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Ttile: Estimated Prevalences of Serious Adverse Events Associated With the AtriClip Device for Left Atrial Appendage Occlusion

To the Editor,

Contractor et al recently reported the adverse events associated with the AtriClip device (Atricure, West Chester, OH) which is used for left atrial appendage exclusion during cardiac surgery, either via median sternotomy or thoracoscopic access (1). They provided interesting data on various adverse events related to the use of this device between December 1, 2015 and November 30, 2021, obtained from the FDA's MAUDE (Manufacturer and User Facility Device Experience) database.

Whilst the data provide useful information on the proportions of the different types of complications, they lack information on the *prevalence* of the adverse events. Consequently, concerns about safety have been raised about the use of the AtriClip. Accordingly, we obtained information on the denominator from AtriCure. During the timeframe of the study, a total of circa 274,000 AtriClips were sold (of which around 41,000 were probably deployed thoracoscopically).

Although a large proportion (75%) of the adverse events were related to technical failures of the device (1), it is reasonable to assume that these would be less likely with the more recent models of the AtriClip.

Under-reporting of adverse events in medicine is well-recognised and must be accounted for, with around a 200-fold fold-factor of under-reporting of device failures (2); more serious adverse events are more likely to be reported than less serious ones. Hence, adjusting for a 100-fold factor of under-reporting of serious adverse events (unrelated to device failure) with the AtriClip, provides the following *prevalences*: 0.5% for perforation/bleeding, 0.2-0.3% for conversion to open sternotomy, and 0.2% for collateral injury. Under-reporting of death is far less likely and assuming a 10-fold factor gives a prevalence of 0.01%. These findings are consistent with those from a systematic review, which found the AtriClip device to be safe and effective (3). In our experience of deploying the AtriClip via a thoracoscopic approach, to date we have not encountered any complications of perforation, coronary artery damage or death.

1) Contractor T, Bhardwaj R, Mandapati R, et al. Adverse events associated with the AtriClip device for left atrial appendage occlusion: A Food and Drug Administration MAUDE database study. Heart Rhythm 2022;19:1204–1205.
2) Frederic SR and Sharon-Lise TN. Postmarketing Surveillance of Medical Devices — Filling in the Gaps. N Engl J Med 2012;366(10):875-7.
3) Toale C, Fitzmaurice GJ, Eaton D, et al. Outcomes of left atrial appendage occlusion using the AtriClip device: a systematic review. Interact Cardiovasc Thorac Surg. 2019;29:655–662.