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## Complex aortic aneurysm management: from technical outcomes to patient-centered insights

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# Functional performance in patients with a complex endovascular aneurysm: results of a single-center retrospective cohort study

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# Performance after Complex Endovascular Aortic Repair: A Single-Center Retrospective Cohort Study

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## ABSTRACT

### Background

Complex endovascular aortic repair (EVAR) procedures provide a treatment option for patients with aortic aneurysms involving visceral branches. Good technical results and short-term outcomes have been reported. Whether complex EVAR provides acceptable functional outcomes is not clear. The current study aims to describe postoperative functional outcomes in complex EVAR patients; an older and relatively frail patient group.

### Methods

A single-center retrospective cohort study was performed, using data from a computerized database of consecutive patients who underwent complex EVAR in the Leiden University Medical Center (LUMC, The Netherlands) between July 2013 and September 2020. As of May 2017, patients scheduled for complex EVAR were referred to a geriatric care pathway to determine (Instrumental) Activities of Daily Living ((I) ADL) scores at baseline and, if informed consent was given, after 12 months. For the total patient group, adverse functional performance outcomes were: discharge to a nursing home and 12-month mortality. For the patients included in geriatric follow-up, the additional outcome was functional decline (defined by a  $\geq 2$  point increase in (I) ADL-score) at 12-months.

### Results

Eighty-two patients underwent complex EVAR, of which 68 (82.9%) were male. Mean age was 73.3 years (SD=6.3). Within 30 days postsurgery, 6 patients (7.3%) died. Mortality within 12 months for the total patient group was 14.6% (n=12). After surgery, no patients had to be discharged to a nursing home. Fifteen patients (18.3%) were discharged to a rehabilitation center. Twenty-three patients gave informed consent and were included in geriatric follow-up. Five patients (21.7%) presented functional decline 12 months postsurgery and 4 patients had died (17.4%) by that time. This means that 39.1% of the patients in the care pathway suffered an adverse outcome.

### Conclusion

To our knowledge, this is the only study that examined functional performance after complex EVAR, using a prospectively maintained database. No patients were newly discharged to a nursing home and functional performance results at 12 months were promising. Future multidisciplinary research could focus on determining which patients are most susceptible to functional decline, to facilitate preventative efforts and aid in patient selection.

## INTRODUCTION

Endovascular aortic repair (EVAR) is well established in clinical practice for treating abdominal aortic aneurysms (AAA) located below the visceral arteries.<sup>1,2</sup> Because of low immediate morbidity and mortality rates compared to open surgical repair (OSR), EVAR is often the procedure of choice.<sup>3,4</sup> In recent years, endovascular techniques for aortic repair have developed extensively. Fenestrated EVAR (FEVAR) and branched EVAR (BEVAR) allow for endovascular treatment of complex aortic aneurysms, comprising segments of the entire aortoiliac tract, including the arch.<sup>5</sup>

These techniques have greatly expanded treatment options. Patients with complex aortic aneurysms who are considered too frail for OSR because of (cardiopulmonary) comorbidities, decreased physical performance, or other factors increasing the risk of adverse outcomes, can now also benefit from a less invasive endovascular approach. However, these complex EVAR procedures have a higher morbidity and mortality rate compared to conventional infrarenal EVAR. Thirty-day mortality rates ranging from 3.4% up to 8.6% have been reported in complex EVAR, compared with an average of 1.2% in conventional EVAR.<sup>6-9</sup> In addition to morbidity and mortality, patients undergoing complex EVAR are at risk of decline in functional performance. Maintaining independent living and quality of life are highly valued outcomes, especially in older patients.<sup>10-12</sup> While high technical success rates are commonly reported, evidence on functional performance after complex EVAR is scarce.<sup>13,14</sup>

Information on postoperative functional performance is important in order to properly inform patients about the consequences of treatment. We evaluated the functional outcomes of patients undergoing complex EVAR in a tertiary referral center. To our knowledge, this study is the only study that examined functional performance after complex EVAR, using a prospectively maintained database.

## METHODS

### Study design and setting

A single-center retrospective cohort study was performed, using data from a prospectively maintained secure computerized database of consecutive patients who underwent complex EVAR in the Leiden University Medical Center; a tertiary referral center (LUMC, The Netherlands). Patients were included since the introduction of complex EVAR in this hospital in July 2013, until September 2020. The database was approved by the LUMC Medical Ethics Committee (METC). Any information not provided by this database was subtracted from patients' medical records. As in the standard care pathway, all patients were seen at 6 weeks, 6 months, and 12 months postsurgery and yearly after that for outpatient-based follow-up. Additional appointments were made

if deemed necessary. Computed tomography angiography, duplex ultrasonography, and abdominal X-ray were used in follow-up. Given the retrospective character of the current study, the METC waived the necessity for informed consent.

As of May 2017, all patients scheduled for complex EVAR were referred to the LUMC geriatric department to undergo a comprehensive geriatric assessment. No selection based on patient demographics was made. Screening included (Instrumental) Activities of Daily Living Scores ((I)ADL), the 6-item Cognitive Impairment Test (6-CIT), and a Mini Nutritional Assessment (MNA). If the patient gave informed consent for follow-up, they were included in the Triage of Elderly Needing Treatment (TENT) study (ID number: NL53575.058.15).<sup>15</sup> For these patients, geriatric scores were gathered again at 12 months postsurgery, by phone. In the current study, (I)ADL-scores were used to examine functional performance.

### **Patients and Procedures**

Complex EVAR was defined as endovascular aortic surgery that entailed correction of an aneurysm including the visceral segment, with or without thoracic involvement. Baseline characteristics were described by demographics, living status, aneurysm characteristics, comorbidities, risk factors, and exercise tolerance by the estimated metabolic equivalent of task (MET) score.<sup>16</sup> (I)ADL-scores were measured by the Katz Index of Independence in Activities of Daily Living (Katz ADL) and the Lawton Instrumental Activities of Daily Living Scale (Lawton IADL).<sup>17,18</sup> The Katz ADL measures the (in)dependency of patients with regard to 6 daily life activities: bathing, getting dressed, toileting, transfers, continence, and feeding. For each activity, patients can score 0 (fully independent) to 2 (dependent). Patients are categorized on a hierarchic 0 to 12 scale, with 0 being independent and 12 being fully dependent in all 6 activities. The Lawton IADL measures the (in)dependency of patients with regard to 8 more complex activities: using the phone, shopping, preparing food, housekeeping, doing laundry, mode of transportation, responsibility for personal medication, and handling finances. Patients are categorized on a 0 to 24 scale, scoring 0 (fully independent) to 3 (not capable/has never performed) per category. The 6-CIT and MNA were used to examine cognitive impairment (score > 7) and malnutrition risk (score < 11), respectively.<sup>19-21</sup> Both the Katz ADL and Lawton IADL are of sufficient validity when conducted by phone.<sup>22,23</sup>

### **Outcomes**

Adverse outcome measures for the total patient group were postoperative discharge to a nursing home and mortality at 12 months post-surgery. Clinical outcomes were: 30-day mortality, length of hospital stay, and major surgical complications defined as complications with a Clavien-Dindo score of III-IV.<sup>24</sup> For the 23 complex EVAR patients included in the TENT-study, the additional adverse outcome was functional decline at 12 months postsurgery. This was defined as an increase of at least 2 points on the Katz ADL and/or Lawton IADL scale. This entails the patient becoming (more) dependent in at least one category and is in line with definitions of functional decline used in other fields.<sup>25-27</sup>

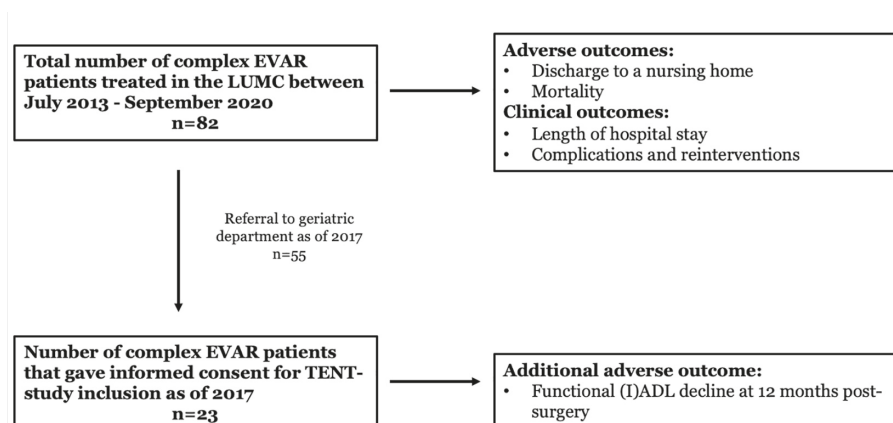
## Statistics

Baseline characteristics were expressed by number of patients and percentages, or as mean with the standard deviation (SD) in case of normal distribution. In case of skewed distribution, characteristics were presented as median with the interquartile range (Q1, Q3). Patients who gave informed consent for geriatric follow-up were compared with patients who did not consent, based on baseline characteristics. The independent t test was used for continuous normally distributed data, chi-square test for categorical data, and the Mann-Whitney U test for skewed data. All analyses were made using IBM SPSS Statistics version 26.

## RESULTS

### Patient characteristics

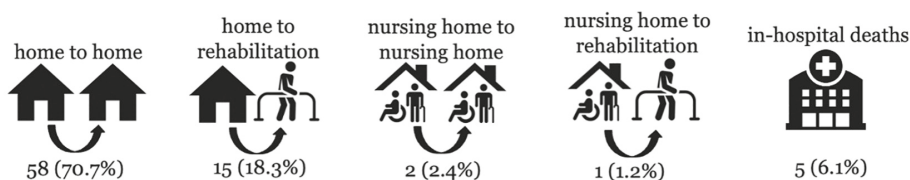
A total of 82 consecutive patients who underwent complex EVAR were included. Figure 1 shows a flowchart of patient inclusion. Table 1 shows the baseline characteristics of these patients; 68 (82.9%) were male, with a mean age of 73.3 years (SD=6.3). Mean aneurysm size was 65.1 mm (SD=11.1) and 17 patients (20.7%) had undergone previous aortic repair surgery (open or endovascular). Most patients (n=77, 93.9%) were hospitalized from home. Three patients (3.7%) were living in a nursing home, 1 patient (1.2%) lived in a homeless shelter and 1 patient (1.2%) had an unknown living situation at admission. The median ADL baseline score was 0.0 (IQR=0.0, 0.0) and the median IADL score was 1.0 (IQR=0.0, 3.75). Aneurysms were treated using FEVAR (59.8%), BEVAR (25.6%), FBEVAR (11.0%, using a graft with fenestrations and branches), and Arch-FEVAR (3.7%).



**Figure 1:** Patient inclusion and study outcomes. EVAR, endovascular aortic repair; (I)ADL, (Instrumental) Activities of Daily Living; LUMC, Leiden University Medical Center; TENT, Triage of Elderly Needing Treatment

## Care dependency at discharge

Figure 2 shows the living status at admission and the destination of discharge after hospital stay. At discharge, 60 patients (73.2%) were able to return to their pre-admission living status, either with or without (additional) home care. Fifteen patients (18.3%) admitted from home, were discharged to a rehabilitation center, which was intended to be temporary. One patient (1.2%) previously living in a nursing home was discharged to a rehabilitation center. It is unknown whether this patient was more care dependent at discharge. No complex EVAR patients were newly admitted to a nursing home post-surgery.

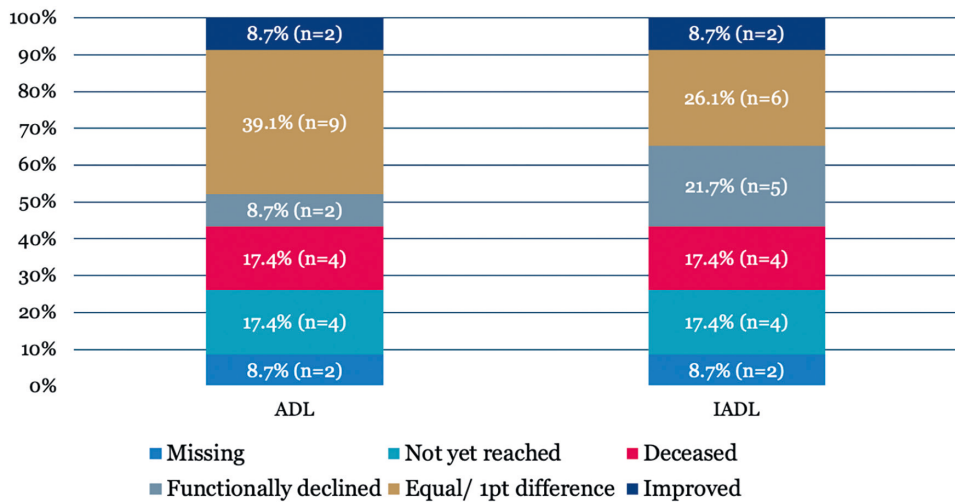


**Figure 2:** Destinations of discharge with number of patients (%).

## Functional performance

Twenty-three out of the 55 complex EVAR patients referred for geriatric assessment gave informed consent for follow-up and were included in the TENT-study for a functional performance analysis (Figure 1). There was no significant difference between the baseline geriatric scores of patients who did give informed consent for follow-up and patients who did not give consent. However, patients who did give informed consent were significantly older compared to patients who did not consent to follow-up (75.6 vs 71.8,  $p=0.027$ ). Baseline geriatric scores of the 23 patients included in follow-up are depicted in Table 2. The median preoperative ADL score of these 23 patients was 0.0 (IQR=0.0, 1.0). The median preoperative IADL-score was 1.0 (IQR=0.0, 4.0). The MNA showed that 3 patients (13.0%) were at risk for malnutrition. Cognitive impairment, measured by the 6-CIT, was present in 1 out of 23 patients (4.3%). Functional outcomes are depicted in Figure 3. At 12 months, 5 patients presented with functional decline (21.7%), 3 patients with IADL decline only, and 2 patients with IADL as well as ADL decline. ADL decline was mainly caused by the need for assistance in bathing and getting dressed ( $n=2$ ). IADL decline was mostly caused by needing assistance in shopping ( $n=3$ ). Mortality at 12 months was 17.4% ( $n=4$ ).

Medical records of the 5 patients who presented (I)ADL decline were searched for postoperative adverse events that could have caused their functional decline. In one patient, a pre-existent cognitive disorder worsened during follow-up. No potential other function-limiting complications were registered for this patient. In 2 patients, major complications following complex EVAR were reported: spinal ischaemia ( $n=1$ ) and arterial occlusion of the lower limb ( $n=1$ ). For two patients, no adverse events were registered during follow-up, while no function-limiting complications of complex EVAR were registered to have occurred.



**Figure 3:** Incidence of functional decline (n(%)) in the 23 patients included in the TENT study at 12 months post-surgery. Functional decline was defined as an increase of at least 2 points in the Katz Activities of Daily Living scale or the Lawton Instrumental Activities of Daily Living Scale. (I)ADL, (Instrumental) Activities of Daily Living; TENT, Triage of Elderly Needing Treatment

### Perioperative outcomes and complications

Perioperative outcomes are depicted in Table 3. Twenty-four complications with a Clavien-Dindo score of III-IV were registered, which meant that surgical, laparoscopic, or radiological intervention was necessary or a life-threatening complication took place during hospital stay. These 24 complications occurred in 19 patients (23.2%), including 2 out of the 5 patients who presented functional decline. Median length of hospital stay was 7.0 days (IQR=4.5, 12.5). Median length of follow-up was 21.5 months (IQR=4.1, 42.9). Complications that occurred during follow-up are presented in Table 4. Complications were detected in 33 patients (40.2%); the most common complication was aneurysm sac enlargement (n=19, 23.2%). In 11 patients (13.4%), 17 surgical reinterventions were necessary for complications during follow-up, including 1 out of the 5 patients that suffered functional decline. In addition, 12 patients (14.6%) needed endoleak repair.

### Mortality

Mortality numbers are depicted in Table 4. Within 30 days post-surgery, 6 patients (7.3%) died. These patients were treated by FEVAR (n=3), arch-FEVAR (n=2), and BEVAR (n=1). Five deaths were procedure related and occurred in the hospital: intraoperative type A dissection (n=1), pneumonia (n=1), respiratory failure (n=2), and renal failure (n=1). Mortality within 12 months was 14.6% (12 patients). Total mortality during follow-up was 22.0% (18 patients), of which 7 deaths (38.9%) were surgery or aneurysm related.

## DISCUSSION

No patients were discharged to a nursing home and mortality rates were 7.3% and 14.6% at 30 days and 12 months, respectively, for the total patient group. Major adverse events occurred in 23.2% of patients. Patients included in the TENT-study suffered functional decline at 12 months postsurgery in 21.7% (n=5) and 12-month mortality was 17.4%.

The value of these results is difficult to interpret because of the lack of data on functional performance after complex EVAR. We can however compare these results with functional performance after conventional EVAR and OSR. *Rectenwald et al*<sup>28</sup> showed that 79.5% of patients who underwent OSR for a thoracoabdominal aneurysm was discharged to their home or a rehabilitation facility (91.5% in our study), whereas 20.5% (0% in our study) was newly discharged to a nursing home. *Arko et al*<sup>29</sup> reported that 21% of EVAR patients and 25% of OSR patients were not able to shop/travel at the same level prior to surgery at 6-month follow-up. In addition, 4% of OSR patients lost the ability to independently bathe/eat as they were used to.<sup>29</sup> These results approximate the 21.7% of patients with functional decline at 12 months in our patient cohort. *Williamson et al*<sup>30</sup> studied patients who underwent OSR for an infrarenal aneurysm, and reported a decrease in 33% of patients in their functional abilities, including transportation and shopping at a mean follow-up of 34 months. *Blomaard et al*<sup>31</sup> showed that 46.2% of patients acutely hospitalized for internal medicine were either deceased or showed functional decline 12 months later. For patients considered frail, this percentage was 67.0%.

By including all 82 consecutive patients that underwent complex EVAR, it was attempted to present an unselected “real-world” patient group, commensurate with patients seen in a daily clinical practice. The 30-day mortality rate found in the current study (7.3%) is higher compared with the mortality rate found by *Van Calster et al*<sup>32</sup> (4.9%) and lower compared with the 30-day mortality rates mentioned by *Oderich et al*<sup>6</sup> (8.2%) and *Tran et al*<sup>7</sup> (8.6%). The difference with *Van Calster et al*<sup>32</sup> could be explained by different procedures being included. A relatively low percentage of patients was treated for extensive aneurysms using BEVAR (9.2% vs. 25.6% in our study) and no patients were treated using Arch-FEVAR (3.7% in the current study). The use of differing definitions of “complex” EVAR should be kept in mind when interpreting results in the available literature.

This study has several limitations. The number of patients that could be included in the (I) ADL analysis (n=23) was small. However, to our knowledge, this study is the only study that examined functional performance after complex EVAR, using a prospectively maintained database.<sup>33</sup> Another limitation is formed by potential confounders for functional decline during follow-up, such as adverse events not related to the complex EVAR procedure and aging. Although a fixed (I)ADL decline per year of aging is not established in the available literature, we cannot ignore that with increasing age, functional performance declines.<sup>34,35</sup> By confining follow-up to 12 months, we attempted to limit the influence of aging as a

confounding factor. Possible confounding adverse events were reported descriptively for the functionally declined patients. Surprisingly, some patients improved in function (Figure 3). Given the fact that patients electively treated for aortic aneurysms are usually asymptomatic prior to surgery, this is remarkable. One explanation could be that follow-up (I)ADL scores were self-reported, which could lead to an overestimation bias.<sup>36,37</sup> It could also be that with treatment of the aneurysm other function-limiting conditions, such as claudication caused by iliac stenosis, improved. In addition, medication use, nutrition, or postoperative home care might have been optimized during hospital stay. This was not further examined in the current study. When comparing functional performance after conventional EVAR, OSR, and hospitalized older patients in other fields, complex EVAR results are promising. Even more so considering the general frailty of complex EVAR patients, which makes this group often not suitable for OSR. However, for some patients, the prospect of losing independence or not being able to return home after surgery is unacceptable and can be reason to renounce treatment.<sup>10-12</sup> Therefore, multidisciplinary efforts should be directed toward preventing postoperative functional decline and care dependency.

## CONCLUSION

The results found in this study give insight in functional performance after complex EVAR. No patients were newly discharged to a nursing home and functional performance results at 12 months were promising. To our knowledge, this is the only study examining functional performance after complex EVAR, by providing data from a prospectively maintained database. Future multidisciplinary research should focus on determining which patients are most susceptible to functional decline, to facilitate preventative efforts and aid in patient selection.

## INTERIM SUMMARY

This chapter presented postoperative outcomes of complex EVAR in the Leiden University Medical Center, examining 82 patients. The 30-day and 1 year mortality rate was 7.3% and 14.6% respectively. Most patients were able to return home; 18.3% of patients were discharged to a rehabilitation center, intended as a temporary stay. No patients were newly discharged to a nursing home. A subgroup was included in functional performance analysis, which showed that 5 out of 23 patients presented with functional decline at 12 months follow-up. Compared with functional outcomes in other fields, complex EVAR results seem to be promising. It would be interesting to be able to predict which patients are most prone to adverse outcomes, in order to adequately inform patients preoperatively and to support decision-making. In Part 2, sarcopenia will be examined as a potential preoperative marker for adverse events after complex EVAR.

## TABLES

**Table 1:** Baseline characteristics

Variable (unit)	Total patient group (n=82)
Age (years), mean (SD)	73.3 (6.3)
Male, n (%)	68 (82.9)
BMI (kg/m <sup>2</sup> ), mean (SD)	26.7 (3.6)
Aneurysm size (mm), mean (SD)	65.1 (11.1)
Procedure type, n (%)	
FEVAR	49 (59.8)
BEVAR	21 (25.6)
FBEVAR	9 (11.0)
Arch-FEVAR	3 (3.7)
ASA-score $\geq 3$ , n (%)	48 (58.5)
Comorbidities, n (%)	
Cardiac	53 (64.6)
Pulmonary	27 (32.9)
eGFR <60 ml/min/1.73m <sup>2</sup> , n (%)	33 (40.2)
CVA/TIA	20 (24.4)
Peripheral vascular disease	16 (19.5)
Diabetes Mellitus type 2	11 (13.4)
Malignancy	
Active	3 (3.7)
Cured	20 (24.4)
Other comorbidities	26 (31.7)
Risk factors, n (%)	
Currently smoking	25 (30.5)
Hypercholesterolemia	26 (31.7)
Hypertension	59 (72.0)
Previous aortic repair, n (%)	17 (20.7)
Low tolerance of exercise (MET 1-4), n (%)	12 (14.6)
Living status, n (%)	
Home	77 (93.9)
Nursing home	3 (3.7)
Other/unknown	2 (2.4)
<b>Baseline (I)ADL-scores</b>	<b>n=40</b>
ADL, median (IQR)	0.0 (0.0, 0.0)
IADL, median (IQR)	1.0 (0.0, 3.75)

AAA: Abdominal Aortic Aneurysm, ACS: Acute Coronary Syndrome, ASA: American Society of Anesthesiologists Classification, COPD: Chronic Obstructive Pulmonary Disease, CVA: Cerebrovascular Accident, eGFR: estimated Glomerular Filtration Rate in ml/min/1,73 m<sup>2</sup>, IQR: Interquartile Range (Q1, Q3), MET: Metabolic Equivalent of Task, MI: Myocardial Infarction, TIA: Transient Ischemic Attack

**Table 2:** Geriatric scores and functional performance of patients included in the TENT-study (n=23)

<b>Geriatric domain</b>	<b>Scores</b>
ADL, median (IQR)	0.0 (0.0, 1.0)
IADL, median (IQR)	1.0 (0.0, 4.0)
Cognitive impaired (6CIT>7), n (%)	1 (4.3)
At risk for malnutrition (MNA<11), n (%)	3 (13.0)
<b>Patients with functional decline at 12 months</b>	<b>Number of patients (%)</b>
Total	5 (21.7)
IADL decline only	3 (13.0)
IADL and ADL decline	2 (8.7)
Deceased	4 (17.4)

ADL: Activities of Daily Living, IADL: Instrumental Activities of Daily Living, IQR: Interquartile Range (Q1, Q3), MNA: Mini Nutritional Assessment, 6CIT: Six item Cognitive Impairment Test

**Table 3:** Perioperative outcomes and surgical complications

<b>Variable (unit)</b>	
Surgical complications Clavien-Dindo III-IV	24
Number of patients, n (%)	19 (23.2)
Length of hospital stay in days, median (IQR)	7.0 (4.5, 12.5)
Preadmission living status and destination of discharge, n (%)	
Home to home	58 (70.7)
Home to rehabilitation center	15 (18.3)
Nursing home to nursing home	2 (2.4)
Other/Unknown	2 (2.4)
Deceased in hospital	5 (6.1)
Newly admitted to a nursing home	0 (0.0)

IQR: Interquartile Range (Q1, Q3)

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