Transvenous lead extraction: the influence of age on patient outcomes in the PROMET study cohort

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Abstract

Background

Cardiac implantable electronic device (CIED) therapy contributes to an improvement in morbidity and mortality across all patient demographics. Patient age is a recognised risk factor for unfavourable outcomes in invasive procedures. This is the largest series of non-laser transvenous lead extraction (TLE) evaluating the association between patient age and procedure outcomes.

Methods

Data of 2205 (3849 leads) patients was collected retrospectively from six European TLE centres between January 2005 – December 2018 in the PROMET study. Of these, 153 patients with 319 leads were excluded for incomplete data. A comparison of outcomes was performed between the age groups young [<50 years], young intermediate [50-69 years], older intermediate [70-79 years] and octogenarian [≥80 years].

Results

Infection was most common indication for TLE in the octogenarian cohort, less common in the younger population (60.1% vs 33.2%, respectively, p<0.01). High-voltage leads were extracted most frequently from young patients, less frequently from octogenarians (31.6% vs 10%, p<0.001), whilst the opposite was evident for pacemaker leads (p<0.001). Rotational sheath use was equally prevalent across all patient groups (p=0.79). Minor and major complications across all the age groups were statistically similar, as was procedural success; the 30-day mortality was most significant in the octogenarian and least in the young patients (4.9% vs 0.4%, p=0.005). Propensity matching multivariate analysis found systemic infection, lead dwell time and patient age (p=0.013, OR 1.064 [1.013-1.116]) increased risk of 30-day mortality.

Conclusion

TLE is safe and effective across all age groups. 30-day mortality risk is significantly higher in the older patients.

Keywords: Transvenous lead extraction, TLE, Age, CIED

1. Introduction

Cardiac implantable electronic device (CIED) therapy has expanded globally, contributing to an improvement in morbidity and mortality across all patient demographics (1)(2). This has been followed by an increase in transvenous lead extractions (TLE) (3)(4). Expert consensus recommends system removal for infection and some non-infectious indications, recognising TLE as a lifesaving procedure (5). Lead extraction does carry risk of morbidity and mortality with several identified risk factors including infection, operator experience, female sex and use of powered sheaths (3)(4)(6)(7)(8). Advanced age is associated with multiple co-morbidities and frailty, increasing the probability of complications from many invasive procedures (9). With an ageing population, TLE will play an increasingly crucial role in the management of this patient group. In this large series, we sought to evaluate the association between age and TLE patient outcomes across six European high-volume extraction centres.

2. Method

The PROMET study collected data of 2205 patients (3849 targeted leads) who had undergone transvenous lead extraction between 2005 and 2018 from six European extraction institutions. Due to insufficient data, 153 patients (319 leads) were excluded for the purpose of this analysis (**figure 1**). All extraction procedures as defined by the Heart Rhythm Society (HRS) (10) and European Heart Rhythm Association (EHRA) (11) were included. The data was subcategorised in to four age groups (12)(13): Young (age <50 years), young intermediate (50-69 years), older intermediate (70-79 years) and octogenarian (80+ years). A retrospective analysis was performed evaluating the effects of age on patient outcomes from TLE.

Extraction techniques

Extractions were performed within the operating theatre, cardiac catheterisation suite or a hybrid lab by a cardiologist or cardiac surgeon with the appropriate skills. All cardiologist led extractions were performed with the availability of a perfusionist, extracorporeal circulation and a cardiac surgeon on-standby. A variety of extraction techniques were used (4). In the early phase of the study, laser powered sheaths (3.6% leads) (SLS II, Philips, USA) were used along with simple polypropylene models (2.91% leads) (Byrd Dilator Sheath, Cook Medical, USA), PTFE sheaths (1.97% leads) (Cook Medical, USA) and femoral tools. Subsequently, all institutions migrated to a multi-step approach centered on rotational sheaths: When simple traction proved to be unsuccessful or was expected to be insufficient, a locking stylet (Liberator, Cook Medical, USA) was used, followed in most cases by rotational tools (Evolution and Evolution RL, Cook Medical, USA; Tightrail, Philips, USA). The femoral approach with snare (Needle's Eye, Cook Medical, USA) was accessed when the superior approach failed.

2.1 Definitions

Procedural success and failure were defined according to the EHRA and HRS expert consensus (10)(11). Complete procedural success was defined as the removal of all lead components from the cardiovascular system whilst remaining free of complications. A complication was described as an unwanted consequence of the extraction procedure that resulted in suffering or disability, requirement for further therapy or a prolonged hospital stay and was subcategorized into minor or major as agreed from prior consensus (5). A major complication was identified if it necessitated a significant intervention (pericardiocentesis, cardiac or vascular surgery) whilst a complication was considered minor if a non-significant intervention was required, such as short-term analgesia for localized pain or drainage of a pocket haematoma. A committee consisting of representatives from each contributing center arbitrated complications for consistency. Any death occurring on the day of the procedure or at a later date but associated with a procedure related complication, was described as a 'procedure related fatality'.

2.2 Statistics

Where appropriate, continuous variables were conveyed as a mean ± standard deviation and median with interquartile range (IQR). Categorical variables were stated as a number and percentage. Data distribution was assessed with a Shapiro-Wilk normality test. The Chi-squared of independence test and Kruskal-Wallis test were used to compare categorical variables (SPSS, IBM corp., NY, USA). A p-value of <0.05 was deemed statistically significant. A multivariate regression analysis was performed of clinical success, complications and 30-day mortality (**figure 1**). Propensity 1:1 score matching according to type of device, infection indication and lead dwell time was then performed comparing octogenarians (≥80-years-old) and non-octogenarians (<80-years-old patients) (SPSS software, IBM corp., NY, USA). Multivariate regression analysis was performed for factors associated with clinical success, complications and 30-day mortality in the propensity matched data (**figure 1**).

3. Results

Overall, 2205 patients with 3849 leads were treated across the six European extraction centers between January 2005 and December 2018. For this study, sufficient data was available for 2052 patients with 3530 targeted leads. The bulk (66.2%) of the extractions were performed in the intermediate age (50-69 and 70-79 years) cohort whilst mostly male patients were treated across all age groups (**figure 2**) (p=0.18). There was no difference in the New York Heart Association (NYHA) class between the groups, despite the finding that the left ventricular ejection fraction (LVEF) was significantly lower in the younger population (38.1% vs 46.9%, <50 vs 80+ years of age, respectively, p<0.01). Previous cardiac surgery was significantly more common in the 50-69 years group (10.1%, p=0.026) (**table 1**).

An infection indication for TLE was most common in the octogenarian population and least common in the younger patients (60.1% vs 33.2%, 80+ vs <50 years of age, respectively, p<0.01), whilst the opposite was evident for non-functional leads (26.4% vs 47.2%, respectively, p<0.01). Device type also varied significantly amongst the age groups. A significantly higher number of implantable cardiac defibrillator (ICD) leads were extracted from younger patients than older patients, whilst pacemaker leads were extracted with a significantly higher frequency in the 80+ years group (p<0.001) (**figure 2**). The octogenarian group were most likely to have passive fixation leads extracted (p=0.013) (**figure 2**). Whilst the use of rotational sheaths appeared statistically similar across all age groups, there was a significantly higher use of general anaesthesia in the younger patients (p=0.001) **(figure 2)**.

3.1 Outcomes

Lead dwell time was significantly longer in the octogenarian group (93.5 vs 84 vs 77 vs 80.8 months; 80+, 70-79, 50-69, <50 years of age, respectively, p=0.0014). There was no significant difference in the procedure time between the age groups and procedural success rate remained statistically similar across all age cohorts (**table 1**), as did major (p=0.38) and minor (p=0.75) complications (**figure 3**). Overall, 30-day mortality significantly increased with age, with the highest rate amongst the octogenarian patients (p=0.005) (**figure 3**).

The multivariate regression analysis for 30-day mortality identified six variables that were associated with a poor-outcome: Patient age, infection indication, extraction of a defibrillator system, greater lead dwell time and presence of systemic infection. The use of a rotational sheath was associated with lower mortality risk (p<0.05). Variates correlating with a greater likelihood of clinical success were the use of a rotational sheath and shorter lead dwell time (p<0.05) (**table 2**).

3.2 Propensity matching

To compare octogenarians (≥80-years-old) and non-octogenarians (<80-years-old), 1:1 propensity score matching was performed pairing 706 patients that statistically match. This analysis revealed a comparable complete procedural success rate (93.5% vs 94.1%, respectively, p=0.76), with no significant difference in minor complications (2.3% vs 3.1%, respectively, p=0.29) or major complications (1.1% vs 1.4%, respectively, p=0.74). Procedural mortality was also similar between the age groups (0.6% vs 0.3%, respectively, p=0.56). Even with propensity matching, there was a numerically higher rate of 30-day mortality in the octogenarian group (5.4%) compared to the <80-year-old patients (2.6%), although not reaching statistical significance (p=0.08) (**table 3**).

A multivariate regression analysis was performed on this propensity matched dataset for factors associated with 30-day mortality. Age, the presence of systemic infection, and greater lead dwell time were associated with greater mortality, whilst the use of the rotational sheath was associated with lower mortality (p<0.05) (**figure 4**). Variables correlating with complications included gender and lead dwell (p<0.05) whilst factors influencing clinical success were lead dwell time, the use of a rotational sheath and presence of systemic infection (p<0.05) (**table 2**).

4. Discussion

To our knowledge this is the largest cohort of TLE evaluating the association of age on patient outcomes. The outcomes of this series suggest that TLE is safe and effective across all age sets. The clinical implications of these findings are important. As the population ages and the number of older patients with cardiac implantable electronic devices (CIED) increases, the proportion of elderly patients eligible for TLE will rise (14). However, there may be reluctance in performing TLE in the elderly population due to their perceived frailty (6)(15), conditioned by the fear of complications with adverse outcomes.

As seen in previous reports, infection was the leading indication for TLE in octogenarian patients (60.1%) (14)(16). This may represent increasing age as an important variable for developing CIED-related infections (16). Also, the octogenarian group of patients are likely to have had a greater number of device-related operations (such as generator changes for battery depletion) than their counterparts as their device dwell time is significantly longer. It is well established that an augmented number of operations increases the risk of infection (17). Device-related infection is associated with a high mortality risk if left untreated (14) and conservative management is often unsuccessful (2). It is also possible that the higher proportion of infection indication in the octogenarian group reflects referral bias - older patients with non-functional leads may undergo addition of a new lead rather than removal of the failed one, whereas infected hardware mandates extraction (16).

Complete procedural success was statistically similar in all groups. Propensity matching analysis also concluded that there was a similar success rate (procedural and clinical) across the age cohorts. This could in part be explained by the similar proportion of patients requiring the use of a rotational sheath (**figure 2**). The multivariate analyses highlighted the use of a rotational tool as an independent variate associated with success and it is well documented that these sheaths are highly effective and with a favourable safety profile (4). However, <50-years-old patients appeared to have a numerically lower rate of procedural success (92.5%) than the older population. Extraction at a younger age is associated with a higher failure rate likely due to heightened fibrous encapsulation of the leads (18). Further yet, this younger population had a significantly higher number of extracted ICD leads (**figure 2**) ($p<0.001$) which can be more challenging to extract owing to the adhesions encasing the coils (19). Importantly, the multivariate analyses performed with and without propensity matching, did not find age as a variate associated with procedural outcome. This is similar to findings of large TLE series (3) and suggests age itself should not be a limiting factor in performing extractions.

The percentage of minor complications was similar across all age cohorts in this study (p=0.75). This was consistent with prior evidence. Pelargonio et al reported minor complications of 4% in the elderly and 2.9% in younger adults (14). There was also no significant difference in major complications between the age groups, (p=0.38) although the trend is suggestive of a marginally higher rate in the <50 years and octogenarian ages **(figure 3)**. This was also the case with propensity matching (**table 3**). The multivariate analysis identified lead dwell time as a significant variate impacting complications. Elderly patients had a significantly longer lead dwell time (93.5 months, p=0.0014) than the younger subjects. This is balanced by the notably younger age and higher number of ICD leads in the <50 age group. These factors considerably promote an adhesive sheath encapsulating the leads, complicating the extraction process and negatively impacting outcomes (20) with higher incidences of complications. Commonly, the high degree of adhesions requires the use of powered sheaths for successful extraction **(figure 5)**, which also increases the risk of complications as indicated by our multivariate regression analysis.

Procedural mortality was extremely low with no meaningful difference between the age ranges (0-0.3%, p=0.75). This is comparable with other large series: ELECTRA, the largest European TLE registry revealed a procedural mortality 0.5% whilst Sood et al demonstrated a procedural mortality of 0.12% in a large North American registry (8). However, 30-day mortality in our study was significantly elevated in the octogenarian group (4.9%, p=0.005), and remained so when the cohorts were best matched with propensity matching analysis. This is in keeping with earlier reports (21) and is likely multifactorial. The higher rate of infection indication for TLE (60.1%, p<0.01), could partly explain the raised mortality figures in this subset. Both advanced age and infection indication are independently associated with long-term mortality in TLE (3)(22). This was reflected in the multivariate analysis and propensity matching within our study where patient age and the presence of systemic infection were independently associated with 30-day mortality. Another significant factor is lead dwell time which has been identified as a significant contributor to 30-day mortality, complications and procedural success. Patients ≥80 years of age in this study had a significantly longer lead dwell time than the other subgroups which in addition to patient age and infection, will have compounded the risk of mortality. This highlights the necessity for careful post-procedural management in this patient cohort as they are unlikely to perish from the procedure itself. In addition, lead dwell time was also identified as a significant influence on 30-day mortality in our study with and without propensity matching.

5. Limitations

The PROMET registry was derived from centres classified as high or medium volume for TLE and therefore the findings of this study may not be applicable to low volume centres or operators. Due to the retrospective nature of this study, confounding variables cannot be accounted for in full despite the propensity matching.

6. Conclusion

Transvenous lead extraction is safe and effective. Procedural outcomes in octogenarian patients are similar to those observed in younger patients. However, 30-day mortality is significantly higher in the older patient cohort which is likely multifactorial and indicates the need for careful post-procedural management of this subgroup. Based on our findings, advanced age alone should not preclude performing TLE.

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Table 1: Characteristics of patient groups

	Young group	Intermediate age group		Octogenarian	
	<50 years	**50-69 years**	**70-79 years**	**80+ years**	**p-value**
n=	322 (15.7%)	700 (34.1%)	659 (32.1%)	371 (18.1%)	
Average age (years)	37.7 ± 9.6	61.4 ± 5.6	75.9 ± 2.8	84.1 ± 3.7	
Leads extracted	499	1231	1146	654	<0.01
Right atrial leads	146	346	353	213	<0.01
Right ventricle leads	304	573	521	275	<0.01
Left ventricle leads	18	85	78	35	<0.01
Unknown leads	31	227	194	131	<0.01
LVEF (n=287)	38.1%	35.6%	40%	46.9%	<0.01
NYHA class (n=157) (%)					
1	33.3	14.9	30.6	11.8	0.14
2	12.5	17.9	24.5	29.4	0.14
3	29.2	50.7	26.5	47.1	0.14
4	25.0	16.4	18.4	11.8	0.14
Previous cardiac surgery (n=570) (%)	4.0	10.1	7.9	6.5	0.026
Indication TLE (%)					
Infection	33.2	40.4	44.8	60.1	<0.01
Non-functional lead	47.2	41.4	36.0	26.4	<0.01
Functional Lead	17.4	14.4	15.3	10.8	<0.01
Thrombosis	1.2	2.3	2.0	1.6	<0.01

Other	0.9	1.4	2.0	1.1	<0.01
Infection (n=507) (%)					
Local	62.0	52.2	58.8	67.2	0.09
Systemic	38.0	47.8	41.2	32.8	0.09
Lead dwell time (months)	80.8	77.0	84.0	93.5	0.0014
Procedure time (mins)	94.0	89.5	85.0	87.0	0.14
Complete procedural success (%)	92.5	94.6	94.8	94.3	0.5
Clinical success (%)	96.9	97.3	96.7	96.4	0.8

Table 2: Multivariate regression analyses, with and without propensity matching

Variables	**p-value**	**Odds ratio**	**LCL**	**UCL**
30-day mortality:				
Patient age	<0.001	1.059	1.026	1.093
High voltage lead	0.009	3.461	1.363	8.787
Infection indication	0.046	2.407	1.014	5.713
Use of rotational tool	0.049	0.459	0.212	0.995
Lead dwell time	0.012	1.007	1.002	1.012
Systemic infection	0.002	3.578	1.627	7.869
Clinical success:				
Use of rotational sheath	0.021	2.059	1.117	3.796
Lead dwell time	<0.001	0.989	0.985	0.993

Complications:				
Use of rotational sheath	0.016	1.942	1.129	3.34
Lead dwell time	<0.001	1.006	1.003	1.01
Clinical Success (Propensity matching):				
Systemic infection	0.02	0.276	0.093	0.817
Use of rotational sheath	0.01	3.578	1.296	9.88
Lead dwell time	0.00	0.983	0.977	0.99
Complications (Propensity matching):				
Gender	<0.001	3.602	1.587	8.174
Lead dwell time	<0.001	1.014	1.007	1.02

Greater lead dwell time reduced the likelihood of success, increased the risk of complications and 30-day mortality. Use of the rotational sheath improved the probability of clinical success and was associated with a lower risk of 30-day mortality. Age and Infection both increased the odds of 30-day mortality.

Table 3: Patient outcomes following propensity score matching

	<80 years	**80+ years**	***p-value***
Complete procedural success (per procedure**)**	93.5%	94.1%	0.76
Clinical Success (per procedure**)**	95.2%	96.3%	0.46
Procedural failure	2.5%	2%	0.61
Minor Complication	2.3%	3.1%	0.29
Major Complication	1.1%	1.4%	0.74
Perioperative mortality	0.6%	0.3%	0.56
30-day mortality	2.6%	5.4%	0.08

Outcomes following propensity matching demonstrated no significant difference in outcomes between the octogenarian and <80 years old population. There was a trend suggestive of a higher 30-day mortality in the octogenarian cohort although statistically insignificant (p=0.08).

Figure 1: Schematic diagram illustrating chronology of statistical analysis

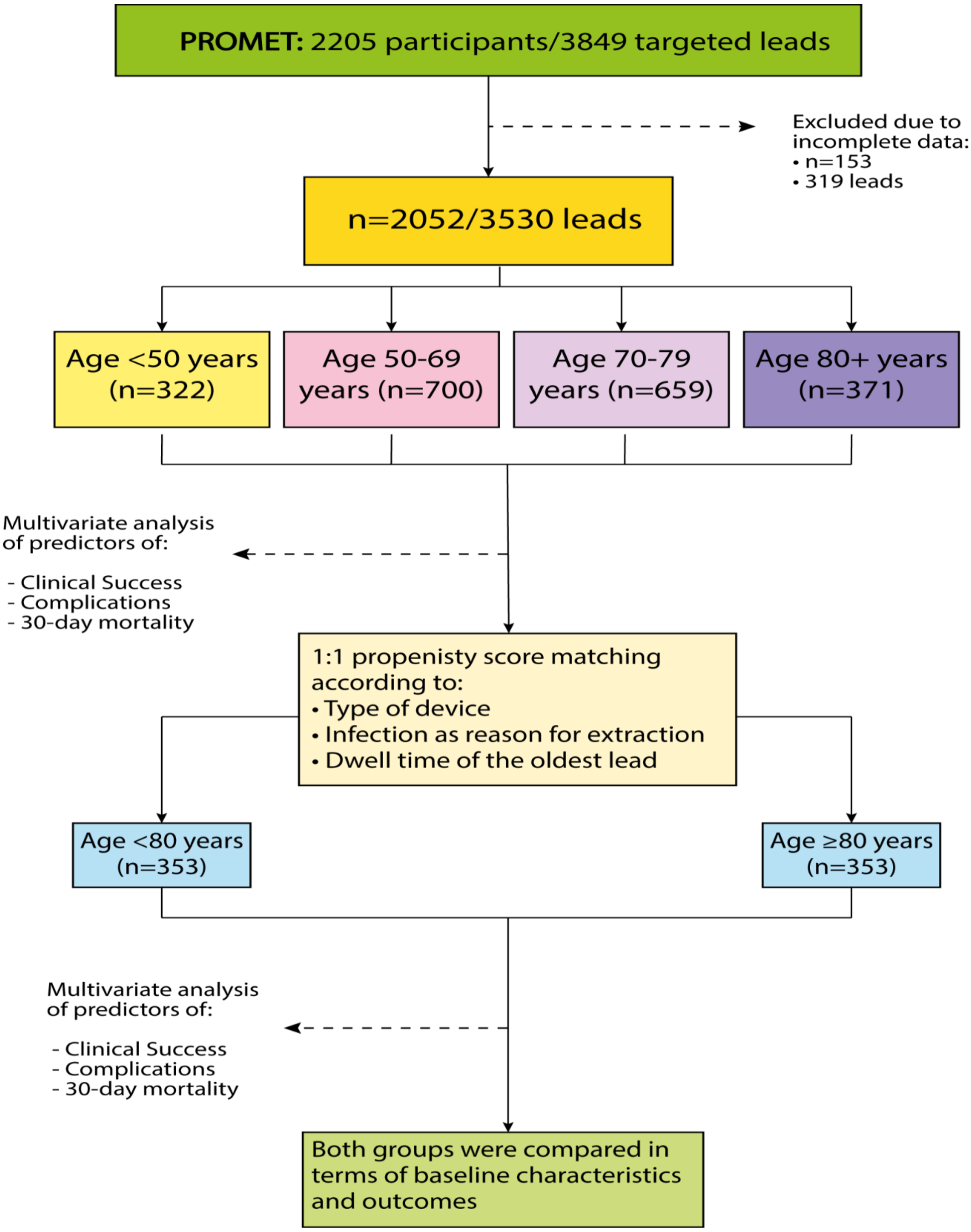

PROMET: 2205 participants/3849 targeted leads
Excluded due to incomplete data:
• n=153
• 319 leads
n=2052/3530 leads
Age <50 years (n=322)
Age 50-69 years (n=700)
Age 70-79 years (n=659)
Age 80+ years (n=371)
Multivariate analysis of predictors of:
- Clinical Success
- Complications
- 30-day mortality
1:1 propenisty score matching according to:
• Type of device
• Infection as reason for extraction
• Dwell time of the oldest lead
Age <80 years (n=353)
Age ≥80 years (n=353)
Multivariate analysis of predictors of:
- Clinical Success
- Complications
- 30-day mortality
Both groups were compared in terms of baseline characteristics and outcomes

Figure 2: Bar graph summarising population demographics

The gender distribution of patients undergoing extraction was similar across all age cohorts (p=0.18). ICDs accounted for a greater proportion of extraction procedures in younger patients (p<0.001) and passive fixation leads were significantly more prevalent in the octogenarian population (p=0.013). Extractions performed under general anaesthesia (GA) were significantly more numerous in the young patient group (p=0.001). Usage of rotational tool was similarly prevalent across all age groups (p=0.79).

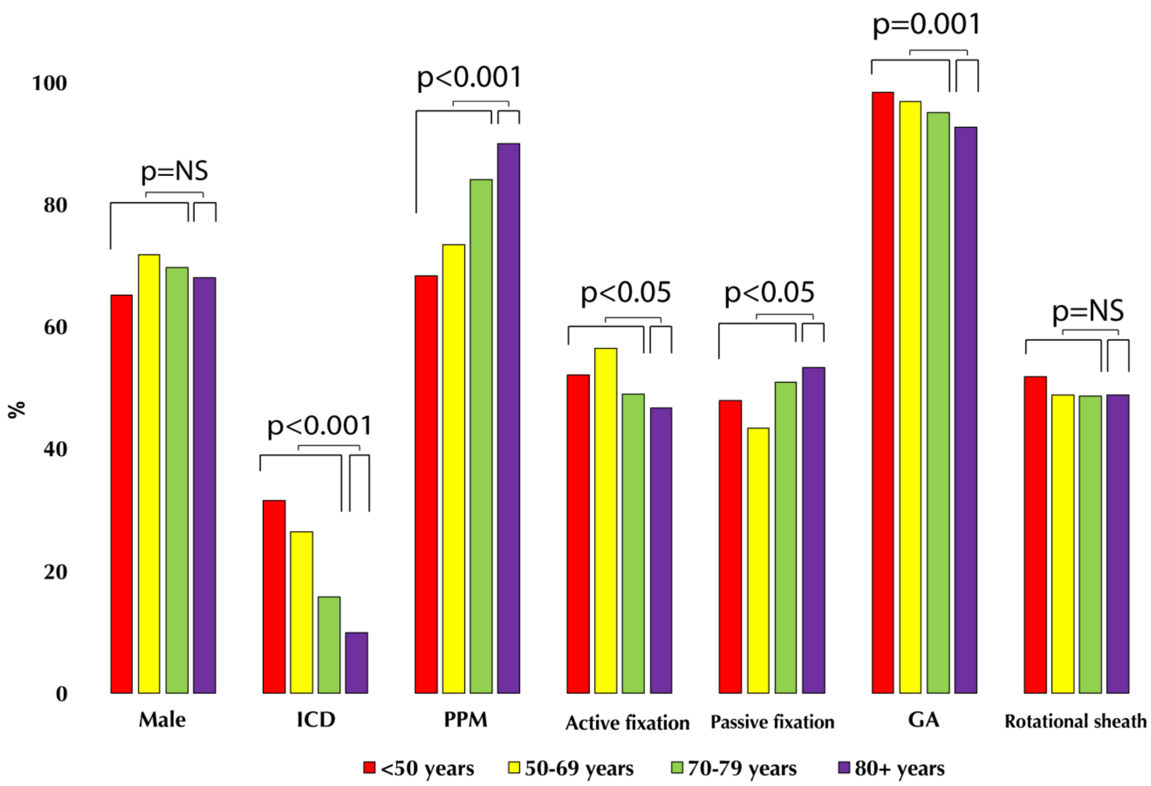


Figure 3: Bar graph demonstrating lead extraction outcomes across the age groups

Minor complications, major complications and procedural mortality were similarly low across all the age groups. There was a significantly higher proportion of 30-day mortality within the octogenarian cohort.

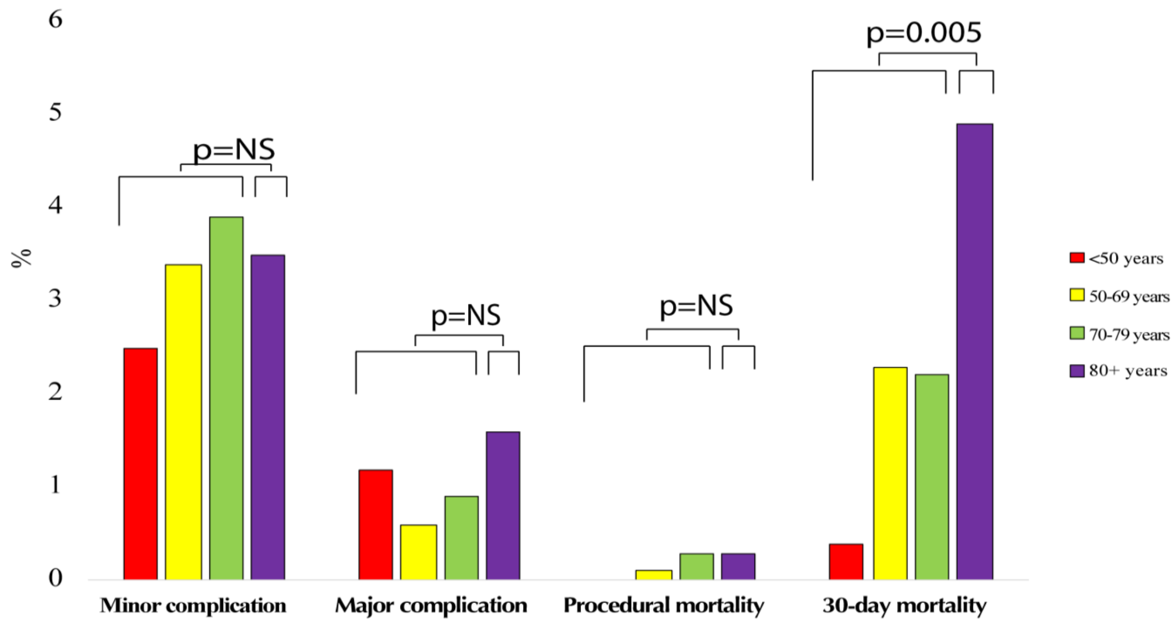
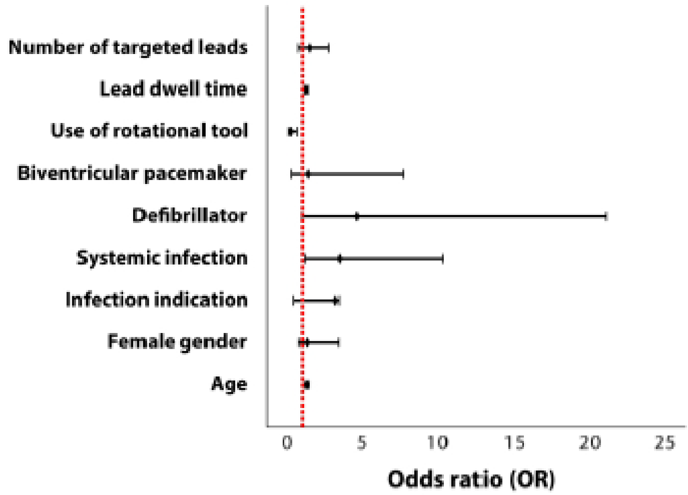


Figure 4: Multivariate analysis of factors associated with 30-day mortality (**propensity matching**)

The presence of systemic infection, older patient age and longer dwell time of the oldest lead were independently associated with a greater risk of mortality within 30 days of extraction. The use of rotational tool was associated with a lower 30-day mortality.



	OR	95% CI	p -value
Number of targeted leads	1.496	0.83 - 2.705	0.183
Lead dwell time	1.01	1.003 - 1.02	0.007
Use of rotational tool	0.226	0.07 - 0.75	0.015
Biventricular pacemaker	1.396	0.25 - 7.69	0.702
Defibrillator	4.61	0.97 - 22.1	0.055
Systemic infection	3.471	1.16 - 10.35	0.026
Infection indication	3.254	0.51 - 3.41	0.564
Female gender	1.322	0.86 - 12.3	0.082
Age	1.064	1.013 - 1.12	0.013

Figure 5: Composite illustration of transvenous lead extractions

A) The use of rotational sheath (arrow) to extract a passive fixation ventricular lead in a patient aged 92 years. **B)** Passive fixation atrial lead successfully extracted from a nonagenarian with a rotational sheath (arrow). **C)** Challenging extraction of a lead with adhesions at the innominate vein despite the use of a rotational tool (arrow) in this octogenarian patient. **D)** Successful extraction of a passive fixation lead using the rotational sheath in this 90-year-old patient with a calcified aorta. **E)** A rotational sheath assisted extraction (arrow) in this 88-year-old patient with a calcified trachea. **F)** Use of the Byrd workstation and with a Needle's Eye snare (arrow) to complete extraction in this 85-year-old lady via the femoral approach.