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CLINICAL RESEARCH

Long-Term Outcomes After Surgical Versus Transcatheter Closure of Atrial Septal Defects in Adults

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Objectives The purpose of this study was to assess the comparative effectiveness and long-term safety of transcatheter versus surgical closure of secundum atrial septal defects (ASD) in adults.

Background Transcatheter ASD closure has largely replaced surgery in most industrialized countries, but long-term data comparing the 2 techniques are limited.

Methods We performed a retrospective population-based cohort study of all patients, ages 18 to 75 years, who had surgical or transcatheter ASD closure in Québec, Canada's second-largest province, using provincial administrative databases. Primary outcomes were long-term (5-year) reintervention and all-cause mortality. Secondary outcomes were short-term (1-year) onset of congestive heart failure, stroke, or transient ischemic attack, and markers of health service use.

Results Of the 718 ASD closures performed between 1988 and 2005, 383 were surgical and 335 were transcatheter. The long-term reintervention rate was higher in patients with transcatheter ASD closure (7.9% vs. 0.3% at 5 years, $p = 0.0038$), but the majority of these reinterventions occurred in the first year. Long-term mortality with the transcatheter technique was not inferior to surgical ASD closure (5.3% vs. 6.3% at 5 years, $p = 1.00$). Secondary outcomes were similar in the 2 groups.

Conclusions Transcatheter ASD closure is associated with a higher long-term reintervention rate and long-term mortality that is not inferior to surgery. Overall, these data support the current practice of using transcatheter ASD closure in the majority of eligible patients and support the decision to intervene on ASD with significant shunts before symptoms become evident. (J Am Coll Cardiol Intv 2013;6:497–503) © 2013 by the American College of Cardiology Foundation

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Congenital defects of the atrial septum are common, accounting for 10% to 17% of congenital heart disease (1). Left untreated, atrial septal defects (ASD) lead to chronic right-sided volume overload and right-sided chamber enlargement. Current guidelines recommend that all patients with hemodynamically significant ASD should undergo ASD closure, regardless of symptoms, in order to prevent long-term complications such as atrial arrhythmias, pulmonary hypertension, and/or paradoxical embolism (2).

Surgical ASD closure has been practiced for over 50 years and has excellent long-term results (3,4). For patients with the most common type of ASD (secundum ASD), a transcatheter option is also available. Transcatheter closure is much less invasive than surgery, has fewer periprocedural complications, and is associated with a shorter length of stay (5). Approximately 80% of secundum ASD are suitable for closure using currently available devices (6,7) and transcatheter closure is now the dominant technique in many centers, despite a lack of long-term data to support this practice (8–10). The present study was designed to examine temporal trends in surgical versus transcatheter ASD closure and to compare long-term reintervention and mortality rates between the 2 techniques.

Abbreviations and Acronyms

ASD = atrial septal defect(s)

CHF = congestive heart failure

CI = confidence interval(s)

HR = hazard ratio(s)

ICD-9 = International Classification of Diseases-Ninth Revision

OR = odds ratio(s)

PFO = patent foramen ovale

RR = rate ratio(s)

TIA = transient ischemic attack

Methods

Data sources. The Québec CHD (Congenital Heart Disease) database is a population-based database of congenital heart disease patients derived from provincial administrative databases that contain comprehensive demographic, diagnostic, and therapeutic records of all patient-linked encounters in Québec, Canada's second largest province (11). It was created by merging Québec's physician claims services database (Régie de l'Assurance Maladie du Québec) and the hospital discharge summary database (Med-Echo). By law, attestation of death is sent to the Québec Health Insurance Board, who systematically updates the medical claims database. This makes documentation of death complete in our database, whether it occurred in or out of hospital.

Study population. Our study population consisted of all ASD patients between the ages of 18 and 75 years who had surgical or transcatheter ASD closure (Fig. 1). To ensure that we had a population of patients with only secundum ASD, we excluded patients with codes for coexisting congenital anomalies and those who had surgical ASD closure billed in the same day as other cardiac surgeries. We excluded patients with patent foramen ovale (PFO) closure by excluding patients with stroke or transient ischemic attack (TIA) in the year prior to intervention. The Amplatzer septal occluder (AGA Medical, St. Jude Medical, St. Paul, Minnesota) was the only device used for ASD closure during the study period.

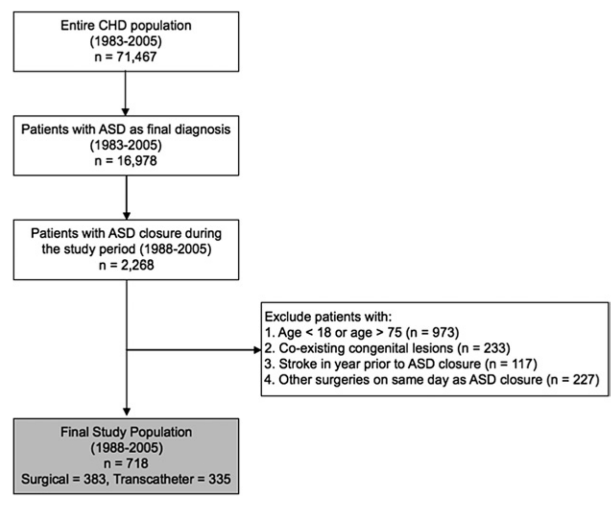

Figure 1. Study Flow Diagram

Schematic representation of how the study population was derived. ASD = atrial septal defect; CHD = congenital heart disease.

Study design. This was a retrospective cohort study. Patients having an ASD intervention were followed from the day of intervention until death or end of study on December 31, 2005, whichever occurred first. Our primary outcomes were long-term (5-year) reintervention and all-cause mortality. Our secondary outcomes were short-term (1-year) onset of congestive heart failure (CHF), stroke or TIA, and markers of health service use. For each clinical secondary outcome, we used a subsample of patients who did not have a history of that comorbidity at baseline. The study was approved by our institutional ethics board and the Québec government agency responsible for privacy of access to information.

Measurements. Baseline characteristics included age, sex, and the following comorbidities, measured in the 5 years before intervention: coronary artery disease; hypertension; diabetes; CHF; pulmonary hypertension; and atrial fibrillation. Comorbidities were defined using codes from the International Classification of Diseases-Ninth Revision (ICD-9). We also included the Charlson comorbidity index (12), an aggregate measure of patients' comorbidities that has been used in other epidemiologic studies using administrative data (13,14).

Reintervention was defined as transcatheter ASD closure or surgical ASD closure that occurred during an observation period that started with the day following the index procedure and continued for the duration of follow-up. For patients who died during the follow-up period, the date of death was taken directly from the medical claims database. The most likely cause of death was determined by reviewing all patient records in the medical claims and hospital discharge databases between the day of intervention and the time of death. The records were independently reviewed by 2 of the authors (M.K. and C.O.) and any disagreements were resolved by consensus.

Clinical secondary outcomes were defined using ICD-9 diagnostic codes billed in the year following the index procedure (428.0 to 428.9 for CHF, 430.0 to 435.9 for stroke/TIA). Markers of health service use (outpatient physician visits, emergency department visits, days spent in a critical care unit, and echocardiograms per patient) were also measured within 1 year of the index procedure, starting with the first day after discharge from the index hospitalization.

Statistical analyses. The primary outcomes of reintervention and mortality were compared at 30 days, 1 year, and 5 years, using the chi-square statistic or Fisher exact test. For these comparisons, we included only the subset of patients who had at least 30 days, 1 year, or 5 years of follow-up. In additional analyses for the mortality outcome, we included all available follow-up for all patients and used Kaplan-Meier curves and crude and adjusted (for Charlson comorbidity index) Cox proportional hazards regression models to examine time to death. From these analyses, we report log-rank statistics, hazard ratios (HRs), and 95% confidence intervals (CIs). Due to the low number of reintervention outcomes, the estimates from the Cox regression analysis for reintervention were unstable and are not presented. The Cox regressions were analyzed as intention-to-treat.

Secondary outcomes at 1-year follow-up were analyzed by crude and adjusted logistic (clinical outcomes) and Poisson regression models (health service use outcomes). From the logistic regression model, we report odds ratios (ORs) and 95% CIs, whereas from the Poisson we report rate ratios (RRs) and 95% CI. The regression models were adjusted for the Charlson comorbidity index. All statistical analyses were carried out using SAS statistical software (version 9.2, SAS Institute Inc., Cary, North Carolina).

Sensitivity analyses. Given that the rate of our primary outcomes was low, we were unable to adjust for more than 1 variable at a time. We chose to adjust for the Charlson index because it provides a composite score of a patient's comorbidities. To examine the robustness of our results, we repeated the primary analysis after adjusting for age and pulmonary hypertension (which is not captured by the Charlson index) and after excluding patients who had a history of pulmonary hypertension. Given the possibility of a cohort effect, we repeated the analysis by excluding patients with ASD closure prior to 1998 (the year transcatheter closure became available).

Results

Of the 718 patients with ASD closure between 1988 and 2005, 383 were closed surgically and 335 had transcatheter closure. The number of transcatheter closures grew rapidly after the technique was introduced, with a corresponding decrease in the number of surgical closures (Fig. 2). The baseline characteristics are presented in Table 1. Patients undergoing transcatheter closure were older and had more comorbidities. A notable exception was pulmonary hypertension, which was more common in the surgical group. The median length of follow-up was also longer in the surgical group (10 years vs. 3 years).

Reintervention rates. There were 2 reinterventions in the surgical group: the first was a surgical intervention that occurred on the first post-operative day; and the second was a transcatheter closure that occurred almost 13 years after the initial procedure. The reintervention rate in the surgical group was 1 of 383 (0.3%) after 30 days, and it remained 0.3% after 1 and 5 years of follow-up. The reintervention rate in the transcatheter group was 6 of 327 (1.8%) after 30 days, 12 of 263 (4.6%) after 1 year, and 3 of 38 (7.9%) after 5 years of follow-up ($p = 0.053$ for 30 days, $p < 0.0001$ for 1 year, and $p = 0.0038$ for 5 years vs. surgical closure). The majority of reinterventions in the transcatheter group occurred in the first year after closure (Fig. 3). Of the 18 transcatheter patients who required reintervention, 17 (94%) had a surgical reintervention. There were no periprocedural deaths associated with reintervention in these patients. When we looked at patients who had transcatheter ASD closure later in the study period (i.e., when operators had more experience), there was a trend toward a lower reintervention rate but it was not statistically significant (data not shown).

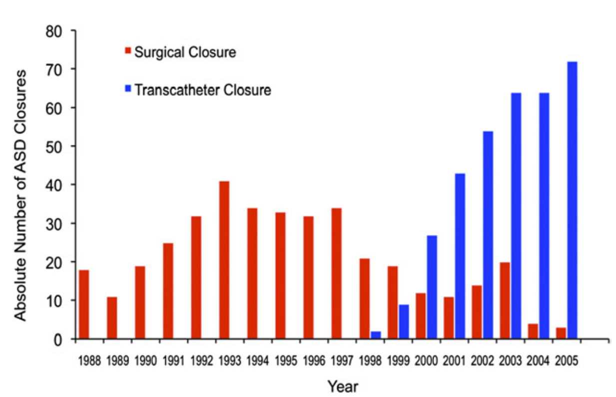

Figure 2. ASD Closure Over Time

Absolute number of secundum atrial septal defect (ASD) closures in the province of Québec. Reintervention procedures are not included in this figure.

Table 1. Baseline Characteristics

	Surgical Closure (n = 383)	Transcatheter Closure (n = 335)	p Value
Age, yrs	43 (32–54)	49 (39–61)	<0.001
Female	273 (71.3)	233 (69.6)	0.613
Comorbidities			
Coronary artery disease	15 (4.0)	4 (1.3)	0.058
Hypertension	94 (24.8)	97 (32.0)	0.037
Diabetes	15 (4.0)	20 (6.6)	0.120
Congestive heart failure	63 (16.6)	37 (12.2)	0.106
Pulmonary hypertension	62 (16.4)	23 (7.6)	<0.001
Atrial fibrillation	76 (20.0)	64 (21.1)	0.731
Charlson comorbidity index	2 (0–3)	2 (0–4)	<0.001
Median follow-up, yrs	10 (7–13)	3 (1–4)	<0.001

Values are median (interquartile range) or n (%).

Mortality. There were no statistically significant differences in mortality between surgical and transcatheter ASD closure at 30 days (1.0% vs. 0.3%, p = 0.38), 1 year (3.2% vs. 0.8%, p = 0.053), and 5 years of follow-up (6.3% vs. 5.3%, p =1.00). However, transcatheter ASD closure was associated with lower long-term mortality when evaluated using Kaplan-Meier curves, log-rank statistics, and HR (Fig. 4). The crude mortality rates in the surgical group were 4 of 383 (1.0%) after 30 days, 12 of 380 (3.2%) after 1 year, and 21 of 331 (6.3%) after 5 years of follow-up. The crude mortality rates in the transcatheter group were 1 of 327 (0.3%) after 30 days, 2 of 263 (0.8%) after 1 year, and 2 of 38 (5.3%) after 5 years of follow-up (p = 0.38 for 30 days, p = 0.053 for 1 year, and p = 1.00 for 5 years vs. surgical closure). The unadjusted HR for mortality was 0.278 (95% CI: 0.095 to 0.810) and this persisted after adjusting for the Charlson comorbidity index (HR: 0.161, 95% CI: 0.053 to 0.491). The most likely cause of death for each patient who died within 5 years of ASD closure is presented in Table 2. There appears to be an increase in both procedure-related deaths and long-term deaths in the surgical cohort. The increased number of long-term deaths is likely due to the fact that surgical patients had longer follow-up in the database than transcatheter patients did.

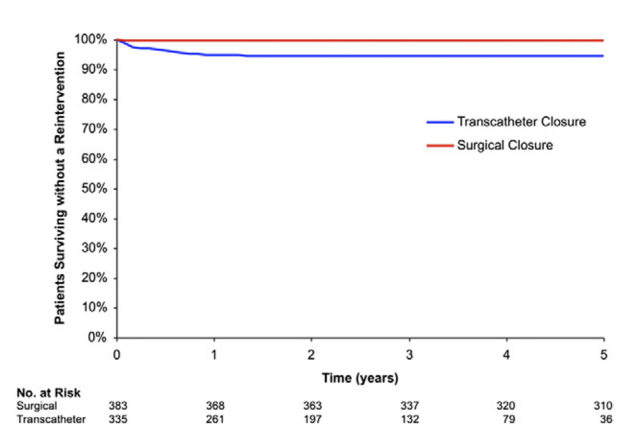

Figure 3. Reintervention After ASD Closure

Kaplan-Meier estimates for time to first reintervention during the first 5 years of follow-up. ASD = atrial septal defect.

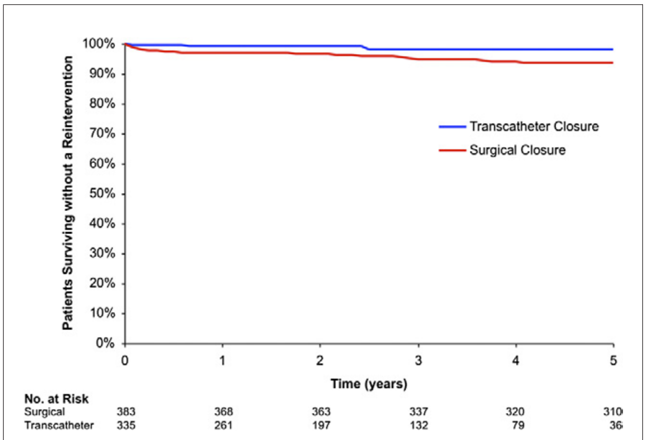

Figure 4. Long-Term Mortality After ASD Closure

Kaplan-Meier estimates for mortality during the first 5 years of follow-up. ASD = atrial septal defect.

Medical complications and health service use. In the year following ASD closure, there was no difference in the crude rate of new-onset CHF (5.0% vs. 3.0%, p =0.30) or stroke/TIA (1.6% vs. 1.8%, p = 0.99) between patients undergoing surgical versus transcatheter ASD closure. The average number of outpatient physician visits per patient (7.5 vs. 6.4, p < 0.001) and the average number of critical care days per patient (0.24 vs. 0.14, p < 0.001) were higher in the surgical cohort. There was no difference in the average number of emergency department visits between patients in the 2 groups (0.92 vs. 0.98, p = 0.61). The number of echocardiograms per patient was higher in the transcatheter group (1.46 vs. 0.63, p < 0.001). These data are summarized in Figure 5.

Sensitivity analyses. Mortality findings observed in the Cox analyses (HR: 0.278, 95% CI: 0.095 to 0.810) did not change after adjusting for age (HR: 0.190, 95% CI: 0.065 to 0.558), history of pulmonary hypertension (HR: 0.293, 95% CI: 0.100 to 0.859), or after excluding patients with pulmonary hypertension (HR: 0.234, 95% CI: 0.077 to 0.711). When we excluded patients with ASD closure prior to 1998 (the year transcatheter closure became available), we observed a trend toward reduced mortality in the transcatheter group that was of borderline significance (HR: 0.283, 95% CI: 0.079 to 1.015, p = 0.053). There was no difference in the rate of CHF (4.4% vs. 7.4%, p = 0.48) or stroke/TIA (2.0% vs. 0%, p = 0.58) in patients undergoing surgical closure before versus after 1998.

Table 2. Mortality After ASD Closure

Patient Age, yrs	Patient Sex	Time of Death (Days After Closure)	Patients at Risk, n	Cause of Death
Transcatheter closure				
63	F	2	334	Procedural (during index hospitalization)
32	F	213	291	Unknown
61	F	904	167	Hypoglycemia
71	F	906	166	Cancer
Surgical closure				
65	M	3	381	Procedural (during index hospitalization)
33	F	3	381	Procedural (during index hospitalization)
27	F	5	380	Procedural (during index hospitalization)
44	F	13	379	Procedural (pulmonary embolism)
68	F	35	378	Procedural (during index hospitalization)
61	F	40	377	Procedural (during index hospitalization)
69	F	58	376	Respiratory arrest
58	F	66	375	Cancer
60	M	104	373	Tuberculosis
29	F	121	371	Cardiac arrest
73	F	190	370	Cancer
62	M	267	369	Cancer
69	F	611	363	Cardiac arrest
57	M	763	361	Cancer
65	F	856	356	Unknown
60	F	926	354	Cancer
61	F	1,013	348	Heart failure
63	F	1,056	342	Cancer
65	M	1,082	337	Heart failure
43	F	1,136	335	Unknown
37	F	1,325	329	Pulmonary embolism
62	F	1,354	327	Cancer
43	F	1,464	319	Unknown

Most likely causes of death in patients who died within 5 years of ASD closure.
ASD = atrial septal defect(s).

Discussion

Transcatheter ASD closure has largely replaced surgery in most industrialized countries, despite a paucity of long-term data to support this practice. It is also recommended in patients with significant shunts, even in the absence of symptoms (2). We designed a population-level study to assess the long-term outcomes of transcatheter versus surgical ASD closure. We found that transcatheter closure had a higher reintervention rate than did surgery, and long-term mortality that was at least as good as that of surgery, supporting the current practice of choosing transcatheter closure whenever possible.

Our data show that the proportion of patients undergoing transcatheter ASD closure has grown dramatically since the technique was introduced, and the transcatheter approach is now the dominant strategy for ASD closure in Québec, Canada (Fig. 2). Our data also show that the absolute number of patients undergoing ASD closure has grown since the technique was introduced, suggesting that the threshold for intervention may be lower now that a less-invasive option is available. These findings are in agreement with a U.S. study that showed an increase in the rate of ASD/PFO closures per capita, during the same period (15).

The decision to close an ASD surgically versus using a transcatheter technique is primarily based on technical factors. Transcatheter closure is favored for small ASD with adequate septal rims, whereas surgical closure is preferred when the defect is close to the atrioventricular valves, the coronary sinus, or the venae cavae. Once a decision is made to proceed with transcatheter closure, the technical success rate is reported to be 96% to 98% (5–7). We observed a 30-day reintervention rate of 1.8%, which is in keeping with the literature.

Failure of the transcatheter technique may occur for several reasons. In some cases, there may be a problem with device position or stability, and these patients require

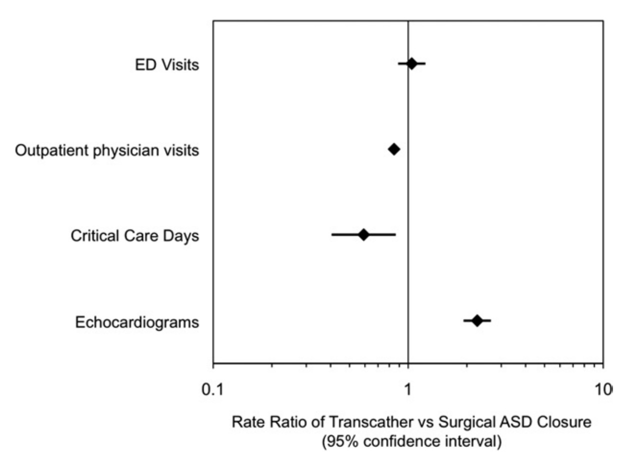

Figure 5. Health Service Use

Health service use in patients undergoing surgical versus transcatheter atrial septal defect (ASD) closure. The data are presented using rate ratios and confidence intervals. ED = emergency department.

elective surgical closure at a later date. In other cases, patients may experience a complication that will require urgent reintervention, such as device embolization, cardiac perforation, erosion, or rupture (16). Although our database did not allow us to identify the specific reasons for reintervention, we found that the majority of reinterventions in patients undergoing transcatheter ASD closure occurred in the first year, predominantly in the first 9 months after ASD closure (Fig. 3). The reintervention rate after 1 year was very low and was comparable to that seen with surgical closure. Our results support the recommendation in the 2008 American College of Cardiology/American Heart Association guidelines that patients with transcatheter ASD closure should undergo regular echocardiographic follow-up in the first year after device closure but only periodically thereafter (2).

We found that patients undergoing transcatheter ASD closure had lower long-term mortality than did patients undergoing surgical closure, when the data were analyzed using log-rank statistics and hazard ratios (Fig. 4). This difference remained significant after adjusting for age, Charlson index, and history of pulmonary hypertension. When we excluded patients with ASD closure prior to 1998 (the year transcatheter closure became available), the trend toward reduced mortality persisted but was no longer statistically significant. There was also no significant difference in mortality when the 2 techniques where compared using the chi-square statistic or Fisher exact test at the pre-specified time points of 30 days, 1 year, and 5 years. Although there were more procedure-related deaths in the surgical group, the majority of late deaths in both groups appear to be unrelated to the ASD closure itself (Table 2). It remains possible that the differences in long-term mortality could be explained by unmeasured differences in the 2 study cohorts for which we cannot correct. However, given that mortality in the transcatheter group was not worse than that in the surgical group, our data support the current practice of using transcatheter closure whenever technically feasible.

Previous studies have found that patients undergoing surgery after experiencing an adverse event related to transcatheter closure have mortality rates that are 15× to 20× higher than those associated with primary elective ASD closure (16,17). We did not observe such a trend in our study, but this may be a reflection of our low event rate.

The rationale for closing a hemodynamically significant ASD is to prevent long-term complications such as heart failure and stroke. One would expect that ASD closure would provide these benefits, irrespective of the method used to close the defect. Indeed, we did not observe a significant difference in the rate of these secondary outcomes between the 2 groups.

One of the advantages of transcatheter ASD closure is that it is less invasive than surgery and is associated with a shorter length of stay and decreased cost (18). Whether these savings hold up in the long term remains to be determined. We found that patients with surgical ASD closure had more outpatient physician visits and critical care days in the first year after closure than did transcatheter patients. On the other hand, patients in the transcatheter group did have higher usage of outpatient echocardiography in the first year after closure and there was a higher rate of reintervention in these patients.

Study limitations. Our data need to be interpreted in light of the following: This was a retrospective study using administrative databases, where there is potential for misclassification of diagnoses due to coding errors. We addressed this limitation by using very strict exclusion criteria. For example, to exclude patients with coexisting congenital heart disease lesions, we excluded patients with diagnostic codes for those lesions as well as patients who had surgical procedures billed that would imply the existence of those lesions. Furthermore, when the Québec CHD database was first created, the authors performed manual chart audits to detect and adjust for discrepancies between the data sources (11). Another limitation is that ICD-9 code 745.5 does not differentiate between ASD and PFO. We addressed this limitation by excluding patients who had a stroke or TIA in the year prior to ASD closure because it would be very unusual to close a PFO in Québec if there was no history of cryptogenic stroke.

This was an observational study, where there is potential for bias due to unmeasured confounding. The decision to close an ASD surgically versus using a transcatheter technique is primarily based on technical factors that cannot be measured with administrative databases. However, it is unlikely that any of these factors are independently associated with our primary or secondary outcomes, minimizing the potential for bias due to confounding by these factors. There is also a possibility of residual confounding because we were only able to adjust for 1 variable at a time. Thus, it is possible that with higher event rates and longer follow-up, the difference between surgery and intervention would have been less pronounced. Nonetheless, the sensitivity analyses we performed support our main conclusions.

Finally, in all of our analyses, we pooled together subjects who underwent surgery between 1998 and 2005 (when the transcatheter alternative was available) and those who underwent surgery before 1998 in order to increase the sample size and power of our analyses. These 2 groups of patients are different because patients who undergo surgery in the modern era (when there is a transcatheter alternative) tend to have larger ASD or multiple fenestrations and are therefore likely to have larger shunts. However, this decision to pool the groups was taken after preliminary Kaplan-Meier and log-rank analyses showed no difference in reintervention and mortality between subjects in the surgical cohort who underwent surgery before and after 1998 (data not shown).

Conclusions

We performed a population-level study to assess the outcomes of surgical versus transcatheter ASD closure in a real-world setting. We found that the proportion of patients undergoing transcatheter closure has grown dramatically since the introduction of the technique and it has become the dominant method for closing secundum ASD. Compared with surgical closure, transcatheter ASD closure is associated with a higher reintervention rate in the first year and long-term mortality that is not inferior to surgery. Secondary outcomes were similar between the 2 groups. Overall, our data support the current practice of using transcatheter closure in the majority of eligible patients and support the decision to intervene on ASD with significant shunts before symptoms become evident.

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Key Words: atrial septal defect ■ cardiac surgery ■ outcomes ■ transcatheter.