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Influence of proton pump inhibitors on the incidence and clinical course of oesophageal fistula following catheter ablation for atrial fibrillation: a subanalysis of the POTTER-AF study

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Introduction

Atrial fibrillation (AF) represents the most common cardiac arrhythmia with an increasing incidence and prevalence worldwide.¹ Pulmonary vein isolation (PVI) via catheter ablation is the cornerstone of AF treatment.¹ Despite years of experience and significant technological advances, oesophageal fistula (OF) remains the most severe complication of catheter ablation for AF, associated with high morbidity and mortality.^{2,3} The POTTER-AF study reported a very low incidence of 0.025%.² Therefore, data on effective preventive measures remain limited. Despite the lack of evidence, proton pump inhibitor (PPI) therapy is a widely adopted prophylactic treatment.^{4,5} While PPIs are considered to be generally well tolerated, recent studies have demonstrated relevant pharmacological interactions and adverse effects, warranting a cautious prescription.⁶ The aim of this study was to evaluate the impact of routine PPI use on the incidence and clinical course of OF in the POTTER-AF study.

Methods

All patients diagnosed with an OF from the POTTER-AF study were stratified based on the use of post-procedural PPI.

Normally distributed variables are reported as mean \pm standard deviation. Non-normally distributed variables are shown as median and inter-quartile range. The unpaired Student's *t*-test was conducted for group comparisons if normally, and the Mann-Whitney *U* test if non-normally distributed. Categorical variables are displayed as absolute numbers and relative frequencies and were compared using Fisher's exact test.

Results

Routine proton pump inhibitor prescription

Of the participating centres, 195 of 214 had available data on institutional routine post-procedural PPI prescription. In 155 centres (79.5%), patients were routinely treated with PPI after an AF ablation procedure. The mean rate of OF in those centres was 0.023% \pm 0.053%, compared to 0.024% \pm 0.067% in centres without routine PPI treatment ($P = 0.842$; Figure 1A).

Throughout the study period, we observed an increase in PPI prescription in the cohort of OF patients, rising from 30% before 2009 to 93% after 2018 (Figure 1B).

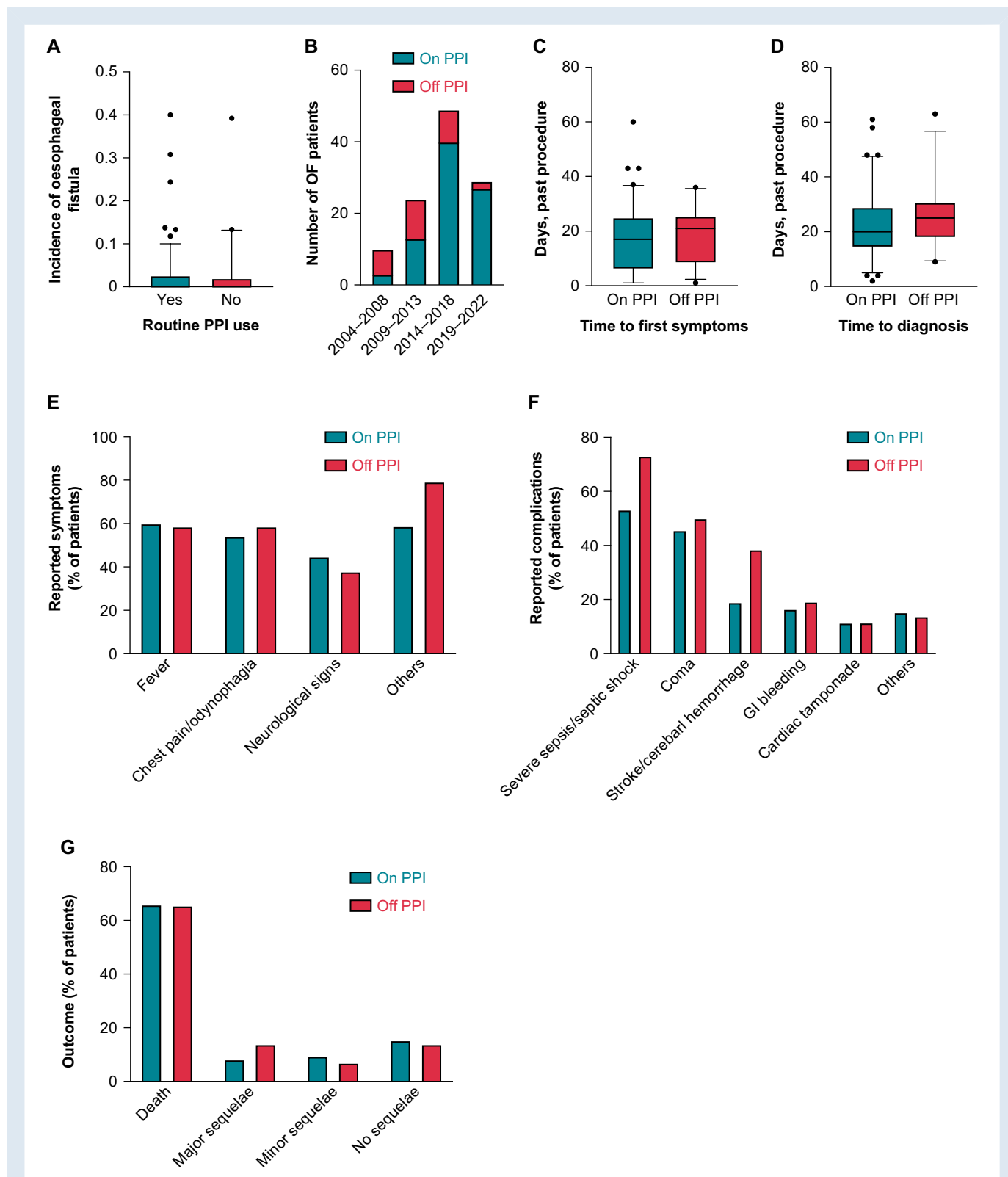


Figure 1 (A) Incidence of OF in relation to institutional routine post-procedural PPI treatment. Data points represent individual institutions. (B) Development of PPI prescription in OF patients over time. Displayed are numbers of OF patients with and without PPI prescription in indicated time frames. (C and D) Time to first symptoms (C) and time to diagnosis (D). Data points represent individual patients. (E) Overview of symptoms on first clinical presentation. (F) Overview of complications. (G) Overview of the outcome of all patients with OF. PPI, proton pump inhibitor; GI, gastrointestinal. The bottom and top edges of the box plots represent the 25th and 75th percentiles, and the lower and upper whiskers give the 5th and 95th percentiles, respectively. The lines within the boxes indicate the median values.

Patient population

Data on periprocedural characteristics, management, outcome and information on post-procedural PPI prescription were available for 114 patients with OF. Patients had a mean age of 62.5 ± 11.4 years. Paroxysmal, persistent, and long-standing persistent AF were present in 43%, 50%, and 7% of patients, respectively. Eighty-five patients (75%) were treated with PPI after the ablation procedure. The proportion of female patients was significantly lower in the cohort with PPI compared to the group without (41.2% vs. 67.9%, $P = 0.017$). No other differences were noted.

The energy source used was radiofrequency in 96.5%, cryoballoon in 2.6%, and laser balloon in 0.6% of patients, with no significant differences between the groups. Contact force measuring catheters were used more often in the 'on PPI' group (56.3% vs. 17.2%, $P < 0.001$). Additional linear ablations in the left atrium were performed in 45.7% of patients.

Patient presentation

The median time between procedure and onset of symptoms was comparable between groups (17.0 (6.0, 25.0) days vs. 21.0 (8.3, 25.5) days for patients 'on PPI' and 'off PPI', respectively, $P = 0.177$; Figure 1C). Similarly, the median time to diagnosis was 20.0 (14.3, 29.0) days in patients treated with PPI and 25.0 (17.8, 30.8) days in those without ($P = 0.123$; Figure 1D).

The primary initial symptoms in patients with and without PPI treatment included fever (60.0% vs. 58.6%, $P = 1.00$), chest pain or odynophagia (54.1% vs. 58.6%, $P = 0.829$), neurological symptoms (stroke or seizures) (44.7% vs. 37.9%, $P = 0.665$), and others (58.8% vs. 79.3%, $P = 0.072$) (Figure 1E).

Complications and outcome

The complication rate did not differ between patients treated with PPI compared to those without (Figure 1F). Most frequently observed were severe sepsis or septic shock (53.2% vs. 73.1%, $P = 0.108$), coma (45.6% vs. 50.0%, $P = 0.821$), stroke or cerebral haemorrhage (19.0% vs. 38.5%, $P = 0.062$), gastrointestinal bleeding (16.5% vs. 19.2%, $P = 0.768$), cardiac tamponade (11.4% vs. 11.5%, $P = 1.00$), or others (15.3% vs. 13.8%, $P = 0.222$).

Mortality was high and comparable in both groups (65.9% for patients 'on PPI' vs. 65.5% for patients 'off PPI', $P = 1.00$; Figure 1G). A total of 7/85 (8.2%) vs. 4/29 (13.8%) and 8/85 (9.4%) vs. 2/29 (6.9%) patients experienced major or minor sequelae, respectively ($P = 0.467$ and $P = 1.00$). Only 13/85 (15.3%) vs. 4/29 (13.8%) patients had no sequelae ($P = 1.00$).

Discussion

The key findings of the study are as follows:

- (1) The incidence of OF did not differ between centres with and without post-procedural PPI prescription.
- (2) Patients with and without PPI had comparable time to symptom onset, complication rate, and mortality.
- (3) The use of PPI following AF ablation has significantly increased over time.

Proton pump inhibitors are widely prescribed after left atrial ablation procedures to reduce gastric acidity, as gastroesophageal reflux is thought to contribute to the progression of ablation-induced oesophageal lesions and OF formation.^{4,5,7,8} Beyond potential prevention, PPI therapy might influence the time course and clinical presentation of OF. However, no difference in OF incidence was observed between centres with or without routine PPI use. Similarly, a study from Ugata et al.⁹ showed no reduction of mortality or severe oesophageal injury with prophylactic PPI. A recent substudy of the MADE-PVI trial suggested a protective effect in

patients with pre-existing reflux oesophagitis.¹⁰ Nevertheless, no definite conclusions can be drawn from those observational or *post hoc* analyses, and no additional evidence supports or contradicts the use of PPI therapy.⁸ As the present study is a retrospective analysis exclusively in patients with OF, the independent and causal influence of post-procedural PPI prescription on the incidence of OF cannot be evaluated.

We observed comparable time to first symptoms, time to diagnosis, symptom burden, complications, and outcome, altogether questioning the effectiveness of PPI in OF prevention. Nevertheless, despite the lack of randomized data, empirical PPI treatment remains a reasonable approach due to its low cost and favourable safety profile, at least for thermal ablations. But trade-offs including relevant pharmacological interactions and an increased risk of infections should be considered.⁶

Limitations

The retrospective nature of the study bears known limitations. Possible practice changes in routine PPI prescription during the observational period were not evaluated. The details on PPI therapy are not known and might have changed over the observational period.

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IRB information

The POTTER-AF study was approved by the Ethics Commission of the University of Luebeck (reference number: AZ 21–291).

Conflict of interest: R.R.T. is a consultant for Boston Scientific, Philips, Medtronic, Biosense Webster, and Abbott Medical; is a shareholder and medical director for Active Health; had received speaker honoraria from Boston Scientific, Biotronik, Biosense Webster, Abbott Medical, Lifetech, and Pfizer; has received research grants from Abbott, Biotronik, Medtronic, Biosense Webster, and Lifetech; and has received travel grants from Abbott, Biosense Webster, Boston Scientific, Medtronic, and Philips. S.S.P. is a medical consultant by Active Health and has received travel grants and congress grants from Lifetech and educational grants and a speaker grant from Abbott Medical. T.B. discloses speaking honoraria and travel expenses from Abbott, Biosense Webster, Biotronik, Boehringer Ingelheim, Boston Scientific, Bristol Myers Squibb, Medtronic, Pfizer, and Zoll, outside the submitted work. K.-H.K. reports grants and personal fees from Abbott Vascular, Medtronic, and Biosense Webster, outside the submitted work. C.-H.H. received travel grants and research grants from Abbott, Haemonetics, Boston Scientific, Lifetech, Biosense Webster, and Cardiofocus and speaker honoraria from Haemonetics, Medtronic, Abbott, Boston Scientific, Novartis, Pfizer, Biosense Webster, Cardiofocus, C.T.I. GmbH, and Doctrina Med. He is a consultant of Boston Scientific, Lifetech, Haemonetics, Biosense Webster, and Cardiofocus. J.V. received speaker honoraria from Abbott, Boston Scientific, Impulse Dynamics, Pfizer, and Doctrina Med. H.P. received honoraria or consultation fees from Bayer, Daiichi Sankyo, Boehringer Ingelheim, Pfizer, Abbott, Biosense Webster, Boston Scientific, and Medtronic and participated in a company sponsored speaker's bureau for Biosense Webster, Abbott, Medtronic, and Boston. M.M. is a consultant and speaker of Abbott Medical, Biosense Webster, Medtronic, and Boston Scientific. P.S. served on advisory boards for Biosense Webster, Boston Scientific, Abbott, and Medtronic. C.S. received research support and lecture fees from Medtronic, Abbott, Boston Scientific, and Biosense Webster. In addition, C.S. is a consultant for Medtronic, Boston Scientific, and Biosense Webster. C.V. received consulting honoraria from Biotronik and Medtronic and training and speaker's honoraria from Medtronic, BMS, and Zoll. S.W. received consulting fees from Abbott, Biosense Webster, Boston Scientific, Bristol Myers Squibb, Boehringer Ingelheim,

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Data availability

Data supporting the POTTER-AF study are curated at the Study Centre of the Department of Rhythmology, University Hospital Schleswig-Holstein, Germany. These data are not shared openly but are available on reasonable request from the corresponding authors.

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