the review and consultation of 10 advisors who were recommended by each professional society. Furthermore, a discussion forum was implemented to collect opinions from individuals from various fields to develop the guidelines and application plan.

□ Regulations and Management Measures of Cosmetic Surgery in Foreign Countries

1. France

France established cosmetic surgery-related legislations in 2003 that are currently enacted. In France, doctors who are allowed to perform plastic or cosmetic surgeries are limited to specialists in plastic surgery, medical specialists in another field, or a medical specialist in another field with plastic surgery qualifications. In addition, the specialty fields that can perform plastic surgery are limited, and only cosmetic surgeries limited to the medical specialties on the association list can be performed. Facilities must receive Haute Autorité de santé certification and requirements such as facility divisions, space configurations, an observation room, and facility equipment regulations are specified. Patients must wait a minimum of 15 days after consultation to decide on the surgery, and this consideration period cannot be reduced. If the surgeon who meets the patient will not perform the entire process of the scheduled surgery (or a certain process), then the surgeon must notify this fact to the patient during the consultation, and this information must be indicated on the estimate sheet.

2. Singapore

In 2008, Singapore established “guidelines on aesthetic practices for doctors” at a major medical society meeting that has been implemented ever since. Singapore has classified cosmetic procedures and surgeries into two lists: A and B. This classification was based on scientific evidence and has determined factors such as the number of requires on the pre-procedure, a

suitable environment to conduct the procedure, and minimum skill requirements according to the type of procedure. List A consists of the cases with a high level of scientific evidence or cases of well-established surgical procedures acceptable in consensus among medical experts. List B consists of the cases with a low level of evidence or procedures that have not been established and medical experts cannot arrive on a consensus as to whether they are acceptable. Practitioners of list A procedures that have a higher invasive degree are limited to surgeons or plastic surgeons, and clinic-level facilities must be equipped with operating rooms. Moreover, the guidelines ensure the billing of the appropriate costs to the patient, and advertising procedures included on list B are prohibited.

3. The United Kingdom

The United Kingdom regulated factors such as recommended personnel and facilities for cosmetic surgery. The current legal conditions to become a surgeon in the United Kingdom are the completion of five years of Medical School, along with a F1 process. Furthermore, the establishment of the Cosmetic Surgery Inter-specialty Committee consisting of professional organizations and representative societies such as the society of plastic surgery, otorhinolaryngology, oral and maxillofacial surgery, ophthalmology, mammoplasty, and gynecology has been recommended to increase professionalism in the surgical staff. Institutions practicing cosmetic surgery must register their facilities and procedures with the Care Quality Commission as that of a “general medical institution.” Advertisements related to cosmetic surgery undergo the same regulations for the Advertising Standards Authority that oversee advertising in all media outlets. Furthermore, standards are suggested for misleading advertisements related to cosmetic surgery.

4. Australia

The Australian government introduced a national registration and approval system for medical specialists in 2009, and afterwards, published the

“Cosmetic Medical and Surgical Procedures: A National Framework-Final Report,” which is an official document that analyzes and regulates the cosmetic surgery field. Through the development of the “Good Medical Practice: A code of conduct for doctors in Australia,” the country strengthened regulations on the workforce in regards to medical procedures and cosmetic surgery, and regulated the mandatory responsibility of post-treatment after cosmetic surgery. Furthermore, Australia strengthened regulations on facilities through a regional licensing system, and enhanced legal regulations on advertising and compensation for damages by indicating duties and responsibilities to the patients through issuing guidelines and recommendations and showed an effort in recognizing the cosmetic surgery industry as a medical sector. However, the regulations of personnel and facilities only apply to healthcare professionals who have registered through the professional registration and approval system, and it has been indicated that the regulations on non-registered healthcare professionals are still lacking.

5. The United States

In the United States, cosmetic services are managed through the laws and guidelines established by the state governments, rather than implementing regulations at the federal level. The main components of the regulation are factors such as the approval and registration of the facility, authorization, meeting requirements to provide medical services, as well as restrictions on specific medical practices and time. Some states that enact a relatively strict management of medical treatment directly publish and revise the guidelines, and other states can reference said guidelines.

Details covered by the guidelines vary according to the complexity of the surgery or the degree of anesthesia used. In addition, the workforce sector specifies in detail the basic requirements to satisfy. The facility guidelines define the necessary medical equipment and medicines to stock in order to perform a surgery or in case of an emergency. In addition, details such as

selecting a patient, planning the surgery, and signing the agreement are covered. Furthermore, the guideline includes general information about surgeries at the clinic such as keeping records on the use of anesthesia and the surgical procedure, the establishment of emergency medical services and transport plans, and infection management.

□ The Adaptation of Guidelines for the Safety of Cosmetic Surgery Users

1. Guideline Adaptation Process

The WHO guideline for safe surgery (2009) was used in the development of safety guidelines for plastic surgery, and the methods for the guideline-based development of quality indicators (Thomas et al, 2012) along with the protocol development method for clinical safety management (Lee, 2011) was referenced for details on each stage. Furthermore, the details of the surgical procedures were based on the patient safety advisory for cosmetic surgery patients provided by the Korean Society of Plastic and Reconstructive Surgeons (2009), through which the adaptation occurred.

The adaptation process of a guideline on cosmetic surgery occurred through the following 8 stages: stage 1, identifying the key issues related to aesthetic plastic surgery; stage 2, conducting a search of evidence-based structural literature; stage 3, examining applicable claims; stage 4, developing guideline details according to the degree of the claims, stage 5, organizing the claims and recommendations by key issues and drafting the guideline; stage 6, agreeing upon the guideline and collecting the opinions of outside experts; stage 7, writing the final draft of the guideline; and stage 8, confirming the guideline and providing strategic methods for expansion.

In order to provide a standard for patient safety in the cosmetic surgery guidelines, key issues were determined and PICOST was set based on the key questions, and the structured literature search method was applied. Final confirmation of the key issues in each major category of patient safety was determined while considering the opinions of clinical experts. Moreover, to increase applicability in South Korea, the contents of operating room

instructions and protocols developed for patient safety were referenced. Furthermore, the surgeries data related to the guidelines in 24 research papers were examined and considered accordingly. After writing a draft of the guidelines by organizing the recommendations and claims for each key issue, two rounds of revisions were performed with clinical experts in the field of plastic surgery and with the reviews of outside researchers in order to reflect the actual details of the clinical practice, as well as to consider other possibilities. After completing the draft, it was sent to the Korean Society of Plastic and Reconstructive Surgeons to proceed with the official opinion collection process, through which the final drafted was produced. The final proposed guidelines suggested to divide the facilities and environment, to divide the surgical procedure (i.e. before, during, and after), and in order to increase clinical utilization, various progress checklists and mandatory templates for the patient were included.

Furthermore, in order to spread the final proposed guideline for cosmetic surgery, a discussion forum was implemented with all related organizations and experts where we sought out the strategies for spreading the proposed cosmetic surgery guidelines for patient safety and we established ways of use.

2. An Analysis on the Acceptability of the Proposed Guidelines

To establish standards and guidelines for the safety of cosmetic surgery users, we conducted a survey with doctors working at 30 clinics that perform plastic or cosmetic surgery to collect data on the opening of medical institutions, the status of the facility, the awareness of patient safety by experts, and the acceptability and necessity of the proposed guidelines on cosmetic surgery.

It was indicated that “performing activities related to patient safety” was properly achieved by experts, and the survey results indicated that the factors that caused the most significant impact on patient safety during surgery, as well as on treatment results, were “the expertise and skills of the

health professional” and “the implementation of safety guidelines during course of the surgery.” In addition, factors required for improving the possible safety issues during cosmetic surgery included establishing patient safety guidelines that consider the Korean situation, establishing provisions regarding qualifications and maintenance training for the professional workforce, and establishing a reporting system for medical malpractice and adverse events. Regarding the development of standards related to facilities and environment in the proposed guideline, the most frequent answers included the standards for emergencies, infection prevention, management of surgical instruments, standards for medical personnel, and the operating room.

We investigated the necessity and acceptability of the guidelines in the clinic that was adapted through review of experts and consensus of professionals. The results indicated that the item reliabilities of the “facilities and environmental guidelines” showed a necessity at 0.919 (average = 3.81) and an acceptability at 0.900 (average = 3.61). For the surgical process, the reliability of “pre-surgery” revealed a necessity at 0.969 (average = 3.97) and an acceptability at 0.964 (average = 3.75). The reliability of “during the surgery” had a necessity at 0.963 (average = 4.17) and an acceptability at 0.954 (average = 4.04). Lastly, the reliability of the “post-surgery” had a necessity at 0.946 (average = 4.05) and an acceptability at 0.93 (average = 3.84).

□ Discussion and Conclusion

This study was conducted with the purpose of adapting the proposed guidelines and reviewing standards limited to cosmetic surgery assumed used at clinics. The management approach of medical personnel and institutions related to cosmetic surgery varies by country. However, both placing high priority on patient safety and enhancing education and training through active efforts were identified as common factors. Therefore, it is necessary to develop further details on various education programs for enhancing the

requirements of personnel.

Guidelines for improving the safety surrounding a surgery correspond to the most basic notion that medical personnel must consider when performing a surgery procedure. In this study, the claims mentioned in literature and regulations related to cosmetic surgery based on the safety standards of general surgery were secured through a search on preceding literature and then presented. They were then reevaluated by experts and related with cosmetic surgery to be provided in an agreeable manner. Therefore, there might be a difference in the depth between the presented process and the general guideline adaptation as the latter involved a more detailed search of the literature related to the level of evidence.

A limitation of this study is that the survey conducted on guidelines acceptability was limited to Seoul, South Korea. Since the Gangnam area in Seoul, where clinics that perform cosmetic surgery are located, was the main location in this paper, the results cannot be generalized nationwide. In addition, because the survey was conducted with experts who were available to cooperate, there can be differences in the level of acceptability with general doctors whom perform cosmetic surgery. Although, the research is in part limited, a relatively consistent result was presented when comparing the necessity and acceptability of the guideline; therefore, the reliability of the survey is relatively high.

Key words : Cosmetic surgery, surgical safety guidelines