Dialysis Technology – what will the Future bring?

Innovative Ways of Monitoring the Vascular Access

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"This text is complementary to an oral presentation held by Kristian Solem on the Berlin Dialysis Seminar on 7-8 December 2012. The presentation must not be considered without bearing in mind that the oral presentation explained the content summarized here in more detail. You are welcome to contact Kristian Solem for further information at Kristian.Solem@Gambro.com.

Please note that some of the methods presented in this presentation are the subjects of ongoing research and development projects whereas others are included in existing products (but are not necessarily identical to the product). The comparison of methods presented is a theoretical comparison of inherent properties of the different methods based on available scientific knowledge, and thus clinical data is not needed to support the conclusions made.

The term "determine supervision" used in the table on page 7 of this presentation refers to the question whether it is possible to know in advance if the respective method will detect an eventual venous needle dislodgement (VND) or not. The minus (-) and plus (+) used in the table are only relative measures, i.e. a minus (-) and a plus (+) is not associated with any absolute value, percentage, or any other absolute measure of high or low quality."

GAMBRO

Venous Needle Monitoring (VNM)
Avoid blood loss during extra-corporeal blood circulation

Venous needle dislodgement (VND) incident

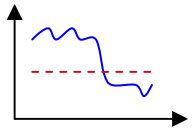
Serious event: Lethal blood loss within 3 - 12 min.

According to literature:

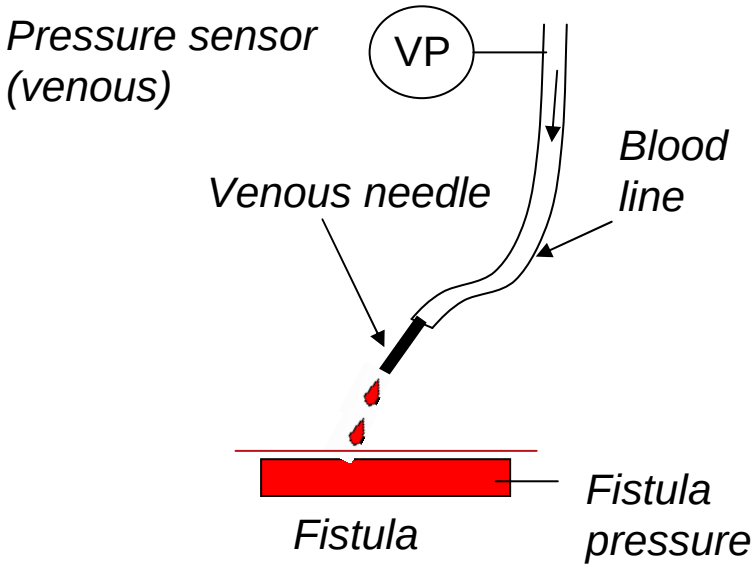
- Incidence rate: 1 / 5000 – 1 / 125000,
- Fatality rate: 10% – 33%,
- At least 1 patient dies in 1.25 million treatments,
- 2 million HD patients worldwide,
- 300 million HD treatments every year,

Today more than 240 patients die every year due to a VND

Venous Pressure Monitoring (VPM) - the conventional method



Venous needle dislodgement may cause a pressure drop that triggers an alarm and the blood pump stops

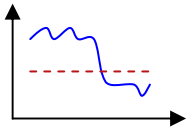


Pro's & Con's

+ Low cost
+ No handling of disposables
- Many false alarms due to e.g. arm movements
- To reduce false alarms, the larm limits are often set too wide => most patients are not supervised!
- Cannot ensure detection of needle disconnected under blanket

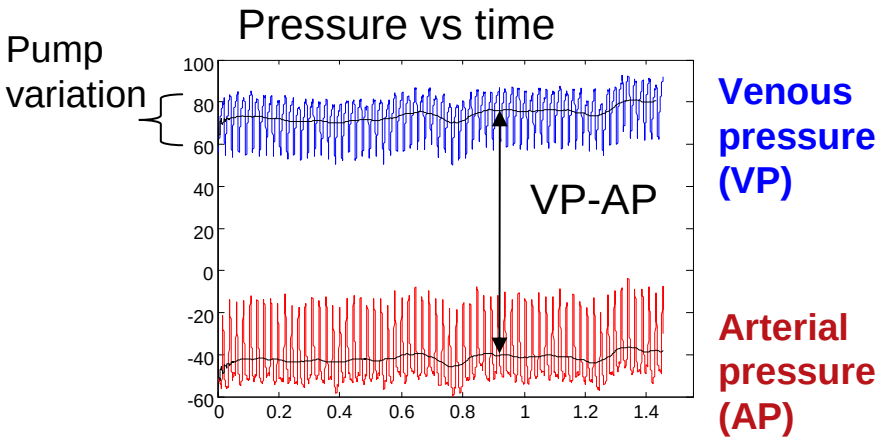
Improved Venous Pressure Monitoring

Based on conventional method and including:



- Suppressing pump pressure variation*
- Detection based on both arterial and venous pressure*

**Included in VAM Fresenius 5008*



Pro's & Con's

\+ More patients monitored since alarm limits can be set more narrow (~15 mmHg)

\+ Less false alarms

\+ Low cost

\+ No handling of disposables

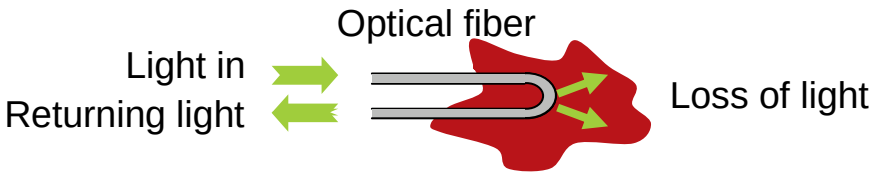
\- Cannot determine if a patient is possible to supervise or not

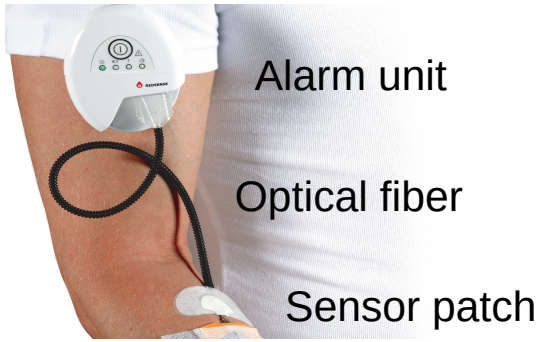
\- Cannot ensure detection of needle disconnected under blanket

\- Sensitive to disturbances from one side only (VP or AP)

VNM-patch: Redsense® Dialysis Alarm

Optical detection of blood leakage using a sensor patch attached close to the venous access





Pro's & Con's

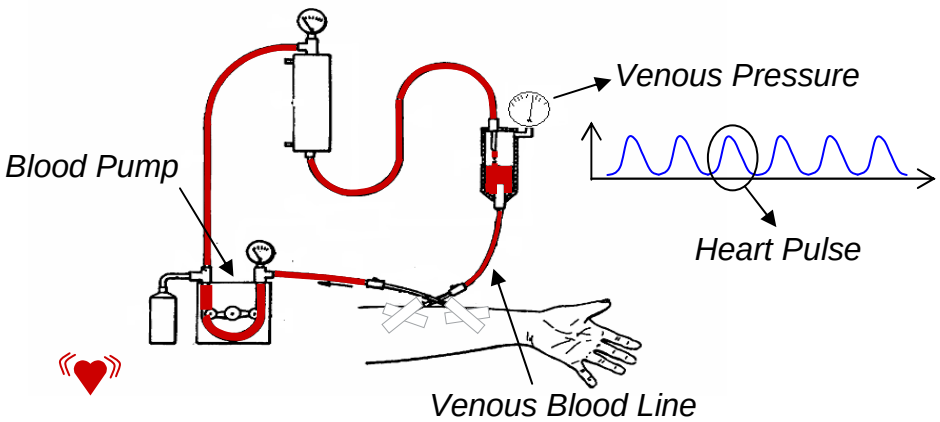
+ High sensitivity can be assumed
+ Detects partial dislodgements
- Function relies on proper attachment of patch to skin
- Audible alarm only – no automatic stop of blood pump
- False alarm due to spillage or small leakage fouls patch which causes cumbersome sensor replacement
- High workload
- High disposable cost

Conductivity based VNM-patches are also available (DRI Sleeper, WetAlert / VenAcc).

Gambro VNM by ”Stethoscope Technology”

- Listen to the heart pulse via the blood line,
- The blood line is used as a ”stethoscope”,
- No heart pulse detected in venous pressure

Indicates venous needle dislodgement.



Pro’s & Con’s

+ Determines if a patient is possible to supervise (~80%)
+ Very high sensitivity for supervisable patients
+ No false alarms since pump is stopped and heart pulse checked
+ Low cost
+ No handling of disposables
- Non-supervisible patients need alternative monitoring

Comparison of Methods

Machine integrated
Disposable sensor

	Determine supervision	Sensitivity	Specificity (False alarm)	Leakage detection	Independent of needle position when dislodged	Fast response	Easy handling	Low cost
VPM	NO	- -	- -	NO	- -	+	+	+ +
Improved VPM	NO	-	-	NO	- -	+	+	+ +
Gambro VNM Stethoscope	YES	+ +	+ +	NO	+ +	-	+	+ +
Redsense	NO	+ +	-	YES	+ +	+	- -	- -

Conclusions

1. Machine integrated methods are cheap and have low workload, but do not have good performance today (”reasonable” performance to a low price).
2. Disposable sensors have the best performance today, but have a high cost and high workload (excellent performance to a high price).
3. Future methods, e.g. Gambro VNM Stethoscope, may combine the best of what is available today, i.e. a excellent performance to a low price.

