Autonomous Blood Draw Device: Interim results from A.D.O.P.T. Trial

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A.D.O.P.T.

Autonomous Blood Drawing Optimization and Performance Testing

Background and Methods

Worldwide, clinical laboratories face challenging phlebotomist shortages. Phlebotomy automation presents a promising solution to help ensuring access to care while optimizing quality of care.
Vitestro develops a medical device that can autonomously perform blood draws, using near-infrared and ultrasound to detect a vein in real-time. The full venipuncture procedure is automated, from applying a tourniquet to placing a bandage.

In the A.D.O.P.T. trial, this premarket technology is iteratively being tested in >10,000 patients across subsequent Study Phases (A, B1, B2, C1, C2). (*ClinicalTrials.gov: NCT05878483*)

This poster reports on unpublished data from the A.D.O.P.T. trial, collected in a subsequent number of 609 patients included in Phase B1 and C1-1. Phase B1 was a study to demonstrate the non-inferiority of the blood draw device for CE-marking. Phase C1 part 1 (denoted as C1-1) was the first follow-up study after the CE-marking study was successfully completed.

Study Phase

- A
- **B1**
- **C1-1**
- B2
- C2

Design
- Single-arm
- Non-inferiority (Phase B1)

Sample size
- 350 patients (Phase B1)
- 259 patients (Phase C1-1)

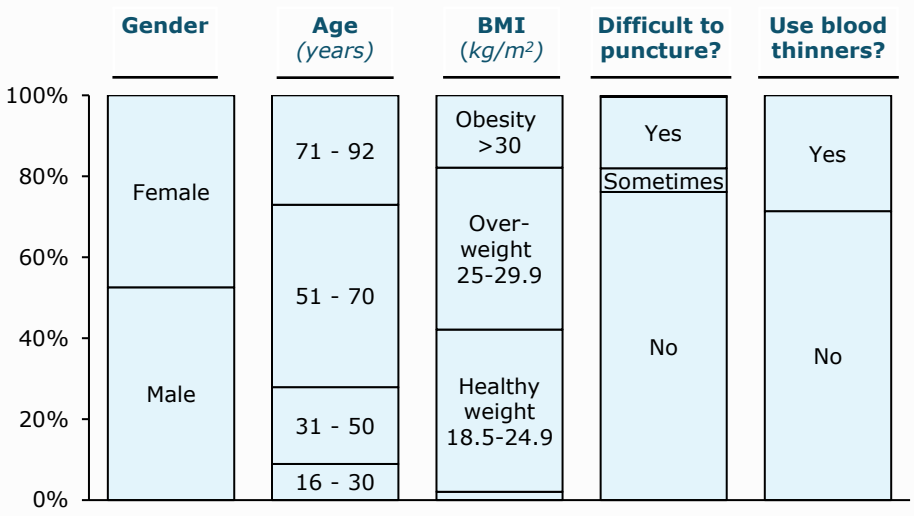
Study procedures
- 1 device blood draw
- 1 attempt allowed
- 2 lithium heparin tubes

Inclusion criteria
- ≥ 16 years
- Both arms available

Exclusion criteria
- Pregnant
- Incapacitated

Results

Study population



Patients were selected randomly in the waiting room of the outpatient blood drawing department of two Dutch teaching hospitals. Patients first participated in this trial, then had their blood drawn for routine purposes. Therefore, they were eligible only if they had both arms available for blood draws. 636 patients were screened, 609 patients (96%) were included in Study Phase B1 and C1-1.

548 patients were included in the analysis as the dropout rate was 10%, mostly due to subjects' time constraints. The study population was diverse. 47% was female. The median age was 60 years (min-max: 17-92 years). 18% indicated that they were difficult to puncture. 18% of the patients were obese (BMI >30). 29% used any type of blood thinners (anticoagulants or antiplatelet medication).

Primary & secondary endpoints

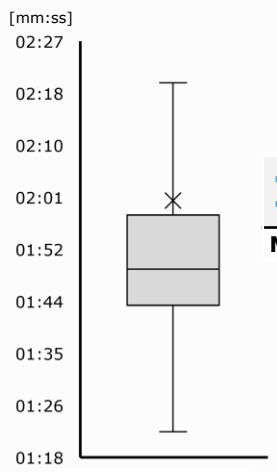
	Results per phase	
Primary endpoint	**Phase B1**	**Phase C1-1**
First-time venipuncture success rate	✓ *(p < 0.001)*	**95%**
Secondary endpoints	**Results combined**	
Rate of hemolyzed samples (>0.5 g/l)	**0.6%**	
Moderate or Serious Adverse Events	**0**	

The primary endpoint was met in Phase B1 for CE marking, demonstrating the non-inferiority of the blood draw device. In study C1-1, the first-time venipuncture success rate was 95% *(95% CI: 92-98%).* In manual phlebotomy, comparable rates of 93-97% have been reported, although lower rates of 80-89% occur depending on vein difficulty and the phlebotomist.[1]

In Phase B1, all secondary endpoints for CE marking were met, demonstrating non-inferiority. In the combined studies, the rate of hemolyzed samples (free Hb of >0.5 g/l) was 0.6% *(95% CI: 0.2%-1.4%).* In manual phlebotomy, comparable rates of 0.7-2.8% have been reported.[2] No Moderate or Serious Adverse Events occurred. Mild AEs occurred in 1.3% *(95% CI: 0.5-2.6%).*

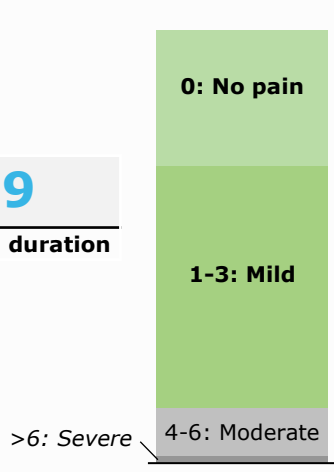
Exploratory endpoints and patient experience

Duration of procedure
From application of tourniquet to placement of the bandage



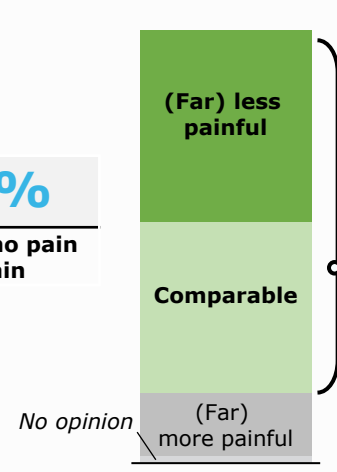
1:49
Median duration

How do you rate the pain on a scale of 0 to 10?
Numerical Rating Scale (NRS)



~90%
Indicate no pain or mild pain

How is the pain compared to manual blood draw?



~85%
Consider the pain less than or similar to manual

Is this blood draw method acceptable for you?

98%
Accept the device blood draw

The median duration of the device blood draw procedure was 1 minute 49 seconds (IQR 14 s).* In manual phlebotomy, a service time of 5 minutes has been reported.[3] This includes both the time for accessing the test order and the time required for the specimen draw.[3] As the former is not included in the device time, the procedure duration is deemed comparable to manual phlebotomy. The patient experience was positive. ~90% of patients experienced no pain or mild pain (median NRS score: 1, IQR 1). ~85% considered the pain less than, or similar to, a manual blood draw. Nearly all patients (98%) accepted the novel blood draw method.

* Only Phase B1 data was available for this endpoint.

References

[1] Hefler et al. Ann. Int. Med. Vol. 140. 2004; Howanitz et al. Arch Pathol Lab Med. Vol. 115, Sept 1991; Howanitz et al. Arch Pathol Lab Med. Vol. 118, June 1994.
[2] Sciacovelli et al. Clin. Chim. Act. Vol. 497. July 2019 (*ranges based of hemolysis data of 25th and 75th percentile of labs, 2017 data).*
[3] Mijailov et al. Arch Pathol Lab Med. Vol 138, July 2014

Conclusions

- In this study, a **premarket autonomous blood draw device was evaluated in ~600 patients.**
- The **study population was diverse,** including all ages, difficult venous access, obesity and anticoagulant use.
- All primary and secondary performance and safety **targets for CE marking were met successfully**.
- First-time success rate, in vitro hemolysis rate, and procedure duration were **comparable to manual phlebotomy**.
- **The patient experience was positive,** with high acceptance by patients.

CE marking expected in Q4 2024

Disclosure: L.G. and J.R. are employees of Vitestro and hold stock options and/or equity. M.F. is a (minority) shareholder. M.D. and T.H. have nothing to disclose.

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