DH-02 Stethee™ versus Littmann®: A Randomised, Crossover, Non-Inferiority Trial

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Introduction

Stethee™, a wireless digital stethoscope, was designed to amplify heart sounds, and aid diagnostic analytics via its artificial intelligence module. However, its basic capability in comparison to Littmann®, the widely used conventional stethoscope, is not known.

Methodology

In this randomised, open-label, two-period crossover, non-inferiority trial, non-specialist doctors with no more than 6 years in practice post-house officer training, were randomly allocated (1:1) to Stethee™ first group or Littmann® first group to auscultate a set of 10 heart sounds simulated by an auscultation manikin **(Fig. 1)**. They were also asked about their preference for stethoscopes in terms of ease of use, audio clarity, and diagnostic accuracy.

The primary endpoint was the % difference of correctly identified heart sounds, with a non-inferiority (NI) margin of 10%.[1] The secondary endpoint was the % difference of correctly identified cardiac diagnoses.

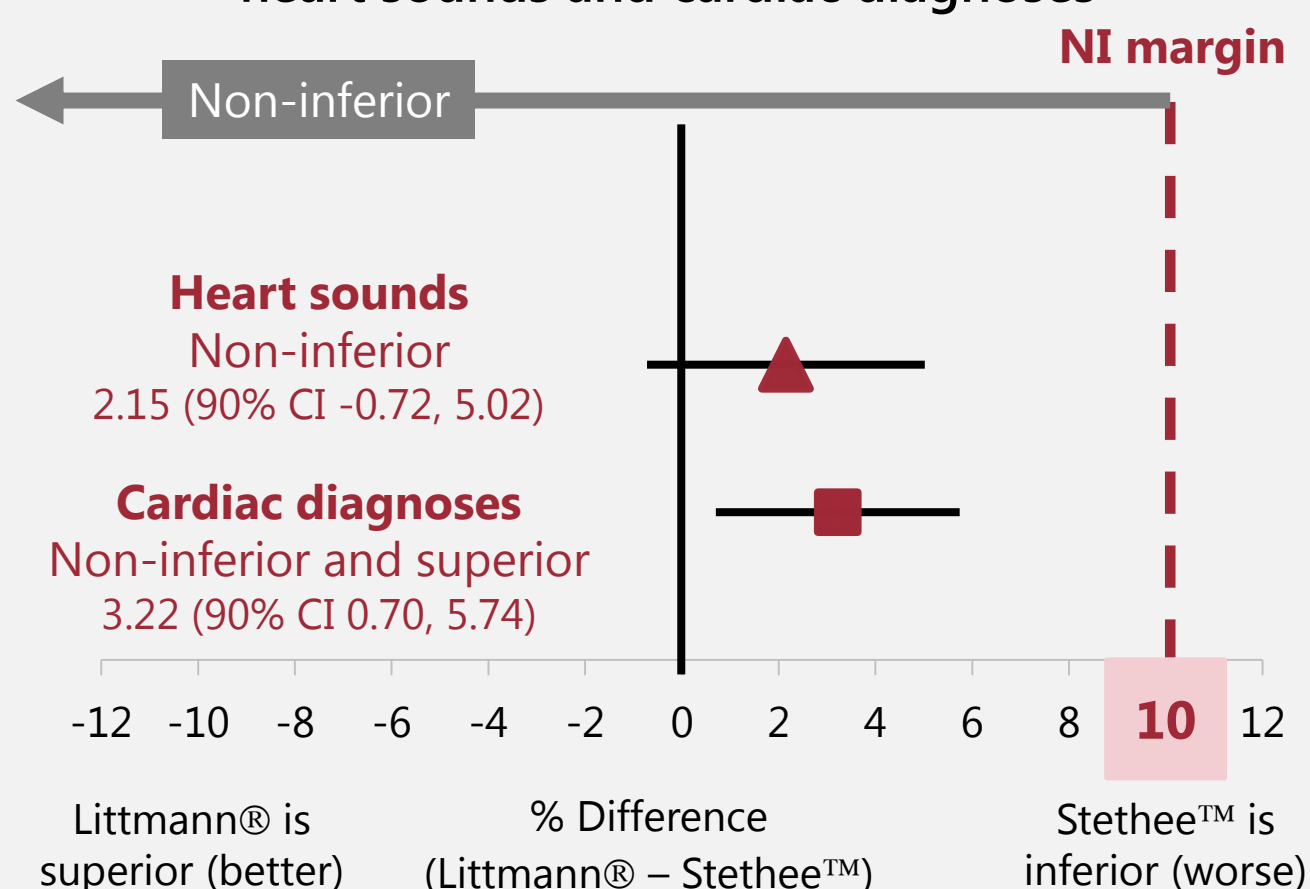### Fig. 1: Crossover design and participant flow
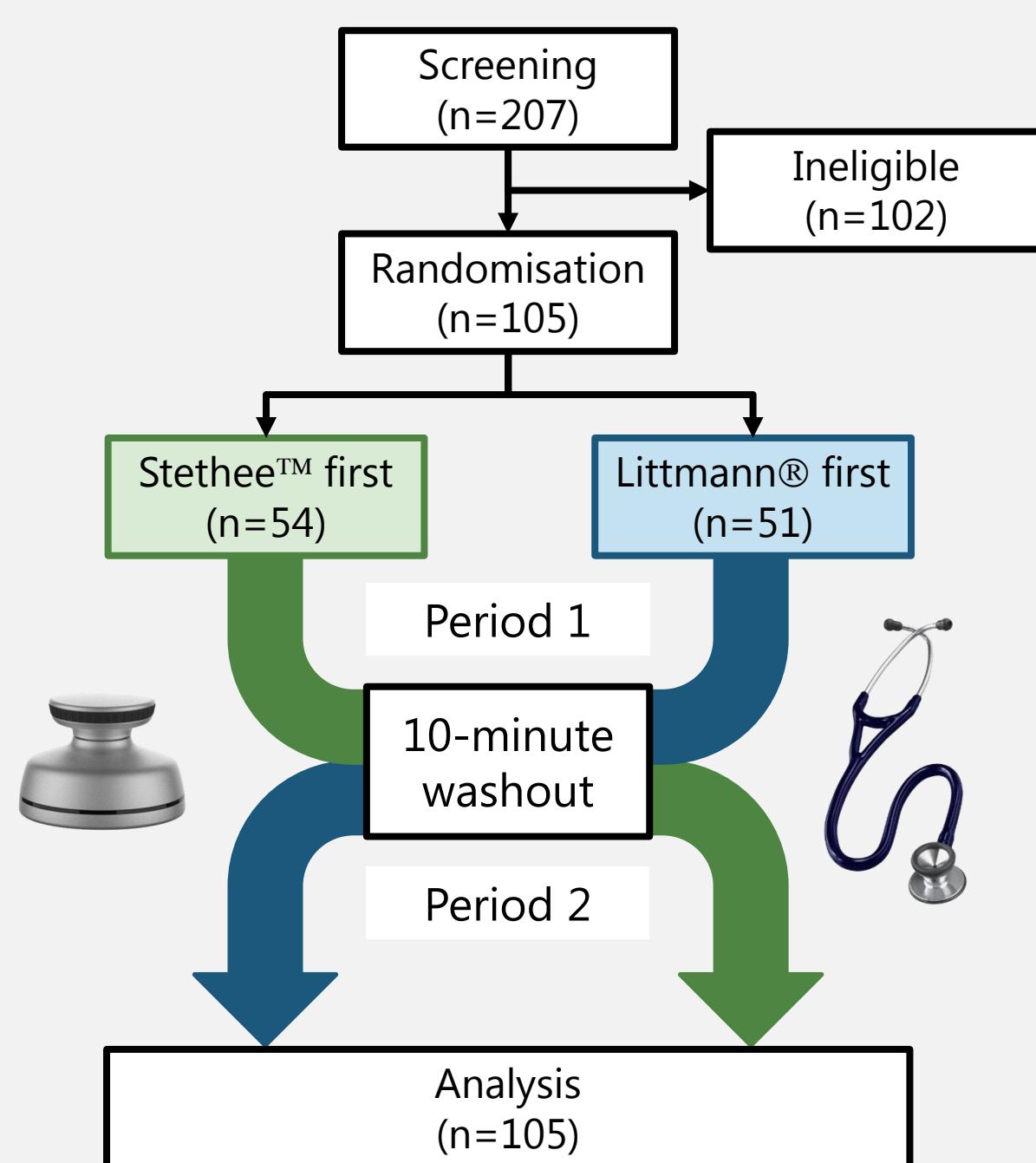
Results

A total of 207 doctors were screened, of whom 105 were randomised and analysed. The Stethee™ first group had a larger number of longer serving doctors, compared to the Littmann® first group **(Table 1)**.
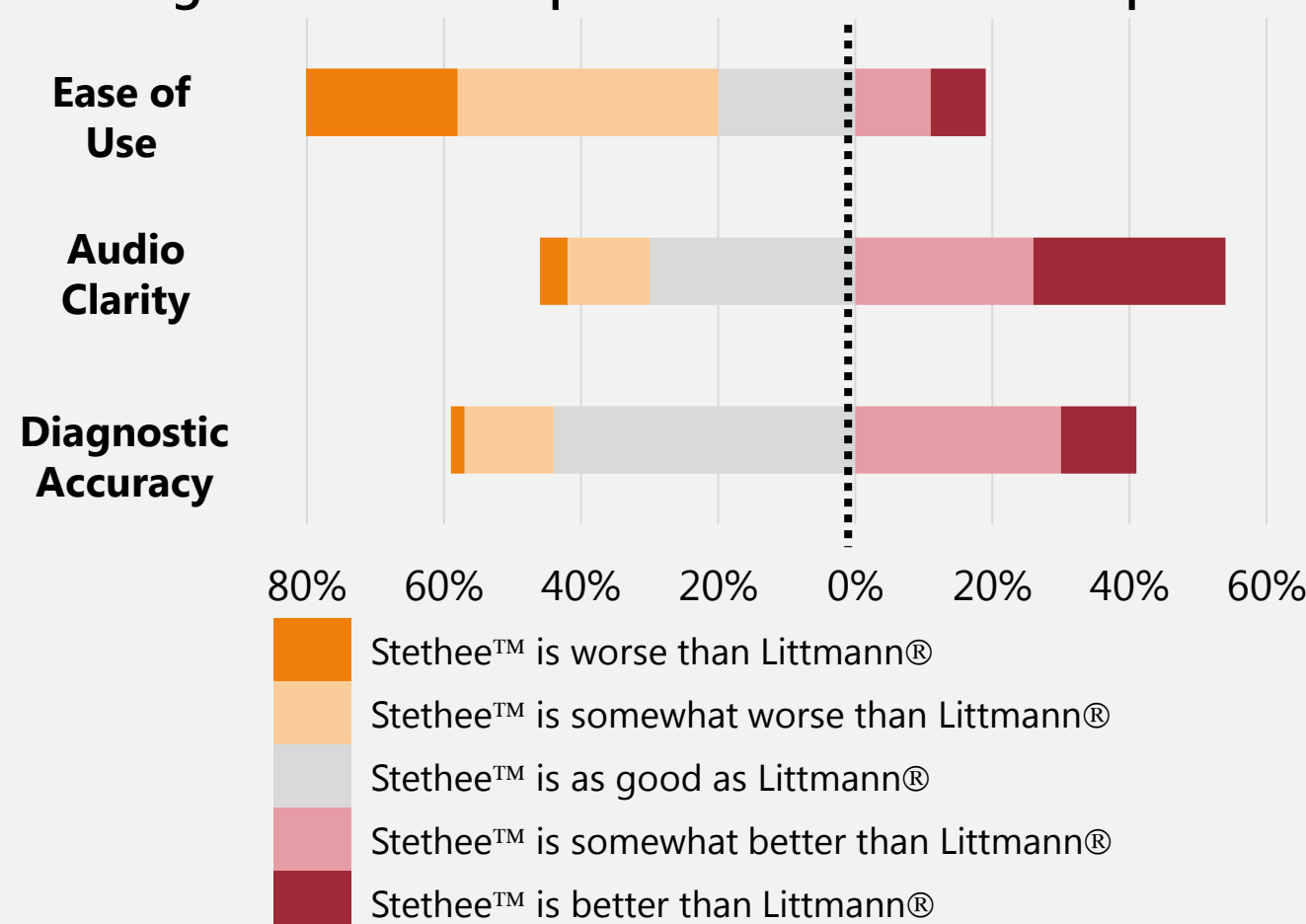
Table 1: Characteristics of the study population

	Stethee™ first (n=54)	Littmann® first (n=51)
Female doctor	59%	61%
≥2 years in practice	**69%**	**51%**
Previous Cardiology rotation	6%	6%
Taking postgrad specialist exam	26%	20%

Fig. 2: Stethee™ versus Littmann® for identification of heart sounds and cardiac diagnoses

Heart sounds
Non-inferior
2.15 (90% CI -0.72, 5.02)

Cardiac diagnoses
Non-inferior and superior
3.22 (90% CI 0.70, 5.74)

Littmann® is superior (better) — % Difference (Littmann® − Stethee™) — Stethee™ is inferior (worse)

Both heart sounds and cardiac diagnoses intervals lie to the **left of the NI margin**, indicating **non-inferiority**.[2]
The cardiac diagnoses interval also **does not cross zero**, indicating **superiority** (in addition to non-inferiority).[2]

Fig. 3: User-rated preference for stethoscope

- Stethee™ is worse than Littmann®
- Stethee™ is somewhat worse than Littmann®
- Stethee™ is as good as Littmann®
- Stethee™ is somewhat better than Littmann®
- Stethee™ is better than Littmann®

Only **19%** doctors rated Stethee™ as **easier to use** than Littmann®. However, **53% and 41%** rated Stethee™ as having **better sound clarity and diagnostic accuracy** than Littmann®, respectively.

Discussion/Conclusion

Stethee™ is **non-inferior to (not worse than)** Littmann® for identifying heart sounds and cardiac diagnoses. Doctors preferred Stethee™ for its **audio quality and diagnostic accuracy**, but found it **less user-friendly** than Littmann®. Further evaluation of the diagnostic accuracy of Stethee™ in specific patient populations will be needed prior to its adoption in clinical practice.

References

1. Nielsen T, Mølgaard H, Ringsted C, Eika B. The development of a new cardiac auscultation test: How do screening and diagnostic skills differ?. Med Teach 2010;32(1):56-61.
2. Committee for Proprietary Medicinal Products (CPMP). Points to consider on switching between superiority and non-inferiority. Br J Clin Pharmacol 2001;52:223-8.

Acknowledgements