Interim results of a clinical and economic evaluation of a rapid AST system – the LIFETIMES study

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The LIFETIMES study

Health and Economic Outcomes Research (HEOR) studies determine whether a new intervention outweighs existing treatments in terms of both cost and health outcomes¹.

The ongoing LIFETIMES HEOR study is a prospective, interventional investigation of the clinical impact of ASTar[®], Q-linea's rapid AST system², when treating patients with a Gram-negative bloodstream infection (BSI). Timely and cost-effective Antimicrobial Susceptibility Testing (AST) is crucial for effectively treating these patients^{3–6}. In this study, clinicians act upon ASTar results by changing the antibiotic course or confirming appropriate empiric therapy. Here, we present interim data from the LIFETIMES study.

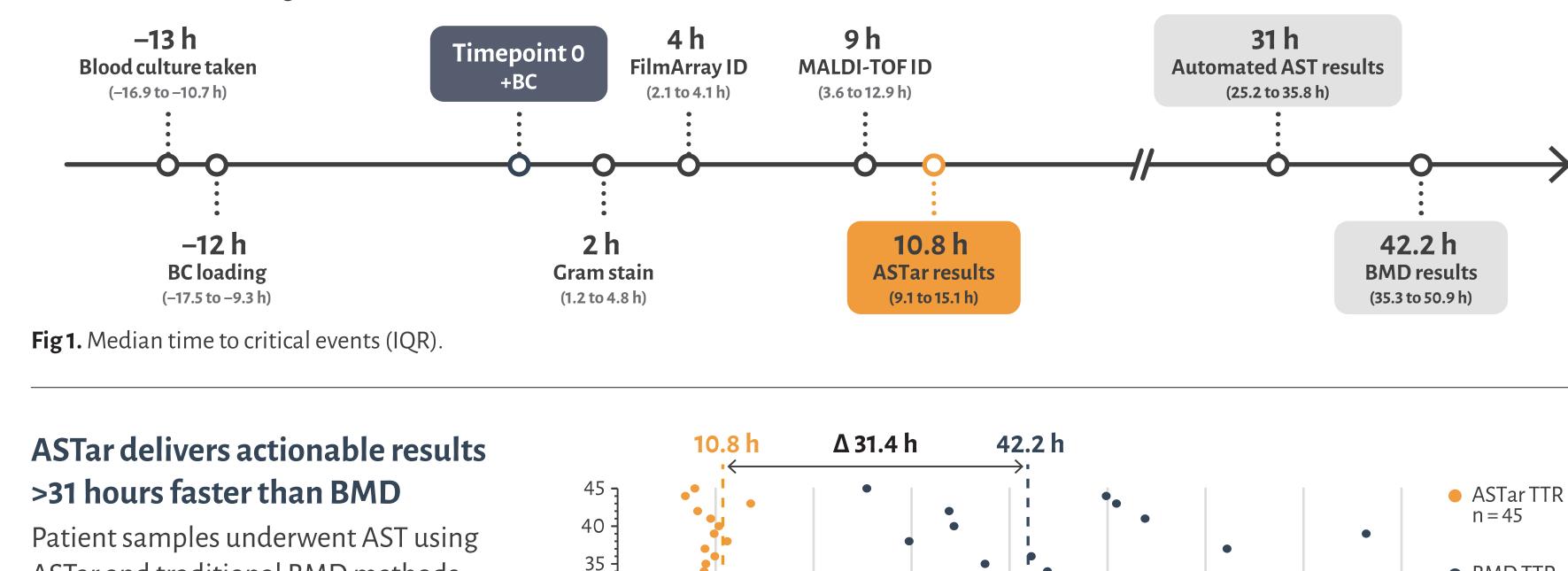
Conclusion

- ASTar had an impact on 14 out of 30 patients (47%)
- ASTar shortens the median time from positive blood culture to AST result by 31.4 hours when compared to traditional BMD and 20 hours when compared to other automated systems
- ASTar performance aligns with traditional BMD overall EA and CA >90%

Results

ASTar expedites the clinical workflow

For 30 patients with complete case reports and 28-day follow-up, the median time was calculated for all critical hospital and laboratory events. Interquartile ranges (IQR) are in brackets. ASTar delivers actionable results significantly faster than other automated AST methods or traditional BMD (Fig 1).



ASTar performs above 94% total EA and above 94% total CA

ASTar MIC data was interpreted and assessed using EUCAST breakpoints and maintained a high agreement with reference BMD methods. The measured total EA was 94.5%, CA was 94.8%, and error rates were within the acceptable range (<3%) (Table 1 and 2).

Table 1. Overall performance data. Essential Agreement (EA), CategoricalAgreement (CA), Very Major Discrepancy (VMD), and Major Discrepancy (MD).

| ASTar vs. traditional BMD | | | | |
|---------------------------|-----------------|------------------|-----------------|--|
| EA #/tot (%) | CA #/tot (%) | VMD #/tot (%) | MD #/tot (%) | |
| 534/565 (94.5%) | 526/555 (94.8%) | 1/91 (1.1%) | 8/436 (1.8%) | |

Table 2. Performance data for all antibiotics used in the study.

| Antimicrobial agent | ASTar vs. traditional BMD | |
|-------------------------------|---------------------------|---------------|
| | EA #/tot (%) | CA #/tot (%) |
| Amikacin | 41/44 (93.2%) | 42/44 (95.5%) |
| Amoxicillin-Clavulanic acid | 18/21 (85.7%) | 18/21 (85.7%) |
| Ampicillin | 2/2 (100%) | 2/2 (100%) |
| Aztreonam | 9/9 (100%) | 9/9 (100%) |
| Cefepime | 33/35 (94.3%) | 32/35 (91.4%) |
| Cefotaxime | 6/6 (100%) | 6/6 (100%) |
| Ceftazidime | 31/38 (81.6%) | 30/38 (78.9%) |
| Ceftazidime-Avibactam | 38/41 (92.7%) | 40/41 (97.6%) |
| Ceftolozane-Tazobactam | 39/40 (97.5%) | 40/40 (100%) |
| Ceftriaxone | 24/26 (92.3%) | 26/26 (100%) |
| Cefuroxime | 3/3 (100%) | 3/3 (100%) |
| Ciprofloxacin | 40/43 (93.0%) | 40/43 (93.0%) |
| Colistin | 15/17 (88.2%) | 17/17 (100%) |
| Ertapenem | 27/27 (100%) | 27/27 (100%) |
| Gentamicin | 32/33 (97.0%) | 33/33 (100%) |
| Levofloxacin | 31/31 (100%) | 20/23 (87.0%) |
| Meropenem | 43/45 (95.6%) | 42/45 (93.3%) |
| Piperacillin-Tazobactam | 40/41 (97.6%) | 38/41 (92.7%) |
| Tigecycline | 6/6 (100%) | 6/6 (100%) |
| Tobramycin | 20/21 (95.2%) | 20/21 (95.2%) |
| Trimethoprim-Sulfamethoxazole | 36/36 (100%) | 36/36 (100%) |

Median times from positive blood culture bottle (+BC) to AST results were compared between the paired samples. Median time (IQR) from positive BCB to ASTar results: 10.8 (6.3 to 20.9) h. Median time (IQR) from positive BCB to BMD results: 42.2 (25.1 to 82.0) h. The overall median time difference between methods was 31.4 h (Fig 2).

ASTar and traditional BMD methods.

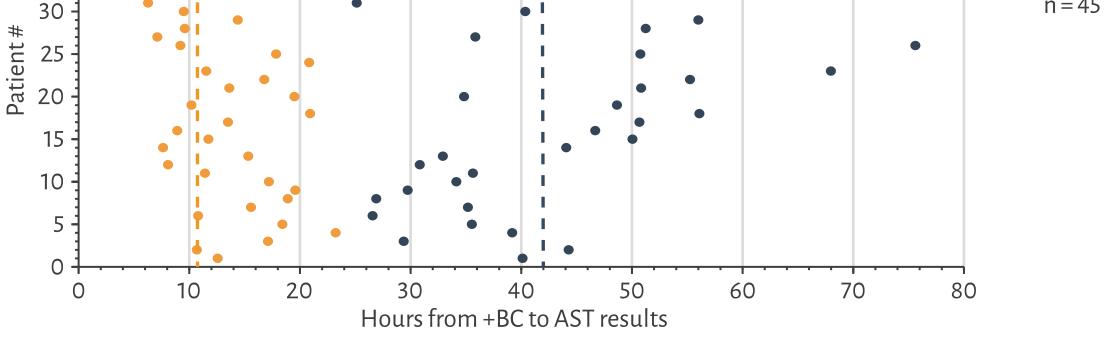


Fig 2. Paired patient samples from ASTar and BMD AST. Median time (IQR) from +BC to AST results.

ASTar drove antibiotic change in 47% of patient cases

We investigated how timely AST results via ASTar influenced treatment adjustment. In 47% of patients (14/30), ASTar prompted antibiotic changes, with the specific type of change dependent on the individual case. As demonstrated, ASTar can guide multiple types of antibiotic adjustment. In 53% of patients (16/30), ASTar confirmed prior therapy (Fig 3).

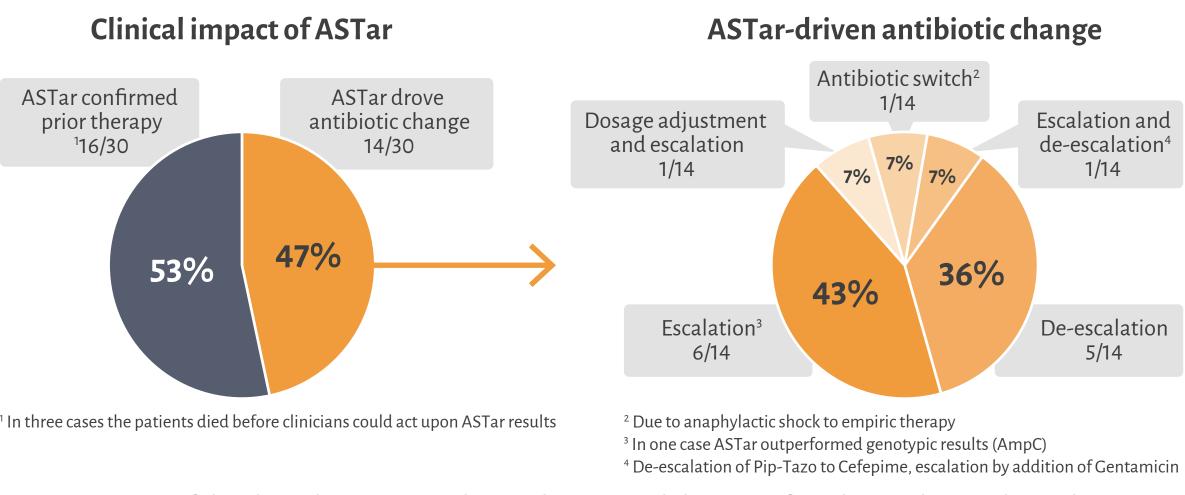


Fig 3. Overview of the clinical impact (antibiotic change) and the type of antibiotic change driven by ASTar.

Materials and methods

References

• BMD TTR

- The HEOR study spans four sites across Italy, a country with high rates of antimicrobial resistance
- ICU patients with a Gram-negative BSI are prospectively enrolled in this study. 45/160 patients are enrolled thus far all of which were used for performance evaluation and 30 of which were used for clinical impact evaluation
- AST results from ASTar and standard of care (BMD) methods have been compared
- MICs are interpreted following EUCAST clinical breakpoints version 13.07

Primary objectives: measure time to optimal antimicrobial therapy or time to awareness of appropriate non-modifiable empiric therapy.

Secondary assessments: time saved, type of treatment adjustment, and duration of antimicrobial therapy.

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