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# Feasibility Study of a Novel Negative-Pressure Renal Assist Device (RAD) After Cardiac Surgery

Evelio Rodriguez, MD, FACS, FACC[1], Milovan Petrovic, MD[2]; Slobodan Micovic[3]; Robert Sladen, MBChB, FCCM[4]
[1]Ascension Saint Thomas Heart, [2]Institute of Cardiovascular Diseases of Vojvodina, [3]Medical School University of Belgrade, [4]Columbia University,

## INTRODUCTION

Patients undergoing cardiac surgery, including coronary artery bypass graft (CABG), valvular surgery, or combination therein, are at a significant risk of suffering renal dysfunction postoperatively. In fact, some studies have reported a 50% or higher incidence rate for AKI in renal impaired patients undergoing cardiac surgeries, which leads to longer hospital stays, higher costs, and significant morbidity/mortality. The rate of infections is 2.5 times higher and mortality risk is 3-4 times higher in patients who develop post cardiac surgery AKI.

## PURPOSE

Acute kidney injury (AKI) is common after cardiac surgery and associated with increased postoperative morbidity, mortality, and prolonged hospitalizations. The purpose of this study is to determine the safety and feasibility of a renal assist device (RAD) in augmenting renal function immediately following cardiac surgery in patients with renal impairment. The ability of the RAD to sustain or enhance renal function in the postoperative period was also evaluated.

## METHODS

**Study Population:** Patients with impaired renal function (eGFR 15 to 60 mL/min/1.73m$^2$) undergoing elective cardiac surgery were enrolled at three sites.

**Procedure:** Specialized ureteral catheters were endoscopically advanced into bilateral renal pelvises by a urologist at the completion of the cardiac operation. Negative pressure treatment (-15mmHg) was initiated in the ICU and continued for 24 hours postoperatively. Seven (7) subjects were treated bilaterally according to protocol without any major protocol deviations. Three (3) subjects were treated unilaterally in deviation to the protocol.

**Assessments:** Blood and urine samples were collected to assess kidney function (serum creatinine and eGFR) at baseline, during RAD treatment, and at postoperative days (POD) 2, 3, 14 and 28. AKI was defined based on KDIGO criteria. Baseline demographics, outcomes and complications were recorded.

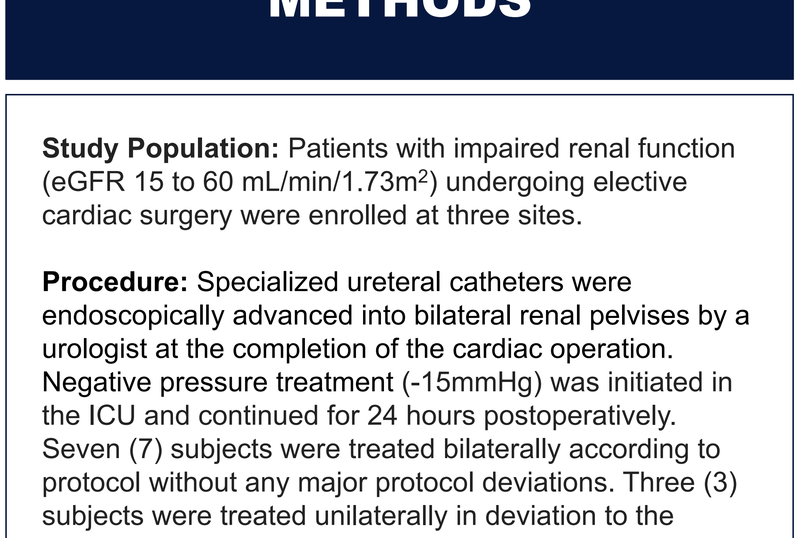


**Figure 1.** Study design.

## RESULTS

| Parameter | Characteristic | All Treated Patients n=10 | Bilaterally Treated Patients n = 7 |
|---|---|---|---|
| **Sex** | Male | 5 (50.0 %) | 3 (42.9 %) |
| | Female | 5 (50.0 %) | 4 (57.1 %) |
| **Race** | White | 10 (100.0 %) | 7 (100.0 %) |
| **Ethnicity** | Not Hispanic | 10 (100.0 %) | 7 (100.0 %) |
| **Age [years]** | Mean (SD) | 71.2 (6.2) | 71.6 (5.3) |
| | Median | 69.5 | 70 |
| | Q1, Q3 | 66, 74 | 68, 74 |
| | Min, Max | 64, 81 | 65, 81 |
| **Height [cm]** | Mean (SD) | 166.5 (10.05) | 163.57 (6.53) |
| | Median | 166.5 | 166 |
| | Q1, Q3 | 156, 173 | 156, 167 |
| | Min, Max | 155, 183 | 155, 173 |
| **Weight [kg]** | Mean (SD) | 78.9 (11.04) | 76.57 (10.44) |
| | Median | 81.5 | 80 |
| | Q1, Q3 | 71, 86 | 67, 84 |
| | Min, Max | 58, 96 | 58, 87 |
| **Diabetes** | Percent | 60% | 42.9% |
| **CKD** | Percent | 100% | 100% |

**Table 1.** Subject demographics.

| Parameter | Characteristic | All Treated Patients n=10 | Bilaterally Treated Patients n = 7 |
|---|---|---|---|
| **Ejection Fraction [%]** | Mean (SD) | 49.2 (12.29) | 48.71 (9.32) |
| | Median | 50 | 49 |
| | Q1, Q3 | 40, 55 | 40, 55 |
| | Min, Max | 28, 68 | 40, 65 |
| **Central Venous Pressure [mmHg]** | Mean (SD) | 7.1 (2.88) | 7.0 (3.06) |
| | Median | 6.5 | 6 |
| | Q1, Q3 | 5, 10 | 5, 10 |
| | Min, Max | 3, 12 | 3, 12 |
| **eGFR [mL/min/1.73m$^2$]** | Mean (SD) | 46.5 (8.58) | 49.57 (8.48) |
| | Median | 46 | 52 |
| | Q1, Q3 | 38, 53 | 39, 57 |
| | Min, Max | 37, 59 | 37, 59 |
| **Creatinine [µmol/L]** | Mean (SD) | 130.7 (36.35) | 127.26 (42.9) |
| | Median | 117.9 | 105 |
| | Q1, Q3 | 103, 150 | 102, 150 |
| | Min, Max | 99, 216 | 99, 216 |
| **Urine Sodium [mmol/L]** | Mean (SD) | 98.2 (27.27) | 106.86 (28.45) |
| | Median | 92 | 120 |
| | Q1, Q3 | 77, 122 | 77, 127 |
| | Min, Max | 62, 140 | 62, 140 |
| **24hr Urine Output [mL]*** | Mean (SD) | 4290.03 (2620.19) | 4264.14 (3020.43) |
| | Median | 3267.85 | 2880 |
| | Q1, Q3 | 2787.1, 5289.8 | 2764.8, 5289.8 |
| | Min, Max | 1954.3, 10697.1 | 1954.3, 10697.1 |

*Intraoperative total urine output extrapolated to 24 hours

**Table 2.** Subject baseline characteristics.

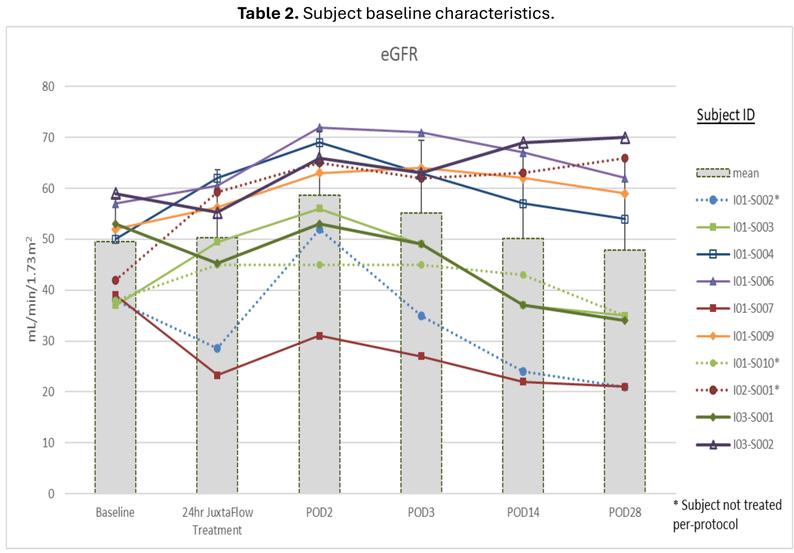


**Figure 2.** eGFR

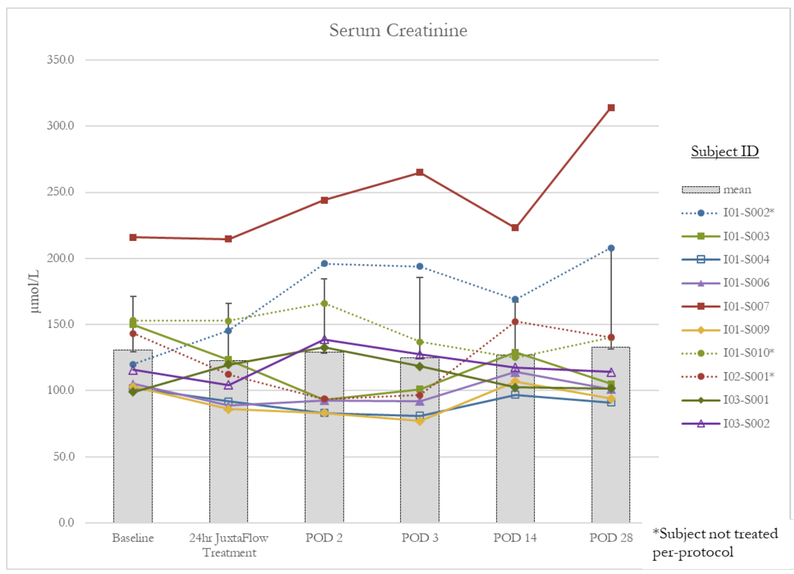


**Figure 3.** Serum Creatinine

| Parameter | Characteristic | All Treated Patients n=10 | Bilaterally Treated Patients n = 7 |
|---|---|---|---|
| **Surgical Type** | CABG | 6 (60.0 %) | 5 (71.4%) |
| | CABG + Valve | 3 (30.0 %) | 1 (10.0%) |
| | Valve only | 1 (10.0 %) | 1 (10.0%) |
| **Time on CPB [min]** | Mean (SD) | 75.1 (36.4) | 60.6 (33.2) |
| **Total cardiac surgery time [min]** | Mean (SD) | 174.7 (40.2) | 160.7 (40.3) |
| **End of surgery to treatment start [min]** | Mean (SD) | 103.5 (29.7) | 93.3 (25.3) |
| **Total JF procedure [min]** | Mean (SD) | 34.9 (14.5) | 29.6 (14.2) |
| **Treatment duration [min]** | Mean (SD) | 1439.8 (12.6) | 1444.4 (5.7) |

**Table 3.** Surgery and JuxtaFlow treatment.

## RESULTS Cont.

| Parameter | Characteristic | All Treated Patients n=10 | Bilaterally Treated Patients n = 7 |
|---|---|---|---|
| **Duration of hospitalization [days]*** | n | 10 | 7 |
| | Mean (SD) | 12.3 (5.4) | 9.9 (2.0) |
| | Median | 11 | 10 |
| | Q1, Q3 | 8, 13 | 8, 11 |
| | Min, Max | 8, 26 | 8, 13 |
| **Duration of critical care [days]*** | n | 10 | 7 |
| | Mean (SD) | 3.9 (1.3) | 3.1 (0.4) |
| | Median | 3 | 3 |
| | Q1, Q3 | 3, 5 | 3, 3 |
| | Min, Max | 3, 6 | 3, 4 |
| **Surgical length of stay [days]**** | n | 10 | 7 |
| | Mean (SD) | 10.1 (5.4) | 8 (1.4) |
| | Median | 8.5 | 8 |
| | Q1, Q3 | 7, 10 | 7, 9 |
| | Min, Max | 6, 24 | 6, 10 |

*Duration = date of discharge – date of admission + 1 day
**Surgical length of stay = date of hospital discharge – surgery date + 1 day

**Table 4.** Subject length of stay (LOS).

| | | All Treated Patients n=10 | | Bilaterally Treated Patients n = 7 | |
|---|---|---|---|---|---|
| **System Organ Class** | Preferred Term | No. of Episodes | No. of Patients (n (%)) | No. of Episodes | No. of Patients (n (%)) |
| **- Overall -** | | 16 | 10 (100%) | 11 | 7 (100%) |
| **Non-urinary tract infections and infestations** | | 2 | 2 (20%) | 1 | 1 (14.3%) |
| | Infection | 2 | 2 (20%) | 1 | 1 (14.3%) |
| **Investigations** | | 2 | 2 (20%) | 2 | 2 (28.6%) |
| | C-reactive protein increased | 2 | 2 (20%) | 2 | 2 (28.6%) |
| **Renal and urinary disorders** | | 12 | 10 (100%) | 8 | 7 (100%) |
| | Microhematuria | 10 | 10 (100%) | 7 | 7 (100%) |
| | Renal impairment | 2 | 2 (100%) | 1 | 1 (14.3%) |

**Table 5.** Adverse events (AEs) related to study procedures. Renal impairment incidences were reported as AKI events as defined by KDIGO criteria.

- There were no mortalities, strokes, returns to the OR or readmissions within 28 days. There were no incidences of gross hematuria.
- 9 out of 10 patients had an improvement in eGFR at POD2.
- Only 2 of the 10 RAD treated subjects experienced a postoperative AKI. Of note, 1 of these subjects was treated unilaterally in deviation to the clinical protocol.
- There was 1 SAE involving improper deployment of the right catheter in the mid-ureter causing urinary obstruction. Patient was treated unilaterally in deviation to the protocol, withdrawn and experienced postoperative worsening of CKD.

## CONCLUSIONS

This feasibility study demonstrates that treatment with a RAD for the initial 24 hours after cardiac surgery in patients with renal impairment appears safe and is associated with preserved renal function up to 28 days after surgery.

This positive effect was most apparent in the seven patients who received successful bilateral RAD therapy.

**A prospective randomized study is necessary to further investigate the efficacy of negative-pressure RAD treatment in sustaining or enhancing renal function, and to examine the potential benefit of RAD treatment initiated prior to CPB.**

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## DISCLOSURES

1. Edwards Lifesciences, 3ive Labs, Abbott, Boston Scientific, Atricure, Egnite
2. none
3. Corcym, Medtronic
4. 3ive Labs

The Society of Thoracic Surgeons

**CONTACT**
Evelio Rodriguez, MD
Ascension Saint Thomas West Hospital Nashville, TN
Email: evelio.rodriguez@ascension.org
Phone: (615) 222-5592