suPAR in clinical decision making suPAR conquers new ground Fresh blood

Bridging the gap in the clinical toolbox

Discharge 56%
Indicates inflammation 32%
Immediate clinical attention 12%
Dear Reader

It is a pleasure to welcoming you to ViroGates' new journal “suPAR News”. We hope you will find it enlightening and entertaining.

As evidenced by the peer-reviewed literature, during the last two decades suPAR has been solidly established in several clinical specialties as the best prognostic biomarker of chronic inflammation. The story of suPAR is told in seconds and can be understood by anyone:

- A low suPAR level in the blood is associated with a good, underlying health condition and a good prognosis, whereas a high suPAR level is associated with the risk of disease progression. This information is useful for multiple clinical and lifestyle-related purposes.

When a message is this easy conveyed, one may imagine the audience must be large. Yet, to date, suPAR is mostly known by the clinical research community and, in less depth, by stakeholders who are of key importance to our company. These include the healthcare personnel treating acute medical patients; the payors including those working in the hospitals’ purchasing groups and government-financed insurance programs; and last, but not least, our shareholders.

It follows we felt the need to disseminate the suPAR story beyond the clinical research environment was obvious and urgent.

One of the solutions we decided to approach, was to found the journal you now hold in your hands. Each issue will cover a theme viewed from several angles. Trends and perspectives will be offered via interviews and short articles from mostly abroad; and all will be presented in an entertaining and easy-going style. We want this journal to be for everyone to read.

The theme of this issue is “Bridging the gap in the clinical toolbox”. We have attempted to illustrate this by featuring articles concentrating on suPAR’s clinical relevance in the acute care setting, spiced with personal accounts by fine people.

suPAR News will appear regularly, first time on April 1, 2019. The journal will be available in both hard-copy and online formats.

On this place, special thanks are directed to Doctor Juan González del Castillo from Hospital El Clínico San Carlos, Madrid, as well as to the Doctors Ariel Lindo and Miguel Callejas from Hospital General de Villarrobledo, Albacete, for their contributions to this issue.

To secure suPAR News stays relevant and prosper requires feedback. We therefore encourage you to contact us anytime with ideas, comments and criticism that can make our new journal better.

Welcome again

Thomas Krarup
Miss Thompson, a retired book-keeper, lives alone with her cat “Major Tom”. Her husband died several years ago, but at age 73 she enjoys life and all her hobbies. One morning in February, she wakes up, feeling all bad. The stomach hurts, the head aches, and she has a hard time breathing. She feels like staying in bed, but the meowing of her cat gets her on her feet. The dizziness almost makes her faint, but she gets to the kitchen. While bending over to feed the cat, she loses control and stumbles onto the floor. She gets back up and calls an ambulance.

At the emergency department she is triaged by a handsome doctor to orange, based on her vital signs. For the decision of whether miss Thompson should have further clinical investigations or can be sent home, blood is taken and sent to the lab. The circulating biomarkers, which are easily measured in blood, give information about organs, presence of disease, and disease severity.

In emergency medicine, the use of biomarkers has changed the approach of diagnosis and treatment procedures. Biomarkers are pivotal in clinical decision-making where they help in diagnostic as well as in prognosis and for improving physicians’ admission or early discharge decisions.

Traditionally, specific biomarkers for e.g. cardiac disease or organ disease have been measured. But in recent years, emergency medicine physicians are becoming accustomed to the use of biomarkers that may lack specificity for any one particular condition, but provide important prognostic information. An example of this is lactate, and therefore a need for admission and intravenous procedures. Biomarkers are pivotal in clinical decision-making.

In their daily decision making in regards to admission and mortality is low – and this aids in the decision to discharge the patient.

2. An elevated suPAR brings to attention that the patient is likely to have a severe condition and high risk of disease progression and mortality – and this aids in the decision to admit and to do additional examinations to uncover why the risk of mortality is high.

3. suPAR goes beyond the clinical symptoms – in a recent paper by Rasmussen et al including more than 17,000 acute medical patients, the authors found that patients with normal vital signs (0-1 in early warning score), but high suPAR, had a high risk of mortality. Now, to get back to miss Thompson, she had a high level of the biomarker CRP and her blood sugar was somewhat elevated; but her other organ markers were fine. Her suPAR level was low for her age and condition. Miss Thompson was, therefore, discharged after having her elevated blood sugar. Her cat Major Tom would have been strung out if miss Thompson had had a high suPAR as this would have pointed towards a developing sepsis and therefore a need for admission and intravenous antibiotics.

There are several reasons why suPAR is becoming part of the clinical routine:

1. It has a high negative predictive value – meaning that if the patient has a low suPAR, the risk of readmission and mortality is low – and this aids in the decision to discharge the patient.

suPAR, which is short for the extravagant name soluble urokinase plasminogen activator receptor, is a protein in the blood. It is the soluble form of the membrane-bound urokinase plasminogen activator receptor (uPAR). suPAR is an unspecific prognostic biomarker, which is elevated by inflammation and correlated to disease severity and risk of mortality (Fig. 1, yellow, orange, and red curves). Therefore, the suPAR level is a strong measure of chronic inflammation and the underlying risk of negative outcomes, including short term mortality (in hospital, 30 days, or 90 days). A low suPAR level (Fig. 1, green curves), on the other hand, is a strong indicator for a good prognosis, because it indicates low risk of re-admission and mortality, and therefore is useful in discharge decisions. Measuring suPAR levels can thus serve as a marker to determine risk of mortality upon hospital admission as well as for monitoring disease progression. This could lead to an earlier intervention time. suPAR measurements can therefore help clinicians in their daily decision making in regards to admission or discharge of patients. Hence, suPAR is a prognostic biomarker useful for risk stratification of acute medical patients in the emergency department.

6) Schultz M. Introducing a prognostic biomarker for risk stratification in emergency departments. PhD thesis, Herlev and Gentofte Hospitals, Department of Cardiology, 2018
suPAR: from research to clinical use
By: Claus Berner

Spain is a great country, not least in a suPAR context. Originally, suPAR was introduced by a local distributor five years ago to doctors for research purposes. These activities resulted in some published studies. We have passed this era and are now moving with full speed into the “clinical routine-use era”.

The Spaniards are open-minded, flexible, and not overly bound by tradition. Establishing a dialogue with the doctors in the emergency departments (EDs) is generally a positive experience as they are curious, serious, and informal at the same time.

Spain has approx. 800 hospitals; and 300 of those have the size and infrastructure needed for being classified as a suPAR target. Last year, contact was established to more than 100 of these hospitals and serious dialogues regarding the routine use of suPAR have been established with approx. 40 EDs.

The two main activities for approaching potential suPAR customers include ED visits and attending the national emergency medicine congress (SEMES).

The national congress is an excellent opportunity to engage with doctors. Just asking “do you know suPAR?” immediately creates a dialogue (Fig. 1). The interest to understand how suPAR can add to the daily discharge/admission decision making is high.

The first visit to an ED is usually a “cold call”. There is no need to ask for an appointment; it is straightforward to enter the department and establishing contact to the Head of the ED. The aim of the first visit is to create awareness of suPAR and secure an appointment for a later meeting where the benefits of suPAR can be established and the pains of the ED can be resolved in more details.

Fig.1. Jakob Knudsen explains the suPAR benefits to doctors at the SEMES conference, Alicante, June 2017.

Using suPAR to improve patient triage

Expected suPAR levels in healthy blood donors (N=9305) is around 2-3 ng/ml1, in patients attending ED around 2-6 ng/ml2,3 and in patients with severe disease and organ failure, suPAR is often in the double-digits4,5. The higher the level, the higher the risk of disease progression and the worse the prognosis.

The usefulness of suPAR in the ED decision making is not only validated via the literature but also via the test we have carried out just now; and we have found that suPAR is surely an important prognostic tool for the ED.

Dr Lindo

“...I liked the fact that here was a biomarker with prognostic capabilities, something we had never had before.”

Dr Lindo and Dr Miguel Callejas (Fig. 1) have just finalized testing the suPAR level of 200 of their patients at the emergency department (ED) at Villarrobledo General Hospital (Fig. 2). The hospital is located near Albacete, which is a two hours’ drive south-east of Madrid. The test results, including measurements of suPAR and other analytical data, have just been reviewed with the objective to address the question: “what value does suPAR add in the clinical setting?”

Dr Ariel Lindo and Dr Miguel Callejas first heard about suPAR at the annual national congress for Emergency Medicine (SEMES) in Alicante in June 2017. Here they learned about suPAR and its qualities at ViroGates’ booth at the congress exhibition.

In collaboration with the hospital’s laboratory, 200 suPAR tests for the suPAR point-of-care device (known as Quick Triage) were provided by ViroGates. After having performed suPAR measurements on 200 patients, a statistical analysis, as well as a medical patient-by-patient evaluation was carried out.

“I liked the fact that here was a biomarker with prognostic capabilities, something we had never had before.”

says Dr Lindo and continues: “We wish to continuously improve patient care; and because suPAR supports the decision regarding either discharge or admission of acute patients, I felt I had to get to know this biomarker better.”

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Speed and efficiency: TurbiLatex sets a new standard for suPAR

By: Thomas Krarup

Turbilatex

Last year, August 20 was a good day: the arrival of TurbiLatex was announced. TurbiLatex could have been the name of the leading figure in a new cartoon. But it is not: TurbiLatex is the name of ViroGates’ new suPAR test, which is measured on a turbidimetric platform.

Why is it important to have a suPAR test on this platform?

The objective of this note is to address precisely this question.

The key focus area of ours is the hospitals’ emergency departments (ED). We believe that using suPAR in the ED as a clinical routine biomarker will make a significant difference for…

- Patients
  - Those, who have a good prognosis and a good basic health condition, can be discharged.
  - Those, who have a non-diagnosed inflammation and may be severely ill, are identified immediately and can be treated without delay.
- Clinicians
  - In a department where fast, clinical judgment is critical, it is important to be empowered to make decisions where there before may have been doubt. The suPAR test allows a more accurate measure of the patients’ survival prognosis and their risk of disease progression.

For any test, an ED depends on a fast result turnaround time (TAT) to optimize clinical decision making and allow timely patient care. The ED’s requirement to a suPAR measurement is no different. Therefore, to better accommodate this need, we decided to expand the availability of our suPAR test from the satellite laboratory placed close to the point-of-care, to the high-throughput turbidimetry platforms available in core labs such as the clinical biochemistry department (CBD) found in most hospitals treating acute medical patients.

By insisting on zero additional process steps should be added, we managed to get a suPAR test onboard the turbidimetry platform without changing the workflows of the ED and the CBD. Thus, the efficiency of these departments remain unaffected.

How are the ED and the CBD linked?

Overall, the CBD is a pivotal department, as its performance is key in assisting clinicians from the ED (and elsewhere) arriving to a sound diagnostic conclusion. Often using fully automated, high-throughput clinical chemistry systems including turbidimetry platforms, the CBD measures a number of biological parameters in any of a patient’s body fluids and send the results to the clinicians in the ED without delay. By making the suPAR measurement available on a fully automated turbidimetry platform, we support the hospitals’ desire to streamline their processes, even under peak workflow situations, while at the same time keeping the TAT short.

Briefly, the workflow is as follows: blood is drawn at the ED and transported to the CBD via a pneumatic tube system or by other vehicles. Depending on the set-up at the CBD, a robot sorts the patient samples without any hands-on steps required by the staff. Also, automatically, the patient samples are then transported to the appropriate analysis system. In the case of suPAR this is the turbidimetry platform. After the analysis, which for suPAR takes a few minutes (<10), the result is immediately made available to the clinicians at the ED via the hospital’s internal information system (HIS/LIS).

What is turbidimetry?

In short this is about measuring the loss of intensity of transmitted light through a patient specimen. The higher the suPAR concentration, the more the light will be scattered and absorbed rather than transmitted. It follows that for clinical routine purposes, turbidimetry expresses the optical property of the patient specimen, which can be translated into the concentration of suPAR.

A more detailed explanation is this: the patient specimen is prepared for the turbidimetry platform as a plasma or serum sample and added to a cuvette, which is a small transparent container. Monoclonal antibodies, which are Y-shaped proteins with two highly specific suPAR-binding sites, are then added into the cuvette (Figs. 1A-B). Our antibodies, engineered to specifically recognize suPAR, bind to the suPAR protein with very high affinity (Fig. 1C). It follows that the higher the concentration of suPAR is in the patient specimen, the higher the aggregation will be between suPAR and the antibodies.

In essence, the turbidimetry platform can quantify the concentration of suPAR in the nano-gram per milliliter range by comparing the actual measurement to a linear calibration curve, created and entered into the system before the analysis of patient specimen. The calibration curve is based on known suPAR concentrations (standardized controls).

We selected Roche Diagnostics’ fully automated, high-throughput clinical chemistry systems including the turbidimetric platforms produced by Siemens, Abbott, and Beckman-Coulter.

Light is then passed through the patient specimen in the cuvette. A part of this light will scatter and another part, be absorbed. By measuring the intensity of the light actually passing through the cuvette, it is possible to very precisely estimate the concentration of suPAR in the patient specimen (see Fig. 2). This is because the intensity of the transmitted light is a function of the concentration of suPAR in the patient specimen.
NUTOPI: a key player in the suPAR game
By: Tomasz Pielak

My history with ViroGates is long and started in the last year (2006) of my Biomedical Laboratory Scientist education. Our projects validated the suPARnostic® ELISA assay on urine, which later gave me the opportunity to ensure implementation of suPAR measurement and prognostication of tuberculosis treatment efficacy in Guinea-Bissau. Three years in Africa gave me the opportunity to be involved in many studies and later becoming Production Manager for ViroGates' products.

NUTOPI Sp. was founded in 2014 as a CRO company. Over the years, NUTOPI has been involved in the development and release of the suPARnostic® Quick Triage, also known as ViroGates' point-of-care test. More recently, we have been involved in the development, validation, and release of the suPARnostic® TurbiLatex products (Fig. 1). NUTOPI has grown during these years and today consists of six fulltime and two on-call employees.

In addition to development, management, and quality control, NUTOPI also performs a series of other laboratory-related tasks for ViroGates, as well as for other customers. These include customer support, handling of product logistics, storage, shipment, and administration. An example of the latter is that NUTOPI supports ViroGates in managing its product quality system.

Being a supplier for ViroGates is a very challenging experience which requires great workflow adaptation and flexibility. It is required to have great balance between experiment planning, performance, and documentation to meet strict deadlines, while at the same time delivering high-quality services and products.

Quality control, for example, is a very challenging task, especially when working with biological materials. It requires great knowledge of the product that is tested, and proven quality measures must be in place. Good communication skills and teamwork are essentials when testing programs are carried out and when challenging issues are to be solved.

NUTOPI will do its outmost to meet the needs of its clients, while keeping the quality high and the cost as low as possible.

Heads up: the heat is on in Spain
By: Claus Berner

A need expressed by many Spanish hospitals is to be able to measure key parameters fast, secure, and not least, via a system where the results are automatically reported to the doctors via the laboratory information system (LIS).

The CE/IVD labelling of the turbidimetric method called TurbiLatex for measuring suPAR on the cobas analysers from Roche Diagnostics, will help suPAR becoming an even more attractive marker for the emergency department (ED).

In the regions Asturias, Basque Country, Aragon, and Madrid, four hospitals have committed to test this new high-throughput method for measuring suPAR in patient samples (Fig. 1).

Dr PhD Juan González del Castillo from the ED of Hospital Clínico San Carlos in Madrid, one of Spain’s leading hospitals, is heading this project. The purpose is twofold: to test the prognostic value of suPAR and how it supports the discharge/admission/readmission decisions, and furthermore, to having suPAR made available on various cobas analysers and making sure that the personnel is getting acquainted with this biomarker.

“...it is essential to have the help of biomarkers, such as suPAR, which can support the discharge decision and give us the confidence that we are doing the right thing...”
- Dr PhD Juan González del Castillo, Hospital Clínico San Carlos, Madrid.

Dr Gonzalez expresses the difficulty and importance of making the right decisions in the ED like this:
“I look much forward to work with my colleagues in the three other hospitals on the suPAR trial in order to strengthen the suPAR message related to the discharge/admission decision. One of the key decisions for an emergency physician is when to discharge the patient. Of course, unnecessary admissions should be avoided. But, on the other hand, the discharge decision must be taken without any risk for the patient’s life, and with the certainty of avoiding the re-admission to the ED.”

Dr Gonzalez pauses and then continues: “Patients evaluated in the ED are increasingly complex, older, and with more accumulated comorbidities, which translate into atypical clinical presentations complicating the decision-making. For this reason, it is essential to have the help of biomarkers, such as suPAR, which can support the discharge decision and give us the confidence that we are doing the right thing.”

It is with great excitement that ViroGates enters into the collaboration with the ED and Laboratory teams of these four hospitals.
2018 was a really exciting and fun year at ViroGates!

In order to let more hospitals know of the advantages of our suPARnostic® products, we conducted an Initial Public Offering (IPO) of ViroGates on June 26, 2018, at Nasdaq First North in Copenhagen and achieved a better financial structure than we have had in the past.

This event has not only meant that there is more focus on what we do on a daily basis, but also that we can now do more of what really matters at this stage: tell the international markets about the benefits of using suPARnostic® in clinical settings, to help triage acute care patients!

It is very exciting to grow from being a company with four employees last spring to 10 people at the end of the year 2018 and especially, to see that new colleagues with very high ambitions and skillsets have joined us. I look so much forward to see how this addition to ViroGates will enable us to more consistently work with the acute care departments, ensuring that we can introduce new products helping physicians deal with the growing number of patients.

Furthermore, it has been a pleasure to see the high degree of interest that hospitals have shown to try out our suPAR products in their daily work. It is especially noteworthy that their experience and feedback have been that our products really help them identifying which patients need additional attention and who can be discharged earlier than before.

2019 looks to be an even more exciting year for ViroGates than last year!
New bridgeheads in Spain, Germany, France, and the Nordics

We would like to welcome five new faces who recently joined the ViroGates team. Each of them has been asked to write a note on their first experiences with ViroGates and their first impressions from the field.

Julio Ajenjo García

The first who will get the floor is our new Sales Manager in Spain, Julio Ajenjo García. Julio has joined us from the Pain Division of Cardiva, where he for more than four years sold devices and consumables to hospital units dealing with surgery and pain treatment. Most of this work targeted a variety of ICUs. Julio holds an MSc in Biology from Complutense University of Madrid and a degree in Sales & Marketing from Universidad Autónoma de Barcelona, Autonomous University of Barcelona.

Julio: Gone are the happy and intense days in the beginning of January with training in Denmark (Fig. 1). Everything was fantastic, with a relaxed atmosphere, fellowship, and a lot of scientific information. All very promising. In my commercial mind, after 20 years of selling hospital products, ViroGates’ advantages, and benefits were crowding together. My mind wanted to store the benefits of suPAR; the scientific evidence; and everything else learned during the training days. Sometime doubts and questions arose. However, as the days went by, doubt was replaced by understanding and visualization of being in front of a product that offers countless benefits in a wide range of specialties.

My first impressions with the Spanish hospitals could not have been better. The interest in suPAR increases as soon as it is correctly explained. First the clinicians are overwhelmed by the amount of studies and data that support the benefits of suPAR. The scientific evidence; and everything else learned during the training days. Sometime doubts and questions arose. However, as the days went by, doubt was replaced by understanding and visualization of being in front of a product that offers countless benefits in a wide range of specialties.

The most exciting event of my first few weeks with ViroGates has been my visit to the congress “SIK 2019”. This was a three-day lasting convention for emergency medicine and intensive care. Being in the middle of emergency medical students, nurses, students of medicine, as well as physicians, I listened to news within topics concerning emergency medicine and intensive care. I also had the pleasure to meet some of the chief physicians from the intensive care units of Baden-Württemberg. Fortunately, most are interested in suPAR as a prognostic marker. To sum up my first German market impressions: some promising meetings have already been scheduled in the upcoming weeks with the overall objective to bringing suPAR to German hospitals. Working out a suPAR market access plan and a marketing strategy are also assignments to be handled in the near future.

“These data are so good that I do not feel it is ethical to send any patient home without first measuring suPAR. I do not stay calm without knowing your suPAR level.”

Stephanie Biener

In Germany Stephanie Biener (Steffi) accepted the position as Sr Key Account Manager. The healthcare system in this country is complex and therefore Steffi’s first assignment, together with colleagues, is to focus on a market access strategy clearing the way for downstream sales. Currently this work is anchored in Munich and Frankfurt am Main, from where we will expand to cover the rest of the country. Steffi joined us from Quidel, where she has been responsible for the sales of medical devices and consumables to German hospitals and labs. Steffi has an MSc in Biology from the Ludwig-Maximilian-University of Munich, as well as a degree as Environmental Protection Officer from the Technical University of Munich.

Steffi: My first days within the company are a quite new experience, as this is the first time I am working for a small Danish company. When talking to possible prospects, their first reactions can be summarized as: “Virogates? suPAR - how does it work?” ViroGates is 100% new to the German clinical market - a good precondition for having interesting talks with a lot of questions around the main point of my work - suPAR.

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In France, we asked Jérôme Bouffel to come onboard as our new Business Development Manager. Amongst his key responsibilities the first year is to introduce suPAR to the EDs and to develop a suPAR market access plan for the French market. Jérôme has 20 years of experience with sales of diagnostics to hospitals and labs for companies including Diasorin, Werfen, and Theradiag. Jérôme holds a degree in Biochemistry; a Diplômé de l’ESVII; as well as advanced-level post-graduate courses in negotiation and strategic selling.

Jérôme: I joined ViroGates, because I am convinced in the added value that suPAR provides to the decision making of discharge and admission for clinicians. Working in the diagnostic field for 20 years, for me having this opportunity of introducing a new biomarker that has a great future, is good for one’s image. As suPAR is almost unknown in France, all research data published confirming the prognostic value of suPAR contributes to the understanding that this biomarker will help the clinicians to a much better approach for discharging patients, helping the current triage system, and reduce crowding in the ED. Everyone in the company is here to spread the message of suPAR with their knowledge and professional skills. Clinicians and clinical biochemists have with suPAR a solution which will also contribute to cost savings on healthcare.

With the objective to secure a rapid suPAR growth in the Nordic countries, Thomas Neil Skov was brought in. Thomas came from a managerial sales position at GSK and brings to the table more than 10 years of sales experience to the life-science and clinical segments, as well as documented results from positions overseeing sales in Central Europe and the Nordics. Thomas holds a degree in Medicine (Diploma) Pharmaconomist from the Danish Pharmaceutical Academy.

Thomas: It is always a pleasure to promote a new product, even though there are challenges on the way. The world within the public sector like the hospitals is very different compared to normal B2B sales, due to the fact that time is something the clinicians don’t have. This also reflects the time it takes to get the initial meeting and the start-up of a suPAR test.

The greatness of having suPAR is the benefits it brings to the ED which allow the clinicians to manage their patients even better than they do now. The EDs and the hospitals experience a much higher pressure due to the bigger population of elderly people, so the “demand” to optimize workflow and discharge more patients within the first few hours is important. This makes suPAR the essential choice of new prognostic marker.

Several Danish and Swedish hospitals wish to test suPAR in the near future and clinicians from some of these hospitals have already submitted applications to their management to achieve this goal. The reason is simple; they need an extra and better tool to optimize their patients’ triage.

I look very much forward to see suPAR in clinical use at more hospitals, because patient outcome is the most important thing.

Finally, we have asked Ditte Bjerre to come onboard and hold the position as our new International Application Scientist. Ditte is an engineer in medical biotechnology with a PhD in genetics from the University of Copenhagen. She joins us from BioNordika, where she was employed as a product specialist. Ditte will be responsible for the clinical communications, work on internal R&D projects, and contribute to external activities like the validation of TurbiLatex on robots from Siemens and Abbott, as well as assisting sales across Europe with scientific and clinical support.

Ditte: I am a person that always seeks challenges and ways to contribute to smaller and greater courses. Being a part of this suPAR journey is exiting. All from being part of the process of getting the knowledge of suPAR widespread in Europe to helping our customers and my colleagues, suPAR is well known in clinic research and a lot of data is already available documenting all the benefits of this biomarker. Now the time has come to make suPAR known in the clinical departments as well. So far, it has been a really good experience. I have been very well received by everyone in ViroGates and have already experienced that clinicians are very interested in our suPAR story. To be a part of the future of suPAR inspired me, and I will work with great enthusiasm every day to make sure that this happens. I am looking forward to take part of this journey all the way.
WHAT AM I GONNA DO?!!