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Review

# Liver Transplantation for Colorectal Liver Metastases

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**Abstract**

Colorectal cancer (CRC) is the third most common malignancy and the second leading cause of cancer-related mortality worldwide. Over 50% of CRC patients develop liver metastases either at diagnosis or during follow-up. While hepatic resection offers 5-year survival rates of 25–60%, only 20–40% of patients have resectable disease, and recurrence rates remain high. The role of liver transplantation (LT) for non-resectable CRLM has re-emerged over the past two decades with promising results in selected patients.

To evaluate the evolving role of LT in non-resectable CRLM, summarizing key studies, patient selection strategies, and outcomes.

We reviewed pivotal studies including SECA I/II, European Consortium, TRANSMET, and recent LDLT series from Toronto, Pittsburgh, and multicenter U.S. cohorts. Inclusion criteria, patient characteristics, surgical and oncological outcomes, and prognostic factors were analyzed.

Early European experiences in the 1980s–1990s showed poor outcomes (5-year overall survival (OS) 12–21%). However, the SECA studies demonstrated 5-year OS of 60–83% in carefully selected patients. The TRANSMET trial, the first randomized study, showed significantly improved 5-year OS in the LT+chemotherapy arm (73.2%) versus chemotherapy alone (9.3%). Living donor liver transplantation (LDLT) series reported comparable survival benefits without impacting organ-sharing systems. Key prognostic factors influencing outcomes include Fong and Oslo scores, tumor biology (KRAS, BRAF, SMAD4 mutations), metabolic tumor volume on PET, CEA levels, and tumor sidedness.

LT for non-resectable CRLM is no longer experimental but a promising option in selected patients with favorable tumor biology and controlled disease. Advances in systemic therapy, imaging, and genomic profiling are critical for refining patient selection. Multidisciplinary collaboration and expansion of LDLT programs may mitigate ethical concerns related to deceased donor organ allocation.

**Keywords:** Colorectal cancer, colorectal liver metastases, liver transplantation, living donor liver transplantation

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Colorectal cancer (CRC) is the third most frequent cancer and the second leading cause of cancer-related death for men and women worldwide.[1] More than 50% of patients with CRC are diagnosed with liver metastases either at the time of initial diagnosis or later during the course of the disease. To elaborate, 15–25% of CRC patients present with distant metastases at diagnosis, and an additional 18–30% will develop distant metastases within 5 years after diagnosis and treatment. The median survival of untreated patients with colorectal liver metastases (CRLM) is approximately 6–13 months. Hepatic resections for CRLM can achieve 5-year survival rates of 25–60%; however, only 20–40% of CRLM cases are resectable, and as few as 10–15% are amenable to curative resection. Nevertheless,

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recurrence occurs in 40–75% of patients within 3 years after hepatic resection, with approximately 50% of recurrences localized to the liver.[2,3]

In patients with CRLM, survival outcomes have improved in the early stages with oxaliplatin-based chemotherapy. However, long-term survival remains poor. Patients treated with regimens containing 5-fluorouracil, irinotecan, and oxaliplatin (including antibody therapies such as cetuximab) have a median overall survival of approximately 20 months, with a 5-year survival rate of only 10%.[4] When a response to systemic chemotherapy is achieved, R1 hepatic resections should be pursued, as studies have shown that R1 resections can yield survival outcomes comparable to R0 resections in such cases. Furthermore, in patients undergoing systemic chemotherapy and hepatic resection, better survival has been observed in those with ECOG performance status 0–1, absence of K-RAS and B-RAF mutations, and left-sided primary colorectal tumors.

Is there a role for liver transplantation (LT) in CRLM? Currently, the waiting list mortality is approximately 25%. Adding CRLM as an indication for transplantation would likely further widen the gap between the demand for liver grafts and their availability. Outcomes of deceased donor liver transplantation (DDLT) for CRLM before the 2000s were poor. Prominent studies from that period reported 5-year survival rates of only 12–21%.[5-7] When these poor outcomes are analyzed, several contributing factors emerge: issues with patient selection, underdeveloped surgical techniques, the absence of standardized immunosuppressive protocols, and suboptimal results from systemic chemotherapy regimens of that era. Following the first publication by Müchlbacher and colleagues from the University of Vienna in 1991, their second study provided a more detailed analysis of the Vienna center's results.[8] This group had, at the time, the most extensive single-center experience in this field. Between 1983 and 1994, they performed LT in 25 patients for CRLM, reporting a 30-day mortality rate of 30% and a 5-year survival rate of 12%. In their initial study, the authors included patients with negative lymph nodes on primary CRC surgical specimens. In their second publication, they retrospectively re-examined the histopathologically negative lymph nodes for micrometastases. Among the 21 patients evaluated, 15 had no micrometastases in their lymph nodes and demonstrated a median survival of 118 months. In contrast, 6 patients with lymph node micrometastases had a median survival of only 28 months. Furthermore, molecular analysis for p53 and K-RAS mutations was performed using MASA (mutant allele-spesific amplification) techniques in 9 of the 21 patients without micrometastases. Mutations were detected in 3 patients, all of whom were still alive at 4, 5, and 20 years of follow-up. The authors concluded that long-term survival was favorable in patients without lymph node metastases (even micrometastases) and negative for p53 and K-RAS mutations. However, it is important to note that this conclusion was based on only 3 patients.

Studies shedding new light on LT for CRLM were initiated in 2006. In Norway, organ donation rates are remarkably high at 25 per million population (pmp) and LT is performed at a rate of 17 pmp annually. Oslo and its surrounding area, with a population of 4.8 million, has a particularly efficient system where patients on the LT waiting list can access a deceased donor organ in less than one month. It is evident that organ donation exceeds the needs of patients requiring LT. Building on this favorable context, a study was launched in 2006 at Oslo University Hospital Rikshospitalet, named SECA. The acronym SECA stands for "Secondary Cancer." The inclusion criteria for LT in CRLM patients were: R0 resection of the primary CRC, absence of extrahepatic metastatic disease, unresectable CRLM confined to the liver, completion of at least 6 weeks of one or more chemotherapy regimens, and an ECOG performance status of 0–1. All patients underwent staging laparotomy prior to LT, during which hilar lymph nodes were assessed via frozen section. Patients without tumor involvement proceeded to LT. Staging laparotomy was performed either on the same day as LT or earlier, without strict adherence to one approach.

While the SECA study was still ongoing, the Oslo team and European Liver Transplant Registry (ELTR) published an article in 2010 titled "Revisiting the Concept".[9] The aim of this article was summarized as reviewing past experiences with LT for CRLM and discussing several factors that could potentially improve outcomes. Interestingly, it also mentioned some preliminary data from an ongoing pilot study (SECA) investigating the role of LT in CRLM treatment. The authors suggested that, with appropriate patient selection using modern imaging techniques, effective chemotherapy regimens, and aggressive multimodal treatment of metastases, long-term survival and even curative outcomes could be achieved. The SECA study reported an overall survival (OS) rate of 94% at 25 months. Remarkably, they speculated that if LT for CRLM could achieve long-term survival rates of ~80% after primary LT and ~50–55% after re-transplantation—comparable to other LT indications—it might be challenging to justify allocating deceased donor liver grafts for these patients, and living donors could become a viable option.

Three years later, the results of the SECA study were published.[10] This study initially enrolled 25 patients with

CRLM, but only 21 underwent DDLT because 4 patients developed extrahepatic metastases and were excluded. Post-transplant, sirolimus was used as immunosuppression, targeting blood levels of 5–10 ng/mL during the first month and 10–20 ng/mL thereafter. The median follow-up was 27 months. OS at 1, 3, and 5 years was 95%, 68%, and 60%, respectively. Thus, the 94% survival at 25 months declined to 60% at 5 years. The 1-year disease-free survival (DFS) was 35%. At the end of the study, 90% of patients (19/21) had experienced recurrence, and 6 patients eventually died of disseminated disease after a median of 24 months. Recurrences typically occurred early, with a median time to recurrence of 6 months. The lungs were the most frequent site of recurrence (13/19). Among the 19 patients with recurrence, 7 had isolated lung metastases, while 7 had lung and liver metastases, 5 had lung and bone metastases, 3 had lung and ovarian/adrenal metastases, 1 had peritoneal metastasis, and 2 had lymph node metastases. Additionally, 2 patients experienced recurrence of rectal cancer. Of the 7 patients with isolated lung metastases, 3 underwent resection, and at 27 months, all 7 were still alive (5-year OS of 72%). The authors concluded that lung metastases after LT for CRLM appeared indolent and did not negatively impact survival. Poor prognostic factors identified in this study included a maximum tumor diameter >55 mm, pre-transplant CEA >80 ng/mL, progression of disease while on pre-transplant chemotherapy, and an interval of less than 2 years between CRC resection and LT.

In 2015, the Oslo group published a new study[11] comparing the results of their SECA trial with those of the NORDIC VII study, which included patients with CRLM treated only with first-line chemotherapy regimens.[12] The NORDIC VII trial (2005–2007) had evaluated various chemotherapy strategies. These can be summarized into three groups: (1) bolus administration of 5-fluorouracil/folinic acid and oxaliplatin; (2) the same regimen combined with cetuximab; and (3) an intermittent administration of the first regimen combined with cetuximab. Notably, no patients in NORDIC VII underwent liver resection for CRLM. The study reported no significant differences in survival among the three groups. Median CEA levels differed markedly between the two studies: 42 ng/mL in NORDIC VII versus 15 ng/mL in SECA. The 5-year overall survival (OS) was 56% in SECA compared to only 9% in NORDIC VII. Even when comparing the 19 longest-surviving patients from NORDIC VII to those in SECA, the 5-year OS remained significantly lower in NORDIC VII (19%) than in SECA.

The European Consortium study was published in 2017 by Toso and colleagues.[13] Four centers from Portugal, Switzerland, and France participated in the study, enrolling a total of 12 patients. Following CRC resection, 11 patients received irinotecan and oxaliplatin-based chemotherapy, with 6 of these also receiving bevacizumab. The remaining patient was treated with hepatic arterial infusion. After a median interval of 41 months, all 12 patients underwent LT. The patients were followed for a median of 26 months. The reported OS rates at 1, 3, and 5 years were 83%, 62%, and 50%, respectively. Six patients developed recurrence, five of whom had pulmonary metastases. At 48 months, four patients remained alive and disease-free, leading the authors to emphasize the significance of this study in demonstrating the potential for long-term cancer-free survival. DFS at 1, 3, and 5 years was reported as 56%, 38%, and 38%, respectively.

The Oslo group published the SECA II study in 2020, involving 15 patients enrolled between 2012 and 2016.[14] Patients remained on the transplant waiting list for a median of 29 days, and the interval between CRC diagnosis and LT was 24 months. The immunosuppressive regimen consisted of tacrolimus for the first 4–6 weeks post-LT, followed by a switch to sirolimus. The mean follow-up duration after LT was 3 years. The inclusion criteria for SECA II were notably more stringent compared to SECA I. For instance, CRLM could have previously undergone resection and relapsed as unresectable disease to qualify for the study. Before starting chemotherapy, no single lesion was allowed to exceed 10 cm in diameter. If the number of lesions exceeded 30, none of them could be larger than 5 cm. Furthermore, patients with such tumor burdens had to show at least a 30% response to chemotherapy according to RECIST criteria. Patients with smaller lesions needed to achieve at least a 10% response to chemotherapy. If the response was less than 10% by RECIST, additional locoregional treatments such as TACE or TARE had to elicit a minimum 20% response for eligibility. In summary, SECA II included patients with more favorable tumor biology compared to SECA I. This was reflected in lower median CEA levels (15 ng/mL in SECA I vs. 2 ng/mL in SECA II) and lower SUVmax values of CRLM (9 vs. 5.9). Consequently, SECA II achieved improved survival outcomes: the 1-, 3-, and 5-year OS rates were 100%, 83%, and 83%, respectively. DFS was 53% at 1 year and 35% at 3 years. Median survival was also stratified: patients with fewer than 8 hepatic metastases had a median survival of 23.4 months, while those without lymph node involvement had a median survival of 11.6 months.

At this point, it is also important to discuss the Fong and Oslo clinical scoring systems. Both are based on adverse prognostic factors, with each criterion contributing 1 point.

The **Fong score**[15] includes the following:

- Development of CRLM within 12 months after CRC resection

- Positive lymph node involvement in the primary CRC
- Liver metastases larger than 5 cm
- CEA level >80 ng/mL

The **Oslo score**[14] incorporates:

- Interval between CRC diagnosis and metastasis <2 years
- Disease progression during chemotherapy
- Largest metastasis >5.5 cm
- CEA level >80 ng/mL

Lower scores in both systems were associated with prolonged survival. In the SECA II study, patients with Fong and Oslo scores of 0–2 had longer median DFS compared to those with scores of 3–4. At 3 years, OS was 75% in patients with lower scores, versus 25% in those with higher scores. In summary, SECA II included patients with more favorable tumor biology and achieved superior outcomes compared to SECA I.

Additionally, Dueland and colleagues published another study in 2020.[16] This analysis included patients from both SECA I and SECA II but only examined those with PET-CT scans performed within 90 days of LT. Patients without PET-CT within this timeframe were excluded to avoid missing potential disease progression. Fourteen patients from SECA I and five from SECA II were included. In this study, patients with a metabolic tumor volume (MTV) <70 $cm^3$ had a 5-year OS of 78%. Those with a Fong score of 0–2 achieved a 5-year OS of 100%, while patients with an Oslo score of 0–2 had a 5-year OS of 67%. Interestingly, CEA levels and KRAS mutation status (mutated or wild-type) did not show a significant impact on survival outcomes.

Living donor liver transplantation (LDLT) may represent a distinct approach in the management of CRLM, as it does not infringe upon the rights of other patients in the organ-sharing system. Elective operations can be planned following appropriate neoadjuvant treatments. Preliminary reports from a study conducted in Toronto outlined the inclusion criteria as follows: the primary CRC must be stage T2a or lower; the CRLM must remain stable or regress for at least 3 months before LT; and pre-transplant CEA levels must demonstrate stability or a downward trend. Additionally, CRC resection must have been performed at least 6 months prior to LT, and patients with BRAF mutations were excluded. During systemic chemotherapy following CRC resection, the disease needed to remain stable for at least 6 months. Furthermore, CEA levels had to be <10 ng/mL. A wash-out period of 4–6 weeks after systemic chemotherapy was required before proceeding to LT. In this study, 7 patients underwent LDLT, with 1- and 3-year OS rates of 100% and 100%, respectively. Recurrence was observed in 2 patients (29%). DFS was 85.7% at 1 year and 68.6% at 3 years. For comparison, 22 patients with similar baseline characteristics underwent resection of CRLM. In this resection group, the 1-year OS was 93.8% and the 3-year OS was 43.3%, while DFS at both 1 and 3 years was only 11.4%. Although overall survival was similar between the two groups, DFS was significantly better in the LT group.[17]

In the United States, one out of every six patients on the LT waiting list dies each year while waiting for an organ. However, this does not mean that the remaining five patients all receive transplants—some eventually do, while others continue to wait. Recent changes in UNOS allocation policies have prioritized patients with higher MELD scores, which has negatively impacted patients with cancer indications for LT. A multicenter study involving three institutions analyzed patients treated between 2017 and 2021.[18] Patients who demonstrated disease progression while receiving systemic therapy were excluded. Twelve patients who had undergone both local and systemic treatments were included; of these, two received DDLT and ten received LDLT. The median interval from metastasis diagnosis to LT was 1.7 years. Local and systemic treatments included liver resection in four patients, hepatic arterial infusion (HAI) chemotherapy in three patients, and tumor ablation in three patients. All patients had received systemic therapy with regimens such as FOLFOX, FOLFIRI, and targeted agents. Genetic analysis revealed KRAS mutations in three patients and one patient each with TP53, SMAD4, and BRAF variations. The median follow-up duration was 1 year. Recurrence was observed in three patients. At 1.5 years, DFS was 62.5% and OS was 100%. By year 3, OS decreased to 75% and DFS to 60%.

In the TRANSMET randomized clinical trial,[19] inclusion criteria were as follows: age 18–65 years, ECOG performance status 0–1, histological confirmation of CRC, confirmed CRLM with curative resection of the primary tumor, no local recurrence on colonoscopy within 1 year prior to enrollment, absence of extrahepatic disease, and stable disease or partial response for more than 3 months according to RECIST criteria on the last chemotherapy protocol. Patients were required to have received no more than three chemotherapy regimens, have no BRAF tumor mutations, serum CEA levels <80 ng/mL or at least a 50% reduction from baseline, and demonstrate adequate compliance. After stopping chemotherapy, patients were planned to undergo LT within 2 months. If progression occurred within those 2 months, LT was deferred, and chemotherapy was resumed. Upon re-establishing disease stability, LT could be reconsidered. In terms of organ allocation, a MELD score of 35 was assigned for prioritization. Immunosuppression consisted of tacrolimus for the first 2 months, followed by everolimus, with corticosteroids continued for 6 months. The study included 20 centers across France (14), Belgium (4), and Italy (2). A total of 157 patients were enrolled, with 94 randomized (47 to the LT+chemotherapy arm and 47 to the chemotherapy-alone arm). LT was performed in 38 patients, with three re-transplantations required; one patient died. Among patients in the chemotherapy arm excluded due to tumor progression, 1-year OS was 71% and 2-year OS was 26%. Post-LT, 68% of patients initiated adjuvant chemotherapy at a median of 71 days, while 32% could not receive adjuvant treatment due to poor fitness. Eligible participants were selected by the local multidisciplinary tumour board a teach centre. Eligibility was assessed by an independent multidisciplinary committee of international expert oncologists, radiologists, and liver surgeons via monthly video conferences in the presence of local investigators. The interim results represented the first large multicenter randomized trial in CRLM and focused on the feasibility and safety of post-LT chemotherapy rather than survival data.

In September 2024, the more detailed results of the TRANSMET trial were published.[20] Post-LT chemotherapy was initiated in uncomplicated cases but was not mandatory. Patients in the LT+chemotherapy group received a median of 21 chemotherapy cycles, compared to 17 cycles in the chemotherapy-alone group. The 5-year overall survival (OS) was 56.6%, with 73.2% in the LT+chemotherapy group versus 9.3% in the chemotherapy-alone group. Among LT patients who experienced recurrence, secondary progression-free survival (PFS) was 35.4 months, and 5-year secondary PFS was 36.1%. The excellent outcomes of the TRANSMET trial were attributed to three key factors:

1. **Strict patient selection,** limiting prior chemotherapy to no more than three regimens.
2. **Independent validation committee** assessments to avoid emotionally driven decisions regarding LT eligibility.
3. **Timely transplantation**, ensuring patients reached LT within 2 months of enrollment.

In the study from Pittsburgh,[21] the inclusion criteria required that the primary CRC be resected with at least a 2 cm surgical margin, LT be considered at least 6 months after CRC diagnosis, patients receive 6–12 weeks of chemotherapy without disease progression, and serum CEA levels be <100 ng/dL. Between 2019 and 2022, 10 patients underwent LDLT. Among these patients, 50% had T3 stage primary CRC and 50% had lymph node involvement. Histologically, 90% of tumors were moderately differentiated. Molecular analysis revealed KRAS mutations in 2 patients, SMAD4 mutation in 1 patient, and PIK3CA mutation in 1 patient. The median interval between CRLM diagnosis and LT was 2.8 years. Each patient received an average of 10.5 cycles of chemotherapy. The selected LT patients had a mean Fong score of 2 and an Oslo score of 1.5. Four donors were altruistic. The median follow-up period was 1.6 years. The mean DFS was 2.2 years, and the mean OS was 3 years. During the study period, 3 patients developed recurrence. At 1.5 years, recurrence-free survival (RFS) was 62% and OS was 100%.

Currently, there is a growing body of research on LT for CRLM. Expanding international experience will be critical in optimizing recipient and donor selection for LT in patients with non-resectable CRLM. Advanced genomic analyses—including liquid biopsy, tissue profiling, and nuclear medicine approaches—will play a pivotal role in refining patient selection and improving outcomes. The landscape of LT for CRLM is far more promising today than it was two decades ago. Factors such as the Fong score, Oslo score, PET-based metabolic tumor volume and liver uptake values, tumor location (right- vs left-sided), histological differentiation, lymph node status of the primary tumor, and tumor-specific genetic mutations all significantly influence post-transplant outcomes. Thus, meticulous patient selection through a multidisciplinary and collaborative approach remains essential.

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