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Impact of institutional case volume of solid organ transplantation on patient outcomes and implications for healthcare policy in Korea

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Solid organ transplantation is distinguished from other high-risk surgical procedures by the fact that it utilizes an extremely limited and precious resource and requires a multidisciplinary team approach. For several decades, institutional experience, as quantified by center volume, has been shown to be strongly associated with patient outcomes and graft survival after solid organ transplantation. The United States has implemented a minimum case volume requirement and performance standards for accreditation as a validated transplantation center. Solid organ transplantation in Europe is also governed by the European Union, which monitors patient outcomes and organ allocation. The number of solid organ transplantation cases in Korea is increasing, with patient outcomes comparable to international standards. However, Korea has outdated regulations regarding hospital facilities, and performance indicators including patient outcomes after transplantation are not monitored. Therefore, centers perform solid organ transplantation with no meaningful oversight. In this review, data regarding the impact of institutional case volume of kidney, liver, lung, and heart transplantation are summarized, followed by a description of current transplantation center regulations in the United States and Europe. The basis for the necessity of adequate transplantation center regulations in Korea is presented.

Keywords: Delayed graft function; Health policy; Mortality; Organ transplantation; Treatment outcome

INTRODUCTION

Numerous studies have demonstrated the relationship between higher institutional case volumes of various procedures and better patient outcomes [1-3]. Risk-adjusted patient mortality after complex high-risk surgical procedures, such as pancreatectomy, esophagectomy, and cystectomy, has been shown to be lower in institutions with higher case volume [3]. An analysis of 206,179 cases of deceased donor kidney transplantation revealed that compared with low-volume centers, higher-volume centers showed significantly lower rates of 1-year graft loss and mortality at 1 month and 1 year [4]. Less complicated emergent operations (e.g., appendectomy or cholecystectomy) for elderly patients also showed a similar correlation between risk-adjusted mortality and center case volume [1]. Conversely, non-emergent, elective procedures tend to show similar mortality rates despite significant differences in case volume [5]. These findings have provided the basis for establishing a minimum case

HIGHLIGHTS

- Higher center volume of organ transplantation is associated with significantly better posttransplant patient outcomes and graft survival.
- Transplantation centers should operate under appropriate regulations, and their performance should be monitored.

volume standard in the United States for accreditation and subspecialty training for the highest-risk surgical procedures, including solid organ transplantation. The main mechanism of the institutional case volume effect may stem from the difference in failure-to-rescue rates between hospitals that perform different numbers of the particular procedure. An evaluation of 37,865 patients who underwent high-risk cancer operations showed that the overall mortality between low- and high-volume centers was comparable. However, despite a higher rate of postoperative hemorrhage in high-volume centers, the failure-to-rescue rate was lower in high-volume centers than in low-volume centers [6].

Successful solid organ transplantation requires an extensive pretransplant work-up for both the donor and the recipient, a skilled and experienced multidisciplinary team, and facilities and personnel with skillsets to take countermeasures against potential posttransplant complications. Recent trends in hospital publicity in Korea have tended to highlight the large cumulative number of cases and near-perfect patient outcomes, especially for complex procedures such as solid organ transplantation. This reflects that institutional cumulative experience is deemed as an indicator of expertise and reliability in the field of healthcare. However, the current requirements for accreditation as a solid organ transplant center in Korea are extremely minimal and have not been revised other than minor details since their first introduction in 2008. Moreover, the Korea Organ Donation Agency (KODA), the coordinating body for organ donation and allocation, only collects the donor and recipient information required for transplantation. There are no standards or outcome measures that transplant centers are required to meet, and there are no repercussions for institutions that show poor patient/graft outcomes, such as forfeiting their status as a solid organ transplant center. The situation is similar for the training of transplant surgeons who perform transplant procedures. Thus, the relationship between center case volume and patient outcome in solid organ transplantation, in addition to suggested necessary improvements in policy and regulations, is discussed in this review.

KIDNEY TRANSPLANTATION

According to the data in the 2021 annual report of the Korean Network for Organ Sharing (KONOS), approximately 2,200 kidney transplantations were performed each year from 2017 to 2021 [7]. Since the Korean Organ Transplantation Registry (KOTRY) first started prospectively collecting data for the national transplant registry in 2014, 82 transplant centers have provided baseline information on recipients and donors, such as comorbidities, lab results, immunosuppressive drugs, posttransplant complications, and recipient mortality. The KOTRY was able to produce a prospective observational cohort involving five types of solid organ transplantation (kidney, liver, heart, lung, and pancreas). According to the KOTRY, the 1-year graft survival rate after kidney transplantation was 98.4% and the 1-year patient survival rate was 97.0% in 2021 (https://www.kotry.org/) [8].

Kidney transplantation shows the highest volume and the lowest posttransplant mortality of all types of solid organ transplantation (Table 1). A previous study evaluated the correlation between transplant volume and patient outcomes in Canada among 5,037 kidney transplantation recipients in five centers. Data were collected from 2000 to 2013 and showed a 16.0% graft loss and an 18.3% mortality rate over the study period, but no significant association between center volume and patient mortality was found [9]. A national study in the United States from 1999 to 2013 examining outcomes in 206,179 adults undergoing deceased donor kidney transplantation showed a significant association between higher transplant center volume and more favorable 1-year observed-to-expected (O:E) ratios of graft loss and patient death [4]. The O:E ratio for 1-year graft failure for low-volume (<32 cases/year), medium-volume (32–74 cases/year), and high-volume (>74 cases/year) centers was 1.12 (low-volume centers: reference group), 1.03 (P=0.05), and 0.97 (P<0.001), respectively. One-year patient mortality showed a similar trend, and the O:E ratio for low-, medium-, and high-volume centers was 1.15 (low-volume centers: reference group), 1.03 (P=0.08), and 0.95 (P=0.001), respectively.

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Table 1. Center volume and patient outcomes after kidney transplantation

Study	No. of patients	No. of centers	Primary outcomes: graft failure, mortality	Cut-off value (case/yr)	Impact of case volume
Axelrod et al. (2004) [10]	60,778	258	1-yr mortality or graft loss	Low (46–75) High (125–278)	Significant
Barbas et al. (2018) [4]	2,016,179	NA	O:E ratio of 1-mo graft loss, 1-mo mortality, and 1-yr mortality	Low (1–31) Medium (32–74) High (>75)	Significant
Tsampalieros et al. (2019) [9]	5,037	5	Death-censored graft loss	Not specified	Significant
Oh et al. (2019) [11]	13,872	74	1-yr graft failure, in-hospital mortality, long-term graft survival	Low (<25) Medium (25–60) High (>60)	Significant
Sonnenberg et al. (2019) [12]	79,581	219	3-yr all-cause graft failure and mortality	Low (<66) High (>196)	Insignificant

NA, not available; O:E, observed-to-expected.

An analysis of the National Healthcare Insurance Service database in Korea also confirmed the case volume effect. Institutions performing kidney transplantations between 2007 and 2016 were divided into low-volume (<24 cases/year), medium-volume (24–60 cases/year), and high-volume (>60 cases/year) centers, and 13,872 adult patients who underwent KT were analyzed. After adjusting for relevant factors, low-volume centers showed significantly higher rates of 1-year graft failure (odds ratio [OR], 1.50; 95% confidence interval [CI], 1.26–1.78; P<0.001) and risk-adjusted mortality (OR, 1.75; 95% CI, 1.15–2.66; P=0.010) than high-volume centers [11].

LIVER TRANSPLANTATION

According to the data in the 2021 annual report of the KONOS, approximately 1,500 liver transplantations were performed each year from 2017 to 2021. The overall 1-year survival rate after liver transplantation was 86.9% and 90.6% for living-donor liver transplantation and 76.4% for deceased-donor liver transplantation [7]. Similar to other types of solid organ transplantation, liver transplantation requires an extensive donor and recipient work-up, complex surgical skills, judicious intraoperative management, and attention to postoperative recovery.

Postoperative complications after liver transplantation are often serious and persist for a prolonged period. Outcomes after liver transplantation were reported in an analysis of 2,563 adult liver transplantation recipients in the 2014–2017 KOTRY database. Among 1,956 living-donor liver transplantation recipients and the 607 deceased-donor liver transplantation recipients followed-up for 14.7±10.6 months, graft loss occurred in 5.0% and 16.1% and death occurred in 4.0% and 14.7%, respectively. Graft loss, rejection, and acute kidney injury were relatively common complications after liver transplantation. In a multivariate analysis, old recipient age and deceased-donor liver transplantation were significant risk factors for mortality and graft loss [13].

Many studies have evaluated the effect of institutional case volume on liver transplantation (Table 2). An analysis of 31,576 deceased-donor liver transplants performed between 2002 and 2008 in the Scientific Registry of Transplant Recipients (SRTR) database showed a positive correlation between hospital case volume and graft survival (hazard ratio [HR], 0.93; 95% CI, 0.89–0.98; P=0.002). An in-depth analysis revealed that despite the higher donor risk index of the allografts received by recipients in high-volume centers (2.31±0.16 in high-volume centers vs. 2.21±0.10 in low-volume centers; P<0.05), patient survival was significantly better in high-volume centers (HR, 0.90; 95% CI, 0.83–0.97; P=0.004) [14]. The in-hospital mortality of patients receiving deceased-donor liver transplantation in high-volume centers was 2.9% compared to 3.4% for their counterparts in low-volume centers (P=0.004) [15]. These results imply that centers with higher case volumes are more successful in performing deceased-donor liver transplantation, even with less optimal liver grafts.

A recent study reported the effect of case volume in

Table 2. Center volume and patient outcomes after liver transplantation

Study	No. of patients	No. of centers	Primary outcomes: mortality	Cut-off value (case/yr)	Impact of case volume
Northup et al. (2006) [16]	9,909	100	90-day mortality	Low (≤20) High (>20)	Insignificant
Salvalaggio et al. (2007) [17]	1,228	86	1-yr mortality Rate of occurrence of hepatic artery thrombosis	Low (<4) High (>25)	Significant
Tracy et al. (2009) [18]	34,661	104	The O:E ratio for 1-yr mortality	Low (<51) Medium (51–80) High (>80)	Change of significance over time
Reese et al. (2009) [19]	3,977	140	1-yr graft failure and 1-yr mortality	Low (<51) Intermediate (51–88) High (>89)	Insignificant
Ozhathil et al. (2011) [14]	15,668	92–102	Graft and patient survival	Low (5–48) Medium (49–77) High (78–215)	Significant
Macomber et al. (2012) [15]	5,130	63	Hospital and ICU length of stay, cost and in-hospital mortality	Low (11–48) Medium (48–75) High (>76)	Significant
Kettelhut et al. (2013) [20]	NA	91–106	1-yr and 1-mo mortality rates, 1-yr risk-adjusted mortality	Low (<30) Medium (31–100) High (>100)	Insignificant
Cheng et al. (2016) [21]	2,938	NA	ICU length of stay, hospital stay, postop complication, 1-yr mortality	Low (<100) High (>100)	Significant
Hsieh et al. (2021) [22]	436	1	In-hospital mortality	Low (<30) High (>30)	Significant
Delman et al. (2022) [23]	3,273	110	1-yr mortality	Very low (1–2) Low (3–5) High (>5)	Significant

O:E, observed-to-expected; ICU, intensive care unit; NA, not available.

2,468 deceased donor liver transplants performed in 54 centers in Korea. Centers were categorized as high-volume (>30 cases/year), medium-volume (10–30 cases/year), and low-volume (<10 cases/year). Multivariable logistic regression analysis showed a significantly higher in-hospital mortality rate in low-volume centers than in high-volume centers (adjusted OR, 1.953; 95% CI, 1.461–2.611; P<0.001) [24]. In a similar study that analyzed 7,073 living-donor liver transplantations performed in Korea, the in-hospital mortality rates after liver transplantation were significantly higher in low-volume centers (<10 cases/year, 6.7%) than in high-volume centers (>50 cases/year, 2.8%). Even after adjusting for relevant factors, low-volume centers showed a higher risk of in-hospital mortality compared to high-volume centers (adjusted OR, 2.287; 95% CI, 1.471–3.557; P<0.001) [25]. A similar impact of institutional case volume was demonstrated in patients undergoing liver retransplantation in Korea. An analysis of 258 re-liver transplantation cases with a cut-off of 64 liver transplantations per year showed that despite no difference in in-hospital mortality after liver transplantation, 1-year mortality was significantly higher in low-volume centers than in high-volume centers (OR, 2.14; 95% CI, 1.05–4.37; P=0.037) [26]. A single-center study that analyzed the impact of annual changes in living donor liver transplantation case volume showed that in-hospital mortality and posttransplant complications were higher in the years with fewer than 30 cases [22].

Studies have reported contradictory results with regard to the relationship between center volume and

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patient outcomes [16,19]. Both of those studies reported that the adjusted 1-year allograft failure and mortality rates did not significantly differ between low- and high-volume centers. Those studies argued that implementing the model for end-stage liver disease system for allograft allocation has undermined the impact of center case volume as a predictor of patient outcomes. A decade-long mandatory annual volume requirement from the U.S. government for the accreditation of transplantation centers led to a more uniform distribution of solid organ transplantation cases among centers. As the field of liver transplantation in the US is somewhat regionalized, not all low-volume centers are the same. Low-volume centers that are located in the same metropolitan region as a high-volume center tend to show a lower posttransplant mortality (HR <1.0, P=0.001), unlike low-volume centers situated in remote areas [27].

HEART TRANSPLANTATION

Compared to other types of solid organ transplantation, heart transplantation requires additional layers of personnel to operate equipment such as the cardiopulmonary bypass machine and extracorporeal membrane oxygenation. Between 2017 and 2021, the annual number of heart transplantations performed in Korea was approximately 160 to 190 cases, with a 1-year survival rate of 84.8% and a 5-year survival rate of 75.4%, which are comparable to international standards [28,29].

The correlation between higher center case volume and better patient outcomes is more prominent for heart transplantation than for other types of solid organ transplantations (Table 3). Data from 13,230 heart transplants performed at 147 centers extracted from the U.S. scientific registry showed that compared to low-volume centers (<5 cases/year), the HR for 1-year posttransplant mortality in high-volume centers (>48 cases/year) was 0.56 (95% CI, 0.46–0.65; P<0.001) [30]. Another study aiming to evaluate whether the center case volume had an impact on postoperative complications after heart transplantation demonstrated that complications were more frequent in low-volume centers (<14.5 cases/year) than in high-volume centers (>27.5 cases/year) (43.4% vs. 36.2%, P<0.001) [31]. In another study that compared 8-year cu-

Table 3. Center volume and patient outcomes after heart transplantation and lung transplantation

Study	No. of patients	No. of centers	Outcome	Cut-off value (case/yr)	Impact of case volume
Heart					
Weiss et al. (2008) [32]	14,401	143	30-day and 1-yr mortality	Low (<10) High (>10)	Significant
Shuhaiber et al. (2010) [30]	13,230	147	1-yr mortality	Very low (1–11) Low (12–21) Medium (22–33) High (>34)	Significant
Grimm et al. (2015) [31]	19,849	144	Survival after postoperative complications	Low (<14.5) Intermediate (14.5–26.5) High (>26.5)	Significant
Lung					
Scarborough et al. (2010) [33]	7,829	74	The O:E ratio for 1-yr mortality	Low (<20) Medium (21–34) High (>35)	Significant
Yoon et al. (2019) [34]	315	7	Risk-adjusted in-hospital mortality and long-term survival (up to 7 yr)	Low (≤5) High (>5)	Insignificant
Jawitz et al. (2021) [35]	7,322	72	Incidence of grade 3 primary graft dysfunction	Low (<70) High (>70)	Significant
Yang et al. (2022) [36]	10,007	71	1-yr survival	Low (<33) High (>33)	Significant

O:E, observed-to-expected.

mulative mortality between high-volume (>40 cases/year) and low-volume (<10 cases/year) heart transplantation centers in 14,401 adults, death after heart transplantation was significantly more common in low-volume centers (HR, 1.35; 95% CI, 1.14–1.60; P<0.001). In addition, performing more than 40 cases per year was associated with a 65% decrease in the odds of 30-day mortality [32].

LUNG TRANSPLANTATION

According to the 2021 KONOS report, the 90-day survival rate after lung transplantation was 81.8% and the 1-year survival rate after lung transplantation was 66.5%. Transplant volume increased significantly from 89 cases in 2016 to over 160 cases in 2021 [7]. Lung transplantation may arguably involve the most complex procedure of all types of solid organ transplantation. Lung transplantation certainly requires comprehensive anesthesia techniques and posttransplant intensive care. Accordingly, lung transplantation also shows a strong relationship between center case volume and (Table 3). A retrospective analysis of adult lung transplants performed in the United States from 2000 to 2007 using data from the SRTR demonstrated a significant O:E ratio difference in 1-year mortality between low-volume centers (<20 cases/year) and high-volume centers (>35 cases/year) (1.21 vs. 0.89, P=0.0008; unadjusted survival rate, 78.2% vs. 84.4%) [33]. A further analysis of data revealed that the difference in the O:E ratio for 1-year mortality was slight in the early period (low, 1.12 vs. high, 0.97; P=0.42) but became significant in the later period (low, 1.26 vs. high, 0.87; P=0.01) when the 7-year study period was divided into three smaller time periods. This finding was in contrast to liver transplantation, which showed a weaker correlation between center volume and patient mortality over time. A temporal sub-analysis follow-up of each center's performance showed that low-volume centers maintained low case volumes, whereas medium- and high-volume centers showed consistent growth in their annual case volume.

The current adult lung transplantation data in Korea somewhat differ from the previous reports. In an analysis of 315 adult patients who underwent lung transplantation at seven centers in Korea between 2007 and 2016, the median center case volume was four cases per year, with an overall in-hospital mortality rate of 25.7%. No statistically significant difference was found in in-hospital mortality between low-volume centers (<5 cases/year) and high-volume centers (>5 cases/year) (32.4% vs. 23.8%; OR, 1.498; 95% CI, 0.811–2.758; P=0.197) [34]. The absence of a relationship between center case volume and mortality may have been due to the relatively small number of overall cases and centers performing lung transplantation.

REGULATIONS REGARDING SOLID ORGAN TRANSPLANTATION

Based on published evidence of center case volume as a strong indicator of patient outcomes, a minimum volume requirement was implemented in the United States for insurance reimbursement claims and validation of legitimate transplant center status based on the 2007 federal mandate. The federal cut-off value of center volume was 10 cases per year for validation, and a review was conducted by the United Network for Organ Sharing registry to determine whether those standards were adequate. Standard clinical experience for the first activation of a Medicare-approved transplant center requires an annual volume of 10 heart transplants, 10 liver transplants, 10 lung transplants, and three kidney transplants. For re-approval, 10 transplants of each organ are required. There is no annual volume requirement for heart-lung and pancreas centers, as well as centers that primarily perform pediatric transplantations. As for patient outcomes, the current review process, which was established by the membership and professional standards committee of the organ procurement and transplantation network and adopted by the Centers for Medicare and Medicaid Services, requires transplant centers to meet three criteria to qualify for review: an O:E ratio of 1-year patient survival and 1-year graft survival greater than 1.5, an observed minus expected survival differential greater than 3, and a one-sided P-value of less than 0.05 for the O:E ratio >1.5 in a comparison of the number of a center's observed patient and graft survival outcomes with the number of the expected patient and graft survival outcomes in that center [37]. Solid organ transplantation in Europe is internationally collaborative and governed by the European Union. In order to procure organs and perform transplantation, each center must be accredited and receive authorization according to each country's legislative laws,

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abiding by the European Union Organ Donation Directive [38]. There are no volume requirements, but patient outcomes not significantly inferior to the national average are expected and the transplant organizations of each country are responsible for regularly monitoring patient outcomes. Transplant surgery training programs in Europe require transplant surgeons in Europe to maintain their current license to practice as a surgeon with 2 years minimum in a transplant unit, and surgeons should also provide a surgical log book, publish scientific papers in the field of transplantation, and demonstrate relevant knowledge as dictated by the European Union of Medical Specialists [39,40].

DISCUSSION

Multiple studies investigating various aspects support the notion that regardless of surgical procedural complexity, higher center volume is strongly associated with improved patient outcomes. Procedures with the highest complexity and risk tend to require extensive preoperative assessment and planning. The superior patient outcomes in centers with higher case volume may be due to meticulous perioperative management, cumulative experience at the institutional level, and lower failure-to-rescue rates.

What distinguishes solid organ transplantation from other high-risk surgical procedures is the unreplaceable value and scarcity of donated organs. The supply of organs does not correspond to the number of patients requiring transplantation, and the situation seems to be getting worse. As we would only ask the jeweler with the most exquisite workmanship to set rare and precious gems, the same should apply to solid organ transplantation, as human lives are at stake. Therefore, organ distribution should not only consider the recipient, but also the status/performance of the institution performing the transplantation procedure. Since 2007, the United States has implemented a surveillance and accreditation process that verifies transplant centers using specific criteria to ensure standards of care and optimize patient outcomes. Transplant centers are required to submit specific data, including annual case volume and patient outcomes in the form of risk-adjusted 1-year patient survival and 1-year graft survival. Transplant programs that demonstrate their ability to successfully perform solid organ transplantation are recognized by Medicare as legitimate transplant centers. However, the current regulations in Korea only require institutions to report outcomes, with no repercussions regarding the performance of the institutions.

In general, the case volume effect seems to be more recognizable in centers with lower volumes and dissolves as the case volume grows. The point beyond which the case volume effect is no longer visible is referred to as the "cut-off." In countries or healthcare systems where centralization or regionalization is already in effect, the case volume effect may not be noticeable. When implementing the case volume effect in policies and regulations, careful consideration should be taken to avoid penalizing low-volume centers with acceptable patient outcomes [33]. At least in the United States, after 14 years of implementation, center volume is no longer a strongly relevant factor for patient outcomes. Regarding organ transplantation, the physical proximity of low- and high-volume centers is already feasible, and further regionalization of transplant centers could lead to further discrimination in the organ allocation process by neglecting those who do not have access to centralized centers [35,41]. An unexpected downside of centralization and regionalization is the disparity in access to transplantation, which also is associated with patients' socioeconomic status and place of residence. Living farther from the transplant center is related to reduced access to deceased donors and inferior posttransplant survival [42-44].

The reality of transplant center regulations in Korea is surprisingly minimal and outdated. The requirements for a transplantation center in Korea consist of the physical presence of an operating room, a postanesthesia recovery room, an intensive care unit, and facilities for laboratory tests, radiologic imaging, and pathology. In terms of personnel, physicians specializing in surgery, anesthesiology, internal medicine (infection and respiratory), rehabilitation medicine, psychiatry, pediatrics, laboratory medicine, and pathology are required. Transplant centers are also required to staff a transplant coordinator nurse, social security worker, and organ-specific specialists for each organ. Organ specialists are mandated to receive transplantation training for more than 6 months in transplant centers, either national or international. In addition, there are no stated requirements for transplant training centers.

The overall transplantation volume is annually increasing in Korea, and when compared to U.S. regulations, any center that meets the minimum standards is allowed to perform solid organ transplantation with nearly no over-

sight. Insurance reimbursement claims do not consider the performance/outcome of the center, the experience or credibility of the transplant surgeon, or the case volume of the center. Reimbursements for organ transplantation also follow the overall scheme of fee-for-service.

Solid organ transplantation is a complex, high-risk procedure requiring a comprehensive multidisciplinary team. As organs are extremely limited and thus valuable, the institutional case volume, which is a proven indicator for favorable patient/graft outcomes globally and in Korea, should be implemented in policies regarding the accreditation of transplant centers and organ allocation. To successfully transition to prioritizing patient outcomes and safety in solid organ transplantation, policies and regulations should be imposed while taking the current landscape of solid organ transplantation in Korea into account.

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Conflict of Interest
No potential conflict of interest relevant to this article was reported.

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