

selection, post-operative hemodynamic care, postoperative immunosuppressive therapy, and outpatient follow-up.

4. This training was completed at a hospital with a cardiothoracic surgery training program approved by the American Board of Thoracic Surgery, or its foreign equivalent, as accepted by the MPSC with a recommendation from the Thoracic Organ Transplantation Committee.
5. The following letters are submitted directly to the OPTN Contractor:
  - a. A letter from the director of the training program verifying that the surgeon has met the above requirements and is qualified to direct a heart transplant program.
  - b. A letter of recommendation from the training program's primary surgeon and transplant program director outlining the individual's overall qualifications to act as primary transplant surgeon, as well as the surgeon's personal integrity, honesty, and familiarity with and experience in adhering to OPTN obligations, and any other matters judged appropriate. The MPSC may request additional recommendation letters from the primary physician, primary surgeon, director, or others affiliated with any transplant program previously served by the surgeon, at its discretion.
  - c. A letter from the surgeon that details the training and experience the surgeon has gained in heart transplantation.

#### B. Twelve-month Heart Transplant Fellowship Pathway

Surgeons can meet the training requirements for primary heart transplant surgeon by completing a 12-month heart transplant fellowship if the following conditions are met:

1. The surgeon performed at least 20 heart or heart/lung transplants as primary surgeon or first assistant during the 12-month heart transplant fellowship. These transplants must be documented in a log that includes the date of transplant, the role of the surgeon in the procedure, and the medical record number or other unique identifier that can be verified by the OPTN Contractor. This log must be signed by the director of the training program.
2. The surgeon performed at least 10 heart or heart/lung procurements as primary surgeon or first assistant under the supervision of a qualified heart transplant surgeon during the 12-month heart transplant fellowship. These procedures must be documented in a log that includes the date of procurement, location of the donor, and Donor ID. This log must be signed by the director of the training program.
3. The surgeon has maintained a current working knowledge of all aspects of heart transplantation, defined as a direct involvement in heart transplant patient care within the last 2 years. This includes performing the transplant operation, donor selection, the use of mechanical circulatory assist devices,

- recipient selection, post-operative hemodynamic care, postoperative immunosuppressive therapy, and outpatient follow-up.
4. This training was completed at a hospital with a cardiothoracic surgery training program approved by the American Board of Thoracic Surgery, or its foreign equivalent, as accepted by the MPSC with a recommendation from the Thoracic Organ Transplantation Committee.
  5. The following letters are submitted directly to the OPTN Contractor:
    - a. A letter from the director of the training program verifying that the surgeon has met the above requirements and is qualified to direct a heart transplant program.
    - b. A letter of recommendation from the training program's primary surgeon and transplant program director outlining the individual's overall qualifications to act as primary transplant surgeon, as well as the surgeon's personal integrity, honesty, and familiarity with and experience in adhering to OPTN obligations, and any other matters judged appropriate. The MPSC may request additional recommendation letters from the primary physician, primary surgeon, director, or others affiliated with any transplant program previously served by the surgeon, at its discretion.
    - c. A letter from the surgeon that details the training and experience the surgeon has gained in heart transplantation.

### C. Clinical Experience Pathway

Surgeons can meet the requirements for primary heart transplant surgeon through clinical experience gained post-fellowship if the following conditions are met:

1. The surgeon has performed 20 or more heart or heart/lung transplants as primary surgeon or first assistant at a designated heart transplant program or its foreign equivalent. These transplants must have been completed over a 2 to 5-year period and include at least 15 of these procedures performed as the primary surgeon. These transplants must be documented in a log that includes the date of transplant, the role of the surgeon in the procedure, and medical record number or other unique identifier that can be verified by the OPTN Contractor. This log should be signed by the program director, division chief, or department chair from program where the experience was gained. Transplants performed during board qualifying surgical residency or fellowship do not count.
2. The surgeon has performed at least 10 heart or heart/lung procurements as primary surgeon or first assistant under the supervision of a qualified heart transplant surgeon. These procedures must be documented in a log that includes the date of procurement, location of the donor, and Donor ID.
3. The surgeon has maintained a current working knowledge of all aspects of heart transplantation, defined as a direct involvement in heart transplant

patient care within the last 2 years. This includes performing the transplant operation, donor selection, the use of mechanical assist devices, recipient selection, post-operative hemodynamic care, postoperative immunosuppressive therapy, and outpatient follow-up.

4. The following letters are submitted directly to the OPTN Contractor:
  - a. A letter from the director of the program where the surgeon acquired transplant experience verifying that the surgeon has met the above requirements and is qualified to direct a heart transplant program.
  - b. A letter of recommendation from the primary surgeon and transplant program director at the transplant program last served by the surgeon outlining the surgeon's overall qualifications to act as primary transplant surgeon, as well as the surgeon's personal integrity, honesty, and familiarity with and experience in adhering to OPTN obligations, and any other matters judged appropriate. The MPSC may request additional recommendation letters from the primary physician, primary surgeon, director, or others affiliated with any transplant program previously served by the surgeon, at its discretion.
  - c. A letter from the surgeon that details the training and experience the surgeon has gained in heart transplantation.

#### D. Alternative Pathway for Predominantly Pediatric Programs

If a surgeon does not meet the requirements for primary heart transplant surgeon through either the training or clinical experience pathways described above, hospitals that serve predominantly pediatric patients may petition the MPSC in writing to consider the surgeon for primary transplant surgeon if the program can demonstrate that the following conditions are met:

1. The surgeon's heart transplant training or experience is equivalent to the residency, fellowship, or clinical experience pathways as described in *Sections H.2.A through H.2.C* above.
2. The surgeon has maintained a current working knowledge of all aspects of heart transplantation and patient care, defined as direct involvement in heart transplant patient care within the last 2 years.
3. The surgeon submits a letter of recommendation from the primary surgeon and transplant program director at the training program or transplant program last served by the surgeon outlining the surgeon's overall qualifications to act as a primary transplant surgeon, as well as the surgeon's personal integrity, honesty, and familiarity with and experience in adhering to OPTN obligations, and any other matters judged appropriate. The MPSC may request additional recommendation letters from the primary physician, primary surgeon, director, or others affiliated with any transplant program previously served by the surgeon, at its discretion.
4. The hospital participates in an informal discussion with the MPSC.

The MPSC or an Ad Hoc Subcommittee of at least 4 MPSC members appointed by the MPSC Chair is authorized to conduct the informal discussion and make an interim determination. Interim determinations are:

- Advisory to the MPSC, Board of Directors, or both, who have the final authority to grant approval of a designated transplant program.
- Effective temporarily, pending final decision by the MPSC or Board.

Any application recommended for rejection by the MPSC or the Board of Directors may entitle the applicant to due process as specified in *Appendix L: Reviews, Actions, and Due Process* of these Bylaws.

### H.3 Primary Heart Transplant Physician Requirements

A designated heart transplant program must have a primary physician who meets *all* the following requirements:

1. The physician must have an M.D., D.O., or equivalent degree from another country, with a current license to practice medicine in the hospital's state or jurisdiction.
2. The physician must be accepted onto the hospital's medical staff, and be practicing on site at this hospital.
3. The physician must have documentation from the hospital credentialing committee that it has verified the physician's state license, board certification, training, and transplant continuing medical education and that the physician is currently a member in good standing of the hospital's medical staff.
4. The physician must have current certification in adult or pediatric cardiology by the American Board of Internal Medicine, the American Board of Pediatrics, or the foreign equivalent.

In addition, the primary transplant physician must have completed at least *one* of the training or experience pathways listed below:

- The 12-month transplant cardiology fellowship pathway, as described in *Section H.3.A. Twelve-month Transplant Cardiology Fellowship Pathway* below.
- The clinical experience pathway, as described in *Section H.3.B. Clinical Experience Pathway* below.

#### A. Twelve-month Transplant Cardiology Fellowship Pathway

Physicians can meet the training requirements for primary heart transplant physician during a 12-month transplant cardiology fellowship if the following conditions are met:

1. During the fellowship period, the physician was directly involved in the primary care of at least 20 newly transplanted heart or heart/lung recipients.

This training will have been under the direct supervision of a qualified heart transplant physician and in conjunction with a heart transplant surgeon. This care must be documented in a log that includes the date of transplant and the medical record number or other unique identifier that can be verified by the OPTN Contractor. This recipient log must be signed by the director of the training program or the primary transplant physician at the transplant program.

2. The physician has maintained a current working knowledge of heart transplantation, defined as direct involvement in heart transplant patient care within the last 2 years. This includes the care of acute and chronic heart failure, donor selection, the use of mechanical circulatory support devices, recipient selection, pre- and post-operative hemodynamic care, post-operative immunosuppressive therapy, histological interpretation and grading of myocardial biopsies for rejection, and long-term outpatient follow-up.
3. The physician should have observed at least 3 organ procurements and 3 heart transplants. The physician should also have observed the evaluation, the donation process, and management of 3 multiple organ donors who are donating a heart or heart/lungs. If the physician has completed these observations, they must be documented in a log that includes the date of procurement, location of the donor, and Donor ID.
4. This training was completed at a hospital with an American Board of Internal Medicine certified fellowship training program in adult cardiology or American Board of Pediatrics certified fellowship training program in pediatric cardiology or its foreign equivalent, as accepted by the MPSC.
5. The following letters are submitted directly to the OPTN Contractor:
  - a. A letter from the director of the training program and the supervising qualified heart transplant physician verifying that the physician has met the above requirements and is qualified to direct a heart transplant program.
  - b. A letter of recommendation from the training program's primary physician and transplant program director outlining the physician's overall qualifications to act as primary transplant physician, as well as the physician's personal integrity, honesty, and familiarity with and experience in adhering to OPTN obligations, and any other matters judged appropriate. The MPSC may request additional recommendation letters from the Primary Physician, primary surgeon, director, or others affiliated with any transplant program previously served by the physician, at its discretion.
  - c. A letter from the physician that details the training and experience the physician has gained in heart transplantation.

## B. Clinical Experience Pathway

A physician can meet the requirements for primary heart transplant physician through acquired clinical experience if the following conditions are met.

1. The physician has been directly involved in the primary care of 20 or more newly transplanted heart or heart/lung recipients and continued to follow these recipients for a minimum of 3 months from transplant. This patient care must have been provided over a 2 to 5-year period on an active heart transplant service as the primary heart transplant physician or under the direct supervision of a qualified heart transplant physician and in conjunction with a heart transplant surgeon at a heart transplant program or its foreign equivalent. This care must be documented in a log that includes the date of transplant and medical record number or other unique identifier that can be verified by the OPTN Contractor. This recipient log should be signed by the director or the primary transplant physician at the transplant program where the physician gained this experience.
2. The physician has maintained a current working knowledge of heart transplantation, defined as direct involvement in heart transplant patient care within the last 2 years. This includes the care of acute and chronic heart failure, donor selection, use of mechanical circulatory support devices, recipient selection, pre- and post-operative hemodynamic care, post-operative immunosuppressive therapy, histological interpretation and grading of myocardial biopsies for rejection, and long-term outpatient follow-up.
3. The physician should have observed at least 3 organ procurements and 3 heart transplants. The physician should also have observed the evaluation, the donation process, and management of 3 multiple organ donors who are donating a heart or heart/lungs. If the physician has completed these observations, they must be documented in a log that includes the date of procurement, location of the donor, and Donor ID.
4. The following letters are submitted directly to the OPTN Contractor:
  - a. A letter from the heart transplant physician or the heart transplant surgeon who has been directly involved with the physician at the transplant program verifying the physician's competence.
  - b. A letter of recommendation from the primary physician and transplant program director at the transplant program last served by the physician outlining the physician's overall qualifications to act as primary transplant physician, as well as the physician's personal integrity, honesty, and familiarity with and experience in adhering to OPTN obligations, and any other matters judged appropriate. The MPSC may request additional recommendation letters from the primary physician, primary surgeon, director, or others affiliated with any transplant program previously served by the physician, at its discretion.
  - c. A letter from the physician that details the training and experience the physician has gained in heart transplantation.

**C. Alternative Pathway for Predominantly Pediatric Programs**

If a physician does not meet the requirements for primary physician through any of the transplant fellowship or clinical experience pathways as described above, hospitals that serve predominantly pediatric patients may petition the MPSC in writing to consider the physician for primary transplant physician if the program can demonstrate that the following conditions are met:

1. That the physician's heart transplant training or experience is equivalent to the fellowship or clinical experience pathways as described in *Sections H.3.A* and *H.3.B* above.
2. The physician has maintained a current working knowledge of all aspects of heart transplantation, defined as direct involvement in heart transplant patient care within the last 2 years.
3. The physician submits a letter of recommendation from the primary physician and transplant program director of the fellowship training program or transplant program last served by the physician outlining the physician's overall qualifications to act as a primary transplant physician, as well as the physician's personal integrity, honesty, and familiarity with and experience in adhering to OPTN Obligations and compliance protocols, and any other matters judged appropriate. The MPSC may request additional recommendation letters from the primary physician, primary surgeon, director, or others affiliated with any transplant program previously served by the physician, at its discretion.
4. The hospital participates in an informal discussion with the MPSC.

The MPSC or an Ad Hoc Subcommittee of at least 4 MPSC members appointed by the MPSC Chair is authorized to conduct the informal discussion and make an interim determination. Interim decisions are:

- Advisory to the MPSC, Board of Directors, or both, which has the final authority to grant approval of a designated transplant program.
- Effective temporarily, pending final decision by the MPSC or Board.

Any application recommended for rejection by the MPSC or the Board of Directors may entitle the applicant to due process as specified in *Appendix L: Reviews, Actions, and Due Process* of these Bylaws.

**D. Conditional Approval for Primary Transplant Physician**

If the primary heart transplant physician changes at an approved heart transplant program, a physician can serve as the primary heart transplant physician for a maximum of 12 months if the following conditions are met:

1. The physician has current board certification in cardiology by the American Board of Internal Medicine, the American Board of Pediatrics, or the foreign equivalent.
2. The physician has 12 months experience on an active heart transplant service as the primary heart transplant physician or under the direct supervision of a qualified heart transplant physician and in conjunction with a heart transplant surgeon at a designated heart transplant program. These 12 months of experience must be acquired within a 2-year period.
3. The physician has maintained a current working knowledge of heart transplantation, defined as direct involvement in heart transplant patient care within the last 2 years. This includes knowledge of acute and chronic heart failure, donor selection, the use of mechanical circulatory support devices, recipient selection, pre- and post-operative hemodynamic care, post-operative immunosuppressive therapy, histological interpretation in grading of myocardial biopsies for rejection, and long-term outpatient follow-up.
4. The physician has been involved in the primary care of 10 or more newly transplanted heart or heart/lung transplant recipients as the heart transplant physician or under the direct supervision of a qualified heart transplant physician or in conjunction with a heart transplant surgeon. The physician will have followed these patients for a minimum of 3 months from the time of transplant. This care must be documented in a log that includes the date of transplant and medical record or other unique identifier that can be verified by the OPTN Contractor. This recipient log should be signed by the program director or the primary transplant physician at the transplant program where the physician gained experience.
5. The physician should have observed at least 3 organ procurements and 3 heart transplants. The physician should also have observed the evaluation, the donation process, and management of at least 3 multiple organ donors who donated a heart or heart/lungs. If the physician has completed these observations, they must be documented in a log that includes the date of procurement, location of the donor, and Donor ID.
6. The program has established and documented a consulting relationship with counterparts at another heart transplant program.
7. The transplant program submits activity reports to the OPTN Contractor every 2 months describing the transplant activity, transplant outcomes, physician recruitment efforts, and other operating conditions as required by the MPSC to demonstrate the ongoing quality and efficient patient care at the program. The activity reports must also demonstrate that the physician is making sufficient progress to meet the required involvement in the primary care of 20 or more heart transplant recipients, or that the program is making sufficient progress in recruiting a physician who meets all requirements for primary heart transplant physician by the end of the 12 month conditional approval period.
8. The following letters are submitted directly to the OPTN Contractor:



- a. A letter from the heart transplant physician or the heart transplant surgeon who has been directly involved with the physician at the transplant program verifying the physician's competence.
- b. A letter of recommendation from the primary physician and director at the transplant program last served by the physician outlining the physician's overall qualifications to act as primary transplant physician, as well as the physician's personal integrity, honesty, and familiarity with and experience in adhering to OPTN obligations, and any other matters judged appropriate. The MPSC may request additional recommendation letters from the primary physician, primary surgeon, director, or others affiliated with any transplant program previously served by the physician, at its discretion.
- c. A letter from the physician that details the training and experience the physician has gained in heart transplantation.

The 12-month conditional approval period begins on the first approval date granted to the personnel change application, whether it is an interim approval granted by the MPSC subcommittee, or an approval granted by the full MPSC. The conditional approval period ends exactly 12 months after this first approval date of the personnel change application.

If the program is unable to demonstrate that it has an individual on site who can meet the requirements as described in *Sections H.3.A through H.3.C* above at the end of the 12-month conditional approval period, it must inactivate. The requirements for program inactivation are described in *Appendix K: Transplant Program Inactivity, Withdrawal, and Termination* of these Bylaws.

The MPSC may consider on a case-by-case basis and grant a 6-month extension to a transplant program that provides substantial evidence of progress toward fulfilling the requirements but is unable to complete the requirements within one year.

## 資料 小児心臓移植の適応判定ガイドンス

## 日本小児循環器学会 臓器移植委員会

日本循環器学会では、主に成人を中心とした心臓移植の適応基準が定められているが、小児では成人より病期の進行が早い場合があることと、成人で必須とされている検査(例えば、心筋生検、運動耐容能検査など)が実施しにくいこと、 $\beta$ 遮断薬・ACE阻害薬の効果についても未だ議論のあること、小児特有の疾患があること(先天性心疾患等)などから、成人とは違った観点から心臓移植の適応を判定する必要がある。

ここでは、日本小児循環器学会移植委員会として、小児期心疾患の心臓移植適応を判定するためのガイドンスを示す。

## I. 小児の心不全の grading

NYHA 機能分類を新生児・乳幼児に当てはめるのは困難である。従って、NYHA 機能分類で判定できない年齢では、哺乳力低下、体重増加不良、発育障害、易感染性(特に繰り返す呼吸器感染)、多呼吸・努力性呼吸なども心不全の grading として考慮する。

## II. 疾患毎の判定ガイドンス

## 1) 拡張型心筋症・拡張相の肥大型心筋症

$\beta$ 遮断薬、ACE阻害薬の有効性にはまだ議論があり、必ずしもこれらの薬剤の使用効果を必須の条件としなくて良い(重症心不全の小児例の予後は不良であり、薬剤の効果を判定する間に病期が進行し、心臓移植の時期を逸し、救命できない例が多いため)。薬剤治療に反応しない心不全症状を認めれば適応と考えられるが、文献から、十分な内科的治療を行った上で、以下の所見を認める拡張型心筋症は予後不良であり、心臓移植の適応と考えられる。

- I LVEDP  $>$  25 mmHg<sup>1,2)</sup>
- II LVEF  $<$  30 %<sup>1,3)</sup>
- III 治療抵抗性の致死性心室性不整脈<sup>1)</sup>
- IV Near-death experience<sup>1)</sup>
- V 2才以降の onset<sup>1,4)</sup>(尚、治療しても改善傾向のない2才未満の症例も適応と考える)
- VI カテコラミンの使用<sup>1)</sup>

尚、薬剤性等の二次性拡張型心筋症もこの基準に準ずる。

## 2) 拘束型心筋症

小児期の本疾患は予後不良なことが多く、心臓移植の適応となる場合がある。文献上、低年齢で発症した症例、心室収縮力が保たれていても小さな心室に比べて心房の大きな症例は予後が悪い。内科的治療を十分行っても以下の所見を認める拘束型心筋症は予後不良であり、心臓移植の適応と考えられる。

- I 肺鬱血の所見(胸部レントゲン所見(Kerley B lines など)、PCWP>18mmHg) <sup>5)</sup>
- II NYHA 機能分類 3 度以上 <sup>5)</sup>
- III 心房拡大(LA/ Ao > 1.5)、心胸郭比>55 % <sup>5,6)</sup>
- IV 肝鬱血の所見〔肝腫大、腹水、肝静脈の怒張、時に蛋白漏出性胃腸症(PLE)〕<sup>5)</sup>
- V 低年齢(特に2才以前)の onset<sup>5,6)</sup>

原疾患が進行すると、肺鬱血のために高肺血管抵抗になったり、肝鬱血のために鬱血性肝硬変になったりする場合があるので、十分にこれらの評価を行うことが重要である。高肺血管抵抗の場合には心肺移植の適応となる。後述するが、肺血管抵抗の可逆性を見るのに、酸素負荷、一酸化窒素負荷は有用である<sup>7)</sup>。

## 3) 左室低形成症候群(HLHS)<sup>8)</sup>

欧米では新生児期・乳児期の心臓移植の適応の大半を占める疾患であるが、欧米でもドナー不足が著しいこと、Norwood から Fontan に至る治療成績が向上したことから、近年 HLHS に対する心臓移植は激減している。このような中で明らかに心臓移植の適応となるのは、以下のような条件に当てはまる場合である。

- I 高度三尖弁閉鎖不全
- II 低右室駆出率(RVEF < 30%)
- III 冠不全(高度大動脈低形成等)
- IV 総肺静脈還流異常合併(但し肺静脈そのものの狭窄なし)<sup>9)</sup>
- V 心房中隔欠損が極めて小さくバルーンなどで拡大できない場合

failed Norwood 症例も、全身状態が心臓移植の禁忌とならない場合には心臓移植の適応と

考えられる。

#### 4) 単心室型先天性心疾患

単心室型先天性心疾患は、小児期～思春期の心臓移植の適応となる先天性心疾患の代表である。Fontan 型手術以前に心臓移植の適応となるものと、Fontan 型手術以降に心臓移植の適応となるものに分けられる。

##### a) Fontan 型手術前<sup>10-13)</sup>

Fontan 手術に耐術できない以下の条件を持った単心室症例で、高肺血管抵抗、肺動脈・肺静脈低形成等の心臓移植の禁忌を伴っていない場合には適応と考えられる。

- I 軽度肺血管抵抗上昇 (PVRI  $< 9 \text{ W.U.} \cdot \text{m}^2$ )
- II 低体心室駆出率 (SVEF  $< 30\%$ )
- III 高度房室弁逆流
- IV カテコラミンの持続投与が必要な場合
- V 治療抵抗性の致死的不整脈

高肺血管抵抗 (PVRI  $9 \text{ W.U.} \cdot \text{m}^2$  以上)、肺動脈・肺静脈低形成等を伴っている場合には、心臓移植の適応ではなく、心肺移植の適応と考えられる。

##### b) Fontan 型手術後

Fontan 型手術後、急性期から遠隔期にかけて、薬剤、ablation、外科的治療で治療できない、以下のような条件に当てはまる場合には適応と考えられる。

- I 治療抵抗性の心不全 (特にカテコラミン持続点滴を要する場合)
- II 高度房室弁逆流
- III コントロールできない PLE<sup>12)</sup>
- IV チアノーゼの著明な肺動静脈瘻<sup>13)</sup>
- V 高度左室流出路狭窄 (外科的修復のできないもの)
- VI 薬剤・ablation・外科治療 (TCPC conversion, Maze 手術など) に耐性の致死的不整脈

多くの場合、肺血管抵抗は低く心臓移植の良い適応となるが、病期が進みすぎて肝硬変などの合併症をきたした場合は適応とならない。

## 5) その他の先天性心疾患

症例毎に検討される内容が変わってくるので、ここでは疾患名のみをあげる。

## I 重症 Ebstein 奇形

Starnes 手術、三尖弁形成等の外科治療を行っても心不全の改善しない症例、等

II 冠動脈異常を伴う純型肺動脈閉鎖<sup>14)</sup>

冠動脈瘻異常があつて、肺動脈弁切開などの右室流出路形成等の右室除圧手術が適応とならない症例、等

## III その他

大血管転換手術、Bland-White-Garland 症候群術後などの術後に、治療抵抗性の重症心不全に陥った場合、等(適応基準は、拡張型心筋症に準じる)

## 6) 心臓腫瘍

横紋筋腫、線維腫などが心臓に広範囲又は多発性にあり、心臓を摘出しない限り根治性がないと考えられ、心臓以外に腫瘍がない場合に適応と考えられる。

## 7) 川崎病

虚血性心筋症に陥り、薬剤治療、冠動脈バイパス術、経皮的冠動脈形成術(PCI)を行なっても重症心不全が治癒できない場合、又は治療抵抗性の致死的不整脈を認める場合<sup>15)</sup>

## III. 適応除外条件

下記の条件を満たす場合には心臓移植の適応とならない。

1 高度の肝腎機能障害

2 高度精神神経障害

精神発達遅延が強く家族の協力があつても、薬剤投与が困難な場合を含む

3 全身性感染症

4 高肺血管抵抗(PVRI > 9 W.U.・m<sup>2</sup>)

高肺血管抵抗は心臓移植手術に耐術しないため、心肺移植の適応となる。

小児例では循環血液量が少ないので、成人のように PVR ではなく、体格を考慮して PVRI で肺血管抵抗を検討する。

高肺血管抵抗の診断基準は未だ議論のあるところであるが、酸素吸入(100%)、一酸化窒素吸入(最大 40~80ppm)などを行い PVRI が 9W.U.・m<sup>2</sup> 以

下又は Transpulmonary gradient が 15 mmHg 以下となった場合には、肺血管抵抗は可逆的であると考え、心臓移植の適応としている施設が多い<sup>7)</sup>。

#### 5 高度肺動脈低形成・肺静脈狭窄

高肺血管抵抗とも関係してくるが、肺血管の異常例は心肺移植の適応となる。心臓移植時に修復可能な肺動脈狭窄、総肺静脈還流異常・部分肺静脈還流異常は心臓移植の適応となる。

尚、これまでの海外の経験から、無脾症、多脾症<sup>16)</sup>は、移植後の予後に差がないため、適応とされている。

#### IV. 心臓移植の適応を判断する上で慎重を要する条件

以下のような症例では、心臓移植の適応を慎重に判定することが望ましい。

- 1 高度な側副血行路を認めるもの
- 2 肺静脈狭窄・肺動脈狭窄を認めるもの
- 3 複数の手術歴のあるもの
- 4 高度の肺動静脈瘻・蛋白漏出性胃腸症を伴うもの
- 5 医師が不適応と判断したもの

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☆ 心臓移植レシピエント・カバーシート ☆  
 小児(11歳未満)/先天性心疾患

患者氏名(イニシャル)

年齢  歳  カ月

性別  男  女

事務局使用  
 受付年月日   
 患者登録番号

チェックシート

- レシピエントカバーシート
- レシピエントデータシート
- 追跡予後調査に関する同意書
- 施設内検討会報告書
- 各種専門医意見書・証明書
- その他...

各種シートは  
<http://plaza.umin.ac.jp/%7Ehearttp/>  
 よりダウンロード可能

カバーレター (簡潔にお書きください)

日本循環器学会心臓移植委員会  
 適応検討小委員会 御中

主治医

施設名



# ☆ 心臓移植レシピエント・データシート 小児・先天性 ☆

患者氏名(イニシャル)   
 申請年月日   
 生年月日   
 年齢  歳  カ月  
 性別  男  女

**事務局使用**  
 受付年月日   
 患者登録番号   
 主治医   
 施設名   
 診療部科   
 電話   
 FAX   
 e-mail

心臓移植予定施設

二次性心筋症・先天性心疾患・その他場合の病名

心臓原疾患

血液型  A  B  O  AB    RH  (+)  (-)    Panel Reactive Activity  %

体重  Kg    身長  cm    体表面積  (自動計算)    BMI  (自動計算)

胸部手術歴  有  無    補助循環  有  無    NYHA分類  I  II  III  IV

最新の心臓カテーテル検査値    検査日

体心室EF(駆出率)  %    mPA(平均肺動脈圧)  mmHg(心カテデータ引用)

CO(心拍出量)  L/min    PAW(肺動脈楔入圧)  mmHg(心カテデータ引用)

CI(心係数)  L/min/m<sup>2</sup> (自動計算)    Qp/Qs(肺体血流比)

PVRI(肺血管抵抗指数) Qp/Qs=1の時  Wood・m<sup>2</sup>(自動計算)

Qp/Qsが1以外の時  Wood・m<sup>2</sup>    PVRIの計算根拠

PeakVO<sub>2</sub>  ml/kg/min    又は 6分間歩行  m    心不全入院歴  回(現在入院も回数に含める)

MRSA(メチシリン耐性黄色ブドウ球菌)  (+)  (-)    MDRP(多剤耐性緑膿菌)  (+)  (-)

移植のインフォームド  
 コンセント(家族)  済  未

本人の移植のインフォームドアセント(小児)  
 インフォームドコンセント(成人)  済  未

施設内適応検討会での検討  済  未

追跡調査のインフォームドコンセント  済  未

現病状 Status分類

- 1 補助人工心臓、IABP、または強心薬(カテコラミン、PDE-III)静注 使用中
- 2 上記以外で除外項目のないもの
- 3 除外項目のあるもの

除外項目とは、下記に示すような、活動性感染症、体外循環禁忌と考えられる脳血管障害、4週間以内の肺梗塞等、一時的に心臓移植の禁忌項目となる項目をさす

脳血管障害  有  無    活動性感染症  有  無    肺梗塞(4週間以内)  有  無

慢性肺疾患  有  無    活動性消化性潰瘍  有  無    全身性疾患  有  無

精神神経学的疾患  有  無    糖尿病  I型  II型  IGT  無

末梢血管障害  有  無    肝機能障害  有  無    腎機能障害  有  無

高血圧  有  無    高脂血症  有  無    肥満(BMI>25)  有  無

染色体異常  有  無  不明    遺伝子異常  有  無  不明

先天性代謝異常  有  無  不明    筋ジストロフィ等  有  無  不明

患者氏名(イニシャル)

性別 男 女

年齢  歳  ヶ月

施設名

心臓原疾患

二次性心筋症・先天性心疾患・その他場合の病名

心臓の概略図添付(先天性心疾患の場合、必須) 有 無

現病歴 必ず発症年(推定)、初診年月日、入院年月日を加え、申請直前までの臨床経過を詳しく記載すること。わかりやすく経時的に記載し、必要ならば検査データなども付け加えること。

既往歴

手術歴 有 無

心臓手術術式名

心臓手術日

心臓手術歴 有 無

一回目  
二回目  
三回目  
四回目

有の場合 →

ペースメーカー、CRT、ICD、CRT-D植込歴

無 PM CRT ICD CRT-D

飲酒歴 有 無

有の場合 →

飲酒量  g/日 (アルコール換算表参照)

飲酒年数  年 禁酒年月日

喫煙歴 有 無

有の場合 →

本/日 × 年

喫煙指数(プリンクマン指数)  (自動計算)

禁煙年月日

輸血歴 有 無

妊娠歴 有 無

血族結婚 有 無

家族歴 有 無

→ 有の場合

心疾患 突然死 悪性腫瘍 その他...

染色体異常 有 無 不明

→ 有の場合

染色体検査結果

遺伝子異常 有 無 不明

→ 有の場合

遺伝子検査結果

先天性代謝異常 有 無 不明

→ 有の場合

先天性代謝異常疾患名

筋ジストロフィ等 有 無 不明

→ 有の場合

筋ジストロフィ等疾患名

家族構成

家族サポート

(具体的に記載)

キーパーソン

待機中の経済的・精神的サポート

臨床症状

NYHA分類 I II III IV コメント(  )

NYHA IV度の既往 有 無 咳痰 有 無 動悸 有 無

労作時息切れ・呼吸困難 有 無 発作性夜間呼吸困難 有 無 起坐呼吸 有 無

体重増加不良 有 無 哺乳力低下(乳幼児の場合) 有 無 易感染性 有 無

胸部圧迫感・胸痛 有 無 易疲労感 有 無 失神発作 有 無

遺伝疾患等による症状 有 無

有の場合 → 精神発達遅滞 呼吸筋力低下 運動筋力低下 肝腎機能障害

具体的な症状

身体所見

血圧  /  mmHg 脈拍数  /分 SpO2(動脈血酸素飽和度)  (%)  
(room air)

心音 所見  ラ音 有 無

肝腫大 有 無 腹水 有 無 浮腫 有 無

検査所見

1) 胸部X線 胸部X線写真添付 有 無

胸部X線施行日

GTR % 肺うっ血 有 無 胸水 有 無

2) 心電図 心電図添付 有 無

心電図施行日

心電図所見

3) ホルター心電図 ホルター心電図レポートサマリー添付 有 無

ホルター心電図施行日

ホルター心電図所見

心室頻拍 持続性 非持続性 無

4) 心エコー 添付 無 Mモード 2D ドプラ 動画 その他...

自動計算 左からより最近のデータを並べてください

年月日			
体心室側心房径(mm)			
大動脈径(mm)			
心室中隔厚(mm)			
体心室後壁厚(mm)			
体心室拡張末期径(mm)			
体心室収縮末期径(mm)			
体心室内径短絡率(FS) (%)			
体心室拡張末期容積(mL)			
体心室収縮末期容積(mL)			
体心室駆出率(EF) (%)			
体心室房室弁閉鎖不全			
肺心室側房室弁閉鎖不全			
大動脈弁閉鎖不全			
体心室壁運動 /その他			
血栓	<input type="radio"/> 有 <input type="radio"/> 無	<input type="radio"/> 有 <input type="radio"/> 無	<input type="radio"/> 有 <input type="radio"/> 無
減速時間(DT, msec)			
E/A			

心エコー所見  
(先天性心疾患の場合)