ORIGINAL RESEARCH

Contemporary Trends in the Use and Outcomes of Surgical Treatment of Tricuspid Regurgitation

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***Background*—**Tricuspid regurgitation (TR), if untreated, is associated with an adverse impact on long-term outcomes. In recent years, there has been an increasing enthusiasm about surgical and transcatheter treatment of patients with severe TR. We aim to evaluate the contemporary trends in the use and outcomes of tricuspid valve (TV) surgery for TR using the National Inpatient Sample.

***Methods and Results*—**Between January 1, 2003 and December 31, 2014, an estimated 45 477 patients underwent TV surgery for TR in the United States, of whom 15% had isolated TV surgery and 85% had TV surgery concomitant with other cardiac surgery. There was a temporal upward trend to treat sicker patients during the study period. Patients who underwent isolated TV repair or replacement had a distinctly different clinical risk profile than those patients who underwent TV surgery simultaneous with other surgery. Isolated TV replacement was associated with high in-hospital mortality (10.9%) and high rates of permanent pacemaker implantation (34.1%) and acute kidney injury requiring dialysis (5.5%). Similarly, isolated TV repair was also associated with high in-hospital mortality (8.1%) and significant rates of permanent pacemaker implantation (10.9%) and new dialysis (4.4%). Isolated TV repair and TV replacement were both associated with protracted hospitalizations and substantial cost.

***Conclusions*—**In contemporary practice, surgical treatment of TR remains underused and is associated with high operative morbidity and mortality, prolonged hospitalizations, and considerable cost. **(*J Am Heart Assoc*. 2017;6:e007597. DOI: 10.1161/JAHA.117.007597.)**

Key Words: tricuspid regurgitation • tricuspid valve • tricuspid valve repair • tricuspid valve replacement

Severe tricuspid regurgitation (TR) is prevalent and negatively affects long-term outcomes.[1–5] However, TR remains undertreated because of the high morbidity and mortality associated with tricuspid valve (TV) surgery.[6–10] Nevertheless, recent developments in the field of transcatheter valve interventions have stimulated a renewed interest in the "forgotten" TV.[11–13] Early in-human experiences demonstrated the feasibility of several transcatheter tricuspid repair and replacement systems in treating TR, but they also highlighted the particularly challenging anatomical features of the TV, subvalvular apparatus, and right ventricle.[14–21] A handful of transcatheter TV therapies are being tested in early feasibility trials (clinicaltrials.gov trial: NCT-02787408, NCT-02339974, NCT-02574650, NCT-02981953, NCT-02471807).[13] Given the growing interest in transcatheter TV therapies, contemporary outcomes of TV surgery are relevant and can be used as a benchmark for early investigations of these therapies. Previous investigations of TV surgery outcomes included small numbers, noncontemporary design, or heterogeneous groups of patients.[6–9]

We aim to use a large contemporary nationwide registry to assess characteristics and outcomes of patients undergoing TV surgery in the United States between January 1, 2003 and December 31, 2014, with a special emphasis on isolated TV repair (TVr) and replacement (TVR).

Methods

The data, analytic methods, and study materials are available to other researchers on request for purposes of reproducing the results or replicating the procedure. Institutional review board approval was obtained. Informed consent requirements

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Accompanying Tables S1 through S5 are available at http://jaha.ahajournals.org/content/6/12/e007597/DC1/embed/inline-supplementary-material-1.pdf

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Clinical Perspective

What Is New?

- Tricuspid valve surgery for tricuspid regurgitation is infrequently performed in the United States.
- In-hospital morbidity and mortality and cost after isolated tricuspid repair or replacement are high and did not change significantly during the past decade.
- These suboptimal outcomes are likely related to patient risk profile and referral timing rather than to the risk of the operation.

What Are the Clinical Implications?

- These data may serve as a benchmark for the emerging transcatheter tricuspid valve therapies.
- Further investigations are needed to assess the impact of late referral on the outcomes of tricuspid valve surgery.

were waived because the data are derived from a nationwide deidentified database.

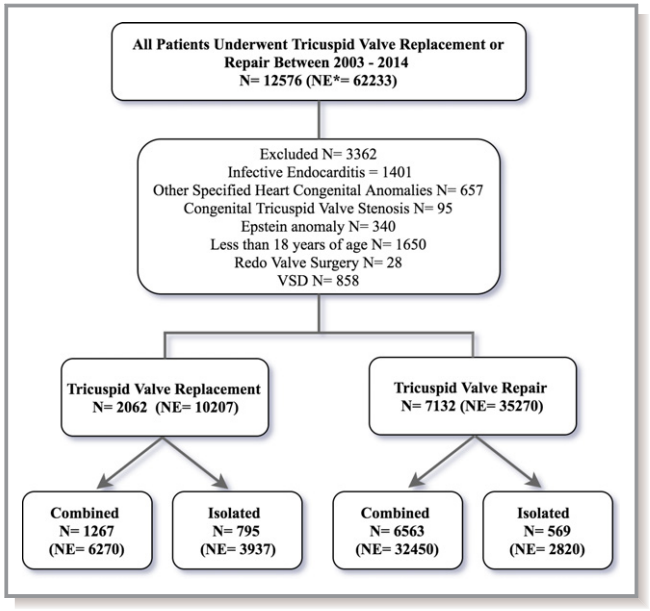

Figure 1. Study flow diagram. NE indicates national estimate; and VSD, ventricular septal defect.

Study Data

The Nationwide Inpatient Sample (NIS) was used to derive patient relevant information between January 2003 and December 2014. The NIS is the largest publicly available all-payer administrative claims-based database and contains information about patient discharges from ≈1000 nonfederal hospitals in 45 states. It contains clinical and resource use information on 5 to 8 million discharges annually, with safeguards to protect the privacy of individual patients, physicians, and hospitals. The NIS shares certain similarities with the Medicare database, including the same *International Classification of Diseases, Ninth Revision, Clinical Modification* (*ICD-9-CM*) coding system for procedures and diagnoses. Contrary to the Medicare database, the NIS includes all payers and patients across all ages. These data are stratified to represent ≈20% of US inpatient hospitalizations across different hospital and geographic regions (random sample). The national estimates (NEs) represent a calculated estimate of the total (100%) US hospitalized population. This is calculated using the Agency for Healthcare Research and Quality sampling and weighting method. Outcomes analysis was performed using the actual 20% sample available in the NIS, whereas the trend analysis was performed using the NE. This is a standard method in other research involving the NIS.

Study Population

Patients aged 18 years and older who underwent TVR (*ICD-9-CM* procedure code 35.27 and 35.28) and TVr (*ICD-9-CM* code 35.14) during the study period were identified. Patients who underwent redo TV surgery (*ICD-9-CM* codes 35.20 and 35.21), those with congenital TV disease (*ICD-9-CM* codes 764.1, 746.2, 745.4, and 746.89), or those with infective endocarditis (*ICD-9-CM* code 571.2) were excluded (Figure 1).

Trends of Use and Outcomes of TV Surgery

Temporal changes in clinical risk profile, hospital and socioeconomic characteristics, type of surgery (TVR versus TVr), and choice of prosthesis in patients undergoing TV surgery were described. The patients were then divided into 2 groups: group 1 included patients who underwent TVR, and group 2 included patients who underwent TVr. For each of the 2 groups, baseline patient comorbidities and procedural characteristics were described. In-hospital mortality, postoperative morbidities, length of stay, disposition patterns, and cost of care were also evaluated. Patient relevant descriptive statistics are presented as frequencies with percentages for categorical variables and as means with SDs for continuous variables. Baseline characteristics were compared between the groups using a Pearson χ^2 test for categorical variables and an independent-sample *t* test for continuous variables. To assess for monotonic trends of use and outcomes, we used the nonparametric Mann-Kendal trend. To estimate the cost of hospitalization, the NIS data were merged with cost/charge ratios available from the Agency for Healthcare Research and Quality Project. We estimated the cost of each inpatient stay by multiplying the total hospital charge with cost/charge ratios. Adjusted cost for each year was calculated in terms of

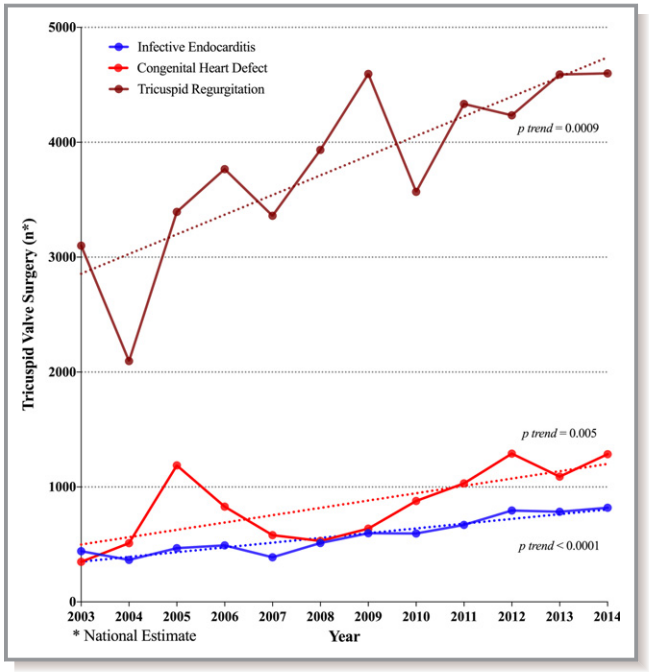

Figure 2. National trends in the use of tricuspid valve surgery in the United States between January 1, 2003 and December 31, 2014. NE indicates national estimate.

the 2014 cost, after adjusting for inflation, according to the latest consumer price index data released by the US government, Department of Labor.[22] All statistical analyses were performed using SPSS, version 24 (IBM Corporation), and R, version 3.3.1.

Results

A total of 9194 patients representing an NE of 45 477 patients who underwent TV surgery were included in our study. Of those patients, 22.4% underwent TVR and 77.6% underwent TVr. The number of patients undergoing TV surgery for TR increased by 48% from 3100 in 2003 to 4600 in 2014 (P_{trend}=0.009) (Figure 2, Table S1). Concomitant cardiac surgery was performed in most patients: 61.4% and 85.2% of patients who underwent TVR and TVr, respectively. During the study period, there was a trend towards performing TV surgery on patients with a higher prevalence of comorbidities and during nonelective admissions (Table 1). Mitral valve repair/replacement remained the most common concomitant procedures with TV surgery.

Characteristics and Outcomes of Patients Undergoing Isolated TVR

A total of 2062 patients (NE=10 207) underwent TVR during the study period, of whom 795 (NE=3937) underwent isolated TVR. Among patients who underwent TVR, the proportion who underwent isolated TVR increased over time (Figure 3). Their mean age was 56±17 years, 57.6% were women, and 71.9% were whites. Comorbidities were common, as illustrated in Table 2. Interestingly, there was a significant number of patients with chronic kidney (23%) and liver (11.1%) disease. Most isolated TVRs were performed at teaching institutions (86%) and during elective admissions (65%). Bioprosthetic valves were used in 61.6% of patients.

In-hospital mortality was high (10.8%) and did not improve over time (Figure 4). With the exception of stroke, which occurred in 1.3% of patients, rates of major postoperative morbidities were high: acute kidney injury occurred in 27.8%, new dialysis was initiated in 5.5%, and permanent pacemakers were implanted in 34.1% of patients. Other postoperative complications were also not uncommon, as summarized in Table 3. Resource use was intensive; mean hospital length of stay was 19±24 days, and mean cost of hospitalization was $84 637±$83 003. Approximately one fifth of patients were discharged to an intermediate-care facility.

Patients who underwent TVR concomitant with other cardiac surgery during the same period represented a different cohort of patients, as illustrated in Table S2. Interestingly, despite being older and having higher incidences of major morbidities, these patients experienced similar unadjusted rates of death, stroke, and acute kidney injury requiring dialysis compared with those who underwent isolated TVR (Table S3).

Characteristics and Outcomes of Patients Undergoing Isolated TVr

A total of 7132 patients (NE=35 270) underwent TVr, of whom 569 (NE=2820) underwent isolated TVr. The number of patients undergoing isolated TVr increased over time but remained minuscule overall (Figure 5). Their mean age was 54±18 years, 51.1% were women, and 64.6% were whites. Despite the younger age of these patients, comorbidities were common (Table 2). Interestingly, a significant percentage of patients (45.8%) underwent isolated TVr during a nonelective admission.

In-hospital mortality occurred in 8.1% of patients and remained unchanged during the study period (Figure 4). Also, rates of postoperative morbidities were high: stroke occurred in 2.3%, a vascular complication requiring surgery occurred in 5.3%, dialysis-requiring kidney injury occurred in 4.4%, and cardiac tamponade occurred in 2.5%. Also, 10.9% of patients required a permanent pacemaker. The mean hospital length of stay was 23±26 days, and the mean cost of hospitalization was $120 849±$123 771. Intermediate-care facilities were used in 20.1% of patients (Table 3).

Table 1. Temporal Changes in Clinical Profiles in Patients Undergoing TVR Between January 1, 2003 and December 31, 2014

Characteristic	2003–2006 (N=625, NE=3059)	2007–2010 (N=644, NE=3219)	2011–2014 (N=793, NE=3928)	*P* Value
Age, mean (SD and 25%, 50%, and 75% quartiles), y	61 (15, 51, 62, 74)	60 (16, 49, 62, 73)	61 (16, 51, 65, 73)	0.332
Age >75 y, n (%)	126 (20.2)	116 (18)	155 (19.5)	0.603
Female sex, n (%)	61 (15)	60 (16)	61 (16)	0.327
Race, n (%)				0.295
White	310 (70)	363 (68.1)	498 (70.3)	
Black	60 (13.5)	69 (12.9)	94 (13.3)	
Hispanic	48 (10.8)	51 (9.6)	52 (7.3)	
Medical comorbidity, n (%)				
Hypertension	220 (36.1)	275 (42.7)	440 (55.5)	<0.001
Diabetes mellitus	88 (14.1)	121 (18.8)	184 (23.2)	<0.001
Prior sternotomy	48 (7.7)	68 (10.6)	106 (13.4)	0.003
Chronic pulmonary disease	85 (13.6)	107 (16.6)	143 (18)	0.077
Atrial fibrillation/flutter	362 (57.9)	338 (52.5)	457 (57.6)	0.082
Anemia	96 (15.4)	132 (20.5)	207 (26.1)	<0.001
Peripheral vascular disease	22 (3.5)	41 (6.4)	75 (9.5)	<0.001
Chronic renal disease	79 (12.6)	124 (19.3)	220 (27.7)	<0.001
Hemodialysis	6 (1)	20 (3.1)	42 (5.3)	<0.001
Coronary artery disease	140 (22.4)	174 (27)	194 (24.5)	<0.001
Concomitant procedures, n (%)				
Any concomitant cardiac surgery	361 (57.7)	409 (63.5)	507 (63.9)	<0.001
Coronary artery bypass	119 (19)	112 (17.4)	87 (11)	<0.001
Aortic valve replacement	106 (17)	87 (13.5)	90 (11.3)	0.009
Mitral valve replacement	284 (45.4)	229 (35.6)	227 (28.6)	<0.001
Mitral valve repair	30 (4.8)	26 (4)	24 (3)	0.222
Cox maze ablation	109 (17.4)	100 (15.5)	73 (9.2)	<0.001
Left atrial appendage ligation	0 (0)	40 (6.2)	90 (11.3)	<0.001
Hospital characteristics, n (%)				
Teaching hospital	475 (76)	496 (78.1)	687 (86.6)	<0.001
Nonelective admission status, n (%)	361 (57.8)	409 (63.7)	507 (64)	0.031

NE indicates national estimate; and TVR, tricuspid valve replacement.

Similar to what was observed in the TVR group, patients who underwent TVr concomitant with other cardiac surgery represented a distinct cohort of older patients with higher prevalences of diabetes mellitus, chronic lung disease, atrial fibrillation, and coronary and peripheral vascular disease (Table S4). Despite that, these patients had lower unadjusted in-hospital morbidity and mortality and cost than those who underwent isolated TVr (Table S5).

Discussion

The main findings of the present investigation are as follows: (1) Isolated TV surgery for TR is uncommon. Most TVR and TVr procedures are done in conjunction with other cardiac surgical procedures. (2) Patients who undergo isolated TV surgery have a distinctive clinical risk profile compared with those who undergo TV surgery concomitant with other cardiac

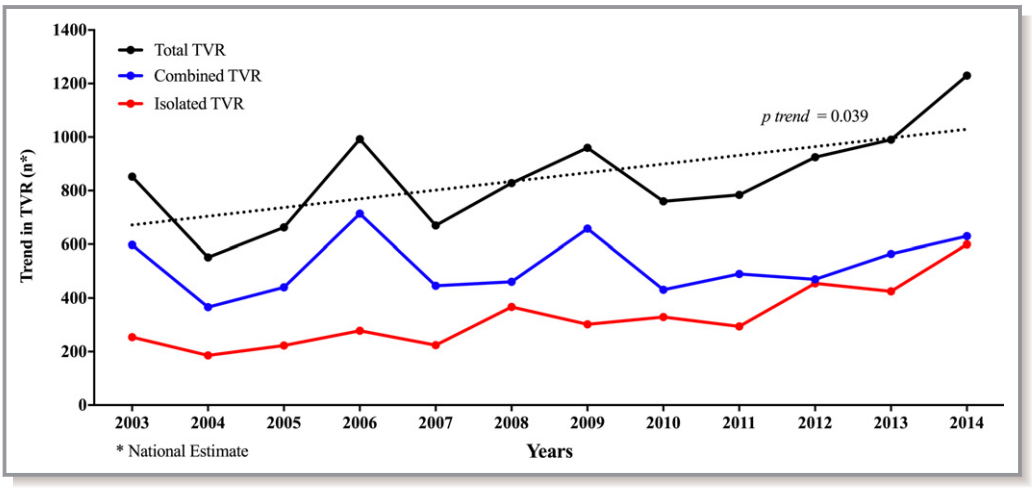

Figure 3. Temporal trend in isolated and combined tricuspid valve replacement for tricuspid regurgitation between January 1, 2003 and December 31, 2014. NE indicates national estimate; and TVR, tricuspid valve replacement.

surgery. (3) In-hospital mortality after isolated TVR and TVr is high and did not change significantly during the past decade. (4) Isolated TVR and TVr are associated with high rates of postoperative morbidities, long hospitalizations, and substantial cost. Isolated TVR is particularly associated with high rates of permanent pacemaker implantation.

Moderate to severe TR affects up to 1.6 million patients in the United States.[23] Most patients experiencing significant TR have concomitant valvular disease. Moderate-to-severe TR is present in 30% to 50% of patients with severe mitral regurgitation and in 12% to 25% of patients with severe aortic stenosis.[4,24–28] TR has been shown to be an independent negative predictor of long-term survival among the following: (1) patients with multivalvular disease undergoing surgical or transcatheter aortic and mitral valve treatment,[1,2,4,25] (2) patients with heart failure who are treated medically,[24,29] and (3) patients with severe isolated TR who are treated medically.[30,31] There is also a growing body of evidence suggesting a potential mortality benefit of early treatment of TR in both patients with isolated TR and those with TR concomitant with mitral valve disease.[23,30,32] Despite that, our study suggests that many patients with TR, especially those with isolated TR, are not undergoing surgery in contemporary practice: between 2003 and 2014, an average of ≈3890 TV surgical procedures for TR were performed annually in the United States; of these, only ≈570 (15%) were done for isolated TR. However, the low rates of TV surgery for TR observed in this study need to be interpreted with caution for several reasons: (1) The incidence rates of TR, rates of referral, and refusal of surgery have not been well studied and cannot be assessed with this data set; therefore, the magnitude of undertreatment of TR cannot be ascertained. (2) Despite the increasing acceptance of the potential role of TV surgery in patients with TR, high-quality supportive evidence is sparse. Indeed, most American College of Cardiology/American Heart Association recommendations on surgery for TR are assigned a weak (level C) class of evidence and do not contain any class I indication for isolated surgery for TR.[33] Nevertheless, our data reveal that TV surgery is infrequently performed, highlighting the need for further investigations of the epidemiological features of TR and its management patterns.[12]

Analysis of the baseline and procedural characteristics of our study's population revealed several intriguing findings: (1) Patients who underwent isolated TV surgery were younger than patients undergoing other valve surgery; the mean age was 56±17 and 54±18 years for patients undergoing isolated TVR and TVr, respectively. Emerging transcatheter therapies for TV diseases may, therefore, need to demonstrate not only safety and efficacy but also long-term durability, perhaps longer than what has been expected in the transcatheter therapies for the mitral and aortic valves. (2) Patients who undergo isolated TVR or TVr represent a distinctly different population than those who undergo TVR or TVr combined with other cardiac surgery. The patients who undergo isolated TVR or TVr have a higher prevalence of chronic kidney and liver diseases and lower prevalences of diabetes mellitus, atrial fibrillation, chronic lung disease, and atherosclerotic coronary and peripheral vascular diseases. The younger age and the higher prevalence of chronic kidney and liver diseases in the isolated TV surgery groups may suggest the presence of more severe TR-related symptoms in this population, warranting isolated TV surgery. (3) A significant proportion (≈40%) of patients who underwent isolated TV surgery for TR had their surgery during a nonelective admission. This supports the perception that patients with TR referred for TV surgery are frequently referred at later stages of their disease. (4) Between 2003 and 2014, there was a

Table 2. Characteristics of Patients Undergoing Isolated TV Surgery Between January 1, 2003 and December 31, 2014

Characteristic	All Patients (N=1364, NE=6757)	Isolated TVr Group (N=569, NE=2820)	Isolated TVR Group (N=795, NE=3937)	*P* Value
Age, mean (SD and 25%, 50%, and 75% quartiles), y	55 (17, 42, 57, 69)	54 (18, 39, 56, 68)	56 (17, 43, 57, 69)	0.022
Female sex, n (%)	749 (54.9)	291 (51.1)	458 (57.6)	0.018
Race, n (%)				0.018
White	773 (68.8)	307 (64.6)	466 (71.9)	
Black	187 (16.7)	99 (20.8)	88 (13.6)	
Hispanic	84 (7.5)	35 (7.4)	49 (7.6)	
Medical comorbidity, n (%)				
Hypertension	587 (43.4)	241 (42.4)	346 (44)	0.56
Diabetes mellitus	243 (17.8)	103 (18.1)	140 (17.6)	0.815
Prior sternotomy	198 (14.5)	64 (11.2)	134 (16.9)	0.004
Chronic pulmonary disease	187 (13.7)	81 (14.2)	106 (13.3)	0.633
Atrial fibrillation/flutter	609 (44.6)	243 (42.7)	366 (46)	0.222
Anemia	295 (21.6)	120 (21.1)	175 (22)	0.683
Coagulopathy	374 (27.6)	155 (27.3)	219 (27.9)	0.816
Conduction abnormalities	40 (2.9)	17 (3)	23 (2.9)	0.919
Peripheral vascular disease	91 (6.7)	37 (6.5)	54 (6.8)	0.832
Chronic renal disease	308 (22.6)	125 (22)	183 (23)	0.647
Hemodialysis	53 (3.9)	17 (3)	36 (4.5)	0.147
Coronary artery disease	182 (13.3)	84 (14.8)	98 (12.3)	0.192
Metastatic cancer	36 (2.7)	1 (0.2)	35 (4.5)	<0.001
Liver disease	108 (8)	21 (3.7)	87 (11.1)	<0.001
Liver cirrhosis	54 (4)	8 (1.4)	46 (5.8)	<0.001
Hospital characteristics, n (%)				
Teaching hospital	1171 (86.1)	489 (86.2)	682 (86)	0.899
Hospital bed size				0.033
Small	52 (3.8)	16 (2.8)	36 (4.5)	
Medium	164 (12.1)	57 (10.1)	107 (13.5)	
Large	1144 (84.1)	494 (87.1)	650 (82)	
Rural location	15 (1.1)	6 (1.1)	9 (1.1)	0.894
Nonelective admission status, n (%)	538 (39.5)	260 (45.8)	278 (35)	<0.001
Surgery on day 0–1 of admission	659 (54.8)	259 (53.4)	400 (55.7)	0.43
Primary payer, n (%)				0.019
Medicare/Medicaid	821 (60.2)	315 (55.4)	506 (63.6)	
Private, including HMO	454 (33.3)	214 (37.6)	240 (30.2)	
Self-pay/no charge/other	43 (3.2)	18 (3.2)	25 (3.1)	
Median household income by percentile, n (%)				0.565
0–25th	359 (27.1)	159 (28.7)	200 (25.9)	
26–50th	324 (24.4)	128 (23.1)	196 (25.4)	
51–75th	321 (24.2)	137 (24.7)	184 (23.8)	
76–100th	323 (24.3)	130 (23.5)	193 (25)	

HMO indicates health maintenance organization; NE, national estimate; TV, tricuspid valve; TVr, TV repair; and TVR, TV replacement.

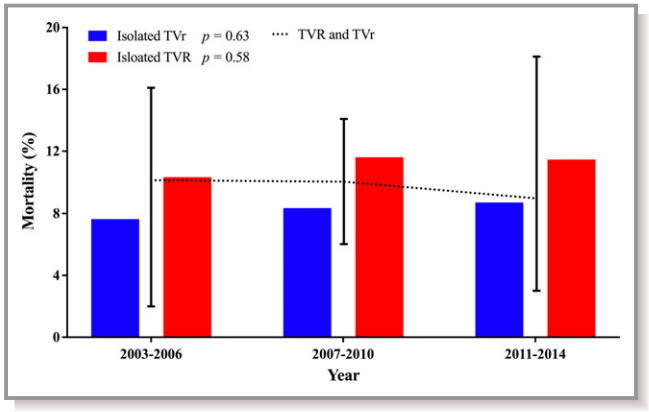

Figure 4. National trends in in-hospital mortality after isolated tricuspid valve surgery for tricuspid regurgitation between January 1, 2003 and December 31, 2014. TVr indicates tricuspid valve repair; and TVR, tricuspid valve replacement.

clear and statistically significant trend towards performing TV surgery in sicker patients with a higher prevalence of major morbidities. (5) Contrary to what has been seen in treatment of mitral regurgitation, current surgical treatment of isolated TR remains primarily one of replacement, not repair.

Isolated TVR and TVr were associated with significant in-hospital mortality (10.9% and 8.1%, respectively). Although these mortality rates did not significantly improve over time, this can partially be related to the trends towards treating sicker patients in more recent years. There rates, however, represent the outcomes of "all comers" who underwent TV surgery and remain several folds higher than contemporary operative mortality rates after isolated mitral valve repair (1.4%–2.6%), mitral valve replacement (3.8%), and aortic valve replacement (2.2%) in the United States.[34–36] The frequency of postoperative morbidities, the protracted hospital length of stay, and the substantial cost of TV surgery were also absorbing: (1) We noted high rates of postoperative permanent pacemaker implantation (34.1% after isolated TVR and 10.9% after isolated TVr), much higher than what has been reported after other valve surgical procedures.[34–36] These findings, nevertheless, are in line with prior single-center reports showing pacemaker rates of 13% to 28% after TV

Table 3. Clinical Outcomes of Patients Undergoing Isolated TV Surgery Between January 1, 2003 and December 31, 2014

Characteristics	All Patients (N=1364, NE=6757)	Isolated TVr Group (N=569, NE=2820)	Isolated TVR Group (N=795, NE=3937)	*P* Value
Clinical outcome, n (%)				
In-hospital death	132 (9.7)	46 (8.1)	86 (10.8)	0.093
Vascular complications	84 (6.2)	40 (7)	44 (5.5)	0.257
Vascular complications requiring surgery	57 (4.1)	30 (5.3)	27 (3.4)	0.088
Permanent pacemaker implantation	333 (24.4)	62 (10.9)	271 (34.1)	<0.001
Clinical stroke	23 (1.7)	13 (2.3)	10 (1.3)	0.146
Acute kidney injury	413 (30.3)	192 (33.7)	221 (27.8)	0.018
Acute kidney injury requiring dialysis	69 (5.1)	25 (4.4)	44 (5.5)	0.343
Blood transfusion	485 (35.6)	186 (32.7)	299 (37.6)	0.061
Cardiac tamponade	23 (1.7)	14 (2.5)	9 (1.1)	0.06
Pneumonia	103 (7.5)	49 (8.6)	54 (6.8)	0.21
Prolonged ventilation	87 (6.4)	42 (7.4)	45 (5.7)	0.2
Wound infection	22 (1.6)	6 (1.1)	16 (2)	0.166
Pulmonary embolism	43 (3.2)	23 (4)	20 (2.5)	0.112
Deep venous thrombosis	15 (1.1)	9 (1.6)	6 (0.8)	0.149
Discharge status, n (%)				0.113
Discharged home	965 (70.7)	408 (71.8)	557 (70.2)	
Discharged to SNF/NH/IC	261 (19.1)	114 (20.1)	147 (18.5)	
Length of stay, mean (SD and 25%, 50%, and 75% quartiles), d	21 (25, 7, 12, 25)	23 (26, 7, 18, 28)	19 (24, 7, 12, 21)	0.013
Length of stay >5 d, n (%)	1173 (86)	483 (84.9)	690 (86.8)	0.317
Cost of hospitalization, mean (SD and 25%, 50%, and 75% quartiles), $	99 575 (99 421, 40 267, 65 906, 109 000)	119 055 (118 574, 38 901, 76 271, 170 760)	85 633 (80 272, 41 082, 62 255, 99 574)	<0.001

IC indicates intermediate-care facility; NE, national estimate; NH, nursing home; SNF, skilled nursing facility; TV, tricuspid valve; TVr, TV repair; and TVR, TV replacement.

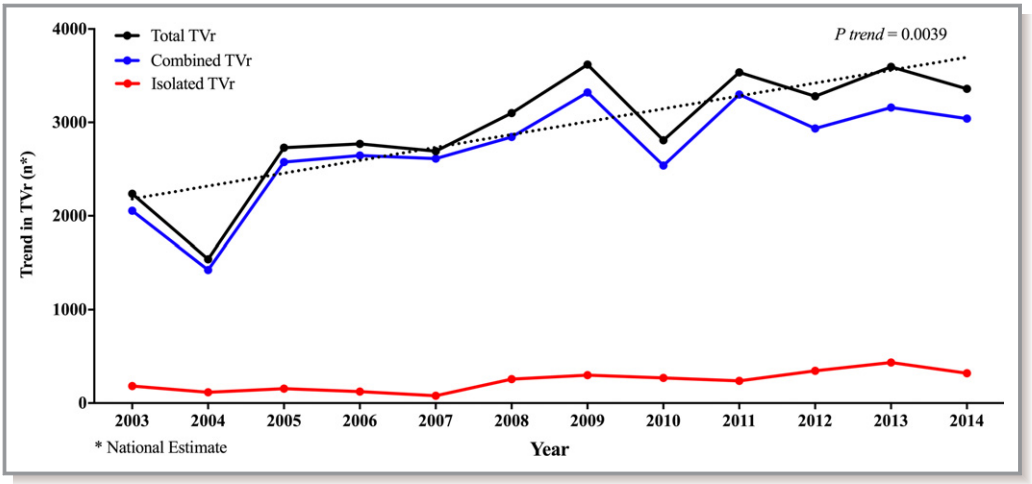

Figure 5. Temporal trend in isolated and combined tricuspid valve repair for tricuspid regurgitation between January 1, 2003 and December 31, 2014. NE indicates national estimate; and TVr, tricuspid valve repair.

surgery and higher odds of needing a pacemaker after TVR versus TVr.[37,38] Several anatomical and technical factors have been implicated in these high rates of pacemaker dependency after TV surgery, including intraoperative hypothermia, cardiopulmonary bypass duration, and the proximity of the atrioventricular node and the atrioventricular nodal artery to the tricuspid annulus.[39,40] (2) New dialysis requirements were high after isolated TVR and TVr (5.5% and 4.4%, respectively). In contemporary practice, <2% of patients undergoing isolated aortic valve replacement and 1% to 2% of patients undergoing mitral valve surgery require dialysis postoperatively.[34–36] This is likely because of the high prevalence of chronic renal and liver disease in patients with TR attributable to right-sided heart failure. (3) Postoperative stroke rate was relatively high (2.3%) among patients who underwent isolated TVr. Further studies are needed to identify the root cause of this higher than expected rate. (4) Mean lengths of stay in our study were 19±24 and 23±26 days after TVR and TVr, respectively. These hospitalizations are significantly longer than contemporaneous hospital length of stay after aortic and mitral valve replacement (6 and 7 days, respectively).[34–36] The protracted stays were also associated with a substantial cost: $84 637±$83 003 for isolated TVR and $120 849±$123 771 for isolated TVr. The higher cost associated with TVr can be partially explained by the differences in patient risk profiles and demographics and the longer hospitalizations in the TVr group.

These cost values, nevertheless, are ≈2-fold higher than parallel cost data published from the NIS for isolated aortic and mitral valve surgical procedures.[41] These data may be encouraging to the rising transcatheter TV therapies. These repair and replacement systems, if deemed safe and effective, are likely to perform well in cost-effectiveness analyses because of the substantial cost resource use associated with TV surgery.

The discussion of these findings would not be complete without alluding to the impact of late presentation on the outcomes of TV surgery. Kilic et al demonstrated an inverse relationship between the duration of disease and outcomes.[8] In their study, surrogates for late presentation exerted a greater effect on mortality than the addition of concomitant other valves procedures. Although identification of disease duration in our database is not possible, the high prevalence of chronic renal and liver disease and the high proportion of nonelective TV operations indicate that late presentation may be common among patients with TR undergoing TVR or TVr in current practice.

Limitations

This study has several limitations. (1) The NIS is derived from hospital claims data and subject to the shortcomings of other administrative data sets. Inconsistencies related to diagnosis coding may underestimate or overestimate adverse events. However, the Agency for Healthcare Research and Quality quality control measures should minimize these possibilities. (2) Cause of TV disease, left ventricular ejection fraction, right ventricular function, duration of TV disease, and baseline and postoperative echocardiographic data are not captured in the NIS. Also, details on specific outcomes beyond hospital discharge are not available in the NIS. (3) Finally, this study included patients who were likely deemed acceptable surgical candidates, which may underestimate the actual morbidity and mortality for higher-risk patients who are being denied TV surgery. Nevertheless, this study provides the largest "real-world" outcomes data on TV surgery for TR, offering important insights into a cohort of patients who will be the focus of multiple investigations in the field of transcatheter TVR and TVr.

Conclusions

In contemporary practice, patients who undergo isolated TVR and TVr experience high postoperative morbidity and mortality, lengthy hospitalizations, and substantial cost. Further investigations to assess the impact of late referral on these outcomes are needed.

Disclosures

None.

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SUPPLEMENTAL MATERIAL

Table S1. Estimated Numbers of Tricuspid Valve Surgeries Performed in the United States Between 2003 and 2014

	Number of Tricuspid Valve Surgeries in The United States			
Year	**Total Number (NE)**	**Tricuspid Regurgitation**	**Congenital Heart Defect**	**Infective Endocarditis**
2003	800 (3849)	642 (3100)	74 (349)	92 (441)
2004	609 (2958)	431 (2096)	106 (511)	75 (366)
2005	1010 (5030)	680 (3394)	238 (1188)	96 (468)
2006	1020 (5029)	775 (3766)	157 (829)	100 (492)
2007	844 (4283)	656 (3361)	122 (581)	76 (388)
2008	1002 (4964)	793 (3934)	108 (531)	104 (513)
2009	1179 (5786)	938 (4595)	128 (638)	122 (598)
2010	977 (4981)	701 (3569)	172 (879)	116 (595)
2011	1263 (5991)	913 (4334)	220 (1032)	140 (670)
2012	1251 (6255)	847 (4235)	258 (1290)	159 (795)
2013	1289 (6445)	918 (4590)	218 (1090)	157 (785)
2014	1332 (6660)	920 (4600)	257 (1285)	164 (820)

NE; national estimate

Table S2. Characteristics of Patients Undergoing Tricuspid Valve Replacement Between 2003-2014

Characteristic	All Patients (N=2062 NE=10207)	Combined TVR (N=1267 NE=6270)	Isolated TVR (N=795 NE=3937)	P value
Age- mean (SD), y	61 (16)	64 (15)	56 (17)	<0.001
Female - no. (%)	1249 (60.6)	791 (62.4)	458 (57.6)	0.029
Race- no. (%)				0.146
White	1171 (69.5)	705 (68.1)	466 (71.9)	
Black	223 (13.2)	135 (13)	88 (13.6)	
Hispanic	151 (9)	102 (9.8)	49 (7.6)	
Medical Comorbidity- no (%)				
Hypertension	935 (45.7)	589 (46.7)	346 (44)	0.235
Diabetes	393 (19.1)	253 (20)	140 (17.6)	0.184
Prior Sternotomy	222 (10.8)	88 (6.9)	134 (16.9)	<0.001
Chronic Pulmonary Disease	335 (16.2)	229 (18.1)	106 (13.3)	0.005
Atrial Fibrillation/Flutter	1157 (56.1)	791 (62.4)	366 (46)	<0.001
Anemia	435 (21.1)	260 (20.5)	175 (22)	0.419
Coagulopathy	604 (29.5)	385 (30.5)	219 (27.9)	0.198
Conduction Abnormalities	59 (2.9)	36 (2.8)	23 (2.9)	0.945
Peripheral Vascular Disease	138 (6.7)	84 (6.6)	54 (6.8)	0.886
Chronic Renal Disease	423 (20.5)	240 (18.9)	183 (23)	0.026
Hemodialysis	68 (3.3)	32 (2.5)	36 (4.5)	0.013
Coronary Artery Disease	508 (24.6)	410 (32.4)	98 (12.3)	<0.001
Metastatic Cancer	67 (3.3)	32 (2.5)	35 (4.5)	0.018
Liver Disease	160 (7.8)	73 (5.8)	87 (11.1)	<0.001
Liver Cirrhosis	86 (4.2)	40 (3.2)	46 (5.8)	0.004
Type of Valve Replacement- no (%)				
Mechanical	988 (47.9)	683 (53.9)	305 (38.4)	<0.001
Bioprosthetic	1074 (52.1)	584 (46.1)	490 (61.6)	<0.001
Concomitant Procedures- no (%)				
Percutaneous coronary intervention	13 (0.6)	13 (1)	0 (0)	<0.001
Coronary artery bypass	318 (15.4)	318 (25.1)	0 (0)	<0.001
Aortic valve replacement	283 (13.7)	283 (22.3)	0 (0)	<0.001
Mitral valve replacement	740 (35.9)	740 (58.4)	0 (0)	<0.001
Mitral valve repair	80 (3.9)	80 (6.3)	0 (0)	<0.001
Cox Maze Ablation	282 (13.7)	282 (22.3)	0 (0)	<0.001

Left atrial appendage ligation	130 (6.3)	130 (10.3)	0 (0)	<0.001
Open ASD\VSD Repair	199 (9.7)	199 (15.7)	0 (0)	<0.001
IABP*/LV** Assist Device Use	168 (8.1)	139 (11)	29 (3.6)	<0.001
Hospital characteristics- no (%)				
Teaching Hospital	1658 (80.8)	976 (77.5)	682 (86)	<0.001
Hospital bed size				0.638
Small	93 (4.5)	57 (4.5)	36 (4.5)	
Medium	296 (14.4)	189 (15)	107 (13.5)	
Large	1664 (81.1)	1014 (80.5)	650 (82)	
Rural location	23 (1.1)	14 (1.1)	9 (1.1)	0.96
Non-elective Admission Status- no (%)	782 (38)	504 (39.8)	278 (35)	0.028
Surgery on day 0-1 of admission	990 (56)	590 (56.1)	400 (55.7)	0.859
Primary Payer- no (%)				0.373
Medicare / Medicaid	1359 (65.9)	853 (67.3)	506 (63.6)	
Private including HMO	583 (28.3)	343 (27.1)	240 (30.2)	
Self-pay/No charge/Other	64 (3.1)	39 (3.1)	25 (3.1)	
Median Household Income- no (%)				0.666
1. 0-25th percentile	526 (26.1)	326 (26.3)	200 (25.9)	
2. 26-50th percentile	494 (24.5)	298 (24)	196 (25.4)	
3. 51-75th percentile	506 (25.1)	322 (26)	184 (23.8)	
4. 76-100th percentile	487 (24.2)	294 (23.7)	193 (25)	

* IABP; intraortic balloon pump, LV; left ventricular

Table S3. Clinical Outcomes of Patients Undergoing Tricuspid Valve Replacement Between 2003-2014

	All Patients (N=2062 NE=10207)	Combined TVR (N=1267 NE=6270)	Isolated TVR (N=795 NE=3937)	P value
Clinical Outcome- no (%)				
In-Hospital Death	245 (11.9)	159 (12.6)	86 (10.8)	0.236
Vascular Complications	109 (5.3)	65 (5.1)	44 (5.5)	0.69
Vascular Complications Requiring Surgery	61 (3)	34 (2.7)	27 (3.4)	0.353
Permanent Pacemaker Implantation	627 (30.4)	356 (28.1)	271 (34.1)	0.004
Clinical Stroke	40 (1.9)	30 (2.4)	10 (1.3)	0.075
Acute Kidney Injury	611 (29.6)	390 (30.8)	221 (27.8)	0.149
Acute Kidney Injury Requiring Dialysis	114 (5.5)	70 (5.5)	44 (5.5)	0.992
Blood Transfusion	750 (36.4)	451 (35.6)	299 (37.6)	0.355
Cardiac Tamponade	24 (1.2)	15 (1.2)	9 (1.1)	0.915
Pneumonia	145 (7)	91 (7.2)	54 (6.8)	0.736
Prolonged ventilation	162 (7.9)	117 (9.2)	45 (5.7)	0.003
Wound infection	38 (1.8)	22 (1.7)	16 (2)	0.65
Pulmonary embolism	35 (1.7)	15 (1.2)	20 (2.5)	0.023
Deep venous thrombosis	21 (1)	15 (1.2)	6 (0.8)	0.345
Discharge Status- no (%)				<0.001
Discharged Home	1275 (61.9)	718 (56.8)	557 (70.2)	
Discharged SNF/NH/IC*	534 (25.9)	387 (30.6)	147 (18.5)	
Length of Stay- mean (SD), d	19 (20)	19 (17)	19 (24)	0.413
Length of stay > 5 days	1850 (89.7)	1160 (91.6)	690 (86.8)	0.001
Cost of hospitalization- mean (SD), $	89760 (79637)	92958 (77326)	84637 (83003)	0.028

* SNF; Skilled nursing facility, NH; Nursing Home; IC; Intermediate Care Facility

Table S4. Characteristics of Patients Undergoing Tricuspid Valve Repair Between 2003-2014

Characteristic	All Patients (N=7132 NE=35270)	Combined TVr (N=6563 NE=32450)	Isolated TVr (N=569 NE=2820)	P value
Age- mean (SD), y	66 (14)	67 (13)	54 (18)	<0.001
Female - no. (%)	4298 (60.3)	4007 (61.1)	291 (51.1)	<0.001
Race- no. (%)				<0.001
White	4011 (71.3)	3704 (71.9)	307 (64.6)	
Black	720 (12.8)	621 (12.1)	99 (20.8)	
Hispanic	404 (7.2)	369 (7.2)	35 (7.4)	
Medical Comorbidity- no (%)				
Hypertension	3740 (52.7)	3499 (53.6)	241 (42.4)	<0.001
Diabetes	1520 (21.3)	1417 (21.6)	103 (18.1)	0.051
Prior Sternotomy	403 (5.7)	339 (5.2)	64 (11.2)	<0.001
Chronic Pulmonary Disease	1389 (19.5)	1308 (19.9)	81 (14.2)	0.001
Atrial Fibrillation/Flutter	4792 (67.2)	4549 (69.3)	243 (42.7)	<0.001
Anemia	1441 (20.2)	1321 (20.1)	120 (21.1)	0.584
Coagulopathy	1995 (28.1)	1840 (28.2)	155 (27.3)	0.647
Conduction Abnormalities	191 (2.7)	174 (2.7)	17 (3)	0.633
Peripheral Vascular Disease	571 (8)	534 (8.1)	37 (6.5)	0.168
Chronic Renal Disease	1286 (18)	1161 (17.7)	125 (22)	0.011
Hemodialysis	163 (2.3)	146 (2.2)	17 (3)	0.243
Coronary Artery Disease	2499 (35)	2415 (36.8)	84 (14.8)	<0.001
Metastatic Cancer	12 (0.2)	11 (0.2)	1 (0.2)	0.967
Liver Disease	198 (2.8)	177 (2.7)	21 (3.7)	0.171
Liver Cirrhosis	80 (1.1)	72 (1.1)	8 (1.4)	0.502
Concomitant Procedures- no (%)				
Percutaneous coronary intervention	42 (0.6)	42 (0.6)	0 (0)	0.056
Coronary artery bypass	1886 (26.4)	1886 (28.7)	0 (0)	<0.001
Aortic valve replacement	1507 (21.1)	1507 (23)	0 (0)	<0.001
Mitral valve replacement	2653 (37.2)	2653 (40.4)	0 (0)	<0.001
Mitral valve repair	2615 (36.7)	2615 (39.8)	0 (0)	<0.001
Cox Maze Ablation	1827 (25.6)	1827 (27.8)	0 (0)	<0.001
Left atrial appendage ligation	950 (13.3)	950 (14.5)	0 (0)	<0.001
Open ASD\VSD Repair	799 (11.2)	799 (12.2)	0 (0)	<0.001
IABP*/LV** Assist Device Use	697 (9.8)	615 (9.4)	82 (14.4)	<0.001
Hospital characteristics- no (%)				
Teaching Hospital	5285 (74.4)	4796 (73.3)	489 (86.2)	<0.001

Hospital bed size				<0.001
Small	374 (5.3)	358 (5.5)	16 (2.8)	
Medium	1086 (15.3)	1029 (15.7)	57 (10.1)	
Large	5647 (79.5)	5153 (78.8)	494 (87.1)	
Rural location	162 (2.3)	156 (2.4)	6 (1.1)	0.042
Non-elective Admission Status- no (%)	2488 (34.9)	2228 (34)	260 (45.8)	<0.001
Surgery on day 0-1 of admission	3540 (62.6)	3281 (63.5)	259 (53.4)	<0.001
Primary Payer- no (%)				<0.001
Medicare / Medicaid	5031 (70.5)	4716 (71.9)	315 (55.4)	
Private including HMO	1783 (25)	1569 (23.9)	214 (37.6)	
Self-pay/No charge/Other	153 (2.1)	135 (2.1)	18 (3.2)	
Median Household Income- no (%)				<0.001
1. 0-25th percentile	1704 (24.5)	1545 (24.1)	159 (28.7)	
2. 26-50th percentile	1838 (26.4)	1710 (26.7)	128 (23.1)	
3. 51-75th percentile	1806 (25.9)	1669 (26)	137 (24.7)	
4. 76-100th percentile	1614 (23.2)	1484 (23.2)	130 (23.5)	

* IABP; intraortic balloon pump, LV; left ventricular

Table S5. Clinical Outcomes of Patients Undergoing Tricuspid Valve Repair Between 2003-2014

	All Patients (N=7132 NE=35270)	Combined TVr (N=6563 NE=32450)	Isolated TVr (N=569 NE=2820)	P value
Clinical Outcome- no (%)				
In-Hospital Death	521 (7.3)	475 (7.2)	46 (8.1)	<0.001
Vascular Complications	337 (4.7)	297 (4.5)	40 (7)	0.375
Vascular Complications Requiring Surgery	213 (3)	183 (2.8)	30 (5.3)	0.023
Permanent Pacemaker Implantation	1083 (15.2)	1021 (15.6)	62 (10.9)	<0.001
Clinical Stroke	139 (1.9)	126 (1.9)	13 (2.3)	0.482
Acute Kidney Injury	1746 (24.5)	1554 (23.7)	192 (33.7)	<0.001
Acute Kidney Injury Requiring Dialysis	228 (3.2)	203 (3.1)	25 (4.4)	0.871
Blood Transfusion	2546 (35.7)	2360 (36)	186 (32.7)	0.015
Cardiac Tamponade	71 (1)	57 (0.9)	14 (2.5)	0.03
Pneumonia	411 (5.8)	362 (5.5)	49 (8.6)	0.001
Prolonged ventilation	374 (5.2)	332 (5.1)	42 (7.4)	0.011
Wound infection	106 (1.5)	100 (1.5)	6 (1.1)	0.002
Pulmonary embolism	60 (0.8)	37 (0.6)	23 (4)	0.33
Deep venous thrombosis	62 (0.9)	53 (0.8)	9 (1.6)	0.126
Discharge Status- no (%)				<0.001
Discharged Home	4531 (63.6)	4123 (62.9)	408 (71.8)	
Discharged SNF/NH/IC*	2068 (29)	1954 (29.8)	114 (20.1)	
Length of Stay- mean (SD), d	16 (15)	15 (14)	23 (26)	<0.001
Length of stay > 5 days	6290 (88.2)	5807 (88.5)	483 (84.9)	0.011
Cost of hospitalization- mean (SD), $	78315.54 (67255)	74761 (58820)	120849 (123771)	<0.001

* SNF; Skilled nursing facility, NH; Nursing Home; IC; Intermediate Care Facility