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Unmet expectations about surgical outcomes and post-donation health-related quality of life among living liver donors

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Unmet expectations about surgical outcomes and post-donation health-related quality of life among living liver donors

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Based on the above article, this dissertation was restructured in accordance with the format of a doctoral dissertation for the College of Nursing, Seoul National University.

Abstract

In South Korea, the number of living donor liver transplantations in 2019 was 1,188. Living liver donors (LLDs) undergo surgery and the postoperative recovery process for altruistic purposes; thus, advocacy for LLDs is important. Basically, it must be confirmed that their health-related quality of life (HRQOL) does not deteriorate significantly after surgery. Regarding the autonomy of LLDs, further discussion on sharing information between healthcare professionals and living donors is required. This communication may help donors realistically anticipate the impact of the donation. In addition, preoperative patient expectations, especially unmet expectations, influence their psychological or physical outcomes.

However, there has been a lack of research comparing the HRQOL of LLDs in South Korea with that of the general population. Moreover, LLD expectations about surgical outcomes and their impact on postoperative well-being have not been sufficiently investigated. Therefore, this study confirmed the level of HRQOL in LLDs and explored LLDs' unmet expectations about surgical outcomes and examined their impact on the donors' HRQOL. It used the expectations model by Calman as a framework to guide this correlation. This model suggested a gap between expectations and experience as an essential predictor of quality of life.

This descriptive cross-sectional study utilized a self-reported survey and medical record reviews. Data were collected at a university hospital in Seoul, South Korea. Among the 535 LLDs who underwent surgery for donation between January 2011 and March 2021, 124 participated in this study. The Korean version of the 12-item Short Form Health Survey version 2 (SF-12v2) was used to measure the HRQOL of LLDs. Unmet expectations regarding surgical outcomes were measured using four items: pain, length of hospital stay, speed of recovery, and complications. Logistic regression model was applied to determine whether the unmet expectations influence HRQOL in LLDs, after controlling age, sex, education level, monthly income, postoperative complications, recipient death, time since donation, and satisfaction with the decision to donate. Odds ratios with 95% confidence interval were used.

The percentage of the participants who reported that their actual experiences for pain, speed of recovery, hospital stay, and complications were worse than expected were 34.7%, 22.6%, 9.7%, and 7.3%, respectively. Physical and mental HRQOLs were 51.48 ± 7.44 and 52.97 ± 8.47, significantly higher than those of the general Korean population. However, young LLDs showed poor mean scores in the physical functioning, role-physical, bodily pain, general health, vitality, social functioning, and role-emotional domains. Unmet expectations about surgical outcomes were

significantly associated with physical and mental HRQOL after controlling for age, sex, education level, income, postoperative complications, recipients' death, time since donation, and satisfaction with the decision to donate. In addition, poor physical component summary scores were predicted by time since donation; poor mental component summary scores were predicted by people with education less than a bachelor's degree and less satisfaction with the decision to donate.

LLDs should be supported in obtaining more accurate and realistic information about surgical outcomes to decrease unmet expectations, which may help improve their quality of life. This finding resonated with the expectations model. When providing information, nurses and clinicians should comprehend the needs, preferences, and expectations of living donors and offer tailored information accordingly. In addition, although LLDs were mostly satisfied with their decision to donate, levels of post-donation regret should be reduced to enhance the mental HRQOL of LLDs.

This study also emphasizes that practical education and support should be provided to concretely shape donor expectations about pain, recovery, and discomfort. Therefore, further research is required to deeply understand pain intensity and duration, full recovery time, and degree of discomfort of LLDs. In addition, healthcare professionals should focus on the postoperative well-being of young donors. By identifying key predictors of the HRQOL for

young donors, effective strategies should be designed to improve their HRQOL.

Keyword: Quality of life, Liver transplantation, Living liver donor, Unmet expectations, Informed consent, Patient education

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List of Abbreviations

ALT	Alanine aminotransferase.
AOR	Adjusted odds ratio.
AST	Aspartate aminotransferase.
BP	Bodily pain.
CI	Confidence interval.
DDLT	Deceased donor liver transplant.
ESLD	End-stage liver diseases.
GH	General health.
HBcAb	Hepatitis B core antibody.
HBsAg	Hepatitis B surface antigen.
HRQOL	Health-related quality of life.
LDLT	Living-donor liver transplantation.
LLD	Living liver donor.
MCS	Mental component summary.
MH	Mental health.
PCS	Physical component summary.
PF	Physical functioning.

QOL	Quality of life.
RE	Role-emotional.
RP	Role-physical.
SF	Social functioning.
SF-12v2	Short form-12 health survey version 2.
SF-36	Short Form-36 health survey.
UOR	Unadjusted odds ratio.
VT	Vitality.

I. Introduction

1. Background

Due to the cadaveric organ shortage and the availability of advanced surgical techniques in South Korea, 75.2% of liver transplantations conducted in 2019 were living donor liver transplantations (LDLTs) (Korean Network for Organ Sharing [KONOS], 2020). The number of living liver donors (LLDs) has increased over the last decade, from 717 in 2008 to 1,188 in 2019 (KONOS, 2011; KONOS, 2020). LLDs in South Korea were mainly immediate family members of the recipients: as of 2019, the donor was a son or daughter (68.0%), spouse (11.3%), sibling (8.9%), parent (3.7%) (KONOS, 2020).

LLDs experience major surgery as a part of the transplantation process. Thus, they take risks for altruistic purposes. For advocacy for LLDs, preoperative efforts have been made from legal, medical, psychological, and ethical perspectives (Jackson et al., 2022; KONOS, 2021; National Law Information Center, 2021; Rudow, 2009). The Organ Transplant Law stipulates that potential LLDs must be volunteers over the age of 16 years; they should give informed consent and have the right to withdraw consent at any time (National Law Information Center, 2021). The donor candidates must pass the evaluation process, including medical history, physical

examination, laboratory evaluation, serologies, markers of liver disease and tumor, and additional medical evaluation (Dirican et al., 2015). In addition, they should receive psychiatric evaluation and consultation on social, family, and financial issues (Dirican et al., 2015). However, regarding the autonomy of LLDs, further discussion is needed on the provision of evidence-based information from experts, the provision of the kind and amount of information preferred by patients, and the confirmation of the donor's understanding of the provided information (Gordon et al., 2011; Zheng et al., 2014). The communication between healthcare professionals and living donors may help donors realistically anticipate the impact of donation (Hays & Matas, 2016).

To date, many researchers have confirmed the safety and stability of surgical outcomes of donor hepatectomy. The mortality rate for LLDs was 0.2%, and the median morbidity rate was 16% (Middleton et al., 2006). In South Korea, a study of 245 cases at one university hospital showed a complication rate of 46.1% (Lee et al., 2014). Moreover, the donations made by LLDs may affect their later daily lives. Although the levels of health-related quality of life (HRQOL) in LLDs are not different or even higher than those in the general population (Benzing et al., 2018; Morooka et al., 2019; Raza et al., 2020; Shen et al., 2016), donation could be a factor that affects later HRQOL. Hesimov et al. (2018) revealed that the physical aspects of the quality of life (QOL) in LLDs decreased immediately after surgery and recovered over the first year.

Prior to surgery, patients develop their own perceptions and expectations regarding surgical outcomes such as pain, speed of recovery, and side effects, and these perceptions may influence the patient's postoperative psychosocial outcomes (Sweeny & Andrews, 2017). Developing unreasonably optimistic expectations about surgical outcomes may negatively influence patients' postoperative experience (Sweeny & Andrews, 2017). Patients' unmet expectations about surgery have been reported to be negatively associated with postoperative functional improvement (Yee et al., 2008).

Previous investigations have reported that LLDs experience larger unanticipated surgical wounds, longer recovery time, worse pain, and more discomfort (Gordon et al., 2011; Raza et al., 2020; Walton-Moss et al., 2007). However, the expectations of LLDs regarding surgical outcomes and their relationships with post-donation HRQOL have not been adequately evaluated.

2. Purpose of Research

This study explored whether the expectations of LLDs regarding surgical outcomes were met and determined their relationship with the post-donation HRQOL of LLDs.

The aims of this study are as follows:

1) To comprehend the unmet expectations of LLDs about surgical outcomes and HRQOL after donation.
2) To compare HRQOL of LLDs after donation to that of general Korean population.
3) To examine the relationships between unmet expectations about surgical outcomes and poor HRQOL.
4) To confirm other predictors of poor HRQOL among LLDs.

3. Terminology

1) Living liver donor

An organ donor supplies their own specific organs (e.g., kidney, liver, pancreas, heart, lung, peripheral blood, bone marrow, and eyeball) to restore the function of other persons' organs without compensation (National Law Information Center, 2021). A living organ donor is someone who has voluntarily donated their kidney, liver, pancreas, pancreatic islet, small intestine, or bone marrow (KONOS, 2020). This study targeted living donors who had undergone partial hepatectomy.

2) Unmet expectation

Patient expectations refer to their perceptions of the probability that certain future events would occur in the clinical setting, including information, care, and treatment (Kravitz, 1996). Unmet expectations are patient expectations that lead to dissonance between expectations and actual experiences for various reasons (Jackson & Kroenke, 2001).

In this study, unmet expectations were limited to preoperative patient expectations about their surgical outcomes (Sweeny & Andrews, 2017). Specific surgical outcomes were drawn from previous studies on postoperative experiences of living donors—the length of hospital stay, speed of recovery, pain, and complications, which were considered important

outcomes for a healthy person who underwent a surgical procedure not for curing their disease (Gordon et al., 2011; Raza et al., 2020; Walton-Moss et al., 2007). Unmet expectations were measured retrospectively by asking, "How was your actual postoperative experience compared to your expectations prior to the donation?"

3) Health-related quality of life

HRQOL refers to the extent to which an individual can function physically and socially and the subjective perception of their physical, mental, and social health in their daily life (Hays and Reeve, 2010).

This study defined HRQOL as scores calculated using a 12-item Short Form Health Survey version 2 (SF-12v2); a higher SF-12v2 score represents better HRQOL (Maruish, 2012).

II. Literature Review

1. Living Donor Liver Transplant

Liver transplantation is the last treatment for end-stage liver disease (ESLD), causing decreased liver function and various complications. Alcoholic liver disease was the most common ESLD for which LT was performed in South Korea, followed by hepatitis B-induced cirrhosis and liver cancer (KONOS, 2022). Per capita alcohol consumption in South Korea continues to increase although it has reached the highest level globally (Jang & Kim, 2018). In 2020, the proportion of HBsAg-positive patients in South Korea was 2.7% (Korea Disease Control and Prevention Agency, 2022), which is higher than that in developed Western countries (Razavi-Shearer et al., 2018). In addition, liver cancer was the second leading cause of death from cancer in South Korea (National Cancer Information Center, 2022). Hence, South Korea may be vulnerable to liver disease.

In 2021, 6,388 people were waiting for LT in South Korea, with an average waiting time of 2,372 days (KONOS, 2022). Because of the gap between supply and demand for liver organs in South Korea, as of 2021, LDLT (1,158 cases) was performed approximately threefold greater than deceased donor liver transplant (DDLT) (KONOS, 2022). The reasons for the lack of cadaveric organs include religious beliefs and the sociocultural

atmosphere (Chen et al., 2013; Rela & Rammohan, 2021).

In addition, LDLT is performed more frequently than DDLT in South Korea owing to differences in recipient prognoses and advances in medical technology. The 5-year survival rate of LDLT recipients was 80.8%, higher than that of DDLT recipients (66.5%) (KONOS, 2022). In addition, LDLT has the advantage of less graft loss and complication compared with DDLT (Kim et al., 2021). Meanwhile, the donor pool has widened with the introduction of innovative medication and therapy; LDLT with a HBcAb-positive donor and ABO incompatible (ABOi) LDLT have become possible (Chen et al., 2013; Hwang et al., 2003). Moreover, with the advancement in surgical technology, donor hepatectomy, which had been performed through open surgery, was replaced with pure laparoscopic hepatectomy, decreasing pain and hospital stay (Au & Chok, 2018) and increasing confidence and satisfaction with body image and surgical wound (Kim et al., 2021). In line with these achievements, LDLT has been steadily increasing (KONOS, 2022) and has evolved as efforts have been made not only for the survival of the recipient but also for the protection and advocacy of the donor.

2. Preoperative Effort to Advocate Living Liver Donors

To date, preoperative efforts have been made from legal, medical, psychosocial, and ethical perspectives to advocate LLDs willing to take risks for recipient lives.

1) A legal perspective

According to the South Korean Organ Transplant Law, the criteria to be a potential living liver donor are stipulated as a volunteer over the age of 16 years who consented to donate their organ; the volunteer with consent to donation can withdraw the consent any time until transplant surgery (Articles 2 and 22) (National Law Information Center, 2021).

Articles 11 and 22 state that voluntary minors over the age of 16 years are allowed to donate to a patient within the fourth degree of kinship with the consent of themselves and their parents. Organ donation from a minor must be considered a last resort in the case of no other options from an adult or a deceased donor (National Law Information Center, 2021).

The Organ Transplant Law also specifies physical examination lists (Article 14) and what physicians must abide by when explaining the matter to patients (Article 23): donors' health status, the surgical procedure for donors and its impact on their health, postoperative care plan, and other transplant-related items that donors have to know in advance (National Law

Information Center, 2021).

2) A medical perspective

Donor candidates undergo a medical and surgical examination per the established evaluation protocol (Dirican et al., 2015). According to Article 23 of the Enforcement Decree of the Organ Transplantation Act, common examinations for all organ donors are as follows: complete blood count, electrolyte, ABO typing, glucose, urinalysis, creatinine, blood urea nitrogen, liver enzyme, total bilirubin, chest X-ray, blood gases, hepatitis screen, anti-cytomegalovirus, syphilis test, and anti-human immunodeficiency virus (National Law Information Center, 2022). Additionally, liver donor candidates are assessed with respect to prothrombin time, partial thromboplastin time, blood group subtyping of ABO, sonography, and volumetry computerized tomography (National Law Information Center, 2022).

More examinations are conducted depending on the transplant center and the age and sex of donor candidates, including esophagogastroduodenoscopy, mammography and Pap smear, and sigmoidoscopy (Yi et al., 2007). If the results of these examinations seem problematic, additional invasive procedures are performed (Yi et al., 2007).

3) A psychosocial perspective

After potential LLDs declare their intent to donate their livers, they receive counseling from a psychiatrist and a social worker to share their motivation for donation and their financial condition, ensure that the decision was made without coercion, and confirm that there was considerable family discussion on that decision (KONOS, 2021; National Law Information Center, 2020). Psychiatrists also evaluate depression, anxiety, and problem drinking in potential donors.

4) An ethical perspective

Ethical considerations are required because liver donation from LLDs is an altruistic action with various motivations. LDLT can be justified from the viewpoint of the principle of utility because it is facilitated by the shortage of deceased organs and allows for allocating cadaveric organs to recipients who do not have living donors (Rudow & Brown Jr, 2005). In addition, LDLT results in greater outcomes for recipient health than DDLT. In addition, the recipient and their family benefit from LDLT.

However, it seems to go against the nonmaleficence principle according to biomedical ethics. Regarding donor advocacy, donor hepatectomy is an unnecessary procedure for a healthy person. Therefore, this situation has been overcome by efforts to establish protocols and infrastructures to protect donors from preoperative to postoperative processes (Rudow & Brown Jr,

2005). Particularly in the decision-making process of liver donation, a reasonable decision must be made per the beneficence principle to determine whether the benefits, including the recipient's life-prolongation, outweigh the risks entailed by a healthy donor undergoing invasive surgery (Lieber et al., 2018).

In building a living donor advocacy system, the principle of respect for autonomy is used as the most important basis among biomedical ethics. This principle emphasizes informed consent, consent that needs voluntary willingness, provision of information from experts, and complete understanding of patients (Schuck, 1994). In previous research, some LLDs reported that they experienced implicit family pressure when deciding donation (Lin et al., 2021), and few donors felt internal or external coercion (Gordon et al., 2011). In addition, donors reported that information needs were unmet, the provided knowledge about risks was deficient, and they experienced unexpected complications (Gordon et al., 2011). Zheng et al. (2014) investigated the source of information and revealed that the way through which many donors acquired information was through the public media, followed by medical centers and then family members. In the United States, donor advocacy teams consisting of multidisciplinary experts, such as the Independent Donor Advocacy Team in New York, were established to educate, evaluate, and manage donors (Rudow, 2009; Sites et al., 2008).

3. Postoperative Outcomes and Patient Expectations

Studies on the postoperative physical health of LLDs have been steadily conducted to confirm the safety of surgery. In most recent studies, no deaths were reported; however, there was a significant variation in complications. A study on 832 LLDs from 15 hospitals in South Korea reported no mortality; 9.3% experienced postoperative complications, and 1.9% experienced grade III complications, including biliary stricture and bile leakage, which required medical interventions according to the Clavien–Dindo classification (Lee et al., 2017). A study on 104 LLDs in Germany reported no mortality with 35.9% of postoperative complications (e.g., bile leak, ascites, and wound infection) and 28.8% of 1-year postoperative complications (e.g., scar problem and pleural effusion) (Benzing et al., 2018). One week after surgery, muscular atrophy was also reported as a complication (Kim et al., 2019). In addition, maldigestion, hernia, duodenal ulcer, compromised immunity, chronic fatigue syndrome, and psychological problems were reported after discharge (Hecht et al., 2019; Jeong, 2011; Kadohisa et al., 2018; Yoo et al., 2004).

The liver regenerated to 89% of its original size from 1 week to 6 months after donation (Middleton et al., 2006), and liver function—aspartate aminotransferase (AST), alanine aminotransferase (ALT), and total bilirubin level—recovered to normal after 1 year (Shen et al., 2016). Shi et al. (2020) concluded through a meta-analysis that pain level was high up to 3 months after surgery and returned to the preoperative level after 6 months. Jeong

(2011) conducted a qualitative study and declared that pain was more severe than expected and lasted for a long time; patients waited for at least 3 months to return to daily life and work. With complications, it took more than 6 months, and if work requires physical labor, it took more than 1 year (Jeong, 2011).

Gordon et al. (2011) reviewed the literature and found that 28%–37% of LLDs had a larger surgical wound than anticipated, 29%–38% expressed longer recovery than expected, and 33%–44% felt unprepared to be in pain. Walton-Moss et al. (2007) reported that 55% of organ donors felt more pain than expected, and 20% were hospitalized longer than expected. Raza et al. (2020) revealed that 54.4% of LLDs felt more surgery-related discomfort than expected before the surgery.

In the preoperative stage, patients can have various types and levels of expectations and optimistic or pessimistic perceptions of their postoperative conditions and surgical effects. In the postoperative stage, these assumptions and perceptions are re-evaluated during real experience. A review comparing expectation-only studies and expectation-comparison studies concluded that the studies measuring unmet expectations could provide stronger evidence for the correlation between expectation and psychosocial outcomes, such as distress, regret, and QOL (Sweeny & Andrews, 2017).

4. Health-related Quality of Life in Living Liver Donors

In terms of advocacy for LLDs, the primary goal of donor hepatectomy is to maintain their normal daily life as before surgery. Therefore, safety from medical aspects and stability from day-to-day aspects should be confirmed. Accordingly, HRQOL has been frequently used as an indicator of stability. The term HRQOL is often used to focus on the impacts of health, disease, and treatment on an individual's well-being (Pristed et al., 2013). Several problems that occur while recovering from surgery and returning to daily life will be revealed by exploring HRQOL after donation. By providing information about HRQOL and rising problems during recovery, donors can realistically anticipate the benefits and harms before surgery, make informed decisions, and avoid disappointment or discomfort about unexpected consequences.

Much research has examined the HRQOL levels of LLDs by comparing those of LLDs with the general population or comparing pre-donation and post-donation. In most studies, the HRQOL of LLDs has been assessed using the Short form-36 health survey (SF-36), consisting of a physical component summary (PCS) and mental component summary (MCS). The PCS and MCS scores of LLDs were statistically equivalent to those of the general population at least 3-year after donation; some health domains were significantly higher than the general norm (Benzing et al., 2018; Morooka et al., 2019; Raza et al.,

2020; Shen et al., 2016). Shen et al. (2016) observed that the postoperative 1- and 2-year group had lower scores in the domains of physical functioning (PF), role-physical (RP), vitality (VT), and mental health (MH) compared with the control group, whereas the postoperative 3- and 4-year group had higher scores in the domains of role-emotional (RE) or bodily pain (BP) compared with the control group.

In intraindividual comparisons over time, MCS scores have not shown significant differences; however, there has been little consistency in the PCS scores after donation (Hesimov et al., 2018; Ladner et al., 2015). Post-donation PCS scores recovered to pre-donation scores in 1 year or were still significantly lower than pre-donation scores (Hesimov et al., 2018; Ladner et al., 2015).

In studies on Korean liver donors, Yoo et al. (2004) compared the HRQOL of LLDs with that of the general population using the Korean Health Profile 1.0; the LLDs reported a lower RP score but greater VT and MH scores. Hong (2005) compared preoperative HRQOL to 1- and 3-month postoperative HRQOL of LLDs using SF-36 version 2.0; their PCS scores declined and did not recover until 3 months after surgery. However, MCS scores decreased 1 month after surgery and recovered to the original level 3 months after surgery (Hong, 2005).

Furthermore, attempts have been made to identify predictors of better HRQOL. In previous research, demographic factors such as age, sex, education level and donation-related factors such as financial costs,

postoperative complications, recipients' death, time since donation, and the donors' satisfaction with donation have been reported to be associated with HRQOL of organ donors (Dew et al., 2018; Janik et al., 2019; Ladner et al., 2015; Morooka et al., 2019; Weng et al., 2019; Wirken et al., 2019). However, studies identifying predictors other than sociodemographic or clinical variables are lacking.

Thus, we suggest investigating HRQOL predictors that emerge during the overall transplant process. This exploration can facilitate LLD postoperative adaptation and serve as a basis for developing an intervention to enhance the HRQOL of LLDs.

III. Theoretical Framework

This study was based on the expectations model suggested by Calman (1984). This model proposed another method to measure QOL. Every aspect of life experience and feeling, as well as the effects of the disease and its treatment, should be estimated to assess QOL (Calman, 1984). In addition, Calman considered QOL a dynamic concept (not static): it constantly changes over time (Calman, 1984; Radbruch & Jaspers, 2019). QOL is largely influenced by an individual's hopes, goals, preferences, and expectations. Therefore, only the individual can evaluate their QOL (Calman, 1984; Radbruch & Jaspers, 2019). Although some people may deal with serious physical, social, or financial problems, they can still maintain a high QOL (Calman, 1984).

In the expectations model, QOL varies depending on the discrepancy between the hopes, ambitions, and expectations of individuals and their current experiences (Calman, 1984). This discrepancy is called the "Calman gap," and narrowing this gap can enhance QOL (Calman, 1984; Radbruch & Jaspers, 2019), as shown in Figure 1. A better QOL can be achieved by matching expectations and experiences, and a poor QOL can result from unfulfilled expectations compared to experiences (Calman, 1984).

The ways to reduce the size of the Calman gap are as follows: 1) efforts and actions of the individuals, people around them, or both to improve

experiences and 2) identifying important issues to the individuals and making expectations about the issues appropriate and realistic (Calman, 1984; Radbruch & Jaspers, 2019). The former process requires energy to grow oneself or for others to support the individual (Calman, 1984). The latter is described as a “respond shift” (Radbruch & Jaspers, 2019).

In clinical settings, patients under treatment can personally develop and modify their expectations about disease prognosis and their future health status (Calman, 1984). Patients report different QOL levels because each patient has different expectations, even in similar medical conditions (Radbruch & Jaspers, 2019). If patients have rational expectations or can adjust expectations to specific circumstances, they may experience a high QOL level (Radbruch & Jaspers, 2019). This model can help healthcare providers, patients, and patient families make treatment decisions (Calman, 1984). In the decision-making process, the Calman gap should be discussed with the patients, especially those under treatments with positive long-term effects but negative short-term effects (Calman, 1984).

To date, the expectations model has been applied to several surgical patients, such as cancer patients (Lee et al., 2022; Symon et al., 2006), orthopedic patients (Saban & Penckofer, 2007; Saier et al., 2017), and obese people after gastric bypass (Pristed et al., 2013; Turnbull et al., 2023). It was presumed that this model could provide a theoretical framework for understanding the QOL of LLDs after donor hepatectomy and its significant predictors of unfulfilled expectations. Therefore, this study used the Calman

expectations model to identify the difference between LLDs' expectations about donor hepatectomy outcomes and their experiences after the surgery and then confirm that the gap would predict their HRQOL.

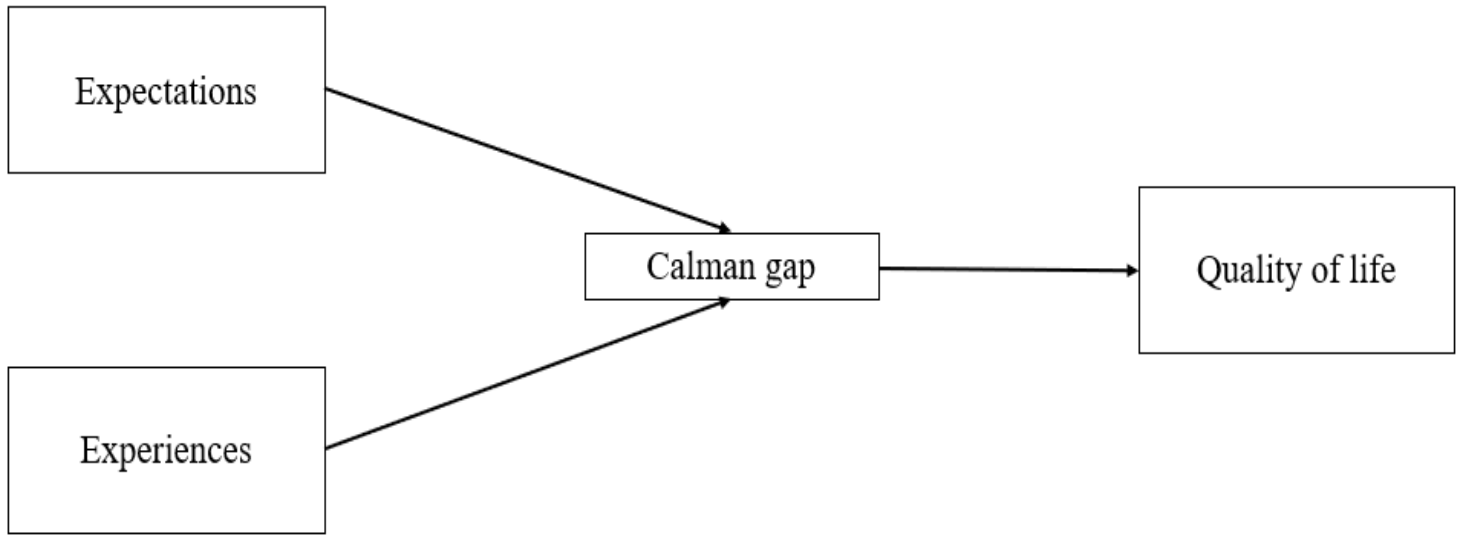


Figure 1. Expectations model by Calman (1984)

In the expectations model, an individual waiting for treatment or care has expectations about its results. After receiving treatment or care, the individual experiences not only its benefit but also its sequelae. Realistically, there is a gap between expectations and experiences (the Calman gap). In LLD cases, they might decide to donate their livers with some expectations about surgical outcomes and recovery and then modify those expectations until donation surgery. After surgery, they may experience pain and several postoperative complications. Preoperative expectations about surgical outcomes can meet or fail to meet the actual postoperative experiences. This phenomenon can be captured by the study variable of unmet expectations.

According to Calman (1984), QOL can be defined as the gap between expectations and experiences. It is a prominent concept among patient-reported outcomes, which evaluate nursing and medical services (Bullinger & Quitmann, 2014). In a healthcare setting, the health-specific QOL of patients has been considerably used to assess their QOL (Radbruch & Jaspers, 2019). Therefore, the HRQOL has been used to measure the QOL of LLDs undergoing transplant procedures.

Furthermore, sociodemographic and donor-specific characteristics that were reported to have a relationship with HRQOL of organ donors were identified through a literature review: age, sex, education level, monthly income, postoperative complications, recipient death, time since donation, and satisfaction with the decision to donate (Dew et al., 2018; Janik et al., 2019; Ladner et al., 2015; Morooka et al., 2019; Weng et al., 2019; Wirken et

al., 2019). Such variables were considered confounders and controlled in the theoretical framework. The theoretical framework of this study is shown in Figure 2.

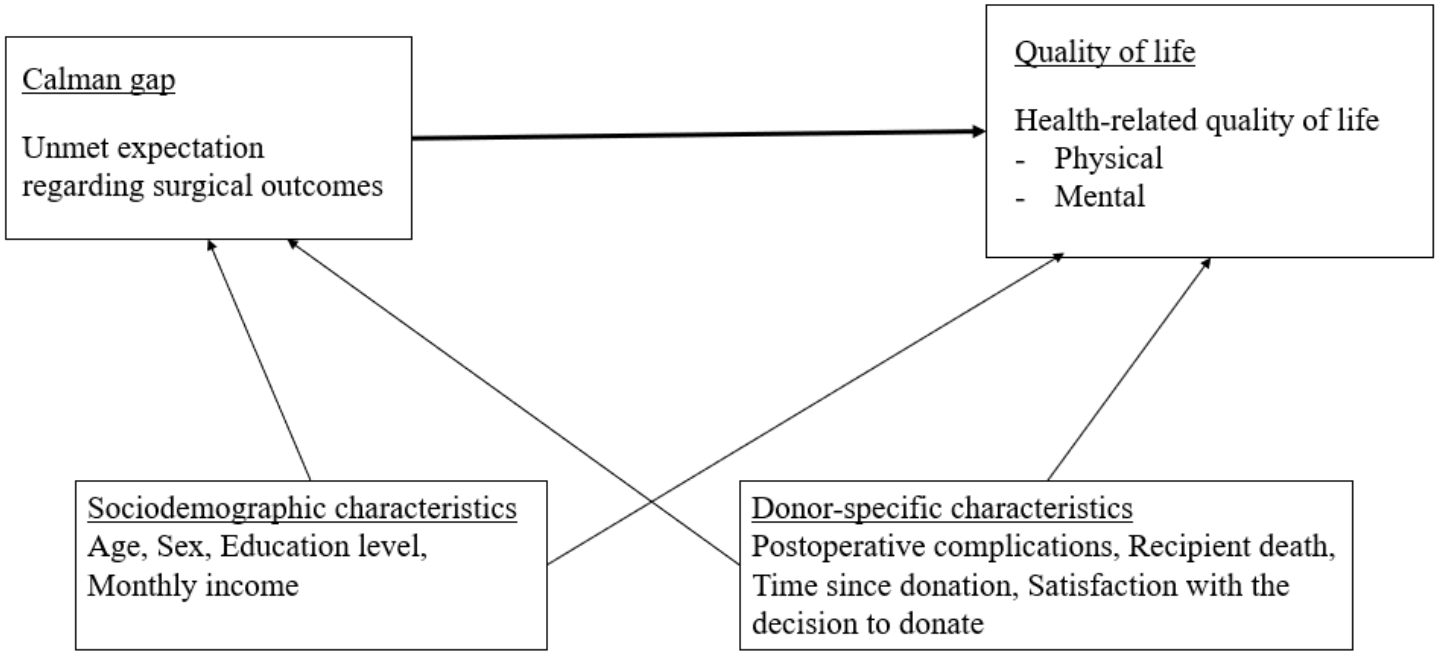


Figure 2. Theoretical framework

IV. Methods

1. Study Design

The cross-sectional descriptive study was conducted. This study aimed to examine the relationship between the unmet expectations of LLDs about the surgical outcomes of donor hepatectomy and HRQOL after donation.

2. Study Participants and Setting

This study was conducted at a large tertiary university hospital in Seoul, South Korea. Eligible participants in this study were LLDs aged between 19 years to 64 years and within second-degree of kinship with the recipients. Donors who had undergone surgery less than one month previously were excluded. The accessible population of this study comprised 535 LLDs who underwent partial hepatectomy at this hospital for the past 10 years (between January 2011 and March 2021). Among a total of 535 potential participants, 124 donors participated in the study.

In this hospital, it is standard for LLDs to be followed up in outpatient clinics 1 week; 1, 3, and 6 months; and 1, 2, 3, 4, and 5 years after discharge.

However, the sample size that could be recruited was limited for two major reasons. Because of the inherent characteristics of LLDs, they are less likely to receive follow-up examinations if they perceive themselves as healthy. Additionally, because data were collected during the COVID-19 pandemic, it is assumed that LLDs with no problem may have been more reluctant to visit the hospital.

3. Instruments

The main and confounding variables used in this study are as follows.

1) Health-related quality of life

To evaluate donors' HRQOL, the SF-12v2 was utilized (Maruish, 2012). The SF-12v2 consists of eight health domains: PF, RP, BP, general health (GH), VT, social functioning (SF), RE, and MH. The scores for these scales were aggregated into PCS and MCS measures. Each item was assessed using a 3-point or 5-point Likert scale, and higher PCS and MCS scores indicated better HRQOL. The SF-12v2 has demonstrated desirable reliability (Cronbach's α = .88) and construct validity in the general Korean population (Kim et al., 2014). In this study, the Cronbach's α was .77, and poor HRQOL

was defined as more than 0.5 SD below the normative mean of the general Korean population (Kang et al., 2021; Kim et al., 2014; Norman et al., 2003).

2) Unmet expectations about surgical outcomes

To determine whether the expectations of LLDs regarding surgical outcomes were met, the donors were asked to respond to this retrospective question: How was your actual postoperative experience compared to your expectations prior to the donation? Surgical outcomes were evaluated using four items: length of hospital stay, speed of recovery, pain, and complications. The answer choices were “better than expected,” “as expected,” and “worse than expected.” When the reality was worse than their expectation, it was identified as an unmet expectation. This question was developed for this study on the basis of previous literature (Gordon et al., 2011; Raza et al., 2020; Sweeny & Andrews, 2017; Walton-Moss et al., 2007) and reviewed by five healthcare professionals (a surgeon and four nurses involved in liver transplant). Face validity was assessed through five LLDs.

3) Confounding variables

We collected donors’ sociodemographic and donor-specific information, including age, sex, education level, monthly income, postoperative complications, recipient death, time since donation, and satisfaction with the decision to donate.

Postoperative complications were categorized into grades I-IV according to the Clavien–Dindo classification (Clavien et al., 1994; Dindo et al., 2004). This classifies surgical complications by severity. Grade I includes a normal postoperative course without any requirement for medication or surgical, endoscopic, and radiographic procedures. However, grade I allows antiemetics, antipyretics, analgetics, diuretics, electrolytes, physiotherapy, and wound dressing at the bedside (Dindo et al., 2004). Grade II includes complications that require medication, total parenteral nutrition, and blood transfusions (Dindo et al., 2004). Grade III includes complications that need surgical, endoscopic, or radiological intervention. If the intervention requires general anesthesia, it is grade IIIb; if not, it is grade IIIa (Dindo et al., 2004). From grade III, complications are considered major problems. Grade IV includes life-threatening complications that must be managed by intermediate care or in the intensive care unit (Dindo et al., 2004).

We then reclassified the complication variables into "no complications" for cases with no complications or "having complications" for those with complications of grades I to IV.

Satisfaction with the decision to donate was measured using the following question: "If you go back to before your donation, would you still donate?" The response to this question was evaluated using a 4-point Likert scale: 1 = "definitely not," 2 = "not likely," 3 = "somewhat likely," 4 = "very likely," with a higher score reflecting higher satisfaction.

4. Ethical Considerations

The present study was approved by the institutional review board of the Seoul National University Hospital (approval No. 2101-074-1187). All participants were fully informed and voluntarily decided to participate in the study. For paper survey, written consent was obtained. For web-based survey, written consent was waived, and submission of the completed survey constituted consent to participate. Data were collected and managed in a way that protected the privacy and confidentiality of the participants.

5. Data Collection

Data were collected using a self-reported survey and retrospective medical record reviews conducted between February and July 2021. The survey was conducted using web-based or paper forms at outpatient clinics. After the survey was completed, the questionnaires and medical records were matched, and practical and specialized data were obtained through medical record reviews. Informed consent was obtained for the survey and the use of clinical data.

Recruit notices were posted on the bulletin boards in outpatient clinics for liver patients to contact all potential participants who underwent donor

hepatectomy from January 2011 to March 2021. The questionnaire was provided in the form preferred by the participants, either a paper or online questionnaire. An online survey was presented via Survey Monkey.

In addition, a researcher visited the outpatient clinic, approached liver donors who finished their appointments with a surgeon for follow-up, and then sufficiently explained the purpose and process of the study to the donors. The researcher conducted a survey after the potential participants gave their consent. It took approximately 20 min to complete the questionnaire. The participants received beverage coupons in appreciation for participating in the study.

Thereafter, the researcher reviewed the medical records of the participants. Consequently, 124 questionnaires and results of clinical data review were obtained.

6. Data Analysis

All statistical analyses were carried out using IBM SPSS Statistics (Version 26). In terms of unmet expectations for surgical outcomes, a dichotomous variable was generated by coding 0 when 0 to 2 items were rated as “worse than expected” and coding 1 when 3 or 4 items were rated as “worse than expected.” Among control variables, age, time since donation by year,

and satisfaction with the decision were considered continuous variables. The other variables were dichotomous: sex (male, “0”; female, “1”), education level (less than bachelors’ degree, “0”; bachelors’ degree or higher, “1”), monthly income (less than 3.5 million Korean won, “0”; 3.5 million Korean won or more, “1”), postoperative complications (no complications, “0”; had complications, “1”), and recipient death (alive, “0”; death, “1”). Missing data were noted for monthly income (2.4%), recipient death (1.6%), and SF-12v2 (0.7%), and the expectation-maximization algorithm was used to impute the missing values for SF-12v2 (in one case, four items were missing; in two cases, two items missing; in three cases, one item missing).

A descriptive analysis of sociodemographic and donor-specific characteristics and unmet expectations was performed using frequencies, percentages, and means with standard deviations (SDs). Pearson’s chi-square tests or Fisher’s exact tests were conducted to examine whether unmet expectations were affected by time since donation owing to recall bias. The time since donation was categorized into “less than three years” and “more than three years.” Subsequently, the differences in the frequency of unmet expectations between the two groups were explored.

Two-sided one-sample *t*-tests were conducted to examine the difference in a two-component summary of HRQOL between LLDs and the general Korean population (Kang et al., 2021). Kang et al. (2021) presented normative mean scores for PCS and MCS of the SF-12 in the general Korean population aged between 20 and 75 years. Poor PCS and MCS scores were

defined as scores more than 0.5 SD below the normative mean of the general population (Norman et al., 2003), and the poor mean scores among LLDs were identified compared with the scores presented by Kang et al. (2021).

In addition, the mean scores of LLDs in all eight domains of the SF-12 were compared with those of the general Korean population (Kim et al., 2014). Kim et al. (2014) presented mean scores for the eight domains (PF, RP, BP, GH, VT, SF, RE, and MH) of SF-12 in the general Korean population according to gender and age groups (19–29, 30–39, 40–49, 50–59, 60–69, and 70 years or older). Poor scores of each domain were defined as scores more than 0.5 SD below the mean scores of the eight domains in the general Korean population (Kim et al., 2021; Norman et al., 2003).

Logistic regression was used to identify influential factors for poor PCS and MCS scores. Unadjusted and adjusted odds ratios and 95% confidence intervals (CI) were estimated using univariable and multivariable logistic regression models, respectively. Poor PCS and MCS scores were coded as 1, and others were coded as 0. In the multivariable analysis, a predictor was unmet expectations for surgical outcomes, and possible confounding variables known to be associated with LLD's PCS and MCS were controlled. These control variables were age, sex, education level, monthly income, postoperative complications, recipient death, time since donation, satisfaction with donation based on the previous research (Dew et al., 2018; Janik et al., 2019; Ladner et al., 2015; Morooka et al., 2019; Weng et al., 2019; Wirken et al., 2019). The predictor and control variables were simultaneously entered

into multivariable adjusted model. The Hosmer–Lemeshow test was applied to evaluate the goodness-of-fit of the models.

V. Results

1. Sample Description

1) Demographic and donor-specific characteristics

The demographic and donor-specific characteristics of LLDs are shown in Table 1. The mean age of the participants was 37.9 ± 11.4 years, ranging from 19 to 63 years. Among the 124 participants, 56.5% were male; 72.6% had a bachelor's degree or higher; and 62.9% had a monthly income of less than 3.5 million Korean won. Majority of the LLDs were children of the recipient (71%).

The mean of length of hospital stay was 9.5 days. Sixty LLDs (48.3%) experienced complications that were categorized by the Clavien–Dindo classification. Three LLDs experienced major complications (Grade III). A small proportion of LDLT recipients (8.9%) was deceased at the time point of survey completion. Two-thirds of the donors (66.1%) underwent surgery for transplant within 3 years. The majority of donors (75.8%) were very satisfied with their decision to donate their liver, and 21% were satisfied with their decision.

Table 1. Characteristics of the living liver donors (N=124)

Variable	n (%)	Mean (SD)
Age at survey completion		37.9 (11.4)
19-29	37 (29.8)	
30-39	35 (28.2)	
40-49	29 (23.4)	
50-59	19 (15.3)	
60-63	4 (3.2)	
Sex		
Male	70 (56.5)	
Female	54 (43.5)	
Education level		
Less than a bachelor's degree	34 (27.4)	
Bachelor's degree or higher	90 (72.6)	
Monthly income (million KRW)		
< 3.5	78 (62.9)	
≥ 3.5	43 (34.7)	
Unknown	3 (2.4)	
Relationship to recipient		
Child	88 (71.0)	
Spouse	17 (13.7)	
Sibling	11 (8.9)	
Parent	8 (6.5)	
Length of hospital stay (days)		9.5 (3.2)
≤ 8	33 (26.6)	
≥ 9, ≤ 11	82 (66.1)	
≥ 12	9 (7.3)	

Table 1. Continued

Variable	n (%)	Mean (SD)
Clavien–Dindo classification		
None	64 (51.6)	
Grade I	50 (40.3)	
Grade II	7 (5.6)	
Grade IIIa	2 (1.6)	
Grade IIIb	1 (0.8)	
Recipient status		
Died	11 (8.9)	
Survived	111 (89.5)	
Unknown	2 (1.6)	
Time since donation (years)		2.1 (2.2)
< 1	34 (27.4)	
≥ 1, < 3	48 (38.7)	
≥ 3, < 5	31 (25.0)	
≥ 5, < 10	9 (7.3)	
≥ 10	2 (1.6)	
Satisfaction with decision to donate		
Definitely not	1 (0.8)	
Not likely	3 (2.4)	
Somewhat likely	26 (21.0)	
Very likely	94 (75.8)	

Note: Adapted from "Does living liver donors' underestimation about surgical outcomes impact on their health-related quality of life after donation?: a descriptive cross-sectional study," by Y. S. Lee, C. K. Koh, N. J. Yi, K. S. Suh, and K. W. Lee, 2022, *Health and Quality of Life Outcomes*, 20(1), p. 146. CC BY 4.0.

2) Surgical complications

According to the Clavien–Dindo classification, postoperative complications were categorized by severity (Table 1): grade I (40.3%), which included fluid collection, subcutaneous emphysema, atelectasis, dizziness and nausea, keloid and hypertrophic scars, wound dehiscence, hematuria, vaginal oozing, fatty liver, chest pain, shoulder pain, fever, and temporarily elevated aspartate transaminase or/and alanine transaminase levels over at least 1 year after the transplantation; grade II (5.6%), which included dyspepsia, gaseous distention, chronic cough, urticarial rash, diarrhea, gastroenteritis, colitis (all requiring antibiotics and etc.), and portal vein stenosis (requiring aspirin); grade IIIa (1.6%), which included common bile duct stenosis, biloma, and pulmonary thromboembolism; or grade IIIb (0.8%), which included hematoma.

Table 2 presents the types of postoperative complications. Abdominal complication (39.1%) was the most common, followed by cardiopulmonary complication (23.9%), surgical wound complication (13.0%), fever (6.5%), hepatic complication (5.4%), and biliary complication (3.3%). Some patients had multiple complications.

Table 2. Postoperative complications

Type of complications	Number of cases (percent of all complications)
Abdominal complication	**36 (39.1)**
Fluid collection (≥5 cm)	7 (7.6)
Dizziness and nausea	7 (7.6)
Diarrhea or steatorrhea	6 (6.5)
Dyspepsia	5 (5.4)
Hematoma	5 (5.4)
Gastroenteritis	2 (2.2)
Gaseous distention	1 (1.1)
Colitis	1 (1.1)
Epigastric discomfort	1 (1.1)
Ileus	1 (1.1)
Cardiopulmonary complication	**22 (23.9)**
Atelectasis	15 (16.3)
Subcutaneous emphysema	4 (4.3)
Chest pain	1 (1.1)
Chronic cough	1 (1.1)
Pulmonary thromboembolism	1 (1.1)
Surgical wound complication	**12 (13.0)**
Keloid or hypertrophic scars	8 (8.7)
Wound discharge or dehiscence	4 (4.3)

Table 2. Continued

Type of complications	Number of cases (percent of all complications)
Fever (≥ 38.0°C after #POD 4)	**6 (6.5)**
Hepatic complication	**5 (5.4)**
Fatty liver	2 (2.2)
Elevated AST/ALT (over at least 1 year after surgery)	2 (2.2)
Portal vein stenosis	1 (1.1)
Biliary complication	**3 (3.3)**
Bile duct stenosis	1 (1.1)
Biloma	1 (1.1)
Cholangitis	1 (1.1)
Others	**8 (8.7)**

AST: aspartate aminotransferase, ALT: alanine aminotransferase, POD: postoperative day. Some patients had multiple complications.

2. Unmet Expectations about Surgical Outcomes

In terms of unmet expectations about surgical outcomes (Table 3), the percentages of the participants who reported worse-than-expected experiences for length of hospital stay, speed of recovery, pain, and complications were 9.7%, 22.6%, 34.7%, and 7.3%, respectively. Preoperative expectations about the length of the hospital stay were met in 34.7% of 124 participants. Most LLDs (79.0%) answered that their experience related to complications was better than expected, and 43.5% answered that their experience of pain was better than expected. Ten LLDs (8.1%) expressed that three or more of the four items of the surgical outcomes were worse than expected.

The associations between unmet expectations about the length of hospital stay, speed of recovery, pain, and complications and time since donation are shown in Tables 4, 5, 6, and 7. There was no difference in unmet expectations about the length of hospital stay, speed of recovery, or pain between LLDs less than 3 years after donation and LLDs more than 3 years after donation. However, unmet expectations about complications were more common for LLDs less than 3 years after donation (p = 0.028). They were likely to say they experienced worse complications than expected compared with LLDs more than 3 years after donation.

Table 3. Frequencies of the four items of postoperative experience in comparison with preoperative expectations (N=124)

	Better than expected	**As expected**	**Worse than expected (unmet expectations)**
Actual postoperative experience of	n (%)	n (%)	n (%)
Length of hospital stay	69 (55.6)	43 (34.7)	12 (9.7)
Speed of recovery	60 (48.4)	36 (29.0)	28 (22.6)
Pain	54 (43.5)	27 (21.8)	43 (34.7)
Complications	98 (79.0)	17 (13.7)	9 (7.3)

Note: Reprinted from "Does living liver donors' underestimation about surgical outcomes impact on their health-related quality of life after donation?: a descriptive cross-sectional study," by Y. S. Lee, C. K. Koh, N. J. Yi, K. S. Suh, and K. W. Lee, 2022, *Health and Quality of Life Outcomes*, 20(1), p. 146. CC BY 4.0.

Table 4. Associations between unmet expectations about the length of hospital stay and time since donation (*n* = 124)

Time since donation		Length of hospital stay		Total
		Better than expected and as expected	Worse than expected (unmet expectations)	
Less than 3 years	n (%)	73 (89.0)	9 (11.0)	82 (100)
More than 3 years	n (%)	39 (92.9)	3 (7.1)	42 (100)
Total	n (%)	112 (90.3)	12 (9.7)	124 (100)
Fisher's exact test			*p* value = 0.749	

Table 5. Associations between unmet expectations about the speed of recovery and time since donation (*n* = 124)

Time since donation		Speed of recovery		Total
		Better than expected and as expected	Worse than expected (unmet expectations)	
Less than 3 years	n (%)	62 (75.6)	20 (24.4)	82 (100)
More than 3 years	n (%)	34 (81.0)	8 (19.0)	42 (100)
Total	n (%)	96 (77.4)	28 (22.6)	124 (100)
Pearson's chi-square test		$\chi^2 = 0.453$	*p* value = 0.501	

Table 6. Associations between unmet expectations about pain and time since donation (*n* = 124)

Time since donation		Pain		Total
		Better than expected and as expected	**Worse than expected (unmet expectations)**	
Less than 3 years	n (%)	53 (64.6)	29 (35.4)	82 (100)
More than 3 years	n (%)	28 (66.7)	14 (33.3)	42 (100)
Total	n (%)	81 (65.3)	43 (34.7)	124 (100)
Pearson's chi-square test		$\chi^2 = 0.051$	*p* value = 0.822	

Table 7. Associations between unmet expectations about complications and time since donation (*n* = 124)

Time since donation		Complications		Total
		Better than expected and as expected	**Worse than expected (unmet expectations)**	
Less than 3 years	n (%)	73 (89.0)	9 (11.0)	82 (100)
More than 3 years	n (%)	42 (100)	0 (0)	42 (100)
Total	n (%)	115 (92.7)	9 (7.3)	124 (100)
Fisher's exact test			*p* value = 0.028	

3. Health-related Quality of Life

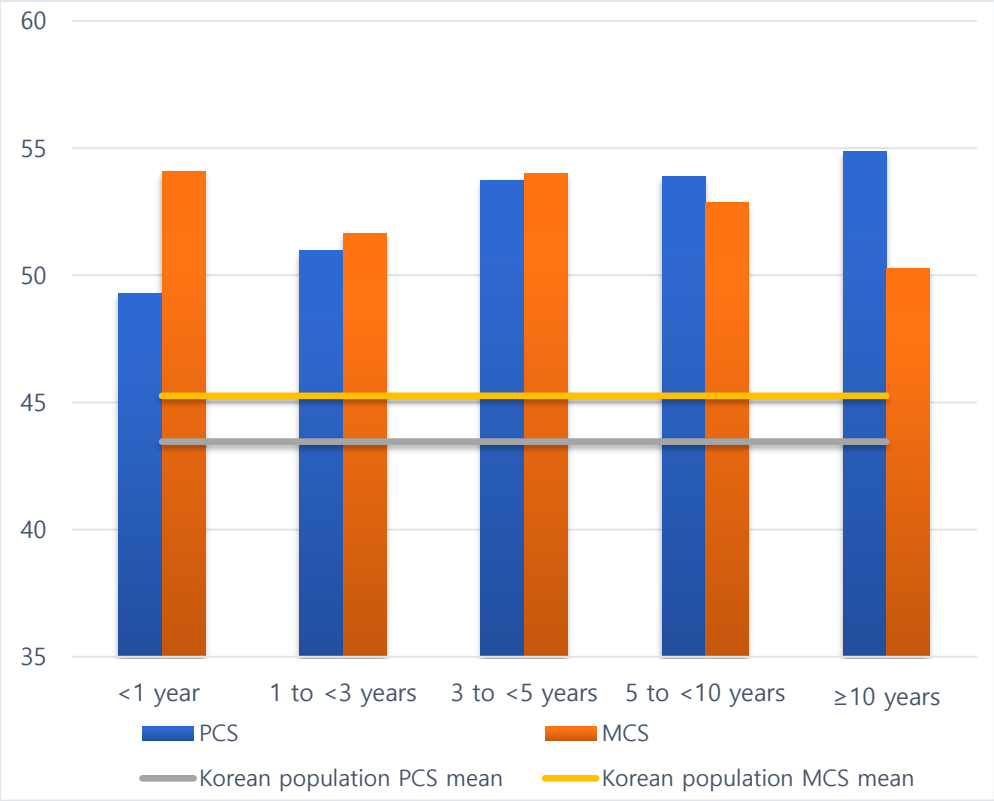
1) Comparison of two-component summary scores

The mean donor SF-12 scores were 51.48 ± 7.44 (PCS) and 52.97 ± 8.47 (MCS) while the normative SF-12 scores for the general Korean population were 43.46 ± 3.05 (PCS) and 45.26 ± 4.35 (MCS) (Kang et al., 2021). The differences were significant (PCS, $t = 12.014$, $p < 0.001$; MCS, $t = 10.133$, $p < 0.001$). In other words, the physical well-being and mental well-being of LLDs were significantly higher than those of the general Korean population.

SF-12 component summary mean scores in LLD by time since donation and those of general Korean population are seen in Figure 3. The mean scores in LLDs less than 1 year after surgery were 49.30 (PCS) and 54.09 (MCS). The mean scores in LLDs more than 1 year but less than 3 years after surgery were 50.97 (PCS) and 51.66 (MCS). The mean scores in LLDs more than 3 years but less than 5 years after surgery were 53.75 (PCS) and 53.98 (MCS). The mean scores in LLDs more than 5 years but less than 10 years after surgery were 53.88 (PCS) and 52.86 (MCS). The mean scores in LLDs 10 years or more after surgery were 54.88 (PCS) and 50.28 (MCS).

Among the study participants, 14 (11.3%) had poor PCS scores, and 16 (12.9%) had poor MCS scores.

Figure 3. SF-12v2 component summary mean scores in LLDs and general Korean population by time since donation



SF-12v2: Short form-12 health survey version 2, LLD: Living liver donor, PCS: Physical component summary, MCS: Mental component summary.

Note: Adapted from "Does living liver donors' underestimation about surgical outcomes impact on their health-related quality of life after donation?: a descriptive cross-sectional study," by Y. S. Lee, C. K. Koh, N. J. Yi, K. S. Suh, and K. W. Lee, 2022, *Health and Quality of Life Outcomes*, 20(1), p. 146. CC BY 4.0.

2) Comparison of eight domain scores

Table 8 shows the mean scores of eight domains of SF-12v2 by sex and age groups. Figure 4 shows the mean scores for LLDs and the general Korean population across eight categories of SF-12v2 by sex (Kim et al., 2014). Males showed a poor score in RP, and females showed a poor score in PF.

Figure 5 displays the mean scores of eight domains of SF-12v2 by age groups compared with the general Korean population norm (Kim et al., 2014). In the age group of 19–29 years, poor scores were shown in the domains of PF, RP, BP, GH, VT, SF, and RE. In the age group of 30–39 years, poor scores were shown in the domains of PF, RP, and BP. Poor scores were shown in the PF, RP, and RE domains in the age group of 40–49 years. There was no poor score across all domains in the age groups of 50–59 and 60–69 years. However, the result of the age group of 60–69 years should be interpreted with caution as the general population ages range from 60 to 69, whereas the LLD group ages range from 60 to 63.

Table 8. Mean scores of eight domains of SF-12v2 by sex and age groups

Variables	PF		RP		BP		GH		VT		SF		RE		MH	
	Mean	SD	Mean	SD	Mean	SD	Mean	SD	Mean	SD	Mean	SD	Mean	SD	Mean	SD
Sex																
Male	90.0	23.5	82.3*	21.9	86.4	24.3	65.0	22.7	64.3	23.9	87.9	19.8	86.4	19.1	75.2	18.5
Female	78.7*	27.6	82.2	23.4	82.4	23.6	66.3	22.3	70.4	24.3	86.6	24.6	86.1	19.2	78.2	18.0
Age group (years)																
19–29	84.5*	26.6	80.4*	24.7	81.8*	28.0	63.5*	25.5	65.5*	27.9	80.4*	30.1	84.5*	20.7	74.3	20.6
30–39	86.4*	21.3	83.9*	19.8	84.3*	21.1	72.7	16.1	73.6	19.1	90.7	15.0	88.2	16.0	77.5	18.4
40–49	84.5*	33.0	82.3*	25.1	89.7	24.6	58.8	24.0	61.2	22.7	89.7	19.5	84.9*	22.3	77.2	14.2
50–59	88.2	21.0	85.5	18.3	86.8	21.0	71.6	18.6	71.1	24.0	93.4	14.0	90.8	15.5	80.3	19.2
60–65	68.8	23.9	68.8	23.9	68.8	12.5	42.5	20.2	43.8	23.9	75.0	20.4	75.0	20.4	65.6	18.8

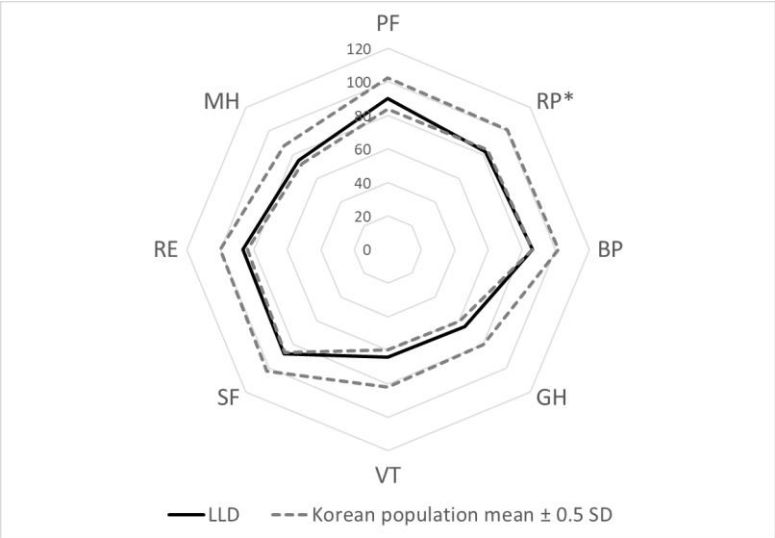
SF-12v2: Short form-12 health survey version 2, PF: physical functioning, RP: role-physical, BP: bodily pain, GH: general health, VT: vitality, SF: social functioning, RE: role-emotional, MH: mental health.

*The score was poor, which was more than 0.5 SD below the normative mean of the general Korean population.

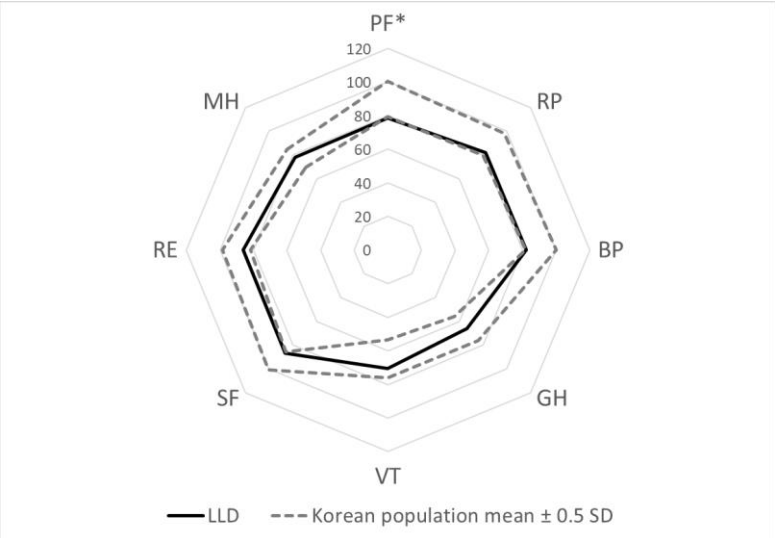
Figure 4. Mean scores of eight domains of SF-12v2 by sex

A: male mean scores, B: female mean scores.

*Poor mean score



(A)



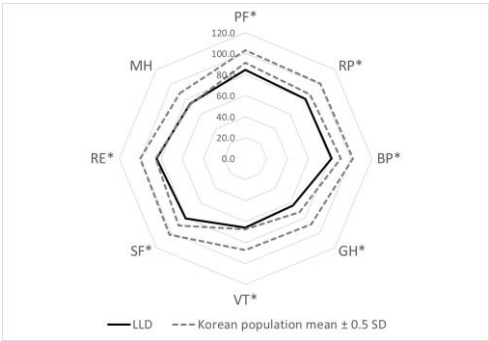
(B)

SF-12v2: Short form-12 health survey version 2, LLD: living liver donor, PF: physical functioning, RP: role-physical, BP: bodily pain, GH: general health, VT: vitality, SF: social functioning, RE: role-emotional, MH: mental health.

Figure 5. Mean scores of eight domains of SF-12v2 by age groups

A: 19–29, B: 30–39, C: 40–49, D: 50–59, E: 60–69 years.

*Poor mean score



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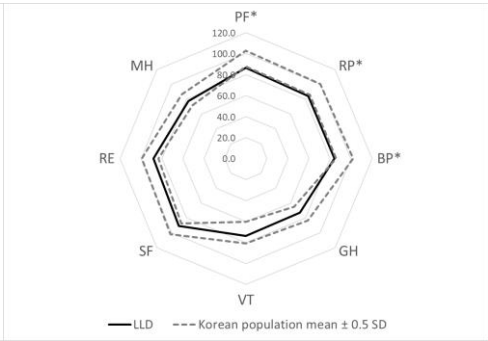

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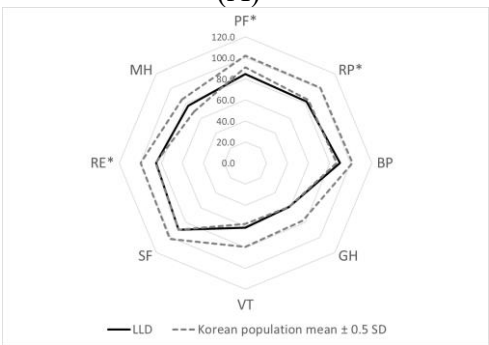

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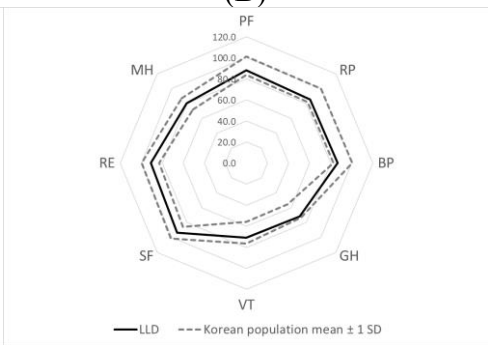

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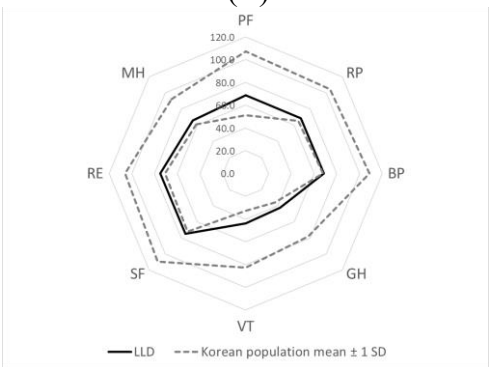

(E)

SF-12v2: Short form-12 health survey version 2, LLD: living liver donor, PF: physical functioning, RP: role-physical, BP: bodily pain, GH: general health, VT: vitality, SF: social functioning, RE: role-emotional, MH: mental health.

4. Logistic Regression Models

1) Logistic regression model for physical well-being

The final logistic regression model for PCS is shown in Table 9. In the univariable model for PCS (Table 9), time since donation and unmet expectations for surgical outcomes were significantly associated with poor PCS scores (unadjusted odds ratio [UOR] 0.53, 95% CI 0.32–0.88; UOR 6.93, 95% CI 1.67–28.74).

For the multivariable logistic regression models for PCS, age, sex, education level, monthly income, postoperative complications, recipient death, time since donation, and satisfaction with the decision to donate were controlled. The multivariable logistic regression model for PCS was significant (X^2 (df = 9) = 19.313, p = 0.023) with acceptable goodness-of-fit statistics (Hosmer–Lemeshow: p = 0.177). In this adjusted model for PCS, unmet expectations for surgical outcomes predicted poor PCS scores (adjusted odds ratio [AOR] 7.46, 95% CI 1.38–40.49) after controlling for age, sex, education level, income, postoperative complications, recipient death, time since donation, and satisfaction with the decision to donate (Table 9). In other words, donors who reported three or four unmet expectations were more likely to have poor PCS scores than those who reported two or fewer unmet expectations. In this model, a shorter interval since donation was also associated with poor PCS scores (AOR 0.50, 95% CI 0.27–0.95).

Table 9. Logistic regression model for poor PCS scores (N=124)

Variable	UOR (95% CI)	p-value	AOR (95% CI)	p-value
Age	1.002 (0.954, 1.052)	0.940	1.013 (0.952, 1.078)	0.674
Female (ref: male)	1.855 (0.603, 5.710)	0.281	2.796 (0.681, 11.478)	0.154
Bachelor's degree or higher (ref: less than a bachelor's degree)	0.644 (0.199, 2.082)	0.463	0.890 (0.209, 3.799)	0.875
Monthly income: ≥ 3.5 million KRW (ref: <3.5 million KRW)	0.786 (0.227, 2.721)	0.704	0.626 (0.146, 2.677)	0.527
Postoperative complications (ref: no complications)	2.082 (0.656, 6.614)	0.214	1.351 (0.354, 5.166)	0.660
Recipient death (ref: recipient alive)	0.000 (0.000)	0.999	0.000 (0.000)	0.999
Time since donation (years)	0.529 (0.316, 0.884)	0.015	0.502 (0.265, 0.952)	0.035

Table 9. Continued

Variable	UOR (95% CI)	p-value	AOR (95% CI)	p-value
Satisfaction with decision to donate	0.777 (0.311, 1.941)	0.589	0.859 (0.242, 3.047)	0.814
Unmet expectations for surgical outcomes: 3-4 items were worse than expected (ref: 0-2 items were worse than expected)	6.933 (1.673, 28.737)	0.008	7.461 (1.375, 40.488)	0.020

PCS: physical component summary, UOR: unadjusted odds ratio, AOR: adjusted odds ratio, CI: confidence interval.

Note: Reprinted from "Does living liver donors' underestimation about surgical outcomes impact on their health-related quality of life after donation?: a descriptive cross-sectional study," by Y. S. Lee, C. K. Koh, N. J. Yi, K. S. Suh, and K. W. Lee, 2022, *Health and Quality of Life Outcomes*, 20(1), p. 146. CC BY 4.0.

2) Logistic regression model for mental well-being

The final logistic regression model for MCS is shown in Table 10. In the univariable model for MCS (Table 10), education level, satisfaction with decision to donate, and unmet expectation were statistically related to poor MCS scores (UOR 0.32, 95% CI 0.11–0.93; UOR 0.37, 95% CI 0.17–0.83; UOR 5.67, 95% CI 1.40–22.97).

For the multivariable logistic regression models for MCS, age, sex, education level, monthly income, postoperative complications, recipient death, time since donation, and satisfaction with the decision to donate were controlled. The multivariable logistic regression model for MCS was significant (X^2 (df = 9) = 18.638, p = 0.028) with acceptable goodness-of-fit statistics (Hosmer–Lemeshow: p = 0.266). In this adjusted model for MCS, unmet expectations for surgical outcomes were a predictor of poor MCS scores after controlling for other factors (AOR 7.15, 95% CI 1.35–37.97) (Table 10). The likelihood of poor MCS scores increased in donors who had three or more items of unmet expectations than in those who had two or fewer items of unmet expectations (AOR 7.15, 95% CI 1.35–37.97). In addition, LLDs having less than a bachelor's degree and less satisfied with decision to donate were likely to experience poor MCS (AOR 0.24, 95% CI 0.06–0.96; AOR 0.30, 95% CI 0.12–0.77).

Table 10. Logistic regression model for poor MCS scores (N=124)

Variable	UOR (95% CI)	p-value	AOR (95% CI)	p-value
Age	1.003	0.900	0.993	0.809
	(0.958, 1.050)		(0.936, 1.053)	
Female	0.547	0.293	0.351	0.136
(ref: male)	(0.178, 1.682)		(0.089, 1.389)	
Bachelor's degree or higher	0.317	0.036	0.239	0.044
(ref: less than a bachelor's degree)	(0.108, 0.929)		(0.060, 0.961)	
Monthly income: ≥ 3.5 million KRW	0.895	0.849	1.017	0.982
(ref: <3.5 million KRW)	(0.285, 2.810)		(0.241, 4.289)	
Postoperative complications	1.077	0.890	0.792	0.722
(ref: no complications)	(0.377, 3.078)		(0.220, 2.858)	
Recipient death	0.640	0.681	0.751	0.812
(ref: recipient alive)	(0.076, 5.366)		(0.071, 7.977)	
Time since donation (years)	0.809	0.205	0.889	0.561
	(0.583, 1.123)		(0.598, 1.322)	

Table 10. Continued

Variable	UOR (95% CI)	p-value	AOR (95% CI)	p-value
Satisfaction with decision to donate	0.373 (0.169, 0.826)	0.015	0.301 (0.117, 0.773)	0.013
Unmet expectations for surgical outcomes:	5.667 (1.398, 22.966)	0.015	7.150 (1.346, 37.972)	0.021
3-4 items were worse than expected (ref: 0-2 items were worse than expected)				

MCS: mental component summary, UOR: unadjusted odds ratio, AOR: adjusted odds ratio, CI: confidence interval.

Note: Reprinted from "Does living liver donors' underestimation about surgical outcomes impact on their health-related quality of life after donation?: a descriptive cross-sectional study," by Y. S. Lee, C. K. Koh, N. J. Yi, K. S. Suh, and K. W. Lee, 2022, *Health and Quality of Life Outcomes*, 20(1), p. 146. CC BY 4.0.

VI. Discussion

1. Unmet Expectations about Surgical Outcomes

This study examined the unmet expectations of LLDs related to surgical outcomes by comparing preoperative expectations and actual experiences. The surgical outcome that most frequently showed a discrepancy between expectation and reality was pain (34.7%), while the outcome where such discrepancies were least frequently reported was complication (7.3%). Meanwhile, 8.1% of LLDs answered that three or four surgical outcomes were worse than anticipated. Additionally, among four items, unmet expectations only about complications were affected by time since donation. LLDs who underwent surgery long ago tended to report complications that were less severe or the same as expected.

Unmet expectations about surgical outcomes such as the length of hospital stay, speed of recovery, pain, and complications can increase psychological distress and symptom-related discomfort after surgery (Sweeny & Andrews, 2017). In the current study, the unmet expectations of LLDs were associated with poorer mental and physical HRQOL. All patients' expectations regarding surgical outcomes cannot be exactly the same as the actual postoperative experience, and unpredictable outcomes and uncertainty may still exist (Gordon et al., 2011; Reese et al., 2015). Moreover, it is

common for patients to have unrealistic optimism and expect unreasonably good surgical outcomes (Sweeny & Andrews, 2017). To decrease these discrepancies between expectations and reality, efforts must be made to help LLDs realistically anticipate surgical outcomes. In this study, the items in which proportion of unmet expectation was less than 10% were length of hospital stay and complications. This indicates that information about the speed of recovery and pain was relatively deficient and vague.

The information given to LLDs needs to include an explanation of the uncertain factors as well as certain factors related to surgical outcomes (Reese et al., 2015). Although LLDs have reported that they were given appropriate and sufficient information (Gordon et al., 2016), the information needs to be examined to determine if it is extensive, accurate, and actual and supports LLDs in maintaining realistic expectations. In addition, Weng et al. (2012), who conducted a qualitative study of Taiwanese LLDs, showed that they may not really receive information about negative surgical outcomes to reduce their anxiety about donation. Therefore, a careful approach regarding LLDs' attitudes toward possible negative surgical outcomes needs to be taken, and research to explore its impact on their unrealistic optimism should be performed.

2. Health-related Quality of Life and Its Predictors

In assessments of the HRQOL of LLDs, the mean donor SF-12 scores were 51.48 ± 7.44 (PCS) and 52.97 ± 8.47 (MCS), which appear to be higher than the normative SF-12 scores for the general Korean population: 43.46 ± 3.05 (PCS), 45.26 ± 4.35 (MCS) (Kang et al., 2021). This suggests that donor hepatectomy is safe and that LLDs remain healthy after donation. However, we can also consider other reasons. Because a liver donor is expected to have passed a medical evaluation, including general physical and mental health examinations, to become a donor (Yi et al., 2007), such evaluations may select individuals healthier than the general population. Moreover, the age of the general population ranged from 20 to 75 years (Kang et al., 2021), whereas that of this study sample ranged from 19 to 63 years. Because the sample of this study was younger than the general population of the study by Kang et al. (2021), the higher mean scores of this study may have been derived. Therefore, a comparison of the mean scores of LLDs before and after donation is recommended.

However, while comparing the eight domains of SF-12 between LLDs and the general Korean population according to sex and age groups (Kim et al., 2014), many domains showed poor scores in the age group of 19–29 years. This group had poor scores in seven domains (PF, RP, BP, GH, VT, SF, and RE). As they could overestimate their health before surgery, the changes they

experienced after surgery may impact their perception of their health more. In addition, they may feel a greater sense of relative deprivation when they see their socially active and physically healthy peers. This result indicated that healthcare professionals in the transplant team should focus on young donors.

This study explored the QOL of LLDs in terms of its relationship with the donors' unmet expectations regarding surgical outcomes. Experiencing a worse-than-expected recovery process was associated with poorer physical and mental QOL, even after controlling for age, sex, education level, income, presence of complications, recipient death, time since donation, and satisfaction with the decision to donate.

Additionally, a shorter period since donation was significantly associated with poor PCS scores. This result is consistent with that of prior studies in which participants reported their HRQOL within one or three postoperative years (Jin et al., 2012; Weng et al., 2019). Furthermore, poor physical well-being is particularly associated with an interval of less than three months since donation (Ladner et al., 2015; Parikh et al., 2010). However, our outcome is in contrast to that reported by Ladner et al. (2015), who suggested that a longer interval from donation increased the likelihood of poor PCS scores. This may also be a plausible result since the postoperative period in their study was relatively evenly distributed from one to eight years and the study participants had been aging in a longitudinal study, which was performed for 11 years.

In our study population, 96.8% of LLDs were satisfied with the decision to donate; thus, 3.2% of LLDs had decisional regrets about liver donation. We found that the more satisfied the donor was with the decision to donate, the more likely he or she was to have better mental HRQOL. This is consistent with the findings of a study on kidney donors by Wirken et al. (2019), which suggested that donors with regret experienced poorer HRQOL, especially in the social functioning and health perception domains.

3. Fulfillment of Expectations and Information

The finding of this study that the unmet expectations of LLDs about the surgical outcomes predicted poor HRQOL after donor hepatectomy supported the Calman expectations model. This conclusion implies that healthcare strategies in the preoperative phase can help enhance the QOL of postoperative patients (Carr et al., 2001).

Patients can maintain or modify their initial expectations. These expectations may be accurate or ambiguous and may be affected by sociodemographic characteristics and previous direct or indirect experiences of receiving healthcare (Kravitz, 1996). Patient expectations may be well-formed based on adequate and sufficient information about the advantages of the procedure and suffering after donation, including pain and side effects

(Waljee et al., 2014). Sweeny and Andrews (2017) stated that healthcare providers should provide well-established information on the beneficial and detrimental effects of surgical procedures for patients. This approach can help patients raise realistic expectations and not overly rely on information from the Internet or other patients.

However, this approach should be practiced with caution because facilitating undue prediction of deterioration or risks can suppress the hopes and positive attitudes of patients and their families, which are crucial to coping with disease (Carver & Antoni, 2004; Radbruch & Jaspers, 2019). Some LLDs felt uncomfortable about repeated disclosure and warning of risk information and misinterpreted the intentions of the transplant team as a discouragement of donation (Gordon et al., 2016). Therefore, healthcare providers and patients must balance optimism and pragmatism (Sweeny & Andrews, 2017).

The literature showed conflicting results on whether providing such information is critical to making decisions. In several studies, most LLDs did not make decisions using risk information because they wanted to donate the liver to save the lives of their loved ones, and they trusted the success of the transplant team (Gordon et al., 2015; Molinari et al., 2014). Another study reported that most LLDs expressed difficulties in decision-making, attributed to uncertainty about whether they could maintain daily life after the transplant surgery (Yu, 2016). That study declared that unmet expectations affected the postoperative adaptation physically and

psychologically, and sharing adequate amounts and types of information in the preoperative phase became more important (Yu, 2016).

LLDs reported unanticipated experiences of higher pain levels and surprisingly shorter lengths of hospital stay (Gordon et al., 2016; O'Connor et al., 2015). They preferred information about the type and duration of common complications, length of hospital stay, recovery period, and postoperative care, including the management of surgical wounds and complication prevention behavior, which would practically impact their daily lives (Jung, 2010; Kim et al., 2007; Yu, 2016). In addition, donors reported that disclosure of new and excessive information left them unable to comprehend or remember all of it (Gordon et al., 2016).

Therefore, not only should nurses and surgeons provide adequate information about the transplantation process, but also the patients should inform the medical staff of the level of understanding of the provided information, the types of desired information, and the degrees of their expectations about postoperative adaptation. By explicitly exchanging information with each other, both can be satisfied with the communication process. The medical team must receive information on the individual characteristics and values of the patients, and the patients must obtain patient-centered or tailored information from the medical team. Accordingly, donors can provide informed consent to liver donation and reasonably calibrate their expectations about surgical outcomes until surgery. Consequently, an approximate fulfillment of expectations may elicit better postoperative

adaptation and HRQOL.

Furthermore, even after the recovery process, nurses and physicians are recommended to discuss the extent of preoperative expectations being met because it could affect their QOL (Saban & Penckofer, 2007). For better management of future patient expectations, the transplant team may be able to recognize aspects that the donors could not anticipate or were dissatisfied with.

4. Nursing Implications

1) Nursing research

This study explored the postoperative HRQOL among LLDs in South Korea using SF-12 (a globally used instrument) and compared it with that of the general Korean population. This is the first study to compare the HRQOL of LLDs more than 1 year after surgery in South Korea with that of the general Korean population. The results of significantly higher mean PCS and MCS scores proved the safety and stability of donor hepatectomy.

Furthermore, this study provided insight into the prediction mechanisms in which QOL can be projected by preoperative patient expectations, supporting the Calman expectations model. This study broadened the application of the expectations model and obtained a hint about the direction to improve HRQOL and adaptation after donation from the

model.

The findings of this study contributed to the body of knowledge about nursing in transplant in terms of the formation of donor expectations. This study advanced the understanding of what items among surgical outcomes are essential for LLDs, who do not differ from healthy individuals. In addition, it stated that LLDs were more likely to underestimate the items of pain and speed of recovery. Further research is needed to accumulate these data.

2) Nursing practice

The current study included surgical outcomes such as the length of hospital stay, postoperative complications, pain, and recovery speed, which can be considered as an evidence while providing information to LLDs in the pre- and postoperative stages. In particular, LLDs reported more unmet expectations for pain and speed of recovery than hospital stay and complications, indicating that nurses should share evidence-based clinical information related to pain and recovery speed.

In the context where HRQOL is a crucial endpoint for LLDs, this study confirmed the effect of unmet expectations on poor HRQOL and the association between a longer period since donation and better physical QOL and between higher satisfaction with the decision to donate and better mental QOL. Accordingly, nurses in practice and policymaking should develop interventions or guidelines to maintain or improve the postoperative HRQOL of LLDs.

Adequate and suitable information and patient-centered education must be provided to balance expectations and reality. Patient-centered communication was defined as understanding patient concerns, needs, and expectations within their unique psychosocial background and establishing a shared understanding between nurses and patients (Epstein et al., 2005). Such patient-centered care can elicit enhanced patient-reported outcomes (Epstein et al., 2005; Wang & Gottumukkala, 2021). In perioperative care, LLD education is essential to make satisfactory decisions, give fully informed consent (Sites et al., 2008), and build realistic expectations. Likewise, nurses or nurse coordinators should receive information from LLDs when nurses educate them about surgical outcomes and HRQOL that donors would expect and experience. This shared communication allows nurses to consider particular individual circumstances and provide patient-centered information.

5. Limitations

This study had some limitations. First, to measure LLDs' HRQOL, we used a generic instrument, the SF-12. This could have disregarded some distinct aspects of the donors; nevertheless, SF-12 is highly utilized and thus suitable for comparison with various populations from different countries.

Second, unmet expectations were measured based on retrospective questions, leading to the possibility of recall bias. Moreover, the used unmet expectations measure was not validated in a strict sense.

Finally, our results were drawn from a survey at one transplantation center at a university hospital; thus, the results had limited generalizability.

VII. Conclusion and Recommendations

1. Conclusion

This study explored LLDs' unmet expectations related to surgical outcomes. Healthy LLDs decide to become surgical patients for altruistic reasons and most are satisfied with their decision to donate during the rest of their lives. However, they go through the postoperative recovery process, and unmet expectations regarding surgical outcomes during this process may have a negative effect on donors' HRQOL.

The specific results of this study are as follows.

First, unmet expectations about surgical outcomes existed. In particular, unmet expectations about the speed of recovery and pain were relatively high. The provided information about these items seemed relatively deficient and vague.

Second, the physical HRQOL mean score for LLDs was significantly higher than that for the general Korean population. However, male donors had a poor mean RP score than the general population, whereas female donors had a poor mean PF score. In addition, young donors (19–20 years) reported significantly poor average PF, RP, BP, and GH scores. Donors in their 30s showed poor average PF, RP, and BP scores. Donors in their 40s showed poor

average PF and RP scores.

Third, physical HRQOL was related to unmet expectations about surgical outcomes and a shorter period since donation. LLDs who experienced more unmet expectations or who recently underwent surgery had poor physical HRQOL.

Fourth, the mental HRQOL mean score for LLDs was significantly higher than that of the general Korean population. However, young donors (19–20 years) reported poor mean VT, SF, and RE scores. Donors in their 40s showed a poor mean RE score.

Fifth, mental HRQOL was related to unmet expectations about surgical outcomes, education level, and satisfaction with the decision to donate. LLDs who experienced more unmet expectations, had education less than a bachelor's degree, or were less satisfied with the decision had poor mental HRQOL.

2. Recommendations

Based on the above research results, we suggest the following recommendations.

First, poor HRQOL was associated with unmet expectations about surgical outcomes. To decrease unmet expectations, healthcare professionals should support LLDs in obtaining more accurate, evidence-based, and

extensive information about surgical outcomes and donation impacts on their activities of daily living. In particular, information related to pain and recovery speed is insufficient for accurate prediction. Therefore, further research is needed to explore the pain severity and duration of LLDs, as well as the full recovery period and discomfort level. Additionally, as most of the validated patient expectation instruments are orthopedic or cardiac patient-related (Waljee et al., 2014), the need to develop reliable and validated instruments or use qualitative methods to capture the preoperative expectations of living donors is proposed.

Second, providing information requires a careful approach. Excessive information can cause LLD anxiety because it makes them overestimate the possibility of risks and become confused by their inability to comprehend all information. Therefore, throughout the perioperative process, healthcare professionals should discuss and communicate closely with donors to provide the type and amount of information donors want and ensure their understanding.

Third, although LLDs were proven healthy, young donors in their late teens and 20s still need postoperative care in physical and mental domains. Effective care interventions should be further researched and developed by identifying their critical factors. In addition, a donor-specific HRQOL instrument that reflects the unique characteristics of LLDs in the context of Korean culture and systems should be developed to deeply understand the HRQOL of Korean LLDs.

Fourth, poor physical HRQOL was associated with a shorter period since donation. Therefore, LLDs should be encouraged to visit follow-up and be educated about postoperative self-care. During future outpatient visits, nurses and physicians should resolve the questions and problems related to their health. Meanwhile, poor mental HRQOL was associated with satisfaction with the decision to donate. For more satisfaction and less regret, research should be conducted to identify the predictors of post-donation regret.

Fifth, further research on patient unmet expectations and their effects on QOL is required from multiple transplant centers with large samples. Furthermore, a prospective longitudinal study should be performed to compare preoperative expectations and actual postoperative experiences, as well as HRQOL, before and after surgery for individual LLDs. The longitudinal study should also identify unmet expectations that may change over time during the postoperative period.

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Appendixes

Appendix 1. The approval by an institutional review board.

서울대학교의과대학/서울대학교병원
의학연구윤리심의위원회

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심의결과통보서

IRB No.	H-2101-074-1187			제출경로	서울대병원		
수신	책임연구자	이남준		소속	간담췌외과	직위	교수
	의뢰기관						
연구과제명	간이식 기증자의 수술 후 기증만족도, 우울, 불안, 건강관련 삶의 질과 그 영향요인						
Protocol No.				Version No.			
생명 윤리법에 따른 분류	■ 인간대상연구 □ 인체유래물연구 □ 배아줄기세포주이용연구 □ 배아연구 □ 체세포복제배아연구 □ 단성생식배아연구 □ 배아생성의료기관 □ 인체유래물은행						
연구종류	■ 임상 시험외 연구	□ 증례보고 □ 생태학적 연구 □ 단면조사연구 ■ 조사,설문,인터뷰 연구 □ 환자군 연구 □ 환자-대조군연구 □ 인체유래물저장소 연구 □ 등록(레지스트리) 연구 □ 시판후사용성적조사 □ 전향적 코호트 연구 □ 후향적 코호트연구 □ 기타					
	□ 임상 시험	연구 대상	□ 의약물 □ 생물학적제제 □ 건강기능식품 □ 의료기기 □ 기타				
			일반명				
			상품명				
		Phase	□ 제1상 □ 제1/2상 □ 제2상 □ 제2/3상 □ 제3상 □ 제4상 □ 생물학적동등성 □ 기타				
		식약처 승인 대상 여부	□ 식약처승인대상 □ 승인 제외 대상				
		임상시험 목적	□ 학술용 □ 국내(MFDS)허가용 □ 해외 허가용				
연구계획서승인일	2021년 02월 15일 (정기보고주기 : 12개월)						
승인유효 만료일	2022년 02월 14일			심의대상	연구계획심의 의뢰서(수정후신속심의에 대한 답변)		
심의종류	신속심의			심의일자	2021년 02월 10일		
접수일자	2021년 02월 08일			심의결과통보일	2021년 02월 15일		
심의목록	1. 연구계획심의 의뢰서(수정후신속심의에 대한 답변) 2. 연구계획서 ver1.2 3. 연구대상자 설명문 및 동의서 ver1.1 4. 연구대상자 서면동의면제사유서 ver1.0 5. 증례기록서 ver1.0 6. 책임연구자의 최근 이력 ver1.0 7. 연구대상자에게 제공되는 서류 설문지 ver1.1 8. 연구대상자 모집 문건 ver1.1 9. 기타 GCP교육이수증(고진강)						
심의결과	승인						

의 학 연 구 윤 리 심 의 위 원 회 위 원

본 통보서에 기재된 사항은 IRB의 기록된 내용과 일치 함을 증명합니다.
본 기관 IRB는 생명윤리 및 안전에 관한 법률, 약사법, 의료기기법 및 ICH-GCP 등 관련
본 연구와 이해관계(Conflict of Interest)가 있는 위원이 있을 경우 연구의 심의에서 배제하였습니다.

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서울대학교의과대학/서울대학교병원
의학연구윤리심의위원회

연구의 위험도	최소위험 연구(minimal risk)
심의의견	검토의견에 대한 답변을 확인하였고, IRB의 승인 기준에 부합하여 승인합니다.

의 학 연 구 윤 리 심 의 위 원 회 위 원 장

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본 연구와 이해관계(Conflict of Interest)가 있는 위원이 있을 경우 연구의 심의에서 배제하였습니다.

서울대학교의과대학/서울대학교병원
의학연구윤리심의위원회

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본 위원회에서 승인된 모든 연구자들은 다음의 사항을 준수하여야 합니다.

1. 연구계획서 및 변경계획서의 승인 이전에 연구대상자의 해당 임상연구의 참여 금지됩니다.
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7. 위원회의 승인을 받은 연구대상자 모집 광고문을 사용해야 합니다.
8. 위원회의 승인은 1년을 초과할 수 없습니다. 1년 이상 연구를 지속하고자 하는 경우에는 반드시 연차지속 보고를 하여야 합니다. 단, 심의면제는 해당 없습니다.
9. 심의결과가 승인이 아닌 경우에는 답변서를 제출하여야 하며, 심의일로부터 6개월 이내에 이루어져야 합니다.
10. 위원회 결정사항에 대하여 심의통보일로부터 1개월 이내에 이의신청을 할 수 있으며, 같은 사항에 대하여 한 번의 이의신청만 가능합니다.
11. 연구 종료 시에는 종료 및 결과보고서를 작성하여 제출해야 합니다.
12. 생명윤리 및 안전에 관한 법률, 약사법/의료기기법, 헬싱키 선언 및 ICH-GCP 가이드라인 등 국내외 관련 법규를 준수하여야 합니다.
13. 헬싱키선언에 따라 첫 연구대상자를 모집하기 전 공개적으로 접근이 가능한 데이터베이스(primary registry)에 연구에 대하여 공개하여야 하며, 예를 들어 http://register.clinicaltrials.gov 를 이용하실 수 있습니다.
14. 승인 받은 연구에 대하여 기관의 내부 점검 및 외부의 실태조사를 받을 수 있습니다. 기관의 내부 점검자, 외부의 모니터요원 및 점검자, 규제기관의 실태조사자 등이 연구 관련 문서(전자문서 포함)에 대한 열람을 요청하는 경우 연구담당자는 이에 적극 협조해야 합니다.

의 학 연 구 윤 리 심 의 위 원 회 위 원 장

본 통보서에 기재된 사항은 IRB의 기록된 내용과 일치 함을 증명합니다.
본 기관 IRB는 생명윤리 및 안전에 관한 법률, 약사법, 의료기기법 및 ICH-GCP 등 관련 법규를 준수합니다.
본 연구와 이해관계(Conflict of Interest)가 있는 위원이 있을 경우 연구의 심의에서 배제하였습니다.

Appendix 2. Recruitment notices for study participants.

연구참여자 모집 공고문

연구에 참여하실 대상자를 모집합니다.

간이식 기증자의 수술 후 기증만족도, 우울, 불안, 건강관련 삶의 질과 그 영향요인

연구 목적: 간 기증자의 수술 후 불안, 우울, 건강관련 삶의 질과 기증 만족도에 개인적, 가족적, 상황적 요인이 미치는 영향을 통합적으로 파악하여, 간 공여자의 삶의 질 향상에 도움이 되는 중재를 제공하기 위한 기초자료를 마련하고자 합니다.

참여자 선정조건: 간 공여를 위해 간 절제술을 받고 퇴원 후 주기적인 외래진료를 받고 있는 자, 만 19세 이상 65세 미만인 자 (• 간공여수술 받은 지 1개월 미만인 자, 간이식 수혜자와 2촌 이내 가족관계 (수혜자의 부모, 자녀, 형제, 배우자) 가 아닌 자는 제외됩니다.)

설문 내용: 기증동기 10문항, 수술 전 불안 8문항, 가족관계성 20문항, 자아 통제감 7문항, 예후관련정보의 충분성 4문항, 수혜자와의 관계 변화 1문항, 기증에 대한 후회 1문항, 불안 2문항, 우울 2문항, 건강관련 삶의 질 12문항, 일반적 특성 12문항의 총 79문항으로 구성된 설문지를 1회 작성하게 될 것이며, 이를 완료하는 데에 약 10-15분이 소요될 것입니다.

참여 방법: 설문이 시작되기 전에 연구참여에 대한 동의 절차가 진행됩니다. 설문작성 완료 후 제공된 봉투에 넣어 밀봉 후 연구담당자에게 제출해 주십시오. 혹은 외래 대기실에 마련된 수거함에 넣어주십시오. 연구 참여 도중 철회 의사가 있으면 언제든지 설문지 작성을 중지하거나 제출을 완료하지 않을 수 있습니다.

참여 시 사례: 설문조사를 완료하신 분께는 감사의 의미로 소정의 답례품(4000원 상당의 스타벅스 기프티콘)을 드립니다.

본 연구의 내용에 관한 문의는 다음 연구 담당자에게 하십시오.

연구담당자: 이예솔 (서울대학교 간호대학, 박사과정)

(Online Survey Version)

연구참여자 모집 공고문

연구에 참여하실 대상자를 모집합니다.

간이식 기증자의 수술 후 기증만족도, 우울, 불안, 건강관련 삶의 질과 그 영향요인

연구 목적: 간 기증자의 수술 후 불안, 우울, 건강관련 삶의 질과 기증 만족도에 개인적, 가족적, 상황적 요인이 미치는 영향을 통합적으로 파악하여, 간 공여자의 삶의 질 향상에 도움이 되는 중재를 제공하기 위한 기초자료를 마련하고자 합니다.

참여자 선정조건: 간 공여를 위해 간 절제술을 받고 퇴원 후 주기적인 외래진료를 받고 있는 자, 만 19세 이상 65세 미만인 자 (• 간공여수술 받은 지 1개월 미만인 자, 간이식 수혜자와 2촌 이내 가족관계(수혜자의 부모, 자녀, 형제, 배우자) 가 아닌 자는 제외됩니다.)

설문 내용: 기증동기 10문항, 수술 전 불안 8문항, 가족관계성 20문항, 자아 통제감 7문항, 예후관련정보의 충분성 4문항, 수혜자와의 관계 변화 1문항, 기증에 대한 후회 1문항, 불안 2문항, 우울 2문항, 건강관련 삶의 질 12문항, 일반적 특성 11문항의 총 78문항으로 구성된 설문지를 1회 작성하게 될 것이며, 이를 완료하는 데에 약 10-15분이 소요될 것입니다.

참여 방법: 인터넷을 이용하여 다음의 URL에 접속하시거나

https://ko.surveymonkey.com/r/ZFC6R53

다음의 QR 코드를 스캔하시면 됩니다.

설문이 시작되기 전에 연구참여에 대한 동의 절차가 진행됩니다. 연구 참여 도중 철회 의사가 있으면 언제든지 온라인 설문지 작성을 중지하거나 창을 닫아 제출을 완료하지 않을 수 있습니다.

참여 시 사례: 설문조사를 완료하신 분께는 감사의 의미로 소정의 답례품(4000원 상당의 스타벅스 기프티콘)을 드립니다.

본 연구의 내용에 관한 문의는 다음 연구 담당자에게 하십시오.

연구담당자: 이예슬 (서울대학교 간호대학, 박사과정)

Appendix 3. Participant informed consent forms.

IRB SNUCM SNUH
의학연구윤리심의위원회

IRB No.: 2101-074-1187
심의결과통보일(Date of Notification): 2021.02.15
IRB승인유효 만료일(Date of Expiry): 2022.02.14

대상자 일련번호	

연구대상자 설명문

1. 연구 제목: 간이식 기증자의 수술 후 기증만족도, 우울, 불안, 건강관련 삶의 질과 그 영향요인

2. 연구책임자: 이남준 (서울대학교 의과대학 교수)

3. 연구의 배경 및 목적

본 연구는 간 기증자의 수술 후 불안, 우울, 건강관련 삶의 질과 기증만족도를 파악하고, 이에 대하여 기증과정의 전반에 걸쳐 존재하는 개인적, 가족적, 상황적 요인이 미치는 영향을 통합적으로 파악하고자 하는 연구입니다.

4. 연구 참여대상자 수 및 참여기간

2001년 1월부터 2020년 12월까지 간 공여 수술을 받은 약 1700명을 대상으로 연구가 진행될 것입니다. 만일 귀하가 참여에 동의해 주시면, 기증동기 10문항, 수술 전 불안 8문항, 가족관계성 20문항, 자아 통제감 7문항, 예후관련정보의 충분성 4문항, 수혜자와의 관계 변화 1문항, 기증에 대한 후회 1문항, 불안 2문항, 우울 2문항, 건강관련 삶의 질 12문항, 일반적 특성 12문항의 총 79문항의 설문지를 작성하게 될 것이며, 설문조사는 약 10-15분 소요될 것으로 예상됩니다.

5. 연구의 절차 및 방법

귀하가 연구 참여의사를 밝혀 주시면 연구자가 제공한 설문지를 1회 작성해 주시면 됩니다. 작성이 완료된 동의서와 설문지는 봉투에 넣어 밀봉하여 주십시오. 일정시간 후 연구책임자가 회수할 것입니다. 혹은, 진료 대기실에 미리 마련해 놓은 열람이 불가능한 상자에 개별적으로 넣어주십시오. 온라인 설문일 경우 제공된 링크에 접속하여 설문지를 작성하신 후 '완료' 버튼을 눌러 주시면 됩니다. 이후에 연구자는 설문지를 제출하신 대상자의 의무기록을 후향적으로 리뷰할 것입니다.

6. 연구대상자에게 예견되는 부작용, 위험과 불편함

본 연구는 설문지를 통한 조사로 신체적인 위험은 없습니다. 연구대상자가 연구참여에 동의한 상태일지라도 어떤 질문에나 대답하지 않을 권리가 있고 설문 내용 중 동의하지 않는 내용이 있다면 언제든지 중단할 수 있기에 연구로 인한 심리적인 부작용도 최소한의 수준을 넘지 않습니다. 또한 후향적 의무기록 리뷰는 연구와 관련된 내용에 대해서만 이루어질 것입니다. 개인정보보호를 위하여 답례품 제공을 위한 개인번호와 이름, 나이, 성별 이외의 다른 개인정보는 수집하지 않을 것이며 수집된 모든 정보는 연구과정에서 철저히 비밀에 지켜지고 연구목적 외에는 사용되지 않을 것입니다. 개인번호가 기입된 페이지는 설문 내용과 관계없이 답례품 발송즉시 분쇄기에 의해 파기될 것입니다. 온라인 설문의 경우 별도의 링크를 통해 번호를 수집하고, 답례품 발송 즉시 해당링크를 삭제할 것입니다. 이밖에 연구 참여 도중 발생할 수 있는 부작용이나 위험, 불편함에 대한 질문이 있으면 담당 연구원에게 즉시 문의해 주십시오.

7. 연구대상자에게 예견되는 이득

귀하가 본 연구에 참여하는데 있어서 직접적인 이득은 없습니다. 그러나 귀하가 제공하는 정보를 통해 간 공여자의 수술 후 우울, 불안, 건강관련 삶의 질에 영향을 미치는 요인을 파악함으로써, 간 공여자의 수술 후 예후에 도움이 되는 중재를 마련하기 위한 근거로 기능할 수 있을 것입니다.

8. 연구 참여 비용 및 손실에 대한 보상

귀하가 본 연구에 참여하는데 있어서 특별한 비용이나 손실이 발생하지 않습니다. 귀하의 연구 참여시 설문지 작성을 위한 시간 할애와 일시적 불편 및 정보 제공에 대한 감사의 뜻으로 설문지를 회수한 후 24시간 이내에 스타벅스 기프티콘이 제공될 것입니다. 귀하가 설문지의 모든 문항에 응답하지 못하였더라도, 연구에 자발적으로 참여하여 설문지를 제출하신 대상자에게 동일하게 보상이 지급됩니다.

9. 자발적 참여 및 동의 철회

본 연구는 자발적으로 참여 의사를 밝히신 분에 한하여 수행될 것입니다. 귀하께서는 참여의사를 결정하기 전에 본 연구가 왜 수행되는지 그리고 연구의 내용이 무엇과 관련 있는지 이해한 후 참여의사를 결정해 주십시오. 귀하는 본 연구에 참여하지 않을 자유가 있으며, 본 연구에 참여하지 않아도 귀하에게는 어떠한 불이익도 없습니다. 또한 귀하가 자발적으로 본 연구에 참여한다고 동의하더라도, 언제든지 어떠한 불이익 없이 참여 도중에 그만 둘 수 있습니다. 연구 동의를 철회하고 싶다면 연구 책임자에게 즉시 말씀해 주십시오. 그만두는 경우 모아진 자료는 즉시 폐기될 것입니다. 온라인 설문의 경우 온라인 설문지의 창을 닫거나 '완료'버튼을 누르지 않으시면 작성된 내용은 수집되지 않습니다.

10. 개인정보보호 및 개인정보 제공에 관한 사항

개인정보관리책임자는 서울대학교 소속의 이예슬입니다. 이러한 개인정보는 연구 책임자 및 연구담당자에게만 접근이 허락되며 이외의 사람은 접근할 수 없습니다. 책임자는 이 연구를 통해 얻은 대상자의 신상을 파악할 수 있는 모든 개인 정보의 비밀 보장을 위해 최선을 다할 것입니다. 작성된 설문지와 동의서는 봉투에 밀봉되어 수거될 것입니다. 또한 설문지와 동의서에 각각 일련번호를 부여하여 모든 정보를 코드화 및 익명화 한 뒤 연구 담당자의 잠금 장치가 있는 보관함에 보관할 예정이며, 연구 이외의 다른 목적으로 사용하지 않을 것입니다. 이 연구데이터는 패스워드가 걸린 파일에 저장되어 연구책임자 및 담당자에게만 접근이 허락되며, 이외의 사람은 접근할 수 없도록 할 것입니다.

동의서는 관련 법령에 따라 3년을 보관한 후 폐기할 예정입니다. 본 연구에서 얻어진 연구 결과가 출판될 때 대상자의 신상은 비밀로 보호될 것입니다. 그러나 만일 법이 요구하면 귀하의 개인정보는 제공될 수도 있습니다. 또한 모니터 요원, 점검 요원, IRB 및 보건복지부장관 등이 관계 법령에 따라 연구의 절차와 자료의 품질을 검증하기 위하여 대상자의 신상에 관한 비밀이 보호되는 범위에서 대상자의 연구기록을 열람할 수 있습니다. 귀하가 본 동의서에 서명하는 것은, 이러한 사항에 대하여 사전에 알고 있었으며 이를 허용한다는 동의로 간주될 것입니다.

11. 담당자 연락처

본 연구에서 발생한 문제가 있거나 우려, 질문이 생길 시 다음의 연구 담당자에게 연락하여 주십시오.
연구 담당자: 이예슬
만일 어느때라도 연구대상자의 권익에 대한 문제, 우려, 질문이 있을 경우 의학연구윤리심의위원회(IRB) (02-2072-0694) 또는 임상연구윤리센터 (02-2072-3509)로 연락하십시오.

대상자 일련번호	

연구대상자 동의서

1. 본인은 임상연구에 대해 구두로 설명을 받고 상기 연구 설명문을 읽었으며 담당 연구원과 이 연구에 대하여 충분히 의논하였습니다.
2. 본인은 연구의 위험과 이득에 관하여 들었으며 나의 질문에 만족할 만한 답변을 얻었습니다.
3. 본인은 이 연구에 참여하는 것에 대하여 자발적으로 동의합니다.
4. 본인은 이후의 치료에 영향을 받지 않고 언제든지 연구의 참여를 거부하거나 연구의 참여를 중도에 철회할 수 있고 이러한 결정이 나에게 어떠한 해가 되지 않을 것이라는 것을 알고 있습니다.
5. 본인은 이 설명서 및 동의서에 서명함으로써 의학 연구 목적으로 나의 개인정보와 전자의무기록(Electronic Health Record, EHR)정보를 현행 법률과 규정이 허용하는 범위 내에서 연구자가 수집하고 처리하는데 동의합니다.
6. 본인은 수집되는 자료가 본 연구 이외에 연구책임자 및 다른 연구자의 연구의 목적으로 사용되는 것에 동의합니다.

연구대상자 성명	서명	날짜(년/월/일)
연구자 성명	서명	날짜(년/월/일)

대상자 일련번호	

연구대상자 동의서 (온라인 서베이용)

1. 본인은 임상연구에 대해 상기 연구 설명문을 읽었으며 담당 연구원과 이 연구에 대하여 충분히 의논하였습니다.
2. 본인은 연구의 위험과 이득에 관하여 들었으며 나의 질문에 만족할 만한 답변을 얻었습니다.
3. 본인은 이 연구에 참여하는 것에 대하여 자발적으로 동의합니다.
4. 본인은 이후의 치료에 영향을 받지 않고 언제든지 연구의 참여를 거부하거나 연구의 참여를 중도에 철회할 수 있고 이러한 결정이 나에게 어떠한 해가 되지 않을 것이라는 것을 알고 있습니다.
5. 본인은 이 설명서 및 동의서에 서명함으로써 의학 연구 목적으로 나의 개인정보와 전자의무기록(Electronic Health Record, EHR)정보를 현행 법률과 규정이 허용하는 범위 내에서 연구자가 수집하고 처리하는데 동의합니다.
6. 본인은 수집되는 자료가 본 연구 이외에 연구책임자 및 다른 연구자의 연구의 목적으로 사용되는 것에 동의합니다.

나는 위 내용에 동의하며 본 연구에 참여하겠습니다.

동의함 □ 동의하지 않음 □

Appendix 4. Quality metric incorporated, license agreement.

DocuSign Envelope ID: FF1F2247-14EF-4FC3-9F5E-DEE2878C50D6

QualityMetric
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QualityMetric Incorporated, LLC LICENSE AGREEMENT

License Number: QM054603

Licensee Name: Seoul National University Hospital

Licensee Address: 101, Daehak-ro, Jongno-gu 03080 KR

Approved Purpose: Health-related quality of life in living liver donors -
Data Collection Method: Tablet

Therapeutic Area: Digestive System

A. Effective Date: This License Agreement (the "Agreement") is made by and between QualityMetric Incorporated, LLC, a Delaware limited liability company, with offices at 1301 Atwood Ave, Suite 216E, Johnston, RI 02919 and Licensee. This Agreement is entered into as of the date of last signature below and is effective for the Study Term set forth on Appendix B.

B. Appendices: Capitalized terms used in this Agreement shall have the meanings assigned to them in Appendix A and Appendix B. The appendices attached hereto are incorporated into and made a part of this Agreement for all purposes.

C. Grant of License: Subject to the terms of this Agreement: (a) QualityMetric Incorporated, LLC grants to Licensee a non-exclusive, non-transferable, non-sublicensable worldwide license to use, solely for the Approved Purpose and during the Study Term, the Licensed Surveys, Software, SMS Scoring Solution, and all intellectual property rights related thereto ("Survey Materials"), in the authorized Data Collection Method, Modes of Administration, and Approved Languages indicated on Appendix B; and to administer the Licensed Surveys only up to the total number of Administrations in any combination of the specific Licensed Surveys and Approved Languages, Data Collection Method, and Modes of Administration; (b) Licensee agrees to purchase the Services described in Appendix B (if applicable); and (c) Licensee agrees to pay QualityMetric Incorporated, LLC the fees on Appendix B ("Fees") in accordance with the invoice to be provided.

D. Electronic Signature: The parties agree that execution of this Agreement by e-Signatures (as defined below) shall have the same legal force and effect as the exchange of original signatures.
Pursuant to this Agreement, e-Signatures shall mean a signature that consists of one or more letters, characters, numbers or other symbols in digital form incorporated in, attached to or associated with the electronic document, that (a)is unique to the person making the signature; (b) the technology or process used to make the signature is under the sole control of the person making the signature; (c) the technology or process can be used to identify the person using the technology or process; and (d) the electronic signature can be linked with an electronic document in such a way that it can be used to determine whether the electronic document has been changed since the electronic signature was incorporated in, attached to or associated with the electronic document.

EXECUTED by the duly authorized representatives as set forth below.

QualityMetric Incorporated, LLC	**Seoul National University Hospital**
Signature: Michelle White 07C0943B03648...	Signature: YSLee
Name: Michelle White	Name: Yesol Lee
Title: Vice President	Title: PhD candidate
Date: 1/12/2021	Date: 01/09/21

Filename: Seoul National University Hospital - Yesol Lee - SLA - QM054603
Template: Generic SLA – 12Aug20

Page 1 of 9

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QUALITYMETRIC INCORPORATED, LLC LICENSE TERMS AND CONDITIONS - APPENDIX A

Attached to and Incorporated into License No. QM054603

1. License Fees and Payment Terms – Licensee agrees to pay the Fees and all other charges on the payment terms specified in Appendix B. All amounts are stated and all payments shall be in, U.S. Dollars. Fees listed in Appendix B are exclusive of any sales taxes, value added taxes, duties, or other withholding. Licensee shall be responsible for all taxes relating to the Fees and the goods and services acquired hereunder.

2. Copyright Protection. The Survey Materials are copyrighted works owned by QualityMetric Incorporated, LLC. Copyright protection means that Licensee cannot reproduce, copy, modify, or distribute the Survey Materials or any part of them without QualityMetric Incorporated, LLC's consent, even if the Survey Materials were not obtained from QualityMetric Incorporated, LLC. This Agreement constitutes QualityMetric Incorporated, LLC's consent for Licensee to use the Survey Materials only as specified in this Agreement.

3. Term and Termination – This Agreement shall be effective until the earlier to occur of (a) completion or termination of Services in connection with the Approved Purpose, or (b) expiration of the Study Term specified in Appendix B, after which the licenses granted hereunder shall terminate and this Agreement shall terminate upon full payment therefore. Notwithstanding the foregoing, either party may terminate this Agreement at any time in the event of a material breach of this Agreement by the other party that is not cured within thirty (30) days following notice to the breaching party.

4. Administration by Third Parties – A third party service provider may administer the Licensed Surveys on behalf of Licensee subject to such third party's execution of QualityMetric Incorporated, LLC's Acknowledgement by Agent form; provided, that Licensee shall not be relieved of its obligations by use of such third party, and Licensee shall be responsible for any breach of this Agreement by such third party. Clinical trial investigator sites are not required to sign the Acknowledgement by Agent form. However, Licensee will inform each investigator site that it may use and administer the Survey Materials only through investigational sites, only on behalf of Licensee, only during the Study Term and only for the Approved Purpose. Licensee shall inform each investigator site that it may not use the Survey Materials for any other purpose and Licensee will provide each investigator site with the Notice to Investigational Sites (completed for each use of the Survey Materials), attached as Appendix C.

5. Trademark and Copyright Notices – Licensee agrees to reproduce the copyright and trademark notices included with the Survey Materials on all reproductions of the Survey Materials permitted hereunder, including electronic reproductions and representations. Licensee shall not alter the wording or order of the items or any other part of the Survey Materials. Licensee shall not create any derivative work from the Survey Materials.

6. Maintenance of Records – Licensee shall maintain accurate records containing information sufficient to verify Licensee's compliance with this Agreement, including, but not limited to, records of the number of reproductions of the Licensed Survey(s) made, the location of and/or confirmation of the destruction of such reproductions, and the number of administrations of the Licensed Survey(s) performed. QualityMetric Incorporated, LLC or a third party auditor of its choice reasonably acceptable to Licensee shall have the right, not more frequently than once in each calendar year and on thirty (30) days advance notice to Licensee, during usual business hours, to examine such records for the sole purpose of verifying Licensee's compliance with the terms of this Agreement. In the event that such examination discloses Licensee's use of the Licensed Surveys exceeds the permitted use hereunder, Licensee shall promptly pay QualityMetric Incorporated, LLC at QualityMetric Incorporated, LLC's then current list price for all such excessive use. If the payment due for such excessive use exceeds 10% of the total fees paid hereunder for use of the Licensed Surveys, Licensee shall reimburse QualityMetric Incorporated, LLC for reasonable, documented costs and expenses incurred in conducting such examination.

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7. Proprietary Rights –

a. Licensee acknowledges that the Survey Materials shall be and remain at all times the property of QualityMetric Incorporated, LLC. Licensee shall have no right, title or interest in the Survey Materials except for the limited license described herein. Licensee shall not use, modify, reproduce, or transmit any of the Survey Materials except as expressly provided hereunder. If the Approved Purpose includes administration of the Licensed Surveys in physical form, Licensee is authorized to make exact reproductions of the Licensed Survey(s) sufficient to support such administrations. Licensee agrees that it shall not challenge or assist any other party in challenging the validity, ownership or enforceability of the Survey Materials.

b. Licensee acknowledges and agrees that the Data Collection Method and Modes of Administration reflected in this Agreement are the only manner in which Licensee may administer the Licensed Surveys.

c. Licensee acknowledges and agrees that scoring of Licensed Survey(s) responses must be performed by QualityMetric Incorporated, LLC or by Licensee through use of a QualityMetric Incorporated, LLC scoring solution. Licensee shall not embed, input, insert, or transfer the Survey Materials, QualityMetric Incorporated, LLC's scoring algorithms (regardless of the source of the algorithms), or any part thereof, into Licensee's systems or applications absent purchase by Licensee of a QualityMetric Incorporated, LLC scoring solution.

d. Licensee acknowledges and agrees that any translations of the Licensed Surveys into any language must be performed by QualityMetric Incorporated, LLC, and QualityMetric Incorporated, LLC retains ownership of any and all translations.

e. Licensee acknowledges and agrees that the results, data and all information obtained through the utilization and administration of the Survey Materials are solely for the Licensee's own use and analysis, consistent with and as contemplated by the Approved Purpose, and may not be sold to, or otherwise, transferred for value (in any manner) to a third party.

f. Licensee may publish aggregated survey results in scientific and/or academic journals, papers, reports and presentations (the "Publications") related to the Approved Purpose. License may cite the Survey Materials and/or the reference materials provided Licensee includes the appropriate copyright and trademarks notices and Licensee does not indicate that QualityMetric Incorporated, LLC has endorsed the Publication in any manner. Licensee may not include a copy or any portion of the Survey Materials in any Publication including screenshots or excerpts of the Survey Materials.

8. Confidentiality; Injunctive Relief – Licensee acknowledges that the Survey Materials are valuable assets of QualityMetric Incorporated, LLC and that the value of the Survey Materials would be significantly impaired by the unauthorized distribution or use of them. Licensee shall ensure that the Survey Materials are not used for unauthorized purposes or by unauthorized persons, and shall promptly report any such unauthorized use to QualityMetric Incorporated, LLC. Licensee acknowledges that, in the event of any material breach of this paragraph by the Licensee, money damages would not be a sufficient remedy, and that QualityMetric Incorporated, LLC shall, to the extent permitted by applicable law, be entitled to equitable relief, including injunction. Such relief shall be in addition to all other remedies available at law or in equity.

9. Disclaimer of Warranty – Licensee acknowledges that complex and sophisticated products such as the Survey Materials are inherently subject to undiscovered defects. QualityMetric Incorporated, LLC cannot and does not represent or warrant to Licensee that the Survey Materials are free from such defects, that operation of the Survey Materials will be uninterrupted or error free, or that its results will be

effective or suitable with respect to any particular application. SURVEY MATERIALS AND SERVICES HEREUNDER ARE PROVIDED AS-IS, AND QUALITYMETRIC INCORPORATED, LLC MAKES NO REPRESENTATIONS OR WARRANTIES, EXPRESS OR IMPLIED, WITH RESPECT TO SUCH SURVEY MATERIALS OR SERVICES, AND DISCLAIMS ALL WARRANTIES INCLUDING WITHOUT LIMITATION ANY WARRANTIES AS TO MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, NON-INFRINGEMENT OR OTHERWISE.

10. Compliance – QualityMetric Incorporated, LLC and Licensee agree that in performing their respective obligations under this Agreement, each shall conduct business in conformance with sound ethical standards of integrity and honesty and in compliance with all applicable laws, rules and regulations. Licensee represents and warrants that it has not and shall never engage in activities or use of the Survey Materials in a manner that is deceptive, scandalous, or involves moral turpitude, or in any other manner that could injure the high market acceptance, good name and reputation of QualityMetric Incorporated, LLC or the Survey Materials.

11. Limitation of Liability – In no event shall either party's total liability to the other party for direct damages arising hereunder exceed the amount of the Fees paid or owed by Licensee to QualityMetric Incorporated, LLC hereunder, except for damages from claims for breach of confidentiality, unauthorized use of Survey Materials or failure to indemnify for which there is no limit on direct damages. Further, in no event shall either party be liable to the other party for any special, punitive, incidental, indirect, or consequential damages, arising from any claimed breach of contract, or any other legal theory, even if such party has been advised of the possibility of such damages.

12. Intellectual Property Indemnification – QualityMetric Incorporated, LLC will defend, at its expense, any action brought against Licensee to the extent that it is based on a third party claim that a Licensed Survey infringes any patent, registered trademark, or copyright, provided that: (a) Licensee notifies QualityMetric Incorporated, LLC in writing within thirty (30) days of its becoming aware of any such claim; (b) QualityMetric Incorporated, LLC has sole control of the defense and all related settlement negotiations, provided that QualityMetric Incorporated, LLC shall not agree to any settlement that includes an admission of wrongdoing on the part of Licensee or requiring any action by Licensee without Licensee's prior written consent; and (c) Licensee provides QualityMetric Incorporated, LLC with the information, authority, and any and all assistance reasonably required by QualityMetric Incorporated, LLC to provide the aforementioned defense. In the event of an action against Licensee alleging infringement of the intellectual property rights of a third party with respect to a Licensed Survey, or in the event QualityMetric Incorporated, LLC believes such a claim is likely, QualityMetric Incorporated, LLC shall be entitled, at its option but without obligation or additional cost to Licensee, to (i) appropriately modify such Licensed Survey so as not to infringe such third party intellectual property rights; provided, that such modifications or substitutions shall not materially affect the function of such Licensed Survey; (ii) obtain a license with respect to the applicable third party intellectual property rights; or (iii) if neither (i) nor (ii) is commercially practicable, terminate Licensee's license hereunder as to the effected Licensed Survey and refund the full license fee therefore. QualityMetric Incorporated, LLC shall have no liability hereunder if the alleged infringement is caused by use of other than the then-most-recent version of such Licensed Survey provided to Licensee by QualityMetric Incorporated, LLC, any combination of a Licensed Survey with non-QualityMetric Incorporated, LLC programs or data, where the Licensed Survey alone would not have given rise to the claim, or (iii) use of a Licensed Survey outside the scope of this Agreement. THIS SECTION STATES THE ENTIRE LIABILITY OF QUALITYMETRIC INCORPORATED, LLC AND LICENSEE'S SOLE AND EXCLUSIVE REMEDY WITH RESPECT TO ANY ALLEGED INFRINGEMENT.

13. Scoring -

a. Licensee acknowledges and agrees that scoring of Licensed Survey responses must be performed by QualityMetric Incorporated, LLC or by Licensee through the use of a QualityMetric Incorporated, LLC scoring solution. Licensee shall not embed, input, or transfer the Survey Materials, QualityMetric Incorporated, LLC's scoring algorithms (regardless of the source of the algorithms), or any part thereof, into any systems or applications without an appropriate written agreement with QualityMetric Incorporated, LLC.

b. Scoring Software. Licensee may install and use one copy of the desktop scoring software provided by QualityMetric Incorporated, LLC to Licensee under this Agreement ("Software") on a single computer, and except for making one back-up copy of the Software, may not otherwise copy the Software. However, upon execution of an Acknowledgement by Agent form by a clinical research organization or other third party vendor acting on Licensee's behalf ("Agent"), Licensee shall have the right to transfer its copy of the Software (without retaining a copy) to the Agent for use solely on Licensee's behalf, provided that Licensee warrants to QualityMetric Incorporated, LLC that Agent shall abide by all terms and conditions of this Agreement and Licensee shall be responsible for any breach of this Agreement by such Agent. The Software may not be copied, shared or used concurrently on different computers. Licensee may not reverse engineer, decompile, or disassemble the Software, nor attempt in any other manner to obtain the source code. The Software and the algorithms it contains are proprietary information of QualityMetric Incorporated, LLC. Licensee shall not attempt to circumvent any function of the Software that limits its use to a certain number of administrations of the Licensed Surveys or to a certain time period. Licensee may not rent or lease the Software to any other person.

c. QualityMetric Incorporated, LLC Smart Measurement System ("SMS") Scoring Solution. The "SMS Scoring Solution" shall mean the algorithmic scoring engine that scores Licensed Survey responses collected on QualityMetric Incorporated, LLC's web-based survey administration interface. Licensee may not reverse engineer, decompile, or disassemble the SMS Scoring Solution, nor attempt in any other manner to obtain the source code for it. The SMS Scoring Solution and the algorithms it contains are proprietary information of QualityMetric Incorporated, LLC. Licensee shall not attempt to circumvent any function of the SMS Scoring Solution that limits its use to a certain number of administrations of the Licensed Surveys or to a certain time period. Licensee may not rent or lease the SMS Scoring Solution to any other person.

14. Form Review – If Appendix B permits Licensee to administer the Licensed Surveys on an electronic device, Licensee is required to submit screen shots or a link to the Licensed Surveys for each Approved Language to QualityMetric Incorporated, LLC. QualityMetric Incorporated, LLC shall perform an initial form review to determine whether the Licensed Surveys have been appropriately migrated to electronic format (the "Initial Review"). QualityMetric Incorporated, LLC will complete its Initial Review of the Licensed Surveys for each Approved Language within two (2) weeks from QualityMetric Incorporated, LLC's receipt of screen shots or website link from Licensee. Upon QualityMetric Incorporated, LLC's completion of the Initial Review, QualityMetric Incorporated, LLC will provide Licensee with a detailed list of revisions that will need to be made before QualityMetric Incorporated, LLC can approve the electronic format. Licensee is required to submit subsequent screen shots or a link to the Licensed Surveys for each Approved Language incorporating any changes required by QualityMetric Incorporated, LLC until QualityMetric Incorporated, LLC provides its final approval of the electronic format. Multiple rounds of review and revisions may be necessary prior to QualityMetric Incorporated, LLC being able to provide final approval of the electronic format. Licensee is solely responsible for the electronic creation of the Licensed Surveys. Nothing in this Agreement prohibits QualityMetric Incorporated, LLC from creating its own electronic forms of Licensed Survey administration. The Licensed Surveys cannot be used in electronic format except as allowed pursuant to the terms and conditions of this Agreement. Licensee acknowledges that there may be response differences due to effects from use of electronic format compared to a static Data Collection Method and Mode of Administration such as paper/pencil. Licensee assumes any and all risk of differential effects resulting from the use of electronic format.

15. Miscellaneous

a. Neither party may use the other party's name in any press release, web site, promotional material or other form of publicity without the prior written approval of such party.

b. This Agreement constitutes the entire and exclusive agreement between the parties and supersedes all previous communications or agreements, either oral or written, with respect to the subject matter hereof. This Agreement may not be modified or amended except by an instrument in writing signed by both parties. The Appendices attached hereto are incorporated into and made a part of this Agreement for all purposes.

c. Any waiver of any breach or default under this Agreement must be in writing and shall not be deemed a waiver of any other or subsequent breach or waiver. Failure or delay by either party to enforce compliance with any term or condition of this Agreement shall not constitute a waiver of such term or condition.

d. If any provision in this Agreement is determined to be invalid or unenforceable, the remaining provisions shall not be affected thereby and shall be binding upon the parties hereto, as though the invalid or unenforceable provision were not contained herein.

e. In the event any Survey Materials or associated QualityMetric Incorporated, LLC intellectual property are exported by Licensee outside of the country in which Licensee is located, Licensee is obligated and solely responsible for ensuring compliance with all applicable import and export laws and regulations of the United States of America and/or any applicable foreign jurisdictions.

f. This Agreement and performance hereunder shall be governed in accordance with the laws of the State of Delaware, but excluding Delaware choice of law principles. With respect to any dispute arising in connection with this Agreement, Licensee consents to the exclusive jurisdiction and venue in the state and federal courts located in Delaware.

g. The terms and conditions of this Agreement supersede the terms of any license agreement embedded in the Software, or any purchase order or other ordering document.

h. Licensee agrees that not using all eight domain scales may compromise the validity of comparisons to norms and other interpretation guidelines.

* * *

APPENDIX B

QualityMetric
We measure health.

LICENSE AGREEMENT - DETAILS

Licensee: Seoul National University Hospital
Yesol Lee
101, Daehak-ro
03080 Jongno-gu
South Korea

License Number: QM054603
Amendment to: N/A
Study Term: 01/02/21 to 01/01/22

Approved Purpose
Health-related quality of life in living liver donors

Licensed Surveys (Modes) and Services:

Item	Description	Mode of Admin	Quantity
SS500	PRO CoRE Licensing Fee		1
	for up to the maximum number of		
	1 provider		
	Individual and Aggregate Level Reports with		
	Below Benchmarks turned on:		
	General US Population Norms		
	Liver-Cirrhosis		
	Liver-Hepatitis A, B, C		
ES0170	SF-12v2, Standard Recall	Paper	1
Approved Languages: South Korea (Korean)			
IS0170	SF-12v2 Interview Script, Std	Interview Script	1
Approved Languages: South Korea (Korean)			
LANGUAGES	South Korea (Korean)		1
ADM012	Patients Enrolled		1,600

IT0105	Timepoints =	2
ADMINS	Administrations (Patients x Timepoints)	3,200
SS517	Keys to score the SF-12v2	3,200
SS805	Keys to Recover Missing Scores	3,200
SS806	Data Quality Evaluation Report	3,200
SS807	SF-6D/Utility Index	3,200
SS808	Medical Expenditure	3,200
EM126	SF-12v2 User's Manual 3rd Ed.	1

Approved Languages:
United States (English)

EM086	SF12v2 Quick Start Guide	1

Approved Languages:
United States (English)

CS00291	Scientific Form Review Per Language NOT Single-Item **********	1

Quote expires 2/8/21

TOTAL FEES: **700.00 USD**

Payment Terms: **Due on Receipt**

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We measure health.

NOTICE TO INVESTIGATIONAL SITES - APPENDIX C

Effective Date: 01/02/21

License: QM054603

Licensee Name: Seoul National University Hospital

Study Term: Beginning on 01/02/21 and ending on 01/01/22

Licensed Surveys: SF-12v2, standard recall in South Korea (Korean)

Approved Purpose: Health-related quality of life in living liver donors

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Appendix 5. The questionnaire (excluding a paid questionnaire–III SF-12)

대상자 일련번호	

I. 다음은 수술 후의 경험에 대한 질문입니다. 기증 수술 전에 의료진 혹은 인터넷 등을 통해 알게 된 정보에 기반하여 예상한 수술의 예후에 비해서 수술 후의 실제 경험은 어땠습니까?

1. 재원기간

① 예상보다 짧았다. ② 예상과 같다. ③ 예상보다 길었다.

2. 통증

① 예상보다 심하지 않았다. ② 예상과 같다. ③ 예상보다 심했다.

3. 퇴원 후 회복속도 및 불편감

① 예상보다 짧거나 심하지 않았다. ② 예상과 같다. ③ 예상보다 길거나 심했다.

4. 합병증

① 예상보다 심하지 않았다. ② 예상과 같다. ③ 예상보다 심했다.

II. 만약 기증 전으로 돌아간다면, 그때도 기증을 할 것입니까?

① 전혀 아니다 ② 아니다 ③ 그렇다 ④ 매우 그렇다

IV. 마지막으로 귀하의 일반적 특성을 묻는 질문입니다.

1) 이름 _____

2) 성별 ① 남자 ② 여자

3) 연령 만 _____세

4) 교육 수준 ① 무학 ② 초졸 ③ 중졸 ④ 고졸(재학포함)
⑤ 대졸(재학포함) ⑥ 대학원 졸(재학포함)

5) 귀하의 월평균 수입은 얼마입니까?
① 150만원 미만 ② 150만원 ~ 250만원 미만 ③ 250만원 ~ 350만원 미만
④ 350만원 ~ 500만원 미만 ⑤ 500만원~1000만원 미만 ⑥ 1000만원 이상

♠ 설문에 응답해 주셔서 감사합니다! 뒷장을 확인해주세요. ♠

설문지 작성에 대한 감사의 표시로 답례품을 증정합니다. 답례품인 기프티콘 (스타벅스 커피쿠폰)을 수신할 휴대전화 번호를 적어주십시오. 본 페이지는 답례품 발송 즉시 파기됩니다.

_____

국문 초록

생존시 간이식 기증자의 수술 결과에 대한 예측 불충족이 수술 후 건강관련 삶의 질에 미치는 영향

이 예 솔

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간호학과

지도교수 고진강

2019년 한국의 생존시 간이식 건수는 1,188건으로, 그 해 간이식의 약 75%가 생존시 간이식으로 이루어졌다. 살아있는 간 기증자는 이타적인 동기를 가지고 간절제술을 받으며, 그 후의 회복 과정까지 감당한다. 따라서 생존시 간이식 기증자를 옹호하기 위하여 법적, 의학적, 심리적, 윤리적 측면에서 다각도의 노력이 이루어져 왔다. 간호사는 수술 전에 기증자와의 충분한 정보 교환 및 공유를 통하여 그들의 자율성을 존중해야 하고, 수술 후에는 그들의 건강관련 삶의 질이 크게 악화된 것은 아닌지 확인해야 한다. 이러한 의사소통 과정을 통하여 간 기증자는 기증 수술이 그들 자신에게 미치는 영향을 현실적으로 예측하는 데에 도움을 받을 수 있다. 환자는 수술 전에 수술 결과에 대한 예측을 하게 되는데, 예측에 비해서 부정적인 결과를 경험한 경우를 예측 불충족이라고 한다. 이 예측 불충족은 환자의 심리적 또는 신체적 건강에 부정적인 영향을 미친다고 보고되어 왔다.

그러나 그동안 국내 생존시 간이식 기증자의 건강관련 삶의 질을

일반 인구 집단과 비교한 연구가 부족하였고, 그들의 수술 결과 예측, 그리고 그 예측과 실제 경험과의 비교가 수술 후 삶의 질에 미치는 영향에 대한 연구도 충분히 이루어지지 않았다. 따라서 본 연구는 살아있는 간 기증자의 건강관련 삶의 질 수준을 확인하고, 수술 결과에 대한 충족되지 않은 예측을 조사한 후, 그 예측 불충족이 간 기증자의 건강관련 삶의 질에 어떠한 영향을 미치는지 파악하였다. 이 관계에 대한 이론적 기틀로 삶의 질을 예측하는 필수적인 변수로서 예측과 경험 사이의 격차를 제안한 Calman의 기대 모델을 적용하였다.

본 연구는 횡단면적 서술적 조사 연구로 자가 보고식 설문지와 의무기록 리뷰를 통하여 자료를 수집하였다. 자료수집은 서울의 일개 대학병원에서 시행되었으며, 해당 병원에서 2011년 1월부터 2021년 3월까지 생존시 간 기증 수술을 받은 535명을 잠재적 연구 대상자로 설정하였다. 그 중 124명이 본 연구에 참여하였다. 간 기증자의 건강관련 삶의 질은 Short Form Health Survey version 2 (SF-12v2)를 사용하여 측정하였다. 수술 결과에 대한 예측 불충족은 통증, 재원기간, 회복 속도, 합병증의 4개 항목에 대하여 측정하였다. 로지스틱 회귀 분석을 통하여 간 기증자의 예측 불충족이 그들의 건강관련 삶의 질에 미치는 영향을 확인하였고, 이때 연령, 성별, 교육 수준, 월 소득, 수술 후 합병증, 수혜자 사망 여부, 기증 후 기간 및 기증 결정에 대한 만족도의 영향은 통제하였다.

실제 경험한 통증, 회복 속도, 재원기간, 합병증이 수술 전 예측보다 더 심하거나 길었다고 응답한 비율은 각각 34.7%, 22.6%, 9.7%, 7.3%였다. 간 기증자의 신체적, 정신적 건강관련 삶의 질은 51.48 ± 7.44점, 52.97 ± 8.47점으로 일반 인구집단에 비해 유의미하게 높았다. 그러나 19-29세의 간 기증자는 신체적 기능, 신체적 역할, 신체적 통증, 일반 건강, 활력, 사회적 기능 및 감정적 역할 영역에서 불량한 평균 점수가 나타났다. 또한 수술 결과에 대한 예측 불충족이 클수록 신체적, 정신적 건강관련 삶의 질이 낮았다. 그 밖에 수술 후 기간이 짧을수록 신체적 건강관련 삶의 질이 낮았으며, 교육 수준이 학사 미만이거나

기증 결정에 대한 만족도가 낮을 때 정신적 건강관련 삶의 질이 낮았다.

따라서 살아있는 간 기증자의 수술 후 삶의 질 향상을 위하여 예측 불충족의 크기를 줄여야 하며, 이를 위해서는 수술 결과에 대하여 보다 정확하고 현실적인 정보를 제공해야 한다. 정보를 제공할 때, 간호사와 임상의는 간 기증자가 선호하는 정보의 종류, 요구하는 정보량, 예측하고 있는 수술 결과에 대하여 파악하고, 그 정보를 기반으로 그들 각자에게 적합한 정보를 제공하여야 한다. 또한 생존시 간 기증자의 대부분은 기증 결정에 대하여 만족하고 있었지만, 그들의 정신적 건강관련 삶의 질 향상을 위해 기증 후 후회 정도를 줄이는 노력은 여전히 중요한 것으로 보인다.

본 연구를 통하여 생존시 간이식 기증자가 통증과 회복속도 및 불편감에 대한 예측을 구체적으로 할 수 있도록 효과적인 교육과 지지가 제공되어야 함을 확인하였다. 이는 그들이 수술 후에 겪는 통증의 강도 및 기간, 회복 속도에 대하여 충분히 파악하기 위한 추가 연구가 필요하다는 점을 시사한다. 또한 20대 간 기증자의 수술 후 삶의 질에 대해 더욱 관심을 가지고 그들의 건강관련 삶의 질에 대한 주요 예측 요인을 규명하여, 삶의 질을 개선하기 위한 효과적인 중재를 설계할 필요가 있겠다.

주요어: 삶의 질, 간 이식, 생존시 간이식 기증자, 예측 불충족, 정보에 근거한 동의, 환자 교육

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