Safety and efficacy of cardiovascular implantable electronic device extraction in elderly patients: A meta-analysis and systematic review

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BACKGROUND Transvenous lead extraction of cardiovascular implantable electronic device (CIED) has been proven safe in the general patient population with the advances in extraction techniques. Octogenarians present a unique challenge given their comorbidities and the perceived increase in morbidity and mortality.

OBJECTIVE To assess the safety and outcomes of CIED extraction in octogenarians to younger patients.

METHODS We performed an extensive literature search and systematic review of studies that compared CIED extraction in octogenarians versus non-octogenarians. We separately assessed the rate of complete procedure success, clinical success, procedural mortality, major and minor complications. Risk ratio (RR) 95% confidence intervals were measured using the Mantel-Haenszel method. The random effects model was used due to heterogeneity across study cohorts.

RESULTS Seven studies with a total of 4,182 patients were included. There was no difference between octogenarians and non-octogenarians in complete procedure success (RR 1.01, 95% CI 1.00 – 1.02, p = 0.19) and clinical success (RR 1.01, 95% CI 1.00 – 1.01, p = 0.13). There was also no difference in procedural mortality (RR 1.43, 95% CI 0.46 – 4.39, p = 0.54), major complication (RR 1.40, 95% CI 0.68 – 2.88, p = 0.36), and minor complication (RR 1.43, 95% CI 0.90 – 2.29, p = 0.13).

CONCLUSION In this study, there was no evidence to suggest a difference in procedural success and complication rates between octogenarians and younger patients. Transvenous lead extraction can be performed safely and effectively in the elderly population.

KEYWORDS Cardiovascular implantable electronic device; Implantable cardioverter-defibrillator; Octogenarian; Pacemaker; Transvenous lead extraction

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Introduction

The use of cardiovascular implantable electronic devices (CIED) such as implantable cardioverter-defibrillators (ICD), permanent pacemakers, and cardiac resynchronization therapy has become increasingly prevalent as an important aspect in the management of chronic heart disease. Inevitably, the increase in CIED implantation has paralleled the rise in need for CIED extraction, driven mainly by systems failure or device infection.[1] Historically, the perceived risk of complications and lack of specialists has limited the performance of lead extractions. However, with growing physician experience and the improvement of extraction techniques,[2–4] CIED extraction is now considered a relatively safe procedure.[5] Prior studies have reported major complication rates of 0.7%–1.9% and minor complication rates of 1.4%–7.2% to be associated with transvenous CIED extraction.[2–4,6,7]

A unique population worth separate consideration is the octogenarians. Given their higher number of comorbidities and likely longer duration of device implantation, CIED extraction may be delayed in favor of conservative treatment owing to the perceived risk of procedural morbidity and mortality. The issue of CIED extraction in octogenarians is of particular concern given the growing number of elderly patients living with CIEDs.[8,9] While some studies have reported old age as a risk factor for worse outcomes in lead extraction,[10] others have shown varying results.[11–17] The purpose of our current study was to perform a systematic review of literature and meta-analysis to assess the safety and success rate of CIED extraction in octogenarians compared to younger patients.

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KEY FINDINGS

- The rates of complete procedural success and clinical success were similar between octogenarians and younger patients.
- Procedural mortality was low in both octogenarians and younger patients. There was no statistically significant difference between the 2 groups.
- There was no statistically significant difference in major and minor complications between the octogenarians and younger patients.

Methods

Literature search

We performed a systematic review of PubMed, Medline, Google scholar, and the Cochrane Library. This was assessed up to January 2020. Restriction to humans was applied. The reference list of all eligible studies was also reviewed. Search terms included (*octogenarian or elderly*) and (*implantable cardioverter-defibrillator or pacemaker or cardiovascular implantable electronic device*) and *extraction*.

Study selection

Studies were selected by 2 independent reviewers. The PRISMA statement for reporting systemic reviews and meta-analyses was applied to the methods for this study.[18] The studies had to fulfill the following criteria to be considered in the analysis: (1) Studies must have reported the safety and efficacy of CIED extraction in an elderly patient group vs a younger control group. (2) Elderly patient group must have a mean age of 80 years or greater. (3) Definition for lead extraction must be consistent with the Heart Rhythm Society expert consensus document.[19] (4) Studies must have been published in a peer-reviewed scientific journal.

Study outcomes

We aimed to compare the rates of complete procedure success, clinical success, procedural mortality, and major and minor complications between the octogenarian and the nonoctogenarian groups. Term definitions were taken from the Heart Rhythm Society expert consensus document.[19]

Data extraction

Two authors (A.L. and F.L.) independently performed the literature search and extracted data from eligible studies. Outcomes were extracted from original manuscripts. Information was gathered using standardized protocol and reporting forms. Discrepancies were resolved by consensus. Two reviewers (A.L. and F.L.) independently assessed the quality items and differences were resolved by consensus.

Individual study quality appraisal

Two authors (A.L. and F.L.) independently assessed the quality and reporting of the studies with the Newcastle-Ottawa scale.[20] Three categories were included in the analysis. Study quality was then classified into 1 of 3 categories: (1) high quality (7–9 points), (2) satisfactory quality (4–6 points), or (3) unsatisfactory quality (0–3 points).

Statistical analysis

Data were summarized across comparison arms using the Mantel-Haenszel risk ratio (RR). Random-effects models for analyses were used owing to heterogeneity across study cohorts. Funnel plot analysis was used to address publication bias.[21] Statistical analysis was performed using Review Manager (RevMan) Version 5.3 (Copenhagen: The Nordic Cochrane Centre, The Cochrane Collaboration; 2014. Continuous variables are presented as means with standard deviations (SD) and categorical or dichotomous variables are presented as numbers with percentage (%).

Results

Study selection and patient characteristics

The initial search resulted in 2188 abstracts, of which 1312 were duplications and 864 were excluded based on titles and abstracts (Figure 1). We included 7 studies in our final analysis with a total of 4182 patients (17% octogenarians). Baseline characteristics are summarized in Table 1. Patients were mostly male with multiple medical comorbidities. More octogenarians underwent lead extraction for the indication of infection than nonoctogenarians (71% vs 56%, $P < .01$), and octogenarians had a lower proportion of ICDs extracted relative to other types of CIEDs (19% vs 44%, $P < .01$). Study characteristics are shown in Table 2. All 7 studies were retrospective in nature; 6 were single-center studies. Year of CIED extraction ranged from 2001 to 2018.

Study endpoints

There was no difference in complete procedural success (RR 1.01, 95% confidence interval [CI] 1.00–1.02, $P = .19$) and clinical success (RR 1.01, 95% CI 1.00–1.01, $P = .13$) between octogenarians and nonoctogenarians (Figure 2). There was also no statistically significant difference in procedural mortality (RR 1.43, 95% CI 0.46–4.39, $P = .54$), major complications (RR 1.40, 95% CI 0.68–2.88, $P = .36$), and minor complications (RR 1.43, 95% CI 0.90–2.29, $P = .13$) (Figures 3 and 4). Thirty-day mortality was comparable between the 2 groups (RR 1.14, 95% CI 0.41–3.15, $P = .80$).

Procedural characteristics

Procedural characteristics are summarized in Table 3. More than 7000 leads were extracted in the included studies. Most lead extractions were performed via the subclavian approach using manual traction or laser sheaths. Two studies reported no difference in procedure time between octogenarians and younger patients.

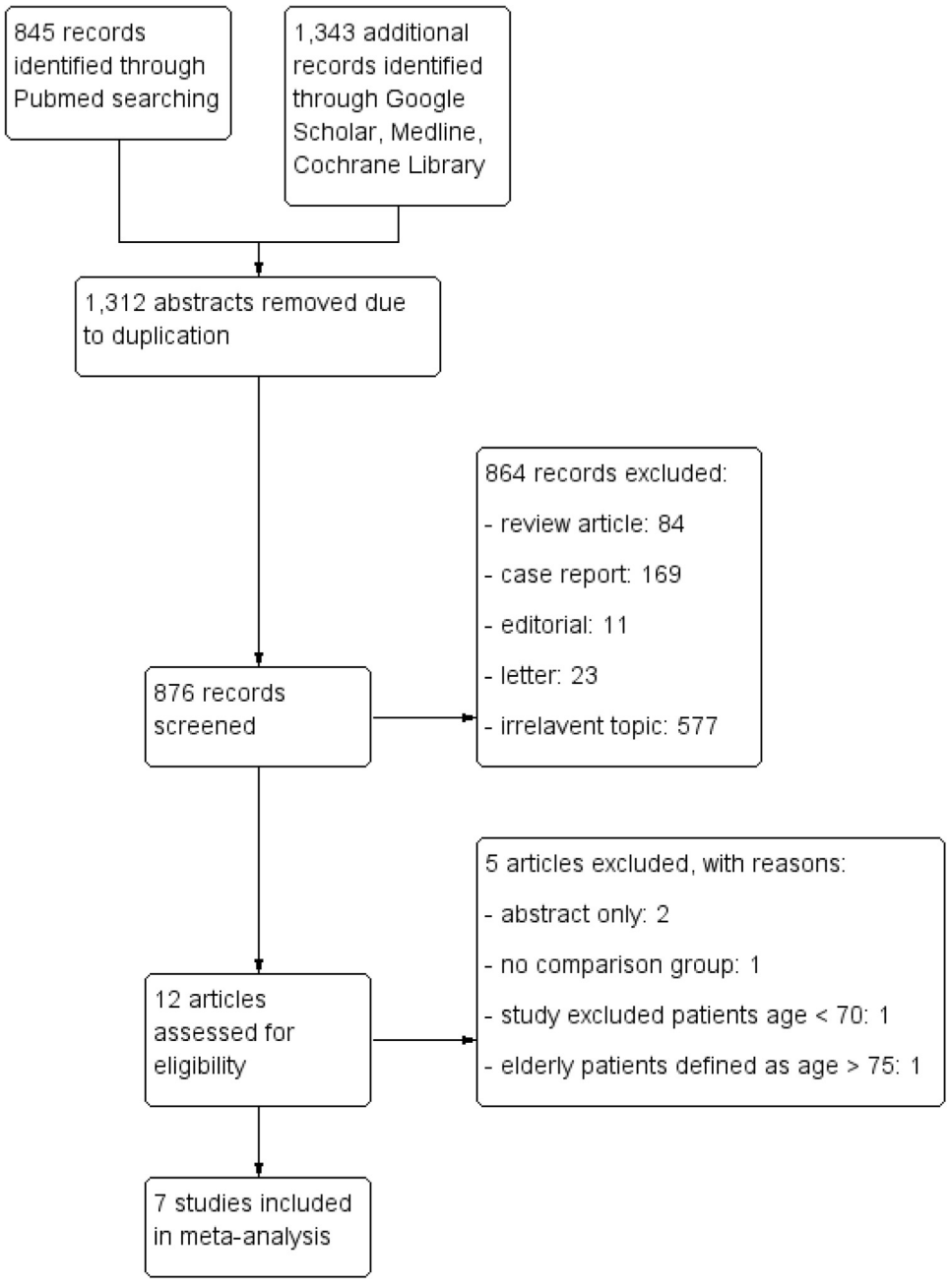

Figure 1 Selection of studies.

Quality assessment and publication bias

Based on the Newcastle-Ottawa scale, 5 of the 7 studies were of high quality, 2 were satisfactory quality, and none were unsatisfactory quality (Table 4). Funnel plots did not reveal publication bias for any of the reported outcomes (Figures 2 and 4).

Discussion

To the best of our knowledge, this is the first meta-analysis and systematic review of studies that have compared the safety and clinical outcomes of CIED extraction in octogenarians vs younger patients. The results of this meta-analysis show similar rates of clinical success and complete procedural success in elderly patients without an increase in procedural death or in major or minor complications.

The proportion of elderly adults in the United States is rising and they account for a large portion of health care consumers, with an estimated annual increase of 5.4%–7.2%.[22] More than 70% of pacemakers implanted in the United States are in patients aged >70 years, and up to two-thirds of ICDs are implanted in patients aged >65 years.[23] Other large registries have shown 12%–20% of ICD implantations are in patients aged >80 years.[24,25] The aging of patients living with

Table 1 Patient demographics and characteristics

	Rodriguez et al		Williams et al		Pelargonio et al		Kempa et al		Kutarski et al		El-Chami et al		Yagishita et al	
Study	Old	Young	Old	Young	Old	Young	Old	Young	Old	Young	Old	Young	Old	Young
Patients	118	388	72	334	150	699	26	134	192	1060	100	674	51	184
Age, y	85±4	64±12	84±3	62±14	84±3	61±10	84±3	60±14	83±3	63±13	85±4	60±15	86±5	67±15
Male	78 (66)	301 (78)	53 (74)	258 (77)	96 (64)	556 (80)	16 (62)	97 (72)	105 (55)	669 (63)	63 (63)	446 (66)	34 (68)	133 (73)
Lead age, mo	60±53	39±44	71	74	42	29	55	40	76	84	71	67	110	88
EF	42±17	35±19	42±14	45±13	49±13	42±14	44±10	40±15	NR	NR	43±15	36±17	57±15	54±16
Device type														
PPM	68 (56)	141 (36)	46 (64)	172 (51)	126 (84)	385 (55)	24 (92)	67 (50)	147 (77)	593 (56)	36 (36)	70 (10)	42 (82)	93 (51)
ICD	35 (28)	181 (47)	11 (15)	96 (29)	24 (16)	314 (45)	2 (8)	63 (47)	14 (7)	305 (29)	48 (48)	496 (74)	3 (6)	63 (34)
CRT-P	2 (3)	1 (1)	1 (1)	20 (6)	Bi-V:	Bi-V:	Bi-V:	Bi-V:	Bi-V:	Bi-V:	Bi-V	Bi-V:	3 (6)	4 (2)
CRT-D	13 (13)	65 (16)	14 (19)	46 (14)	38	170	0 (0)	4 (3)	31 (16)	162 (15)	16 (16)	108 (16)	3 (6)	24 (13)
Indications														
Infection	99 (84)	296 (76)	58 (80)	207 (62)	133 (89)	573 (82)	15 (58)	64 (48)	102 (53)	448 (42)	47 (47)	225 (33)	50 (98)	116 (63)
Lead failure	17 (14)	84 (21)	9 (13)	96 (29)	NR	NR	6 (23)	56 (42)	NR	NR	39 (39)	339 (50)	1 (2)	49 (27)
Device upgrade	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	7 (7)	64 (10)	0 (0)	9 (5)
SVC syndrome	NR	NR	1 (1)	3 (1)	NR	NR	0 (0)	2 (1)	NR	NR	NR	NR	0 (0)	2 (1)
Chronic pain	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	0 (0)	2 (1)
Other	NR	NR	4 (6)	28 (8)	NR	NR	5 (19)	12 (9)	NR	NR	7 (7)	46 (7)	0 (0)	6 (3)
Comorbidities														
HTN	104 (88)	324 (84)	25 (41)	89 (30)	122 (81)	502 (72)	16 (62)	61 (46)	NR	NR	77 (77)	411 (61)	27 (53)	70 (38)
DM	45 (38)	190 (49)	6 (10)	30 (10)	60 (40)	222 (32)	11 (42)	37 (28)	NR	NR	19 (19)	206 (31)	13 (26)	40 (22)
CAD	72 (61)	261 (67)	35 (57)	117 (38)	41 (27)	264 (38)	12 (47)	60 (45)	NR	NR	50 (50)	265 (39)	10 (20)	31 (17)
CKD	26 (22)	84 (22)	12 (18)	44 (14)	83 (55)	182 (26)	4 (15)	21 (16)	NR	NR	25 (25)	131 (19)	3 (6)	7 (4)
CVA	NR	NR	8 (13)	18 (6)	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR
COPD	NR	NR	7 (12)	28 (9)	69 (46)	133 (19)	NR	NR	NR	NR	NR	NR	NR	NR

Values presented as mean ± standard deviation for continuous variables and number (percentage) for categorical variables.

Bi-V = biventricular; CAD = coronary artery disease; CKD = chronic kidney disease; COPD = chronic obstructive pulmonary disease; CRT-D = cardiac resynchronization therapy defibrillator; CRT-P = cardiac resynchronization therapy pacemaker; CVA = cerebrovascular accident; DM = diabetes mellitus; EF = ejection fraction; HTN = hypertension; ICD = implantable cardioverter-defibrillator; NR = not reported; PPM = permanent pacemaker; SVC = superior vena cava.

Table 2 Study characteristics

Study	Rodriguez et al	Williams et al	Pelargonio et al	Kempa et al	Kutarski et al	El-Chami et al	Yagishita et al
Study design	Retrospective	Retrospective	Retrospective	Retrospective	Retrospective	Retrospective	Retrospective
Years of extraction	2004–2009	2001–2011	2005–2011	2003–2011	2006–2013	2007–2016	2013–2018
Year of publication	2011	2012	2012	2012	2013	2017	2019
Study site	Single center	Single center	Multicenter	Single center	Single center	Single center	Single center
Single operator	Yes	No	No	Not reported	Yes	No	Not reported
Follow-up	30 days	At least 30 days	Not reported	Not reported	Not reported	3 years	Not reported

CIED is a global phenomenon, as similar findings have been described in areas outside the United States, including Canada,[26] Italy,[27] and Korea.[28] It is therefore important to expand the literature on the safety and efficacy of CIED extraction in elderly patients.

A survey of 38 high-volume medical centers in Europe showed increasing age as a factor for hesitancy of clinicians in proceeding with lead extraction,[29] likely owing to higher perceived risk for adverse events. Since then, several studies have evaluated age as a predictor of perioperative complications in transvenous lead extractions. In a multicenter study using data from the National Cardiovascular Data Registry Implantable Cardioverter-Defibrillator Registry involving 11,304 extraction procedures, age was not found to be associated with major complications on univariate analysis, with an odds ratio of 1.00.[30] In a separate registry study involving 91,890 transvenous lead extractions, more elderly patients experienced procedural complications, but the results were not statistically significant when adjusted with multivariate analysis.[31] Contrary to the above, Maytin and colleagues[32] reported increasing age at time of lead extraction as a correlate with increased mortality risk. Similarly, a meta-analysis involving 62 studies suggested increasing age as a risk factor for major complications or death in patients who undergo laser lead extraction.[10] The ambiguity in literature on safety of lead extractions in elderly patients may be due to the overall low complication rate, making accurate risk analysis difficult.

One of the concerns for increased periprocedural complications for octogenarians arises from the assumption that older patients are frailer and have more comorbidities. However, it is important to note that this was not consistently observed in the studies included in this meta-analysis. In a study by Rodriguez and colleagues,[11] the majority of patients had 3 or more comorbidities but there was no statistically significant difference between the octogenarians and the younger cohort. In a separate study by Williams and colleagues,[12] octogenarians had more comorbidities than nonoctogenarians but only the difference in ischemic heart disease was statistically significant when the prevalence of each comorbidity is compared individually. In other studies, octogenarians actually had lower prevalence of coronary artery disease and diabetes, and higher ejection fraction, compared to nonoctogenarians.[13,17] This finding may be attributed to

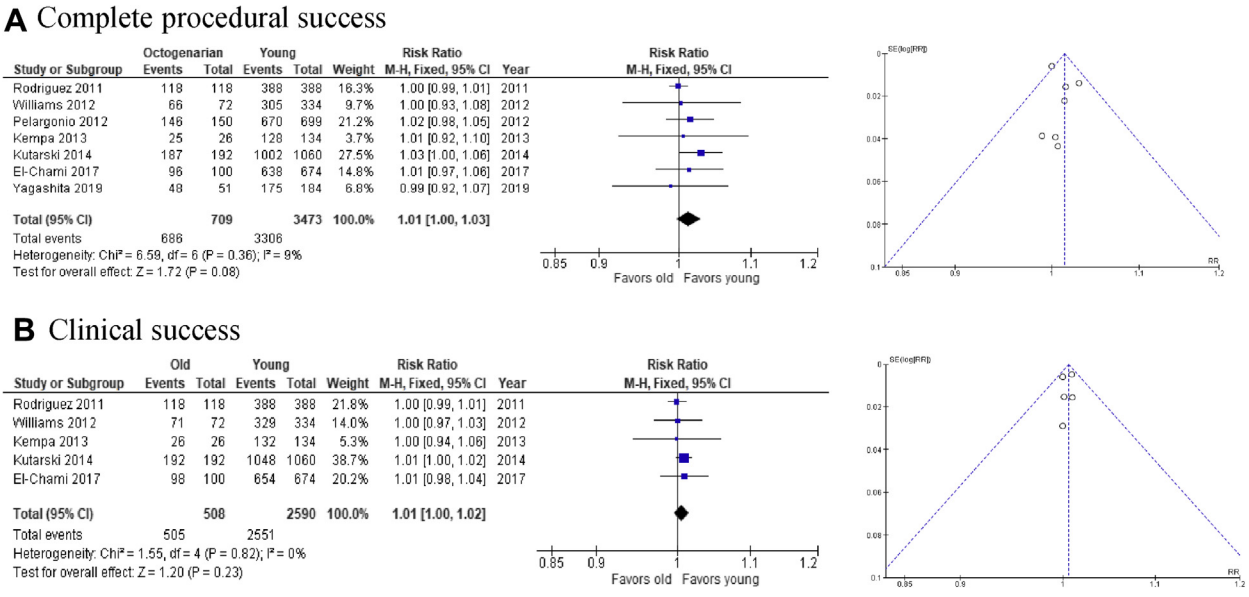

Figure 2 Forest plot and funnel plot of efficacy outcomes of cardiovascular implantable electronic device extraction in octogenarians vs younger patients. **A:** Complete procedural success. **B:** Clinical success.

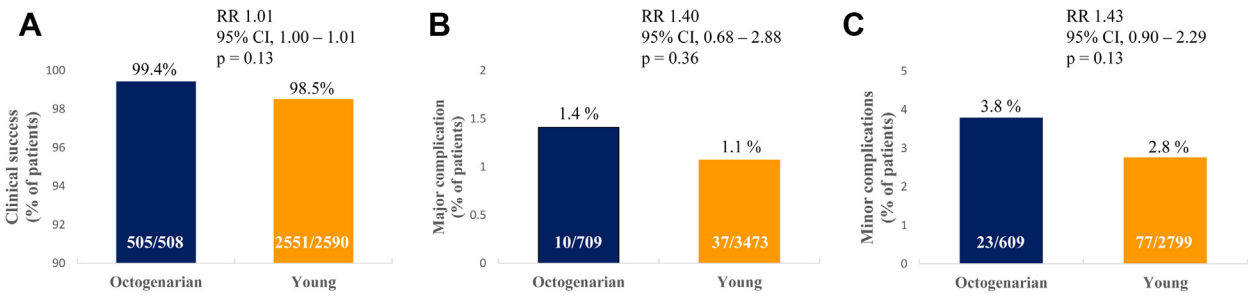

Figure 3 Comparative analysis of **A:** clinical success, **B:** major complication, and **C:** minor complication of device extraction in octogenarians vs younger control group.

the fact that older patients with higher numbers of comorbidities may not receive CIED implantation in the first place. Although previous landmark trials have shown decreased mortality with ICD and cardiac resynchronization therapy in certain patient populations, this benefit is less well defined in octogenarians, given their lower ratio of arrhythmic to nonarrhythmic deaths.

Prior works have reported 30-day mortality in patients undergoing lead extraction to be 2%–3%.[33,34] However, this was not more commonly observed in octogenarians based on this current meta-analysis. One of the included studies assessed mortality up to 3 years after lead extraction between octogenarians and the younger cohort.[17] Although there was a slight divergence of Kaplan-Meier survival curve after 1.5 years favoring younger patients, this was not statistically significant ($P = .203$). This finding suggests long-term outcomes of lead extraction in octogenarians are excellent and comparable to younger patients.

Notably, more patients in the octogenarian group underwent lead extraction for the indication of CIED infection compared to the nonoctogenarian group. This is

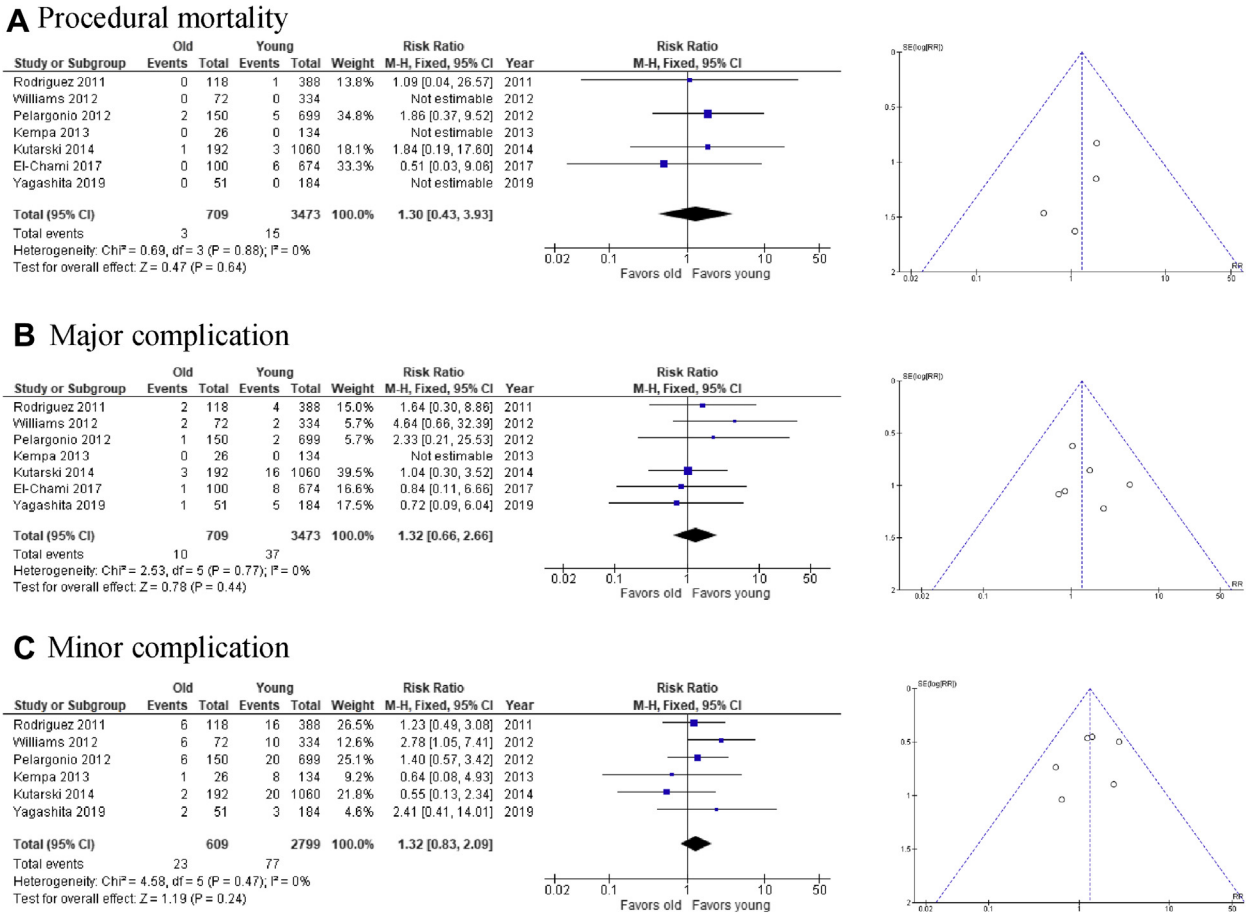

Figure 4 Forest plot and funnel plot of safety outcomes of cardiovascular implantable electronic device extraction in octogenarians vs younger patients. **A:** Procedural mortality. **B:** Major complication. **C:** Minor complication.

Table 3 Procedural characteristics

	Rodriguez et al		Williams et al		Pelargonio et al		Kempa et al		Kutarski et al		El-Chami et al		Yagishita et al	
Study	Old	Young	Old	Young	Old	Young	Old	Young	Old	Young	Old	Young	Old	Young
Patients, n	118	388	72	334	150	699	26	134	192	1060	100	674	51	184
Procedure time	NR	NR	88±53	92±52	NR	NR	NR	NR	104±46	111±48	NR	NR	NR	NR
Technique														
MT	0 (0)	0 (0)	35 (49)	168 (50)	26 (17)	109 (15)	NR	NR	NR	NR	42 (42)	277 (41)	0 (0)	0 (0)
LS	118 (100)	388 (100)	37 (51)	166 50)	124 (83)	578 (83)	NR	NR	NR	NR	41 (41)	304 (45)	44 (86)	165 (90)
MS	0 (0)	0 (0)	0 (0)	0 (0 0	0 (0)	12 (2)	NR	NR	NR	NR	17 (17)	93 (14)	7 (14)	19 (10)
Leads extracted														
Total	253	814	141	657	301	1410	35	185	2137		1078	170	NR	NR
Atrial	99 (39)	295 (36)	57 (40)	254 (39)	97 (32)	484 (34)	12 (34)	65 (35)			NR	NR	NR	NR
									914 (43)					
Ventricular	145 (57)	442 (54)	70 (50)	344 (52)	166 (55)	753 (53)	23 (66)	116 (63)			NR	NR	NR	NR
									1145 (54)					
CS	9 (4)	77 (10)	14 (10)	59 (9)	38 (13)	173 (13)	0 (0)	4 (2)			NR	NR	NR	NR
									78 (3)					
Approach														
Subclavian	116 (98)	379 (98)	70 (97)	331 (97)	NR	NR	25 (96)	131 (98)	NR	NR	96 (96)	640 (95)	NR	NR
Femoral	2 (2)	9 (2)	2 (3)	11 (3)	NR	NR	1 (4)	3 (2)	NR	NR	4 (4)	34 (5)	NR	NR

Values presented as mean ± standard deviation for continuous variables and number (percentage) for categorical variables.
CS = coronary sinus; LS = laser sheath; MS = mechanical sheath; MT = manual traction; NR = not reported.

Table 4 Newcastle-Ottawa scale of the included studies

Study	Selection[†]	Comparability[‡]	Outcome[§]
Rodriguez et al	3	1	2
Williams et al	3	1	3
Pelargonio et al	3	1	3
Kempa et al	3	1	2
Kutarski et al	3	2	3
El-Chami et al	3	1	3
Yagishita et al	3	1	3

[†]Maximum 4 stars.
[‡]Maximum 2 stars.
[§]Maximum 3 stars.

consistent with clinical practice, as the decision to proceed with CIED extraction is a result of shared decision-making considering the risks vs potential benefits of the procedure. Although extraction of an infected CIED is a class I indication, other common indications listed in the included studies (ie, lead failure, device upgrade) are more often performed in younger patients, as they are expected to live long enough to derive the long-term benefits. Although this may introduce selection bias, in the context that extraction of infected CIEDs has previously been associated with an increased risk for procedural complications,[30,35] octogenarians did not experience more adverse outcomes despite having more infected lead extractions. Another notable difference is the lower proportion of defibrillating leads extracted in octogenarians, which can be more difficult to extract and may be associated with a higher risk of adverse outcomes.[19]

The current meta-analysis has several limitations that should be acknowledged. First, most of the studies included were single-center experiences and, in some cases, single-operator outcomes, which limits the generalizability of our findings. This is especially important, as procedural success has been associated with proceduralist experience. Next, there was notable heterogeneity on lead characteristics and indications for extraction in the studies. Multiple risk factors reported in literature to be associated with increased complications were not addressed in this study, as the lack of data available precludes the performance of sensitivity analysis. Third, all included studies were retrospective and our findings are limited by the nature of retrospective designs.

Conclusion

In patients undergoing CIED extraction, there is no evidence to suggest a difference in procedural success and complication rates between octogenarians and younger patients. Based on our meta-analysis, clinicians may consider CIED extraction in elderly patients as a safe and effective management option.

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